

Vaccination Guideline for Pandemic Influenza

March 26, 2007

Pandemic Influenza Experts Advisory Committee

Guideline for Vaccination of Pandemic Influenza (Overview)

	Pre-pandemic vaccine	Pandemic vaccine
When to begin preparing for vaccination	Immediately following the declaration of Phase 4A	As soon as vaccine becomes available from Phase 4 onwards
Target Population	Health care workers Workers in social services etc. *1	Entire Japanese population (If there are restrictions to vaccine production capacity, distribute as indicated by *2.)
Supply and Administration	Agencies and prefectural governments shall formulate vaccination plans, based on which the Ministry of Health, Labour and Welfare shall determine the target population and distribution priority officially following declaration of Phase 4A.	While suppliers are producing pandemic vaccines, the Ministry of Health, Labour and Welfare shall determine the target population and distribution priority based on the characteristics of the pandemic influenza virus.
Organizer	Prefectural governments	Municipalities (Prefectural governments in the case of vaccination to health care workers and workers in social services etc.)
Category	Group vaccination	
Location	Local health and welfare centers (However, medical institutions may vaccinate their own employees. If entities providing social services have clinics or similar facilities in their buildings, vaccination may be administered to employees at such facilities.)	

*1

“Workers in social services” include individuals involved in the following services.

- 1) Security
- 2) Utilities
- 3) Crisis management at the central and local governments
- 4) Information provision to sustain the minimum quality of life
- 5) Transportation of supplies required to sustain the minimum requirement of utilities

*2

	If the pandemic influenza primarily causes severe conditions in adults	If the pandemic influenza primarily causes severe conditions in the elderly
Prioritize the minimization of the death	<ol style="list-style-type: none"> 1) Healthcare workers and workers in social services, etc. 2) Medically high-risk individuals 3) Adults 4) Children 5) the Elderly 	<ol style="list-style-type: none"> 1) Health care workers and workers in social services, etc. 2) Medically high-risk individuals 3) the Elderly 4) Children 5) Adults

Prioritize the protection of the future of Japan (Examination required)	<ol style="list-style-type: none"> 1) Health care workers and workers in social services etc. 2) Children 3) Medically high-risk individuals 4) Adults 5) the Elderly 	<ol style="list-style-type: none"> 1) Health care workers and workers in social services etc. 2) Children 3) Medically high-risk individuals 4) the Elderly 5) Adults
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Vaccination Guideline for Pandemic Influenza

1. Objectives

- Vaccines are expected to become an effective method to prevent the spread of infection in the case of an outbreak of an influenza pandemic. According to the Pandemic Influenza Preparedness Action Plan created by the Government of Japan in November 2005, the production and stockpiling of pre-pandemic bulk vaccine is part of the nation's initial response to an influenza pandemic, to ensure that health care workers and workers in public services can receive emergency vaccination.*
- According to the Pandemic Influenza Preparedness Action Plan, “Pending the supply of pandemic vaccines, vaccination of pre-pandemic vaccines to health care workers and workers in public services around the nation should be commenced as necessary, at their own consent,” and “ The administration pandemic vaccines to those who wish should be commenced as soon as they become available.” In addition, “When the amount of supply is limited, a detailed list of those groups who will be given top priority for treatment with antiviral drugs, such as healthcare workers, workers in public services, and high-risk patients, should be made.”
- These guidelines aim to provide the target population, prioritization, administration schemes (location, personnel, etc.) and other specifications on vaccination, thereby ensuring that the central and local governments, health care workers, vaccine suppliers and other related entities will be able to respond optimally to Phase 4 onwards if an influenza pandemic occurs.

* In FY2006, the Government of Japan stockpiled approximately 10 million doses (two vaccinations per person) of 15 μ g HA bulk vaccine antigen.

2. Types of pandemic influenza vaccines

(1) Pre-pandemic vaccines

- Prepandemic vaccines are those manufactured from viruses isolated either from patients who contracted the virus from birds via bird-to-human infection or from an infected bird prior to the outbreak of a pandemic (Currently vaccines are produced using an H5N1 subtype.)
- Prepandemic vaccines are used as prototypes to compile data for approval of its use to produce pandemic vaccines by the Pharmaceutical Affairs Law so that manufacturing can be started promptly once a pandemic influenza occurs. During an outbreak, prepandemic vaccines shall also be administered in place of pandemic vaccines if its supply is pending or if the amount of its supply is limited.

