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Recommendations for good practice in pandemic preparedness for National Influenza Centres

**Evaluation of how pandemic preparedness
activities aided National Influenza Centres in the
WHO European Region in the response to
pandemic (H1N1) 2009**

ABSTRACT

To assist Member States with the revision of their pandemic plans with respect to laboratory activities after the 2009 influenza H1N1 pandemic, WHO/Europe performed an evaluation of the usefulness of pandemic plans and preparedness activities undertaken by laboratory networks and WHO in the response to the pandemic. Using a systematic approach, National Influenza Centres and national influenza reference laboratories in six Member States were interviewed by telephone. Six major themes considered essential to pandemic preparedness for laboratories were identified: communication; coordination/collaboration; capacity; adaptation; leadership; and support. Key issues and recommendations for good practice in pandemic preparedness for National Influenza Centres and WHO were subsequently identified. Pandemic preparedness had generally been successful, with close collaboration between laboratory networks in countries, formal plan approval, laboratory accreditation process and international/national information sourcing emerging as important success factors. Future preparedness activities should continue to emphasize these areas, as well as improve planning for: diagnostic capacity building; control on high diagnostic demands; clinical-laboratory feedback mechanisms; management of media requests to laboratory staff; and real-time monitoring of antiviral resistance.

Keywords

LABORATORY NETWORKS
NATIONAL INFLUENZA CENTRES
DISASTER PLANNING – organization and administration
DISEASE OUTBREAKS – prevention and control
INFLUENZA, HUMAN
INFLUENZA A VIRUS, H1N1 SUBTYPE
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Background

National Influenza Centres (NICs) form the backbone of the World Health Organization (WHO)-coordinated Global Influenza Surveillance Network (GISN). As described in the WHO terms of reference for NICs¹, these national institutions serve as key points of contact between the WHO and its Member States, and they provide virus isolates for influenza vaccine strain selection, risk assessment and antiviral susceptibility monitoring. These activities sustain national, regional and global virological and epidemiological surveillance that is required for the routine surveillance of influenza epidemics, as well as for responding effectively to unusual outbreaks or influenza pandemics. Country-to-country variation in NIC roles and capacities exists and the successful implementation of pandemic preparedness activities by NICs depends largely on the availability of resources and the commitment of national authorities. Hence, continued government support is required to ensure the sustainability of the roles of NICs in influenza surveillance and response, including their participation in national pandemic preparedness planning.

The proposed roles of NICs in pandemic preparedness have been described in a WHO guidance document². During the inter-pandemic period (or influenza season), this role involves isolating and characterizing antigenically influenza viruses and sending representative virus isolates to WHO collaborating centres for reference and research on influenza (WHO CC)³ for further antigenic and genetic analysis. In the European Region, NICs⁴ provide surveillance data on a weekly basis to WHO through either Tessy, the surveillance platform of the European Centre for Disease Prevention and Control (ECDC), for EU and EEA Member States, or through EuroFlu, the WHO/Europe regional influenza surveillance platform. The data are published weekly in an electronic bulletin⁵ and are simultaneously transferred to the WHO global platform FluNet where it is incorporated in global updates.

Depending on the country and NIC capacities, NICs may also coordinate and support national networks of influenza laboratories (including laboratories within health care facilities). At the start of each season they provide support to sentinel networks, including the provision of sampling materials.

They also assist national authorities in integrating laboratory-related components into national pandemic plans.

As part of early warning and response activities, NICs alert national authorities and WHO (using communication channels agreed upon nationally and according to International Health Regulations, where appropriate) to unusual outbreaks of influenza or influenza-like illness, and/or any virus isolates that are not readily identifiable, other indications of the emergence of influenza viruses with pandemic potential, occurrences of antiviral resistance and other findings that may be of public health concern. All such viruses are shared immediately with the WHO CC⁶. Should the emergence of a virus with pandemic potential be suspected, collaboration with epidemiologists to undertake early risk assessment is important and sufficient capacity and resources need to be made available to meet the high demands that may ensue from enhanced surveillance. Once the virus is widespread and a pandemic has been declared, NICs monitor further spread and, where capacities allow, characteristics of the pandemic virus including antiviral susceptibility, antigenic drift and virulence. They continue to share representative viruses with the WHO CC to assist in the process of vaccine production and to support the effective clinical management of pandemic infection.

