PAHO-CDC

Generic Protocol

for

Influenza Surveillance

PAHO Health Surveillance and Disease Management Area
Communicable Disease Unit
Viral Disease Team

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1. Preface

Despite the substantial contribution of human influenza to morbidity and mortality, surveillance for the disease has not been standardized worldwide, and the epidemiology of the illness in tropical, subtropical, and developing regions is not as well understood as it is in other parts of the world. In addition, the current epizootic of avian influenza A (H5N1) among poultry and wild birds, and the concomitant risk to human health highlight the necessity for surveillance systems capable of detecting influenza viruses with pandemic potential.

In 2005, at the 58th World Health Assembly, the World Health Organization (WHO) formally adopted the revised International Health Regulations (IHR 2005) as a key global instrument against the international spread of disease (1). The Assembly also adopted a resolution entitled Strengthening Pandemic Influenza Preparedness and Response (2), which calls for WHO and its Member States to fortify and coordinate national strategies to prepare for an influenza pandemic. The following year, WHO adopted a resolution, Application of the International Health Regulations (2005), to address the pandemic threat from human cases of avian influenza (3). The resolution urges Member States to immediately comply on a voluntary basis with the revised IHR 2005 and to follow all mechanisms and procedures set out therein for any disease that might constitute a public health emergency of international concern. The document also urges the application of Part II of the IHR 2005 pertaining to surveillance, information-sharing, consultation, verification, and public health response with regard to any new influenza subtype with pandemic potential.

**Surveillance is the foundation of all efforts to understand and control influenza.**

The monitoring of epidemic influenza disease patterns is essential for yearly planning of prevention and response activities, for the identification of groups at high risk for complications, and for estimating the burden of influenza in terms of both health and economic impact (4). Influenza surveillance is essential for early detection and for the antigenic and genetic evaluation of new variants or subtypes of the influenza virus, including any strains with pandemic potential.

The **purpose** of this generic protocol is to provide support for Pan American Health Organization (PAHO) Member States to improve influenza surveillance by integrating epidemiologic and laboratory components into a single system. To that end, the protocol proposes strengthening the national capacity of PAHO Member States by developing a sentinel surveillance system and an influenza notifiable disease surveillance system, both of which will complement existing structures whenever present.

An **expected result** of this activity is that the new surveillance system, which will be implemented with standardized methodologies and procedures, will allow for the assessment of influenza activity throughout the Region of the Americas and will enable the comparison of circulating influenza strains -- and the number of patients meeting case definitions for infectious respiratory disease -- with other WHO Regions with other sub-regions of the Americas, and between PAHO Member States.
The development of this generic protocol constitutes a collaborative effort by the PAHO, WHO Regional Office for the Americas, the Centers for Disease Control and Prevention of the United States (CDC), and representatives of PAHO Member States.

2. Background

2.1. General

Influenza is an acute contagious viral respiratory disease characterized by fever, headache, myalgia, prostration, coryza, sore throat, and cough (5, 6). Symptoms and signs differ according to the age of those infected (5). Hospitalization and deaths occur mainly in high-risk groups: children in their first two years of life, the elderly, and the chronically ill (7, 8).

The influenza virus spreads rapidly around the world in seasonal epidemics (9). In temperate regions, seasonal influenza typically occurs every year in the late fall or winter (9). In tropical and subtropical regions, the seasonality of influenza is less clearly defined, with background activity occurring year-round (10). The disease causes a considerable economic burden in relation to health care costs and lost productivity in temperate regions (8). Moreover, there is increasing evidence that the burden of influenza disease in tropical and subtropical countries may be substantial (10).

Influenza infection is caused by RNA viruses belonging to the Orthomyxoviridae family. There are three types of influenza viruses, A, B, and C, and humans can be infected with all three types (9). Influenza A and B viruses cause epidemic disease in humans and type C viruses usually cause a mild, cold-like illness. Influenza A viruses are further designated by subtype according to their surface proteins: hemagglutinin and neuraminidase (9). To date, 16 hemagglutinin and 9 neuraminidase subtypes have been identified (11). Influenza A infects multiple species, including humans, other mammals, and wild and domestic birds (9). The current human influenza A subtypes in circulation are H1N1 and H3N2 (12).

Frequent changes occur in the genetic makeup of influenza A viruses, and these changes constitute the basis for epidemics and pandemics (9). Minor genetic changes are called ‘antigenic drift’ and result in immunologically significant alterations to virus surface antigens. Drift is an ongoing process that results in the appearance of new antigenic variants requiring yearly updates to the strain composition of the influenza vaccine (6). Major genetic changes are called ‘antigenic shift’ and represent a more radical change that refers to the appearance of an influenza virus bearing either a novel hemagglutinin or a novel combination of hemagglutinin and neuraminidase. Antigenic shift may occur as a result of mutation or genetic reassortment of human and animal influenza A viruses (9). Antigenic shifts can lead to pandemics, but only if the new virus is sufficiently transmissible among humans to maintain epidemic activity and is capable of causing disease (9). Yearly vaccination is recommended for those at highest risk of morbidity and mortality (7).

Influenza antiviral therapy is an important adjunct to the annual influenza vaccination for the treatment and prevention of influenza. Influenza antiviral drugs are effective in preventing infection, and they reduce the symptoms of infection when started during the early stages of the
disease and can decrease influenza-associated complications (7). There are two classes of antiviral medications with activity against influenza viruses: the adamantanes, including amantadine and rimantadine; and the neuraminidase inhibitors, including oseltamivir and zanamivir. The adamantane class, which only has activity against influenza A viruses, has been in use for decades; however, high rates of adamantane resistance have been reported recently in the United States, Canada, and Asia (13, 14). Given the resistance of human influenza to the adamantane class of antiviral drugs, the neuraminidase inhibitors oseltamivir and zanamivir are recommended by WHO for the treatment and prophylaxis of human influenza virus infection (15).

2.2. Pandemic Influenza

An influenza pandemic can occur only if there is efficient and sustained viral transmission of an influenza subtype to which few people are immune (9). In the last hundred years, three global pandemics have occurred. The 1918 pandemic (influenza A/H1N1) is believed to have killed at least 40 million people worldwide, with the highest death rates occurring among young adults (16). Two other pandemics occurred in 1957 (influenza A/H2N2) and in 1968 (influenza A/H3N2), causing substantial morbidity and mortality (16). Unlike seasonal influenza epidemics, these three pandemics caused severe disease among younger, healthy individuals (8).

Currently, an epizootic of avian influenza A/H5N1 has infected poultry and wild birds in over 50 countries on three continents (17). H5N1 has rarely infected people (18), but it may have the potential to mutate into a strain that can more easily infect humans. Whether the next influenza pandemic will be due to H5N1 or to a different influenza strain is uncertain, but global influenza surveillance is critical for the detection of new strains of influenza as they emerge. Animal and public health surveillance must be coordinated in this effort. Only in this way can the world community be prepared to take effective prevention and control measures.

2.3. Influenza Surveillance

In 1947, WHO established the WHO Global Influenza Surveillance Network (FluNet), which currently comprises 116 National Influenza Centers with laboratories in 87 countries and four WHO Collaborating Centers for Reference and Research of Influenza (19).

The objectives of FluNet are to

- Monitor the influenza viruses in circulation and make annual recommendations on influenza vaccine composition for the Northern and Southern Hemispheres.
- Detect, as early as possible, any unusual influenza strains in human populations that could have pandemic potential.
- Provide, in collaboration with key National Reference Laboratories, prototype influenza vaccine strains and standardized reagents for influenza vaccine production and testing.
In the Region of the Americas, there are 25 National Influenza Centers connected to the WHO Collaborating Center for Reference and Research of Influenza at CDC in Atlanta, Georgia, USA (20).

Increased participation by each PAHO Member State in the surveillance for influenza viruses will enhance each country's ability to monitor the following: viral respiratory diseases including influenza, influenza-like illness (ILI), and severe acute respiratory infection (SARI); develop vaccine policy; and help build global and regional strategies for the prevention and control of influenza.

3. Justification for a Surveillance System

Influenza is thought to result in between three and five million cases of severe illness and in 250,000 to 500,000 deaths worldwide each year (8). In the Region of the Americas, data from 2004 indicate that incidence rates of ILI varied from 862 cases per 100,000 inhabitants in Chile to 2,833 cases per 100,000 in Paraguay (21). Extrapolating these figures to the Latin America and the Caribbean populations, a total of 4.7–15 million cases of ILI could be expected in a single year (20). In Argentina, the rate of reported influenza cases is 1,855 for every 100,000 inhabitants (22).

As of October 2006, human infection by avian influenza A/H5N1 has been rare. The first case of human H5N1 virus infection occurred in Hong Kong in 1997; and from 2003 to 27 November 2006, the cumulative number of human cases that were laboratory confirmed by WHO numbered 258 in 10 countries, with 153 deaths (18).

The importance of the recently adopted IHR 2005 and the reality of a pandemic threat are highlighted by the fact that limited, non-sustained H5N1 virus transmission between humans has been reported (23). To date there is no evidence to suggest that the transmission properties of H5N1 have changed since 2003. These incidents serve to emphasize the importance of surveillance as the foundation for efforts to understand and control influenza disease.

