

Report of the Review Meeting on Measures against Pandemic Influenza (A/H1N1)

1. Introduction

Following the outbreak of pandemic influenza (A/H1N1) abroad in April of 2009, the Japanese government set the primary objective of government policies in order to minimize mortality and morbidity due to pandemic influenza (A/H1N1). The Japanese government had been making efforts to conduct public health measures (including public relations, intensive quarantine, surveillance, and temporary closures of schools), strengthen relevant medical systems, and supply H1N1 vaccines to inoculate people.

At this stage where the first surge of the pandemic was over, mortality rate in Japan was significantly lower than those in other nations. Thus, it could presumably be considered that the primary objective of keeping low level of mortality and morbidity was almost achieved. Although the reasons for this low mortality rate have yet to be identified, the following factors seem to be contributing to the favourable result: closure of schools across wider areas, good access to medical services, high standard of medical care, dedicated efforts of medical professionals, prompt prescription of anti-influenza medicines, and high public health awareness among the public such as hand washing and gargling. This accomplishment can also be attributed to the efforts of both each Japanese citizen and the front-line medical professionals working in hospitals, clinics and pharmacies.

However, we should not be complacent with the low mortality rate alone; it is also important to evaluate measures taken by the Ministry of Health, Labour and Welfare (hereafter, the Ministry) and then utilize them in counteracting resurgence of the H1N1 influenza and any other possible emerging or re-emerging infectious diseases in future. In particular, there remain possibilities for emerging a novel influenza such as H5N1, thus it is crucial to prepare possible preventive measures beforehand, assuming various different scenarios because the severity of the future pathogen is unknown.

During a series of seven meetings, we discussed and reviewed how to extract lessons from the Pandemic influenza. In order to gain a broad understanding of the situation and to learn lessons and best practices based on the reality, more than 40 experts and special guests were invited to make comments on the pandemic response.

This report was compiled by summarizing discussions and including recommendations to the Ministry. The Ministry is to utilize this report in order to take national measures for a future pandemic, cooperating closely with the relevant Ministries and Agencies, and publicizing the implementation process on an as-needed basis.

2. General Matters

(1) Background Information

In response to the outbreak of pandemic influenza (A/H1N1) at the end of April 2009, the Ministry collected and analyzed the information to take risk management measures immediately. There is a certain degree of understanding that the Ministry achieved a measure of legitimacy, however various issues have been also pointed out in terms of pandemic response.

This report intends to summarize lessons learned and provide recommendations based on the meetings where the participants reviewed and analyzed the facts and opinions, through listening to comments from both those invited and the Ministry officials.

We recognized that time and preparation were limited as listed below when the pandemic occurred. Under these conditions, we categorized specific recommendations for improvement into two categories; fundamental/framework issues or operational issues.

- The action plan and guidelines had been prepared before the pandemic, but these were originally intended to target an outbreak of the highly pathogenic avian influenza (H5N1);
- The action plan and guidelines were short on concrete and detailed measures for a situation where a mass epidemic suddenly breaks out;
- The outbreak occurred just after a revision of the Guidelines in February 2009; therefore, both national and local governments were not well prepared or well coordinated in implementing measures based on the updated guidelines, as observed in quarantine system;
- The pandemic vaccine could not be supplied in large quantity because domestic production system was yet to be strengthened;
- A legal framework had not been developed to enable temporary vaccinations in response to low pathogenic novel influenza.

(2) Recommendations

Discussions were held separately on each subject at the meetings. Through conducting such discussions, common issues overarching several subjects were identified. Therefore, general recommendations for common issues are described here;

[Flexible actions based on pathogenicity]

1. Multiple optional countermeasures based on multiple scenarios should be prepared beforehand, taking into account 1) impacts on health (not only considering the infectivity but also the fatalities of the virus), and 2) limitations of the effects and feasibility of preventive measures including quarantine measures and temporary closures of schools. Judging from reality, appropriate countermeasures should be selected from different options in a flexible manner. However at the initial stage of pandemics, epidemiological information such as pathogenicity and infectivity would be unknown or uncertain. In this case, assuming a high pathogenicity, we need to take into consideration the possibility of adopting the measure to maximize safety and security.

From this perspective, the action plan and guidelines need to be revised based on the current guidance documents to enable prompt and smooth actions when a new pandemic occurs in the future.