(2) Pandemic vaccines

- Pandemic vaccines are those manufactured from viruses that caused human-to-human infection, or those having the same antigenicity.
- Pandemic vaccines are manufactured after a pandemic influenza occurs and the virus is isolated. Depending on the timing of the pandemic influenza outbreak and the timing of the manufacturing of seasonal influenza vaccines, it may take approximately one year from the procurement of materials (eggs and others) to the completion of a pandemic vaccine.

3. Basic principles for vaccination (from Phase 4 onwards)

- If human-to-human transmission occurs overseas, and if the WHO declares Phase 4, the Ministry of Health, Labour and Welfare shall consult the Pandemic Influenza Experts Advisory Committee on whether the administration of stockpiled prepandemic vaccines should be limited to health care workers and workers in public services, and, if not, on what the scope and priority of vaccine distribution should be. The ministry shall make decisions on the distribution of the vaccine taking this committee's input into consideration, and vaccination should be commenced only after due consideration of the available amount of vaccines, the scope and priority of vaccination. It should be noted that because it may take one or two months to make the administrable form of vaccine from the stockpiled bulk prepandemic vaccine, it may be too late to commence vaccination after the announcement of Phase 4B, where an outbreak in Japan has already occurred.
- Production of pandemic vaccines shall be started after eggs and other materials required for the manufacturing are secured, and after an isolated pandemic influenza virus strain has been identified. Candidate strains for vaccine production must be exported and imported by the WHO Collaborating Centers etc. For this process to be ensured, related governmental agencies must establish collaborative partnerships during Phase 3.
- If the timing of production of pandemic vaccines overlaps with that of the production of seasonal flu vaccines, the Ministry of Health, Labour and Welfare shall consult the Pandemic Influenza Experts Advisory Committee on the consequences that can be expected from interfering with the production of seasonal influenza vaccines, and determine whether the production of seasonal flu vaccines shall be discontinued at once and switched to pandemic influenza vaccines.
- If there is a limited supply of pandemic vaccines, they shall be administered to health care workers and workers in public services at their own consent, particularly if they are at high risk of infection by pandemic influenza. If prepandemic vaccines are effective in preventing infection by the pandemic influenza virus that can cause human-to-human transmission, and if an additional vaccination with a pandemic influenza vaccine seems unnecessary, health care workers and workers in social services who have already received the prepandemic vaccine may be excluded from the group of people initially included in the scope of administration of pandemic vaccines defined in the Action Plan.
- The ministry shall evaluate the need for additional vaccines, and take initiative in directing the additional production of pandemic vaccines (or prepandemic vaccines based on the antigenicity and development status).

- Once vaccination has commenced, the ministry shall evaluate its efficacy and collect and analyze information about adverse effects.
- The ministry shall continuously review the virus strains used for pandemic vaccines, selecting new strains more effective than the previous to ensure the development and manufacturing of the best available vaccines.

4. Administration of prepandemic vaccines

(1) Scope

- In the event that the supply of pandemic vaccines is still pending at the time of outbreak, prepandemic vaccines shall be administered to health care workers and workers in social services as an emergency measure to protect the lives and day-to-day activities of the general public with limited resources. Vaccines shall be administered first to those with the highest risk of infection by pandemic influenza, which will be determined by the content of their occupation, work locations, etc, with their consent. It must be noted that there is no guarantee of the efficacy and safety of the vaccine, since it is a new vaccine that has never been administered to human beings before..
- An outbreak of an influenza pandemic is expected to occur in waves, each one lasting for about two months. “Health care workers and workers in social services” is defined as individuals involved in medical and social services that may threaten the health and social functions of the general public if they are discontinued for two-months.

- 1) Health care workers etc. (Vaccination administered to the minimum number of individuals required to sustain essential operations)

Principle: Individuals involved in medical services that may threaten the lives of the general public in the case of discontinuation

e.g. Health care workers; ambulance staff; drug manufacturers and merchandisers

Note: Of the above, individuals who are likely to contact (suspected) pandemic influenza patients directly in an early stage, such as staff of designated medical institutions for infectious diseases, staff of high-fever outpatient departments and ambulance staff, shall be vaccinated first.

