International Workshop on Pandemic Response and International Health Regulations: Further Acceleration of Pandemic Preparedness

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THE INTERNATIONAL WORKSHOP ON PANDEMIC RESPONSE AND THE INTERNATIONAL HEALTH REGULATIONS: FURTHER ACCELERATION OF PANDEMIC PREPAREDNESS

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IN COORDINATION WITH:

World Health Organization
Western Pacific Region

Ministry of Health
People's Republic of China

Ministry of Health, Labour and Welfare
Japan

Ministry for Health, Welfare and Family Affairs
Republic of Korea

IN COORDINATION WITH:
NOTE

The views expressed in the report are those of the participants in the International Workshop on Pandemic Response and the International Health Regulations: Further Acceleration of Pandemic Preparedness and do not necessarily reflect the policies of the Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the International Workshop on Pandemic Response and the International Health Regulations: Further Acceleration of Pandemic Preparedness held in Manila, Philippines on 29 to 30 September 2009.
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EXECUTIVE SUMMARY

The International Workshop on Pandemic Response and International Health Regulations: Further Acceleration of Pandemic Preparedness was held in Manila, Philippines from 29 to 30 September 2009. The workshop was jointly convened by the People’s Republic of China, Japan, and the Republic of Korea and WHO’s Western Pacific Regional Office in coordination with the Secretariat of the Association of Southeast Asian Nations (ASEAN).

The objectives of the workshop were to:

1. Provide updated information on pandemic (H1N1) 2009 and share country experiences of pandemic response activities to further pandemic preparedness and response;
2. Review the implications of IHR (2005) during the pandemic response; and to
3. Strengthen the international collaboration network to respond to the pandemic in the Region.

In the coming months of the winter season in the Northern Hemisphere, the further spread of pandemic (H1N1) 2009 virus is unavoidable. The pandemic situation is unpredictable and still evolving, and requires constant monitoring. In this regard, participants noted the importance of risk assessment, particularly severity assessment, and advanced health care facility planning. There is an urgent need to accelerate pandemic preparedness. To facilitate this effort, WHO’s Western Pacific Regional Office has developed a Framework of Action, which includes strengthened national systems to perform pandemic risk assessments and increasing health care systems surge capacity.

The International Health Regulations (IHR 2005) have played an essential role in the sharing of information at international and regional levels since the more recent outbreak of pandemic (H1N1) 2009. The continued sharing of pandemic information internationally through this framework will be vital in the coming months. In particular, it is recommended that critical pandemic information, including information regarding pandemic severity, drug resistance and vaccine adverse events, be shared under the framework. National IHR focal points are providing timely and invaluable information through this system. Accordingly, it was recommended that the function and role of National IHR focal points be strengthened and maintained, including participation in the pandemic response Command and Control structure.

Monitoring and assessment of the severity of pandemic (H1N1) 2009 is a crucial component of pandemic preparedness and response. It was recommended that national systems be in place to collect information for conducting pandemic risk assessments, and to detect, assess and respond to unusual events. It was also recommended that pandemic risk assessments, especially severity assessments, be conducted through the timely collection, analysis and sharing of key epidemiological, clinical and virological data on relevant indicators, such as severe and fatal cases, numbers of hospitalizations, changes in virus sequencing, and disease characteristics.
A number of antiviral-resistant pandemic (H1N1) 2009 influenza viruses have been reported. Laboratory-based and event-based surveillance should be strengthened to detect antiviral-resistant strains, and to collect and share relevant or unusual epidemiological and clinical information that may indicate antiviral treatment failure. Pandemic vaccines are becoming available and will be widely used by many countries. Any adverse events that may occur following immunization, if not appropriately investigated and managed, may affect the success of the vaccination programme domestically and internationally. In this regard, it was recommended that country systems be strengthened and developed to detect, report, verify, assess, and respond to adverse events following pandemic (H1N1) vaccination.
INTRODUCTION

The International Workshop on Pandemic Response and International Health Regulations: Further Acceleration of Pandemic Preparedness was held at the WHO Western Pacific Regional Office in Manila, Philippines from 29 to 30 September 2009.

1.1 OBJECTIVES

The objectives of the workshop were:

1. to provide updated information on pandemic (H1N1) 2009 and share country experiences of pandemic response activities to further pandemic preparedness and response;
2. to review the implications of the international health regulations (IHR) 2005 during the pandemic response; and
3. to strengthen the international collaboration network to respond to pandemic in the Region.

1.2 ORGANIZATION

The workshop was jointly convened by the People’s Republic of China, Japan, and the Republic of Korea and WHO’s Western Pacific Regional Office in coordination with the Secretariat of the Association of Southeast Asian Nations (ASEAN). Attending the workshop were participants from countries in the Western Pacific and South-East Asia Region, observers from the Korea Foundation for International Healthcare – Dr Lee Jong-Wook Memorial Fund, relevant WHO staff and temporary advisers. For a list of participants and programme of activities, please see Annexes 3 and 4.

1.3 OPENING CEREMONY

Dr Shin Young-soo (Regional Director, WHO Western Pacific Regional Office) welcomed all participants and observers, and expressed his sincere appreciation to the representatives of the People’s Republic of China, Japan, and the Republic of Korea for convening the workshop. He emphasized the importance of international collaboration in response to pandemic influenza (H1N1) 2009 and also pointed out that there is an urgent need to closely monitor the evolving pandemic and to accelerate and strengthen the response capacity. He stressed that the International Health Regulations (2005) should continue to be used to share important information between Member States and WHO, and among countries. "...the current pandemic is a real case to test how our Member States in this region are able to work collectively and jointly in the fight against a public health emergency..."

Representatives of the People’s Republic of China, Japan, and the Republic of Korea each gave welcome remarks to the workshop. Mr Chang Jae Hyuk (Director, Ministry of Health, Welfare and Family Affairs, the Republic of Korea) noted that the workshop offered a good opportunity to upgrade preparedness for the pandemic influenza threat. Mr Jia Bo (Principal Staff Member, Ministry of Health, the People’s Republic of China) highlighted the importance of international collaboration in responding to the evolving public health emergency facing the world since April. Dr Takuya Sugie, (Deputy Director, International Affairs Division, Ministry of Health, Labour and Welfare, Japan) noted the timeliness of the workshop given the oncoming northern hemisphere winter season.
2. PROCEEDINGS

2.1 Plenary 1: Pandemic (H1N1) 2009 and International Health Regulations (2005)

2.1.1 Regional Update on Pandemic (H1N1)

Dr Takeshi Kasai (Regional Adviser, Communicable Disease Surveillance and Response, WHO Western Pacific Regional Office) presented the global and Regional situation of pandemic (H1N1) 2009. The virus is now widespread across the globe, though the epidemiological situation differs by countries and location. It is very difficult to predict what will happen, but it is plausible to assume that extensive community-level transmission will occur in the upcoming northern hemisphere winter season. The virus itself has not yet undergone any significant change and the majority of cases have been mild. Drug resistance has been reported, but so far these have all been sporadic cases.

"...the virus is extremely unpredictable, and we must remain vigilant and prepare..."

2.1.2 Framework for Action in Response to the Pandemic

Dr Satoko Otsu (Medical Officer, Pandemic Preparedness), Communicable Disease Surveillance and Response, WHO Western Pacific Regional Office) provided an overview of the Framework for Action in response to the pandemic. As the spread of the pandemic virus develops from sporadic cases to widespread and extensive community-level transmission, different interventions have to be taken in accordance with each stage. For example, in countries with widespread community transmission, mitigation strategies should be taken rather than containment strategies that are no longer plausible or efficient at that level of pandemic virus spread. The Framework of Action can be used by countries to structure their response to the evolving situation.

