厚生労働行政推進調査事業費（厚生労働科学特別研究事業）
総括研究報告書

国際保健規則（IHR）に基づく合同外部評価に向けた実施体制と評価手法に関する研究：疫学調査・サーベイランス・人材育成に関する検討

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研究要旨：我が国の健康危機管理体制の中で、疫学調査・サーベイランス（D2）・人材育成（FETP）(D4)に関する体制について各評価項目の関係領域を総合的に洗い出し、JEE ミッションに向けて関連の資料を英語で準備するとともに、厚生労働省の担当課とも協議のうえ、評価点の検討、問題点の抽出等を行った。このプロセスを通じて、国内の関係者と課題を協議したこと、また、JEE ミッションにおいて、海外の各分野の専門家から現実的な提案が出されたことは、今後の国内の健康危機管理体制の強化につながることと考える。

A．研究目的

改正国際保健規則(IHR)に基づくコア・キャパシティ構築を強化するため、従来の自己評価方式から外部評価の視点（合同外部評価；JEE）を加えた、新たな「モニタリング・評価枠組み」へと移行しつつある。2018年2月末に我が国もJEEを受け入れる事を正式決定した事を受け、自己評価書を取りまとめることになった。しかし、健康危機管理体制について国際的基準に基づき国の体制を総括的に評価するのは初の試みである。また、評価項目は19項目もの分野があり、様々な分野（省庁・部局）が関係しており、従来の国内行政には馴染みが無いテーマや、従来の枠組みに跨る領域も含まれており、これまで検討をしたことのない視点での評価が含まれる。その中で、外部評価で正当な評価を得るためには、幅広い分野にわたる専門的知見と評価に関する国際的な動向を踏まえた適切な自己評価書を取りまとめる必要がある。一方でWHOが示す評価指標も未成熟な部分があり、専門的知見からの評価手法の妥当性に関するフィードバックを先進国として行う責任もある。本研究は、JEEの実施に関する国際的動向を明らかにし、評価体制と評価手法を確立することを目的とする。

特に本分担研究では、我が国の健康危機管理体制の中で、疫学調査・サーベイランス（D2）・人材育成（FETP）(D4)に関する体制について各評価項目の関係領域を総合的に洗い出し、JEEミッションに向けて関連の資料を英語で準備するとともに、厚生労働省の担当課とも協議のうえ、評価点の検討、問題点の抽出等を行うことを活動の目的とした。

B．研究方法

1．英語の背景文書の準備

JEE評価ツールの疫学調査・サーベイ

ランス（D2）については、感染症発生動向調査実施要綱の英訳をし、また、JEE評価ツールの内容も考慮しながら、感染研の担当者とともに、日本の感染症サーベイランスの説明文書、感染研における感染症分野のEvent-based surveillanceについて、英語での背景文書を作成した。加えて、感染症関連対訳表も作成した。

人材育成（FETP）(D4)については、JEE評価ツールに即して英語で概要を説明する文書を作成した。

2. その他の関係資料の準備

JEE評価ツールの日本語への翻訳案の修正、クイックアセスメントや内部評価書案の作成、対訳表の作成、設問に関する検討と資料収集を行った。

3. 外部ミッション後の活動

また、外部評価ミッションで得られたこれらの分野の提言について今後の対応策について検討を行った。そして、JEE評価ツールに関して改善意見の検討を行った。

（倫理面への配慮）

本研究は、動物実験の実施を含まない。また、個人情報等を扱う性質のものではなく、特段倫理的配慮を必要とる事項はない。

Ｃ．研究結果

1. 英語の背景文書の準備

感染症発生動向調査実施要綱の英語版は、厚生労働省担当課等のクリアランスを経て、厚生労働省ウエブサイト（http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kenkou/kekkaku-kansenshou/kekkaku-kansenshou11/01.html#list01）において、感染症発生動向調査実施要綱（実施要綱）（英語仮訳）として掲載済みであるとともに、JEEの外部評価団向けの資料としても利用された(資料II-5-1)。

日本の感染症サーベイランスの説明文書の英語版の作成をし、厚生労働省担当課等のクリアランスを経て、国立感染症研究所感染症疫学センターのウエブサイト（https://www.niid.go.jp/niid/ja/idss.html）に、Infectious Disease Surveillance System in Japan（February 2018）（英語仮訳)として掲載済みであるとともに、JEEの外部評価団向けの資料としても利用された（資料II-5-2）。

感染研における感染症分野のEvent based surveillanceの英語版を作成し、JEEの外部評価団向けの資料として利用された（資料II-5-3）。

感染症関連対訳表を作成し、厚生労働省ウエブサイトにおいて公開するとともに（http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kenkou/kekkaku-kansenshou/taiyakuhyou/index.html）、資料準備に使用した（資料II-5-4）。

日本のFETPに関する説明文書の英語版を作成し、JEEの外部評価団向けの資料として利用された（資料II-5-5）。

2. その他の関係資料の準備

JEE評価ツールの翻訳案の修正については、総括報告書資料I-1に示した。疫学調査・サーベイランス（D2）・人材育成（FETP）(D4)分野に関してクイックアセスメントを行い、また、内部評価書案を作成するとともに、対訳表の作成（総括報告資料I-2）証拠文書の整理を行った（総括報告資料I-2）。内部評価書案の作成に際しては、強み(Strengths/Best Practices)・弱み(Areas which need strengthening and challenges)についての検討をグループワーク形式で2017年9月25日に行ってまとめた。

3. 外部ミッション後の活動

外部評価ミッションで得られた対象分野の提言についての今後の対応策についての検討およびJEE評価ツールに関する改善意見については、総括報告書資料I-4の当該分野に検討結果を記載した。

Ｄ．考察

サーベイランスについて

- 日本のシステムの国際的な透明性向上：感染症発生動向調査実施要綱の英語版とともに、日本の感染症サーベイランスの説明文書の英語版を作成し、ウエブサイトにおいて公開したことにより、日本のサーベイランスシステムについての情報を必要とする行政やアカデミアなどの分野の外国人にとって有用な情報源となることが期待される。
- 人員配置：サーベイランスのように、継続性が重要な業務において、健康危機時を想定して人員配置を考えるべきという意見が JEE の外部評価団の中から出たことは重要な指摘であると考える。
- 急性事例のリスク評価：方法論については、WHO においても検討が続いている中、感染症疫学センターとしては、海外で発生した事例に対する短期～中期的な対応方針決定のためのリスク評価、日々発生する事例に対する短期的な対応方針決定のためのリスク評価の二本立てで、活動をしてきたところである。引き続き、WHO とも協力して技術的な検討を行うとともに、自治体レベルにおいてリスク評価への理解を深める活動を行っていく必要がある。
- 強み、弱みの整理：プロセスを通じて、系統的にシステムの強み、弱みを整理し、国内のステークホルダーと共有し、あわせて海外の各分野の専門家を交えて、議論をするよい機会となった。

要員育成(FETP)

- 国内の体制強化において、特に自治体レベルの体制強化の重要性が指摘された。地方分権をしている日本の仕組みにおいては、合理的な指摘であると考える。指摘を受けたとおり、自治体に勤務する FETP がその核となることができるよう、さらなる体制の整備が必要である。
- JEE の外部評価団からの提言を受けて、国際的な活動に積極的に貢献をすることは、国内の体制整備にも有効であるという観点からの国内の議論も今後は必要であろう。

Ｅ．結論

JEE ミッションを受け入れるにあたり、国内の関係者と課題を協議したこと、関連の文書を英語で整理したことは、また、海外の各分野の専門家から現実的な提案が出されたことは、今後の国内の健康危機管理体制の強化につながることと考える。

Ｇ．研究発表

１．論文発表

なし

２．学会発表

なし

H. 知的財産権の出願･登録状況

（予定を含む。）

1. 特許取得

特に無し

2. 実用新案登録

特に無し

3. その他

特に無し

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 pneumonia* 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) pyrexia at or above 38^{o}C and respiratory symptoms (excluding those clearly due to

trauma or organic disease) or (115) pyrexia and rash or vesicles (excluding cases where the suspected case clearly represents symptoms of a patient with a Category II, III, IV or V Infectious Disease).

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 + (population – 75,000 persons)/130,000 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 reporting criteria separately established for each suspected case.

(2) Selection of sentinel sites

a. Suspected case sentinel sites
In order to locally monitor the occurrence of suspected cases, a prefectural government shall select suspected case 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. Also, in selecting sentinel sites, consideration shall be given so that the occurrence of suspected cases 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.

For the target suspected case listed in (114) of Part II, medical facilities declaring that they have a pediatric department (i.e., medical facilities mainly providing pediatric medical services) or medical facilities declaring that they have an internal medicine department (i.e., medical facilities mainly providing internal medical services) shall be designated as primary suspected case sentinel sites.

For the target suspected case listed in (115) of Part II, medical facilities declaring that they have a pediatric department (i.e., medical facilities mainly providing pediatric medical services), medical facilities declaring that they have an internal medicine department (i.e., medical facilities mainly providing internal medical services) or medical facilities declaring that they have a dermatology department (i.e., medical facilities mainly providing dermatological medical services) shall be designated as secondary suspected case sentinel sites.

Also, the number of sentinel sites for each suspected case shall be calculated based on the calculation formula shown below. With respect to medical facilities declaring that they have an internal medicine department, consideration shall be given so that at least one hospital satisfying the requirements for a designated sentinel site listed in Part V, 3 (2) a. (v) is included among them per secondary medical area.

Population in the jurisdiction of a Public Health Center	Number of sentinel sites
< 30,000 persons	3
30,000 – 75,000 persons	4
75,000 – 125,000 persons	7
≥ 125,000 persons	7 + 6 x (population – 125,000 persons)/100,000 persons

(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) a. 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 syndromic 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 syndromic surveillance system, the Public Health Center shall immediately enter the suspected case information obtained from the relevant suspected case sentinel site into the syndromic 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 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 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.

Appended Form

Public Health Center code □□-□□-□□

Public Health Center registered notifiable disease report ID □□□□-□□□□-□□□□□

PHI receipt No. (specimen provider No.) □□□□□□□□

Test Slip for Categories I, II, III, IV and V Infectious Diseases, Pandemic Influenza (Novel Influenza or Re-emerging Influenza), and Designated Infectious Diseases (Pathogen)

Patient	Gender	(M / F)
	Age	(yr mo)
	Name	
	Address	

If the medical facility is a sentinel site, circle appropriate items.
- Influenza sentinel site - Pediatric sentinel site
- Ophthalmology sentinel site - STI sentinel site – Designated sentinel site

[Attending physician or equivalent's use only]

Name of medical facility, etc. and name of attending or other physician (author)		
Specimen dispatch date	MM DD, YYYY Isolate (no, yes, under testing)	
Diagnosis		
Date of onset	MM DD, YYYY	
Hospitalized or outpatient	Hospitalized patient Outpatient	
Specimen	Date of collection	MM DD, YYYY
	Type of specimen [Circle one appropriate item]	- Feces (intestinal content, rectal swab) - Spinal fluid - Urine - Vomit - Sputum - Tracheal aspirate - Puncture fluid (ascites, pleural effusion, joint fluid, other [ ]) - Throat swab (gargle, nasal discharge) - Skin lesion (vesicular content, crust, wound) - Conjunctival swab (conjunctival scrapings, eye discharge) - Genital/urethral/cervical scrapings/secretion - Cytology/biopsy/autopsy material (organ:) - Blood (whole blood, serum, plasma, anticoagulant [ ]) - Other ( )
Clinical information	Clinical signs and symptoms, etc. [Circle all appropriate items] (excluding underlying illness)	- Asymptomatic - Gastroenteritis (diarrhea, hemafecia, nausea, vomiting, abdominal pain) - Headache - Pyrexia (maximum °C) - Keratitis, conjunctivitis, keratoconjunctivitis - Febrile convulsion - Arthralgia (arthritis), myalgia - Meningitis, disturbance of consciousness, paralysis (site:) - Stomatitis - Upper respiratory inflammation (pharyngitis/pharyngeal pain, tonsillitis) - Central nervous system symptoms (encephalitis, encephalopathy, myelitis, other [ ]) - Lower respiratory inflammation (pneumonia, bronchitis) - Vesicules - Rash (papules, erythema, roseola) - Circulatory disorder (myocarditis, pericarditis, cardiac failure) - Hemorrhagic tendency, systemic - Jaundice - Liver dysfunction - Lymph node swelling (site:), salivary gland swelling, edema (site:) - Renal dysfunction (HUS, hematuria, oliguria, proteinuria, polyuria, renal failure) - Shock symptoms (hypotension, circulatory failure) - Genitourinary symptoms (cystitis, urethritis, vulvitis, cervicitis) - Other symptoms (symptoms and clinical signs other than the above) 「 」
Underlying illness		
Outcome	Under follow-up, relieved, recovered, with sequelae, died (cause:)	

Message from attending physician, etc. to Public Health Institute

*Use of rapid influenza test kit (no, yes: manufacturer [ ]: [negative, positive, pending])
*Administration of anti-influenza drug (no, yes: drug name [ ]
Administration start date: MM DD, YYYY [prophylactic, therapeutic]
Administration end date: MMDD, YYYY

[Public Health Center or equivalent's use only] (may be filled out by attending physician)

Epidemiological situation	- Sporadic - Endemic - Family outbreak (no, yes) - Mass outbreak (no, yes) - Municipality where outbreak occurred ( ) If yes (childcare center, kindergarten, elementary school, junior high school, high school, university/college, quarters/dormitory, hospital, elderly nursing home [including care facility], welfare facility/children's home, inn/hotel, restaurant, business establishment, foreign tour, domestic tour, other [ ])	
Most recent overseas travel	Country	
	Period	MM DD, YYYY – MM DD, YYYY
Vaccination history	(no, yes, unknown) Last vaccination date: MM DD, YYYY	
	Vaccine name: (Lot No.)	