PAHO Member States have developed different surveillance modalities with different levels of development and outcomes measured; some of them are designed to integrate morbidity, virologic, and mortality surveillance (22, 24, 25). However, it is necessary to develop generic guidelines for these surveillance systems to enable comparison of the results of surveillance data, to standardize criteria to permit better analysis and interpretation, and to evaluate the performance of national surveillance systems.

In addition to participating in FluNet, most PAHO Member States have a notifiable disease surveillance system for communicable diseases with the potential to cause an epidemic. These systems include the reporting of outbreaks of ILI, influenza, and pneumonia to health authorities so that they can monitor morbidity and institute disease-control measures. Some countries have additional surveillance activities that complement the national reporting system: a sentinel system for the surveillance of influenza activity; a system for the detection of strains currently in circulation; or a system for monitoring mortality due to pneumonia and other severe respiratory diseases.
In the current context of avian influenza outbreaks in humans and the consequent risk of pandemic influenza, PAHO is carrying out different activities to strengthen influenza surveillance. Epidemiologic surveillance is a fundamental tool for evaluating disease burden, and with it, countries can evaluate the impact of preparedness and control measures should a new virus subtype with pandemic potential be detected.

Current epidemiologic data are limited in some countries, such as those in tropical regions where influenza seasonality is not fully characterized, making it difficult to select vaccine strains and to determine the appropriate timing for vaccination. In addition, the existing surveillance systems have low sensitivity for detecting new influenza strains, and they are not integrated with animal-health surveillance.

Moreover, there is a need to develop practical support for local, intermediate, and national health teams to enable them to organize and implement an influenza surveillance system representative of the geographic and demographic makeup of a country. Such a system would need to integrate surveillance of circulating influenza strains and influenza-associated morbidity and mortality to meet surveillance objectives.

4. Objectives of an Influenza Surveillance System

The **general objectives** for any influenza surveillance system follow:

1. Detect unusual or unexpected viral respiratory outbreaks.
2. Determine the epidemiologic characteristics of influenza and other viral respiratory diseases (caused by, for example, Adenovirus, Parainfluenza, and Respiratory Syncytial Virus) in the Region of the Americas.
3. Monitor influenza viruses and make recommendations for annual vaccine composition, determine the concordance between the vaccine and currently circulating strains; detect, in a timely manner, the appearance of new subtypes.
4. Estimate the burden of ILI and SARI in humans.
5. Guide the development of policies and guidelines for influenza prevention and control.

To fulfill these objectives, we propose the following systems to complement the existing national influenza surveillance:

- **A sentinel surveillance system** for ILI in clinic patients and for SARI and SARI-related mortality in hospital patients will help improve the existing surveillance system by expediting collection, aggregation, interpretation, and dissemination of more specific and complete data on influenza and other respiratory viruses.
- **An enhanced nationwide notifiable disease surveillance system** for unusual or unexpected occurrences of acute respiratory infections will allow for the detection,
verification, and investigation of influenza-related events in a timely manner and for the adoption of the necessary control measures.

The Sentinel Surveillance and Enhanced National Notifiable Disease Surveillance systems are further described below, and implementation protocols for influenza surveillance and reporting follow in Sections 5 and 6, respectively.

4.1. Sentinel Surveillance System

The sentinel surveillance system for ILI in ambulatory clinic patients and for SARI in hospitalized patients is intended to meet the general surveillance objectives.

A sentinel surveillance system is proposed because it has the following attributes:

- **Simplicity:** Sentinel surveillance is based in health facilities that already have the necessary infrastructure, equipment, and trained staff.
- **Sensitivity:** Sentinel surveillance can detect when the number of actual cases have exceeded the number of expected cases and, thus, allows for the calculation of an epidemic threshold.
- **Specificity:** Laboratory confirmation allows for illnesses caused by influenza to be discerned from those with other etiologies, thus limiting the number of false positive cases.
- **Timeliness:** Because of existing infrastructures, such a surveillance system would be efficient at collecting timely influenza case data.
- **Acceptability:** Health care facilities can be chosen for system implementation where there is a commitment and willingness to participate.
- **Quality of Information:** Data collected in a few, high-quality sites can be extrapolated to the general population and be used to estimate the incidence of disease.
- **Representativeness:** Usually a sentinel system cannot meet this attribute, but due to the prevalence of influenza, investigation of just a portion of all cases can bring valuable information that can be extrapolated to the general population.

The Sentinel Surveillance System comprises

- **ILI Surveillance:** Ambulatory clinic-based sentinel surveillance for illnesses that meet the case definition of ILI.
- **SARI Surveillance:** Hospital-based sentinel surveillance for illnesses and deaths that meet the case definition for SARI.

Ideally, both of these components will be implemented within a country, and the resulting information will be used to meet the established surveillance objectives. However, if a country’s resources and technical capacity cannot support both components, SARI surveillance in sentinel hospitals is recommended as a minimum standard.

The Sentinel Surveillance System components

- **Surveillance System** – This includes all surveillance activities including Enhanced Nationwide Notifiable Disease Surveillance, Sentinel Surveillance, and other surveillance enhancements.
• **Sentinel Surveillance** – Respiratory infection surveillance based in select surveillance hospitals and clinics that uses a clinical case definition and systematic sampling of a subset of cases for laboratory confirmation.

• **Sentinel Unit** – This is the most basic level of the Surveillance System. The Sentinel Unit is comprised of a Local Epidemiology Office, Sentinel Hospital(s), Sentinel Clinic(s), and a Local Sentinel Laboratory.

• **Local Epidemiology Office** – This is the office that oversees the most basic level of the Surveillance System and integrates surveillance data in the area under its responsibility.

• **Sentinel Hospital** – This is a component of the Sentinel Unit. Cases meeting the definition of Severe Acute Respiratory Infection are recorded in Sentinel Hospitals.

• **Sentinel Clinic** – This is a component of the Sentinel Unit. Cases meeting the definition of Influenza-like Illness are recorded in Sentinel Clinics.

• **Sentinel Laboratory** – This is the laboratory component of most Sentinel Units.

• **National Reference Laboratory** – This is the reference laboratory for the entire Surveillance System. Often, it will be a National Influenza Center. It receives clinical specimens from Local Sentinel Laboratories for confirmation and other tests.

• **Intermediate Level Epidemiology Office** – This office within the Surveillance System is one level above the Sentinel Unit. In many countries, this will be a Provincial Health Department. The role of the Intermediate Epidemiology Office will be to collect, aggregate, analyze, and disseminate Sentinel Unit surveillance data from the area under its responsibility. Small countries and countries with few Sentinel Units may choose not to have this level of organization.

• **National Level Epidemiology Office** – This is the highest level of the Surveillance System above the Intermediate Level Epidemiology Offices. In many countries, this will be the National Ministry of Health. The role of the National Level Epidemiology Office will be to collect, aggregate, analyze, and disseminate all surveillance data from within the country.

### 4.2. Enhanced Nationwide Notifiable Disease Surveillance System

IHR 2005 requires that any case of influenza caused by a new virus subtype be immediately reported (within 24 hours) to WHO (26). Many of the PAHO Member States have passive surveillance systems by which diseases with epidemic potential are reported to health authorities for outbreak investigation and for the institution of control measures, and these systems can be used to meet the IHR 2005 reporting requirement. However, other countries have inadequate surveillance systems and cannot meet this requirement. It is essential that such countries strengthen their national surveillance capacity to detect, verify, investigate, and respond to unusual or unexpected influenza-like events. If a country’s resources for disease surveillance are limited, it is recommended that a system of Nationwide Surveillance be prioritized over sentinel surveillance.

To improve the sensitivity of such systems for influenza surveillance, health care providers will be educated about and reminded to watch for patients at risk of developing infections from new or emerging viruses, such as H5N1. In addition, public health authorities must implement active surveillance of the media and other unofficial reported information to complement the official disease information they collect. Clinical and laboratory reports, as well as reports by lay people,
about unusual or unexpected respiratory diseases will initiate public health inquiries and, if necessary, outbreak investigations. Respiratory infections associated with epidemiologic triggers (e.g., clusters of unusual severity, related to travel, or exposure to sick animals) should initiate outbreak investigations.

5. Sentinel Surveillance

5.1. Introduction

A Sentinel Unit comprises a network of health care facilities and a local laboratory. These establishments integrate morbidity, mortality, and laboratory data, and they generate high-quality, timely information.

A Sentinel Unit would comprise a Sentinel Hospital or a Sentinel Clinic, or both. Ideally, the patient populations served by the Sentinel Unit would be well characterized, and therefore allow for the calculation of attack rates (cases per service population over time). In most cases, however, the size of the population served by sentinel sites may be difficult to determine, and surveillance data will be presented as a proportion of cases per total clinic consultations or total hospitalizations.

