

Pandemic contingency planning checklist for National Influenza Centres (NICs) and other national influenza laboratories

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Introduction

During a human influenza pandemic – and the period of high alert leading up to it – it is expected that there will be a significantly increased level of demand for laboratory services. To help plan for the increased requirements likely to be placed upon National Influenza Centres (NICs) it will be important to determine the degree to which the anticipated surge level will exceed routine NIC operations and to plan accordingly.

Political and institutional commitment will be needed in both the development and implementation of a contingency plan to ensure the effectiveness and continuity of NIC activities. The development and coordination of the contingency plan must involve high-level national decision-makers, preferably within the Ministry/Department of Health.

As a first step, the anticipated capacity and associated logistical requirements that will be placed on the NIC and other institutions during a pandemic must be assessed. The actions and resources that will be needed to establish and maintain the required surge capacity can then be identified. As part of this, an emergency budget must be prepared through which the funds needed to implement the contingency plan will be made available. Assessments will need to be made and contingency-planning measures (Annex A) developed and put in place in all the following operational activity areas:

1. Ensuring the availability of facilities, staff and equipment
2. Stockpiling supplies
3. Testing strategies, protocols and algorithms
4. Laboratory biosafety and transportation of specimens
5. Data management
6. Communications

1. Ensuring the availability of facilities, staff and equipment

Availability of laboratory and office space

Extra laboratory and office space will be needed during a pandemic. Testing activities will therefore have to be prioritized and non-urgent testing postponed. To gain more space to cope with the increased workload, it may also be helpful to transfer influenza diagnostic technologies to other laboratories that have been assessed to have the required capability. Additional freezer space will be required for the storage of specimens, isolates and nucleic acid extracts. If a Biosafety Level-3 (BSL3) laboratory is available, it should, if possible, be reserved for influenza-related work.

Availability of trained staff

Contingency planning must be in place to ensure the availability of additional appropriately trained staff during periods when laboratories will have to deal with a significantly increased number of specimens, develop and validate new methods, and perform additional tests on clinical specimens and viral isolates. Such staff must be prepared to work with potentially infectious and high-risk materials and must be adequately trained in all the procedures that need to be performed during a pandemic and the period leading up to it.

NICs located in a large laboratory institution or close to other institutions with laboratories (such as universities and research institutes) should extend their training activities to workers in these other laboratories. NICs in countries with little or no relevant additional laboratory facilities may offer training to laboratory workers in major hospitals. A register of all additional staff trained in influenza diagnostics should then be maintained at the NIC.

Less-well-trained staff from other laboratories can assist with tasks such as the tracking of specimens, and preparation of specimen-collection kits. However, all additional laboratory staff must be properly trained for the level of task demanded and fully briefed on the situation. The responsibilities of all staff must be clearly defined and a chain of command put in place. Information systems holding the records of all laboratory and supporting personnel should be updated regularly. During a pandemic, staff will also need to be available outside official office hours and to cover for staff members on sick leave because of influenza or other illness. A clear plan should be put in place with details of work shifts and backup personnel. Medical surveillance should be undertaken and attendance records monitored daily as unusual absences could alert the NIC management to the possibility of laboratory-acquired infection.

Equipment

The NIC should have a back-up power source for use during power outages. Other required back-up equipment (such as a biosafety cabinet, PCR machines and incubators for cell culture) can either be purchased in advance or sourced from other laboratories. Increased storage capacity must also be in place, including ensured access to an additional dedicated freezer for pandemic influenza material – either by prior purchase or by clearing an existing freezer to make space. As part of contingency planning, the NIC must maintain an updated inventory of all laboratory equipment, keep detailed records of equipment maintenance and validate surge equipment in advance in order to ensure that sufficient equipment to cope with any surge in demand will be available. An equipment maintenance contract should be in place to ensure the rapid repair of instrumentation should this be necessary.