[Public Health Institute's use only]

Author's name		
Antibody detection method (fluorescent, IP, ELISA, CF, HI, PA, neutralizing, immunoblot, gel precipitation, agglutination reaction, other [ ]) Results ( )		
Pathogen detection	Date of detection	MM DD, YYYY
	Detection method [Circle methods with positive results]	- Isolation culture (cell culture: cell name [ ]) Artificial medium, embryonated egg, animal, other [ ]) - Antigen detection (fluorescent, EIA, RPHA, LA, PA, IC [immunochromatography], other [ ]) - Gene detection 1. Non-amplification (hybrid, PAGE, other [ ]) 2. Amplification (PCR, real-time (hybri), PCR+sequence, LAMP, other [ ]) - Electron microscopy - Microscopy
Detected pathogens (group, type, subtype)		

[Other information of note]

Note 1: Please fill out the patient's name and address in case of testing of any of the Category I or II Infectious Diseases, the Pandemic Influenza (Novel Influenza or Re-emerging Influenza), or any New Infectious Disease to be conducted under Article 16-3, 26-3, 26-4, 44-7 and 50 of the Infectious Disease Act.
Note 2: Please fill out the attending physician's use only section to the extent possible as of the specimen dispatch date.
Note 3: Please provide the vaccination history to the extent relevant to the disease.
Note 4: If the medical facility (including a private laboratory) has isolated the pathogen, please send the isolate to the Public Health Institute (PHI).

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Infectious Disease Surveillance System in Japan

Infectious Disease Surveillance Center, National Institute of Infectious Diseases
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1. Structure of the Infectious Disease Surveillance System in Japan

The infectious disease surveillance system in Japan mainly consists of (1) pathogen reporting (laboratory-based surveillance) and (2) patient reporting. In the National Epidemiological Surveillance of Infectious Diseases (NESID) Program, information concerning infectious diseases in Japan is collected and published, and occurrence and trends are assessed, based on reporting from physicians and veterinarians. This system of infectious disease surveillance in Japan is pursuant to Articles 12 through 16 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (hereinafter, referred to as the "Infectious Diseases Control Law"), in effect since April 1, 1999. The NESID Program defines appropriate systems to be established, through cooperation from physicians and other healthcare professionals, with the aim of taking effective and adequate measures toward the prevention, diagnosis, and treatment of infectious diseases and preventing their occurrence and spread, through the accurate assessment and analysis of infectious disease information, rapid provision and disclosure of the resultant information to the general public and healthcare professionals, verification of the detection status and characteristics of pathogens that are circulating, and formulation of adequate infection control measures, through the collection and analysis of pathogen information. The notifiable disease and sentinel surveillance systems are comprehensive; notifiable disease surveillance consists of seven category I infectious diseases, seven category II infectious diseases, five category III infectious diseases, 44 category IV infectious diseases, and 23 category V infectious diseases. Sentinel surveillance comprehensively includes the sentinel surveillance of influenza, 10 pediatric diseases at sentinel pediatric sites, eight diseases at designated sentinel sites, two diseases at ophthalmology sentinel sites, and four sexually transmitted infections (STI) at STI sentinel sites. In addition, a system of reporting from suspected case sentinel sites was introduced on April 1, 2007, in order to collect information from designated medical facilities in the suspected case stage, before the physician's confirmatory diagnosis, so that the occurrence of an infectious disease can be rapidly identified, including those due to bioterrorism. The revised Infectious Diseases Control Law was proclaimed on November 21, 2013, incorporating the strengthened functions of pathogen information collection.

2. History of the NESID Program

In Japan, the laboratory-based surveillance system was established before a system for patient reporting was introduced. Funded by the national budget, laboratory-based surveillance first began in July 1981 and targeted 18 diseases. In January 1987, an online system was introduced that targeted 27 diseases. In this manner, the Program has been operated with stepwise enhancement and expansion. After the Infectious Diseases Control Law was established in September 1998 and took effect in April 1999, the Program was positioned as a statutory initiative. A system for patient reporting was also established at that time. Under the Program, a physician who diagnoses a target disease makes a notification, and the Public Health Center (PHC) verifies the notification and registers the information in the NESID system. The NESID system is a central database

that supports a centralized data management system, created in May 2006 by integrating and modifying the online system for pathogen reports with the patient report system that had been used for patient report collection. A private enterprise contracted by the Ministry of Health, Labour and Welfare (MHLW) manages the database.

3. Operation of the NESID Program

The following regulations and documents are applicable to the Program:

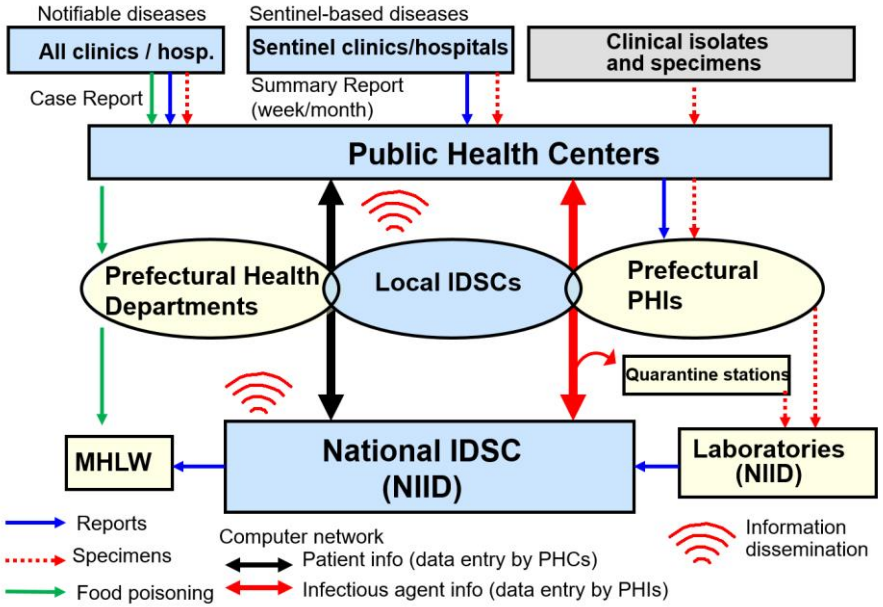
- Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law")
- Enforcement Order of the Act ("Order")
- Regulation for Enforcement of the Act ("Regulation")
- Implementation Manual for the National Epidemiological Surveillance of Infectious Diseases Program ("Manual")
- Reporting Criteria
- Report Form ("Form")

Implementing entities are the national government and the prefectural and city governments (including special wards) with PHCs (hereinafter collectively referred to as "local government" or "local governments"). The Central Infectious Disease Surveillance Center is established within the Infectious Disease Surveillance Center (IDSC) of the National Institute of Infectious Diseases (NIID), and plays an essential role in collecting and analyzing patient information, suspected case information, and pathogen information reported from local governments, and in promptly providing and disclosing the resultant information to local governments as national information. A local IDSC is established in each local government (within the Public Health Institute (PHI), in principle), for the purposes of collecting and analyzing patient information, suspected case information, and pathogen information (including laboratory information; the same applies hereinafter) within the jurisdiction area of the local government, and of reporting such information to the head office of the local government, while promptly providing and disclosing such information, together with national information, to medical associations and other related organizations.

The reportable items under the Infectious Diseases Control Law are specified in Article 12, while the details of NESID are specified in Article 14 of the Infectious Diseases Control Law. Reporting requirements for physicians are specified in Article 4 of the Regulation. The Infectious Diseases Control Law requires the governor of a prefecture to report the received information to the Minister of Health, Labour and Welfare. In practice, a physician fills out a Report Form and sends it to a PHC by facsimile or by other means, in accordance with the Manual. The PHC confirms the received Form and immediately enters and registers the received information into the online NESID system. The subsequent data exchange is performed through a computer network. The local IDSC verifies the received patient information, and checks it for any data entry error, missing data, fulfillment of the Reporting Criteria, discrepancies from what would be expected from public health knowledge, and any other such inadequacies. If there is any inadequacy, the PHC corrects it or collects additional information. In principle, only a PHC may register, update, or delete patient information in the NESID system, and only a local IDSC may perform the verification process. Once patient information is registered

in the central NESID database, it becomes accessible by NIID and responsible divisions at MHLW. A PHC and a local IDSC are able to access information within their geographical areas and aggregate information from other municipalities. The flow is the same not only for notifiable diseases, but also for sentinel-based diseases, where a PHC enters information reported from a sentinel site into NESID, and a local IDSC undertakes reporting to the national government. An overview of the Program as described above is indicated in Figure 1.

Figure 1. The National Epidemiological Surveillance of Infectious Diseases (NESID) Program structure (patient-based and laboratory-based surveillance)



4. Methods for Data Quality Control in the Program

Data quality control in the NESID system is undertaken both by the system and by personnel at user institutions. The system ensures efficient operation, as well as a certain level of information volume and accuracy, through its systematized information collection process. Personnel at user institutions check for any missing or inaccurate information, and make up for any inadequacies in the system when system updating lags behind

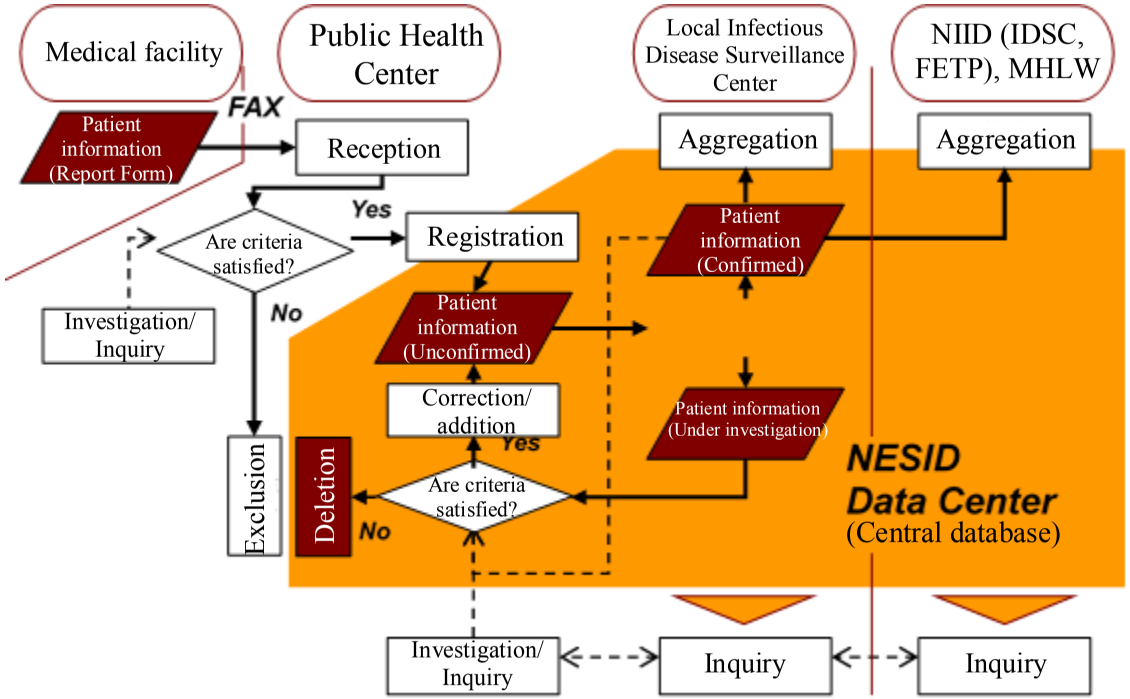
regulatory changes. At present, the system mainly performs two data checks as described below.

- **Logical check**: The system ensures data accuracy by returning an error message when a PHC attempts to register information with incomplete data (i.e., missing data for required categories) or with a logical inconsistency and the data content entered requires revision.
- **Duplication check**: The system checks its database for possible duplicate entries based on the name, date of birth, disease code, and sex of a case patient. Such entries are notified to the relevant PHC, which in turn deletes the duplication.

- Training of surveillance personnel at municipalities

A training course is provided for surveillance personnel at municipalities in concurrence with the initial introductory course for the Field Epidemiology Training Program (FETP), which is held at the NIID in April every year. Individual municipalities also implement training for their personnel. When there is a substantial change to the NESID system, training is also provided at the national level. An information session at the national level was also held after the pathogen system was modified in April 2016. The NESID system has an online help service provided by a contractor, which enables self-learning. At the same time, the study group for "Strengthening Infectious Disease Surveillance and Risk Assessment in Preparation for the Outbreak of Emerging and Re-emerging Infectious Diseases", funded by the Grants-in-Aid for Scientific Research (KAKENHI), periodically issues the "Guidelines for Improving Reporting Quality in the NESID Program", thereby aiding in quality control of the data. In addition, daily meetings are held at IDSC, where disease information reported through NESID is shared, and inquiry is made with the reporting municipality when necessary, contributing to quality control (Figure 2).

