

Implementation Manual for the National Epidemiological Surveillance of Infectious Diseases Program

Part I. Purpose and Aim

The National Epidemiological Surveillance of Infectious Diseases (NESID) Program was started in July 1981 with 18 target diseases. It has been operated with reinforcement and expansion along the way, including the adoption of a computerized online system and an increase in the target diseases to 27 diseases since January 1987. In response to the enactment of the Act on the Prevention of Infectious Disease and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998; hereinafter referred to as the “Act”) in September 1998 and its enforcement from April 1999, the NESID Program was positioned as a statutory measure. This program will build an appropriate system with cooperation from physicians and other healthcare workers, in order to prevent outbreaks and spread of various infectious diseases by ensuring that measures are taken for the effective and appropriate prevention, diagnosis and treatment of infectious diseases through the accurate monitoring and analysis of information on the occurrences of infectious diseases and through prompt provision and public disclosure of findings from such monitoring and analysis to the general public and healthcare workers, in order to design appropriate measures against infectious diseases by monitoring the detection status of, and identifying the characteristics of, circulating pathogens through collection and analysis of information on the pathogens.

Part II. Target Infectious Diseases

Target infectious diseases of this surveillance program shall be as follows.

1. Infectious diseases requiring report of all cases (notifiable diseases)

Category I Infectious Diseases

(1) Ebola hemorrhagic fever, (2) Crimean-Congo hemorrhagic fever, (3) smallpox, (4) South American hemorrhagic fever, (5) plague, (6) Marburg disease, (7) Lassa fever.

Category II Infectious Diseases

(8) Poliomyelitis, (9) tuberculosis, (10) diphtheria, (11) severe acute respiratory syndrome (only if the pathogen is SARS coronavirus of the genus *Betacoronavirus*), (12) Middle East respiratory syndrome (only if the pathogen is MERS coronavirus of genus *Betacoronavirus*), (13) avian influenza (H5N1), (14) avian influenza (H7N9).

Category III Infectious Diseases

(15) Cholera, (16) shigellosis, (17) Enterohemorrhagic *Escherichia coli* infection, (18) typhoid fever, (19) paratyphoid fever.

Category IV Infectious Diseases

(20) Hepatitis E, (21) West Nile fever (including West Nile encephalitis), (22) hepatitis A, (23) echinococcosis, (24) yellow fever, (25) psittacosis, (26) Omsk hemorrhagic fever, (27) relapsing fever, (28) Kyasanur Forest disease, (29) Q fever, (30) rabies, (31) coccidioidomycosis, (32) monkeypox, (33) Zika virus infection, (34) severe fever with thrombocytopenia syndrome (only if the pathogen is SFTS virus of the genus *Phlebovirus*),

(35) hemorrhagic fever with renal syndrome, (36) Western equine encephalitis, (37) tick-borne encephalitis, (38) anthrax, (39) Chikungunya fever, (40) Tsutsugamushi disease, (41) dengue fever, (42) Eastern equine encephalitis, (43) avian influenza (excluding H5N1 and H7N9), (44) Nipah virus infection, (45) Japanese spotted fever, (46) Japanese encephalitis, (47) Hantavirus pulmonary syndrome, (48) B virus disease, (49) glanders, (50) brucellosis, (51) Venezuelan equine encephalitis, (52) Hendra virus infection, (53) typhus, (54) botulism, (55) malaria, (56) tularemia, (57) Lyme disease, (58) Lyssavirus infection, (59) Rift Valley fever, (60) melioidosis, (61) legionellosis, (62) leptospirosis, (63) Rocky Mountain spotted fever

Category V Infectious Diseases (notifiable diseases)

(64) Amebic dysentery, (65) viral hepatitis (excluding hepatitis E and A), (66) carbapenem-resistant Enterobacteriaceae infection, (67) Acute flaccid paralysis (excluding poliomyelitis) (68) acute encephalitis (excluding West Nile encephalitis, Western equine encephalitis, tick-borne encephalitis, Eastern equine encephalitis, Japanese encephalitis, Venezuelan equine encephalitis and Rift Valley fever), (69) cryptosporidiosis, (70) Creutzfeldt-Jakob disease, (71) severe invasive streptococcal infection, (72) acquired immunodeficiency syndrome, (73) giardiasis, (74) invasive *Haemophilus influenzae* disease, (75) invasive meningococcal disease, (76) invasive pneumococcal disease, (77) varicella (only if the patient requires hospitalization), (78) congenital rubella syndrome, (79) syphilis, (80) disseminated cryptococcosis, (81) tetanus, (82) vancomycin-resistant *Staphylococcus aureus* infection, (83) vancomycin-resistant enterococcal infection, (84) pertussis, (85) rubella, (86) measles, (87) multidrug-resistant Acinetobacter infection.

Pandemic Influenza (Novel Influenza or Re-emerging Influenza)

(112) Pandemic Influenza (Novel Influenza), (113) Re-emerging Influenza.

Designated infectious diseases

None.

2. Infectious diseases to be monitored under sentinel surveillance

Category V Infectious Diseases (sentinel surveillance)

(88) RS virus infection, (889) pharyngoconjunctival fever, (90) group A streptococcal pharyngitis, (91) infectious gastroenteritis, (92) varicella, (93) hand, foot and mouth disease, (94) erythema infectiosum, (95) exanthema subitum, (96) herpangina, (97) mumps, (98) influenza (excluding avian influenza and Pandemic Influenza (Novel Influenza or Re-emerging Influenza)), (99) acute hemorrhagic conjunctivitis (100) epidemic keratoconjunctivitis, (101) genital chlamydial infection, (102) genital herpes simplex virus infection, (103) condylomata acuminata, (104) gonococcal infection, (105) chlamydial pneumonia (excluding psittacosis), (106) bacterial meningitis (excluding cases where the cause is identified as *Haemophilus influenzae*, *Neisseria meningitidis* or *Streptococcus pneumoniae*), (107) penicillin-resistant *Streptococcus pneumoniae* infection, (108) Mycoplasma pneumonia, (109) aseptic meningitis, (110) methicillin-resistant *Staphylococcus aureus* infection, (111) multidrug-resistant *Pseudomonas aeruginosa* infection.