¹ <http://www.who.int/csr/disease/influenza/influenzanelwork/en/index.html>

² http://www.who.int/csr/disease/avian_influenza/guidelines/RoleNICsMayf.pdf

³ <http://www.who.int/csr/disease/influenza/collabcentres/en/index.html>

⁴ NIC in EU/EEA countries form the Community Network of Reference Laboratories for Human Influenza in Europe (CNRL)
http://www.ecdc.europa.eu/en/activities/surveillance/EISN/laboratory_network/Pages/laboratory_network.aspx

⁵ <http://www.euroflu.org/index.php>

http://ecdc.europa.eu/EN/HEALTHTOPICS/SEASONAL_INFLUENZA/EPIDEMIOLOGICAL_DATA/Pages/Weekly_Influenza_Surveillance_Overview.aspx

⁶ http://www.who.int/csr/disease/influenza/influenzanelwork/2010_12_06_clinical_specimens_for_virus_isolation_and_virus_for_shipment_from_nic_to_who_collaborating_center.pdf

In view of the importance and volume of activities undertaken by NICs between and during pandemics, collaboration with and support from the national health authorities is crucial for ensuring that surge capacity and sustainability planning is developed to meet new and increased demands for laboratory testing during a pandemic and to ensure that national preparedness plans are developed, functional and implemented. Support from international organizations is also important: WHO/Europe, in coordination with the WHO CC, NIMR, United Kingdom, WHO headquarters and with ECDC, provides NICs with tools for capacity building and laboratory networking.

The importance of such collaborative efforts is illustrated by the pandemic preparedness activities that were undertaken by NICs within the WHO European Region and by the prominent role of NICs in the response to pandemic influenza A (H1N1) 2009.

Experience of National Influenza Centres during the response to pandemic (H1N1) 2009

On 27 April 2009, two days after WHO declared a "Public Health Emergency of International Concern" (PHEIC) upon the advice of the Emergency Committee called under the International Health Regulations (IHR), WHO raised the global pandemic alert level from phase 3 to phase 4. Two days later phase 4 was raised to phase 5, providing the signal of an imminent pandemic. A new influenza virus was identified and the network of laboratories around the world began the vital and challenging work of investigating and reporting cases. NICs in the European Region, as elsewhere in the world, played a frontline role in the response to the pandemic; their first task was to ensure that they could detect cases infected with the new virus. Molecular detection assays (polymerase chain reaction; PCR) were developed as soon as the genetic sequence of the virus was made available by the WHO CC, CDC, Atlanta, which also supplied NICs with PCR kits.



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The first cases in the European Region were reported in the week of 27 April 2009 by 11 countries. By 11 June 2009, nearly 30 000 cases had been confirmed in 74 countries, 30 of which were in the European Region. Based on the global geographical spread of the new H1N1 virus, WHO officially raised the global alert level to phase 6, declaring that a global pandemic of novel influenza A (H1N1) was underway. By 24 August 2009, 48 out of 53 European Member States had reported their first cases. In most European countries the majority of cases were in travellers from North America and Mexico, the first affected countries.

By October 2009, most European Member States experienced increased influenza activity in the community reflected in increased rates of ILI and/or ARI, as well as increases in the number of severe cases, which continued into early January 2010⁷. By the end of the pandemic, more than 214 countries worldwide reported laboratory-confirmed cases of H1N1, including at least 18 398 related-deaths.

During the summer of 2009, WHO/Europe interviewed NICs in four countries and published a summary of the challenges faced on WHO/Europe web site⁸. On the one hand, NICs within the European Region gained significant experience from the pandemic (H1N1) 2009, particularly in laboratories just starting to

⁷ http://www.euroflu.org/cgi-files/bulletin_v2.cgi

⁸ <http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/influenza/pandemic-h1n1-2009/whoeurope-news-and-updates/gathering-vital-evidence-the-work-of-influenza-laboratories-on-pandemic-h1n1-2009>

perform PCR. On the other hand, the rapid spread of the H1N1 virus and the enhanced surveillance performed in many countries during the summer of 2009 caused increased pressure on the testing capacities of laboratories. As the virus spread in the community, many NICs became responsible for testing hospitalized cases in countries that introduced mandatory national notification of severe cases, in addition to performing testing as part of routine ILI/ARI surveillance, which substantially increased their workload. Typically, the volume of samples received for testing increased about 5–10 fold, and during the 2009-2010 season about 10 times more influenza virus detections were reported to EuroFlu compared with the 2008-2009 winter season⁹. Due to limited human resources available, laboratory personnel worked double shifts to meet the demands of increased testing, reporting to health authorities and responding to media requests. Although collaboration (e.g. sample exchange, surveillance data) was reported to be good between laboratories across European countries, some laboratories experienced the requests for methodological advice as a further increase to the pressure.