Figure 2. Quality control and processing of case patient information in NESID



5. Diseases Targeted in the Program

Diseases targeted in the Program include 1) category I infectious diseases, category II infectious diseases, category III infectious diseases, category IV infectious diseases, certain category V infectious diseases, pandemic influenza (novel influenza or re-emerging influenza), and designated infectious diseases, as is within the scope of notifiable disease surveillance; 2) certain category V infectious diseases, and suspected cases specified by MHLW Order as defined in Article 14, Paragraph 1 of the Infectious Diseases Control Law, as is within the scope of sentinel surveillance; and 3) avian influenza (H5N1) classified as a category II infectious disease, as a target for reporting the results of active epidemiological investigation through an online system. Actions that are legally authorized to prevent the spread of infection are defined for each disease category (Table 1). Notifiable disease surveillance becomes necessary when (1) it is required to prevent the expansion of infection to surrounding areas, and when (2)

it is not possible to assess trends accurately through a sentinel-based approach, due to the low frequency of occurrence of the relevant infectious disease. Reporting is required in the suspected stage for category I infectious diseases, certain category II infectious diseases, novel influenza or re-emerging influenza, and measles and rubella (category V infectious diseases), so that response can be planned before diagnosis is confirmed. Sentinel surveillance is necessary when situational awareness is required but monitoring of all cases is not, due to the large number of patients. For each of these infectious diseases, nationwide standardized notification criteria have been established (http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kenkou/kekkaku-kansenshou/kekkaku-kansenshou11/01.html). For certain infectious diseases such as category I infectious diseases and category II infectious diseases, the process begins at the clinically suspect stage, and the required processes pertaining to diagnostic methods and response measures such as quarantine are clearly specified (e.g., through government notices), which are updated as appropriate based on the situation overseas and the likelihood of importation into Japan.

Table 1. Overview of key actions based on the Infectious Diseases Control Law*

Overview of key actions based on the Infectious Diseases Control Law						
	Category I infectious diseases	Category II infectious diseases	Category III infectious diseases	Category IV infectious diseases	Category V infectious diseases	Pandemic influenza (novel influenza or re-emerging influenza)
Examples of diseases	Ebola hemorrhagic fever, plague, etc.	Tuberculosis, SARS, etc.	Cholera, shigellosis, etc.	Yellow fever, malaria, etc.	Influenza, syphilis, etc.	Pandemic influenza (novel influenza), re-emerging influenza, etc.
Specified by:	Law	Law	Law	Law/Cabinet Order	Law/Cabinet Order	Law (enforced upon publication by the Minister)
Quarantine [Quarantine Act]	○	×	×	×	×	○
Retention [Quarantine Act]	○	×	×	×	×	○
Laboratory [Quarantine Act]	○	× * Possible for avian influenza (H5N1)	×	×	×	○
Application to asymptomatic carriers	○	×	×	×	×	○
Application to suspected cases	○	○	×	×	×	○
Recommended/involuntary hospitalization	○	○ (As specified by Cabinet Order)	×	×	×	○ (When justifiable as a suspected case)
Restriction on employment	○	○	×	×	×	○
Recommendation/implementation of health checks	○	○	○	×	×	○
Restriction on the relocation of dead bodies	○	○	○	×	×	
Restriction on the use of domestic water	○	○	○	×	×	
Extermination of rodents, insects, etc.	○	○	○	×	×	○
Disposal of contaminated articles	○	○	○	○	×	○
Disinfection of contaminated locations	○	○	○	○	×	○
Reporting by veterinarians	○	○	○	○	○	○
Reporting by physicians	○ (Immediately)	○ (Immediately)	○ (Immediately)	○ (Immediately)	○ (Within seven days)	○ (Immediately)
Implementation of active epidemiological investigation	○	○	○	○	○	○
Restriction of building entry/containment	○	×	×	×	×	△
Restriction of traffic	○	×	×	×	×	△
Request for reporting on health condition	×	×	×	×	×	○
Request for restraint from outings	×	×	×	×	×	○

*for Category V infectious diseases, invasive meningococcal infection, measles, and rubella require immediate reporting

<u>Diseases subject to notifiable disease surveillance</u>

- Category I infectious diseases

Infectious diseases that are extremely threatening from a comprehensive viewpoint, based on factors such as infectivity and seriousness of disease; category I infectious diseases are subject to notifiable disease surveillance, and require immediate reporting.

Ebola hemorrhagic fever, Crimean-Congo hemorrhagic fever, smallpox, South American hemorrhagic fever, plague, Marburg disease, Lassa fever.

- Category II infectious diseases

Infectious diseases that are highly threatening from a comprehensive viewpoint, based on factors such as infectivity and severity; category II infectious diseases are subject to notifiable disease surveillance, and require immediate reporting.

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

- Category III infectious diseases

Infectious diseases that are not highly threatening from a comprehensive viewpoint, based on factors such as infectivity and severity, but that may lead to an outbreak through employment in certain occupations; category III infectious diseases are subject to notifiable disease surveillance, and require immediate reporting.

Cholera, shigellosis, enterohemorrhagic *Escherichia coli* infection, typhoid fever, paratyphoid fever.

- Category IV infectious diseases

Infectious diseases where human-to-human transmission is generally rare, but that require actions such as the disinfection or disposal of animals/articles, due to transmission via animals, food, drink, or other articles; category IV infectious diseases are subject to notifiable disease surveillance, and require immediate reporting.

Hepatitis E, West Nile fever (including West Nile encephalitis), hepatitis A, echinococcosis, yellow fever, psittacosis, Omsk hemorrhagic fever, relapsing fever, Kyasanur Forest disease, Q fever, rabies, coccidioidomycosis, monkeypox, Zika virus infection, severe fever with thrombocytopenia syndrome (only if the pathogen is SFTS virus of the genus *Phlebovirus*), hemorrhagic fever with renal syndrome, Western equine encephalitis, tick-borne encephalitis, anthrax, chikungunya fever, Tsutsugamushi disease, dengue fever, Eastern equine encephalitis, avian influenza (excluding H5N1 and H7N9), Nipah virus infection, Japanese spotted fever, Japanese encephalitis, Hantavirus pulmonary syndrome, B virus disease, glanders, brucellosis, Venezuelan equine encephalitis, Hendra virus infection, typhus, botulism, malaria, tularemia, Lyme disease, Lyssavirus infection, Rift Valley fever, melioidosis, legionellosis, leptospirosis, Rocky Mountain spotted fever.

- Category V infectious diseases

Infectious diseases that require the prevention of occurrence and spread, through the operation of NESID and through the provision and feedback

of the resultant necessary information to the general public and healthcare professionals. Most of the following category V infectious diseases are subject to notifiable disease surveillance and require reporting within seven days (immediate reporting is required for invasive meningococcal infection, measles, and rubella).

Amebic dysentery, viral hepatitis (excluding hepatitis E and A), carbapenem-resistant Enterobacteriaceae infection, acute encephalitis (excluding West Nile encephalitis, Western equine encephalitis, tick-borne encephalitis, Eastern equine encephalitis, Japanese encephalitis, Venezuelan equine encephalitis, and Rift Valley fever), cryptosporidiosis, Creutzfeldt-Jakob disease, severe invasive streptococcal infection, acquired immunodeficiency syndrome, giardiasis, invasive *Haemophilus influenzae* disease, invasive meningococcal disease, invasive pneumococcal disease, varicella (only if the patient requires hospitalization), congenital rubella syndrome, syphilis, disseminated cryptococcosis, tetanus, vancomycin-resistant *Staphylococcus aureus* infection, vancomycin-resistant enterococcal infection, pertussis, rubella, measles, multidrug-resistant *Acinetobacter* infection.

- Pandemic influenza (novel influenza or re-emerging influenza)

Novel influenza or re-emerging influenza is subject to notifiable disease surveillance, and shall be reported in the suspected stage.
Pandemic influenza (novel influenza): a type of influenza caused by a virus that has recently acquired the capacity for human-to-human transmission, and that is regarded to have the potential to seriously affect the lives and health of people through rapid, nationwide spread.
Re-emerging influenza: a type of influenza that once spread on a global scale and has recently re-emerged after a long period of non-circulation, and that is regarded to have the potential to seriously affect the lives and health of people through rapid, nationwide spread.

- Designated infectious diseases

Known infectious diseases that are not classified in category I, II, or III above, but that require actions equivalent thereto (specified by Cabinet Order, and applies for one year only).

<u>Diseases subject to sentinel surveillance</u>

- Diseases to be reported by pediatric sentinel sites (approx. 3,000 pediatric medical facilities across Japan); reports should be submitted on a weekly basis (Monday through Sunday).

RS virus infection, pharyngoconjunctival fever, group A streptococcal pharyngitis, infectious gastroenteritis, varicella, hand, foot and mouth disease, erythema infectiosum, exanthema subitum, herpangina, mumps.

- Diseases to be reported by influenza sentinel sites (approx. 5,000 internal and pediatric medical facilities across Japan) and by designated sentinel sites (approx. 500 internal and surgical medical facilities across Japan, each with at least 300 beds); reports should be submitted on a weekly basis (Monday through Sunday).

Influenza (excluding avian influenza and Pandemic Influenza (Novel Influenza or Re-emerging Influenza))

- Diseases to be reported by ophthalmology sentinel sites (approx. 700 ophthalmologic facilities across Japan); reports should be submitted on a

weekly basis (Monday through Sunday).

Acute hemorrhagic conjunctivitis, epidemic keratoconjunctivitis.

• Diseases to be reported by sexually transmitted infections sentinel sites (approx. 1,000 medical facilities of obstetrics and gynecology, urology, dermatology, etc. across Japan); reports should be submitted on a monthly basis.

Genital chlamydial infection, genital herpes simplex virus infection, condylomata acuminata, gonococcal infection.

• Diseases to be reported by designated sentinel sites (approx. 500 medical facilities across Japan, each with at least 300 beds); reports should be submitted on a weekly basis (Monday through Sunday).

Infectious gastroenteritis (only if the pathogen is rotavirus), chlamydial pneumonia (excluding psittacosis), bacterial meningitis (excluding cases where the cause is identified as *Haemophilus influenzae*, *Neisseria meningitides*, or *Streptococcus pneumoniae*), penicillin-resistant *Streptococcus pneumoniae* infection, mycoplasma pneumonia, aseptic meningitis, methicillin-resistant *Staphylococcus aureus* infection, multidrug-resistant *Pseudomonas aeruginosa* infection.

• Diseases to be reported by suspected case sentinel sites (approx. 5,000 internal and pediatric medical facilities across Japan).

Pyrexia at or above 38°C and respiratory symptoms (excluding those clearly due to trauma or organic disease) or pyrexia and rash or vesicles (excluding cases where the suspected case clearly represents symptoms of a patient with a category II, III, IV or V infectious disease).

Results of active epidemiological investigation reportable through the online system

• Category II infectious diseases

Avian influenza (H5N1).