Suspected cases determined by an Order of the Ministry of Health, Labour and Welfare as referred to in Article 14, paragraph 1 of the Act:

(114) Any symptoms such as, pyrexia, respiratory symptoms, rash, gastrointestinal

symptoms, neurological symptoms and other symptoms suspected of infectious diseases, of which doctors diagnosed the necessity of taking intensive care and any other equivalent measures based on common medical knowledge, and judged that the symptoms cannot be diagnosed as specific infectious diseases.

3. Target diseases for which active epidemiological investigation results shall be reported through the online system

Category II Infectious Diseases
(13) Avian influenza (H5N1)

Part III. Implementing Entities

Implementing entities shall be the national government, the prefectural governments, and the city governments (including special wards) with a Public Health Center(s).

Part IV. Establishment of Implementation System

1. Central infectious disease surveillance center

The central infectious disease surveillance center shall be established at the Infectious Disease Surveillance Center of the National Institute of Infectious Diseases. Its mission is to play a central role in the collection and analysis of patient information, suspected case information and pathogen information (including test information; hereinafter the same applies) reported from prefectural governments, cities with a Public Health Center(s), and special wards (hereinafter collectively referred to as “Prefectural Governments”) and in the prompt provision and disclosure from findings of such collection and analysis to Prefectural Governments as nationwide information.

2. Local infectious disease surveillance centers and designated prefectural infectious disease surveillance centers

A local infectious disease surveillance center shall be established within the territory of each Prefectural Government, at the relevant Public Health Institute in principle. The mission is to collect, analyze, and report, to the head office of the relevant Prefectural Government, the patient information, suspected case information and pathogen information in the territory of the Prefectural Government, as well as to promptly provide and disclose such information, together with nationwide information, to the relevant medical associations and other organizations concerned. Of the local infectious disease surveillance centers in each prefecture, one shall be designated as the designated prefectural infectious disease surveillance center, through consultation between the prefectural government, the city governments with a Public Health Center(s) to be located, and the special wards and other parties concerned; and shall collect and analyze patient information, suspected case information and pathogen information from the entire territory of the prefecture and shall send findings from such collection and analysis to each of the relevant local infectious disease surveillance centers.

The head office of a Prefectural Government may serve as a substitute for the local infectious disease surveillance center.

3. Designated notification facilities and designated submitting facilities (sentinel surveillance)

- (1) With respect to the infectious diseases to be monitored under sentinel surveillance, each prefectural government shall select, in advance, patient sentinel sites and suspected case sentinel sites as designated notification facilities as set forth in Article 14, paragraph 1 of the Act, in order to collect patient information and suspected case information.
- (2) With respect to the Category V Infectious Diseases for sentinel surveillance, each prefectural government shall select, in advance, sentinel sites for laboratory-based surveillance in order to collect patient specimens or pathogens of such infectious diseases (hereinafter collectively referred to as “Specimens”). With respect to the Category V Infectious Diseases as referred to in Article 7-2 of the Regulation for Enforcement of the Act, sentinel sites for laboratory-based surveillance shall be selected as the designated submitting facilities as set forth in Article 14-2, paragraph 1 of the Act.

4. Infectious disease surveillance committee

- (1) Central infectious disease surveillance committee

In order to ensure the appropriate operation of this surveillance program, a central infectious disease surveillance committee consisting of a representative(s) of the National Institute of Infectious Diseases, representatives of Public Health Centers and Public Health Institutes in all parts of the country, and other academic experts involved in measures against infectious disease shall be established at the Ministry of Health, Labour and Welfare. The central infectious disease surveillance center shall serve as the secretariat of the committee.

- (2) Prefectural infectious disease surveillance committees

In order to ensure the effective and efficient operation of the collection and analysis of information from within the territory of each prefecture, a prefectural infectious disease surveillance committee consisting of specialists in pediatrics, internal medicine, ophthalmology, dermatology, urology, gynecology, microbiology, epidemiology, veterinary medicine, entomology, etc., representatives of Public Health Centers and Public Health Institutes, representatives of the local medical association, etc. (approximately 10 members) shall be established at the prefectural government.

5. Laboratory testing facilities

Testing the specimen involved in this surveillance program in the territory of each Prefectural Government shall be conducted at the Public Health Institute, Public Health Centers or other laboratory testing facilities (hereinafter collectively referred to as the “Public Health Institutes”). The Public Health Institutes shall strive to ensure the reliability of tests by conducting tests according to the separately established guidelines for the management of operations involved in the test of pathogens at laboratory testing facilities (hereinafter referred to as the “Pathogen Testing Guidelines”).

Prefectural Governments shall coordinate the roles of laboratory testing facilities so that tests in the territory of each Prefectural Government will be conducted appropriately. The Prefectural

Governments with no Public Health Institutes shall refer testing services to the Public Health Institutes established by another Prefectural Government and shall otherwise ensure the creation of a program for conducting tests.