Some of the pressure experienced by NICs (and affiliated reference laboratories) in the European Region during the pandemic was relieved by multi-faceted support provided by WHO. In addition to guidance on laboratory testing, biosafety and sample transport procedures, WHO also facilitated the shipment of PCR kits and other reagents provided by CDC, as well as sampling materials to laboratories that lacked sustainable resources. WHO continued to provide proficiency panels through the WHO External Quality Assessment Programme (EQAP)¹⁰, which was updated to include the pandemic (H1N1) virus. Surveillance information and situation updates were provided through the EuroFlu bulletin and the WHO/Europe web site. Global and regional teleconferences on virological issues were held, which were deemed extremely useful by laboratories for sharing experience and good practice.

Post-Pandemic (H1N1) 2009 NIC Activities

As described above, NICs played a critical front-line role during the pandemic response. Thus, the development and implementation of pandemic preparedness and response plans must be an integral part of NIC activities. After entering the post-pandemic phase on 10 August 2010, WHO recommended that Member States assess and, if necessary, revise their pandemic plans. This includes planning for virological surveillance and response performed by NICs.

The valuable experience gained by NICs during the pandemic can be used as a learning framework upon which future pandemic preparedness activities necessary for effective response can be improved. Therefore, to support these efforts, WHO/Europe performed an evaluation on how pandemic preparedness undertaken by NICs within the European Region aided the response to the 2009 pandemic. The outcome of this evaluation is a set of recommendations for good practice for the laboratory aspects of pandemic preparedness. This is expected to assist NICs and WHO in the revision of their pandemic plans. These recommendations complement the in-depth evaluation performed by WHO/Europe in seven Member States, which focused on key stakeholder groups other than the NICs¹¹.

Evaluation objectives

The aim of this evaluation was to provide recommendations to assist NICs and Member States in the WHO European Region in the revision of their pandemic plans. This was done by evaluating how pandemic preparedness activities aided the response of NICs to the 2009 pandemic. Subsequently, the evaluation was used to identify good practices for future pandemic planning. The evaluation also addressed ways in which WHO can improve its support to NICs.

⁹ <http://www.euroflu.org/cgi-files/figures2002.cgi?year=2010&week=39®ion=Europe&type=v&pilot=Y>;
<http://www.euroflu.org/cgi-files/figures2002.cgi?year=2009&week=39®ion=Europe&type=v>

¹⁰ <http://www.who.int/wer/2011/wer8603/en/index.html>

¹¹ <http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/influenza/publications/2010/recommendations-for-good-practice-in-pandemic-preparedness-identified-through-evaluation-of-the-response-to-pandemic-h1n1-2009>

The following specific objectives were targeted:

- a) to describe the process of laboratory pandemic planning in Member States;
- b) to describe how well the laboratory preparedness corresponded to the response needed by identifying activities that were considered adequate or inadequate for the response;
- b) to determine what could have been done differently to improve the usefulness of these activities during the response; and
- c) to determine future support required from WHO.

Evaluation methodology

The usefulness of pandemic preparedness activities undertaken by NICs in countries of the WHO European Region and the WHO support provided for responding effectively to the pandemic (H1N1) 2009 was evaluated qualitatively among nine NICs and national influenza reference laboratories in six countries, which were considered to provide good representation of the diversity of countries in the WHO European Region. These included Estonia, the Netherlands, Republic of Moldova, Romania, Turkey and Ukraine. The Ministries of Health of these countries received a formal request from WHO/Europe to participate.

Information was obtained by conducting telephone interviews using a questionnaire with open-ended questions that covered the objectives described above. The head of the National Influenza Centre and other relevant laboratory staff from each participating Member State were asked a set of key questions from a formatted guide questionnaire covering the stages of the planning process, implementation of activities before the pandemic and use of the plan during the pandemic response. Reflections on what could have been done differently during these stages and expectations from WHO for future support were also addressed. In total, 6 interviews were conducted, constituting 36 hours of recorded material. Recording facilitated data analysis, which was conducted through transcription, as well as common content organization using a matrix and coding to allow themes to emerge. The NIC data analysis was then aggregated across the Member States, and six themes in pandemic preparedness were identified. The pandemic preparedness activities that worked well or did not work well were categorized under these six themes:

capacity; communication; coordination/collaboration; support; leadership; and adaptation.

A summary table containing the results was generated (Annex 1) which formed the basis for discussion during the second stage of the evaluation, namely a workshop for participants from the six countries held at the Regional Office on 15 November 2010. Participants worked in a group and made additions to the summary table based on presentations made during the workshop. Participants then identified from the summary table a list of priority issues and developed recommendations.

For a more detailed description of the methodology and results, please contact the Regional Office (influenza@euro.who.int).