"...effective pandemic response requires an interlinked national system of surveillance, health care response, public health interventions, and communication – coordinated under a central command system..."

2.1.3 Application of IHR in Pandemic (H1N1) 2009

Dr Ailin Li (Medical Officer, Communicable Disease Surveillance and Response, WHO Western Pacific Regional Office) presented the application of IHR in pandemic (H1N1) 2009, beginning with an overview of the concept of IHR as a global legal framework to ensure public health security and the role of National IHR Focal Points (NFPs) and IHR Emergency Committees in this system. IHR (2005) has been widely applied to many aspects of the pandemic, including reporting, risk assessment, information sharing, and coordinated response. In the ongoing pandemic situation, IHR has proven to be a valuable mechanism to share information that allows the pandemic risk to be assessed and the global and regional situation to be monitored. NFPs have been critical in facilitating IHR communication. Some challenges remain, however, in the currently evolving pandemic, especially on continuing to share relevant information for robust risk assessments and pandemic severity assessments.

"...IHR has proven to be an effective mechanism to share important and timely information about the pandemic ... we need to maintain the current momentum in IHR communications..."

2.1.4 WHO Surveillance Guidance
Dr Reiko Tsuyuoka (Epidemiologist, Communicable Disease Surveillance and Response, WHO Representative Office, the Lao People’s Democratic Republic) presented an overview of WHO’s surveillance guidance. Many countries have been working on strengthening routine surveillance systems, such as Influenza-Like Illness (ILI), severe acute respiratory illness (SARI) surveillance systems and event-based surveillance systems that are critical for routine monitoring as well as pandemic monitoring. All countries can benefit from the collection and assessment of each individual country’s data. Currently, countries are requested to send their surveillance data to WHO through the IHR channel on a weekly basis. The data is then analysed by WHO to produce information on changes in levels of ILI activity, geographic spread of the disease, changes in the virulence of virus, etc., which are then shared with Member States to inform their own decision-making.

“…Member States should build on the capacity of existing routine surveillance systems for pandemic monitoring, such as ILI, SARI and event-based surveillance systems…”

2.2 Plenary 2: Pandemic (H1N1): Country System for Pandemic Monitoring and Assessment

The second plenary session included an overview of national command and control systems, the role of the National IHR Focal Point in the command system, influenza and SARI surveillance systems, pandemic severity monitoring, detection of drug resistant virus strains, and the system to manage adverse events following immunization (AEFI) of the People’s Republic of China, Japan, and the Republic of Korea. Annex 1 shows pandemic response and National IHR Focal Point Systems in these three countries.

2.2.1 The People’s Republic of China: Country System for Pandemic Monitoring and Assessment

Dr Xu Min (Section Chief of Health Emergency, Ministry of Health, the People’s Republic of China) gave a presentation on the country’s response and preparedness to the pandemic. A joint prevention and control working mechanism has been established for influenza A/H1N1 response, led by the Ministry of Health and joined by 33 national departments. The existing national ILI and event-based surveillance system has been significantly enhanced in response to the pandemic. The National IHR Focal Point is a vital part of the national command and control structure for the pandemic. Information on pandemic (H1N1) 2009 has been shared with WHO in an open, transparent, and timely manner. Severity is monitored with the main indicators including the number of severe cases and deaths and their proportion among the case total. Drug resistance surveillance along with etiological surveillance is used for everity assessment.

“…the existing national ILI surveillance system has been significantly enhanced in response to the pandemic, with a total of 411 laboratories and 556 sentinel hospitals participating in the system…”
2.2.2 Japan: Country System for Pandemic Monitoring and Assessment

Dr Tamano Matsu (Senior Researcher, Infectious Diseases Surveillance Centre (IDSC), National Institute of Infectious Diseases (NIID), Japan) and Dr Teppi Kiuchi (International Health Risk Management Coordinator, Ministry of Health, Labour and Welfare, Japan) reviewed the country’s response and preparedness to the pandemic. The NFP for Japan is the Office of Health Emergency Preparedness and Response, Ministry of Health, Labour and Welfare, which plays a key role in response to pandemic influenza with final decisions made by Cabinet Headquarters. To respond to pandemic (H1N1) 2009, Japan modified its surveillance strategies as the virus became more widespread. A case-based surveillance system was in operation by 23 July 2009, followed by cluster surveillance and hospitalized case surveillance system with pre-existing surveillance systems for ILI (including more than 5000 sentinel sites nationwide), influenza and school ILI absenteeism.

"...for pandemic influenza (H1N1) 2009, surveillance strategies were modified as the virus became more widespread…"

2.2.3 The Republic of Korea: Country System for Pandemic Monitoring and Assessment

Dr Lee Dong Han (Medical Officer, Korea Center for Disease Control and Prevention) introduced the country’s response and preparedness to the pandemic. The central headquarters for influenza control is in charge of pandemic response at the central level, operated by the Ministry of Health, Welfare and Family Affairs with technical support by the Korea Center for Disease Control and Prevention. The country also conducted a pandemic severity assessment, taking into consideration multiple dimensions. The NFP takes on the important roles of disseminating information received from other countries to relevant organizations and of facilitating communication among the organizations in the national system. Surveillance systems for seasonal influenza such as ILI surveillance, hospital-based surveillance, and laboratory surveillance have been used to monitor the pandemic activity.

"... Pandemic severity assessment in-country has multiple dimensions…"

2.3 Plenary 3: Health Care System Surge Capacity

2.3.1 New Zealand: Country Planning and Experience

Dr Fran McGrath (Deputy Director of Public Health, Health and Disability Systems Strategy Directorate, Ministry of Health, New Zealand) presented the health care system surge capacity of New Zealand via teleconference call. Currently in the downward phase in terms of influenza activity, New Zealand has taken mitigation strategies since 19 June 2009, focusing on facilitated communication with health care personnel and provision of consistent and transparent information to the media and public. Despite the majority of cases being mild, hospitals were overwhelmed. In order to manage the surge capacity of health care system, ‘flu centres’ only for people with ILI symptoms were set up in some districts, and ICU services additionally strengthened with trained human resources were coordinated.

"... despite the majority of pandemic influenza (H1N1) cases being mild, some hospitals were overwhelmed…"
2.3.2 MALAYSIA: COUNTRY PLANNING AND EXPERIENCE

Dr Mohamed Paid Yusof (Principal Assistant Deputy Director, Disease Control Division, Ministry of Health, Malaysia) reviewed the country’s health care system surge capacity. The national command and control system was activated 26 April 2009 in response to the pandemic situation. As of 25 September 2009, there have been 11,464 confirmed cases and 77 deaths by influenza A (H1N1) in Malaysia. Mitigation strategies were started on 10 July. Based on the Malaysian National Influenza Pandemic Preparedness Plan (NIPPP), interim guidelines on surveillance of influenza A (H1N1) and guidelines on clinical management of patient under investigation have been developed. The Ministry of Health has functioned as lead agency and major coordinator in response to the pandemic.

"... a centralised command operations room was activated 26 April 2009 in response to the pandemic situation..."