Part V. Implementation of the surveillance program

1. The Categories I, II, III, IV and V ((75), (85) and (86) of Part II) Infectious Diseases, Pandemic Influenza (Novel Influenza or Re-emerging Influenza), and designated infectious diseases

(1) Reporting intervals and implementation procedures

a. Physician who made a diagnosis

If a physician diagnoses any of the Categories I, II, III, IV or V ((74), (85) and (86) of Part II) Infectious Diseases, any of the Pandemic Influenza (Novel Influenza or Re-emerging Influenza), or any of the designated infectious diseases according to the notification criteria and other applicable notifications, the physician shall immediately notify the relevant Public Health Center according to the criteria separately established.

b. Medical facilities or the like having possession of Specimens

Upon receipt of a request or order from the Public Health Center or the like to provide Specimens for pathogen testing of the patient, the relevant medical facility or the like shall provide such Specimens accompanied by a test slip in the appended form.

c. Public Health Center

(i) The Public Health Center which receives the notification shall immediately enter the information notified into the NESID system. If pathogen testing is considered necessary by the Public Health Center, the Public Health Center shall request or otherwise ask the medical facility or the like having possession of Specimens to provide the Specimens for pathogen testing, by attaching the request a test slip in the appended form. If necessary, the relevant Public Health Institute shall be consulted regarding the decision as to necessity of pathogen testing, the conduct of pathogen testing, and other related matters.

(ii) Upon receipt of the Specimens, the Public Health Center shall refer the Specimens to the relevant Public Health Institute for testing by attaching a test slip in the appended form.

(iii) The Public Health Center shall monitor the occurrence and other aspects of the infectious disease notified, and shall provide such occurrence and other aspects to, and ensure the cooperation with, the relevant municipal governments, designated notification facilities, designated submitting facilities and other relevant medical facilities, the medical associations, the boards of education and other organizations concerned.

d. Public Health Institutes

(i) Upon receipt of a test slip in the appended form and of Specimens, the Public Health Institutes shall test such Specimens in accordance with the Pathogen Testing Guidelines separately established and shall notify the results of such testing through the relevant Public Health Center to the physician who made the

diagnosis, as well as send the results to the relevant Public Health Centers, the head office of the relevant Prefectural Government, and the relevant local infectious disease surveillance center using the appended form. Also, the pathogen information shall be promptly reported to the central infectious disease surveillance center. (A Prefectural Government which contracts out testing services shall make such a report at its own responsibility.)

- (ii) If the relevant Public Health Institutes has difficulty conducting any test, it shall request cooperation from another Prefectural Government or the National Institute of Infectious Diseases where necessary.
 - (iii) The Public Health Institutes shall send the Specimens to the National Institute of Infectious Diseases: if the patient has been diagnosed with any of the Category I Infectious Diseases; in case of emergency such as an outbreak of infectious disease beyond the territory of a prefecture; or if requested by the national government to submit such Specimens.
- e. National Institute of Infectious Diseases
The National Institute of Infectious Diseases shall conduct testing of the Specimens referred for testing or submitted from the Public Health Institutes, and shall notify the results of such testing to the relevant Public Health Institutes and the central infectious disease surveillance center.
- f. Local infectious disease surveillance center and designated prefectural infectious disease surveillance center
- (i) Upon entry from a Public Health Center of patient information from within the territory of the relevant Prefectural Government, the relevant local infectious disease surveillance center shall check the registered information.
 - (ii) The local infectious disease surveillance center shall collect and analyze all patient information and pathogen information from within the territory of the relevant Prefectural Government and shall provide and disclose to the relevant Public Health Centers and other organizations concerned the findings from such information together with the prefectural and nationwide information published through such a medium as the weekly report (or the monthly report if the publication is on a monthly basis).
 - (iii) The designated prefectural infectious disease surveillance center shall collect and analyze all patient information and pathogen information from within the territory of the relevant prefecture and shall provide and disclose to the relevant local infectious disease surveillance centers and other organizations concerned the findings from such information together with the nationwide information published through such a medium as the weekly report (or the monthly report if the publication is on a monthly basis).
- g. Central infectious disease surveillance center
- (i) The central infectious disease surveillance center shall compile nationwide information, which shall be produced by promptly aggregating the patient information identified at the local infectious disease surveillance centers and by analyzing and assessing the resulting information, into such a medium as a weekly report (or a monthly report if the compilation is on a monthly basis) together with the results of collection and analysis of the notifiable Category V Infectious Diseases, the Category V Infectious Diseases to be monitored under sentinel surveillance, and suspected cases, and shall provide such report to other

Prefectural Governments.

- (ii) The central infectious disease surveillance center shall conduct analysis and assessment of the pathogen information reported under paragraph d. (i) above and the information obtained from the testing conducted by the National Institute of Infectious Diseases in accordance with paragraph e. above and shall provide the results of such analysis and assessment to Prefectural Governments by promptly compiling such results into such a medium as a weekly report (or a monthly report if the compilation is on a monthly basis).

h. Head office of each Prefectural Government

The head office of each Prefectural Government shall utilize, in taking measures against infectious diseases, patient information and pathogen information collected and analyzed by the relevant local infectious disease surveillance center, and shall cooperate and coordinate with organizations concerned. Also, in case of emergency or if requested by the national government to take action, the head office of the relevant Prefectural Government shall directly collect necessary information and, in cooperation with the national government and other Prefectural Governments, take prompt action.