Priority issues and recommendations for good practice in pandemic preparedness

The evaluation showed that all of the participants had taken part in national pandemic planning activities. All participants considered that pandemic planning activities had been useful in the response to the 2009 pandemic. However, a number of areas for improvement were identified. During the evaluation process, a list of issues considered important for good pandemic preparedness and response was developed, as well as recommendations for good practice and areas in which WHO support is needed.

Issues important for good pandemic preparedness and response:

1. Political commitment to continuous capacity building
2. Involvement of NICs in outbreak management and multi-laboratory coordination mechanism
3. Prioritization of testing to avoid overload
4. Real-time antiviral resistance monitoring system
5. Surveillance system for severe acute respiratory infections (SARI)
6. Early implementation of 24/7 information hotline for health professionals
7. Opportunities for sharing experiences between countries
8. WHO support

Recommendations for good practice

1. Political commitment to continuous capacity building

To undertake pandemic preparedness effectively and to be able to detect emerging pandemic viruses early, strong government commitment to building capacity in NICs and laboratory networks is needed. The following is required:

- government funding for pandemic preparedness, including training, purchase of equipment and rapid access to reagents and other supplies;
- a laboratory preparedness plan that includes early evaluation, different possible scenarios (e.g. various clinical attack rates) and procedures for scaling up laboratory capacity;
- laboratory capacity scaled up through appointing additional laboratories (e.g. other public health laboratories or laboratories located in universities/hospitals) to support NICs;
 - Such collaboration with a laboratory network needs to be established in the preparedness phase to ensure rapid activation during a pandemic.
- standardized protocols for the uniform sampling of patients and handling of specimens used by all laboratories in the network;
 - Stocks of sampling materials should be available in case a pandemic occurs.
- sampling and transport capacity established by training of personnel at additional labs and testing transport mechanisms before the pandemic;
- protocols to validate virus detection kits (PCR) and rapid external quality assurance programmes in place at the national and international level (such as the WHO EQAP); and
- enhanced communication capacity of NICs to deal with questions from general practitioners and hospitals.

2. Involvement of NICs in outbreak management and multi-laboratory coordination mechanism

For NICs to undertake pandemic preparedness activities effectively, multi-group activities will need to be coordinated. These include:

- the implementation of an outbreak management team, which includes participation of the NIC (if there is a laboratory network, other laboratories may also be included).

3. Prioritization of testing to avoid overload

Although the pandemic was relatively mild, there was a high diagnostic demand from hospitals, general practitioners and in some cases from the public, upon which NICs and other laboratories had little or no control. An effective prioritization mechanism for testing samples needs to be established at the national level and communicated to relevant stakeholders to ensure the rational use of diagnostic capacity and avoid overload of the laboratories. To do this:

- A national laboratory preparedness plan must address this prioritization issue; the principles for prioritization should be described, as well as the logistics plan and the role

of the NIC and other laboratories. Epidemiologists and clinicians should be involved in the development of the plan.

- The primary task of the NIC is surveillance; during a pandemic, there will be an increase in demands on virological analyses for surveillance, as well as diagnostic, purposes. NICs must continue their surveillance activities during all stages of a pandemic and plans for the prioritization of testing should take this into account, especially within a limited resource environment.
- The national plan for the prioritization of testing should include guidance on how many samples are to be sent for surveillance and testing purposes to the different laboratories involved in the response.
- The number (and possibly type) of samples sent for testing will differ according to the different stages of the pandemic. Below is an example of such stages:
 - In the period of first introduction of the virus to the country, the focus will be on detection and characterization of the first cases and possibly contacts, as well as testing of cases from outbreaks. This enhanced surveillance will place strains on NIC capacities and should be supported by other laboratories, where possible.
 - Later, if the virus starts to spread in the community, where possible, existing routine sentinel community and hospital surveillance will be relied on using the same sampling strategies (and number of samples collected) as those for seasonal influenza.
 - Should new surveillance systems be introduced, such as national notification and testing of severe cases, this will likely also lead to overload and must be planned for beforehand.
- Plans must be flexible, allowing for adjustments to be made according to the local situation during an actual pandemic. Communication channels with relevant institutions and professionals must be in place before the pandemic, so that plans can be developed together, shared and adjusted in a timely fashion, should a pandemic occur.