[Prompt and rational decision-making system]

2. It is necessary to analyze a pandemic situation and make decisions swiftly and appropriately, thus the government needs to clarify the decision-making process and authorities responsible. In addition, the government also needs to properly grasp the opinions of experts and the reality faced by medical facilities and local governments so as to develop a prompt and rational decision-making system. Furthermore, the process of discussion should be transparent as much as possible.

[Relationship with Local Governments and preparedness]

3. As a wide range of stakeholders including local governments are involved in pandemic responses, it is essential to enhance preparedness by discussing policies and countermeasures with these stakeholders and repeatedly conducting practical trainings prior to pandemics.

The Ministry needs to determine as many public health issues as possible in advance, collecting national opinions on pandemic responses widely through comments from the public. It is also necessary to clarify and confirm roles and responsibilities between central and local governments with regards to appropriate

levels of discretionary powers.

[Enhancement of a risk management system for infectious diseases]

4. It is necessary to further strengthen countermeasures at the onset of an outbreak, and to develop a system to collect/ provide /communicate/disclose information in the pre-pandemic phase. For this purpose, it is essential to strengthen the institutional capacity and human resources of the Ministry and the National Institute of Infectious Diseases (NIID; the Infectious Diseases Surveillance Center and the Influenza Virus Research Center, in particular), quarantine stations, public health centers and prefectural/city institutes of public health (hereafter, the Institutes). The government needs to significantly improve risk management skills specialized in infectious diseases through strengthening staff structures and individual capacities at these institutions. It is also necessary to determine future roles and the division of labor to clarify relationships among relevant institutions and organizations mentioned above. Particularly, the NIID should be better organized and staffed by reference to the US Centers for Disease Control (US-CDC) and other international organizations in charge of infectious diseases.

Moreover, as to institutional capacity or risk management at the Ministry, it is necessary to develop, recruit and maintain human resources with expertise in infectious diseases, along with administrative capacities including communication and management skills.

[Development of legal systems]

5. The effective implementation of countermeasures requires that the legal base of various countermeasures be clarified, including overall policies against communicable diseases (classification of infectious diseases and the roles of medical facilities). Based on International Health Regulations and opinions from local governments and relevant academic societies, it could be considered necessary to revise the “Preventive Vaccinations Law” and “Law Concerning the Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases”.

3. Surveillance

Recommendations

A. Issues that require revision or consideration of frameworks/systems, and advance preparations.

1. Surveillance of hospitalization, morbidity and mortality cases as well as cluster surveillance, which have been introduced for the pandemic (A/H1N1), should be reviewed. The Ministry should consider the timing and method of this surveillance taking into account the necessity and the workload of the local governments and medical facilities, including the non-pandemic period. This review should be based on disclosure of existing databases and opinions of those who were in charge of reporting cases for the surveillance.
2. The Ministry should examine and strengthen; 1) unification of the implementation structures for the surveillance conducted separately by the Ministry and the NIID, and 2) entire methods and systems relating to surveillance including disclosure of results and particularly the way of evaluation.
3. The Ministry should strengthen routine surveillance systems in NIID, public health centers and the institutes, by referring to surveillance systems of various other countries and listening to opinions from local governments. In particular, improvement of the Institutes' capacities and laboratory functions including utilization of polymerase chain reaction (PCR) should be strengthened and the legal roles/positions of the institutes should be examined.
4. In addition, training for the person in charge of surveillance should be further improved.

B. Operational Issues

1. As to definitions of cases, "definition of cases for clinical diagnosis" and "that for surveillance" should be clearly set out and distinguished. Furthermore, taking into account processing capacities, "case definition for surveillance" should be defined so that the institutes and public health centers could manage to apply these definitions appropriately in accordance with their objectives.
2. To avoid confusion in prefectural governments and medical facilities, methods of surveillance need to be changed swiftly and appropriately in accordance with the severity of pathogen and pandemic situation.