Table 2. Infectious diseases subject to the Infectious Diseases Control Law

Classification	Applicable infectious diseases and remarks
Category I infectious diseases	**[Law]** Ebola hemorrhagic fever, Crimean-Congo hemorrhagic fever, smallpox, South American hemorrhagic fever, plague, Marburg disease, Lassa fever
Category II infectious diseases	**[Law]** Acute poliomyelitis, diphtheria, severe acute respiratory syndrome (only if the pathogen is SARS coronavirus), tuberculosis, Middle East respiratory syndrome (only if the pathogen is MERS coronavirus), avian influenza (only if the pathogen is influenza A virus of genus *Influenzavirus A*, with a serum subtype H5N1 or H7N9; hereinafter collectively referred to as "specified avian influenza")
Category III infectious diseases	**[Law]** Enterohemorrhagic *Escherichia coli* infection, cholera, shigellosis, typhoid fever, paratyphoid fever
Category IV infectious diseases	**[Law]** Hepatitis E, hepatitis A, yellow fever, Q fever, rabies, anthrax, avian influenza (excluding specified avian influenza), botulism, malaria, tularemia **[Cabinet Order]** West Nile fever, echinococcosis, psittacosis, Omsk hemorrhagic fever, relapsing fever, Kyasanur Forest disease, coccidioidomycosis, monkeypox, Zika virus infection, severe fever with thrombocytopenia syndrome (only if the pathogen is SFTS virus of the genus *Phlebovirus*), hemorrhagic fever with renal syndrome, Western equine encephalitis, tick-borne encephalitis, chikungunya fever, Tsutsugamushi disease, dengue fever, Eastern equine encephalitis, Nipah virus infection, Japanese spotted fever, Japanese encephalitis, Hantavirus pulmonary syndrome, B virus disease, glanders, brucellosis, Venezuelan equine encephalitis, Hendra virus infection, epidemic typhus, Lyme disease, Lyssavirus infection, Rift Valley fever, melioidosis, legionellosis, leptospirosis, Rocky Mountain spotted fever
Category V infectious diseases	**[Law]** Influenza (excluding avian influenza and novel influenza or re-emerging influenza), viral hepatitis (excluding hepatitis E and A), cryptosporidiosis, acquired immunodeficiency syndrome, genital chlamydial infection, syphilis, measles, methicillin-resistant *Staphylococcus aureus* infection **[Order]** Amebiasis, RS virus infection, pharyngoconjunctival fever, group A streptococcal pharyngitis, carbapenem-resistant Enterobacteriaceae infection, infectious gastroenteritis, acute hemorrhagic conjunctivitis, acute encephalitis (excluding West Nile encephalitis, Western equine encephalitis, tick-borne encephalitis, Eastern equine encephalitis, Japanese encephalitis, Venezuelan equine encephalitis, and Rift Valley fever), chlamydial pneumonia (excluding psittacosis), Creutzfeldt-Jakob disease, severe invasive streptococcal infection, bacterial meningitis, giardiasis, invasive *Haemophilus influenzae* infection, invasive meningococcal infection, invasive pneumococcal disease, varicella, genital herpes simplex virus infection, condylomata acuminata, congenital rubella syndrome, hand, foot and mouth disease, erythema infectiosum, exanthema subitum, disseminated cryptococcal infection, tetanus, vancomycin-resistant *Staphylococcus aureus* infection, vancomycin-resistant enterococcal infection, pertussis, rubella, penicillin-resistant *Streptococcus pneumoniae* infection, herpangina, mycoplasma pneumonia, aseptic meningitis, multidrug-resistant *Acinetobacter* infection, multidrug-resistant *Pseudomonas aeruginosa* infection, epidemic keratoconjunctivitis, mumps, gonococcal infection
Designated infectious diseases	**[Cabinet Order]** (None at present) * Designated by a Cabinet Order, which expires after one year, but may be extended only once
New Infectious diseases	(None at present)
Pandemic influenza (novel influenza or re-emerging influenza)	**[Law]** Novel influenza, re-emerging influenza

6. Selection of Sentinel Sites for the Reporting of Diseases Subject to Sentinel Surveillance

1) 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.

(1) For the following target infectious diseases of RS virus infection, pharyngoconjunctival fever, group A streptococcal pharyngitis, infectious gastroenteritis, varicella, hand, foot and mouth disease, erythema infectiosum, exanthema subitum, herpangina, and mumps, 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 cases, 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

(2) For influenza (excluding avian influenza and pandemic influenza (novel influenza or re-emerging influenza); hereinafter the same applies), as one 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.

(3) For the target infectious diseases of acute hemorrhagic conjunctivitis and epidemic keratoconjunctivitis, 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

(4) For the target infectious diseases of genital chlamydial infection, genital herpes simplex virus infection, condylomata acuminata, and gonococcal infection, 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 + (population – 75,000 persons)/130,000 persons

(v) For the target infectious diseases, infectious gastroenteritis (only if the pathogen is rotavirus) and chlamydial pneumonia (excluding psittacosis), bacterial meningitis (excluding cases where the cause is identified as *Haemophilus influenzae*, *Neisseria meningitides*, or *Streptococcus pneumoniae*), penicillin-resistant *Streptococcus pneumoniae* infection, mycoplasma pneumonia, aseptic meningitis, methicillin-resistant *Staphylococcus aureus* infection, and multidrug-resistant *Pseudomonas aeruginosa* infection, 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.

(2) 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. (1) 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. (2) Approximately 10% of pediatric sentinel sites, influenza sentinel sites, and ophthalmology sentinel sites are respectively designated as pediatric, influenza, and ophthalmology sentinel sites for laboratory-based surveillance. In the selection of influenza sentinel sites for laboratory-based surveillance, at least 10% of pediatric sentinel sites and at least 10% of internal sentinel sites, respectively not fewer than three and two sites, should be selected and specified as designated submitting facilities pursuant to Article 14-2, Paragraph 1 of the Infectious Diseases Control Law. All of the designated sentinel sites should be regarded as designated sentinel sites for laboratory-based surveillance, targeting infectious gastroenteritis (only if the pathogen is rotavirus), bacterial meningitis (excluding cases where the cause is identified as *Haemophilus influenzae*, *Neisseria meningitides*, or *Streptococcus pneumoniae*), and aseptic meningitis.

7. Laboratory-based Surveillance

In Japan, a laboratory-based surveillance system was established before a patient reporting system was introduced. The system was initiated through a network of PHIs and the former National Institute of Health (present NIID), centering around the Hygienic and Bacteriological Technology Council, which was organized in 1980.

Based on a series of revisions of orders (MHLW Order No. 147 of 2015) that followed the revision of the Act and the revision of the Manual (HSB Notification 1109 No. 3 of 2015), a PHC that receives a Report Form is authorized to request or order a physician who has diagnosed a reported patient, or a medical facility that retains a reported sample, to provide a sample or pathogen information for laboratory tests to a PHI, as part of the active epidemiological investigation. NIID and local PHIs across Japan have jointly created Pathogen Testing Guidelines, and have revised them in accordance with progress in science and technology, in order to standardize laboratory tests related to infectious disease reporting. Training is implemented for PHIs in order to help their staff acquire and maintain capacities to perform tests on diseases subject to the Infectious Diseases Control Law. Standard operating procedures (SOPs) have also been established and quality control is implemented. The close network that joins PHIs and NIID has been developed over a long history, and can be regarded as an asset to Japan. At present, laboratory-based surveillance, as part of infectious disease surveillance, is structured as indicated in Figure 3. Infectious diseases, excluding some such as STIs, are subject to laboratory-based surveillance. In the process of submitting a laboratory sample, a physician enters the age, sex, and clinical information of a patient into a laboratory test form (Figure 4), and attaches it to the sample to be submitted. The PHC adds epidemiological information to the laboratory test form and submits it together with the sample to the PHI, which in turn uses the received sample to conduct analyses such as diagnosis of the pathogen of the disease, identification of the pathogen type, genetic analysis, and/or analysis of antimicrobial resistance. The PHI then enters the test results into the laboratory test form and notifies the PHC, while reporting the pathogen detection information to NIID. The acquired test information is very useful for providing appropriate healthcare to a patient based on the laboratory diagnosis, for detecting common features among geographically widespread sporadic cases or detecting geographically widespread occurrence, for identifying the cause, and for preventing future occurrence. In addition to NESID, test results concerning foodborne outbreaks (i.e., food poisoning events) and those not from humans but from the environment, food, or animals, are also reported under the “Other” reporting category on the laboratory test form. The quarantine stations report pathogens detected in test results on persons returning to or entering the country from overseas.

The series of revisions of orders (MHLW Order No. 147 of 2015) that followed the revision of the Infectious Diseases Control Law, and the revision of the Manual (HSB Notification 1109 No. 3 of 2015), provide laboratory-based surveillance with a clear statutory basis.

Submission of the following types of samples is expected under laboratory-based surveillance.

1) Category I infectious diseases through category V infectious diseases that are subject to notifiable disease surveillance
2) Samples of pandemic influenza (novel influenza or re-emerging influenza) and new infectious diseases
3) Samples of category V infectious diseases that are subject to sentinel surveillance from the designated submitting facilities (i.e., sentinel sites for laboratory-based surveillance) and the designated sentinel sites

4) Samples from active epidemiological investigation

• Online system for laboratory-based surveillance

In May 2006, the online system for reporting detected pathogens was integrated with the system for collecting patient information and other systems into a single central database that supports a centralized data management system (the electronic NESID system). A pathogen detection information system was established as a sub-system within the NESID system, and has archived and updated data reported from PHIs since 1980.

• Reporting items in the pathogen detection information system

1) Case-based pathogen report form: A number is assigned to each sample provider (e.g., patient), and information is entered for each detected pathogen, including basic information such as the age and sex of the sample provider (e.g., patient) and date of onset and other information such as clinical symptoms, laboratory materials, detection methods, and epidemiologic information.

2) Outbreak pathogen report form: To report the investigative results of a pathogen in an outbreak and the summary of the outbreak, an outbreak pathogen report form may be used. A number is assigned to each outbreak event of gastroenteritis, including food poisoning events, and a summary of the event (e.g., suspected transmission route, duration of outbreak, suspected location of infection, number of patients, number of persons tested positive for the pathogen) is entered for each detected pathogen. An outbreak in this context is defined as infection of two or more patients, excluding those within the same household. A facility refers to a place where multiple persons live together communally, other than at home. The outbreak pathogen report form can be used for the following cases.

(1) Transmission via drinking water is suspected
(2) Infection via a common food source is suspected among patients at the same facility, nursing home, or school
(3) Human-to-human infection is suspected among patients at the same facility, nursing home, or school
(4) Infection via a common food source is suspected, with patients having several different addresses
(5) Patients are occurring sporadically in a geographically widespread area, and pathogens detected from the patients have a common epidemiologic marker (e.g., phage type, special biological properties, PFGE type, MLVA type, base sequence), with a suspected common source of infection

3) Non-human pathogenic agent detection form: Pathogens that are detected in food, the environment, and animals are entered on a monthly basis.

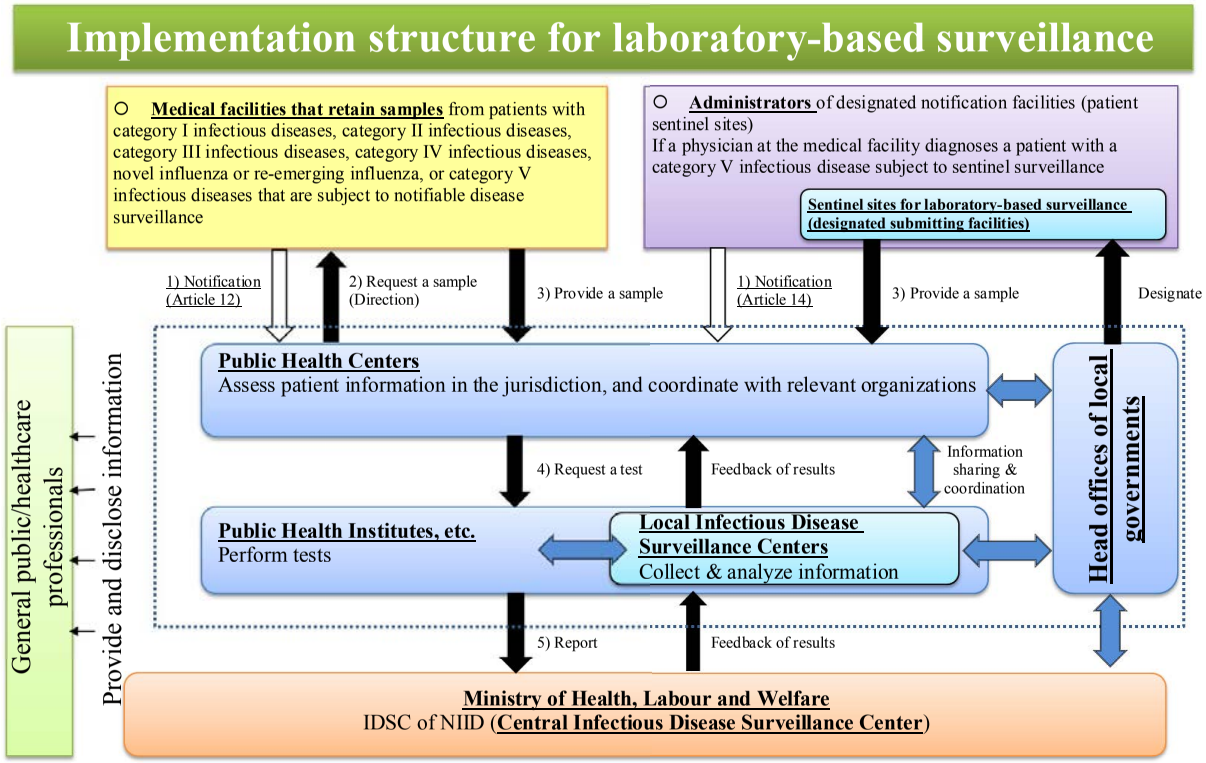
4) Pathogenic bacteria detection report (3A, PHIs and PHCs): Detections of pathogenic bacteria, including those from sporadic cases and outbreaks, and the distribution of detections from imported cases, are entered on a monthly basis.

5) Confirmation of reported data: NIID and the Infectious Agents Surveillance Report Office confirm the data reported to the database on the following day, and changes the status to “publicized”. These data become accessible in NESID as a preliminary report, and are aggregated.

6) Regular form: Figures and tables for the regular form are automatically generated (in the same consistent format) based on the “publicized”

data. The Infectious Agents Surveillance Report Office confirms the generated regular form before it is openly released on the Internet.