4. Real-time antiviral resistance monitoring system

Antiviral drugs are crucial early in a pandemic, particularly when specific influenza vaccines are not yet available. The incidence of anti-viral resistance, however, is likely to increase with increased utilization. This leads to a decrease in antiviral drugs' effectiveness for treating patients and this is of particular significance in immunocompromised individuals. It is therefore important for Member States to be able to rapidly detect and monitor antiviral susceptibility and the emergence of resistance. This can be achieved through:

- NICs having a real-time antiviral resistance monitoring system in place prior to the pandemic;
- NICs having basic capacity levels to implement the monitoring system during a pandemic (e.g. at least having PCR in place to detect a known mutation);
- NICs that will introduce antiviral resistance monitoring receiving training in assays, validation (EQA) and interpretation of results;
- NICs that do not have the capacity to perform antiviral resistance monitoring shipping all viruses from patients suspected of harbouring a resistant virus to a WHO CC, as well as representative viruses from routine surveillance¹²; and
- NICs possibly establishing an agreement with another laboratory in the region to perform routine antiviral resistance monitoring.

5. Surveillance system for severe acute respiratory infections (SARI)

During the pandemic, the lack of routine sentinel surveillance systems for severe disease caused by influenza was highlighted. During the past two years, a number of countries have implemented sentinel

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http://www.who.int/csr/disease/influenza/influenznetwork/2010_12_06_clinical_specimens_for_virus_isolation_and_virus_for_shipment_from_nic_to_who_collaborating_center.pdf

SARI surveillance in hospitals¹³. The NIC staff participating in this evaluation considered that such a system would improve the effectiveness of the virological surveillance and made the following recommendations:

- Member States should consider having in place sentinel SARI surveillance.
- This will require additional human resources and funding made available by health authorities to the sentinel site hospitals, clinicians, nurses, epidemiologists and virologists involved in this surveillance.
- In addition, testing would need to be performed to determine respiratory pathogens other than influenza causing SARI.
- A national plan or protocol describing the sentinel SARI surveillance would need to be established (covering staff involved, including focal points and responsibilities, sentinel sites, sampling strategies, selection of laboratories for testing, transport, testing algorithms, etc., as described in WHO/Europe guidance for sentinel influenza surveillance in humans¹⁴).

6. Early implementation of 24/7 information hotline for health professionals

During the first few weeks or months of the pandemic, a system for addressing laboratory-related questions should be available to avoid overburdening the capacity of NICs. The following is needed:

- The national pandemic plan should include provisions for a national 24/7 hotline for health professionals (e.g. general practitioners, hospitals) and public health specialists to obtain information on, for example, case definitions, prioritization of sampling and testing, where to send samples, etc.
- Health care professionals should be aware of the hotline and should be informed of its activation as soon as the emergence of a pandemic virus is suspected.

7. Opportunities for sharing experiences between countries

To create an efficient platform for sharing experience among countries:

- networks need to be built with neighbouring countries;
- informal e-mail discussion lists can be used on the EuroFlu platform;
- increased use of the country comments section in the ECDC WISO/EuroFlu bulletin should be encouraged; and
- regular meetings should be held (in addition to the annual regional network meetings organized by WHO/Europe and ECDC¹⁵, a meeting before season to inform the networks of new developments should be planned).

8. WHO Support

Laboratory networks in the European Region requested WHO support in various aspects of pandemic preparedness. These include support in capacity building, pandemic preparedness simulation exercises and guidance on containment measures at the laboratory level. For this support to be effective, the following is necessary:

- During a pandemic, WHO should inform NICs which WHO guidance is in the pipeline to avoid duplication and so that newly developed guidelines can be communicated in a timely fashion to other laboratories in national networks.
- Rapid translation of WHO guidance into Russian is needed.

¹³ www.euroflu.org

¹⁴ <http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/influenza/publications/2009/who-regional-office-for-europe-guidance-for-sentinel-influenza-surveillance-in-humans>

¹⁵ <http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/influenza/activities/surveillance-and-epidemiology/surveillance-meetings/2011-joint-whoecdc-regional-office-for-europe-influenza-surveillance-meeting>

- Clear statements on biosafety requirements for handling pandemic viruses need to be provided.
- WHO should facilitate more opportunities for sharing information and experiences during a pandemic.
- Support from WHO with laboratory diagnostics, laboratory quality and surveillance system improvement, especially SARI, needs to be continued in the inter-pandemic period.
- WHO should provide recommendations for prioritization of sampling for testing and surveillance purposes during a pandemic.

Conclusions

This evaluation demonstrated the usefulness of pandemic preparedness activities undertaken by NICs in response to the 2009 pandemic. Support from WHO was considered to have been worthwhile and to have improved the pandemic response in 2009–2010. The broad range of preparedness tasks undertaken by NICs was deemed important and influential. As laboratory services and networks require significant investments and resources in a rapidly changing field, political and financial commitments are needed for NICs to remain effective in their multi-faceted role, particularly to sustain capacity for a high level of alert in influenza. Clear strengths in the countries included: close collaboration between laboratory networks; formal approval process of plans; laboratory certification process; and international/national information sourcing.