2. Stockpiling supplies

Stockpiling reagents

Contingency planning must consider the fact that some reagents (for example, PCR oligonucleotides) have a long shelf life while others do not and cannot therefore be stored for long periods. Conversely it has to be recognized that there may be a long lead-time for the delivery of supplies in resource-limited countries. In general, maintaining stockpiles of reagents sufficient for at least three months of activity at the current capacity of the NIC is a good strategy. Information systems to track existing and projected required levels of reagents, kits, consumables and other stock should be established to guide procurement and cope with any surge in demands.

NICs may also wish to establish networks and reach agreement on the exchange of reagents in order to ensure that surge requirements can be met. Communication channels with suppliers on the current availability and stockpiling of essential kits and reagents should be kept open; and alternative kits and reagents evaluated in case a regular supplier is unable to deliver requested items.

Stockpiling antiviral drugs

Preparations should be made to ensure that antiviral drugs stockpiled nationally could rapidly be made available should laboratory staff require treatment or prophylaxis. NICs should also maintain a small supply of antiviral drugs in case of a laboratory accident. Policies on the treatment and prophylaxis of laboratory staff should be developed in advance in cooperation with physicians responsible for occupational health.

Stockpiling personal protective equipment

NICs must maintain a stock of personal protective equipment sufficient for at least three months of increased activities. Guidelines on how NICs can access national and international stockpiles must be available.

3. Testing strategies, protocols and algorithms

The NIC contingency plan should clearly outline the strategies to be used for the testing of specimens at various stages of a pandemic. In the lead up to a pandemic and during its early stages, every specimen should be tested using a testing algorithm that provides the highest specificity and sensitivity. However, as the pandemic virus becomes more widespread and the number of possible clinical specimens becomes very large, criteria for the selection of specimens to be tested will need to be established and applied. The testing strategy adopted will depend upon the capabilities and resources of the laboratory but in all cases should be based on national strategies for pandemic surveillance.

Testing protocols and algorithms will need to be agreed upon in collaboration with epidemiologists and the national laboratory network during the course of the pandemic. In addition to WHO testing protocols in-house protocols can also be used. However, each protocol must be thoroughly validated before being put into routine use. Testing algorithms should also be established in line with national and global pandemic surveillance strategies^{1,2,3} and should be in accordance with WHO guidance.

In addition to diagnosis and surveillance activities, the NIC should, where possible, also have the capacity in place to undertake specific virological investigations (e.g., antiviral sensitivity testing, antigenic characterization and molecular epidemiology). Laboratories should retain a fraction of the clinical specimen for further testing at NIC or other qualified reference laboratories.

To increase their capacity in all these areas, NICs should plan in advance the coordination of all its diagnostic and related activities with other laboratories (hospital, university and private). In countries or areas where the capacity for diagnostic testing is limited or non-existent, WHO

¹ *Optimizing laboratory-testing strategies for the virological surveillance of pandemic (H1N1) influenza in phases 5 and 6.* In preparation.

² <http://www.who.int/csr/resources/publications/swineflu/surveillance/en/index.html>

³ For the most up-to-date guidance see http://www.who.int/csr/resources/publications/swineflu/interim_guidance/en/index.html

Collaborating Centres for Reference & Research on Influenza (WHOCCs) and appropriate laboratories within the WHO Global Influenza Surveillance Network (GISN) can provide assistance.

4. Laboratory biosafety and transportation of specimens

Laboratory biosafety and biosecurity

Access to a biosafety cabinet is crucial to laboratory biosafety and, as outlined above, ensuring access to a back-up unit should be part of contingency planning. Work on clinical specimens possibly containing viruses of pandemic potential and on the virus itself must be conducted at the appropriate biosafety level as recommended by WHO.^{4,5} Access to laboratories must also be restricted to qualified and accredited personnel. It is strongly recommended that all staff working with potential pandemic influenza viruses be vaccinated against seasonal influenza.

Transport of specimens in-country

The NIC contingency plan should consider the possible disruption of the routine transport system – or refusal by the system to transport specimens during a pandemic. Standard operating procedures (SOPs) for specimen collection, packaging and transportation, and for the decontamination of possible spillage sites, must be in place.