- 2) Workers in social services etc. (Vaccination administered to the minimum number of individuals required to sustain essential operations)

- i) Security

Principle: Individuals involved in social services that may threaten social security and order in the case of discontinuation

e.g. Firefighters, police officers, self defense force members, coast guard officers, reformatory officers

ii) Utilities

Principle: Individuals involved in social services that may threaten the minimum quality of life in the case of discontinuation

e.g. Staff of electricity, water, gas and oil utilities; food merchandisers

iii) Crisis management at the central and local governments

Principle: Individuals involved in social services that may threaten the minimum quality of life and social order in the case of discontinuation

e.g. Diet members, local council members, governors, mayors, central and local government officials involved in crisis management

Note: Of the above, individuals who are likely to contact (suspected) pandemic influenza patients directly in an early stage, such as staff of quarantine stations, immigration authorities, customs, health centers and other public health agencies, shall be vaccinated first.

iv) Information provision to sustain the minimum quality of life

Principle: Individuals involved in services that may threaten social order due to lack of information in the case of discontinuation

e.g. Members of press, important network services and management

v) Transportation

Principle: Individuals involved in the transport of supplies required to sustain electricity, water, gas, oil, food and other utility services

e.g. Staff of railroad, road, cargo, air and sea transportation

(2) Supply and administration

Preparations

- 1) The Ministry of Health, Labour and Welfare shall consult experts and related governmental agencies to determine jobs and industries to be categorized as “health care workers and workers in social services” and formulate guidelines to enable agencies and prefectural governments to formulate vaccination plans.
- 2) Government offices and prefectural governments shall notify business entities etc. of the abovementioned guidelines, who shall, in turn, submit a list of jobs and industries and the number of health care workers and workers in social services who need to be vaccinated. The submitted list shall also include descriptions of jobs and industries chosen, and why their operations are considered to require vaccination.
- 3) The government offices and prefectural governments shall confirm whether the

submitted information satisfies the guidelines distributed by the Ministry of Health, Labour and Welfare, and report that information to the ministry, coupled with the overall number of targeted individuals, planned locations of vaccine administration and the number of vaccines expected to be administered at each location, as well as their vaccination plans.

- 4) The Ministry of Health, Labour and Welfare shall determine a governmental policy on the scope and priority of vaccination, based on the reports from agencies and prefectural governments, which shall in turn modify their reports if required by the abovementioned policy, and reply to the ministry.

Response from Phase 4A onwards

- 1) The Ministry of Health, Labour and Welfare shall call and consult the Pandemic Influenza Experts Advisory Committee and review schemes for vaccine supply and administration and determine specific details for vaccination based on expert advice.
- 2) In response to the vaccination details determined by the Ministry of Health, Labour and Welfare, government offices and prefectural governments shall send pre-examination forms and notification of vaccination to the chosen health care workers and workers in social services, or request municipalities to send such documentation.
- 3) The Ministry of Health, Labour and Welfare shall deliver vaccines to individual vaccination locations through wholesalers etc., according to the amount requested by each government office and prefectural government. The locations of vaccine storage shall not be disclosed and will be kept under guard to ensure the safety in transport and storage of the vaccines.

(3) Locations

- In principle, vaccines shall be administered in groups. Vaccination shall be organized by prefectural governments and administer vaccines at local health and welfare centers etc. with the help of municipalities.
- Medical institutions may vaccinate their own employees. If entities providing social services have clinics or similar facilities in their buildings, vaccination may be administered to employees at such facilities. If vaccination will be provided at such institutions or facilities instead of at local health or welfare centers, the managers of such institutions or entities shall consult the governing prefectural governments to establish an appropriate vaccinating environment in advance.

(4) Personnel and equipment

Related agencies of the central and prefectural governments shall request medical associations for cooperation in securing physicians and tools for group vaccination. Guards will be set up to ensure the safety of vaccine transportation and administration.