Surveillance for ILI among ambulatory patients is conducted in sentinel clinics, and surveillance for SARI-associated morbidity and mortality is conducted in sentinel hospitals. In both cases, laboratory confirmation of a subset is obtained by testing a determined number of systematically chosen cases. Local Sentinel Laboratories test the samples for influenza and other respiratory viruses, and those with results positive for influenza are then characterized at the National Reference Laboratory or at a WHO-affiliated National Influenza Center. Epidemiologic, clinical, and laboratory data are analyzed in Local Epidemiology Offices and then sent to epidemiology offices at the national level for consolidation and nation-wide analyses. PAHO will analyze regional information to determine the impact of influenza outbreaks and to contribute to the evaluation and implementation of disease-control interventions.

5.2. Case Definitions

It is important to use standardized case definitions that enable comparisons of disease between different areas within a country and also between countries.

There are two case definitions used by the influenza surveillance system:

1. Influenza-like illness (ILI) is used by Sentinel Clinics. ILI is defined according to WHO criteria (27):
   - Sudden onset of a fever over 38°C, AND
   - Cough or sore throat, AND
   - An absence of other diagnoses.
2. **Severe Acute Respiratory Infections (SARI)** is used by Sentinel Hospitals and as part of Nationwide Surveillance. The definition for SARI is adapted from the WHO protocol on rapid response (28). **For persons ≥5 years old:**

- Sudden onset of fever over 38°C, **AND**
- Cough or sore throat, **AND**
- Shortness of breath or difficulty breathing, **AND**
- Requiring hospital admission

The **SARI** definition **for children <5 years old** is adapted from the program for Integrated Management of Childhood Illness (29):

Any child <5 years old clinically suspected of having Pneumonia or Severe/very Severe Pneumonia (see annex), and requiring hospital admission.

A **confirmed case of influenza** is defined as any case with laboratory test results positive for influenza virus.

5.3. **Surveillance of Influenza-Like Illness (ILI) in Ambulatory Patients**

Select Sentinel Clinics will be used to monitor for ILI among ambulatory patients. The determination of ILI will be made on the basis of the clinical case definition, and surveillance monitoring will be coordinated by an existing local-level epidemiology office. ILI surveillance activities facilitate burden-of-disease estimates, aid in understanding influenza-related costs, and provide specimens for analysis and for identification of a vaccine strain.

Patient age and date of consultation will be recorded for all ILI cases. Additional epidemiologic and clinical data will be systematically recorded for a subset of cases selected for laboratory testing of clinical specimens. Clinical specimens will be tested in Local Surveillance Laboratories.

The choice of ILI surveillance sites will be left to individual countries. An example of a good surveillance site might be a clinic that provides care to a broad range of patients, that is connected to a Sentinel Hospital, and that has access to a Surveillance laboratory for immunofluorescence testing. If established as Sentinel Clinics, such sites would allow for the pooling of resources and would facilitate laboratory testing. There may be instances, however, when a desirable site for ILI surveillance is not near a hospital or Surveillance Laboratory. These sites can still be considered for ILI surveillance provided that surveillance activities can be coordinated with the surveillance system and that clinical specimens can be regularly and rapidly sent to a Surveillance Laboratory with the capacity to perform immunofluorescence testing.

ILI surveillance sites should be chosen to cover a representative sample of the population. A country may choose to establish ILI surveillance in an urgent care clinic or emergency room to capture individuals with signs of moderate ILI who might bypass ambulatory clinics and who might not require hospital admission. These are cases that would not be captured in a SARI surveillance system.
Substantial data regarding the epidemiology and burden of viral respiratory infections can be obtained from a minimal number of well-run Sentinel Clinics. It is recommended that a country prioritize the collection of quality surveillance data from a minimal number of Sentinel Clinics over the early implementation of numerous sites. Adequate piloting and evaluation should be performed before any new Sentinel Clinics are added.

5.4. Surveillance of Severe Acute Respiratory Infection (SARI) in Hospitalized Patients

This system will monitor selected hospitals for patients with severe respiratory disease that meet the case definition for SARI. SARI surveillance is useful for monitoring disease trends and for characterizing severe influenza-related disease. In the same way as with ILI surveillance, these activities facilitate the estimation of disease burden, aid in understanding influenza-related costs, and provide specimens for analysis and identification of a vaccine strain.

Procedures are the same as for ILI surveillance: Patient age and date of consultation will be recorded for all cases, and additional epidemiologic and clinical data will be systematically recorded for a subset of cases selected for laboratory testing of clinical specimens. Clinical specimens will be tested in Local Surveillance Laboratories.

Unlike ILI surveillance, SARI surveillance calls for hospitals to make a weekly report by patient age group on SARI-related deaths. This information serves to detect any increase in mortality from influenza during epidemic periods and to monitor the impact of any intervention programs.

If a country has no existing active hospital-based surveillance, SARI surveillance should be implemented in a minimal number of Sentinel Sites. Countries with existing hospital-based respiratory infection surveillance may incorporate SARI surveillance into their current system, permitting standardization across the PAHO region.

The selection of hospitals to carry out SARI surveillance will be left to the individual countries. In areas where no similar surveillance systems exist, an effort should be made initially to select sites that have the best chance of success. For example, a good choice for an initial Sentinel Hospital would be an efficient general hospital that has a laboratory capable of performing immunofluorescence testing, that serves a defined and characterized population; and that has a history of collaboration between the hospital epidemiologist, clinical laboratory, and local health department.

Substantial data regarding the epidemiology and burden of severe viral respiratory infections can be obtained from a minimal number of well-run surveillance hospitals. It is recommended that a country prioritize the collection of quality surveillance data from a lesser number of surveillance hospitals over the early implementation in a greater number of sites. Adequate piloting and evaluation should be performed before adding any new Sentinel Hospitals.
5.5. Specific Objectives

- Determine, on a weekly basis and by age category, the proportion of outpatient clinic visits that are attributable to ILI, and the proportion of confirmed positive cases of influenza and other selected respiratory viruses among ILI case-patients.

- Determine, on a weekly basis and by age category, the proportion of hospitalizations attributable to SARI and the proportion of confirmed positive cases of influenza and other selected respiratory viruses among SARI case-patients.

- Provide epidemiologic and clinical characteristics of confirmed influenza cases among ambulatory patients with ILI and among hospitalized patients with SARI.

- Describe the frequency, temporal trends, and geographic distribution of disease caused by laboratory diagnosed influenza and other respiratory viruses (Respiratory Syncytial Virus, Adenovirus, and Parainfluenza) among specimens obtained from patients with ILI and SARI.

- Determine the proportion of SARI-associated deaths among all hospitalizations and among all hospitalized deaths.

- Isolate and antigenically characterize influenza viruses within the National Reference Laboratory to inform vaccine selection and to identify new influenza subtypes

- Rapidly identify strains that cannot be subtyped or that are of avian subtypes and immediately send isolates to the WHO Collaborating Center for further confirmation and testing.

5.6. Selection of Sentinel Sites

The selection of sentinel sites will depend on multiple factors, many of which are particular to a country or location; however, in all cases, it is recommended that the number and choice of facilities be based on demographic and geographic criteria that will enable an approximation of the national situation during influenza epidemics. To meet these criteria, a Sentinel Site should have the following characteristics:

- Ideally, the facility should be an established general hospital that tends to both adults and children and that contains an ambulatory primary care center; if no hospital serving all age groups exists, then two hospitals (one for children and another for adults) with adequate coverage of all age groups in the population should be selected.

- If no facility with the aforementioned characteristics exists, then one inpatient facility and one outpatient primary care facility can be selected as Sentinel Sites.

- If possible, the Sentinel Site should be selected from a location where it is possible to estimate the service population size and in an area where the service population is representative of groups of national interest (e.g. nationally representative or representative of key minority groups).

- The facility should contain a laboratory with staff trained by the National Reference Laboratory in immunofluorescence testing for respiratory viruses. If the facility is unable
to comply with this last criterion, its specimens should be processed by a different laboratory with appropriately trained staff or by the National Reference Laboratory.

- The Sentinel Site should have its own coordinator, preferably the person overseeing hospital epidemiology or a representative of the local or Intermediate Epidemiology Office.
- The Sentinel Site should have the capacity and staff to obtain patient samples at the Sentinel Hospital or Sentinel Clinic and be capable of processing them.

### 5.7. Organization of Surveillance Facilities

Local surveillance units should be composed of a coordinating Local Epidemiology Office (in a Sentinel Hospital or in the local or intermediate-level Health Department), Sentinel Hospital(s), Sentinel Clinic(s), and a Local Sentinel Laboratory. The Local Epidemiology Office will oversee all surveillance components (epidemiologic, clinical, and laboratory), each of which will require a part-time staff member to supervise surveillance operations. It is also recommended that there be an intermediate-level (state/provincial/regional) surveillance coordinator as well as a national-level surveillance coordinator at the Ministry of Health.

The use of an Intermediate Level Epidemiology Office will depend on the existing public health and surveillance system structures of a given country. Some nations—especially small nations or those with only a few Sentinel Sites—may find intermediate-level surveillance to be unnecessary and may choose to send surveillance information directly to the national office for aggregation.

### Functions and Levels of Responsibility

We recommend defining functions and levels of responsibility according to existing surveillance structures within each country. Accordingly, responsibility might be delegated as follows:

**Local Epidemiology Office**

- Monitor system implementation
- Collect data in a timely fashion
- Process, analyze, and report the data at the local level, integrating laboratory results
- Make weekly reports to the intermediate or national level.