Figure 3. Implementation structure for laboratory-based surveillance



* Provision of results to reporting physicians or to sentinel sites (sentinel sites for laboratory-based surveillance and other sentinel sites) should be undertaken when necessary

Figure 4. Laboratory test form

Appended Form

Public Health Center code □□-□□-□□

Public Health Center registered notifiable disease report ID □□□□-□□□□-□□□□□

PHI receipt No. (specimen provider No.) □□□□□□□□

Test Slip for Categories I, II, III, IV and V Infectious Diseases, Pandemic Influenza (Novel Influenza or Re-emerging Influenza), and Designated Infectious Diseases (Pathogen)

Patient	Gender	(M / F)
	Age	(yr mo)
	Name	
	Address	

[Attending physician or equivalent's use only]

If the medical facility is a sentinel site, circle appropriate items.
- Influenza sentinel site - Pediatric sentinel site
- Ophthalmology sentinel site - STI sentinel site – Designated sentinel site

Name of medical facility, etc. and name of attending or other physician (author)		
Specimen dispatch date		MM DD, YYYY Isolate (no, yes, under testing)
Diagnosis		
Date of onset		MM DD, YYYY
Specimen	Date of collection	MM DD, YYYY
	Type of specimen [Circle one appropriate item]	- Feces (intestinal content, rectal swab) - Spinal fluid - Urine - Vomit - Sputum - Tracheal aspirate - Puncture fluid (ascites, pleural effusion, joint fluid, other [ ]) - Throat swab (gargle, nasal discharge) - Skin lesion (vesicular content, crust, wound) - Conjunctival swab (conjunctival scrapings, eye discharge) - Genital/urethral/cervical scrapings/secretion - Cytology/biopsy/autopsy material (organ:) - Blood (whole blood, serum, plasma, anticoagulant [ ]) - Other ( )
Clinical information	Clinical signs and symptoms, etc. [Circle all appropriate items] (excluding underlying illness)	- Asymptomatic - Gastroenteritis (diarrhea, hemafecia, nausea, vomiting, abdominal pain) - Headache - Pyrexia (maximum °C) - Keratitis, conjunctivitis, keratoconjunctivitis - Febrile convulsion - Arthralgia (arthritis), myalgia - Meningitis, disturbance of consciousness, paralysis (site:) - Stomatitis - Upper respiratory inflammation (pharyngitis/pharyngeal pain, tonsillitis) - Central nervous system symptoms (encephalitis, encephalopathy, myelitis, other [ ]) - Lower respiratory inflammation (pneumonia, bronchitis) - Vesicules - Rash (papules, erythema, roseola) - Circulatory disorder (myocarditis, pericarditis, cardiac failure) - Hemorrhagic tendency, systemic - Jaundice - Liver dysfunction - Lymph node swelling (site:), salivary gland swelling, edema (site:) - Renal dysfunction (HUS, hematuria, oliguria, proteinuria, polyuria, renal failure) - Shock symptoms (hypotension, circulatory failure) - Genitourinary symptoms (cystitis, urethritis, vulvitis, cervicitis) - Other symptoms (symptoms and clinical signs other than the above) [ ]
Underlying illness		
Outcome		Under follow-up, relieved, recovered, with sequelae, died (cause:)

Message from attending physician, etc. to Public Health Institute

*Use of rapid influenza test kit (no, yes: manufacturer [ ]: [negative, positive, pending])
*Administration of anti-influenza drug (no, yes: drug name [ ]
Administration start date: MM DD, YYYY [prophylactic, therapeutic]

[Public Health Center or equivalent's use only] (may be filled out by attending physician)

Epidemiological situation	- Sporadic - Endemic - Family outbreak (no, yes) - Mass outbreak (no, yes) - Municipality where outbreak occurred ( ) If yes (childcare center, kindergarten, elementary school, junior high school, high school, university/college, quarters/dormitory, hospital, elderly nursing home [including care facility], welfare facility/children's home, inn/hotel, restaurant, business establishment, foreign tour, domestic tour, other [ ])	
Most recent overseas travel	Country	
	Period	MM DD, YYYY – MM DD, YYYY
Vaccination history	(no, yes, unknown)	Last vaccination date: MM DD, YYYY
	Vaccine name:	(Lot No.)

[Public Health Institute's use only]

Author's name		
Antibody detection method (fluorescent, IP, ELISA, CF, HI, PA, neutralizing, immunoblot, gel precipitation, agglutination reaction, other [ ]) Results ( )		
Pathogen detection	Date of detection	MM DD, YYYY
	Detection method [Circle methods with positive results]	- Isolation culture (cell culture: cell name [ ]) Artificial medium, embryonated egg, animal, other [ ]) - Antigen detection (fluorescent, EIA, RPHA, LA, PA, IC [immunochromatography], other [ ]) - Gene detection 1. Non-amplification (hybrid, PAGE, other [ ]) 2. Amplification (PCR, PCR+hybrid, PCR+sequence, LAMP, other [ ]) - Electron microscopy - Microscopy
Detected pathogens (group, type, subtype)		

[Other information of note]

Note 1: Please fill out the patient's name and address in case of testing of any of the Category I or II Infectious Diseases, the Pandemic Influenza (Novel Influenza or Re-emerging Influenza), or any New Infectious Disease to be conducted under Article 16-3, 26-3, 26-4, 44-7 and 50 of the Infectious Disease Act.
Note 2: Please fill out the attending physician's use only section to the extent possible as of the specimen dispatch date.
Note 3: Please provide the vaccination history to the extent relevant to the disease.
Note 4: If the medical facility (including a private laboratory) has isolated the pathogen, please send the isolate to the Public Health Institute (PHI).

8. New Infectious Diseases

1) Definition of new infectious diseases

Diseases that are regarded as transmitted from human to human, with symptoms and/or treatment outcomes that clearly differ from those of known infectious diseases, resulting in serious conditions in the case of infection, and with a potential of seriously affecting the lives and health of people through its spread.

2) How persons who are suspected of infection with a new infectious disease should be managed

Because a new infectious disease has characteristics that its symptoms and/or treatment outcomes clearly differ from those of known infectious diseases, and that its pathogen is unknown, it is extremely difficult to identify patients who are suspected of infection with a new infectious disease. Actions must be taken with the possibility of a novel pathogen that cannot be classified under the concepts of existing infectious disease pathogens. The International Health Regulations, issued by the World Health Organization, indicate five syndromes that require reporting from Member States prior to the confirmed diagnosis of pathogens. HSB Notification No. 536, dated March 30, 1999, issued by the Director-General of the Health Service Bureau, indicates a guideline for handling persons who are suspected of infection with a new infectious disease: when they satisfy any of the five syndromes below, but cannot be diagnosed with a known disease, and when 1) infectivity to others is extremely high and 2) seriousness of the disease is high (e.g., fatality is abnormally high).

(1) Acute hemorrhagic fever syndrome
(2) Acute respiratory syndrome
(3) Acute diarrhea syndrome
(4) Acute jaundice syndrome
(5) Acute neural syndrome

3) Coordination between the national government and local governments when there is an occurrence of a new infectious disease

When it is considered necessary to prevent the spread of a new infectious disease, the prefectural governor (in this case, including the city mayors and the heads of special wards with PHCs; the same applies hereinafter) may take actions including the recommendation of health checks and hospitalization. When it is considered necessary to prevent the occurrence or spread of a new infectious disease, the prefectural governors and the heads of municipalities may take actions including disinfection, on condition that such actions are reported to the MHLW in advance, and that technical guidance and advice are received from the Minister that incorporate inputs from the Public Health Council.

If a physician reports a patient who is suspected of infection with a new infectious disease, the competent health department of the prefectural government should immediately report, by phone or in writing, to the Tuberculosis and Infectious Diseases Control Division, Health Service Bureau, MHLW, regardless of provisions in the Manual (HSB Notification No. 458, dated March 19, 1999, issued by the Director-General of the

Health Service Bureau).

Once conditions specific to the new infectious disease and actions to be taken to prevent its spread have been identified through the collection and analysis of related information, the national government must take actions to apply the whole or part of the Infectious Diseases Control Law, regarding the new infectious disease as a category I infectious disease, for a time period not longer than one year, pursuant to the Cabinet Order.

9. Provision of information acquired through the NESID Program

To provide information acquired through the NESID Program, NIID publishes a preliminary report in the form of a spreadsheet every Tuesday containing the weekly aggregated data, and the Infectious Diseases Weekly Report (IDWR) every Friday on the NIID website (https://www.niid.go.jp/niid/ja/data.html). NIID also issues an Infectious Agents Surveillance Report (IASR) on a monthly basis. Additionally, annual reports with data for each disease are published on the NIID website. NIID also publishes information based on a disease's epidemic situation and risk assessment. For example, attention is focused on a particular infectious disease, based on the epidemic situation and risk assessment, and is highlighted and explained once a month in IDWR (https://www.niid.go.jp/niid/ja/chumoku.html). Epidemiological data on diseases of high importance are published, including severe fever with thrombocytopenia syndrome (SFTS; https://www.niid.go.jp/niid/ja/diseases/sa/sfts.html), aggregated data of the reported cases of imported dengue fever (trends in the cases of imported dengue fever in Japan https://www.niid.go.jp/niid/ja/dengue-m/690-idsc/6663-dengue-imported.html), and the reported cases of syphilis (trends in the cases of syphilis in Japan, https://www.niid.go.jp/niid/ja/id/1626-disease-based/ha/syphilis/idsc/idwr-sokuhou/7816-syphilis-data.html). The respective reports are published on the website every month for SFTS and dengue fever, and every quarter for syphilis. NIID also responds to the spread of infectious diseases with high urgency in a timely manner, e.g., the measles outbreak in Kansai International Airport in 2016 (https://www.niid.go.jp/niid/ja/id/222-disease-based/ma/measles/idsc/trend/6865-measles-kankuu-20161102.html) and risk communication about measles infection during overseas travel (https://www.niid.go.jp/niid/ja/id/655-disease-based/ma/measles/idsc/6709-20160825.html). In addition, NIID conducts risk assessment of important infectious diseases that are occurring overseas and may affect Japan (e.g., outbreak of avian influenza H7N9 in China: https://www.niid.go.jp/niid/ja/flu-m/flutoppage/2276-flu2013h7n9/a-h7n9-niid/7490-riskassess-170831.html; yellow fever: https://www.niid.go.jp/niid/ja/id/1142-disease-based/a/yellow-fever/idsc/7244-yellow-fever-ra-20170501.html; Zika virus infection: https://www.niid.go.jp/niid/ja/id/2358-disease-based/sa/zika-fever/7169-zikara-11-170331.html). To provide information on the influenza situation, NIID generates "influenza level maps", notifying when the alert level and the warning level are exceeded, based on the number of patients who sought healthcare at the approximately 5,000 influenza sentinel sites across Japan ("influenza level maps": https://www.niid.go.jp/niid/ja/flu-map.html). Antigenicity analysis, genetic analysis, and anti-influenza drug-resistance analysis are performed using the isolated strains of influenza virus, as collected through laboratory-based surveillance, and the results of these analyses are published on the website on a periodic basis (antigenicity and genetic analyses: https://www.niid.go.jp/niid/ja/flu-antigen-phylogeny.html; detected drug-resistant strain information: https://www.niid.go.jp/niid/ja/influ-resist.html). As for the results of laboratory-based surveillance, "regular forms" as graphs and aggregated data tables in consistent formats are published on the website (preliminary report graphs on virus data:

https://www.niid.go.jp/niid/ja/iasr/510-surveillance/iasr/graphs/1532-iasrgv.html; preliminary report graphs on bacteria data: https://www.niid.go.jp/niid/ja/iasr/510-surveillance/iasr/graphs/1524-iasrgb.html; preliminary aggregated data tables on virus data: https://www.niid.go.jp/niid/ja/iasr/511-surveillance/iasr/tables/1493-iasrtv.html; preliminary aggregated data tables on bacteria data: https://www.niid.go.jp/niid/ja/iasr/511-surveillance/iasr/tables/1525-iasrb.html). The surveillance of tuberculosis, a category II infectious disease, is undertaken by the Department of Epidemiology and Clinical Research, Research Institute of Tuberculosis, Anti-Tuberculosis Association, and the surveillance for acquired immunodeficiency syndrome, a category V infectious disease, is undertaken by the AIDS Response Office, Tuberculosis and Infectious Diseases Control Division, MHLW.

Operation of event-based surveillance (EBS) for infectious diseases at the National Institute of Infectious Diseases, Japan

Infectious Disease Surveillance Center (IDSC) of the National Institute of Infectious Diseases (NIID)

■ Information sources of EBS

The EBS system that is routinely operated in Japan is described below. The information comes from a variety of sources—legally notifiable disease reports (the notifiable disease list covers the vast majority of known infectious diseases of public health importance, and several key syndromes are notifiable at the clinically suspect stage), events that are legally mandated to be notified (e.g. food poisoning events and nosocomial events), and informal/unofficial sources (e.g. media and mailing lists).

Utilization of reports based on the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (hereinafter, referred to as the "Infectious Diseases Control Law").

