Guideline for the Surveillance of Pandemic Influenza (From Phase 4 Onwards)

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Pandemic Influenza Experts Advisory Committee

Guidelines for the Surveillance of Pandemic Influenza From Phase 4 Onwards (Overview)

Type of Surveillance	Support system for the Investigation of Suspected Cases	Outpatient Syndromic Surveillance	Hospitalized Patient Pneumonic Syndrome Surveillance	Cluster Surveillance	Surveillance of Influenza-Like Diseases During Pandemic	Surveillance for the Prompt Identification of Deaths during Pandemic	Vaccine Adverse Event Surveillance	Virological Surveillance	Clinical Process Information-Sharing System
Information to be Collected	Basic patient information, test requests and results, history of conducts, contact history, health examination of individuals who had contact with pandemic influenza patients	Number of outpatients indicating fevers over 38°C and respiratory symptoms by age group	Hospitalized patients indicating pneumonic symptoms	The presence of at least three patients indicating similar symptoms who are linked epidemiologically	Number of outpatients indicating fevers over 38°C and respiratory symptoms by age group	Number of overall deaths from pandemic influenza	Dates of vaccination, lot numbers, symptoms of adverse events etc.	Antigenicity, genetic types, drug resistance etc.	Death rate, adverse events, resistance
Entities Collecting Data	Health centers, Local health institutes, National Institute of Infectious Diseases	Designated outpatient medical institutions	All medical institutions carrying beds for internal medicine and pediatrics patients		Designated outpatient medical institutions	Health centers	All vaccinating medical institutions	Local health institutes, National Institute of Infectious Diseases	Designated outpatient medical institutions
Surveillance Period	Phase 3A to the discontinuation of early response	Phase 4A to the discontinuation of early response	Phase 4A to the discontinuation of early response	Phase 4A to the discontinuation of early response	Discontinuation of early response to the end of Phase 6B†	Discontinuation of early response to the end of Phase 6B	Start of vaccination to the end of vaccination	Phase 3A to the end of Phase 6B	Phase 4B to the declaration of the end of pandemic by the government
Supporting System	NESID support system for the investigation of suspected cases	NESID syndrome surveillance	NESID syndrome surveillance		NESID syndrome surveillance（Same as outpatient syndromic surveillance）	NESID system for prompt identification of influenza-related deaths	NESID syndrome surveillance	NESID syndrome surveillance（NESID support system for the investigation of suspected cases）	

Guidelines for the Surveillance of Pandemic Influenza (From Phase 4 Onwards)

1. Objectives

- "Surveillance" refers to the systematic collection, analysis and interpretation of data required for the planning, implementation and evaluation of countermeasures against diseases, through continuous monitoring of the situation and trend of disease occurrence, enabling the establishment of effective countermeasures based on the results of prompt and regular surveillance feed back to stakeholders.

- It is unknown when and where an influenza pandemic will occur. Therefore, it is extremely important to detect its outbreak in Japan as early as possible through surveillance, and prevent the spread of infection to minimize damage.

- If infection spreads, it is indispensable to identify the outbreak status and disease characteristics through surveillance, thereby contributing to the formulation of administrative strategy to prevent the further spread of infection, the development of treatment policies at clinical institutions, and information provision to local residents.

2. Overview of different types of surveillance (See attached table)

(1) Support System for the Investigation of Suspected Cases

Surveillance to link suspected cases to a diagnosis based on epidemiological linkage and abnormal symptoms for the purpose of identifying patients of new influenza subtypes

(2) Syndromic Surveillance

Surveillance for the early detection of outbreak of an infectious disease, through the identification of rapid increases in patients with the target disease based on the number of patients with specified symptoms prior to a diagnosis confirmation from a physician

- Outpatient Syndromic Surveillance
  Surveillance for the prompt report of outpatients cases with fevers over 38°C and respiratory symptoms

- Hospitalized Patient Pneumonic Syndrome Surveillance
  Surveillance for the prompt report of patients with serious pneumonic symptoms that require hospitalization

(3) Cluster surveillance

Surveillance to identify the occurrence of group infection (e.g. clusters in households and medical institutions), through the identification of at least three patients from the same medical institution who are epidemiologically linked indicating similar symptoms, or one of whom is a health care worker; Contributes to early detection and response measures together with syndromic surveillance

(4) Surveillance of Influenza-Like Diseases During A Pandemic

As soon as the index case of pandemic influenza is identified, strategic early response measures shall be commenced. However, if the infection spreads despite such efforts, the number of patients shall be continuously monitored through the surveillance of influenza-like diseases during the pandemic, which will report the characteristics (syndrome) of influenza-like disease symptoms. This surveillance contributes to the investigation of countermeasures that are effective against the spread of infection by identifying the process of spread based on continuous monitoring. It uses the same method as the outpatient syndromic surveillance system.

(5) Pandemic Death Count Surveillance System

Surveillance to promptly report the number of deaths; It estimates death rates from the number of infected patients, and will provide information to clinical institutions and the general public to contributing to the formulation of countermeasures appropriate for the estimated death rate.