**Hospital and Ambulatory Clinic**

- Record SARI or ILI cases by age group using standardized data collection forms, including any cases of SARI–associated deaths.
- Obtain and transport respiratory specimens according to established criteria and complete the data collection forms.
Local Sentinel Laboratory
- Process respiratory specimens for influenza A and B and other respiratory viruses (adenovirus, parainfluenza, and respiratory syncytial virus), by immunofluorescence testing under adequate biosafety conditions as defined by WHO.
- Communicate laboratory results in a timely manner to the originating practitioner.
- Make weekly reports of test results to the Epidemiology Office (local or intermediate, depending on the organization of the sentinel unit) and to the National Reference Laboratory.
- Send all specimens with results positive for influenza and a proportion of negative results to the National Reference Laboratory for further testing.

Intermediate Level Epidemiology Office
- Provide support to the surveillance system under its responsibility.
- Train hospital and outpatient health care staff.
- Consolidate and analyze information from the Sentinel Sites under its responsibility.
- Make influenza epidemiologic situation reports to local and national authorities on a regular basis.
- Ensure the proper collection of patient information and clinical samples at Sentinel Sites and ensure that samples are properly transported to the National Reference Laboratory.

National Level Epidemiology Office
- Coordinate the implementation of the surveillance system.
- Provide resources for operation of the system.
- Consolidate information forwarded from the intermediate levels.
- Analyze information on the weekly epidemiologic situation.
- Set up national and international public health alerts in the event of influenza outbreaks or other situations of concern.
- Disseminate information and results via periodic reports (e.g., e-mail, website, periodic epidemiologic bulletins) to the public, the surveillance system, and stakeholders.

It is recommended that the National Epidemiology Office define strategies (e.g., training, certificates of appreciation, periodic reminders) to stimulate and reinforce the effective operation of the system at the local and intermediate levels.

National Reference Laboratory
- Train and supervise surveillance laboratories in immunofluorescence testing and in biosafety practices.
- Isolate and characterize influenza virus from positive samples according to WHO-defined biosafety conditions.
- Evaluate a percentage of negative samples sent by the local level.
- Isolate and characterize novel viruses.
• Consolidate and analyze national laboratory data and prepare reports on a weekly basis.
• Send virologic surveillance reports to Sentinel Sites, states or provinces, and to the Ministry of Health.
• Report results to PAHO/WHO via FluNet.

5.8. Implementation

The implementation of surveillance is a responsibility of the national level of public health, in conjunction with the intermediate and local levels, and will depend on the public health organization in each country.

The number of persons under surveillance will depend on the number of Sentinel Hospitals and Sentinel Clinics and the size of their patient populations. Prior to surveillance implementation, the total number of weekly admissions during the prior year for pneumonia and influenza should be determined by chart review. This will aid in the determination of the systematic sampling strategy and will provide a SARI baseline estimate. The number of patients sampled for laboratory testing will depend on the Surveillance Laboratory’s ability to process, test, and ship specimens; the number of epidemiologists who can oversee data collection and analysis; and the method by which cases are chosen for testing. In general, broad population coverage by the surveillance system is less important than the efficient collection of quality data by a few Sentinel Hospitals and Sentinel Clinics.

Consideration should be given to resources needed for the operation of Sentinel Hospitals and Sentinel Clinics, including necessary training, evaluation, and supervision. Health care staff should have training in the use of case definitions and data collection forms, epidemiologic information flow, and sample collection and transport.

The National Reference Laboratory will train surveillance laboratories in immunofluorescence testing and biosafety measures. The Laboratory should coordinate with the national level regarding required supplies and human resources. PAHO/WHO and CDC will provide support for national-level training workshops.

5.9. Surveillance Data Collection and Flow

All countries—especially those without a well-defined influenza season—should maintain surveillance activities year-round in order to detect sporadic cases of disease. Sentinel Clinics, Sentinel Hospitals, and Local Surveillance Laboratories will collect epidemiologic and laboratory data on a daily basis, and the data will be sent to the Epidemiology Office for consolidation on a weekly basis.

It is important that standardized data collection forms be used for recording case-patient data. Such forms are included in Annex 1 of this document. A specific form should be used to collect clinical and epidemiologic data from systematically chosen ILI and SARI cases and from case-patients from whom respiratory samples are obtained. The collected data should be recorded by health care providers tending to the case-patients since they are in a position to directly obtain information. In ILI and SARI cases, age and epidemiologic week will be registered, using the
forms provided for collecting aggregate data on ILI and SARI cases. Depending on a country’s ability to collect data, optional information (e.g., sex of the patient) may be reported to the Epidemiology Office.

5.10. Processing Respiratory Samples

The capacity of the Local Surveillance Laboratories will determine the number of specimens tested as part of surveillance activities. Coordination between the laboratory and the Sentinel Hospital or Sentinel Clinic is essential for ensuring that systematic sampling methods are used. The maximum number of specimens that theoretically could be processed weekly by a laboratory should correlate with the maximum number of patients sampled.

To exclude sampling bias, a systematic sampling method must be employed. A recommended sampling method would be the testing of every x number of cases admitted with SARI, with x being equal to the number of weekly SARI cases admitted to the Sentinel Hospital divided by the maximum number of specimens a Surveillance laboratory could process weekly. For example, if a hospital admits 80 SARI patients weekly during the peak of influenza season, and if the maximum weekly number of specimens that a laboratory can process is 20, then a suitable systematic sampling during the peak of the influenza season would be every fourth SARI case. Ideally, a Surveillance Laboratory will be able to test between most and all SARI cases in a sentinel hospital.

For ILI surveillance, a system similar to the SARI sampling process is recommended (obtaining a clinical specimen from every x number of cases). Many Sentinel Clinics will find this logistically difficult. At the minimum, it is recommended that specimens taken from cases occur on the same day or days weekly and attempt to represent a broad demographic range. An example of an adequate system would be the sampling of ILI cases every Tuesday morning from a family medicine clinic that serves a broad range of patients. In this example, care should be taken to ensure that patients seen on Tuesday mornings are not appreciably different from those seen on other days (e.g. it is not the usual morning for doing all diabetic foot care in the clinic).

During periods outside the peak influenza season, a greater proportion of cases can be systematically sampled. Medical services within the Sentinel Hospital or Clinic should include all those providing care for acute respiratory disease (e.g. internal medicine, pediatrics, geriatrics, and others).

5.10.1. Sampling Criteria

Patients will be tested for respiratory viruses by immunofluorescence testing based on the following criteria:

- Patient meets the clinical case definition of ILI or SARI where appropriate, AND
- Patient is systematically chosen for testing, AND
- The onset of symptoms falls within 72 hours of sample collection.
Taking a sample within 72 hours after onset of symptoms will improve the accuracy of immunofluorescence. The frequency of false negative immunofluorescence tests will increase over the course of influenza infection as viral shedding decreases.

A case that has any Nationwide Surveillance investigation trigger will be counted, but must initiate outbreak response mechanisms outlined in Section 6. Evaluation of such cases will be according to Nationwide Surveillance protocols.

If a case is chosen for testing by the systematic sampling process, but that case does not meet the sampling criteria, the patient declines testing, or the patient is not tested for any other reason, the next patient with SARI or ILI should be tested.

5.10.2. Sampling Logistics

It is recommended that any cases that meet the sampling criteria defined above have clinical specimens taken as soon as possible during the course of their hospitalization. This may occur when they are assessed for admission in an emergency room or after their admission to the hospital. Ambulatory cases that meet these sampling criteria should have clinical specimens taken while they are still in the Sentinel Clinic.

Samples from ILI and SARI cases will be taken by doctors or trained medical personnel, in accordance with the procedures established in each country. In cases involving ILI, a nasal swab should be taken from adults, and for children under five a nasopharyngeal swab or aspirate is recommended. For SARI cases, a nasopharyngeal swab or aspirate is recommended. These specimens should be kept refrigerated in transport media and should be sent as soon as possible to the Sentinel Laboratory along with the data collection form. Commercial transport media or media developed at the lab can be used in accordance with WHO guidelines (see Annex 2).

At the Surveillance Laboratory, specimens testing positive for the influenza virus should be stored in transport media at a temperature of 4°C and sent within one week to the National Reference Laboratory.

5.10.3. Processing and Testing

Specimens will be processed and tested at the Surveillance laboratory for the presence of viral antigens (Adenovirus, Influenza A and B, Parainfluenza, and Respiratory syncytial virus) using the Immunofluorescence Antibody test. Ideally, this technique should be carried out using Biosafety Level 2 (BSL2) practices (30). However, in suspected cases of avian influenza, unusual or unexpected cases or outbreaks of ILI/SARI, they should be processed under BSL3 conditions, using Biosafety Level 3 (BSL3) practices, at the National Reference Laboratory (31).