2.3.3 THAILAND: COUNTRY PLANNING AND EXPERIENCE

Dr Darika Kingnate (Director, Department of Disease Control, Ministry of Public Health, Thailand) and Mr Pasakorn Akarasewi Director, Bureau of Epidemiology, Department of Disease Control, Ministry of Public Health, Thailand) gave a presentation on the health care system surge capacity of the country. Based on the Second National Strategic Plan for Prevention and Control of Avian and Pandemic Influenza Preparedness (2008-2010), the whole society, from the central level to provincial and county-level communities, is involved in the planning and response to pandemic influenza. Being in 'Phase C' with sustained transmission in communities, the nation has taken mitigation strategies with adaptive measures to manage the surge capacity of the health care system.

"... it was vital to ensure the -whole-of-society approach in response to the pandemic and engage non-health sectors ..."

2.3.4 VIET NAM: COUNTRY PLANNING AND EXPERIENCE

Dr Nguyen Van Hien (Director of Network Direction Division, General Department of Preventive Medicine and Environment, Ministry of Health, Viet Nam) reviewed the health care system surge capacity of Viet Nam. Based on the Action Plan for Pandemic Influenza Preparedness and Response in Vietnam, the country is now in “Scenario 2 (transmission in community), Stage 2 (pandemic occurring in Vietnam)” with 8,213 confirmed cases and 13 deaths as of 25 September 2009. The central government has been directly in charge of pandemic response, calling for the whole political system and mass media to participate in pandemic response in support of technical assistance by the health sector.

"... the whole government and mass media are to participate in pandemic response in support of technical assistance by the health sector..."
3. **GROUP DISCUSSION**

Participants discussed issues of pandemic severity monitoring and information sharing under the IHR framework in two group discussion sessions. There were also two groups for each session, with Group A facilitated by Dr Vernon Lee with the support of Dr Phengta Vonphrachanh as Rapporteur. Group B was facilitated by Dr Allan Li and supported by Dr Enrique A. Tayag as Rapporteur. Group discussion questions and members are shown in Annexes 5 and 6.

### 3.1 GROUP DISCUSSION 1: MONITORING PANDEMIC SEVERITY

Prior to the group discussion, Dr Vernon Lee (Head, Preventive Medicine, Headquarters Medical Corps, Ministry of Defence, Singapore) reviewed the importance of the assessment of pandemic severity and components at the country level.

Discussions focused on the monitoring and assessment of the severity of pandemic (H1N1) 2009 as a crucial component of pandemic response and preparedness. It was understood that while some countries have conducted their own pandemic severity assessment, others are currently planning to do so.

The objectives of the first group discussion were:

1. to briefly review and share country experiences in conducting pandemic severity assessment; and
2. to identify important components of severity assessment that are of common international interests.

It was noted that different countries have differing pandemic surveillance systems or structures for assessment and monitoring of the pandemic situation. ILI surveillance was commonly being used as a proxy for Pandemic (H1N1) 2009 surveillance and other disease-based surveillance systems (SARI, severe pneumonia) and event-based systems (clusters) were also being used as indicators of pandemic (H1N1) 2009 activity. Drug resistance and changes in the virus and virulence were highlighted as important aspects of pandemic severity. In some countries, laboratory-based virological surveillance systems were in place, but others had no such system established.

At the country-level, pandemic preparedness and situation assessments are being conducted (such as assessments of clinical management procedures). However, there is a lack of standard concepts and methodologies for pandemic severity assessment, and more guidance and clarity about the requisite components and information are needed. Although many assessment formats exist, there is a lack of standard concepts and methodologies for assessment. When developing a standardized pandemic severity assessment, it is also important to consider the type of (domestic) data collected as well as the type of data that should be shared internationally. Risk communication in relation to communicating the result of a severity assessment is challenging, and the capacity of non-health sectors should also be considered.
Detailed indicators of pandemic severity may vary from country to country, however participants agreed that the following basic factors should be included as part of a pandemic severity assessment at country level:

- Epidemiological factors;
- Clinical factors;
- Virological factors;
- Demographic factors (population vulnerability);
- and
- National response capacity.

The accurate calculation of case fatality rate (CFR) in the current pandemic is proving to be extremely problematic because during the mitigation stage all cases are no longer confirmed and counted, leading to an underestimated denominator (and over-estimated CFR). Because of this, comparison of CFRs among regions and countries will have little value unless the methodology of data collection and calculation is understood and standardized.

Pandemic severity information of international concern should also be shared internationally. Participants identified and discussed a range of information (outlined in the below table) that would be of international interest and that should be shared via established channels of information exchange, such as the IHR framework.

Table 1. Suggested pandemic information to be shared

| Epidemiological aspects | • Severe cases, hospitalizations and fatalities  
| • Geographical spread, especially at international border areas  
| • Change of outbreak pattern  
| • Unusual events (after domestic investigation, e.g. change of risk factors)  
| • Changes in surveillance and data collection methodology |
| Virological aspects | • Drug resistance  
| • Viral mutation  
| • Vaccine efficacy and adverse effects (after domestic investigation) |
| Clinical aspects | • Successful management of cases (with permission of clinicians and investigation)  
| • Severe cases, hospitalizations and fatalities  
| • Clinical course and outcomes |
| Change in Public Health Measures | • Key measures undertaken  
| • Trigger for public health intervention |
3.2 Group Discussion 2: Information Sharing Under the IHR Framework

The discussion focussed on the use of the International Health Regulations (2005) as the global legal framework for sharing information regarding pandemic (H1N1) 2009. This framework has been well and widely applied in the current influenza pandemic response, and National IHR Focal Points have played a vital role in providing timely information on initial pandemic cases and regular updates on the evolving pandemic situation.

The objectives of the second group discussion were:

1. to review the roles of National Focal Points (NFP) in the current pandemic response;
2. to identify the information to be shared under the IHR framework in the evolving pandemic situation; and
3. to discuss and identify mechanisms for sharing information with other countries, especially through the secure IHR Event Information Site (EIS).

There was general agreement with the tabled draft paper NFP role in the current pandemic response (Please see Annex 2). It was noted that in order to fulfil this role, the National IHR Focal Point should have good communication with the responsible units to coordinate the required information for timely reporting to the international community and WHO. The NFP does not have to be in charge, but it should have timely access to this information if it is included in the national command and control structure for pandemic response.

Participants commented that it had proven difficult in the current pandemic response to meet the requirement of submitting a detailed case report for the first 100 severe or death cases related to pandemic (H1N1) 2009 and that the sharing of these case reports would be challenging. More specific details about the information requested was also requested (e.g. details needed when reporting drug resistance, adverse effects, unusual events, public health interventions). It was also noted by some participants that there should be a balance struck between the required information to be provided and reasonable demands on the time of the NFP.

There was wide agreement on the areas of information that should be shared between Member States and WHO, and among countries under the IHR framework, including:

- Severe and fatal cases related to pandemic (H1N1) 2009;
- Changes in disease characteristics and severity;
- Surveillance data for special or institutional settings (if the data exist);
- Detection of drug-resistant virus strains;
- Adverse events following immunization with pandemic (H1N1) vaccine;
- Other unusual/unexpected events; and
- Crucial public health interventions implemented.
With regards to drug resistance, most countries had systems and protocols for laboratory and event-based surveillance and the detection of drug-resistant virus strains. However, some countries did not have the laboratory capacity to perform this role, and protocols for laboratory requirements and sharing information about drug resistance were not always clear.

In most countries, there are already existing systems for monitoring and investigating adverse events following immunization, which can be readily applied to pandemic vaccination. Information regarding adverse events following pandemic immunization should be shared among Member States, and the NFP should have or should establish communication with the appropriate unit to be able to access information of international concern. Such information would include:

- Type of vaccine used and manufacture details (batch, manufacture date, expiration date);
- Signs, symptoms, and severity of reaction following immunization;
- Period of time from receiving vaccine to adverse reaction; and
- Case history (age, underlying conditions, etc.).