(6) Vaccine Side Effect Surveillance System

A system to report side effect of vaccines that contributes to the determination of whether or not vaccination should be continued

(7) Virological Surveillance

Surveys antigenicity, genetic types, and sensitivity to antiviral drugs of prevailing pandemic influenza, thereby contributing to the evaluation of vaccine effectiveness and treatment methods

(8) Clinical Information-Sharing System

An information sharing system through which health care workers can exchange methods for diagnosis and treatment on an Internet website, where pathologic characteristics, clinical processes, treatment records and other information of pandemic influenza are registered

3. Basic strategies

- At present, the “National Epidemiological Surveillance of Infectious Diseases (NESID) support system for the investigation of suspected cases” is targeted at the H5N1 subtypes. This system is capable of identifying the index case of an influenza subtype new to Japan, by linking cases based on epidemiological correlation (e.g. contact history/ travel history) and indicating clinical symptoms similar to influenza H5N1 cases. These identification methods shall apply to subtypes other than H5N1 as well. (“About the Partial Revision of the Implementation Guidelines for Research Projects on the Trends of Infectious Disease Occurrence” issued by the Manager of the Tuberculosis and Infectious Diseases Control Division of the Ministry of Health, Labour and Welfare, Kenkan-hatsu No. 1122003, November 22, 2006)

- If pandemic influenza occurs in Japan under unexpected circumstances, and if the above system is unable to identify such occurrence, syndromic surveillance and/or cluster surveillance shall be conducted for early detection.

○ If the occurrence of pandemic influenza is confirmed, and strategic early response is required, the "National Epidemiological Surveillance of Infectious Diseases (NESID) support system to research suspected cases" shall be bolstered in the geographical area where infection occurs and in surrounding areas. If strategic early response fails to prevent the spread of infection, information shall be collected through individual surveillance methods on the number of patients, deaths, and available beds, the status of patients in serious conditions, the efficacy of vaccines and their adverse effects, antigenicity, and genetic types, and the virus's sensitivity to antiviral drugs. This information will contribute to the formulation and revision of countermeasures against the further spread of infection, as well as providing the relevant information to health care workers and the general public. In Phase 4B, the regular weekly reporting of influenza patients at fixed-point medical institutions as a Class 5 infectious disease shall shift to the surveillance of Influenza-like diseases during a pandemic by increasing the number of fixed points and increasing the reporting frequency from weekly to daily.

○ Information collected by individual surveillance methods through the NESID shall be compiled and analyzed by the Ministry of Health, Labour and Welfare; the National Institute of Infectious Diseases; the governments of prefectures, the twelve major cities, special districts and cities operating health centers; health centers; local health institutes. Surveillance results shall then be fed back to Local infectious disease information centers and other institutions having access rights to the NESID and be used to update local and national countermeasures against pandemic influenza.

Attachment

Surveillance Type	Phase 3A	Phase 4A	Phase 6B	Supporting systems
Support system for the investigation of suspected cases	→	→		NESID support system to research suspected cases
Outpatient syndromic surveillance		→	→	NESID syndromic surveillance
Hospitalized patient pneumonic syndrome surveillance		→	Influenza-like diseases surveillance ~~during pandemic~~	NESID syndromic surveillance
Cluster surveillance		→		
Mortality Surveillance			→	NESID pandemic trend research for prompt identification of influenza-related deaths
Vaccine adverse event surveillance		→	→	NESID syndromic surveillance
Virological surveillance	→	→	→	NESID pathogen surveillance

* NESID: National Epidemiological Surveillance of Infectious Diseases

Details of individual surveillance methods (See Attachments)

Attachments

Support System for the Investigation of Suspected Cases

1. Objectives of the system

- ○ A subsystem for the NESID pandemic trend research of infectious diseases, aiming at the control and registration of information about suspected patients of an infectious disease with the risk of a pandemic (focused on the history of conducts and information on contact of individuals with (suspected) patients); The Government of Japan is in charge of implementation.
- ○ Medical institutions shall report “cases designated for observation” etc. to health centers.

2. Operations of the system

- ○ Health centers shall register patients in the aforementioned system.
- ○ Local governments, the Ministry of Health, Labour and Welfare, and the National Institute of Infectious Diseases shall share and respond to the registered patient’s information (personal data, clinical information, travel history, history of conducts, contact information of individuals with (suspected) patients etc.).

3. Targeted disease

Pandemic influenza

4. Participating institutions

- ○ Health centers
- ○ Governments of prefectures, and cities and special districts operating health centers (“governments of prefectures etc.”)
- ○ Local health institutes
- ○ Infectious Disease Surveillance Center, National Institute of Infectious Diseases
- ○ Ministry of Health, Labour and Welfare

5. Access rights

(1) Access to individual data

Access rights shall be detention for individual participating institutions and individual users in such institutions, because data registered in this system contain personal information.