- Diseases subject to notifiable disease surveillance: Seven (7) category I infectious diseases, seven (7) category II infectious diseases, five (5) category III infectious diseases, 44 category IV infectious diseases, and 22 category V infectious diseases are specified in the National Epidemiologic Surveillance of Infectious Disease (NESID) Program, which, together with the diseases subject to sentinel surveillance, includes almost all known infectious diseases considered to be important from a public health perspective. In principle, a laboratory-confirmed diagnosis is necessary for a case to be notified under notifiable disease surveillance; however, for diseases with high transmission potential, such as category I infectious diseases (viral hemorrhagic fevers), certain category II infectious diseases (severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS)), and measles, notification is mandated at the clinically suspected stage. This allows, based on a legal framework, for implementation of responses corresponding to the risks posed to prevent the spread of infection at an early stage. These diseases for which notification is requested at the suspected stage include the following acute syndromes: acute hemorrhagic fever syndrome, acute respiratory syndrome, acute diarrhea syndrome and acute neural syndrome. In addition, for category I infectious diseases (viral hemorrhagic fevers) and certain category II infectious diseases (SARS and MERS), as well as infectious diseases in other categories, in cases in which laboratory tests cannot be conducted to confirm diagnoses at a medical facility or commercial laboratory, tests shall be conducted at a Public Health Institute (PHI) or at NIID, following a

risk assessment at a Public Health Center (PHC). In fact, for suspected cases of MERS and Ebola, there has been timely reporting, sample collection, and testing, all at an early stage, in recent years (with all cases confirmed to be negative). Furthermore, each disease category in the Infectious Diseases Control Law is matched to a specific level of response in principal; however, in reality, local municipalities conduct risk assessment, as appropriate, and determine the response on a case-by-case basis. Therefore, although notifiable disease surveillance involves reporting based on a standard case definition, since each case is subjected to risk assessment and responded to accordingly, it strongly possesses characteristics of EBS. (In fact, the clinical case definition of a suspected case is often not clearly specified, and thus, the reason for suspecting and deciding to report is often based on a physician's judgement. Asymptomatic carriers of category I to IV infectious diseases are also subjects for notification. These aspects also reflect the strongly event-based nature of reporting by physicians) As Japan has a well-established healthcare system with universal health coverage, allowing for easy healthcare access, its system which employs physician notifications provides a sensitive and efficient source of information. In terms of education, as medical students are taught about the Infectious Diseases Control Law as well as diseases subject to notification, physician awareness is considered to be relatively high.

- When a notification is submitted by a physician for a suspected patient with a new infectious disease (which is characterized by symptoms and treatment outcomes that are clearly different from those of known infectious diseases, and a pathogen that is unknown/unidentified), the case shall be immediately reported, by phone or in writing, to the Tuberculosis and Infectious Diseases Control Division, Health Service Bureau, Ministry of Health, Labour and Welfare (MHLW).
- Pandemic influenza (novel influenza or re-emerging influenza) shall be reported in the suspected stage.
- Designated infectious diseases are defined as infectious diseases requiring actions equivalent to category I to III infectious diseases (specified by a cabinet order; applicable for one year only), and a system is established to immediately handle them as notifiable diseases.
- Information collection based on Article 15 of the Infectious Diseases Control Law: Information collected through active epidemiological investigation under Article 15 (epidemiological information, pathogen information, etc.) shall be used for response following appropriate risk assessment, and is conducted as EBS by PHC. This active epidemiological investigation is used based on a flexible all-hazards approach, and plays an important role in EBS. For example, there was an increase in acute encephalopathy cases, which prompted an active epidemiological investigation that suggested *Pleurocybella porrigens* (poisonous mushroom) as a possible causative agent (see http://idsc.nih.go.jp/iasr/28/334/dj3345.html).

- Suspected cases determined by an order of MHLW, as referred to in Article 14, Paragraph 1 of the Infectious Diseases Control Law, are reported by internal medicine and pediatric sentinel sites, and consist of the following two report types: 1) pyrexia at or above 38˚C and respiratory symptoms (excluding those clearly due to trauma or organic disease); 2) pyrexia and rash or vesicles. In some subnational jurisdictions, for cases reported through this channel, a PHC will conduct risk assessment for the notified cases and operate this system as EBS.
- PHIs/NIID have a high laboratory diagnostic capability; for example, a novel norovirus has been detected in their laboratories and specialized testing, such as for acute encephalitis of unknown cause, can be conducted at these facilities. Therefore, information from laboratories is also an important resource for EBS.

Information collected based on other laws and administrative notifications

- The following reports are available as sources of information for EBS: Reports on food poisoning, including symptomatic complaints (Food Sanitation Act); reports on school absence and temporary school closing due to infectious diseases (School Health and Safety Act); reports on case clusters at social welfare facilities (notification for "Reports upon the occurrence of infectious diseases at social welfare facilities"); reports on nosocomial infection outbreaks to PHCs (notification no. 0617-1, issued by the director of the Medical Institution Management Support Division, Health Policy Bureau on June 17, 2011); the reporting system for suspected adverse reactions after immunization (Immunization Act); and notifications of unnatural death (Medical Practitioners' Act). In addition, from a risk management perspective, the importance of systems with the capacity for response against public health events and risk awareness/management are stated in the Basic Guidelines for Health Risk Management and the Guidelines for Health Risk Management Caused by Infectious Diseases. However, for events that fall under jurisdictions other than public health departments and agencies (e.g., unnatural death is notified to the police department), utilization of information by public health departments and agencies may be restricted. Furthermore, regarding reports based on laws and notifications, both the reporting side (e.g., a healthcare facility with a cluster of cases) and the reported side (e.g., PHC) may adhere too strictly to the reporting rules (e.g., a cluster of 10 cases or more), and it is desirable to establish a system where risk assessment is done more flexibly by respective PHCs.

Utilization of other official information

- Formal information provided by local public health is utilized by both the national government and other local public health entities as a highly reliable source of information for EBS.
- Regarding research results obtained using public research funding, when researchers obtain information that may have a serious influence on the life and health of people in the course of their research (hereinafter, referred to as "health risk information"), such information should

be immediately shared with MHLW.

- Information disclosed in Disease Outbreak News (DON) or provided to the International Health Regulations (IHR) National Focal Point (NFP) by the World Health Organization (WHO) is used for EBS by the national government, as both sources of information are highly accurate.

Utilization of informal information

- The Field Epidemiology Training Program (FETP), based at NIID, collects information from both domestic and international media, as well as from mailing-lists such as ProMED at least once per day on weekdays and at other times, as appropriate, and determines the response by the NIID after assessing the information (see below reference material for details). The information is then provided to relevant stakeholders together with the results of assessment.
- Public health departments and agencies receive various informal information regarding infectious disease outbreaks, and through the appropriate process, such information is collated and verified via risk assessment.

■ Summary of the characteristics of EBS in Japan

As described above, EBS, which is a key factor in detecting infectious disease events of public health concern, is in operation in Japan with most of its systems based on legal grounds. However, as it depends on multiple laws, it is difficult to grasp a holistic picture in practice and is not specifically described under the current legal system in Japan.

Under the structure of administration in Japan, risk assessment for an acute infectious disease event of public health concern detected through EBS is conducted, in principle, by subnational-level jurisdictions (prefectures and cities designated by government ordinance). However, as the capacity varies among jurisdictions, for cases in which local governments cannot respond (e.g., large-scale events, deaths due to diseases with unknown causes) and cases that involve multiple municipalities, a system has been established where the national government takes the initiative in conducting risk assessment and provides support to the relevant municipalities (Article 15 of the Infectious Diseases Control Law).

In special circumstances, for the domestic occurrence of cases that represent a public health emergency of international concern (PHEIC), the domestic occurrence of emerging/re-emerging infectious diseases, and the domestic occurrence of cases that meet IHR Annex 2, the national government is expected to take the initiative in conducting risk assessment, in collaboration with the relevant jurisdictions.

For risk assessment in EBS, in addition to risk assessment to determine response for acute infectious disease events of public health concern, risk assessment with the aim of establishing a mid- to long-

term plan is expected. The national government is currently responsible for the latter.

■ Training for EBS and risk assessment

NIID conducts EBS of acute infectious disease events as a part of on-the-job training for FETP (see below reference materials for an outline of the training). In addition to risk assessment of acute infectious disease events, FETP is involved in mid- to long-term risk assessment.

Training in the risk assessment of acute infectious disease events is provided for responsible personnel in municipalities in the forms of a training session by the Japanese Society of Public Health, the FETP introductory course, and other training sessions organized by subnational-level public health, using case studies and other learning materials.

In addition, since FY2016, IDSC has provided training in the risk assessment of acute infectious disease events for medical attaches working in diplomatic establishments abroad, in response to a request from the Consular Affairs Bureau of the Ministry of Foreign Affairs, so they may independently conduct risk assessment for Japanese nationals living abroad. This collaboration would also provide useful information regarding risk assessment for the importation of infectious diseases into Japan.

Reference Material

■ EBS conducted at NIID

1. Purpose

By rapidly detecting and conducting risk assessment of health risk events caused by infectious diseases, NIID becomes capable of taking the necessary measures in a timely manner.

2. Events included in EBS

Acute events of infectious diseases are subjected to EBS. However, in the early phase of case detection, the etiology of disease, including whether it is infectious or not, may be unknown. Therefore, an all-hazards approach is taken until the responsible entity for response is determined.

For a deliberate event (e.g., crimes including terrorism) or food poisoning cases covered in the Food Sanitation Act, for which the structure of the administrative response is clearly specified in domestic laws, the NIID should assume its presumed role.

3. Method

(1) Place of implementation

IDSC, NIID

(2) Persons responsible for implementation

Staff and trainees of FETP in IDSC, NIID

(3) Information resources

For domestic events:

- NESID Program (daily check): Conduct a daily review of the notified NESID data with staff members of Division II of IDSC, NIID.
- FETP participants screen domestic news (both central and local), press releases by subnational-level governments, etc., using Internet search engines (e.g., Google, Yahoo).
- Other information included in sources of information for EBS (as described above) provided to NIID.

For overseas events, the following and other relevant websites are screened at least once per day on weekdays:

- WHO Disease Outbreak News (http://www.who.int/csr/don/en/)
- ProMED-mail (https://www.promedmail.org/)
- Center for Infectious Disease Research and Policy, University of Minnesota (http://www.cidrap.umn.edu/)
- Outbreak News Today (http://outbreaknewstoday.com/)
- HealthMap (http://www.healthmap.org/en/)
- Avian flu diary (http://afludiary.blogspot.jp/)

(4) Event triage (initial risk assessment)

The criteria for which FETP screens events to prepare for response to health risks on behalf of the NIID should be as follows:

i. unusual event/situation

ii. large public health impact (e.g., higher severity/mortality, nosocomial infection)

iii. possibility of further spread

iv. possibility of the need for risk communication due to high social/political interest/perception.

For events occurring overseas, FETP screens the following as potential health risk events:

i. pandemic-prone diseases (e.g., MERS, avian influenza)

ii. cases with the possibility of affecting Japanese citizens (living in Japan/abroad)

iii. infectious disease events/situations that require a change in existing guidelines in Japan (including emerging infectious diseases).

(5) Rapid risk assessment

In the meetings held every morning in IDSC, the health risk events selected based on the above screening criteria are discussed and assessed for risk. In the risk assessment, discussions should be carried out to form an agreement among the implementing bodies for risk assessment, in consideration of the status of exposure to pathogens, nature of the pathogen (if known), susceptibility to the pathogen

in the exposed (or suspected to be exposed) population, capacity of the responsible departments/agencies and healthcare system at the municipal level, necessity of response at the national level, etc.

(6) Information-sharing regarding events

Depending on the response, based on the risk level as determined via risk assessment, information-sharing with relevant departments/agencies or the provision of information is requested as below:

- Provision of information: no response necessary; only a presentation of the event
- Verification of information related to the event, or request for further information: e.g., inquiry to the relevant subnational-level jurisdiction
- Provision of information on the event that may require a response/preparedness activity in the future
- Provision of information requiring rapid response/preparedness activity

(7) Database management

Event opened: For events continuously selected by initial risk assessment and cases which require continuous and systematic information collection due to inadequate information during rapid risk assessment (i.e., ongoing and/or developing events, in both cases), open the event site in Outbreak Tracking System (OTS; stand-alone database managed in the FETP office) and monitor the situation of events. Output a daily report from OTS in PDF format (hereinafter, referred to as “the Report”) and send the Report to NIID senior management on a daily basis.

Follow-up: Update the progress of the event (occurrence of new case patients, implementation of new policies/measures) based on both official information (e.g., WHO situation report, WHO DON) and unofficial information. Update the risk assessment, as appropriate. In addition, for pandemic-prone diseases including MERS and avian influenza, as well as emerging infectious diseases such as Zika virus infection, a comprehensive risk assessment should be updated and disclosed publicly on the NIID website, as needed.

Event closure: The event is closed if the following criteria are met: there has been no updated information, no new cases, no change in response, etc. for more than 2 weeks (or a set period based on the incubation period of the causative agent); consultation with NIID or active epidemiological investigation is completed.

Archives: The records and documents on closed events are stored in OTS; events are re-opened when monitoring is deemed necessary.

感染症関連日本語英語対訳表

Japanese-English translation for words and terms on infectious diseases.

本一覧表に掲載している英訳は、平成29年12月5日現在における感染症に係る仮訳になります。政府として統一した英訳を定めたものではありませんのでご注意ください。
The following list provides the English translation for words and terms with regard to infectious diseases as of December 5, 2017. These translations have not been collectively authorized by the Government of Japan.

