Laboratory biorisk management for laboratories handling human specimens suspected or confirmed to contain influenza A (H1N1) causing the current international epidemics

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These interim recommendations are subject to change as more information becomes available.

This document is divided into two parts:

1. Biorisk management checklist for laboratory managers and staff.

2. Recommendations addressing minimal/essential working conditions associated with specific manipulations in laboratory settings.

It is suggested that laboratory managers and workers first go through the checklist, and then review their laboratory policy for handling specimens in the light of the recommendations provided.

1. Biorisk management checklist for laboratory managers and staff

The following checklist has been developed to provide guidance for laboratories that are receiving and processing specimens from persons suspected or confirmed to be infected with influenza A (H1N1).

The list is not intended to be exhaustive but provides a starting point in ensuring that laboratories are prepared for the receipt of specimens and any additional workload that could arise from the heightened surveillance for infected persons and from the clinical diagnostic concerns in the WHO pandemic phases.

Other essential resources will include any local and national legislation, together with:

1. WHO *Laboratory Biosafety Manual, 3rd edition*, 2004

2. *CWA15793 Laboratory Biorisk Management*, 2008

Checklist for laboratory managers and staff

Biorisk Management System	1. Adequate management resources (e.g. time, funds) are available 2. Staff have been advised that maintaining a safe workplace is of primary importance and procedures must be followed and no shortcuts taken despite potentially increased workloads

	3. Sufficient trained staff and other resources are available, including: • Management • Scientific staff • Specialist staff, e.g. biosafety officer (BSO) • Support staff, e.g. waste management, cleaners, maintenance, transport 4. Staff are available to cover additional working hours (e.g. evenings, weekends) 5. Reviewed and updated protocols and working practice policies are available and communicated (e.g. safe work practices, decontamination) 6. Relevant sources of information on good biosafety practices have been identified and reviewed (e.g. WHO *Laboratory Biosafety Manual*, 3rd edition)
Risk Assessment	1. Working practices including spills and aerosol generating activities are addressed 2. Management of additional numbers of specimens, staff and other abnormal working conditions / hours are considered 3. Infection control in the workplace (e.g. sneezing, cleaning) is reviewed and staff has been alerted 4. Illness in the workforce and significant staff absence is included
Biological Agents and Toxin Inventory and Information	1. A system to inventory specimens and cultures is in place and regularly updated 2. Sufficient storage capacity for specimens and cultures is available 3. specimens are adequately labeled and can be identified
General Safety	1. Good housekeeping practices are in place and the laboratory is clean and tidy 2. A review of general working conditions has been conducted (e.g. electrical safety, fire safety)
Personnel and Competency	1. Training and awareness plans as well as Standard Operating Procedure (SOP) compliance programmes are in place for all staff 2. Trained and competent personnel are available, including any additional / temporary staff members required 3. Only competent personnel who have received training specific to influenza A (H1N1) can work with potentially positive materials; including scientific and support staff
Good Microbiological Technique	1. Procedures have been reviewed for hazardous activities (e.g. generation of aerosols, use of centrifuges / cabinets, waste management) 2. Validated, edited and updated SOPs ensuring clear, concise and consistent processes are followed
Personal Protective Equipment (PPE)	1. Adequate and appropriate PPE has been identified, supplies (masks, respirators, lab coats, etc.) are available and staff are trained in their use
Human Factors	1. Provision has been made for adequate rest and other welfare issues (e.g. workplace stress, concern for family members) have been set in place 2. Regular team meetings and briefings have been set in place to ensure good communication will be maintained 3. All staff (i.e. scientific and support) are informed of the risk associated with influenza A (H1N1) infection, symptoms, reporting procedures and

	support from the facility/organization in the event of illness
Health Care	1. Vaccination needs and provision schemes are identified 2. A policy for availability, use, and training for the administration of antivirals is in place 3. Any symptoms to be reported immediately to laboratory management or other entities are identified
Emergency Response and Contingency Planning	1. Stable power supply with adequate backup (e.g. generators) is functional, validated and available 2. Laboratory capacity from other departments in the event of need is available and accessible 3. Fire, flooding and other risks will not be increased as a result of the changed working conditions
Accident / Incident Investigation	1. Process for incident reporting and investigation exists
Facility Physical Requirements	1. Sufficient space, including storage of specimens and other materials (e.g. waste) is available
Equipment and Maintenance	1. Access to appropriate biological safety cabinets (BSCs) and other essential equipment is ensured 2. Ensure equipment has been adequately maintained and validated, preferably with a stockpile of replacement parts
Decontamination, Disinfection and Sterilization	1. Procedures for adequate decontamination of all waste and other materials are identified 2. Adequate supplies of required disinfectants and other materials are ensured
Transport Procedures	1. Adequate supplies, including appropriate shipping containers, are available for transport 2. Procedures are in place for receipt and opening of specimens 3. Anyone sending specimens is aware of the required transport procedures 4. Procedures are in place to ensure materials can be transported safely to and from the laboratory
Security	1. Good, general security controls are in place including those required to address abnormal working hours and conditions (e.g. additional personnel)

2. Recommendations addressing minimal/essential working conditions associated with specific manipulations in laboratory settings

The additional recommendations provided below address minimal/essential working conditions associated with specific manipulations in laboratory settings:

Routine laboratory procedures, including diagnostic work and PCR analysis

Diagnostic laboratory work and PCR analysis on clinical specimens from patients who are suspected or confirmed cases of influenza A (H1N1) infection should be conducted adopting practices and procedures described for basic laboratory - Biosafety Level 2 (BSL2), as detailed in the WHO *Laboratory biosafety manual*, 3rd edition.