(2) Specific examples

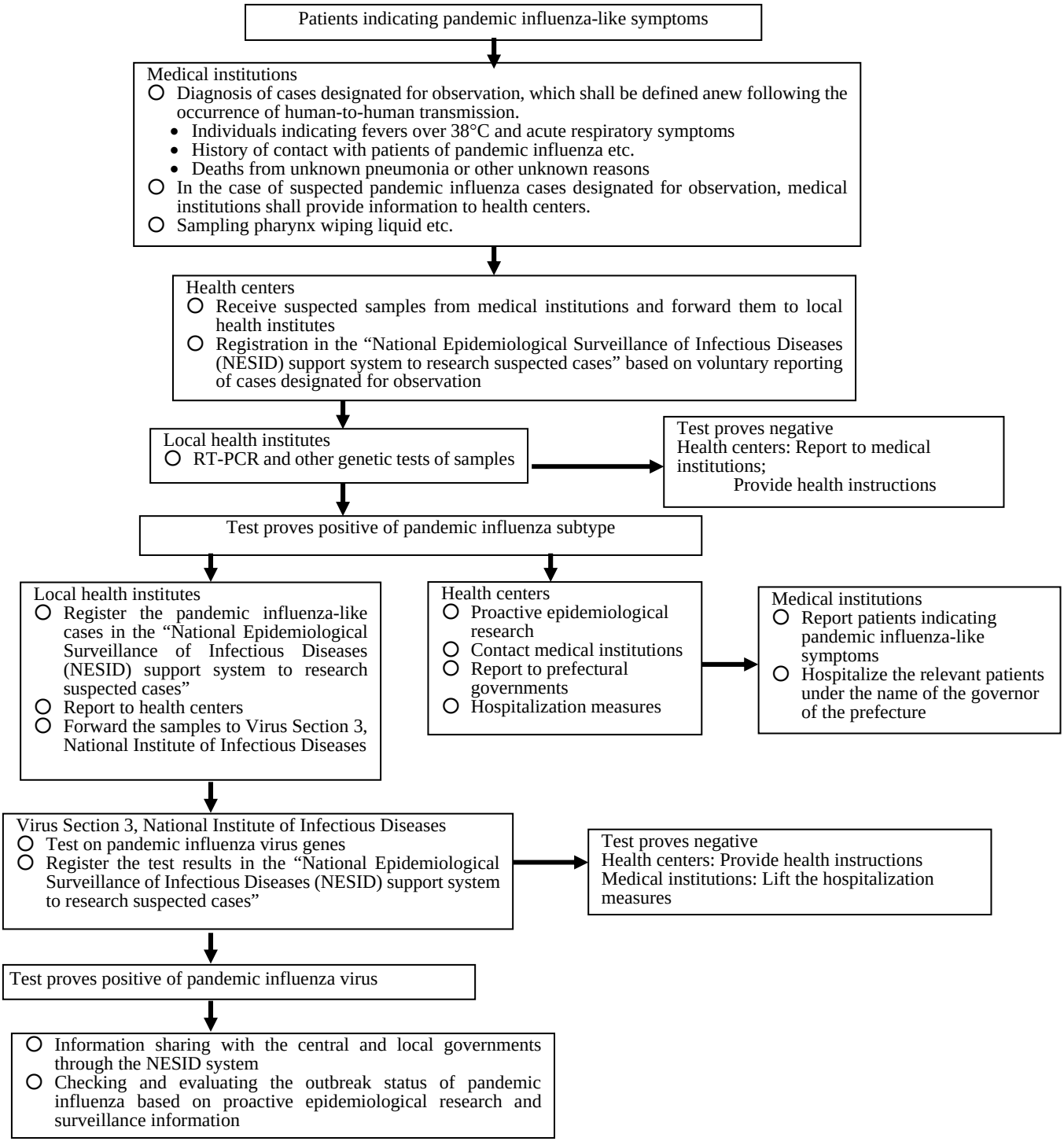
- ○ The National Institute of Infectious Diseases can access individual data, but at other institutions, only specified users may access individual data.

○ Compiled data are accessible for all of the Ministry of Health, Labour and Welfare, the National Institute of Infectious Diseases, and quarantine stations.

○ The governments of prefectures etc. can access national compiled data. The governments of prefectures etc. where the targeted infection occurs may also access the data of their own and other prefectures' compiled data.

○ Health centers can access compiled data of Japan, prefectures in which they are located, prefectures where infection occurs, and all health centers in the same district. Health centers cannot access other information in this system.

Surveillance Concept When Patients of Pandemic Influenza Are Identified



Outpatient Syndromic Surveillance

1. Objectives

For pandemic influenza preparedness in Phase 4A, it is crucial to identify the domestic occurrence of infection as early as possible. Outpatient syndromic surveillance aims at contribution to the early identification of pandemic influenza, through detecting the accumulation of patients in mild conditions.

2. Overview

Cooperating medical institutions shall register the number of patients satisfying specified reporting standards by age group in outpatient syndromic surveillance of the "National Epidemiological Surveillance of Infectious Diseases (NESID) syndromic surveillance." The central government, the governments of prefectures, health centers, local infectious disease information centers etc. shall check the data in their jurisdiction continuously, and respond promptly if an abnormal increase in patients is identified (such as sampling for laboratory tests).