Based on the interviews, common thematic elements should be viewed by individual NICs of the Member States as essential factors to consider when revising, re-formulating or rejuvenating national pandemic plans (and associated preparedness activities) during the post-pandemic evaluation period. These are:

- communication
- coordination/collaboration
- capacity
- adaptation
- leadership
- support

In terms of the 2009–2010 response by NICs in the European Region, the most problematic areas and those where preparedness activities in the post-pandemic recovery period require stronger emphasis, as well as improvement in planning, are:

- political commitment for diagnostic capacity building
- control on high diagnostic demands
- clinicians-laboratory feedback system
- outbreak management teams that include NICs
- shielding laboratory staff from media demands
- real-time antiviral resistance monitoring

The findings from this exercise should be used to strengthen European pandemic planning during the post pandemic recovery period.

Annex 1. Summary of findings

Laboratory Networks	Capacity	Coordination/ Collaboration	Leadership	Communication	Support	Adaptation
<p>Planning: Worked well</p>	<ul style="list-style-type: none"> • training of lab personnel (improved skills) • early evaluation and protocol for scaling up of lab capacity (e.g. PPE, staff, diagnostics) • related experience (H5N1) • contact tracing • hospital access to lab services 	<ul style="list-style-type: none"> • coordination of planning process with MoH, PH and NIC specialists • inter-sectoral collaboration • lab network for assistance in outbreaks • standardized protocol for handling of specimens 	<ul style="list-style-type: none"> • delegation of responsibilities to relevant organizations by MoH for plan development • approval of plan by MoH or NIC • laboratory certification programme for secondary labs e.g. at universities and hospitals 	<ul style="list-style-type: none"> • national & international workshops & seminars • upfront agreements between labs/hospitals • detailed communication strategies • multi-stakeholder discussions (e.g. pharmaceuticals, regional, hospitals, labs, etc.), table top exercises 	<ul style="list-style-type: none"> • international organization(s) and national government for financing PPA, training & purchase of diagnostic material & equipment • appointment of additional labs • WHO Guidelines 	<ul style="list-style-type: none"> • adapting planning focus from H5N1 to H1N1 diagnostics • ongoing evaluation of planning process • preparation for different scenarios, e.g. various attack rates
<p>Didn't work well</p>	<ul style="list-style-type: none"> • requirements for additional personnel not specified 	<ul style="list-style-type: none"> • follow up content of plan (after dissemination) 	<ul style="list-style-type: none"> • reference status of only some labs approved internationally 	<p>N/A</p>	<ul style="list-style-type: none"> • specific roles need clearer definition 	<ul style="list-style-type: none"> • revision and evaluation of plan before pandemic
<p>Implementation of plan before pandemic: Worked well</p>	<ul style="list-style-type: none"> • diagnostic equipment and lab materials/consumables • surveillance for early detection 	<ul style="list-style-type: none"> • multi-group coordinated actions, outbreak management team • implementation, establish collaboration with external labs 	<ul style="list-style-type: none"> • appointment of persons for implementation of PPA measures • government set implementation deadlines • rapid authorization from national medicine agency 	<ul style="list-style-type: none"> • feedback reporting system of implementation status to government, seminars, lab service centres & epidemiologists, rapid sharing of data within lab network, e-mail alert system 	<ul style="list-style-type: none"> • international support for desktop exercise and containment measures, between-lab quality assurance system implementation 	<ul style="list-style-type: none"> • lessons learnt from H5N1 experience applied to H1N1 pandemic, e.g. PPE, sample transportation, storage, virus containment, case isolation and notification system tested for identifying required changes
<p>Didn't work well</p>	<ul style="list-style-type: none"> • lacking technical capacity, lab infrastructure, PPE, vaccines and AV • provision of real-time AV resistance monitoring system • difficulties setting up system for sample collection, transport & testing overload 	<ul style="list-style-type: none"> • strategy for rapid response system implementation • complicated sampling logistics 	<ul style="list-style-type: none"> • commitment in capacity building 	<ul style="list-style-type: none"> • complicated implementation of communication lines • no agreement on sampling logistics and AV resistance/virulence markers 	<ul style="list-style-type: none"> • surveillance system for severe cases not in place 	<p>N/A</p>