2. Category V Infectious Diseases requiring report of all cases (excluding (75), (85) and (86) of Part II) (notifiable diseases)

(1) Reporting intervals and implementation procedures

a. Physician who made a diagnosis

If a physician diagnoses a patient with any of the notifiable Category V Infectious Diseases requiring report of all cases (excluding (75), (85) and (86) of Part II), the physician shall notify the relevant Public Health Center within seven days following the diagnosis according to the criteria separately established.

b. Medical facilities or the like having possession of Specimens

Upon receipt of a request from the Public Health Center or the like to provide Specimens for pathogen testing of the relevant patient, the relevant medical facility or the like shall, in cooperation with such Public Health Center, provide such Specimens accompanied by a test slip in the appended form.

c. Public Health Center

(i) The Public Health Center which receives the notification shall immediately enter the information notified into NESID system. Also, if pathogen testing is considered necessary by the Public Health Center, the Public Health Center shall request the medical facility or the like having possession of Specimens to provide the Specimens for pathogen testing, by attaching to the request a test slip in the appended form. If necessary, moreover, the relevant Public Health Institute shall be consulted regarding the decision as to necessity of pathogen testing, the conduct of pathogen testing, and other related matters.

(ii) Upon receipt of the Specimens, the Public Health Center shall refer the Specimens to the relevant Public Health Institute for testing by attaching a test slip in the appended form.

(iii) The Public Health Center shall monitor the occurrence and other aspects of the infectious disease notified, and shall provide such occurrence and other aspects

to, and ensure the cooperation with, the relevant municipal governments, designated notification facilities, designated submitting facilities and other relevant medical facilities, the medical associations, the boards of education and other organizations concerned.

d. Public Health Institute

- (i) Upon receipt of a test slip in the appended form and of Specimens, the Public Health Institute shall test such Specimens in accordance with the Pathogen Testing Guidelines separately established and shall notify the results of such testing through the Public Health Center to the physician who made the diagnosis, as well as sending the results to the Public Health Centers, the head office of the Prefectural Government, and the local infectious disease surveillance center using the appended form. Also, the pathogen information shall be promptly reported to the central infectious disease surveillance center. (A Prefectural Government which contracts out testing services shall make such a report at its own responsibility.)
- (ii) If the Public Health Institute has difficulty conducting any test, it shall request cooperation from another Prefectural Government or the National Institute of Infectious Diseases where necessary.
- (iii) The Public Health Institute shall send the Specimens to the National Institute of Infectious Diseases: in case of emergency such as an outbreak of infectious disease beyond the territory of a prefecture; or if requested by the national government to submit such Specimens.

e. National Institute of Infectious Diseases

The National Institute of Infectious Diseases shall conduct testing of the Specimens referred for testing or submitted from the Public Health Institute and shall notify the results of such testing to the relevant Public Health Institute and the central infectious disease surveillance center.

f. Local infectious disease surveillance center and designated prefectural infectious disease surveillance center

- (i) Upon entry from a Public Health Center of patient information from within the territory of the relevant Prefectural Government, the relevant local infectious disease surveillance center shall confirm the registered information.
- (ii) The local infectious disease surveillance center shall collect and analyze all patient information and pathogen information from within the territory of the relevant Prefectural Government and shall provide and disclose to the relevant Public Health Centers and other organizations concerned the findings from such information together with the prefectural and nationwide information published through such a medium as a weekly report (or the monthly report if the publication is on a monthly basis).
- (iii) The designated prefectural infectious disease surveillance center shall collect and analyze all patient information and pathogen information from within the territory of the relevant prefecture and shall provide and disclose to the local infectious disease surveillance centers and other organizations concerned the findings from such information together with the nationwide information published through such a medium as a weekly report (or the monthly report if the publication is on a monthly basis).

- g. Central infectious disease surveillance center
 - (i) The central infectious disease surveillance center shall compile nationwide information, which shall be produced by promptly aggregating the patient information identified at local infectious disease surveillance centers and by analyzing and assessing the resulting information, into such a medium as a weekly report (or a monthly report if the compilation is on a monthly basis) together with the results of collection and analysis of the Categories I through IV Infectious Diseases, Pandemic Influenza (Novel Influenza or Re-emerging Influenza), the designated infectious diseases, the Category V Infectious Diseases to be monitored under sentinel surveillance, and suspected cases, and shall provide such report to Prefectural Governments.
 - (ii) The central infectious disease surveillance center shall conduct analysis and assessment of the pathogen information reported under paragraph d. (i) above and the information obtained from the testing conducted by the National Institute of Infectious Diseases in accordance with paragraph e. above and shall provide the results of such analysis and assessment to Prefectural Governments by promptly compiling the results into such a medium as a weekly report (or a monthly report if the compilation is on a monthly basis).
- h. Head office of each Prefectural Government

The head office of each Prefectural Government shall utilize, in taking measures against infectious diseases, patient information and pathogen information collected and analyzed by the local infectious disease surveillance center and shall cooperate and coordinate with organizations concerned. Also, in case of emergency or if requested by the national government to take action, the head office of the relevant Prefectural Government shall directly collect necessary information and, in cooperation with the national government and other Prefectural Governments, take prompt action.

3. Category V Infectious Diseases to be monitored under sentinel surveillance

(1) Condition of a target infectious disease

A case of a target infectious disease shall be a patient diagnosed with the disease based on the reporting criteria separately established for each of the Category V Infectious Diseases to be monitored under sentinel surveillance.

(2) Selection of sentinel sites

a. Patient sentinel sites

In order to locally monitor the occurrence of the Category V Infectious Diseases to be monitored under sentinel surveillance, each prefectural government shall select patient sentinel sites from medical facilities as randomly as possible by paying attention to the following points and with the assistance of the relevant medical associations and others. In selecting sentinel sites, consideration shall be given so that the occurrence of infectious diseases in the entire prefecture concerned can be monitored as much as possible, by taking into account the distribution of the prefecture's population and medical facilities, among other things.

- (i) For the target infectious diseases listed in (88) through (97) of Part II, medical facilities declaring that they have a pediatric department (i.e., medical facilities

mainly providing pediatric medical services) shall be designated as pediatric sentinel sites. The number of pediatric sentinel sites shall be calculated based on the calculation formula shown below. In such a case, each medical facility designated as a pediatric sentinel site shall strive to cooperate as an influenza sentinel site mentioned in (ii) below.