Risk communication would be a very important issue if an adverse event actually occurred. Some participants also felt that immediate preliminary information-sharing, even before a full investigation, would be critical.

Most participants felt that the secure IHR Event Information Site (EIS) was a useful mechanism to share information. However, some Member States may need to clarify their reporting mechanisms between responsible unit for immunization, NFP, decision-makers and WHO, as high-level authorization may be needed depending on the sensitivity of the information (technical or policy level). Some participants also felt that the quality of information shared could be improved, and further clarification was requested on how WHO intended to collect the information discussed during the workshop.
4. CONCLUSIONS

1. Participants greatly appreciated this important and timely meeting convened by the People’s Republic of China, Japan, and the Republic of Korea with its focus of information sharing under the framework of the International Health Regulations (2005) and pandemic severity assessment during the pandemic.

2. Further spread of pandemic (H1N1) 2009 virus within countries and globally is unavoidable. The pandemic situation is unpredictable and still evolving.

3. The majority of pandemic (H1N1) 2009 cases have been mild, but countries with extensive transmission have experienced pressure on health care services, such as increased hospitalizations and ICU admissions. Participants noted the importance of advance health care facility planning (including patient management and infection control) and public risk communication to advise appropriate health-seeking behaviour.

4. There is an urgent need to accelerate pandemic preparedness, even during containment and mitigation stages. WHO has developed a Framework of Action to assist pandemic preparedness, including strengthened national systems to perform pandemic risk assessments and preparation of health care system surge capacity.

5. The International Health Regulations (2005) are a key global legal framework for sharing information related to pandemic (H1N1) 2009. IHR has been widely and well applied in the current pandemic response. Timely notifications and reporting from countries around the world, including the Asia Pacific Region, have allowed the global and regional pandemic situation to be monitored and assessed, and technical guidance to be developed and implemented. The role of National IHR Focal Points is proving invaluable in providing timely and sufficient information.

6. Continued sharing of pandemic information internationally through the International Health Regulations (2005) framework is vital in the coming months. Participants identified priority areas of information to be collected and shared with the international community, such as changes in pandemic severity, drug resistance, vaccine adverse events and key interventions.

7. Monitoring and assessment of the severity of pandemic (H1N1) 2009 is a crucial component of pandemic preparedness and response. Severity assessment components of international interest have not been clearly identified.

8. A number of antiviral-resistant pandemic (H1N1) 2009 influenza viruses have been reported to WHO. It was noted that there is a difference in capacity for detecting and reporting such cases among countries of the Asia Pacific Region.

9. Pandemic vaccines are becoming available and will be used by many countries. In some countries, there is no established formal communication system for the National IHR Focal Point to communicate with the relevant unit or agency responsible for adverse events following immunization. Any adverse events that may occur following immunization, if not appropriately investigated and managed, may impact the success of the vaccination program domestically and internationally.
5. RECOMMENDATIONS

Recognizing the urgency and the importance of accelerating pandemic preparedness and response during the current (H1N1) 2009 pandemic, the meeting recommends that Member Countries should take the following steps.

Maintain the current momentum in IHR communications and continue to strengthen the function and role of National IHR Focal Points in the current pandemic (H1N1) 2009 response, including participation of the National IHR Focal Point in the pandemic response Command and Control structure.

1. Accelerate pandemic preparedness and ensure national systems are in place to collect information for pandemic risk assessment (especially severity assessment), and to detect, assess and respond to unusual events, such as changes in disease patterns, virulence, drug resistance, and vaccine adverse events.

2. Share critical pandemic information under the framework of the International Health Regulations (2005), including information regarding pandemic severity, drug resistance, vaccine adverse events and any other important, unexpected or unusual events.

3. Conduct pandemic risk assessments, especially severity assessments, through the timely collection, analysis, and sharing of key epidemiological, clinical and virological data, on relevant indicators such as severe and fatal cases, the number of hospitalizations, changes in virus sequencing, and disease characteristics.

4. Strengthen laboratory-based and event-based surveillance to detect antiviral-resistant strains, and collect and share relevant or unusual epidemiological and clinical information that may indicate antiviral treatment failure. It is important for countries to develop, strengthen or maintain national systems and capacities to detect and report antiviral-resistant virus strains and high-risk clinical situations and to conduct epidemiological investigations, when required.

5. Strengthen country systems and develop protocols to detect, report, verify, assess, and respond to adverse events following pandemic (H1N1) vaccination. Existing surveillance systems, including event-based surveillance systems, should be utilized and enhanced to detect and report vaccine adverse events (such as Guillain-Barré Syndrome cases). Mechanisms should be in place for rapid investigation of adverse events including the collection and sharing of critical information of international concern. To facilitate the sharing of this information, National IHR Focal Points should establish formal communication channels with the relevant agencies managing adverse events following immunization and risk communication systems should be in place to address any adverse event of public concern.

6. To seek technical guidance (from WHO) on the type of information required for pandemic risk assessment, especially severity assessment components of international interest. When required, this information should also be shared internationally through channels such as the secure IHR Event Information Site.
## ANNEX 1: Pandemic response and National IHR Focal Point Systems

(China, Japan and Republic of Korea)

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<th>China</th>
<th>Japan</th>
<th>Republic of Korea</th>
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| **National Pandemic Command and control system** | • Joint prevention and control working mechanism established for influenza A/H1N1 response  
• Led by Ministry of Health and joined by 33 departments. | • Cabinet Headquarter for H1N1 Response – established under cabinet approval at October 2007, consisting of Prime Minister and ministers | - Central Headquarters for Influenza Control  
  • Ministry for Health, Welfare & Family Affairs  
  - Central Office of Infectious Disease Control  
  - Centers for Disease Control and Prevention |
| **NFP role in the command system** | • Function included in the command  
• MOH is NFP and the leading authority of Joint Prevention and Control Working Mechanism  
• NFP is a bridge of information sharing between the command system and the international community/WHO | • Function included in the command structure  
• MHLW Headquarter for H1N1 Response | - Function is included in the command structure  
- NFP role held by the Director General of Center for Communicable Disease Surveillance and Response, KCDC |