Specimen Flow at Surveillance Laboratories

Optimally, all of the specimens testing positive for influenza will be sent to the National Reference Laboratory within one week for confirmation and further analyses. If this is not
feasible, through agreement with the National Reference Laboratory, a representative sample of the positive laboratory tests can be sent for further testing. There may be times during epidemic periods when the National Reference Laboratory is unable to process all positive specimens. In these instances, a majority of positive specimens should be randomly chosen and sent to the National Reference Laboratory.

Among specimens testing negative for influenza, 10% should be randomly chosen monthly for confirmation by the National Reference Laboratory. During epidemics a representative sample may be processed if the capacity of the National Reference Laboratory is exceeded.

**Isolate/Specimen Flow at the National Reference Laboratory**

The National Reference Laboratory should perform preliminary antigenic and, if possible, genetic characterization on the virus isolates grown at the facility.

The National Reference Laboratory should then send representative virus isolates and low-reacting viruses to the CDC WHO Collaborating Centers for Influenza at least once a month during the surveillance period.

If any viruses cannot be subtyped using the WHO reagent kit, the National Reference Laboratory should notify WHO and CDC and immediately send the virus isolate to the CDC WHO Collaborating Centers for Influenza for analysis.

**5.11. Data Analysis**

Data analysis will describe the distribution of cases over time, cases by age category, and cases by local surveillance level. When possible, population-based incidence data should be reported. Proportions should be reported by numerator and denominator.

The surveillance laboratories associated with the Sentinel Clinics and Sentinel Hospitals will record the frequency and percentage of positive viruses by type and strain.

The following parameters should be used for the analysis of local surveillance data:

**Sentinel Clinic surveillance analyses by epidemiologic week**

- Proportion of ILI cases per total consultations
- Proportion of ILI cases per total consultations by age category
- If possible, population-based incidence of ILI in aggregate and by age-category (when size of service population is known)
- Proportion of ILI cases testing positive for influenza and other respiratory viruses per the total number of ILI cases

**Sentinel Hospital surveillance analyses by epidemiologic week**

- Proportion of SARI cases per total hospitalizations
• Proportion of SARI cases per total hospitalizations by age category
• If possible, population-based incidence of SARI in aggregate and by age category (when size of service population is known)
• Proportion of SARI cases testing positive for influenza and other respiratory viruses per the total number of cases tested
• Proportion of deaths among SARI cases per the total number of hospitalizations.
• Proportion of deaths among SARI cases per the total number of hospital deaths
• If possible, population-based incidence of SARI associated deaths in aggregate and by age category (when size of service population is known)

Based on information from five years of surveillance, weekly baselines can be calculated for the above analyses. In the case of the proportion of SARI associated hospitalizations and deaths, baselines can be determined using retrospective information from hospital records. Comparison with previous years using mobile averages can also be performed. These data will aid in the determination of influenza seasonality.

Intermediate level data analysis will depend on the number of Sentinel Sites within an area of responsibility. Such data analysis will be consolidations of all Sentinel Site data according to the same parameters as those outlined for local-level data analysis.

National-level data analysis will use the same parameters as local-level data but may include consolidation of all collected data and the comparison of data collected by intermediate- and local-levels. Analysis will assess the burden of disease on the national health care system and characterize disease rates across the country. National data consolidation will permit comparisons between countries as well as for an assessment of regional trends throughout the PAHO coverage area.

5.12. Sentinel Surveillance Performance Indicators

To evaluate the efficiency and success of the system, a number of “process indicators” and “outcome indicators” have been established. Additionally, at least once yearly, local surveillance reviews are recommended to ensure data quality, protocol adherence, and standardization across a country. Such reviews may incorporate the following:

• Hospital and clinic record audits to determine whether cases of ILI and SARI are being accurately recorded
• Assessment of local staff knowledge of protocols and case definitions
• Laboratory equipment and staff assessment
• Laboratory data audits to determine reporting accuracy
• Continuing education concerning notifiable disease surveillance and sentinel surveillance protocols
• The opportunity for local staff to give feedback about Surveillance System inefficiencies
Other quality assurance

The “process” and “outcome” indicators are presented in the following table and will allow for system evaluation in accordance with the specific objectives of the Sentinel Surveillance system:

<table>
<thead>
<tr>
<th>Specific Objectives</th>
<th>Process Indicators</th>
<th>Outcome Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine weekly proportions of ILI among clinic visits</td>
<td>Number of ILI case reports made within one week per number of surveillance weeks. Goal &gt;80%</td>
<td>Number of ILI case reports made (including zero reports) per number of surveillance weeks. Goal &gt;95%</td>
</tr>
<tr>
<td>Provide epidemiologic and clinical characteristics of confirmed Influenza cases among ambulatory patients with ILI and those hospitalized with SARI</td>
<td>Number of ILI and SARI cases sampled for testing per number of ILI and SARI cases counted. Goal for ILI cases &gt;2%. Goal for SARI cases &gt;50%</td>
<td>Number of ILI and SARI cases sampled for testing that has a completed clinical-epidemiologic form per number of ILI and SARI cases sampled for testing. Goal &gt;80%</td>
</tr>
<tr>
<td>Determine the proportion of cases of influenza and other select respiratory viruses confirmed as positive among all ILI and SARI cases.</td>
<td>Number of samples taken from SARI cases within one day of hospital admission per total number of samples taken. Goal &gt;80%</td>
<td>Number of samples tested for ILI and SARI cases per total number of samples taken. Goal &gt;95%</td>
</tr>
<tr>
<td>Describe the frequency, temporal trends, seasonality, and geographical distribution of the influenza virus and other respiratory viruses among samples taken from patients with ILI and SARI</td>
<td>Proportion of laboratory reports made within one week per number of surveillance weeks. Goal &gt;80%</td>
<td>Number of weekly laboratory reports per number of surveillance weeks. Goal &gt;95%</td>
</tr>
<tr>
<td>Determine the percentage of patients hospitalized who died from SARI out of the total number of those hospitalized</td>
<td>Number of SARI associated death reports made within one week per total number of surveillance weeks. Goal &gt;80%</td>
<td>Number of SARI associated death reports (including zero reports) per total number of surveillance weeks. Goal &gt;95%</td>
</tr>
<tr>
<td>Specific Objectives</td>
<td>Process Indicators</td>
<td>Outcome Indicators</td>
</tr>
<tr>
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</tr>
<tr>
<td>Isolation and antigenic characterization of influenza viruses for vaccine selection in the National Influenza Centers and identification of new subtypes the influenza virus</td>
<td>Weeks reported to FluNet out of total number of surveillance weeks. Goal &gt;80%</td>
<td>Number of characterized viruses sent to CDC per total number of viruses characterized. Goal &gt;50%</td>
</tr>
<tr>
<td>Rapid identification of subtypes incapable of being characterized or avian subtype strains, confirmation for speedy provision to WHO Collaborating Center</td>
<td>Number of reports to PAHO/WHO made within 48 hours of results on cases where subtyping could not be done or where there are new subtypes per total number of such reports. Goal &gt;80%</td>
<td>Number of reports of test results made within 48 hours by WHO Collaborating Centers of samples shipped for rapid subtyping per total number of samples shipped for rapid subtyping. Goal &gt;80%</td>
</tr>
</tbody>
</table>

### 6. Enhanced Nationwide Notifiable Disease Surveillance

#### 6.1. Introduction

The timely detection of all unusual or unexpected respiratory infection outbreaks is essential for the effective implementation of control measures to limit morbidity and mortality. An infectious disease surveillance system should have the capability to detect and respond to outbreaks of both human influenza and atypical respiratory infections. Moreover, the early detection of sustained human-to-human transmission of a virus of pandemic potential is crucial for the implementation of control measures to either stop or slow the spread of the disease.

An Enhanced Nationwide Notifiable Disease Surveillance System (Nationwide Surveillance) can provide an early warning for outbreaks of respiratory diseases with pandemic potential. Such a system requires universal awareness of reporting triggers and an efficient reporting mechanism. Any training for Nationwide Surveillance will involve teaching clinicians to remain alert for unusual or unexpected diseases and to report suspected outbreaks or atypical pneumonia cases to the appropriate public health authorities. Integration of surveillance with animal health authorities is essential for the detection of outbreaks involving zoonotic diseases and any subsequent implementation of control measures. Notification should prompt further inquiry and outbreak investigations when appropriate. The existing public health system in a country will provide the basic structure for reporting and investigation. In most countries, the population covered by Sentinel Sites will be limited and concentrated in specific geographic areas. Therefore, Nationwide Surveillance is essential to detect cases and outbreaks of unusual or unexpected infections.

To improve system sensitivity, notifiable disease reporting must be implemented with nationwide identification and notification training. Including drug dispensers, coroners, and others with potential interaction with individuals with respiratory infections can expand the coverage of the system beyond clinics and hospitals. The routine monitoring of media reports and rumors of disease activity may also provide early knowledge of notifiable disease activity.
Regular reminders, inquiries, and training of reporters will enhance the system and improve system sensitivity.

The focus on Nationwide Surveillance should be the investigation and the outbreak response to notifiable events as indicated and defined in the revised International Health Regulations (IHR) and in the WHO pandemic influenza draft protocol for rapid response and containment (28, 32).