Population in the jurisdiction of a Public Health Center	Number of sentinel sites
< 30,000 persons	1
30,000 – 75,000 persons	2
≥ 75,000 persons	3 + (population – 75,000 persons)/50,000 persons

- (ii) For influenza listed in (98) of Part II (excluding avian influenza and Pandemic Influenza (Novel Influenza or Re-emerging Influenza); hereinafter the same applies) of the target infectious diseases, medical facilities declaring that they have an internal medicine department (i.e., medical facilities mainly providing internal medical services) shall be designated as internal medicine sentinel sites in addition to those of the pediatric sentinel sites selected under item (i) above that cooperate as influenza sentinel sites, and both types of sentinel sites shall be influenza sentinel sites, from which the designated sentinel sites separately set forth in item (v) below shall be designated. The number of internal medicine sentinel sites shall be calculated based on the calculation formula shown below.

Population in the jurisdiction of a Public Health Center	Number of sentinel sites
< 75,000 persons	1
75,000 – 125,000 persons	2
≥ 125,000 persons	3 + (population – 125,000 persons)/100,000 persons

Note that the notification criteria for designated sentinel sites limit notifiable cases to hospitalized patients, unlike those for influenza sentinel sites.

- (iii) For the target infectious diseases listed in (99) and (100) of Part II, medical facilities declaring that they have an ophthalmology department (i.e., medical facilities mainly providing ophthalmic medical services) shall be designated as ophthalmology sentinel sites. The number of ophthalmology sentinel sites shall be calculated based on the calculation formula shown below.

Population in the jurisdiction of a Public Health Center	Number of sentinel sites
< 125,000 persons	0
≥ 125,000 persons	1 + (population – 125,000 persons)/150,000 persons

- (iv) For the target infectious diseases listed in (101) through (104) of Part II, medical facilities declaring that they have a gynecology and obstetrics department, obstetrics department or gynecology department (i.e., a gynecology and obstetrics specialty), a department whose name is combined with sexually transmitted infections (STIs) pursuant to the provisions of Article 3-2, paragraph 1, item (i), c and d (2) of the Enforcement Order of the Medical Care Act

(Cabinet Order No. 326 of 1948), a urology department or dermatology department (i.e., medical facilities mainly providing medical services of the specialty so declared) shall be designated as STI sentinel sites. The number of STI sentinel sites shall be calculated based on the calculation formula shown below.

Population in the jurisdiction of a Public Health Center	Number of sentinel sites
<75,000 persons	0
≥ 75,000 persons	$1 + (\text{population} - 75,000 \text{ persons}) / 130,000 \text{ persons}$

- (v) For the target infectious diseases listed in (91) of Part II whose pathogen is rotavirus and the target infectious diseases listed in (105) through (111) of Part II, at least one hospital which has facilities capable of hospitalizing at least 300 patients and which declares that it has internal medicine and surgery departments (i.e., a hospital providing pediatric and internal medical services) shall be designated as at least one designated sentinel site per secondary medical area, since most target patients are hospitalized patients.
- b. Sentinel sites for laboratory-based surveillance
- In order to collect test information such as the isolation of a pathogen, each prefectural government shall select sentinel sites for laboratory-based surveillance by paying attention to the following points and with the assistance of the relevant medical associations and others. Also, in selecting sentinel sites, consideration shall be given so that the occurrence of infectious diseases in the entire prefecture concerned can be monitored as much as possible, by taking into account the distribution of the prefecture's population and medical facilities, among other things.
- (i) When selecting medical facilities as sentinel sites for laboratory-based surveillance, such selection shall, in principle, be made from among the medical facilities selected as patient sentinel sites.
- (ii) Approximately 10% of the patient sentinel sites selected under paragraph a. (i) above shall be selected as pediatric sentinel sites for laboratory-based surveillance whose target infectious diseases shall be those listed in (88) through (97) of Part II.
- (iii) Approximately 10% of the patient sentinel sites selected under paragraph a. (ii) above shall be selected as influenza sentinel sites for laboratory-based surveillance whose target infectious disease shall be that listed in (98) of Part II. In selecting influenza sentinel sites for laboratory-based surveillance, moreover, at least 10% and no less than three of the pediatric sentinel sites and at least 10% and no less than two of the internal medicine sentinel sites shall be selected, and the sentinel sites so selected shall be designated as designated submitting facilities as set forth in Article 14-2, paragraph 1 of the Act.
- (iv) Approximately 10% of the patient sentinel sites selected under paragraph a. (iii) above shall be selected as ophthalmology sentinel sites for laboratory-based surveillance whose target infectious diseases shall be those listed in (99) and (100) of Part II.
- (v) All patient sentinel sites selected under paragraph a. (v) above shall be designated sentinel sites for laboratory-based surveillance whose target infectious diseases shall be the infectious disease listed in (91) of Part II whose pathogen is rotavirus and the infectious diseases listed in (106) and (109) of Part

II.

(3) Reporting intervals

- a. The reporting intervals shall be one week (from Monday to Sunday) for patient information on any of the patient sentinel sites selected under subsection (2) a. (i), (ii), (iii) and (v) above (excluding patient information on (107), (110) and (111) of Part II) and one calendar month for information on patient on any of the patient sentinel sites selected under subsection (2) a. (iv) and (v) above (patient information on (107), (110) and (111) of Part II only).
- b. The reporting interval shall be one week (from Monday to Sunday) for pathogen information on any of the sentinel sites for laboratory-based surveillance selected under subsection (2) b. (iii) above during an epidemic period of influenza as listed in (97) of Part II (i.e., during a period commencing upon the number of patients per patient sentinel site selected under subsection (2) a. (ii) above exceeding 1 for a prefecture and ending upon that number falling below 1) and one calendar month for such information during non-epidemic period (i.e., period other than the epidemic period). The reporting interval shall be one calendar month for pathogen information on all other sentinel sites for laboratory-based surveillance.

