Faculty Biosafety Committee (FBC)
Faculty of Health Sciences
University of Cape Town

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BIOSAFETY GUIDELINES FOR RESEARCH ON COVID-19 AND SARS-COV-2

Research on COVID-19 and its aetiologic agent, SARS-CoV-2, is deemed "essential" at UCT. The Health & Safety (H&S) and Biosafety risks are, however, significant and carry important practical considerations for research design, and subsequent laboratory management and maintenance. To ensure best practice, we have consulted with H&S structures within UCT's Institute of Infectious Disease & Molecular Medicine (IDM) and a number of international institutions which have developed guidelines for working with infectious materials from COVID-19 patients. The following represent the consensus guidelines extracted from that process and are heavily informed by the ***Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*** developed by the US Centers for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html).

Guidelines which will apply to all proposed laboratory work:

1. SARS-CoV-2 is a biosafety level (BSL) 3 pathogen. Propagative work (for example virus culture, virus isolation or neutralization assays) must be conducted in a BSL-3 laboratory using BSL-3 practices (see point **3** below).
2. The following procedures can be conducted under BSL-2 conditions (or BSL-2^{+} conditions, where risk of aerosolization is significant):

   Note that Initial specimen processing (before inactivation) must be performed in a validated biological safety cabinet under Biosafety Level 2 (BSL-2) containment or equivalent primary containment device.

   a) Routine Diagnostic Testing

   Routine diagnostic testing of clinical specimens can be performed in a BSL-2 laboratory using standard procedures and precautions. Such activities include the following (*provided the risk of generating aerosols is minimal or zero*):

   i. Using automated instruments and analysers
   ii. Processing initial samples (respiratory, serum/blood, tissue, stool, urine)
   iii. Staining and microscopic analysis of fixed smears
   iv. Examination of bacterial cultures
   v. Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
   vi. Final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container)
   vii. Using inactivated specimens, such as specimens in nucleic acid extraction buffer
   viii. Performing electron microscopic studies with glutaraldehyde-fixed grids

   b) Decentralized and Point-of-Care Testing

   For diagnostic testing of specimens conducted outside of a BSL-2 laboratory, such as rapid respiratory testing performed at the point of care, use standard precautions to provide a barrier between the specimen and personnel during specimen manipulation. For collection and testing of blood for antibodies using Rapid Test Devices (RTDs), standard precautions apply. For additional information on specimen collection, handling, and testing refer to ***Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19)*** (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) or ***Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs)*** (https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html).

   c) Procedures with a High Likelihood of Generating Droplets or Aerosols

   i. Procedures with a high likelihood of generating aerosols or droplets must be done in a certified Class II Biological Safety Cabinet (BSC). Additional precautions may also be used to provide a barrier between the specimen and personnel; examples of these additional precautions include personal protective equipment (PPE) such as a surgical respirator or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

   ii. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood of generating infectious droplets and aerosols.

d) Environmental Specimen Testing

i. Procedures that concentrate viruses, such as precipitation or membrane filtration, must be performed under BSL2^{+} conditions; that is, in a laboratory with unidirectional airflow and BSL-3 precautions, including respiratory protection and a designated area for donning and doffing PPE. The donning and doffing space should not be in the workspace. Work should be performed in a certified Class II BSC.

ii. This guidance is intended only for those laboratories that perform virus concentration procedures, such as wastewater/ sewage surveillance testing, not public health or clinical diagnostic laboratories that handle COVID-19 clinical specimens or laboratories that perform culture and isolation of SARS-CoV-2. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes or large volumes, and the likelihood to generate infectious droplets and aerosols.