6.2. Objectives

- Detect outbreaks of SARI in a timely manner
- Detect cases or outbreaks of ILI or SARI among groups at risk of infection by H5N1 and atypical viruses in a timely manner
- Detect outbreaks of respiratory infections with pandemic potential in a timely manner
- Initiate outbreak investigations and implement control measures in a timely manner

6.3. Triggers for Outbreak Investigations

The following events should trigger public health department notification and inquiry prior to laboratory confirmation:

- An excess number of SARI cases in a health care facility or community
- Clusters of SARI
- Atypical cases of ILI or SARI, including disease related to animal exposure
- Any rumors of clusters of SARI or of atypical respiratory infections, including disease related to animal exposure
- Possible other triggers for outbreak investigation may include clusters of animal deaths or excessive absenteeism from schools, institutions, and workplaces

Excess Number of SARI Cases

An outbreak investigation should be initiated by an increased number of SARI cases over an established threshold, either in a geographically defined area or over a short period of time. The investigation can be initiated anywhere in the country by the existing public health structures.

Clusters of SARI

For the purpose of influenza outbreak detection, a cluster is defined as three or more persons geospatially or socially linked with onset of SARI within 10 days of each other (28). Such events may be evidence of efficient and sustained human-to-human transmission of H5N1 or the emergence of a novel respiratory virus.
Atypical SARI Cases
Illnesses that meet the above definitions should be investigated immediately when found among the following:

- SARI among health care workers or other occupational exposure
- SARI among travelers to high-risk areas
- Outbreaks involving two or more family members

Investigation should be initiated prior to laboratory confirmation of etiologic agent. Countries that do not have adequate capacity to establish a probable diagnosis within 48 hours of atypical SARI case identification should request immediate support from WHO. Such events may be evidence of efficient and sustained human-to-human transmission of H5N1 or the emergence of a novel respiratory virus.

Unofficial Reported Information Surveillance
This involves inquiry into unofficial reports of respiratory infections identified from media reports, the public, professional groups, laboratories, ProMed, or persons in the influenza surveillance network. It may involve a single case, for example, reports of ILI in a poultry worker with contact to suspected H5N1-infected poultry, or an unusual or unexpected outbreak of ILI or SARI. Unofficial reported information surveillance has been shown to be an important aspect of surveillance in recent cases of Avian Influenza A/H5N1 in Southeast Asia (33).

Suspected human cases of influenza related to animal exposure
To date, cases of human infection with the avian influenza A viruses have been sporadic and rare events, even in areas where the virus is widespread among poultry. Any transition in the behavior and epidemiology of the currently circulating virus may indicate increased transmissibility between humans and will most likely result in an event sufficiently ‘unusual’ to be detected by alert clinicians or by the public health system.

Suspected human cases of influenza related to animal exposure include situations where at least one case with ILI or SARI exhibits a history strongly suggesting potential exposure to the avian influenza A virus, within seven days prior to symptom onset, such as:

- Travel to or residence in an area affected by influenza outbreaks in birds or other animals.
- Direct contact with dead or diseased birds or other animals in an affected area.
- Close contact with human cases of avian influenza virus infection (living or deceased) or with a person who has unexplained SARI.
- Cases involving possible occupational exposure, including employment as an animal culler, veterinarian, laboratory worker, or health care worker

In an effort to capture novel emerging infections in addition to potential H5N1 virus infection, these criteria are intentionally broader than existing WHO reporting criteria for suspected human cases of H5N1 virus infection (34).
6.4. Nationwide Surveillance System Organization

Organization of Nationwide Surveillance will depend on the existing surveillance infrastructure within a country, the public health system and governmental hierarchy, and the availability of resources. It is important to form and prepare integrated health teams for surveillance and rapid response that include clinicians, laboratorians, communication specialists, and animal- and public health authorities. Teams should be established in such a way that it would be feasible for them to respond to reported trigger cases in a timely manner. This would likely involve national and intermediate level Rapid Response Teams (RRT). They would be trained in outbreak investigation techniques and control measures. The state/provincial and national levels must have resources for personal protective equipment, rapid communications, transportation, and shipment of specimens.

In accordance with IHR, there is a need for laboratory diagnosis within 48 hours of detection of any unusual, unexpected, or unexplained events. Therefore, we recommend that samples taken in the setting of an outbreak investigation should be sent directly to the National Reference Laboratory for processing and testing/shipment to the WHO Collaborating Center at CDC. Samples from patients and laboratory testing must conform to existing guidelines (4, 35, 36).

6.5. Nationwide Surveillance System Education and Awareness

The implementation of Nationwide Surveillance must include intensive, nationwide education of potential system reporters. This should include, at a minimum, all health care providers, diagnostic laboratorians, coroners, and drug dispensers. And it may also include others with potential exposure to individuals with severe or atypical respiratory infections such as traditional healers, religious leaders, or unlicensed medical practitioners. All potential reporters need to be made aware of trigger events, understand the reporting process, and be able to report notifiable cases in a timely manner.

Concurrent with training of potential system reporters, nationwide public education and awareness campaigns will improve system sensitivity. Messages targeted to the general population via various media including print, radio and television can improve awareness of severe and atypical respiratory infections. These public service messages should address general disease information including risk factors for infection, methods to reduce individual risk, and events that should be reported to public or animal health authorities. These events should include clusters of SARI, illness associated with exposure to animals, or clusters of disease in animals. As with notifiable disease reports by health care professionals, public reports of clusters of human or animal disease will flow through existing public health system channels.

Regular training refreshers should be provided to potential system reporters in the form of newsletters, phone calls from members of the surveillance system, and in-service training. In addition, public awareness campaigns should continue indefinitely in order to maintain public knowledge of disease, reportable events, and the reporting process. Ongoing knowledge, attitude, and perception surveillance of potential system reporters and the general public can inform education campaign content and aid in message targeting.
Additionally, surveillance system staff should make regular reminders of notifiable events to potential reporters and inquire about cases meeting notification triggers that may have gone unreported.

6.6. Nationwide Surveillance System Reporting

To the extent possible, the reporting of notifiable diseases should be made within existing public health reporting channels. In most countries, notification will begin at the local level which must be capable to promptly initiate inquiry into severe or atypical respiratory infections. If reporting is initially made to provincial or national levels, a country must be able to rapidly respond at a local level – either through alerting local health departments or by immediate travel to the reporting area.

The initial inquiries can begin via several different mechanisms:

- Travel to or residence in an area affected by influenza outbreaks in birds or other animals.
- Active media or unofficial reported information surveillance by the local health department detects potential clusters of animal disease or clusters of atypical or severe respiratory infections among humans.
- Hospital registry audits or direct inquiries made to area clinicians by local health departments detect notifiable cases.
- Informal reports made by lay persons detect potential clusters of animal disease or of atypical or severe respiratory infections among humans.
- Official notifiable disease reports of suspected cases.

A local inquiry may be all that is necessary if a reported case is of low severity without clinical or epidemiologic features associated with avian influenza or other novel viral infections. RRT investigation may be initiated if there are epidemiologic or clinical characteristics associated with novel virus infections. For example, a local investigation would be appropriate for a primary school outbreak of mild, febrile respiratory illness without recent travel or exposure to sick animals. A RRT investigation would be appropriate for an outbreak of a febrile respiratory disease among poultry workers with exposure to sick birds.

6.7. Rapid Response to Investigation Triggers

Triggers for outbreak response must be assessed by public health authorities to determine whether they represent a public health emergency of local, national, or international concern. Once the public health emergency is established, an outbreak investigation should be initiated.

Risk communication and outbreak investigations for suspected cases of H5N1 virus infection or atypical respiratory infections should be performed following existing guidelines (37-40). Although the WHO guidelines for investigation of human cases of avian influenza A (H5N1) are disease specific, much of the guidance is generalizable to the investigation of viral respiratory infections with pandemic potential. We recommend that this document form the foundation for outbreak investigations initiated by the Nationwide Surveillance System. It is beyond the scope of this protocol to describe outbreak investigations, response, and communications in detail.
6.8. Nationwide Surveillance Responsibilities

At each level within a country’s existing public health structure, someone must be designated as the official point of contact for all outbreak reports and investigations. Individuals designated for outbreak response and infection control must have the knowledge and training to effectively carry out their duties. Ideally, RRTs that respond to outbreak triggers should be located all over the country to enable them to investigate any given outbreak within 48 hours.