Laboratory Networks	Capacity	Coordination/ Collaboration	Leadership	Communication	Support	Adaptation
<p>Use of plan in response: Worked well</p>	<ul style="list-style-type: none"> early case detection rapid acquirement of lab materials, reagents and diagnostic equipments for service reinforcement, new lab data logging tools increased sample handling capacity by outbreak assistance labs 	<ul style="list-style-type: none"> efficient multi-stakeholder response collaboration (different levels and organizations) lab network working closely together 	<ul style="list-style-type: none"> emergency commission directing plan revision working group, rapid mechanism for approval of revised plan 	<ul style="list-style-type: none"> information sources from national & international channels, meeting with national emergency committee, inter-lab and relevant parties information dissemination notification channels for population discussions and feedback opportunity, information dissemination through free mobile network, regular meetings 24/7 hotline 	<ul style="list-style-type: none"> WHO, CDC, ECDC & MoH recommendations international support in lab diagnostics, quality and surveillance system improvement reporting cases to WHO/EuroFlu 	<ul style="list-style-type: none"> MoH mandate on revision of surveillance system, revision of case definition & situation evaluation criteria reorganization of emergency service and hospital infrastructure plan adaptation to national situation using WHO & CDC guidance development of new guidance for clinical AV resistance testing
<p>Didn't work well</p>	<ul style="list-style-type: none"> insufficient diagnostic capacity to meet demand (management, number of staff) real-time surveillance 	<ul style="list-style-type: none"> more universal mechanism for response coordination measures at national level no active monitoring of virological changes collecting follow-up specimens 	<ul style="list-style-type: none"> no mandate/control on high diagnostic demand from hospitals, GPs and population when pandemic mild (i.e. human behavioural factor) 	<ul style="list-style-type: none"> responding to requests from press and media mass media control insufficient data to allow robust conclusions on severity late translation of international data/guidelines lack of lab specialist representation in media 	<ul style="list-style-type: none"> financial resource mobilization link between clinical and virological data not communicated (e.g. feedback system) lack of national plan guidance on how many samples to be sent for testing 	<ul style="list-style-type: none"> adaptation of new H1N1 recommendations to national requirements and epidemiological situation adaptation of clinical protocol for pregnant women, children and young adults
<p>Expectations from WHO:</p>	<ul style="list-style-type: none"> more training provision new methods facilitation conferences 	<p>N/A</p>	<p>N/A</p>	<ul style="list-style-type: none"> get more information and data at early stage of pandemic clearer pandemic severity criteria more information on viral resistance to better inform the public of the risk 	<ul style="list-style-type: none"> creating opportunity for experience sharing between countries discussions & support on real-time diagnostics and sentinel surveillance raise issue of need for dedicated budget lines for lab component of PPA 	<ul style="list-style-type: none"> revise definition of pandemic phases

Annex 2. Evaluation Interview Guide

**Interview guide: evaluation of how pandemic preparedness aided
the response to the pandemic (H1N1) 2009**

**National Influenza Laboratories
Version 14 July 2010**

Section A: The planning process (25 minutes)

- 1) Were you familiar with the national pandemic plan before the pandemic (H1N1) 2009?
- 2) Does the national pandemic plan include a section on laboratory and if yes, could you tell us how was this developed:
 - a. Did you give input to development of the laboratory section of the national pandemic plan? If yes, what input was given?
 - b. Were other persons involved in the actual writing process and if so, how did you work together, how frequently did you meet?
 - c. When was development of the laboratory component of the plan initiated and finalized and what was the approval process?
 - d. Were the necessary finances to implement the laboratory component of the plan identified?
 - e. Which factors were important for developing the laboratory component of the national pandemic plan?
- 3) How did you prepare for a pandemic in your laboratory? Was a pandemic plan for the laboratory developed? When was development of the plan initiated/finalized and what was the approval process? What was the status of the plan as of March 2009? Were necessary finances identified for implementation? What was important for developing the laboratory plan?
- 4) Was the laboratory plan developed on initiative of your laboratory or institute or in response to a request from the national level?

The following questions apply to both the laboratory section of the national plan as well as the laboratory plan, if available

- 5) Was guidance sought from WHO, other international organizations or other labs? If WHO guidance was used, which exactly and which WHO guidance was most useful (eg. WHO global plan or checklist; NIC document, other)?
- 6) Has the plan been revised or evaluated before the pandemic? What were triggers for revision of the plan?
- 7) Was a specific scenario used as a basis for the pandemic plan?
- 8) To which stakeholders was the plan disseminated?