![Office of Health Emergency Preparedness and Response (NFP)]
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<tr>
<th>National IHR Focal Point coordination with other units</th>
<th>• Coordination established with concerned unit</th>
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| Influenza and SARI surveillance | • National web-based surveillance reporting system  
• **Enhanced ILI surveillance:**  
  63 → **411** Laboratories  
  197 → **556** Sentinel Hospitals  
• Influenza outbreak: reporting, investigation, response, evaluation  
• Human AI: routine (unexplained pneumonia), emergency (active surveillance after AI outbreaks in animals)  
• A/H1N1 influenza | • ILI surveillance: Sentinel clinics (3000 pediatric, 2000 internal medicine), # of cases classified by age group and gender  
• Influenza virus surveillance: 500 sentinel clinics, outbreak clusters, severe cases; HI test, drug resistance (with detailed case information)  
• School ILI absentee surveillance: All nursery, elementary, junior-high, high schools; # of absentees, # of school closure  
• Also case-based, cluster and hospitalized case surveillance  
• Virus surveillance to monitor trend of virus type (assess ratio of Pandemic (H1N1) 2009 in influenza trend) | • ILI surveillance: Increase sentinel surveillance sites (628 → **826**)  
• Hospital-based surveillance for Community Acquired Pneumonia: 40 major hospitals, weekly reporting on age, sex, admission date, date for diagnosis, causative agents  
• Laboratory surveillance: 128 sentinel sites, cooperating with 17 provincial Institutes for Health and Environment  
• Specific influenza virus surveillance  
• Absenteeism monitoring, etc |
| Pandemic severity monitoring system | • Implemented with main indicators including # of severe case (or SARI surveillance), # deaths and % among total cases  
• Severity assessed with etiological and drug resistance surveillance | • Implemented with surveillance on hospitalization and death cases  
• Altered antigenicity confirmation testing via ongoing detailed virus analysis to selected specimens | • Determined by the number of cases, fatality, response capacity etc |
<table>
<thead>
<tr>
<th>Responsible unit for severity assessment</th>
<th>MoH</th>
<th>MHLW (Headquarters for H1N1 response)</th>
<th>Crisis Evaluation Committee (chaired by DG of Disease Policy, Ministry of Health)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring of drug resistance</td>
<td>Virus isolation in qualified network labs and NIC</td>
<td>Virus surveillance to monitor trend of virus mutation, drug sensitivity and altered antigenicity</td>
<td>Drug resistance testing for 20% of isolated viruses by KCDC</td>
</tr>
<tr>
<td></td>
<td>Genetic and antigenic characterization in NIC</td>
<td>Prefecture IDSCs conduct confirmation test for drug resistance</td>
<td>Subtype and antigenic characterization of virus isolates through HI test, PCR, and genetic analysis</td>
</tr>
<tr>
<td></td>
<td>Antiviral drug resistance in NIC</td>
<td>National IDSC (NIID) conducts detailed gene analysis and confirmation test for drug resistance (drug sensitivity test)</td>
<td>Participation in the Flu-Net</td>
</tr>
<tr>
<td></td>
<td>Submit to WHO CCs for annual vaccine recommendation</td>
<td>Incorporate drug resistance monitoring with Prefectural IDSCs and National IDSC (NIID) with information collected from overseas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Surveillance of resistance to new antiviral drugs such as neuraminidase inhibitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continue surveillance of resistance to existing antiviral drugs such as amantadine and rimantadine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responsible unit for drug resistance</td>
<td>NIC</td>
<td>MHLW (Headquarters for H1N1 response)</td>
<td>Division of Influenza and Respiratory Viruses, Korea NIH</td>
</tr>
<tr>
<td>Response to drug resistance (standard operation procedures)</td>
<td>Checking whether the strain is transmitted to others</td>
<td></td>
<td>Consider using alternative drugs</td>
</tr>
</tbody>
</table>
| Monitoring and assessment of vaccine adverse events | Established system for AEFI reporting, investigation and diagnosis, analysis and assessment | Established Post-Marketing Surveillance system for approved drugs | Established AEFI Management system
- Surveillance
- Investigation
- Specific for influenza A (H1N1)
  - Active surveillance
  - Surveillance for baseline GBS
  - SMS service for the vaccinee |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible unit for vaccine adverse events</td>
<td>Online database for information on AEFI</td>
<td>Additional cohort monitoring survey for H1N1 vaccine to collect more detailed efficacy and safety information (under construction)</td>
<td>Korea CDC (Division of NIP and EPI)</td>
</tr>
<tr>
<td></td>
<td>Reporting format for individual cases and clusters (including data on demographic, vaccination, date of occurrence, detection and reporting, clinical picture and diagnosis, etc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SFDA, MoH</td>
<td>MHLW (Headquarters for H1N1 response)</td>
<td></td>
</tr>
</tbody>
</table>
| Response to vaccine adverse events (standard operation procedures) | Established system for AEFI response (including risk communication) | | Established AEFI Management system
- Rapid response
- National vaccine injury compensation program
- Reporting website (for patients) |
<table>
<thead>
<tr>
<th><strong>Event-based surveillance system</strong></th>
<th><strong>List of events requiring notification from local governments to MHLW</strong></th>
<th><strong>•</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Established web-based system for event surveillance and reporting</td>
<td>• 10+ patients with ILI of hospitalized patients or staff at Medical Institutions</td>
<td></td>
</tr>
<tr>
<td>• To report the following events to health administrations</td>
<td>• 10+ patients with ILI of residences, users or staffs at Welfare facilities.</td>
<td></td>
</tr>
<tr>
<td>- ARI / ILI outbreak</td>
<td>• Confirmed hospitalized H1N1 patients on assisted ventilation, influenza encephalopathy or ICU</td>
<td></td>
</tr>
<tr>
<td>- A(H1N1) outbreak</td>
<td>• Confirmed death cases (including post-lab confirmation)</td>
<td></td>
</tr>
<tr>
<td>- Severe and death cases of A(H1N1)</td>
<td>• Confirmed altered antigenicity or drug resistance by gene analysis</td>
<td></td>
</tr>
<tr>
<td>- H5N1 cases</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ANNEX 2: NFP Role in the current pandemic response

In the context of the current Pandemic (H1N1) 2009, the NFP should ensure that IHR obligations continue to be met and are integrated with decision-making processes in the national command and control system or structure.

The role of the NFP should include:

1. Ensuring that the National IHR Focal Point (NFP) should be part of the national command and control structure for pandemic preparedness and response;

2. Maintaining an overview of public health surveillance and response systems, and country measures in response to Pandemic (H1N1) 2009, including areas such as:
   - ILI and SARI, event-based and laboratory-based surveillance systems
   - surveillance and reporting systems for drug resistance and vaccine adverse events
   - response system, e.g. field investigation on disease clusters and adverse events
   - shifting pandemic response strategies, e.g. from 'containment' to 'mitigation'
   - health care system response and surge capacity
   - decision-making processes for and implementation of public health interventions, e.g. international border measures, school closures, cancelation of mass gatherings

3. Communicate with relevant sectors concerning WHO temporary recommendations on pandemic response under the IHR (2005) and monitor country compliance with such recommended measures;

4. Ensuring a national system and procedures are in place for the NFP to consolidate and analyse pandemic information from, and disseminate information to, the health sector and other government agencies;

5. Ensuring mechanisms and procedures (including fast clearance) are in place for effective communication with WHO and other NFPs;

6. Using and supporting the IHR Decision Instrument (Annex 2) for assessment and notification of any event that may constitute a Public Health Emergency of International Concern (PHEIC);

7. Notifying (within 24 hours) and/or consulting with WHO when the first cases of Pandemic (H1N1) 2009 or other unusual events are detected;

8. Responding to verification requests from WHO related to Pandemic (H1N1) 2009;

9. Further communication and information sharing with WHO, including:
   - weekly summary report on cases and deaths, and qualitative indicators
   - detailed case reports for fatal and severe cases
   - evidence of drug resistance
   - adverse events following pandemic influenza vaccination
   - changes in disease patterns and viruses
   - any other unusual or unexpected events
   - key and changing interventions

10. Using the secure IHR Event Information Site (EIS) to share information with other countries and to gather information to inform national pandemic response;

11. Facilitating collection of country evidence and operational research data on important public health measures, such as international border measures and school closures.
ANNEX 3: List of Participants and Secretariat

INTERNATIONAL WORKSHOP ON
PANDEMIC RESPONSE AND INTERNATIONAL HEALTH REGULATIONS:
FURTHER ACCELERATION OF PANDEMIC PREPAREDNESS
Manila, Philippines
29 - 30 September 2009