Transport of specimens to reference laboratories and to WHOCCs

SOPs for the transport of specimens and viruses to WHOCCs must also be in place. The strategy and protocols for specimen transport available on the WHO web site must be followed to ensure that global surveillance goals are met. International transport must be arranged according to the International Air Transport Association (IATA) rules and all shipments must be accompanied by the required documents. National and international export and import permits must be obtained in a timely manner prior to shipping. Personnel responsible for specimen packaging and transport must be trained in dangerous goods shipment.

5. Data management

Detailed and accurate data collection during the early stages of a pandemic is vital. Such data will be an important source of the information needed to guide the development of major criteria (such as case definition), and to determine the type of samples to be collected, the sample-collection strategies, and laboratory testing algorithms to be used.

At the very minimum, the conventional filing of forms and results will be essential. Information can then be captured electronically to facilitate sample tracking and allow for the transfer of data into local and international databases. This in turn will facilitate data sharing with the national laboratory network and with epidemiologists to allow for review of the case definition and for situational analyses to be conducted. The ability to link different laboratory and epidemiology databases using patient identification numbers will be vitally important for tracking purposes. It is recommended that conventional paper documentation and filing activities be maintained to provide back-up records in the event of the failure of electronic systems, and to allow for quality-assurance assessments of electronic data entry.

⁴ http://www.who.int/csr/resources/publications/swineflu/interim_guidance/en/index.html

⁵ http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

The use of an electronic system by a designated group of personnel specifically assigned to this task will aid the handling of a large volume of samples. However, creating a separate database for outbreak and/or pandemic situations may lead to an increased workload and should be avoided as far as practicable. For data collection, NICs may instead modify the existing data-capture systems to accommodate the new case definition for the newly emergent virus. NICs should then use a simple standardized system for reporting cases to WHO, containing the following information for each sample collected:

- demographics;
- clinical signs, symptoms and date of onset of illness;
- type of specimens taken for investigations;
- time and date of specimen collection;
- date received in the laboratory;
- condition of the specimens when received;
- the laboratory test performed;
- test results;
- the date the results were reported; and
- specimen/virus/derivatives (RNA, cDNA) storage location.

6. Communications

A robust communications system should be established in advance between NICs, WHO, GISN, WHOCCs, the Ministry/Department of Health, the national laboratory network and other relevant partners. Effective communications between the NIC and its national and international partners will be vital in coordinating the resources required to cope with the situation.

Key points of contact between the NIC and its partners include:

- **WHO** – will provide the case definition, influenza laboratory guidelines, global surveillance goals, criteria for technical interpretation and space on the GISN web site for emergency questions and communication within WHO regions.
- **WHOCCs** – will provide technical advice and feedback on the analysis of the specimens and isolates received.
- **Ministry/Department of Health** – will provide crucial information on the diagnosis of cases, and on national policies and support structures.
- **National laboratory network** – will provide back-up surge capacity for diagnosis and submit samples from suspected cases for confirmation and further characterization.

As part of contingency planning objectives, NICs should therefore ensure that communications capacity is in place and is sufficiently operational to:

- initiate requests to national health authorities for developing and maintaining electronic data storage and transmission systems;
- coordinate with epidemiologists and information analysts in order to agree upon the formats to be used for data collection, analyses and reporting;
- keep laboratory staff fully informed and involved in all planning and related activities during regular meetings within the laboratory;
- provide background information and other facts about influenza diagnosis and disease to designated and trained spokespeople;
- develop mechanisms for consistent communication on laboratory-based influenza information to inform regular national and/or international situation updates;

- provide WHO with immediate information on the isolation of unusual viruses or disease outbreaks as well as any other relevant information;
- share test protocols and other relevant technical materials with national and international partners; and
- report weekly to WHO (FluNet)⁶ on the number of specimens collected and processed for influenza and on the number of specimens tested that are positive for influenza by subtype.

⁶ Either directly through remote data entry to: <http://www.who.int/flunet> or by reporting data to the WHO regional office database with timely subsequent data uploaded to FluNet.

Annex A: Checklist for NIC contingency planning

Please check Yes/No box

1. Business continuity preparedness

1a. Does the plan include specific methods for maintaining critical competence during periods with high workloads and risk of staff absenteeism due to illness?