5. Administration of pandemic vaccines

(1) Scope

- Pandemic vaccines shall be administered to the entire Japanese population. However, if there are limitations to production capacity, vaccination will be provided first to health care workers and workers in public services with their consent, particularly those who are at high risk of infection. If pre-pandemic vaccines are effective in preventing infection by a virus that can cause human-to-human transmission, and if additional administration of pandemic influenza vaccines seems unnecessary, health care workers and workers in social services who have already received a pre-pandemic vaccine may be excluded from the group of individuals included in the scope of administration of pandemic vaccines defined in the action plan.
- Other individuals shall be categorized into four categories indicated below. The primary goal of vaccination shall be to minimize the death toll and protect the future of Japan. The Central Government shall examine the prioritization of vaccine administration after consideration of such principles. The order of vaccination prioritization may vary depending on the pandemic influenza virus.
 - Medically high-risk individuals: Individuals having respiratory or cardiovascular diseases etc., who are likely to fall into serious conditions if infected
 - Children: Supports Japan's future
 - Adults: Sustains social functions (excludes health care workers and workers in social services etc. mentioned in the above paragraph)
 - the Elderly: Individuals who are likely to fall into serious conditions if infected
- 1) If the focus of vaccination is placed on minimizing the number of people with serious conditions and minimizing the death toll from pandemic influenza,
 - In the case of a pandemic influenza type that causes serious conditions in adults and juveniles* (Assuming medically high-risk individuals are more susceptible than adults, and adults more than children):
 - i) Medical high-risk individuals, ii) Adults, iii) Children, and iv) the Elderly
 - In the case of a pandemic influenza type that causes serious conditions in the elderly population (Assuming medically high-risk individuals are more susceptible than the elderly, and children more than adults):
 - i) Medically high-risk individuals, ii) the Elderly, iii) Children, and iv) Adults

- 2) If the focus of vaccination is placed on protecting the future of Japan,
 - In the case of a pandemic influenza type that causes serious conditions in adults and juveniles* (Assuming medically high-risk individuals are more susceptible than adults, and adults more than children):
 - i) Children, ii) Medically high-risk individuals, iii) Adults, and iv) Aged individuals
 - In the case of a pandemic influenza type that causes serious conditions in the elderly population (Assuming medically high-risk individuals are more susceptible than the elderly, and children more than adults):
 - i) Children, ii) Medically high-risk individuals, iii) the Elderly, and iv) Adults
- * In the case of the 1918 Spanish influenza pandemic, critical cases were most common among adults and juveniles. The recent outbreak of infection by the H5N1 influenza virus in Vietnam and Indonesia also resulted in critical cases mostly among adults and juveniles.

(2) Supply and administration

- 1) While suppliers are producing pandemic vaccines, the Ministry of Health, Labour and Welfare shall determine the order of priority of vaccine administration among the medically high risk individuals, the elderly, adults and children, as well as develop specific methods for vaccination after consulting experts on the traits of the influenza,virus that actually caused the pandemic.
- 2) Municipalities shall report the numbers in each group (medically at high risk, elderly, adults, children) to the prefectural governments, which shall in turn compile the reported numbers with the numbers of health care workers and workers in social services etc., and report these figures to the Ministry of Health, Labour and Welfare. Government agencies shall modify as necessary the numbers of workers in social services etc. that have been reported to the ministry as recipients of pre-pandemic vaccination, and report the adjusted figure to the ministry.
- 3) As soon as the pandemic vaccines become available, government agencies, prefectural governments, and the municipalities, shall send pre-examination forms and notifications of vaccination to the targeted individuals.
- 4) The Ministry of Health, Labour and Welfare shall deliver vaccines in multiple phases to individual vaccination locations through wholesalers etc., according to the doses requested by each agency and prefectural government. The location of vaccine storage shall not be disclosed and will be kept under guard to ensure the safety in transport and storage of vaccines.

(3) Locations

- In principle, vaccines shall be administered in groups. Vaccination shall be organized by municipalities, and administered at local health and welfare centers with the permission of the prefectural governments. Prefectural governments shall organize vaccination provided to health care workers and workers in social services.
- Medical institutions may vaccinate their own employees. If entities providing social services have clinics or similar facilities in their buildings, vaccination may be administered to employees at such facilities. If vaccination will be provided at such institutions or facilities, instead of at local health or welfare centers, the managers of such institutions or entities shall consult the governing prefectural governments and establish an appropriate vaccinating environment in advance.

(4) Personnel and equipment

Related agencies of the central and local governments shall request medical associations for cooperation in securing physicians and tools for group vaccination. Guards will be set up to ensure safety during vaccine transportation and administration.