3. Roles of participating institutions

(1) Participating medical institutions

Outpatient syndromic surveillance shall commence following the declaration of Phase 4A by the Government of Japan. During the surveillance period, medical institutions shall input the specified information of outpatients checked at their facilities between 00:00 and 24:00 every day (the respective numbers of all outpatients indicating fevers over 38°C and respiratory symptoms, in the age groups of 0 to 15, 16 to 64, and 65 and over, checked on every business day; data shall be transmitted even if the number of the relevant patients is "0"), in the computer display of the NESID syndromic surveillance. The data shall be transmitted by twelve noon of the following day. If abnormalities are suspected, medical institutions shall provide information promptly to health centers, governments of prefectures etc. Outpatient syndromic surveillance shall be discontinued as strategic early response is ended, and shift to influenza-like diseases surveillance during pandemic.

* Standards for selecting participating medical institutions

- ○ Medical institutions other than high-fever outpatient departments
  - Owns PCs connected to the Internet
  - Internet Explorer 6.0 or Netscape Navigator 7.1 is available as a browser
  - Normal fixed-point medical institutions for influenza, or other medical institutions operating pediatric and/or internal medicine departments

- ○ High-fever outpatient departments
  - All facilities

* Standards for the number of selected medical institutions

- ○ Medical institutions other than high-fever outpatient departments

- Approximately, requests for participation shall be made with twice as many medical institutions as the number of fixed-point medical institutions for influenza, securing 1.5 times as many medical institutions that actually participate in surveillance (It is preferable that participating medical institutions distribute evenly throughout prefectures, municipalities etc.).

○ High-fever outpatient departments
- All facilities

(2) Health centers

○ Following the declaration of Phase 4A by the Government of Japan, health centers shall check continuously the status of registration by medical institutions in their jurisdiction.
○ If an abnormal increase is identified in the number of patients, or if the system automatically detects an abnormal increase in the number of patients, health centers shall confirm the data and respond promptly if pandemic influenza is suspected.
○ Outpatient syndromic surveillance shall be discontinued as strategic early response is ended, and shift to influenza-like diseases surveillance during pandemic.

(3) Governments of prefectures etc.

○ In Phase 3A, the governments of prefectures etc. shall examine the geographic distribution of medical institutions in their jurisdiction, and register participating medical institutions in outpatient syndromic surveillance of the "National Epidemiological Surveillance of Infectious Diseases (NESID) syndromic surveillance," after obtaining the consent of the relevant medical institutions. The governments of prefectures etc. shall also provide seminars to health centers and representative departments of participating medical institutions. The governments shall compile the e-mail addresses of contact persons of the governments and health centers, and send the list in a csv file to the Infectious Disease Surveillance Center, National Institute of Infectious Diseases.
○ The governments shall also check continuously the status of registration by medical institutions in their jurisdiction.
○ If a participating medical institution cannot input its data on the computer, the supervising government shall perform the inputting.
○ If an abnormal increase is identified in the number of patients, or if the system automatically detects an abnormal increase in the number of patients, the governments shall ensure that required actions are taken without delay.
○ In particular, if there is an increase of patients across the borders of health centers' jurisdiction, the supervising governments shall inform the relevant health centers.
○ The governments shall emphasize and disseminate to related departments that outpatient syndromic surveillance shall be discontinued as early response is ended, and shift to influenza-like diseases surveillance during pandemic.

(4) Ministry of Health, Labour and Welfare; and National Institute of Infectious Diseases

○ Following the declaration of Phase 4A, the above indicated entities shall check continuously the status of registration by medical institutions nationwide.

- These entities shall provide technical support as necessary, including the formulation of required manuals. In particular, these entities shall indicate the standards for determining “abnormal” increases in patients.
- If an abnormal increase is identified in the number of patients, these entities shall provide instructions and advice on required actions.
- These entities shall discontinue outpatient syndromic surveillance as strategic early response is ended, and determine and notify the shift to post-strategic early response suspected cases surveillance.
- If pandemic enters remission, the above indicated entities shall collect opinions of medical institutions, governments of prefectures etc., health centers and other related institutions, on the problems and required improvements for the current surveillance system. Necessary improvement measures shall be taken subsequently.

Notes:

- Although outpatient syndromic surveillance is the most important means for early detection, calculation of the number of patients to be reported requires enormous workload. The workload, however, may be reduced dramatically if participating medical institutions have electronic medical chart systems in place, which enables automatic calculation. (The input of data into outpatient syndromic surveillance of the “National Epidemiological Surveillance of Infectious Diseases (NESID) syndromic surveillance” is an easy job requiring only three minutes or so.)
- Therefore, it is preferable that prefectural governments select participating medical institutions for outpatient syndromic surveillance considering the availability of automatic calculation by electronic medical chart systems. The Infectious Disease Surveillance Center, National Institute of Infectious Diseases, provides technical support required for the introduction of such systems.