1. TEMPORARY ADVISERS

Dr Bounpheng PHILAVONG
Assistant Director
Head of Health and Population Unit
Bureau for Resources Development
ASEAN Secretariat
70 A Jalan Sisingamangaraja
Jakarta 12110
Indonesia
Tel. No: (6221) 726 2991 or 724 3372 Ext 423
Fax No: (6221) 739 8234 or 724 3504
Email: b.philavong@asean.org

Dr Vernon LEE Jian Ming
Head, Preventive Medicine
Headquarters Medical Corps
Ministry of Defence
701 Transit Road, Level 2
Singapore
Tel. No: (65) 9792 8896
Fax No: (65) 6453 1015
Email: vernonljm@hotmail.com

Dr Kyung Min SONG
Senior Researcher
Division of VPC and NIP
Korea Centers for Disease Control and Prevention
194, Tongilo, Eunpyung-gu
Seoul
Republic of Korea
Tel. No: (822) 380 2925
Fax No: (822) 352 823
E-mail: bar83bie@cdc.go.kr

3. PARTICIPANTS

WESTERN PACIFIC REGION

CAMBODIA

Dr Sok SRUN
Deputy Director
Department of Hospital Services
Ministry of Health
#151-153 Kampuchea Krom Avenue
Khan 7 Makara
Phnom Penh
Tel. No.: (855) 23 427 566
Fax No.: (855) 23 426 841
E-mail: soksrun@camnet.com.kh

Dr SENG Heng
Chief of Surveillance Bureau
Communicable Disease Control
Department
Ministry of Health
#151-153 Kampuchea Krom Avenue
Khan 7 Makara
Phnom Penh
Tel. No.: (855) 12 852 782
Fax No.: (855) 23 426 841
E-mail: hengedc@gmail.com

PEOPLE’S REPUBLIC OF CHINA

Dr XU Min
Section Chief of Health Emergency
Ministry of Health
No. 1 Xizhi Men Wai, Nan Lu
Beijing 100044
Tel. No.: (8610) 6879 2298
Fax No.: (8610) 6879 2280
E-mail: xumin@moh.gov.cn
yjxm@yahoo.cn

2. CONSULTANT

Ms Qiu Yi KHUT
279 Goodwood Road
Kings Park SA 5034
Adelaide
Australia
Tel. No.: (614) 5003 3820
Fax No.: (614) 5003 3820
E-mail: qiuvi.khut@gmail.com
Dr WANG Lu  
Principal Staff Member/Section Chief  
Ministry of Health  
No. Xizhimenwai, South Road  
Beijing 100044  
Tel. No. : (8610) 6879 2663  
Fax No. : (8610) 6879 2554  
E-mail : wanglu@moh.gov.cn

Mr JIA Bo  
Principal Staff Member  
Ministry of Health  
No. Xizhimenwai, South Road  
Beijing 100044  
Tel. No. : (8610) 6879 2298  
Fax No. : (8610) 6879 2280  
E-mail : jiabo@moh.gov.cn

LAO'S PEOPLE DEMOCRATIC REPUBLIC

Dr Phengta VONPHRACHANH  
Director for National Center for Laboratory and Epidemiology  
Head of IHR National Focal Point  
Ministry of Health  
Km 3, Thadeua Road  
Vientiane Capital  
Tel. No. : (856) 21 312351  
Fax No. : (856) 21 350 209  
(856) 21 214 001  
E-mail : phengta@hotmail.com

Dr Somphone SOULAPHY  
Deputy Director of Prevention Division  
Department of Hygiene and Prevention.  
Ministry of Health  
Km 3, Thadeua Road  
Vientiane Capital  
Tel. No. : (856) 21 214010  
Fax No. : (856) 21 241924  
E-mail: sphone59@yahoo.com

MALAYSIA

Dr Mohamed Paid YUSOF  
Principal Assistant Deputy Director (Disease Control)  
Disease Control Division  
Ministry of Health  
Block E10, Complex E  
Precinct 1, Federal Government Administrative Centre, 62590 Putrajaya  
Tel. No. : (603) 8883 4421  
Mob. No. : (6019) 654 8020  
Fax No. : (603) 8884 1013  
E-mail : drmdpaid@moh.gov.my

Mr Liew Kuet BOON  
Assistant Director  
Enviromental Health Officer U41  
International Health Unit  
Disease Control Division  
Ministry of Health  
Level 3, Block E10, Complex E  
Precinct 1, Federal Government Administrative Centre, 62590 Putrajaya  
Tel. No. : (603) 8883 4100  
Fax No. : (603) 8889 1013  
E-mail : kbliew@moh.gov.my

JAPAN

Dr Takuya SUGIE  
Deputy Director  
International Affairs Division  
Ministry of Health, Labour and Welfare  
1-2-2 Kasumigaseki, Chiyoda-ku  
Tokyo  
Tel. No. : (813) 3595 2404  
Fax No. : (813) 3501 2532  
E-mail : sugie-takuya@mhlw.go.jp

Dr Tamano MATSUI  
Senior Researcher  
Infectious Disease Surveillance Center  
National Institute of Infectious Diseases  
1-23-1, Shinjuku-ku  
Tokyo 162-8640  
Tel. No. : (813) 5285 1111  
Fax No. : (813) 5285 1233  
E-mail : djyu@nih.go.jp

Dr Teppei KIUCHI  
International Health Risk Management Coordinator  
Office of Health Emergency Preparedness and Response  
Ministry of Health, Labour and Welfare  
1-2-2, Kasumigaseki, Chiyoda  
Tokyo 100-8916  
Tel. No. : (813) 3595 2171  
Fax No. : (813) 3503 0183  
E-mail : kiuchi-teppei@mhlw.go.jp
PHILIPPINES

Dr Enrique A. TAYAG
Director IV
National Epidemiology Center
Department of Health
Tayuman, Sta Cruz
Manila
Tel. No. : (632) 743 1937/712 6780
Fax No. : (632) 743 6076
Email : erictayag4health@yahoo.com

Dr Lyndon L. LEE SUY
National Programme Manager
Dengue and Emerging Infectious Diseases
Department of Health
San Lazaro Compound
Tayuman, Sta Cruz
Manila
Tel. No. : (632) 711 6808
Fax No. : (632) 711 6808
Mob. No. : (63) 917 852 7880
Email : donleesuymd@yahoo.com

SINGAPORE

Mr Han Hwi KWANG
Senior Public Health Analyst
Communicable Disease Division
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854
Tel. No. : (65) 6325 8353
Fax No. : (65) 6325 4679
Email : han_wi_kwang@moh.gov.sg

VIET NAM

Dr NGUYEN Xuan Tung
Expert
Division of Communicable Disease Control
General Department of Preventive Medicine
And Environmental Health
Ministry of Health
135/1 Nui Truc Street
Ba Dinh District
Ha Noi
Tel. No. : (844) 3845 6255
Fax No. : (844) 3736 6241
Email : ntxtung@yahoo.com

Dr NGUYEN Van Hien
Director of Network Direction Division
General Department of Preventive Medicine
and Environment
Ministry of Health
135/1 Nui Truc, Ba Dinh
Ha Noi
Tel. No. : (84-4) 373 68159
Fax No. : (84-4) 373 67853
Email : hiennytdp@yahoo.com
SOUTH EAST ASIA REGION