6. Procedures for preventive vaccination

- Locations administering vaccination shall be equipped with drugs and devices required to treat adverse effects such as anaphylactic shock that may occur immediately after the administration of the vaccine.
- Each vaccination location shall put up a reception desk where representatives will check to see that each patient receiving vaccination is on the vaccination register that will be compiled in advance. Representatives shall also interview individuals on their history of with (suspected) pandemic influenza patients.
- Temperatures shall be taken immediately before vaccination, so representatives shall ensure the availability of clinical thermometers at reception desks. If an individual is confirmed to have a fever (a temperature of 37.5°C or higher or determined during the interview), or to manifest respiratory symptoms etc., he or she shall be taken to a room designated for individuals manifesting symptoms, where they will be examined by a physician.
- If an individual is confirmed not to have a fever, he or she shall be admitted to the waiting room. Before entering the waiting room, representatives shall hand out printed explanations on the efficacy, side effects, procedures and other details of vaccination, and instruct patients to read it before being examined by a physician. If necessary, organizers of vaccination shall hold a briefing meeting to applicants in advance or otherwise provide targets of vaccination with information identified by that point. In the waiting room, representatives shall also distribute pre-examination sheets and instruct patients to fill them out before being examined by a physician. Any questions that the patient has shall be answered as much as possible while they are waiting.
- Physicians shall read the information indicated on pre-examination sheets carefully. Particular attention must be paid to underlying diseases that may interfere with or require

special care if the patient receives vaccination.

- Physicians shall examine each individual carefully and record the relevant findings as accurately as possible.
- Physicians shall determine whether vaccination shall be provided, based on the information given in the pre-examination form and obtained during the physical examination.
- If an individual is considered unfit to receive vaccination based on the pre-examination form and the physical examination (except for those already manifesting symptoms), representatives shall provide the patient with sufficient explanation as to why he or she cannot receive the vaccination and notify them of the next planned vaccination date (unless they are determined to be unfit for vaccination for an extended period of time). Necessary instructions shall also be provided before such individuals go home. Individuals who are suspected of infection by pandemic influenza, based on the pre-examination form and the physical examination, shall be transferred to medical institutions capable of providing them the level of care they need.
- If an individual is considered fit to be vaccinated that day, they should be asked to think of any questions they may have before receiving the vaccination.
- Interviewing and examining physicians shall confirm the intentions of targeted individuals, and advise them to fill a form of written consent if they consent to the vaccination.
- Vaccinating physicians shall conduct vaccination after confirming that the relevant individual is fit to vaccination by checking relevant documents.
- If human-to-human transmission has occurred, or is likely to occur in Japan, representatives shall take infection prevention measures as necessary and make adjustments according to the actual pandemic situation.
- Representatives involved in the vaccination process itself shall wear masks, goggles, gowns etc., and take all other necessary protection measures to prevent being infected.

7. Side effects following vaccination and the reporting of side effects

- Individuals who receive vaccination shall be guided to monitoring booths and monitored carefully for at least thirty minutes for serious side effects, such as anaphylactic shock.
- If an individual is confirmed not to manifest changes in physical conditions, representatives shall provide hand written post-vaccination instructions before he or she goes home. (The written instructions shall include methods for responding to suspected side effects of vaccination, subsequent procedures, etc.)
- Representatives shall distribute Health Status Survey Sheets (Attachment 1) to a proportion of vaccinated individuals, and request them to monitor their health over the following month, and return the sheets to the governing prefectures in the case of health care workers and workers in social services, and to the municipalities in the case of all other individuals. Prefectural governments and municipalities shall tally the numbers of returned envelopes and Health Status Survey Sheets.
- Representatives shall indicate clearly the contact information of physicians administering vaccines, prefectural governments, or municipalities, so that vaccinated individuals have somebody they can contact with any concerns after they go home.
- If an individual suspects side effects from vaccination, he or she shall consult a medical institution immediately and report to the governing prefectural government or municipality.
- If a physician suspects side effects manifested by a vaccinated individual, he or she shall submit the Vaccination Side Effect Report (Attachments 2 and 3) to the governing prefectural government or municipality, according to the reporting standards.
- If a prefectural government or municipality receives the Vaccination Side Effect Report, the officials shall determine whether the reported side effects require emergency response. If emergency response is required, the officials shall report it immediately using the National Epidemiological Surveillance of Infectious Diseases (NESID) system, and simultaneously forward the Side Effect Report to the Ministry of Health, Labour and Welfare.
- Prefectural governments and the Ministry of Health, Labour and Welfare shall summon a meeting of experts of vaccine side-effect and take prompt actions after taking their advice into consideration.

8. Evaluation

- The National Institute of Infectious Diseases shall conduct blood tests on a proportion of vaccinated individuals at their consent, with the cooperation of medical institutions and local governments. The tests will measure antibody counts against virus strains, thereby evaluating the efficacy of the administered vaccine.
- To guarantee the generalizability of the evaluation of vaccine efficacy, subjects of the blood tests shall be selected from a wide range of geographical areas.