Hospitalized Patient Pneumonic Syndrome Surveillance

1. Objectives

For pandemic influenza preparedness in Phase 4A, it is crucial to identify the domestic occurrence of infection as early as possible. Hospitalized patient pneumonic syndrome surveillance aims at contribution to the early identification of pandemic influenza, through detecting the minor accumulation of patients in serious conditions.

2. Overview

If pneumonic patients requiring hospitalization are identified at medical institutions having beds for internal medicine and/or pediatrics, the relevant medical institutions shall input the data in the NESID syndrome surveillance system on the Internet. At that time, the medical institutions shall input the information of organizations and facilities to which the relevant patients belong (e.g. nurseries, kindergartens, schools, offices, welfare facilities for senior citizens), as well as mutual relationship between registered patients. The central government, the governments of prefectures, health centers etc. shall check the data in their jurisdiction continuously, and respond promptly if an accumulation of two or more cases is identified in the same facility or family, including confirmation of suspected patients of pandemic influenza.

3. Roles of participating institutions

(1) Participating medical institutions (All medical institutions having beds for internal medicine and pediatrics)

- ○ Following the declaration of Phase 4A, the relevant medical institutions shall register persons in charge of reporting in the hospitalized patient pneumonic syndrome surveillance of the NESID syndromic surveillance system.
- ○ If pneumonic patients requiring hospitalization are identified, the relevant medical institutions shall register their information in the hospitalized patient pneumonic syndrome surveillance of the NESID syndromic surveillance system within 24 hours.
- ○ Information requiring registration includes the age, sex and date of hospitalization of each patient, facilities and organizations to which the patient belongs, mutual relationship between patients, symptoms (types of pneumonia (pneumonia, interstitial pneumonia etc.), and causes for pneumonia (pathogen, unknown, etc.).
- ○ Hospitalized patient pneumonic syndrome surveillance shall be discontinued when strategic early response is no longer capable of preventing the spread of infection.

(2) Health centers

- ○ Following the declaration of Phase 4A by the Government of Japan, health centers shall check continuously the status of registration by medical institutions in their jurisdiction, paying particular attention to facilities and organizations information and mutual relationship between registered patients.
- ○ Health centers shall respond promptly if an accumulation of two or more cases is identified in the same facility or family, including confirmation of suspected patients of pandemic influenza, and identification of cases designated for observation.
- ○ Hospitalized patient pneumonic syndrome surveillance shall be discontinued when strategic early response is no longer capable of preventing the spread of infection.

(3) Governments of prefectures etc.

- In Phase 3A, the governments of prefectures etc. shall designate “reporting medical institutions” in their jurisdiction, and register them in hospitalized patient pneumonic syndrome surveillance of the NESID syndromic surveillance system,
- In Phase 3A, the governments of prefectures etc. shall also provide seminars to health centers and representative departments of participating medical institutions.
- If a participating medical institution cannot input its data on the computer, the supervising government shall perform the inputting upon request from such institution.
- The governments shall also check continuously the status of registration by medical institutions in their jurisdiction, paying particular attention to facilities and organizations information and mutual relationship between registered patients.
- If an accumulation is identified, the governments shall ensure that required actions are taken without delay.
- If there is an accumulation of patients across the borders of health centers’ jurisdiction, the supervising governments shall inform the relevant health centers.
- Hospitalized patient pneumonic syndrome surveillance shall be discontinued when strategic early response is no longer capable of preventing the spread of infection.

(4) Ministry of Health, Labour and Welfare; and National Institute of Infectious Diseases

- The above indicated entities shall check continuously the status of hospitalized patient pneumonic syndrome surveillance nationwide, and provide technical support as necessary.
- These entities shall provide technical support as necessary, including the formulation of required manuals.
- These entities shall check continuously the status of registration by medical institutions nationwide, paying particular attention to facilities and organizations information and mutual relationship between registered patients in multiple prefectures.
- If there is an accumulation of patients across the borders of prefectures, the above indicated entities shall inform the relevant prefectural governments.
- If an accumulation of patients is identified, these entities shall provide instructions on required actions.
- These entities shall notify the discontinuation of hospitalized patient pneumonic syndrome surveillance as strategic early response is ended.
- If pandemic enters remission, the above indicated entities shall collect opinions of medical institutions, governments of prefectures etc., health centers and other related institutions, on the problems and required improvements for the current surveillance system. Necessary improvement measures shall be taken subsequently.

Cluster Surveillance

1. Objectives

Cluster surveillance aims to detect clusters of cases, if the local index case is left unidentified as suspected patients and infects other individuals.

2. Overview

Cluster surveillance aims to identify the occurrence of pandemic influenza, through promptly investigating at least three patients indicating similar symptoms (such as high fevers and upper airway symptoms, or contracting and/or dying from pneumonia) at medical institutions, who are epidemiologically linked with each other (e.g. family members living in the same household), or one of whom is a health care worker.

3. Roles of participating institutions

(1) Participating medical institutions (All medical institutions)

Medical institutions shall report the following cases and information to health centers, from the declaration of Phase 4A by the Government of Japan until the time when strategic early response is no longer capable of preventing the spread of infection.