Prompts/details for the above questions:

-
- (Q 1) Range of persons and professional groups involved
- (Q 3) eg. necessary finances organized, surge capacity

- (Q 5) WHO, other organizations; was the guidance or input useful and why?
- (Q 7) Planning assumptions: attack rate, case fatality rate, hospitalization
- (Q 2e/3) What were the critical issues: e.g. time, expert input, external support etc

Section B: Implementation of the plan before the pandemic (25 minutes)

- 9) Did the plan identify actions that required putting in place before the pandemic?
- Which were they? What got implemented? What specifically facilitated their implementation? *Where these things implemented because the national plan or WHO guidance (WHO Global plan/checklist) said they should be or what determined their implementation?*
 - Were things implemented before the pandemic that with hindsight need not have been implemented?
- 10) Were there things needed/implemented in the response that should have been implemented beforehand? What were they? Why were they not implemented before the pandemic?
- 11) Was the pandemic plan tested in exercises?
- Which elements were tested and with whom?
 - How were lessons learned incorporated into the pandemic plan/pandemic preparedness activities

- (Q 10/11) Implemented: e.g. stockpiles of reagents and other laboratory materials; PPE; procedures for dealing with large number/sudden increase in samples; surge capacity planning; Tamiflu for staff;
- (Q 10a) what were the critical issues: e.g. time, specific input from experts, external support, ring-fencing of staff duties etc
- (Q 10b) Do you think it was the right decision to implement these things, e.g. were (such large/small) stockpiles of reagents needed or would a smaller/bigger stockpile have been better?

**Section C: Use of the plan in the response to the pandemic (H1N1) 2009
(40 minutes)**

- 12) Did you use the plan you had written in the response to the pandemic (please answer for both the laboratory section of the national plan and for the specific lab plan, if available)? Did you use other documents? Which?
- 13) At the start of the pandemic, what was the trigger to implement/activate the plan? What exactly did you do to implement/activate the plan?
 - a. What did you disseminate and to whom?
- 14) Which parts of the plan were used? If the plan, or components of the plan, were not used, why not?
 - a. What was used/implemented instead?
 - b. What could have been in the plan to make it more useful?
 - c. Could anything have made the WHO guidance/documents more useful?
- 15) Did you need to develop any new documents or response strategies that were not envisaged in the plan? How were these developed? Were they disseminated and to whom?
- 16) Were triggers for action/de-escalation during the pandemic clear to you?
- 17) Where did your information come from? Were you able to distil the available information? Were you able to make timely decisions?
- 18) Was there any information or support that you needed from the national/regional level during the pandemic that you did not get?
- 19) Was it clear what was expected from you at different stages of the pandemic?
- 20) Were there mechanisms in place that allowed you to feed back problems from the front line to relevant authorities at regional/national level?
- 21) Were there communication channels that did not work? Were there communication channels that were not anticipated but that proved important?
- 22) Thinking about your expected role during a pandemic, how did your actual role play out in comparison?
- 23) What were the main things that were done differently in the response than envisaged in the planning process?

Prompts/details for the above questions:

- (Q 13) sent emails, held a meeting, sent out the plan etc.
- (Q14b and c) Technical vs. policy document; WHO documents refers to documents developed before the pandemic and after the start of the pandemic
- (Q 15) If no, refer to gaps in plan. E.g. did you miss a clearly defined list of responsibilities in the plan, or division of tasks among other labs in the country

- (Q 16) Triggers could be in the national plan or in the lab-specific plan, they could be the first case in the country, first death in the country, more than x number of cases, declaration of new phase by WHO, directive to the lab from the public health authority or MoH
- (Q 17) If there is no mention of WHO phases/recommendations: Do you know what WHO recommended for each phase? Was this what you did?
- (Q 18) Internal: within the lab/institute outside government. External: WHO, ECDC
- (Q19) Technical, scientific, politics , logistic, financial

Section D: Reflection on what could have been done differently in the planning phase (30 minutes)

- 25) Which pandemic preparedness activities were the most useful to your response to the pandemic? Why?
- 26) Which pandemic preparedness activities were the least useful to your response to the pandemic? Why?
- 27) How could the plan/pandemic preparedness activities have been more useful/how could it have better served the response?
- 28) If you had to start again, what would your plan/ pandemic preparedness activities include/look like? Who would you engage with/involve?
- 29) What are your next steps (evaluation, revision of plan)?
- 30) What do you expect from WHO for future pandemic preparedness activities?

Prompts/details for the above questions:

- (Q 25) Was it most useful to have a detailed plan, frequent meetings, exercises, stockpiles, surge capacity, training etc
- (Q 25) National as well as WHO pandemic preparedness activities (workshops, missions, guidance documents, training, surveillance platform)
- (Q 30) What WHO (EURO) did related to pandemic preparedness: shipped CDC PCR kits for pandemic (H1N1) and other reagents during the response; missions, trainings, workshops, regional meetings, guidance documents, EuroFlu surveillance platform.