Health Status Survey Sheet following Prepandemic or Pandemic Vaccination against Pa

Please cooperate in a survey on your health status over the months following vaccination that may be used as data to improve future vaccinations. Personal information will be handled with sufficient care, so that it will not be disclosed by any means.

Date of recording (Month Day, Year):

Sex: M / F	Date of birth (Month Day, Year):	Date of vaccination (Month Day, Year):	Vaccine manufacturer and lot number
		Age: years and months old	History of receiving influenza vaccine

Symptoms caused by vaccination	Y / N	
Medication used to treat symptoms caused by vaccination	Y / N	If yes, indicate the category (internal or external), drug name (), and period of administration (from to)
Consultation with medical institutions due to symptoms caused by vaccination	Y / N	If yes, indicate the relevant period: Year (from to), consulted medical institution () and consulted department ()
Absence from school, nursery or office due to symptoms caused by vaccination	Y / N	If yes, indicate the relevant period: Year (from to), and please describe the reasons ()

General symptoms		
1. Fever of 37.5oC or over	Y / N	If yes, indicate the relevant period (Specify all the dates with the fever of 37.5C or higher) (), the highest temperature recorded (C), and the days with the fever ()
2. Chills	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions ()
3. Fatigue	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions ()
4. Joint pains	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and the extent of pain (Please select from the following: none, mild, moderate, severe)
5. Muscle pains	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and the extent of pain (Please select from the following: none, mild, moderate, severe)
6. Headaches	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and the extent of pain (Please select from the following: none, mild, moderate, severe)
7. Difficulty of hearing	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and please describe the symptoms ()
8. Difficulty breathing	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and please describe the symptoms ()
9. Swollen lymph nodes	Y / N	If yes, indicate the relevant period: Year (from to), the relevant regions (), and the extent of swelling (Please select from the following: none, mild, moderate, severe)
10. Rash	Y / N	If yes, indicate the relevant period: Year (from to), and the extent of eruption (innumerable throughout the entire body / 51 or more through the body / 26-50 through the body / 1-25 through the body / 1-5 through the body / none)
11. Anaphylactic shock or other allergic reactions	Y / N	If yes, indicate the relevant period: Year (from to), and describe the reaction in detail ()
12. Convulsion	Y / N	If yes, indicate the relevant period: Year (from to), time of convulsion () min., and the relevant region ()
13. Declined muscle strength, paralysis or similar conditions	Y / N	If yes, indicate the relevant period: Year (from to), and please describe the conditions in detail ()
14. Other symptoms	Y / N	If yes, indicate the relevant period: Year (from to), and please describe the symptoms in detail ()

Localized symptoms		
15. Redness of vaccinated region	Y / N	If yes, indicate the relevant period: Year (from to), and the largest diameter of reddening cm (Date:)
16. Swelling of vaccinated region	Y / N	If yes, indicate the relevant period: Year (from to), the largest diameter of swell cm, and the date when the swell disappear ()
17. Itchiness of vaccinated region	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and the extent of itch (Please select from the following: none, mild, moderate, severe)
18. Pain of vaccinated region	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and the extent of pain (Please select from the following: none, mild, moderate, severe)
19. Hotness of vaccinated region	Y / N	If yes, indicate the relevant period: Year (from to), the date of worst conditions (), and please describe ()

If you have any other concerns or remarks, please describe below:

Thank you for your cooperation.

Vaccination Side Effect Report (Prepandemic Influenza Vaccine)