* Standards for reporting

- ○ At least three pneumonic patients were identified within ten (10) days, indicating chest x-ray with clear shadowing, who belong to the same family living in the same household, belong to the same facilities or organizations, and/or include a health care worker of the relevant medical institution etc., suggesting epidemiological relationship possible of human-to-human transmission.
- ○ At least three patients indicated high fevers and other influenza symptoms within ten (10) days, who belong to the same family living in the same household, belong to the same facilities or organizations, and/or include a health care worker of the relevant medical institution etc., suggesting epidemiological relationship possible of human-to-human transmission.

* Information to report

The age, sex and occupation of each patient, epidemiological relationship between patients, clinical symptoms, clinical laboratory data (CBC, CRP, ESR and other inflammation findings, transaminase values, chest x-ray findings); and the description of the relevant cluster including the details of medical treatment

(2) Health centers

Health centers shall receive reports from medical institutions as above, and commence proactive epidemiological research including laboratory diagnosis of pandemic influenza, from the declaration of Phase 4A by the Government of Japan until the time when strategic early response is no longer capable of preventing the spread of infection.

Surveillance of Influenza-like Diseases during Pandemic

1. Objectives

Following the discontinuation of early response, the normal weekly reporting of influenza patients at fixed-point medical institutions as a Class 5 infectious disease shall shift to influenza-like diseases surveillance during pandemic, by increasing the number of fixed points and increasing the reporting frequency from weekly to daily. The surveillance of influenza-like diseases during a pandemic aims to collect materials for decision making on countermeasures against pandemic influenza, through prompt identification and feedback of infection trends.

2. Overview

Cooperating medical institutions shall register the number of patients satisfying specified reporting standards by age group in the post-strategic early response suspected cases surveillance in the NESID syndromic surveillance system. The central government, the governments of prefectures, health centers etc. shall check the data in their jurisdiction continuously, and take actions as necessary.

3. Roles of participating institutions

(1) Participating medical institutions (Medical institutions cooperating in outpatient syndromic surveillance)

Following the discontinuation of strategic early response, medical institutions shall input the specified information of outpatients checked at their facilities between 00:00 and 24:00 every day (the respective numbers of all outpatients indicating fevers over 38°C and respiratory symptoms, in the age groups of 0 to 15, 16 to 64, and 65 and over, checked on every business day), in the computer display of the NESID syndromic surveillance. The data shall be transmitted by twelve noon of the following day. If a medical institution cannot input its data on the computer, it shall send the data by facsimile etc. to the supervising governments of prefectures etc. Influenza-like diseases surveillance during pandemic shall be returned to the normal fixed-point reporting for Class 5 when the end of pandemic influenza is declared.

(2) Health centers

- ○ Following the discontinuation of strategic early response, health centers shall check the status of registration by medical institutions in their jurisdiction, and utilize the data for countermeasures against pandemic influenza.

(3) Governments of prefectures etc.

- ○ If triage operations at medical institutions are planned following the discontinuation of strategic early response, the governments of prefectures etc. shall register such medical institutions in outpatient syndromic surveillance of the NESID syndromic surveillance system. If plans have not been formulated in advance, registration shall be completed as soon as the relevant medical institutions are prepared for triage.
- ○ Governments of prefectures etc. shall check the status of registration by medical institutions in their jurisdiction, and utilize the data for countermeasures against pandemic influenza.

- If a participating medical institution cannot input its data on the computer, the supervising government shall perform the inputting upon request from such institution.

(4) Ministry of Health, Labour and Welfare

- Following the discontinuation of strategic early response, the Ministry of Health, Labour and Welfare shall check the status of registration by medical institutions in their jurisdiction, and utilize the data for the allocation of medical resources etc. The ministry shall also use the data in combination with information collected by other surveillance methods, to evaluate death rates and vaccination effects.
- The ministry shall provide technical support as necessary, including the formulation of required manuals.
- If pandemic enters remission, the ministry shall collect opinions of medical institutions, governments of prefectures etc., health centers and other related institutions, on the problems and required improvements for the current surveillance system. Necessary improvement measures shall be taken subsequently.
- The ministry shall instruct the discontinuation of influenza-like diseases surveillance during pandemic, and return to the normal fixed-point reporting for Class 5 when the end of pandemic influenza is declared.

Surveillance for the Prompt Identification of Deaths during Pandemic

1. Objectives

Following the discontinuation of strategic early response, surveillance for the prompt identification of deaths during pandemic is commenced to identify the number of deaths due to pandemic influenza as part of pathogenicity information, and feed back the data to countermeasures against pandemic influenza.

2. Overview

Surveillance for prompt identification of deaths during pandemic seeks to identify the number of deaths promptly, based on and improving the Project for Prompt Identification of Influenza-related Deaths (using the NESID influenza-related deaths reporting system), which is regularly implemented in the influenza season of every year in the twelve major cities and the Metropolitan special districts. The required improvements and operational changes in the NESID influenza-related deaths reporting system are as follows.

(1) Surveillance for the prompt identification of deaths during pandemic shall be implemented at all health centers.