Yes

No

If yes, please complete the following:

By mobilizing existing trained staff and other qualified staff inside the NIC with specific skills?

Yes

No

By mobilizing other qualified staff from outside the NIC?

Yes

No

If yes, have the external laboratories been assessed to determine whether there is the capacity and expertise to assist?

Yes

No

Are all critical skills duplicated so that the laboratory is able to continue all its critical functions during periods of staff absenteeism?

Yes

No

Are plans in place for staff to rest and recover during prolonged high-workload periods?

Yes

No

Host institution support resilience

Does the host institution have a business continuity plan that addresses the maintenance of critical support/infrastructure during a pandemic?

Yes

No

1b. Expedited testing preparedness

Does the plan address the potential need for expedited diagnostic testing preparedness?

Yes

No

Are arrangements in place for rapid diagnostic response outside normal working hours?

Yes

No

2. Space

Does the plan address the need for additional space through the utilization of other laboratories?

Yes

No

Has additional space been planned for storage of reagents, PPE, etc.?

Yes

No

Does this include refrigerated and freezer storage?

Yes

No

Has sufficient storage capacity been planned for storage of specimens, virus isolates, etc.?

Yes

No

3. Equipment

Has the need for supplementary/back-up equipment been addressed?

Yes

No

If yes, which equipment?

4. Stockpiling reagents and PPE

Are there operating procedures in place for stockpiling of reagents?

Yes

No

Has a stockpile of reagents and PPE been secured?

Yes

No

5. Laboratory protocols

Are protocols for PCR, testing strategy, interpretation, turn-around time as well as quality and biosafety issues in place?

Yes

No

6. Laboratory safety and security

Has the plan addressed the following safety and security issues?

The use of additional biosafety cabinets?

Yes

No

Has safety training of personnel been addressed?

Yes

No

Are there current guidelines on safety precautions including management of accidents and medical surveillance?

Yes

No

Are safety audits carried out?

Yes

No

Is entry to the labs restricted to key staff only?

Yes

No

Are the laboratories and freezers, etc. locked when not in use?

Yes

No

Is there a BSL3 laboratory available for virus isolation? (Note: This is not essential for detection of virus by PCR.)

Yes

No

Is this a dedicated influenza BSL3 laboratory?

Yes

No

Have staff had hands-on training in a BSL3 laboratory?

Yes

No

7. Transport of specimens to reference laboratories/collaborating centres

Are there comprehensive operating procedures available for the shipment of specimens to reference laboratories/collaborating centres?

Yes

No

Has Category B shipment to a WHOCC been tested in practice recently?

Yes

No

Has Category A shipment to a WHOCC been tested in practice recently?

Yes

No

8. Data management

Is there a plan for handling the additional data entry and analysis requirements?

Yes

No

If yes, how?

Is there a plan to share the test results with partners?

Yes

No

If yes, how?

9. Communication – local and international

Have channels of communication been identified, both at a local and international level?

Yes

No

10. Quality assurance

Is an external quality assessment programme in place?

Yes

No

Are there stocks of positive control RNA or virus for regular validation of influenza A PCR test performance?

Yes

No

Do the stocks include influenza A positive material (any A subtype) for influenza A testing?

Yes

No

Do the stocks include pandemic (H1N1) 2009 positive material?

Yes

No

11. Issues requiring consensus among countries

Are there procedures for the sharing of clinical samples between countries in place?

Yes

No

If yes, have material transfer agreements been addressed?

Yes

No

Has fast tracking of the issuance of import/export permits been addressed between countries in which specimens will be transported?

Yes

No

Have transportation cost issues been addressed?

Yes

No

12. Role of laboratory during an influenza pandemic

Which roles below have been planned for by the laboratory?

Performing PCR testing on specimens from suspected cases

Yes

No

Performing virus isolation and characterization

Yes

No

Performing specific serology on close contacts

Yes

No

Performing antiviral resistance testing

Yes

No

Performing gene sequencing

Yes

No

Sending isolates to WHOCCs

Yes

No