4. Public relations (PR) and risk communication

Recommendations

A. Issues that require revision or consideration of frameworks/systems, and advance preparations.

1. From a stage prior to any outbreak, the capacity to collect and disseminate information about infectious diseases, including global information, should be drastically improved in cooperation with the Ministry of Foreign Affairs and foreign diplomatic missions. An official structure specialized for public relations and risk communication should be established and its staffing system should be also strengthened.
2. From a risk management perspective, when an influenza outbreak occurs, it is extremely important to provide immediate and accurate information to the public. On the other hand, the national government needs to take the responsibility for uniformly providing pandemic information across the country in cooperation with prefectures and municipalities in order to avoid confusion caused by regional variations of information.
3. It is crucial that all relevant offices (not only national government but also local governments or field medical offices such as public health centers, municipal health centers, prefectural offices and medical facilities/fronts) need to acquire knowledge and awareness of a new pandemic and provide easy-to-understand information to the public. In addition, development of a structure should be considered to confirm the degree of public understanding from time to time to see if the government messages are conveyed to the public as originally planned. This structure could also feedback its findings to improve public relations.
4. It is important to discuss a concrete form of information dissemination and public relations to deal with personal data related to infectious diseases in cooperation with the media, patient groups and legal professionals at all levels including local stakeholders. Strengthening training, education and dialogues with the relevant officials is also desirable.
5. Outbreak responses and contact points should be identified and confirmed in advance, in order to enable the early establishment of hotlines to contact personnels in the national and local governments, as well as among the national government and relevant medical entities such as Medical Associations. Especially when emergency and/or high-profile cases occur, it is important for the national and local governments in charge to be able to collaborate closely in sharing and disseminating information. For this purpose, the following are expected to improve PR; 1) points of information exchange are unified, 2) publication contents are

consulted and integrated, and 3) timing of publication is coordinated.

6. In cooperation with local governments, it is necessary to consider how to provide information, taking into account “people/groups vulnerable to information” such as foreigners, the disabled and the elderly.
7. The national government needs to swiftly deliver the latest and correct information to local governments and front-line medical institutes. Thus, it is necessary to consider how to provide information quickly and directly, including the use of Internet.
8. The national government should also consider a system where information and consultation can be provided in response to inquiries and public anxiety.

B. Operational Issues

1. During the event of pandemic, it is necessary to provide known information to the public through specifically dedicated spokesperson to avoid differing information being transmitted from multiple sources. In addition, if wrong information is broadcast, the responsibility for PR should be clearly defined and its content should be centralized to deliver correct information.
2. In light of this purpose, various efforts should be made to provide the "correct" information in concrete terms meticulously and frequently. At the same time, the government needs to recognize the diverse questions raised by the public, enterprises and business owners and develop/disseminate a “Q&A”.

Particular attention will be required to avoid any malicious slander or harmful rumors due to public anxiety or inaccurate information.

In addition, in order to provide accurate information to the public, the transparency of discussion should be ensured, for example by taking minutes when listening to experts and healthcare professionals in the field. Efforts should also be made to integrate these opinions accurately and conduct precise publicity for avoiding any confusion. With regard to public comments, the processes of discussion and utilization need to be made as clear as possible to the public.

3. When the content of measures is communicated or determined, the background and rationale are disclosed and provided to the public in an easy-to-understand manner. Government notifications and announcements should also be as concise and clear as possible, and a summary sheet or a related Q&A should be made

available.

4. In interpandemic periods, intensified efforts should be made to disseminate the danger of a novel influenza.

5. Quarantine policy

Recommendations

- A. Issues that require revision or consideration of frameworks/systems, and advance preparations.

1. The national government should be able to consider revisions to expeditiously limit quarantine policies based on the pathogenicity of virus, characteristics of symptoms, epidemic situation within the country and abroad, information from foreign countries on quarantine measures, and expert opinions.
2. In order to make early decisions, such as limiting quarantine measures, the Ministry and the NIID need to construct a system that enables early detection of the occurrence of infectious diseases abroad as well as collecting/analyzing epidemic information in affected countries.
3. With regards to monitoring the health of anyone entering Japan, a quarantine system should be established to allow a flexible response, minimizing the number of persons under investigation and clarifying the criteria for suspending the monitoring. To monitor these persons effectively and efficiently, the following should be considered; quarantine efficacies, response capabilities of public health centers, the impact on human health including not only infectivity but also fatality.
4. Some believe that quarantine does play at least a certain role in delaying the spread of infection. However, this has yet to be confirmed with rigorous scientific evidence of its effectiveness. Therefore, the more scientific knowledge and information about the effectiveness of quarantine measures should be collected. Moreover, creating opportunities to collect opinions from experts and others should be considered.
5. The term of "Mizugiwa-Taisaku" ("waterside measures" when translating it into English literally) could be misleading in that it could be considered "measures that completely prevent infiltration". Thus, it is necessary to consider a better wording to show precise idea and to make people fully understand the role of the policy.
6. Prior to any outbreak, it is necessary to examine what kind of measures should be taken at the point of entry against infectious diseases including a pandemic

influenza and to practice the measures on a regular/preparatory basis.