(2) Surveillance for the prompt identification of deaths during pandemic shall identify the number of overall deaths, regardless of detailed death causes.

(3) Municipalities shall report to health centers within 36 hours of accepting death notifications, and health centers shall register the deaths within 39 hours.

3. Roles of participating institutions

(1) Municipal departments in charge of accepting death notifications

From the discontinuation of strategic early response until the declaration of the end of pandemic, the relevant departments shall assign individuals and determine forms for the reporting as above, through consultation with governing health centers. The assigned individuals shall report to governing health centers the number of death notifications accepted between 00:00 and 24:00 every day. The reporting shall be completed by twelve noon of the following day.

(2) Health centers

From the discontinuation of strategic early response until the declaration of the end of pandemic, health centers shall assign individuals and determine forms for the reporting as above, through consultation with municipal departments in charge of accepting death notifications. Health centers shall also input the death reports from municipalities in their jurisdiction in the NESID influenza-related deaths reporting system, no later than 15:00 every day.

(3) Governments of prefectures etc.

In Phase 3A, the governments of prefectures etc. shall provide seminars on the system for prompt identification of deaths during pandemic, to health centers and municipal departments in charge of accepting death notifications. Communication systems and reporting forms shall be confirmed in such seminars. The governments shall also check the status of registration by health centers in their jurisdiction, no later than 15:00 every day. This protocol shall be repeated every day until the end of pandemic is declared.

(4) Ministry of Health, Labour and Welfare; and National Institute of Infectious Diseases

- In Phase 3A, the above indicated entities shall determine the details of the system for prompt identification of deaths during pandemic.
- These entities shall provide technical support as necessary, including the formulation of required manuals.
- These entities shall check the status of registration nationwide, no later than 18:00 every day.
- If the death rate, or the fatality rate combined with the infection status based on influenza-like diseases surveillance during pandemic, is higher than expected, the above indicated entities shall review the overall countermeasures immediately. If the death or fatality rate is lower than expected, these entities shall reduce or discontinue the countermeasures.
- If pandemic enters remission, the above indicated entities shall collect opinions of municipal departments in charge of accepting death notifications, governments of prefectures etc., health centers and other related institutions, on the problems and required improvements for the current surveillance system. Necessary improvement measures shall be taken subsequently.
- The two entities shall repeat the protocol as above until the end of pandemic is declared.

System for Prompt Identification of Adverse Events due to Vaccination

1. Objectives

The system for prompt identification of adverse events due to vaccination aims to identify the status of adverse events on a real time basis, as reference data of determining the appropriateness and scope of vaccination. Vaccination shall be discontinued, limited to specified targets, or provided at modified priorities as necessary, even during the pandemic process.

2. Overview

All medical institutions shall input and share the information of patients indicating suspected adverse events due to vaccination. If an accumulation is identified for specific manufacturers, lot numbers, or dates or facilities of vaccination, prompt actions shall be taken. Possible risks due to age and underlying diseases shall also be identified. This system shall be implemented in combination with the system for prompt identification of vaccination rates, which reports the population and rates of vaccination. The two systems shall enable real-time identification of the incidence rate of adverse events.

3. Roles of participating institutions

(1) Participating medical institutions (All medical institutions having the internal medicine, pediatrics and emergency outpatient departments)

- Medical institutions shall register persons in charge of reporting to the system for prompt identification of adverse events due to vaccination in the NESID syndromic surveillance system.
- If a medical institution consults a patient indicating critical conditions of suspected adverse events due to pandemic influenza vaccination, that institution shall input the age and sex of the relevant patient, the municipality, the date of consultation, the manufacturer and lot number of the vaccine, symptoms of adverse events, and the date and facility of vaccination, within 24 hours.
- If a medical institution cannot input its data on the computer, it shall send the data by facsimile etc. to the supervising governments of prefectures etc.
- The system for prompt identification of adverse events due to vaccination shall be kept in place from the commencement of vaccination until a specified substantial length of time has passed after vaccination is ended.

(2) Health centers

- Health centers shall check every day the status of registration by medical institutions in their jurisdiction, from the commencement of vaccination until a specified substantial length of time has passed after vaccination is ended.

(3) Governments of prefectures etc.

- The governments of prefectures etc. shall register the participating medical institutions in their jurisdiction in the system for prompt identification of adverse events due to vaccination in the NESID syndromic surveillance system, prior to the commencement of

vaccination. The governments shall also instruct the registered medical institutions to report (suspected) adverse events as above.

- The governments of prefectures etc. shall provide seminars to health centers and representative departments of participating medical institutions, prior to the commencement of vaccination.
- If a participating medical institution cannot input its data on the computer, the supervising government shall perform the inputting upon request from such institution.
- The governments shall identify the status of registration in their jurisdiction, and report the vaccination status to the central government. They shall also provide appropriate information combining such statuses with the situations of infection and adverse events.
- The governments shall repeat the above protocol from the commencement of vaccination until a specified substantial length of time has passed after vaccination is ended.