日本語表記（正式名） Japanese	英語表記（仮訳） English Translation
感染症の予防及び感染症の患者に対する医療に関する法律	Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (the Infectious Diseases Control Law)
検疫法	Quarantine Act
政令	Cabinet Order
省令	Order
施行規則	Regulation for Enforcement
施行令	Enforcement Order
感染症発生動向調査事業実施要綱	Implementation manual for the National Epidemiologic Surveillance of Infectious Disease Program
感染症発生動向調査	National Epidemiological Surveillance of Infectious Diseases (NESID)
感染症発生動向調査事業	National Epidemiological Surveillance of Infectious Diseases (NESID) Program
感染症発生動向調査システム	National Epidemiological Surveillance of Infectious Diseases (NESID) System
積極的疫学調査	Active epidemiological investigation
病原体検査要領	Pathogen Testing Guidelines
検疫感染症	Quarantinable Infectious Diseases
新型インフルエンザ等感染症	Pandemic Influenza (Novel Influenza or Re-emerging Influenza)
新型インフルエンザ	Pandemic Influenza (Novel Influenza)
新感染症	New Infectious Disease
再興型インフルエンザ	Re-emerging Influenza
指定感染症	Designated infectious diseases
全数把握	Notifiable disease surveillance
定点把握	Sentinel surveillance
患者定点	Patient sentinel sites
小児科定点	Pediatric sentinel sites
インフルエンザ定点	Influenza sentinel sites
内科定点	Internal medicine sentinel sites
性感染症定点	Sexually transmitted infections sentinel sites (STI sentinel sites)
眼科定点	Ophthalmology sentinel sites
基幹定点	Designated sentinel sites
病原体定点	Sentinel sites for laboratory-based surveillance
病原体個票	Case-based pathogenic agent report form
報告基準	Reporting criteria
中央感染症情報センター	Central infectious disease surveillance center
地方感染症情報センター	Local infectious disease surveillance center
基幹地方感染症情報センター	Designated prefectural infectious disease surveillance center
感染症発生動向調査委員会	Infectious disease surveillance committee
中央感染症発生動向調査委員会	Central infectious disease surveillance committee
地方感染症発生動向調査委員会	Prefectural infectious disease surveillance committee
地方衛生研究所	Public Health Institute
保健所	Public Health Center
健康局長	Director-General of the Health Services Bureau
特別区	special ward
本庁	head office
二次医療圏	secondary medical area
教育委員会	Board of education
一類感染症	Category I Infectious Diseases
二類感染症	Category II Infectious Diseases
三類感染症	Category III Infectious Diseases
四類感染症	Category IV Infectious Diseases
五類感染症	Category V Infectious Diseases
一種病原体	Class I pathogens
二種病原体	Class Ⅱpathogens
三種病原体	Class Ⅲpathogens
四種病原体	Class Ⅳpathogens
医療機関（診療所も含む）	medical facility
医師会	medical association
調査単位	reporting interval
指定届出機関	Designated notification facility
指定提出機関	Designated submitting facility

FETP-J (Field Epidemiology Training Program- Japan)

Infectious Disease Surveillance Center,
National Institute of Infectious Diseases
As of November 2017

■ Objectives

To develop field epidemiologists who can take rapid and correct actions to assess the situation and investigate the cause of infectious diseases at the time of an epidemic or an outbreak, and who can contribute to the maintenance/improvement of high quality surveillance systems for infectious diseases .

■ Overview

- Start of program : September 1999
- Two years of on-the-job training at the Infectious Disease Surveillance Center of the National Institute of Infectious Diseases (NIID) to learn how to respond to infectious diseases outbreaks and perform infectious disease surveillance, among other aspects.
- Working language: Japanese. However, English is used at certain occasions, such as when a non-Japanese lecturer is invited to provide a short seminar.
- Trainers: one center director, one division chief (Japan FETP graduate), four senior research scientists (includes one Japan FETP graduate and one EIS graduate), and one research scientist (Japan FETP graduate)

■ Eligibility and status of participants

- Eligibility for enrollment: candidates for FETP should have a strong interest in risk management of infectious diseases and have undergone at least 2 years of clinical training or have at least 3 years' experience in public health service. Types of occupation include those with a specialized qualification, such as physicians, dentists, veterinarians, pharmacists, public health nurses, nurses, laboratory technicians, and food sanitation inspectors.
- Employment: Intended mainly for officials who are seconded by local governments (salary is paid by the home institution) and specialists, such as physicians working in medical institutions and who want to work in the public health field in the future. From 2017, the latter trainees became eligible for receiving a salary from NIID as contractual staff.
- Selection process: Regarding the selection of participants dispatched from municipalities, candidates are selected in each municipality, and the FETP Steering Committee makes the final decision through an interview with the candidates. Regarding other participants, candidates should apply directly; the FETP Steering Committee will make a selection by holding an interview with the candidates.
  Note: The members of the FETP Steering Committee consists of the following; Director-General, Deputy Director-General, Director of the Department of Administration, Chief of Planning and Coordination, Director of the Department of Bacteriology I, Director of the Department of Virology II, Chief of the Division of International Cooperation, Director of the Infectious Disease Surveillance Center, and Chief of Division 1 at the Infectious Disease Surveillance Center. The Director of the Infectious Disease Surveillance Center acts as Chairman of the Committee. The roles of the Committee are to accept participants for training and to discuss necessary matters regarding methods for training and operations.

■ Curriculum

- Lectures

- Introductory course: A 4-week course which includes learning methods for epidemiological / statistical research, lectures from each Laboratory divisions at NIID, acquiring basic knowledge on related laws and regulations, case studies, etc.
- Short-term seminar: A week long lecture series on statistics, nosocominal infection, molecular epidemiology, preparation of English thesis, etc. (English)
- Special seminar: As appropriate, provided by a variety of lecturers on influenza and other infectious diseases, modeling, etc.

◆ On-site training
- Information collection on outbreaks, risk assessment, on-site epidemiological studies, and responses
- Analysis / evaluation methods for infectious disease surveillance data

◆ Dissemination of information
- Utilizing / disseminating information on infection control by writing articles on IASR, etc.
- Presenting infectious disease epidemiological research results at the academic meetings in Japan and abroad

◆ Training opportunities
- Lectures on infectious disease risk management / on-site epidemiology for the staff members of municipalities and participants from overseas, facilitation of case studies, etc.

◆ Long-term research
- One epidemiological research study should be voluntarily planned and conducted during 2 years of training.

◆ Others
- Training at the Ministry of Health, Labour and Welfare (roughly 2 months): Option for participants from municipalities (upon request) .
- Activities overseas (Training at the WHO Western Pacific Regional Office, participation in overseas research projects, etc.): Option
- Interchange with FETPs in other countries

Example of an annual schedule

First year	- Learn the basics of infectious disease epidemiology -	
	Events / training	On-site epidemiological studies / research
April	Opening ceremony / Participation in the Initial Introductory Course (Part of the lectures provided by foreign lecturers)	• Surveillance services System evaluation for surveillance Analysis / reduction of surveillance data • Dispatch for on-site epidemiological study (response to outbreaks) • Risk assessment • Poster presentations in workshops on risk management • Preparation / revision of a response manual for municipalities • Long-term research
May	Participation in an internal introductory lecture	
June		
July		
August		
September		
October	Workshop on risk management	
November		
December		
January		
February		
March	Presentation meeting for lo participants who have comp program	

Training outside the Center

(Ministry of Health, Labour and Welfare, lecturers of seminars, etc.)

Second year	- Learn from instruction / education -	
	Events / training	On-site epidemiological studies / research
April	Opening ceremony / Instruction and lectures for first year FETP participants in the Initial Introductory Course	Instruction for first year FETP participants • Surveillance services System evaluation for surveillance Analysis / reduction of surveillance data • Dispatch for on-site epidemiological study (response to outbreaks) • Risk assessment • Poster presentations in workshops on risk management • Preparation / revision of a response manual for municipalities • Long-term research
May	Give a lecture for first year FETP participants in the internal introduction	
June		
July		
August		
September		
October	Workshop on risk management	
November		
December		
January		
February		
March	Presentation meeting for long-term research / Closing ceremony	

◇Training outside the Center

(WPRO, National Institute of Public Health, etc.)

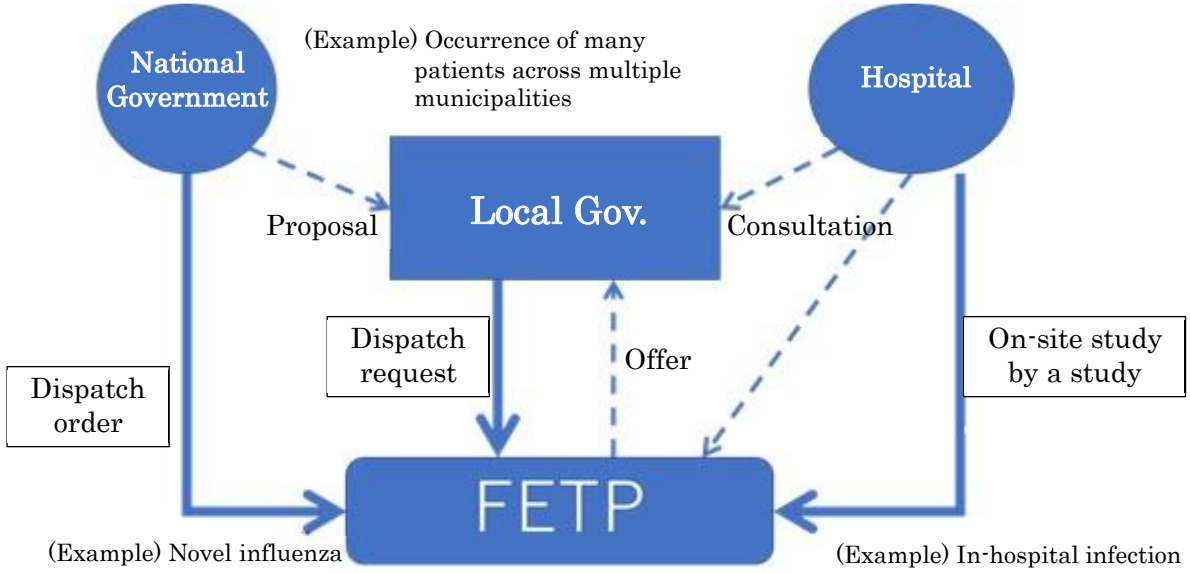
◇Presentation in academic meetings

(including meetings overseas)

* For the second year of training, training organized by each dispatching municipality can be integrated into the program. Please contact the Center, in advance.

■ **Framework for outbreak dispatch**

Based on Japanese institutions, municipalities have the responsibility and authority for responding to outbreaks. In response to a Municipality's request for dispatch of an on-site epidemiological response, the FETP (combination of training program participants and instructional staff) will conduct on-site activities to support the Municipality. In addition, FETP will be dispatched and work together with municipal staffs against National-level concerns such as Novel Influenza outbreak, based on a request of the National Government. For nosocominal infections, the FETP may work based on a dispatch request from municipalities, or may give support for medical institutions within the framework of a study group. In FY2016, in the framework of Health Labour Sciences Research, the FETP received a review from external experts on a case of measles outbreak, regarding the usefulness of a request for FETP dispatch from a municipality standpoint.



■ **Response to outbreaks**

To date, there have been roughly 3 to 15 dispatch requests for outbreak investigation per year (average of 6.3 cases per year). Each FETPs will be engaged in more than one investigation per year during its 2-year training program. Following are the list of outbreak investigation which have contributed to the long-term countermeasures.

Year of occurrence	Cases	Long-term countermeasure taken
2006-2008	Epidemics and institutional mass outbreaks of measles centered on groups in their 10s to 20s	Reflection in the "Guideline for Measles Control in School" and the "Specific Infectious Disease Prevention Policy for Measles" (Temporary measures for vaccination in the 3rd and 4th quarters)
2011	Mass outbreak of *Escherichia coli* O111 infection related to a chain of grilled meat restaurants	Establishment of "Standards for Meats to be Eaten Raw" and "Standards for Beef Liver"
2012	Mass outbreak of *Escherichia coli* O157 infection related to pickled white cabbage	Revision of "Code of Hygienic Practice for Pickled Vegetables"
2013	Regional epidemics of Rubella in Kagoshima Prefecture	Reflection to the "Guideline for Rubella Control in the Work Place" and "Preventative Policy for Specific Infectious Diseases on Rubella"
2015	Nosocomial infection caused by *Carbapenem-resistant enterobacteriaceae* (CRE)	Preparation of "Risk Assessment and a Guide for the Response of Public Health Centers for CRE"

■ **Number of participants**

- For the 1st to 19th cohort: 1-9 participants per cohort (median of 4 participants). A total of 10 participants in two cohorts can be accepted, at maximum due to challenges including instructors, residential room space for participants, etc.
- Of 77 participants in the 1st to 19th programs, 21 participants were dispatched by their

municipalities.