(4) Implementation procedures

- a. Patient sentinel sites
 - (i) For the purpose of ensuring the prompt provision of information, a medical facility selected as a patient sentinel site shall monitor the occurrence of patients in accordance with the reporting criteria separately established for examination and treatment during the period of each reporting interval.
 - (ii) The designated notification facilities for the infectious diseases to be monitored under sentinel surveillance selected under subsection (2) a. above shall record the occurrence of patients during each reporting interval in accordance with the criteria separately established.
 - (iii) The notification as referred to in item (ii) above shall be made in accordance with Article 7 of the Regulation for Enforcement of the Act.
- b. Sentinel sites for laboratory-based surveillance
 - (i) Each medical facilities selected as a sentinel site for laboratory-based surveillance shall collect Specimens for pathogen testing where necessary.
 - (ii) Such sentinel site for laboratory-based surveillance shall promptly send such Specimens, accompanied by a test slip in the appended form, to the relevant Public Health Institute.
 - (iii) Each of the sentinel sites for laboratory-based surveillance selected under subsection (2) b. (ii) shall send at least one type of specimen of approximately four patients per each reporting interval with respect to several infectious diseases selected in advance by the relevant Prefectural Government from the target infectious diseases listed in (88) through (97) of Part II considering the occurrence of patients and other factors.
 - (iv) Each of the sentinel sites for laboratory-based surveillance selected under subsection (2) b. (iii) shall send at least one specimen per reporting interval with respect to influenza listed in (98) of Part II (including influenza-like illness).

- c. Medical facility or the like having possession of Specimens
Upon receipt of a request from the Public Health Center or the like to provide Specimens for pathogen testing of the patient concerned, the relevant medical facility or the like shall, in cooperation with such Public Health Center, provide such Specimens accompanied by a test slip in the appended form.
- d. Public Health Center
 - (i) The Public Health Center shall enter the patient information obtained from the patient sentinel sites into NESID system no later than Tuesday of the week following the week of surveillance if the reporting interval for patient information is one week or no later than the third day of the month following the month of surveillance if the reporting interval for patient information is one calendar month. At the same time, the Public Health Center shall report any outbreaks of any of the target infectious diseases and other information of note to the head of the relevant Prefectural Government and the relevant local infectious disease surveillance center. Also, if pathogen testing is considered necessary by the Public Health Center, the Public Health Center shall request the medical facility or the like having possession of Specimens to provide the Specimens for pathogen testing, by attaching to the request a test slip in the appended form. If necessary, moreover, the relevant Public Health Institute shall be consulted regarding the decision as to necessity of pathogen, the conduct of pathogen testing, and other related matters.
 - (ii) Upon receipt of the Specimens, the Public Health Center shall refer the Specimens to the relevant Public Health Institute for testing by attaching a test slip in the appended form.
 - (iii) The Public Health Center shall monitor the occurrence and other aspects of the Category V Infectious Diseases to be monitored under sentinel surveillance, and shall provide such occurrence and other aspects to, and ensure the cooperation with, the relevant municipal governments, designated notification facilities, designated submitting facilities and other relevant medical facilities, the medical associations, the boards of education and other organizations concerned.
- e. Public Health Institute
 - (i) Upon receipt of a test slip in the appended form and of Specimens, the Public Health Institute shall test such Specimens in accordance with the Pathogen Testing Guidelines separately established and shall notify the results of such testing as pathogen information to the relevant sentinel sites for laboratory-based surveillance, as well as sending the results to the head office of the relevant Prefectural Government and the relevant local infectious disease surveillance center. Also, the pathogen information shall be promptly reported to the central infectious disease surveillance center. (A Prefectural Government which contracts out testing services shall make such a report at its own responsibility.)
 - (ii) If the Public Health Institute has difficulty conducting any test, it shall request cooperation from another Prefectural Government or the National Institute of Infectious Diseases where necessary.
 - (iii) The Public Health Institute shall send the Specimens to the National Institute of Infectious Diseases: in case of emergency such as an outbreak of infectious disease beyond the territory of a prefecture; or if requested by the national government to submit such Specimens.

- f. National Institute of Infectious Diseases
The National Institute of Infectious Diseases shall conduct testing of the Specimens referred for testing or submitted from the Public Health Institute and shall notify the results of such testing to the relevant Public Health Institute and the central infectious disease surveillance center.

- g. Local infectious disease surveillance center and designated prefectural infectious disease surveillance center
 - (i) Upon entry from a Public Health Center of patient information from within the territory of the relevant Prefectural Government, the relevant local infectious disease surveillance center shall confirm the registered information.
 - (ii) The local infectious disease surveillance center shall collect and analyze all patient information and pathogen information from within the territory of the relevant Prefectural Government and shall provide and disclose to the relevant Public Health Centers and other organizations concerned the findings from such information together with the prefectural and nationwide information published through such a medium as the weekly report (or the monthly report if the publication is on a monthly basis).
 - (iii) The designated prefectural infectious disease surveillance center shall collect and analyze all patient information and pathogen information from within the territory of the relevant prefecture and shall provide and disclose to the relevant local infectious disease surveillance centers and other organizations concerned the findings from such information together with the nationwide information published through such a medium as a weekly report (or the monthly report if the publication is on a monthly basis).