(4) Ministry of Health, Labour and Welfare; and National Institute of Infectious Diseases

- The above indicated entities shall identify and notify the details of the system for prompt identification of adverse events due to vaccination, prior to the commencement of vaccination.
- The above indicated entities shall check the implementation status of the system for prompt identification of adverse events due to vaccination nationwide.
- These entities shall provide technical support as necessary, including the formulation of required manuals.
- If adverse events are identified extensively, the above indicated entities shall review the vaccination process or otherwise respond as appropriate.
- If pandemic enters remission, the above indicated entities shall collect opinions of medical institutions, governments of prefectures etc., health centers and other related institutions, on the problems and required improvements for the current surveillance system. Necessary improvement measures shall be taken subsequently.
- The two entities shall repeat the above protocol from the commencement of vaccination until a specified substantial length of time has passed after vaccination is ended.

Virological Surveillance during Pandemic

1. Objectives

Virological surveillance during pandemic aims to evaluate (and improve as necessary) vaccine effects and treatment methods, through identifying the antigenicity, genetic types, and sensitivity to antiviral drugs of prevailing pandemic influenza virus.

2. Overview

In principle, virological surveillance during pandemic shall be conducted in the same mechanism used for the virological research of normal influenza. Fixed-point medical institutions for pathogen sampling (comprising both outpatients institutions and hospitalization institutions) shall take and submit samples to local health institutes, in accordance with the sampling policy indicated below, and in usual procedures they use for local pathogen surveillance. Local health institutes shall isolate and analyze the submitted virus in the same procedures as seasonal influenza.

3. Roles of participating institutions

(1) Participating medical institutions (Medical institutions cooperating in influenza-like diseases surveillance during pandemic)

Following the start of local outbreak, a participating medical institution shall take a sample (pharynx wiping liquid) from the first patient visiting its facilities on the day of the week specified by the governing municipality every week, indicating normal influenza-like symptoms (or proving positive by a quick diagnosis kit), and submit that sample to a local health institute in the same jurisdiction. Medical institutions handling hospitalized influenza patients shall take samples from serious cases developing pneumonia or encephalopathy, and/or cases that appear to be clinically resistant to antiviral drugs, and submit those samples to local health institutes in the same jurisdiction.

(2) Local governments

Local governments shall request approximately 10% of medical institutions cooperating in influenza-like diseases surveillance during pandemic for fixed-point pathogen surveillance, and assign them to differing days of the week.

(3) Local health institutes

Local health institutes shall process the submitted samples in the same manner as normal (seasonal) influenza, and input the number of overall samples and samples proving positive in the NESID pathogen surveillance system. A specified number of isolated strains shall be forwarded to Virus Section 3, National Institute of Infectious Diseases, for further analysis.

(4) Virus Section 3, National Institute of Infectious Diseases

Virus Section 3, National Institute of Infectious Disease, shall evaluate changes in pathogenicity through surveillance data reported nationwide, conduct further virological analysis of isolated strains, and share information with related institutions, thereby leading to prompt required response.

Clinical Process Information Sharing System

1. Objectives

Few findings are present on pathologic characteristics, clinical process, and treatment records of pandemic influenza patients. Such clinical characteristics are also expected to transform over time. Therefore, the clinical process information sharing system aims to identify the efficacy of oseltamivir phosphate (product name: Tamiflu), occurrence of drug resistance, sensitivity and specificity of speedy diagnosis kits, and other diagnosis-related information on a real time basis. This system also contributes to the formulation of countermeasures against pandemic influenza, through calculation of death rates and hospitalization rates (rates of developing serious conditions)

2. Overview

The clinical process information sharing system shall collect required data systematically through designated physicians. Collected data are analyzed at the Pandemic Influenza Experts Advisory Committee, leading to information provision on the Internet etc. to the general public, as well as municipal governments and diagnosing physicians.

3. Roles of participating institutions

(1) Medical institutions designated by the governments of prefectures etc., in charge of hospitalization or outpatient treatment of pandemic influenza

- In the secondary medicine zone where infection occurs, a medical institution in charge of high-fever outpatient treatment and another in charge of hospitalization shall formulate a surveillance unit. Respective institutions shall contact the prefectural information center to obtain an ID and a password.
- If a participating medical institution consults a patient of pandemic influenza, that institution shall register the efficacy of oseltamivir phosphate, occurrence of drug resistance, effectiveness of speedy diagnosis kits, and other diagnosis-related information including pathologic characteristics, clinical process, treatment records and outcome of the relevant patient. The medical institution shall revise the registered data over time in line with the development.
- The above protocol shall be continued from Phase 4B until the central government declares the end of this system.

(2) Governments of prefectures etc. and health centers

- The above indicated entities shall prepare for the formulation of surveillance units (of participating medical institutions) as above.
- These entities shall issue IDs and passwords to medical institutions, in collaboration with the National Institute of Infectious Diseases.

(3) National Institute of Infectious Diseases

- The National Institute of Infectious Diseases shall establish and operate the clinical process information sharing system.
- The Institute shall provide technical support as necessary, including the formulation of required manuals.
- The Institute shall disclose the information collected through this system to the general public, paying attention to the protection of personal information.