B. Operational Issues

1. Quarantine stations are required to build a close cooperation system with various local governments through trainings and exercises prior to any outbreak.
2. In providing additional human resources as assistants to quarantine stations during outbreaks, it is necessary to dispatch these people from feasible organizations which can manage to provide human resources for a certain period of time. The reason behind this is to improve the operational efficiency by avoiding negative impacts on domestic preparatory efforts to strengthen medical services and on operations of them after the onset of an outbreak. In addition, these possible dispatched assistants should be trained about quarantine and a method of developing consensus at the field level should be discussed beforehand.

6. Public Health Measures (Temporary Closure of Schools and other facilities, etc.) Recommendations

A. Issues that require revision or consideration of frameworks/systems, and advance preparations.

1. The temporary closure of schools, day nurseries, and commuting facilities for social welfare services (hereinafter, "schools & facilities") was considered effective to a certain extent in the recent case. It is necessary to analyze the actual situation of closures, including activities/programs of the targeted people during the closures through accumulating knowledge and disclosing information. Furthermore, it is also necessary to investigate the effects and future roles/procedures of the temporary closures of schools & facilities.
2. The national government needs to establish and show certain standards (policies and criteria) about the closures regarding to requesting temporary closures of schools & facilities based on the pathogenicity, and then local governments should determine their operations according to the actual situations of future epidemics.
3. When the temporary closures of schools & facilities, restraints on conducting business and suspension of public gatherings/events are voluntarily requested, social and economic impacts will occur- for example guardians of infected children and employees could be obliged to take leaves. Therefore, the national government needs to consider the above circumstances and decide the necessity of planning

countermeasures or consider the way of operations such as formulating Business Continuity Plans (BCPs) for enterprises. In addition, further publicity is necessary to gain understanding of the social and economic impacts for such measures.

4. A network system should be established so that information regarding the temporary closures of schools & facilities can be shared immediately among stakeholders, including local medical institutions, medical associations, schools and facilities.

B. Operational Issues

1. With regard to operations to close schools and facilities, it is necessary to implement these operations in collaboration with neighbouring municipalities. As to public relations, it is also necessary for the public to gain better understanding of the temporary closures.

2. Any closure of schools and facilities will have no effect if students and the targeted people do not understand the reason behind it or how to behave during the closures. Thus, more publicity on those matters will be necessary.

In addition, the national government needs to provide specific guidance on period for which any people infected will need to stay home and on timing for them to return to work, taking clinical information into account.

3. The correct information should be provided further in a more prompt manner, as there were some cases who did not necessarily seek medical services. For example, employers uniformly requested infected employees to have medical examinations by diagnosis kit and obtain certificates of recovery.

7. Medical System

Recommendations

- A. Issues that require revision or consideration of frameworks/systems, and advance preparations.

1. Based on fundamental policy and ideas presented by the national government, each prefecture needs to proceed to examine necessary medical service delivery systems in accordance with the regional circumstances. The national government

needs to provide the necessary supports for them.

Specifically, financial assistance will be necessary for infectious disease controls, for example securing medical staffs, setting up and/or maintaining facilities and equipments of medical institutions specialized in receiving high-risk persons, including negative pressure rooms to prevent nosocomial infections.

2. About establishing febrile counselling centers and fever clinics for outpatients, the following factors relating to the centers/clinics should be considered, while pathogenicity is also taken into account – the appropriateness of establishing these centers/ clinics, the target patients, expected roles/functions and an overall system.