To: Governor of _____ Prefecture

Vaccinated Individual	Name		Sex	1. M 2. F	Age	____ years, ____ months old Date of birth: (MM/DD/YYYY)		
	Address					Telephone Number		
	Name of guardian if patient is a minor							
Reporting Individual	Name	(Signature or name and seal) 1. Vaccinator 2. Physician 3. Vaccinated individual or his/her guardian 4. Other()						
	Address							
Vaccination Details	Date & time of vaccination	Date:			Time:	:	am / pm	
	Number of pre-pandemic Vaccination				Date of previous vaccination:			
	Type of vaccine	Manufacturer			Lot No.			
		Region			Category	(Group vaccination)		
	Temperature before vaccination	°C						
	Family history				Occupation			
Points requiring attention in the pre-examination sheet (e.g. allergies, underlying diseases, vaccinations or diseases over the past month)						1. Yes	2. No	
Overview of side effects	Date & time of manifestation	Date:			Time:	:	am / pm	
	General Information (symptoms, signs, clinical progress, laboratory tests)				<u>If the general information satisfies requirements for 'serious conditions', please also report to the NESID system. (Reported / Not yet reported)</u>			
	Other suspected diseases							
* Prognosis	1. Death Autopsy Findings ()							
	2. Serious Conditions (with risk of death)							
	3. Hospitalization (Hospital:		Date of hospitalization:		Date of discharge:)			
	4. Aftereffects							
	5. Other ()							
* Recovery	1. Recovered		2. Not yet recovered		3. Unknown			
No. of reports	1. Initial report		2. Second report		3. Third or later report			

The following column is used by the prefectural government:

Date & Time of receipt	Date:	Time: :	Sign or seal of recipient
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If a vaccinated individual satisfies the standards for reporting pre-pandemic or pandemic vaccination side effects, he or she shall be reported to the governor of the prefecture of that individual's residence, using this report form. Indicate the necessary information in each column. The columns marked * may be completed after monitoring the progress of the patient (i.e. in the second and later reports). If an individual satisfying the standards for serious conditions is identified, this information shall be reported to the NESID system in addition to the filing of this form. When reporting to the NESID, report immediately and report only the items indicated in bold letters.

- [Notes] 1. Use A-4 sized paper to print out this form.
2. For items with multiple choices, circle the appropriate number.

This report is aimed at identifying the status of side effects to assure the safety of vaccination.
I understand the above objective and consent to the forwarding of this report to the prefectural government and the Ministry of Health, Labour and Welfare.

Signature of vaccinated individual or his/her guardian: _____

Vaccination Side Effect Report (Prepandemic Influenza Vaccine)

To: Mayor of

Municipality

Vaccinated Individual	Name		Sex	1. M 2. F	Age	_____years, _____months old		
	Address					Telephone Number		
	Name of guardian if patient is a minor							
Reporting Individual	Name	(Signature or name and seal)						
	Address	1. Vaccinator 2. Physician 3. Vaccinated individual or his/her guardian 4. Other ()						
Vaccination Details	Date & time	Date:			Time:	:	am / pm	
	No. of prepandemic & pandemic vaccinations	Prepandemic vaccines: Pandemic vaccine:		Date of prepandemic vaccination: Date of prepandemic vaccination: Date of pandemic vaccination:				
	Type of vaccine	Manufacturer			Lot No.			
		Region			Category	(Group vaccination)		
	Temperature before vaccination	°C						
	Family history					Occupation		
	Points requiring attention in the pre-examination sheet (Allergies, underlying diseases, vaccinations or diseases over the past month)							1. Yes 2. No
Overview of Side Effects	Date & time of manifestation	Date:			Time:	:	am / pm	
	General Information (symptoms, signs, clinical progress, laboratory tests)				If the general information satisfies the requirement for 'serious conditions', please also report to the NESID system. (Reported / Not yet reported)			
	Other suspected diseases							
* Prognosis	1. Death Autopsy Findings ()							
	2. Serious Conditions (with risk of death)							
	3. Hospitalization (Hospital:		Date of hospitalization:		Date of discharge:)	
	4. Aftereffects							
	5. Other ()							
* Recovery	1. Recovered		2. Not yet recovered		3. Unknown			
No. of reports	1. Initial report		2. Second report		3. Third or later report			

The following column is used by the municipality:

Date & Time of receipt	Date:		Time:	:		Sign or seal of recipient	
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If a vaccinated individual satisfying the standards for prepandemic or pandemic vaccination side effect reporting standards is identified, he or she shall be reported to the governor of the prefecture of that person's residence, using this report form. Indicate necessary information in each column. The columns marked * may be filled after monitoring the progress (i.e. in the second and later reports). If an individual satisfying the standards for serious conditions is identified, reporting shall be made to the NESID system in addition. In such cases, report immediately to the NESID the items indicated in bold letters only.

[Notes] 1. Use A-4 sized paper to print out this form.

2. For items with multiple choices, circle the appropriate number.

This report is aimed at identifying the status of side effects to assure the safety of vaccination.

I understand the above objective and consent to the forwarding of this report to the prefectural government and the Ministry of Health, Labour and Welfare.

Signature of vaccinated individual or his/her guardian: _____