INDONESIA

Dr Priagung Adhi BAWONO  
Chief of Standardization and Partnership Section of  
Sub Directorate Health Quarantine  
Directorate of Surveillance, Immunization and Maternal Health, Directorate General of DC & EH  
Ministry of Health Republic of Indonesia  
Jln.Percetakan Negara No.29, Jakarta  
Tel. No. : (6221) 426 6920  
Fax No. : (6221) 426 6920  
Mob. No. : (6281) 381 611 177/(6287) 881 814 205  
E-mail : priagungb@yahoo.com

THAILAND

Dr Darika KINNATE  
Director  
Department of Disease Control  
Ministry of Public Health  
Tiwanond Road, Nonthaburi 11000  
Tel. No. : (662) 590 3155/590 3275  
Fax No. : (662) 589 2515  
E-mail : darika.kingnate@gmail.com

Mr Pasakorn AKARASEWI  
Director  
Bureau of Epidemiology  
Department of Disease Control  
Ministry of Public Health  
Tiwanond Road, Nonthaburi 11000  
Tel. No. : (662) 591 8577  
Fax No. : (662) 591 8579  
E-mail : pasakorn.sewi@gmail.com

Fax No. : (822) 386 3155  
E-mail : smcho@kfih.org

5. OBSERVERS

KOREA FOUNDATION FOR INTERNATIONAL HEALTHCARE - DR LEE JONG-WOOK MEMORIAL FUND  
Ms Myong-Sun CHO  
Manager, Overseas Project Team 2  
7TH Floor, Korea Federation of Small and Medium Business Building  
16-2 Yeouido-dong, Youngdeungpo-gu Seoul 150-740  
Republic of Korea  
Tel. No. : (822) 6910-9060  
Mob. No.: (8210) 3262 8225

Ms SANG-MI Kim  
Assistant Manager, Overseas Project Team  
27TH Floor, Korea Federation of Small and Medium Business Building  
16-2 Yeouido-dong, Youngdeungpo-gu Seoul 150-740  
Republic of Korea  
Tel. No. : (822) 6910 9063  
Fax No. : (822) 386 3155  
E-mail : smkim@kfih.org

6. ASEAN SECRETARIAT

Dr Luningning Elio VILLA  
Programme Facilitator  
Health and Communicable Diseases Division  
70 A Jalan Sisingamangaraja  
Jakarta 12110  
Tel. No. : (6221) 726 2991 ext 393  
Fax No. : (6221) 739 8234  
E-mail : luningning@asean.org

Ms Audiba T. SUWARSO  
Technical Officer  
Health and Communicable Diseases Division  
Cross-Sectoral Cooperation Directorate  
ASEAN Socio-Cultural Community Department  
ASEAN Secretariat  
70A Jalan Sisingamangaraja  
Jakarta 12110  
Tel. No. : (6221) 726 2991 ext. 368  
Fax No. : (6221) 739 8234, 724 3504  
E-mail : audiba @asean.org
7. SECRETARIAT

WHO/WPRO

Dato' Dr Tee Ah Sian
Director
Combating Communicable Diseases
World Health Organization
Regional Office for the Western Pacific
P.O. Box 2932
1000 Manila
Philippines
Tel. No. : (632) 5289701
Fax No. : (632) 521 1036
E-mail : teeahsian@wpro.who.int

Dr Takeshi KASAI (Responsible Officer)
Regional Adviser
Communicable Disease Surveillance and Response
World Health Organization
Regional Office for the Western Pacific
P.O. Box 2932
1000 Manila
Philippines
Tel. No. : (632) 528 9730
Fax No. : (632) 521 1036
E-mail : kasait@wpro.who.int

Dr Satoko OTSU
Medical Officer for Pandemic Preparedness
Communicable Disease Surveillance and Response
World Health Organization
Regional Office for the Western Pacific
P.O. Box 2932
1000 Manila
Philippines
Tel. No. : (632) 528 9916
Fax No. : (632) 521 1036
E-mail : otsus@wpro.who.int

Dr Ailan LI
Medical Officer (IHR)
Communicable Disease Surveillance and Response
World Health Organization
Regional Office for the Western Pacific
P.O. Box 2932
1000 Manila
Philippines
Tel. No. : (632) 528 9784
Fax No. : (632) 521 1036
E-mail : lia@wpro.who.int

Dr Youngmee JEE
Scientist/Laboratory Virologist
Expanded Programme on Immunization
World Health Organization
Regional Office for the Western Pacific
P.O. Box 2932
1000 Manila
Philippines
Tel. No. : (632) 528 9744

Dr Ki Dong PARK
Technical Officer
Country Support Unit
Programme Development and Operations
World Health Organization
Regional Office for the Western Pacific
P.O. Box 2932
1000 Manila
Philippines
Tel. No. : (632) 528 9042
Fax No. : (632) 521 1036
E-mail : parkki@wpro.who.int

Ms Maggs MAC GUINNESS
Technical Officer – Pandemic Planning
World Health Organisation
No. 177, St. Pasteur (51)
Phnom Penh
PO Box 1217
Cambodia
Tel. No. : (855) 23 216 610
Fax No. : (855) 23 216 211
Mob. No. : (855) 12 2306 057
E-mail : macguinnessm@wpro.who.int

Dr Reiko TSUYUOKA
Epidemiologist
Communicable Disease Surveillance and Response
World Health Organization
Ban Phonxay, 23 Singha Road
Vientiane
Lao People’s Democratic Republic
Tel. No. : (856) 21 353 902/04
Fax No. : (856) 21 35 3905
E-mail : tsuyuokar@wpro.who.int
ANNEX 4: Programme of Activities

INTERNATIONAL WORKSHOP ON
PANDEMIC RESPONSE AND INTERNATIONAL HEALTH REGULATIONS
AND THE FURTHER ACCELERATION OF PANDEMIC PREPAREDNESS

Manila, Philippines
29 - 30 September 2009

Day 1 – Tuesday, 29 September 2009

08:00–08:30 Registration

08:30–09:30 Opening Session

Opening remarks
  - Dr Shin Young-soo, Regional Director, WHO WPRO

Group photo

Welcome remarks by the People’s Republic of China, Japan, and the Republic of Korea representatives
  - Korea: Mr Chang Jae Hyuk, Director, Ministry of Health, Welfare and Family Affairs, Republic of Korea
  - China: Mr Jia Bo, Principal Staff Member, Ministry of Health, China
  - Japan: Dr Takuya Sugie, Deputy Director, International Affairs Division, Ministry of Health, Labour and Welfare, Japan

Self Introduction

Objectives and agenda
  - Dr Takeshi Kasai

Administrative announcements
  - Dr Satoko Otsu

09:30-10:00 Coffee break

10:00 – 12:00 Plenary 1: Pandemic (H1N1) 2009 and IHR
  Chair: China (Mr Jia Bo)

10:00 – 10:20 Global and regional update on pandemic (H1N1) 2009 (WHO)
  - Dr Takeshi Kasai

10:20 – 10:40 Framework for action in response to the pandemic (WHO)
  - Satoko Otsu

10:40 – 11:10 Application of IHR in pandemic (H1N1) 2009 (WHO)
  - Dr Ailan Li

11:10 – 11:30 WHO surveillance guidance (WHO)
  - Dr Reiko Tsuyuoka

11:30 – 12:00 Questions and clarifications

12:00 – 13:00 Lunch break
13:00 – 14:30  **Plenary 2: Pandemic (H1N1): Country system for pandemic monitoring and assessment**  
*Chair: WHO WPRO (Dr Takeshi Kasai)*

13:00 – 14:30  China: Country system for pandemic monitoring and assessment  
- *Dr Xu Min, Section Chief of Health Emergency, Ministry of Health of China*  
- *Questions and clarifications*