Particular attentions should be also paid to the following points:

- (1) Prefectures should be able to flexibly determine the necessity of their establishment.
 - (2) Names of the centers/clinics should be carefully chosen in accordance with their role and to avoid misleading the public.
 - (3) Functions and roles should be publicized thoroughly.
3. It is necessary for national and local governments to promote human resource development - infectious diseases specialists at the local level (for example, medical doctors in charge of infectious diseases, epidemiologists specialized in infectious disease, and health administrative officers who have knowledge of public health and/or infectious diseases).
 4. In order to establish a system where medical personnel can cooperate in maintaining the regional medical system, it should be considered to provide Personal Protective Equipment (PPE) and to compensate for absence from work or death/sequelae of medical personnels.
 5. It is necessary to further strengthen cooperation among medical facilities and government administration. In order to do so, it should be considered that some stakeholder organizations, such as public health centers and medical associations, take coordination role among medical facilities.
 6. Stockpiling and usage of medical products including anti-influenza virus drugs should be clearly re-defined by the type of medical products

B. Operational Issues

1. A system should be considered where local government can receive advice from field epidemiologists, in order for local governments to make appropriate judgement on whether the region concerned is in "infection expansion period" or "epidemic period". The system is also able to shift smoothly role of clinics for outpatients with fever, or to suspend hospitalization measures.
2. A system should be considered to provide necessary and accurate information to medical facilities swiftly.

8. Vaccination

Recommendations

- A. Issues that require revision or consideration of frameworks/systems, and advance preparations.

1. From the point of view of national security, it is necessary to expand the vaccine productivity in order to assure vaccines for the entire Japanese population as quickly as practical. It is also necessary to support vaccine manufactures and promote the development of cell culture vaccines, nasal vaccines and so on. In addition, imported vaccines should be considered as a means of procuring vaccines from a risk-management perspective in cooperation with overseas manufacturers,.
2. Preparation to ensure the vaccination system should be promoted. For this purpose, vaccination guidelines should be established as soon as possible through listening to opinions from the field, based on the recent experiences during pandemic responses and the Pandemic Influenza Preparedness Action Plan. The implementation body, cost burden and group vaccinations should be also considered.
3. Regarding to vaccinations, it is necessary to consult and coordinate with related organizations such as medical associations, in response to an outbreak of any new infectious diseases or pathogenic variation of existing infectious diseases. An effective and feasible system at the local level should be planned in advance by taking into account reservation system, location and method of vaccination.
4. In order to make an immediate and precise evaluation on adverse reactions caused by vaccination, establishing a system should be considered. This system should recognize and keep track of; implementation of the vaccinations, occurrence of adverse reactions by vaccination, and adverse reactions caused by agents other than vaccines.

B. Operational Issues

1. Decision processes should be clarified with regards to number of times administered, cost of vaccinations (including the prices of the vaccines) and procurement of overseas vaccines. Discussions should be made transparent to the greatest extent possible with demonstrating evidence, and then the minutes should be published as soon as possible.
2. Although priority targets for vaccination are determined by the national government after listening to a wide range of public opinions, they will need to be operated flexibly by prefectures and municipalities in accordance with local circumstances.
3. Regarding to supply of vaccines for future novel influenza, establishment of a system should be considered so that vaccines could be delivered in a quick and smooth manner with the cooperation of stakeholders, including the national and local governments. It is also necessary to conduct discussion on how to build a feasible and practical vaccination system by reference to examples and experiences from various places.

(With regard to the superfluous stock of novel influenza (A/H1N1) vaccines recently purchased by medical institutions, the maximum and prompt efforts should be made to solve excess stock-piling problems, including with an option of returning them to the manufacturers.)

9. Conclusion

In order to substantially improve issues summarized in this report with regard to the recent pandemic influenza (A/H1N1), the national government need to take actions promptly in revising the Pandemic Influenza Action Plan and Guidelines with fully respecting the recommendations made in this report. In addition, after the national government has completely examined balance of the roles and responsibilities of national and local governments, then prefectures and municipalities need to establish or revise implementable action plans according to local circumstances, based on revisions of measures such as the Action Plan by the national government.

Crisis management procedures need to be prepared not only after an outbreak but also before onset of any novel influenza. In particular, drastic improvement could not be expected without enhancing staff structures and improving the budget for infectious diseases including novel influenza. As this issue has been previously pointed out repeatedly, on this occasion, we would like to conclude this report by strongly requesting

realization of a strengthened pandemic preparedness system before onset of next outbreak.