- h. Central infectious disease surveillance center
 - (i) The central infectious disease surveillance center shall compile nationwide information, which shall be produced by promptly aggregating the patient information identified at the local infectious disease surveillance centers and by analyzing and assessing the resulting information, into such a medium as a weekly report (or a monthly report if the compilation is on a monthly basis) together with the results of collection and analysis of the Categories I through IV Infectious Diseases, Pandemic Influenza (Novel Influenza or Re-emerging Influenza), the designated infectious diseases, the notifiable Category V Infectious Diseases, and suspected cases, and shall provide such report to other Prefectural Governments.
 - (ii) The central infectious disease surveillance center shall conduct analysis and assessment of the pathogen information reported under paragraph e. (i) above and the information obtained from the testing conducted by the National Institute of Infectious Diseases in accordance with paragraph f. above and shall provide the results of such analysis and assessment to all Prefectural Governments by promptly compiling such results into such a medium as a weekly report (or a monthly report if the compilation is on a monthly basis).

h. Head office of each Prefectural Government

The head office of each Prefectural Government shall utilize, in taking measures against infectious diseases, patient information and pathogen information collected and analyzed by the relevant local infectious disease surveillance center and shall cooperate and coordinates with organizations concerned. Also, in case of emergency or if requested by the national government to take action, the head office of the relevant Prefectural Government shall directly collect necessary information and, in cooperation with the national government and other Prefectural Governments, take prompt action.

4. Suspected cases determined by an Order of the Ministry of Health, Labour and Welfare as referred to in Article 14, paragraph 1 of the Act:

(1) Condition of a target suspected case

A target suspected case shall be a patient diagnosed as a suspected case based on the notification criteria separately established.

(2) Selection of sentinel sites

In order to grasp the occurrence of suspected cases, a prefectural government shall select suspected case sentinel sites from medical facilities with the assistance of the relevant medical associations and others.

In order to grasp the occurrence of suspected case in a territory of the prefecture optimally, distribution of both the population and the medical facilities, etc should be taken in to account to select the sentinel sites.

To select the medical facilities for sentinel sites, following category must be met in the order of priority from a to c.

a. Medical facilities registered for the specific intensive care unit management fee (1 to 4), the specific pediatric intensive care unit management fee and the high-care unit hospitalization medical care fee (1 to 2), based on medical fee remuneration.

b. Medical institutions for infectious diseases based on law

- Medical institutions of specified infectious diseases based on law
- Medical institutions of Class 1 specified infectious diseases based on law
- Medical institutions of Class 2 specified infectious diseases based on law

c. Medical institutions, which is appropriate to be settled as the suspected case sentinel sites to grasp the suspected case occurrence during mass gathering (a group of large number of people gathered for the same purpose in a limited area for a certain period). (For example, medical facilities that may be visited by players and people involved in the event during a large-scale sports event etc.)

Prefectural governments should work on establishing a cooperative system between the medical institutions appointed for suspected case sentinel sites and the medical institutions not appointed for the sentinel site in advance.

Prefectural government should also take a consideration, to grasp the situation of

suspected case accurately and rapidly, by sharing information, such as a list of suspected case sentinel sites and consultation services, among the medical institutions not appointed for suspected case sentinel sites to be able to consult when there are suspected case of disease which corresponds to the notification criteria specified by law.

(3) Implementation procedures

a. Suspected case sentinel sites

- (i) For the purpose of ensuring the prompt provision of information, each medical facility selected as a suspected case sentinel site shall immediately monitor the occurrence of suspected cases in accordance with the reporting criteria separately established for examination and treatment.
- (ii) The designated notification facilities for the infectious diseases to be monitored under sentinel surveillance selected under subsection (2) . above shall immediately record the occurrence of suspected cases in accordance with the criteria separately established. In principle, the notification of suspected cases shall be made by entering such information into the general-purpose surveillance system.
- (iii) The notification as referred to in item (ii) above shall be made in accordance with Article 7 of the Regulation for Enforcement of the Act.

b. Public Health Center

- (i) If suspected case sentinel sites cannot enter the data into the general-purpose surveillance system, the Public Health Center shall immediately enter the suspected case information obtained from the relevant suspected case sentinel site into the general-purpose surveillance system, and the Public Health Center shall also report any outbreaks of any of the target suspected cases and other information of note to the head of the relevant Prefectural Government and the relevant local infectious disease surveillance center.
- (ii) The Public Health Center shall monitor the occurrence and other aspects of suspected cases and shall provide such occurrence and other aspects to, and ensure the cooperation with, the relevant municipal governments, designated notification facilities, designated submitting facilities and other relevant medical facilities, the medical association, the boards of education and other organizations concerned.

c. Local infectious disease surveillance center and designated prefectural infectious disease surveillance center

- (i) Upon entry from a Public Health Center of suspected case information from the territory of the relevant Prefectural Government, the relevant local infectious disease surveillance center shall confirm the registered information.
- (ii) The local infectious disease surveillance center shall collect and analyze all suspected case information from within the territory of the relevant Prefectural Government and shall provide and disclose to the relevant Public Health Centers and other organizations concerned the findings from such information together with the prefectural and nationwide information published through such a medium as a weekly report.
- (iii) The relevant designated prefectural infectious disease surveillance center shall collect and analyze all suspected case information from within the territory of the relevant prefecture and shall provide and disclose to the relevant local

infectious disease surveillance centers and other organizations concerned the findings from such information together with the nationwide information published through such a medium as a weekly report.

d. Central infectious disease surveillance center

The central infectious disease surveillance center shall compile nationwide information, which shall be produced by promptly aggregating the suspected case information identified at all local infectious disease surveillance centers and by analyzing and assessing the resulting information, into such a medium as a weekly report together with the results of collection and analysis of the Categories I through IV Infectious Diseases, Pandemic Influenza (Novel Influenza or Re-emerging Influenza), the designated infectious diseases, the notifiable Category V Infectious Diseases, and the Category V Infectious Diseases to be monitored under sentinel surveillance, and shall provide such report to the Prefectural Governments.

e. Head office of each Prefectural Government

The head office of each Prefectural Government shall utilize, in taking measures against infectious diseases, suspected case information collected and analyzed by the relevant local infectious disease surveillance center and shall cooperate and coordinate with organizations concerned. Also, in case of emergency or if requested by the national government to take action, the head office of the relevant Prefectural Government shall directly collect necessary information and, in cooperation with the national government and other Prefectural Governments, take prompt action.