Responsibilities for Nationwide Surveillance, by level, are delineated as follows:

**Local Level**
- Identify and verify outbreak triggers
- Immediately report the outbreak to the intermediate (regional) and/or national levels
- Initiate inquiry into reported cases (case confirmation)
- Take clinical specimens
- Apply control measures
- Implement corrective measures as follow-up once the outbreak has been dealt with
- Determine whether criteria for RRT investigation met

**Intermediate Level**
- Integrate information from the region.
- Provide technical support to outbreak investigation and for establishing control measures.
- Provide help in implementing control measures.
- Alert the regional network of the outbreak.
- Report to the national level
- Maintain RRT equipment and training

**National Level**
- Integrate outbreak information at the national level.
- Ensure coordination with other actors involved in the outbreak (laboratory, environmental health, animal health).
- Provide technical support to outbreak investigation and assure the implementation of control measures.
- Coordinate with the National IHR focal point.
- Alert the national network of the outbreak.
- Make recommendations for corrective measures and follow up their implementation once the outbreak has been controlled.
- Support RRT equipment and training
6.9. Nationwide Surveillance System Performance Indicators

To evaluate the efficiency and success of the system, a number of “process indicators” and “outcome indicators” have been established. As in Sentinel Surveillance, at least once a year, Nationwide Surveillance reviews at local or intermediate levels are recommended to ensure data quality, protocol adherence, and standardization across a country. Such reviews may incorporate the following:

- Review of all notifiable disease reports (official and unofficial) and actions taken
- Review of all RRT investigations (with a focus on each component of outbreak response –e.g., clinical, epidemiologic, veterinary, laboratory, communications, and other)
- Continuing education concerning notifiable disease surveillance and sentinel surveillance protocols
- Other quality assurance

The “process” and “outcome” indicators are presented in the following table and will allow for system evaluation in accordance with the specific objectives of Nationwide Surveillance:

<table>
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<tr>
<th>Specific Objectives</th>
<th>Process Indicators</th>
<th>Outcome Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timely detection of unusual or unexpected SARI outbreaks.</td>
<td>Number of SARI outbreaks reported within 48 hours of onset per total number of outbreaks investigated.</td>
<td>Number of SARI outbreaks verified per total number of SARI alerts made.</td>
</tr>
<tr>
<td>Investigation by the health care system of any reports of unusual or unexpected cases of SARI stemming from any source and, when appropriate, as well as initiation of outbreak investigations.</td>
<td>Number of SARI outbreaks investigated within 48 hours of onset per total number of outbreaks investigated.</td>
<td>Number of outbreaks investigated per total number of outbreaks reported. Goal &gt;90%</td>
</tr>
<tr>
<td>Timely detection and verification of ILI or SARI outbreaks in groups at risk of infection by the avian influence virus or by emerging viruses.</td>
<td>Number of SARI outbreaks investigated where control measures were recommended within 48 hours of onset per total number of outbreaks investigated.</td>
<td>Number of SARI outbreaks investigated where control measures were taken within 48 hours of onset per total number of outbreaks investigated.</td>
</tr>
</tbody>
</table>

8. References
9. Annexes

Annex 1: Surveillance Data Collection and Flow, Registry Instruments

Data-Collection Responsibilities

Those who form the clinical team at the Sentinel Clinic or Hospital should register cases of ILI or SARI by age group on a daily basis and should send the resultant report to the Epidemiology Coordinator once a week. In cases where health care providers use their own registry instruments, the Coordinator of Epidemiology should collect the data and transfer it to the forms used for its consolidation. In both cases, data should ideally be entered into an electronic database, where the person in charge of local laboratories will also be entering laboratory data.

Minimal Data Elements to Be Collected

1. Sentinel Ambulatory Clinics shall minimally record the following data:
   - Influenza by epidemiologic week
   - Number of ILI consultations by age group
   - Number of consultations by age group
   - Number of individuals tested for respiratory viruses by age group, linked to medical record / surveillance number.

2. Sentinel Hospitals shall minimally record the following data:
   - Influenza by epidemiologic week
   - Number of patients admitted who have received care for SARI by age group
   - Number of admissions by age group
   - Number of patients who died from SARI by age group
   - Number of individuals tested for respiratory viruses by age group, linked to medical record / surveillance number.

3. Sentinel Ambulatory Clinics and Hospitals shall additionally record the following data for all individuals tested for respiratory viruses:
   - Hospital / ambulatory clinic data
     - Patient’s name
     - Patient’s age
     - Patient’s sex
     - Medical record / surveillance number
     - Date of onset
     - Date of sampling
     - Vaccination status during a given time period
     - Travel information
     - Contact with disease and/or outbreak (community or institutional)
     - Treatment provided
Clinical data

4. Sentinel Local Laboratories shall minimally record the following data:
   - Number and type of viruses detected in ambulatory patients per epidemiologic week by age group and linked to medical record / surveillance number
   - Number and type of viruses detected in hospitalized patients per epidemiologic week by age group and linked to medical record / surveillance number
   - Number of specimens received from Sentinel Clinics, linked to medical record / surveillance number
   - Number of specimens received from Sentinel Hospitals, linked to medical record / surveillance number

5. Surveillance Laboratory shall minimally record the following data elements for each respiratory specimen received:
   - Medical record / surveillance number
   - Specimen date
   - Patient’s age
   - Patient’s city, state or province of origin

6. Reference Laboratories shall minimally record the following data elements for each respiratory specimen received:
   - Laboratory number
   - Specimen date
   - Patient’s age
   - Patient’s city, state or province of origin
   - Type

Information Generated by the National Reference Laboratory

   - Laboratory number
   - Specimen date
   - Patient’s age
   - Patient’s city, state or province of origin
   - Isolation system
   - Type
   - Subtype
   - Isolate designation
   - Similarity to reference strain (Yes/No)
   - Whether further identification is in progress (Yes/No)

Dissemination of Data Collected from the Influenza Surveillance System

The Local Epidemiology Office shall disseminate the following information to Sentinel Clinics and Hospitals, staff in surveillance offices, and the Surveillance Laboratory on a weekly basis:
   - Number of new cases of ILI and total number of clinic consultations
• Number of new cases of SARI and total number of hospitalized cases
• Number of deaths from SARI and total number of all hospitalized or deceased cases
• Number of hospitalized cases where samples have been sent for laboratory testing
• Number of cases in clinics where samples have been sent for laboratory testing
• Number of laboratory tests among SARI cases with positive results
• Number of laboratory tests among ILI cases with positive results

The Intermediate Level Epidemiology Office will disseminate the following information to all Sentinel Sites located within the state/province, on a weekly basis:
• Aggregate the number of new cases of ILI and the total number of patient consultations in clinics within the state/province.
• Aggregate the number of new cases of SARI and the total number of hospitalized cases within the state/province.
• Aggregate the number of deaths from SARI and the total number of all patients hospitalized or deceased cases within the state/province.
• Aggregate the number of hospitalized cases where samples have been sent for laboratory testing within the state/province.
• Aggregate number of cases in clinics where samples have been sent for laboratory testing within the state/province
• Aggregate the number of laboratory tests among SARI cases with positive results within the state/province.
• Aggregate the number of laboratory tests among ILI cases with positive results within the state/province.

The National Epidemiology Office will perform the following:
• Consolidate and analyze all national data.
• Prepare weekly reports based on national surveillance data, to be periodically disseminated in accordance with existing processes, e.g. via fax, e-mail, Internet, bulletins, or other methods.
• At least every week, send a report to each level of the surveillance system, using the most expeditious means possible.

The National Reference Laboratory will perform the following:
• Report on the characterization of the influenza viruses received from each local laboratory.
• Consolidate the information received from these laboratories at the regional or national level.

Registry Instrument
We recommend using a form to record this information, ideally directly into a computer or onto a computational system spreadsheet.
1. **Weekly Collection Form for Aggregate ILI Case Data**
   When filling out this form, the customary care registries are to be used where health care providers have recorded cases of a patient’s initial consultation for ILI. Every week total figures will be compiled for consultations from all causes.
   Additionally recorded will be the number of cases where diagnostic care was provided by age group (under 6 months, 6–23 months, 2–4 years, 5–14 years, 15–49 years, 50–64 years, and over 65 years of age) and by epidemiologic week—in addition to the total number of cases where comprehensive care has been provided out of the total number of cases involving care.

2. **Weekly Collection Form for Aggregate SARI Case Data**
   When filling out the form, customary care registries are to be used where health care providers have recorded cases of hospitalization for SARI. Every week total figures will be compiled for hospitalizations from all causes.
   The number of cases where diagnostic care was provided will be recorded by age group (under 6 months, 6–23 months, 2–4 years, 5–14 years, 15–49 years, 50–64 years, and over 65 years of age) and by epidemiologic week—in addition to the total number of cases of where comprehensive care has been provided out of the total number of cases involving care.

3. **Weekly Collection Form for Fatal SARI Cases**
   When filling out the form, death certificates will be used where health care providers have registered the primary cause as death by SARI. The number of deaths will be recorded by diagnosis and age group (under 6 months, 6–23 months, 2–4 years, 5–14 years, 15–49 years, 50–64 years, and over 65 years of age), as well as epidemiologic week.

4. **Epidemiologic Data Form for ILI and SARI Cases and Sample Shipment (Clinical Epidemiologic Record)**
   For cases studied utilizing respiratory samples, we recommend using a specific form, ideally a spreadsheet that is part of a computerized system. Baseline data will be included for identification (patient’s name, age, sex, and record number), date of sampling, clinical and epidemiologic data (previous vaccinations, isolated case or [community or institutional] outbreak, and treatment). This form will make it possible to describe detected cases of influenza and other respiratory viruses in epidemiologic terms. The latter should be used when sending the sample to the laboratory.