■ **Efforts to increase the dispatch number from municipalities**

- Implementation of interviews with the person-in-charge of municipalities (FY2016): In spite of the fact that the high quality of the FETP is appreciated at the scene of municipalities, in reality, this is not likely to lead to FETP dispatch. There are various reasons for this: can't afford to dispatch staff due to understaff at the municipalities, difficult to leave a post vacant for 2 years, difficult to persuade the Human Resources Division, English ability, research and thesis preparation are not priorities in municipalities, etc.
- From FY2016 to FY2017, the following improvements were made;
  - Preparation of materials on FETP which appeals to Human Resources Departments and senior executives to dispatch staff including concrete explanation of results to be obtained from sending staff to FETP (see attached reference materials).
  - Introduction of the "1 + 1 Program": From FY2017, the "1 + 1 Program" has become an option for FETPs dispatched by municipalities. In this program, 1st year training is conducted at NIID facilities, while 2nd year training is conducted in the municipalities in cooperation with NIID. This system has less burden for understaffed municipalities and also allows us to provide trainings dedicated to the participant competencies for each municipality. In this case, 2nd year training plans should be individually established after consultation with the municipalities.

■ **Current status of participants**

Current status of FETP alumni (as of October 2017)

Of 70 participants who have completed the FETP training program
Municipalities: 19 participants
National Institute of Infectious Diseases: 6 participants
Ministry of Defense: 7 participants
Ministry of Health, Labour and Welfare: 2 participants

◆Breakdown of municipalities◆
Tokyo Metropolitan: 3 participants
Chiba Prefecture: 2 participants
Hiroshima Prefecture: 2 participants
Others: 12 participants

Others (1 participant each):
Sapporo City, Iwate Prefecture, Kawasaki City, Yokosuka City, Yokohama City, Shiga Prefecture, Kyoto City, Osaka Prefecture, Osaka City, Hyogo Prefecture, Shimane Prefecture, Naha City

Expanding network of FETP alumni throughout Japan
(including alumni working in hospitals)

As of November 1, 2017

Actual situation of ex-participants
the FETP program
(as of November 1, 2017)

- See the reference for specific details regarding the activities of participants who completed the program and work at municipalities.
- For participants who are not dispatched by municipalities, working at municipalities after program completion is recommended as a contribution to the establishment of a National risk management system. For instance, we provide opportunities for non-municipalities dispatched FETPS to meet personal from municipalities through the workshop on infectious disease risk management for municipalities (organized once each year by the National Institute of Infectious Diseases). With the implementation of the "1 + 1 Program", it is expected that more opportunities to be involved to outbreak investigation through remains in their municipalities.
- FETP alumni who continues to work at the National Institute of Infectious Diseases (NIID) engage in the training of FETP participants, in some form.
- Among the FETP alumni who work at medical institutions, there are 14 who work at designated medical institutions for specified infectious diseases. They also contribute to the preparation of a response manual for emerging and re-emerging infectious diseases developed by NIID, as well as the preparation of a response manual for Anti-microbial resistance (AMR)."

■ Activities of FETP graduates

- Creation of a mailing list: A place for bidirectional information sharing between current FETP fellows and alumni
- Roster management: Updating current professions, maintenance of contact addresses
- Efforts to establish a system for making active relationships, including requests for FETP graduates to be lecturers at workshops on FETP.

■ Others

- Acceptance of municipality staff other than FETP trainees: The Initial Introductory Course (4 weeks) is basically implemented as a training program for FETP participants. However, exclusive participation of municipality staff in this course is also accepted, which helps to improve the competency of field epidemiology in municipalities. In addition, a 2-day surveillance training session for representative from municipalities is implemented in the Initial Introductory Course (short-term seminar). The Initial Introductory Course also accepts participants in the Infectious

Disease Emergency Specialist Training Program (IDES) organized by the Ministry of Health, Labour and Welfare, specialists who engage in infection control at medical institutions, and university officials in the field of public health, which helps to expand on-site epidemiology in Japan, as well as to establish a network in Japan.

■ **Advantages of the FETP**

- Synergistic effect is achieved during the program through interactions between trainees sent from local governments and specialists with a background in hospital employment (mostly physicians)
- A wide range of activities leveraging the network of graduates working at local governments and specialists such as those working at designated medical facilities for infectious diseases.
- High quality field epidemiology investigations based on the maturing cooperative relationship with local governments, as well as the cooperation with relevant laboratory units at NIID, and the results of these investigations being reflected in government policies.

■ **Points for improvement of the FETP**

- To increase the number of graduates working for local governments: along with the efforts to increase the number of trainees sent by local governments, NIID should promote the establishment of a system that facilitates career paths for graduates with a background in hospital employment to work for local governments upon completion of the program. It is also important to provide opportunities for trainees and graduates (especially local government officials) to interact regularly.
- To increase the number of relevant NIID staff, considering the work burden associated with simultaneously handling trainees with diverse backgrounds, with varying levels of expectations and capacities.
- As a new employment mechanism for FETP trainees has been established, to create a framework/mechanisms that will enable FETP trainees to have proactive engagement in activities both domestic and overseas, i.e. stronger partnerships with local governments, international organizations, and U.S. CDC, as well as further collaboration with foreign FETPs.

Reference material: Activity status of major participants who completed the FETP program and work at municipalities

(1) Hiroshima Prefecture: 2 participants (April 1, 2012 – March 31, 2014 / April 1, 2014 – March 31, 2016)

There are 2 ex-participants (one veterinarian and one dentist). One ex-participant was assigned to a post equivalent to the manager in the Main Office at the Hiroshima Infectious Disease, Disease Control Center (Hiroshima CDC; Main Office Department), and plays a central role in responses and measures for infectious diseases in Hiroshima Prefecture. Recently, he made a large contribution to research, sharing a variety of information in Hiroshima Prefecture as well as activities for enlightenment regarding outbreaks of legionellosis in public baths, as well as measles outbreaks.

One ex-participant (veterinarian) moved to the North Welfare and Environment Office / North Public Health Center from this fiscal year, and works as chief of the environment office / Director of the Public Health Center, while the other participant (dentist) also undertook training at the Tuberculosis and Infectious Diseases Control Division and Inspection and Safety Division of the Ministry of Health, Labour and Welfare during participation in the FETP, and utilizes the human network established through the training in his current works in the municipality.
Website of Hiroshima CDC: http://www.pref.hiroshima.lg.jp/site/hcdc/

(2) Kawasaki City: 1 participant (April 1, 2011 – March 31, 2013)

One ex-participant belongs to the Infectious Disease Surveillance Center of Kawasaki City Institute of Health Safety as Director. Centered on this ex-participant, FETP-K (Kawasaki) was created, and a network of on-site epidemiological specialists in Kawasaki City was established to foster on-site epidemiological specialists, as the core of infection control.

He comprehensively supports infectious disease control and the response of health risk management by a fostering younger workforce, and contributes to the health maintenance of citizens in Kawasaki City. FETP-K has established a cooperative relationship with the FETP-J, and has also created a system for mutual cooperation, including participation in the FETP-J's Initial Introductory Training Course, acceptance of FETP-J participants into FETP-K activities, etc.

(3) Tokyo Metropolitan: 3 participants (April 1, 2003 – March 31, 2005 / April 1, 2007 – March 31, 2009 / April 1, 2010 – March 31, 2012)

As of May 2017, one ex-participant is working as Manager of Infectious Disease Control, Health Safety Division, Tokyo Metropolitan Welfare and Health Bureau, while another is working as the Manager responsible for epidemiological information, Health Risk Management Division, Planning and Adjustment Division, and a third is working as Manager of Health Prevention in Adachi Ward. These ex-participants play central roles in the planning and implementation of infectious disease control for the Tokyo Olympic and Paralympic Games in 2020, in addition to times of peace. Furthermore, all three of these ex-participants have engaged in operations for infectious disease surveillance at the Tokyo Metropolitan Infectious Disease Surveillance Center, leading to the enhancement of infectious disease control in times of peace.

(4) Shimane Prefecture: 1 participant (April 1, 2011 – March 31, 2013)

One ex-participant belongs to the Shimane Prefectural Institute of Public Health and Environmental Science. After completing the FETP training, he worked at a public health center as well as a municipal public health institute. However, when an outbreak occurs in the Prefecture, information is sent to him, and he takes the role of providing advice to guide the response. In one case involving an outbreak of *Escherichia coli* O157 infection in a high school dormitory in 2015, he played the role of gathering information in the Prefecture, as well as serving as a liaison with the FETP for research. He is positioned as an outbreak consultant, and is expected to utilize the knowledge obtained in the FETP training at any position he may move to within the Prefecture.

(5) Chiba Prefecture: 2 participants (April 1, 2011 – March 31, 2013 / April 1, 2015 – March 31, 2017)

There are 2 ex-participants and 1 current participant. One ex-participant joined the Division of Epidemiology, Chiba Public Health Institute (and infectious disease information center) after completing the FETP training, while the other belongs to the Chosei Public Health Center.

Each of these individuals engages in activities as a special consultant for infectious diseases in Chiba Prefecture, and gives advice for response and research support at the time of occurrence of outbreaks. In addition, in times of peace, they give instruction in training for persons responsible for infectious diseases at public health centers. The deployment of more than one FETP ex-participants in the Prefecture has led to an enhancement of its capacity to response to outbreaks, with superior mobility. As these two ex-participants had been researchers studying bacteria and viruses, respectively prior participating in FETP training, they still play a role in connecting the laboratory with the front line.

The current training participant is a public health nurse with experience in infectious disease control, and is expected to play a central role in infectious disease control after completing the program.

(6) Osaka City: 1 participant (April 1, 2002 – March 31, 2004)

One ex-participant has been assigned as Director of Osaka City Public Health Center since FY2017. Osaka City and Infectious Disease Surveillance Center had previously engaged mutual communication, and exchanged information and dispatched FETP participants at the time of outbreaks. In the case of an in-hospital infection caused by Carbapenem-resistant enterobacteriaceae infection that occurred in 2014, this ex-participant played a central role in coordination among Public Health Centers, hospitals, the Institute for Health, National Institute of Infectious Disease, and an established External Committee, and contributed to ending the case.

In the response to an invasive meningococcal infection that occurred in 2015, this ex-participant implemented an active epidemiological study with the staff of Osaka Public Health Center, and a proposal made based on the results led a change of specimen from the conventional 'spinal fluid and blood' (only) to 'spinal fluid, blood, and other sterile sites.'

(7) Kyoto City: 1 participant (April 1, 2007 – March 31, 2009)

One ex-participant works as Manger responsible for Health and Safety, Medical Sanitation Promotion Office, Health and Welfare Bureau, Kyoto City Welfare Division, and also works in the Medical Hygiene Department, which is responsible for medical safety. In city known for international tourism, where more than 50 million people visit each year from Japan and overseas, the ex-participant utilizes his FETP experience in Japan and overseas, to play an important role from the viewpoint of infectious disease control and risk management.

● Participants who completed the FETP – Breakdown by municipality

	Name of Municipality	Membership of professional institutions	Type of business	Period of training
1	Osaka City	Osaka City Public Health Center	Physician	April 1, 2002 – March 31, 2004
2	Tokyo Metropolitan	Health Division, Adachi Ward, Tokyo Metropolitan	Physician	April 1, 2003 – March 31, 2005
3	Sapporo City	Sapporo City Public Health Center	Physician	April 1, 2004 – March 31, 2006
4	Iwate Prefecture	Environmental Life Division	Veterinarian	April 1, 2004 – March 31, 2006
5	Shiga Prefecture	Shiga Prefectural Institute of Public Health	Laboratory technician	April 1, 2005 – March 31, 2007
6	Hyogo Prefecture	Ako Health and Welfare Office	Physician	April 1, 2005 – March 31, 2007
7	Kyoto City	Kyoto City Shimo-gyo Ward	Physician	April 1, 2007 – March 31, 2009
8	Tokyo Metropolitan	Tokyo Metropolitan Welfare Office	Physician	April 1, 2007 – March 31, 2009
9	Yokosuka City	Yokosuka City Public Health Center	Physician	April 1, 2007 – March 31, 2009
10	Yokohama City	Sakae Ward Welfare and Health Center, Health Safety Division of Health and Welfare Bureau (additional post)	Physician	April 1, 2008 – March 31, 2010
11	Osaka Prefecture	Osaka Psychiatric Medical Center, Osaka Prefectural Medical Center for Respiratory Allergy (additional post)	Physician	April 1, 2009 – March 31, 2011
12	Tokyo Metropolitan	Tokyo Metropolitan Institute of Public Health	Physician	April 1, 2010 – March 31, 2012
13	Shimane Prefecture	Shimane Prefecture, Izumo Public Health Center	Physician	April 1, 2011 – March 31, 2013
14	Chiba Prefecture	Chosei Health and Welfare Center (Chosei Public Health Center)	Laboratory Technician	April 1, 2011 – March 31, 2013
15	Kawasaki City	Institute of Health and Safety, Kawasaki City Health and Welfare Bureau	Physician	April 1, 2011 – March 31, 2013
16	Hiroshima Prefecture	Hiroshima North Welfare and Environment Office / North Public Health Center	Veterinarian	April 1, 2012 – March 31, 2014
17	Hiroshima Prefecture	Hiroshima Health and Welfare Bureau	Dentist	April 1, 2014 – March 31, 2016
18	Chiba Prefecture	Chiba Public Health Institute	Veterinarian	April 1, 2015 – March 31, 2017
19	Naha City	Naha Public Health Center	Physician	April 1, 2015 – March 31, 2017