5. Implementation procedures for the online reporting of active epidemiological investigation results

(1) Public Health Center

Each Public Health Center which conducted active epidemiological investigation of avian influenza (H5N1) shall immediately enter the investigation findings into the suspected case* surveillance support system in accordance with the criteria separately established.

All Specimens submitted by medical facilities shall be accompanied by a test request slip issued by the suspected case surveillance support system.

(2) Public Health Institute

a. Upon receipt of a test request slip and Specimens, the relevant Public Health Institute shall test the Specimens concerned in accordance with the Pathogen Testing Guidelines separately established and shall immediately enter the results into the suspected case* surveillance support system.

b. When reporting the results of active epidemiological investigation of avian influenza (H5N1) to the Ministry of Health, Labour and Welfare, the Specimens shall be sent to the National Institute of Infectious Diseases in accordance with Article 9, paragraph 2 of the Regulation for Enforcement of the Act.

(3) National Institute of Infectious Diseases

The National Institute of Infectious Diseases shall conduct testing of the Specimens sent from the Public Health Institute and shall immediately enter the results into the suspected case* surveillance support system.

*“Suspected case” here refers to those listed under Part II. 3, “Target diseases for which active epidemiological investigation results shall be reported through the online system” (i.e. a suspected case of avian influenza (H5N1) infection).

6. Other matters

- (1) While the NESID Program should be conducted according to nationwide standardized criteria, it is expected that an effective and efficient NESID Program will be built on a local basis by making additions based on the situation in the territory of each Prefectural Government, as appropriate, with respect to parts other than the implementation procedures set forth above.
- (2) If any ordinance-designated city or special ward government contracts out test services to any other local government, such contracting-out shall be subject to the provisions of Article 252-14 of the Local Autonomy Act (Act No. 67 of 1947).
- (3) All Specimens that shall be handled for the NESID Program shall be used for developing measures to prevent the outbreak and spread of infectious diseases and for improving public health and not for any other purposes. When collecting specimens, it is desirable that the person from whom the specimens are collected or his/her legal representative is informed of the intended use of the specimens and obtain his/her consent. If such specimens are used for any research or study whose purpose is outside the purposes set forth above, such use shall be in accordance with the Ethical Guidelines on Biomedical Research Involving Human Subjects and other regulations separately established.
- (4) Any matters not specified herein shall be determined by the Director-General of the Health Service Bureau as appropriate.

Part VI. Expenses

Of all expenses to be incurred in this surveillance program, the expenses to be paid by prefectural governments that are to be incurred in the affairs involved in this surveillance under the provisions of Articles 14 through 16, 16-3, 26-3 and 26-4 (including the cases where these provisions are applied mutatis mutandis in Article 50), and 44-7 of the Act shall be borne by the national government pursuant to the provisions of Article 61 of the Act.

Part VII. Times of Implementation

This Implementation Manual shall come into force from April 1, 1999. However, the provisions regarding pathogen information and sentinel sites for laboratory-based surveillance may be implemented as soon as each Prefectural Government is ready for their implementation.

The amendment of this Implementation Manual shall come into force from November 1, 2002.

The partial amendment of this Implementation Manual shall come into force from November 5, 2003.

The partial amendment of this Implementation Manual shall come into force from April 1, 2006.

The partial amendment of this Implementation Manual shall come into force from June 12, 2006.

The partial amendment of this Implementation Manual shall come into force from November 22, 2006.

The partial amendment of this Implementation Manual shall come into force from April 1, 2007.

The partial amendment of this Implementation Manual shall come into force from January 1, 2008.

The partial amendment of this Implementation Manual shall come into force from April 1, 2008.

The partial amendment of this Implementation Manual shall come into force from May 12, 2008.

The partial amendment of this Implementation Manual shall come into force from February 1, 2011.

The partial amendment of this Implementation Manual shall come into force from September 5, 2011. However, the designation as referred to in Part V, 3 (2)(ii) shall come into force from July 29, 2011.

The partial amendment of this Implementation Manual shall come into force from March 4, 2013.

The partial amendment of this Implementation Manual shall come into force from April 1, 2013.

The partial amendment of this Implementation Manual shall come into force from May 6, 2013.

The partial amendment of this Implementation Manual shall come into force from October 14, 2013.

The partial amendment of this Implementation Manual shall come into force from July 26, 2014.

The partial amendment of this Implementation Manual shall come into force from September 19, 2014.

The partial amendment of this Implementation Manual shall come into force from January 21, 2015.

The partial amendment of this Implementation Manual shall come into force from May 21, 2015.

The partial amendment of this Implementation Manual shall come into force from April 1, 2016. However, the amendment related to the addition to the target infectious diseases in

Part II, 1 shall come into force From February 15, 2016.

The partial amendment of this Implementation Manual shall come into force from January 1, 2018.

The partial amendment of this Implementation Manual shall come into force from March 1, 2018.

The partial amendment of this Implementation Manual shall come into force from May 1, 2018.

The partial amendment of this Implementation Manual shall come into force from April 1, 2019.