Examples of routine laboratory procedures that require BSL2 include:

- Diagnostic testing of serum, blood (including haematology and clinical chemistry), respiratory tract specimens, or other specimens
- Manipulations involving neutralized or inactivated (lysed, fixed, or otherwise treated) virus particles and/or incomplete, non-infectious portions of the viral genome
- Routine examination of mycotic and bacterial cultures

When handling and processing specimens, good laboratory practices should be followed:

- Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in the laboratory working areas.
- Appropriate personal protective equipment should be worn.
- All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets.
- All manipulations of potentially infectious materials, including those that may cause splashes, droplets, or aerosols of infectious materials (e.g. loading and unloading of sealed centrifuge cups, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials whose internal pressure may be different from the ambient pressure) should be performed in appropriately maintained and validated biological safety cabinets (BSCs). Use of Class II BSCs should be considered to protect work surface materials as well as personnel and the environment.
- The use of hypodermic needles and syringes should be limited. They must not be used as substitutes for pipetting devices or for any purpose other than parenteral injection or aspiration of fluids from laboratory animals. Contaminated sharps should always be collected in puncture-proof containers fitted with covers and treated as infectious waste.
- Mouth pipetting must be strictly forbidden.
- Adequate biohazard containers should be available for appropriate disposal of contaminated materials and be located in the immediate working area.
- Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day. Generally, freshly prepared bleach solutions are appropriate for dealing with biohazardous spillage. More information on disinfection and sterilization is provided in the WHO *Laboratory biosafety manual, 3rd edition.*
- Personnel must wash their hands often – especially after handling infectious materials and animals, before leaving the laboratory working areas, and before eating.
- Personal protective equipment must be removed before leaving the laboratory.

When a procedure or process cannot be conducted within a BSC, an appropriate combination of PPE (including respiratory and eye protection) and physical containment devices (e.g. centrifuge safety cups or sealed rotors) MUST be used.

Viral isolation

Viral isolation on clinical specimens from patients who are suspected or confirmed cases of influenza A (H1N1) infection should only be performed in laboratories capable of meeting the following additional essential (minimal) containment requirements:

- A controlled ventilation system maintains directional airflow into the laboratory room.
- Exhaust air from the laboratory room is not recirculated to other areas within the building. Air should be HEPA filtered, if reconditioned and recirculated within the laboratory. When exhaust air from the laboratory is discharged to the outdoors, it must be dispersed away from occupied buildings and air intakes. This air may be discharged through HEPA filters.
- All manipulations of infectious or potentially infectious materials must be performed in appropriately maintained and validated BSCs.
- Access to the laboratory is restricted when work is in progress.
- Practices recommended for containment laboratories — Biosafety Level 3 in the WHO *Laboratory biosafety manual*, 3rd edition, are rigorously followed.
- Laboratory workers should wear protective equipment, including disposable gloves, solid-front or wrap-around gowns, scrub suits, or coveralls with sleeves that fully cover the forearms, head coverings, shoe covers or dedicated shoes, eye protection (goggles or face shield), and respiratory protection (fit-tested particulate respirator, e.g. EU FFP2, US NIOSH-certified N95 or equivalent, or higher protection), because of the risk of aerosol or droplet exposure.
- A dedicated hand-wash sink should be available in the laboratory.
- Centrifugation of specimens should be performed using sealed centrifuge rotors or sample cups. These rotors or cups should be loaded and unloaded in a BSC.
- All materials transported within and between laboratories should be placed in a secondary container to minimize the potential for breakage or a spill. An example includes transfer of materials from the biological safety cabinet to an incubator and vice versa. Specimens leaving the BSC should be surface decontaminated.

Animal work

The following activities require animal facility — Biosafety Level 3 facilities and work practices, as detailed in the WHO *Laboratory biosafety manual*, 3rd edition.

- Inoculation of animals for potential recovery of the agent from influenza A (H1N1) specimens
- Any protocol involving animal inoculation for confirmation and/or characterization of putative influenza A (H1N1) agents

Appropriate disinfectants

- Disinfectants with proven activity against enveloped viruses include chlorine, alcohol, peroxygen, quaternary ammonium compounds and phenolic compounds and should be adequate if used according to manufacturer's recommendations.

- Work surfaces and equipment should be decontaminated after specimens are processed. More information on disinfection and sterilization is provided in the WHO *laboratory biosafety manual*, 3rd edition.

Contaminated waste

- Contaminated sharps should always be collected in puncture-proof containers fitted with covers and treated as infectious waste.

- The disposal of infectious laboratory waste is subject to various local, regional, national and international regulations. Handling, transport and disposal of infectious laboratory waste should adhere to applicable regulations. More information on disposal of infectious waste is provided in the WHO *laboratory biosafety manual*, 3rd edition.

Occupational health

- All laboratory personnel should immediately report any symptoms of influenza-like illness to their medical authorities so that they can be given medical advice for prophylaxis and/or treatment.

- Incidents or accidents involving potential or actual exposure to influenza A (H1N1) should be immediately reported and any affected area/equipment appropriately decontaminated. Personnel who may have been exposed should to seek medical advice for prophylaxis and/or treatment as soon as possible.

Referral of specimens to laboratories with appropriate containment measures in place

Laboratories not able to meet the above biosafety recommendations should consider transferring specimens to regional reference laboratories or WHO Collaborating Centres for influenza as appropriate.

Shipping requirements for influenza A (H1N1) specimens

Shipping requirements for influenza A (H1N1) specimens are described under: http://www.who.int/csr/resources/publications/swineflu/instructions-shipments/en/index.html