5. **Form for Reporting Weekly Laboratory Results from ILI and SARI Cases**
   The laboratory will individually report to hospital services the results of any samples they send out. The laboratory will make weekly reports on the number of cases and specimens tested, on positive cases by age, and on the number of negative cases. This report will be sent to the Epidemiology Coordinator using the Laboratory Results Form. The laboratory can also add the distribution of the number of samples by age group in order to monitor the representation of all age groups.
# Weekly Data Collection Form for Cases of Influenza-Like Illness (ILI)

**Definition of ILI:** Person with a fever of rapid onset (over 38°C), cough, and sore throat, in the absence of another diagnosis.

<table>
<thead>
<tr>
<th>Date (Day, week)</th>
<th>Total Visits</th>
<th>Under 6 months</th>
<th>6–23 months</th>
<th>Under 2</th>
<th>2-4 years</th>
<th>5-14 years</th>
<th>15-49 years</th>
<th>50-64 years</th>
<th>Over 65</th>
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<tbody>
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<td>Monday</td>
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</table>

**Total for Week**

| Population | Incidence Rate (per 100,000) | |
|------------|-----------------------------| |

**Surveillance Coordinator:**  
Signature
## Weekly Data Collection Form for Severe Acute Respiratory Infection (SARI) Hospitalizations

<table>
<thead>
<tr>
<th>Health Service, Department of Health, Region</th>
<th>Epidemiologic Week #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentinel Hospital</td>
<td>Date of Report</td>
</tr>
</tbody>
</table>

### Surveillance of Severe Acute Respiratory Infection (SARI)

<table>
<thead>
<tr>
<th>Number of Visits</th>
<th>Total</th>
<th>Under 6 months</th>
<th>6–23 months</th>
<th>2–4 years</th>
<th>5–14 years</th>
<th>15–49 years</th>
<th>50–64 years</th>
<th>Over 65</th>
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- **Monday**
- **Tuesday**
- **Wednesday**
- **Thursday**
- **Friday**
- **Saturday**
- **Sunday**

**Total for Week**

**Population**

**Incidence Rate (per 100,000)**

**Surveillance Coordinator:**

**Signature**
# Weekly Data Collection Form for Hospitalized Deaths

## Surveillance of Mortality Due to Severe Acute Respiratory Infection (SARI)

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Under 6 months</th>
<th>6–23 months</th>
<th>2–4 years</th>
<th>5–14 years</th>
<th>15–49 years</th>
<th>50–64 years</th>
<th>Over 65</th>
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<tbody>
<tr>
<td></td>
<td>Total # dead</td>
<td># dead from SARI</td>
<td>Total # dead</td>
<td># dead from SARI</td>
<td>Total # dead</td>
<td># dead from SARI</td>
<td>Total # dead</td>
<td># dead from SARI</td>
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<tr>
<td>Incidence Rate (per 100,000)</td>
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</tbody>
</table>

**Surveillance Coordinator:**

**Signature:**
Clinical Epidemiologic Record for ILI and SARI

Doctor: .................................................................
Address: ......................................................................
City/Town: ...................................................................
Province: ....................................................................
Tel: ( ) ..................................Fax: ................................
E-mail: ........................................................................

ILI  SARI

Laboratory Where Shipped:

Case ID #..................................................................................................................................

Last Name, First Name.................................................................................................................

Date of Birth: ....../...../............... Age: ..................... Sex:..................

Date of Onset of Illness: ....../...../............... Epidemiologic Week # .........................

Date Sample Taken: ....../...../..........

Flu Shot: Yes [ ] No [ ] Date of Vaccination: ....../...../............... 

Clinical Profile

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever over 38ºC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhinorrhea</td>
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<tr>
<td>Pharyngitis</td>
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<tr>
<td>Conjunctivitis</td>
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<tr>
<td>Otitis</td>
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<tr>
<td>Bronchitis</td>
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<tr>
<td>Bronchiolitis</td>
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<tr>
<td>Pneumonia</td>
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<tr>
<td>Cough</td>
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<tr>
<td>Shortness of Breath</td>
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<tr>
<td>Adenopathies</td>
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<tr>
<td>Asthenia</td>
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<tr>
<td>Headaches</td>
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<tr>
<td>Myalgia</td>
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<tr>
<td>Vomiting</td>
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<td>Diarrhea</td>
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<tr>
<td>Rashes</td>
<td></td>
<td></td>
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<tr>
<td>Sporadic case</td>
<td></td>
<td></td>
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<tr>
<td>Symptom onset during outbreak</td>
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</tbody>
</table>

Observations: ...........................................................................................................

Treatment: Antivirals  Yes [ ] No [ ] Type:.................................

Antibiotics  Yes [ ] No [ ] Type:.................................
## Weekly Laboratory Results
### Weekly Influenza Sentinel Surveillance Report

<table>
<thead>
<tr>
<th>Patients Hospitalized with Severe Acute Respiratory Infection (SARI)</th>
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<tbody>
<tr>
<td><strong>Health Service, Department of Health, Region</strong></td>
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<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Etiologic Agent</strong></td>
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<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td>SARI</td>
</tr>
<tr>
<td>RSV</td>
</tr>
<tr>
<td>Adenovirus</td>
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<tr>
<td>Parainfluenza</td>
</tr>
<tr>
<td>Influenza A</td>
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<tr>
<td>Influenza B</td>
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<tr>
<td>Negative</td>
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<tr>
<td><strong>Total</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Ambulatory Patients with Influenza Like Illness (ILI)</th>
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<tbody>
<tr>
<td><strong>Health Service, Department of Health, Region</strong></td>
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</tr>
<tr>
<td><strong>Etiologic Agent</strong></td>
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</tr>
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<td><strong>Total</strong></td>
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<tr>
<td>ILI</td>
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<td>Adenovirus</td>
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<td>Parainfluenza</td>
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<td>Influenza A</td>
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<td>Influenza B</td>
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<td>Negative</td>
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<tr>
<td><strong>Total</strong></td>
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<table>
<thead>
<tr>
<th><strong>Total Isolates Tested</strong></th>
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<tbody>
<tr>
<td>40</td>
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</table>
### Weekly Laboratory Results Line Listing

<table>
<thead>
<tr>
<th>Surveillance Laboratory:</th>
<th>Epidemiologic Week #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case ID #</strong></td>
<td><strong>Specimen Source</strong></td>
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</table>
Annex 2: Techniques for Respiratory Sampling

1. Nasal Swab
   - Insert a dry polyester or Dacron swab into the nostril in line with the palate, using a rotary motion and putting pressure on the walls of the nasal septum so as to drag out the greatest possible quantity of cells.
   - Introduce the swab into the tube that contains the transport medium:
     - If a **commercial medium** is used, place the swab in the transportation tube and press the bottom of the tube in order to liberate the medium or put pressure on the padding at the bottom.
     - If a **laboratory-prepared medium** is used, cut any leftover rod off the swab so that only the part that adheres to the swab remains in the tube. Close the tube with the cover. Swabs should always be kept moist during shipping.

2. Pharyngeal Swab
   - Using a swab, brush both tonsils and the back of the pharynx; then introduce the swab into the transport medium as indicated in the previous section.
   - In a laboratory-prepared medium, the two swabs (nasal and pharyngeal) can be incorporated into a single transport medium.

3. Nasopharyngeal Aspirator
   - **Materials**
     - Nasopharyngeal aspiration kit
     - Test tube rack, ice bath
     - Vacuum pump
     - Container with disinfectant solution
   - **Method**
     - Break open the envelope containing the aspiration kit and connect the end of the tube that is smaller in diameter to the aspiration tube.
     - Connect the other end of greater diameter to the vacuum pump.
     - Insert the feeding tube to the patient’s nostril.
     - Remove the tube by rotating it smoothly, then repeat the procedure with the other nostril.
     - Aspirate a volume of about 8–10 ml of cold tampon solution, pH 7.2, through the collector tube to drag out the whole secretion.
     - Change the cover of the collector tube and identify it with the patient’s data.
     - Send the sample to the laboratory immediately, along with the sample shipment form, ensuring that it remains in an ice bath until the time of its arrival at the laboratory.
Annex 3: IMCI case definitions:

- **Pneumonia:**
  - A child with cough or difficult breathing who has fast breathing and no general danger signs, no chest indrawing and no stridor when calm is classified as having PNEUMONIA.

- **Severe Pneumonia or Very Severe Disease**
  - A child with cough or difficult breathing and with any of the following signs—any general danger sign, chest indrawing or stridor in a calm child—is classified as having SEVERE PNEUMONIA OR VERY SEVERE DISEASE.

<table>
<thead>
<tr>
<th>General signs of danger:</th>
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<tbody>
<tr>
<td>o Child unable to drink or be breastfeed</td>
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<tr>
<td>o Child is lethargic or unconscious.</td>
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<td>o Child vomits everything</td>
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<td>o Convulsions</td>
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<tr>
<th>Difficult breathing:</th>
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<tbody>
<tr>
<td>o <strong>If the child is:</strong> 2 months up to 12 months <strong>Fast breathing is:</strong> 50 breaths per minute or more</td>
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<tr>
<td>o <strong>the child is:</strong> 12 months up to 5 years <strong>Fast breathing is:</strong> 40 breaths per minute or more)</td>
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</table>