Japan: Country system for pandemic monitoring and assessment  
- *Dr Tamano Matsui, Senior Researcher, Infectious Disease Surveillance Center, National Institute of Infectious Diseases, Japan*  
- *Questions and clarifications*

Republic of Korea: Country system for pandemic monitoring and assessment  
- *Dr Dong Han Lee, Medical Officer, Korea Centers for Disease Control and Prevention, Division of Public Health Crisis Response, Republic of Korea*  
- *Questions and clarifications*

14:30 – 15:00  **Coffee break**

15:00 – 17:00  **Group discussion 1: Monitoring of pandemic severity**  
*Chair: WHO WPRO (Dr Takeshi Kasai)*

15:00-15:20  Severity assessment (WHO)  
- *Dr Vernon Lee*

15:20-17:00  Group discussion

18:00  **Reception**

**Day 2 – 30 September (Wednesday)**

08:30 – 08:40  Wrap up of Day 1  
- *Dr Vernon Lee*

08:40 – 10:00  **Plenary 3: Country planning and experience**  
*Chair: Japan (Dr Tayuka Sugie)*

08:40 – 09:00  New Zealand: Country planning and experience  
- (via teleconference) *Dr Fran McGrath, Deputy Director of Public Health, Health & Disability Systems Strategy Directorate, Ministry of Health, New Zealand*

09:00 – 09:20  Malaysia: Country planning and experience  
- *Dr Mohamed Paid Yusof, Principal Assistant Deputy Director (Disease Control), Disease Control Division, Ministry of Health, Malaysia*

09:20 – 09:40  Thailand: Country planning and experience  
- *Dr Darika Kingnate, Director, Department of Disease Control, Ministry of Public Health, Thailand and Mr Pasakorn Akarasewi, Director, Bureau of Epidemiology, Department of Disease Control, Ministry of Public Health, Thailand*
09:40 – 10:00  
**Viet Nam: Country planning and experience**  
- Dr Nguyen Van Hien, Director of Network Direction Division, General Department of Preventive Medicine and Environment, Ministry of Health, Viet Nam

10:00 – 10:30  
*Coffee break*

10:30 – 12:30  
**Group discussion 2: Information sharing under the IHR framework**  
*Chair: Japan (Dr Tayuka Sugie)*

10:30 – 12:30  
Group discussion

12:30 – 14:00  
*Lunch break*

14:00 – 15:00  
**Group Feedback**  
*Chair: Republic of Korea (Dr Hansung Lee)*

Group 1: Feedback  
- Dr Phengta Vonphrachanh, Director for National Center for Laboratory and Epidemiology, Head of IHR National Focal Point, Ministry of Health, Lao PDR

Group 2: Feedback  
- Dr Enrique Tayag, Director IV, National Epidemiology Center, Department of Health, Philippines

Questions & clarifications

15:00 – 15:30  
*Coffee break*

15:30 – 16:30  
**Plenary 4: Conclusions & next steps**  
*Chair: Republic of Korea (Dr Hansung Lee)*

CONCLUSIONS ET RECOMMANDATIONS

Closing remarks  
- Dr Takeshi Kasai
ANNEX 5: Group Discussion Questions

Group Discussion 1:
Monitoring pandemic severity

Introduction:
Monitoring and assessment of the severity of pandemic (H1N1) 2009 is a crucial component of pandemic response and preparedness. It is understood that while some countries have conducted their own pandemic severity assessment, others are currently planning to do so. There is an urgent need to identify components of pandemic severity assessment.

Objectives of group discussion:
• to briefly review and share country experience in conducting pandemic severity assessment;
• to identify important components of severity assessment that are of common international interests.

Proposed questions for discussion
1. How is the current pandemic (H1N1) situation being assessed and monitored in your country?
2. Has your country carried out a pandemic severity assessment?
   a. If yes, how has the assessment been conducted? What data have been collected for the severity assessment? What are the experiences and lessons learned from conducting your severity assessment?
   b. If not, do you plan to conduct a severity assessment? How does your country plan to conduct a severity assessment?
3. What information do you wish to see from other countries in term of pandemic severity assessments?
Group Discussion 2:
Information sharing under the IHR framework

Introduction:
The International Health Regulations (2005) are a global legal framework for sharing of information on pandemic (H1N1) 2009. They have been widely applied in the current influenza pandemic response. The National IHR Focal Points have been playing a vital role in providing timely formation on the initial pandemic cases and regular updates on pandemic situation.

The pandemic situation is unpredictable and still evolving. There is a continuing need for countries to share pandemic information with international community.

Objectives of group discussion:

- to review roles of National IHR Focal Points (NFP) in the current pandemic response;
- to identify what information to be shared under the IHR framework in the evolving pandemic situation;
- to discuss and identify mechanisms for sharing information with other countries, especially through the secure IHR Event Information Site (EIS).

Proposed questions for discussion

1. What are the roles of National IHR Focal Points in pandemic response and preparedness? (please review the 1-page draft discussion paper and provide comments)

2. What areas of information should be shared between Member States and WHO, and amongst countries under the IHR framework?
   - Severe and fatal cases related to pandemic (H1N1) 2009
   - Changes in disease characteristics and severity
   - Surveillance data for ILI, SARI, pneumonia, hospitalization etc.
   - Detection of drug resistant virus strains
   - Adverse events following use of pandemic influenza (H1N1) vaccines
   - Adverse events following use of antiviral drugs and other medicines
   - Other unusual or unexpected events

3. Regarding drug resistance:
   a. Does your country have a national system (e.g. lab surveillance and/or event-based surveillance) and written protocols to detect drug resistant virus strains and events?
   b. Where and how do you collect information related to drug resistance? Which institutes/agencies (e.g. NIC) in your country will collect or have access to such information?

4. Regarding vaccine adverse events:
   a. If an unexpected adverse event or death is occurring following pandemic influenza vaccination in your country, how would you know about this event? Does your country have national system(s) and written protocols to detect and investigate such vaccine adverse events?
   b. What information do you wish to know from a country that reports a vaccine adverse event?

5. How should information about pandemic severity, drug resistance and vaccine adverse events be used and disseminated to other countries? How can the IHR Event Information Site (EIS) be fully utilized to share such information among NFPs?
# ANNEX 6: Group Discussion Members

## Group A

**Facilitator:** Dr Vernon Lee  
(2nd day: Dr Satoko Otsu)

**Note taker:** Ms Qiu Yi Khut

**Country:**

1. **Japan**  
   - Dr Takuya Sugie  
   - Dr Tamano Matsui  
   - Dr Teppei Kiuchi

2. **Laos**  
   - Dr Phengta Vonphrachanh (Rapporteur)  
   - Dr Somphone Soulaphy

3. **Malaysia**  
   - Dr Mohamed Paid Yusof  
   - Mr Liew Kuet Boon

4. **Singapore**  
   - Mr Han Hwi KANG

5. **Indonesia**  
   - Dr Priagung Adhi Bawono

6. **Viet Nam**  
   - Dr Nguyen Xuan Tung  
   - Dr Nguyen Van Hien

**ASEAN Secretariat:**  
- Dr Luningning Elio Villa

**Secretariat:**  
- Dr Reiko Tsuyuoka  
- Dr Takeshi Kasai
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**ASEAN Secretariat:**

- Dr Bounpheng Philavong
- Ms Audibaa T. Suwarso

**Secretariat:**

- Dr Ki Dong Park
- Dr Youngmee Jee
- Ms Maggs Mac Guinness