3. For procedures requiring BSL-3 containment: existing BSL-3 operating and safety procedures will need to be modified significantly to ensure maintenance of acceptable biosafety standards and the safety of personnel. These modifications will include:
   a) SARS-CoV-2 (Culture) work must occur within a BSL-3 laboratory, preferably one which is used solely or primarily for this purpose; if possible, it is preferable to limit work to a specific area within the designated BSL-3 laboratory (*i.e*., room with biological safety cabinet).
   b) No other personnel will be allowed into the laboratory while SARS-CoV-2 work is ongoing; to ensure this is managed strictly, all users must complete – and adhere to – a laboratory booking schedule and/ or a record must be maintained providing clear indication of the work planned or performed.
   c) A dedicated incubator and freezer space must be allocated to SARS-CoV-2 samples.
   d) In addition to standard BSL-3 PPE, all personnel working with SARS-CoV-2 must wear eye protection.
   e) Tyvek suits and respirators must be worn; given the depletion of PPE under the COVID-19 pandemic, the use of the suits and respirators can be extended beyond single use, unless these items are compromised in which case they must be discarded immediately. For suits, use can be extended up to ONE WEEK. For respirators, users are encouraged to consult the relevant CDC Guidelines (Appendix C, attached) which stipulate the following (for N95 respirators):

      i. Discard respirators following use during aerosol generating procedures.
      ii. Discard respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
      iii. Hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.
      iv. Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).
      v. Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene as described above.
      vi. Use a pair of clean (non-sterile) gloves when donning a used respirator and performing a user seal check. Discard gloves after the respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.

   f) Separate consumables must be dedicated for SARS-CoV-2 work and must be labelled accordingly.

4. Detailed SOPs, including Risk Assessments for every step, must be prepared for handling all SARS-CoV-2-infected material and must be submitted for formal H&S risk assessment. For this purpose, a template developed by WHO is strongly recommended (***Appendix B***); see https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2

The above is very important. The FBC continues to receive applications which contain generic statements and generalizations such as "Appropriate precautions will be employed by all personnel in the collection, shipping and handling of all specimens for this study, as currently recommended by the CDC and the NIH or other applicable agencies." Such statements will not be considered adequate by the FBC or IBC: the requirement to submit a detailed risk assessment is to ensure that the applicant and research team involved is cognizant of the relevant precautions and processes and can apply them in their own context. For this reason, mere

reference to established guidelines and protocols is not sufficient; applications will be returned, causing delays in the approval process.

5. To expedite review, applications for Faculty Biosafety Committee (FBC) approval should be submitted simultaneously for H&S and FBC approval. FBC applications must be sent to Sidney.Engelbrecht@uct.ac.za with a copy to the FBC Chair (digby.warner@uct.ac.za).
6. Thereafter, FBC-reviewed proposals will be submitted automatically to UCT's Institutional Biosafety Committee (IBC) for assessment.
7. ***No work should be initiated without IBC approval***.

Additional notes:

1. **Opinion from international institutions approached is that standard animal BSL3 protections may not be enough for SARS-CoV-2**; therefore, no applications for animal work with SARS-CoV-2 will be considered.
2. The additional PPE requirements of SARS-CoV-2/ COVID-19 work must be carefully considered. BSL-2 and BSL-3 laboratories carry limited stocks of PPE. This, coupled with the prevailing uncertainty about the future availability of replacement stocks (from vendors and other sources), means that the long-term sustainability of any research work might be precarious. For this reason:
   a. the risk/ benefit analysis of any proposal should include an assessment of the impact of PPE-intensive research activities on the local availability of these items; and
   b. **all FBC applications will be required to include a clear statement regarding the ability to maintain adequate PPE for the work proposed**.

ESSENTIAL REFERENCES (see Appendices A-D, attached):

1. ***Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)***; US Centers for Disease Control and Prevention https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
2. ***Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV) Interim Guidance***, 13 May 2020; WHO [Note: updated version]
3. ***Cleaning and disinfection of environmental surfaces in the context of COVID-19 Interim Guidance,*** 15 May 2020; WHO [Note: updated version]
4. ***Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings***; US Centers for Disease Control and Prevention https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

APPENDIX A

CDC GUIDELINES ON COVID-19 LABORATORY BIOSAFETY

Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Summary of Recent Changes

Revisions made on March 31, 2020 include recommendations for:

- Environmental Specimen testing guidance related to procedures that concentrate viruses

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March 31, 2020

Until more information becomes available, precautions should be taken in handling specimens that are suspected or confirmed for SARS-CoV-2. Timely communication between clinical and laboratory staff is essential to minimize the risk incurred in handling specimens from patients with possible SARS-CoV-2 infection. Such specimens should be labeled accordingly, and the laboratory should be alerted to ensure proper specimen handling. General and specific biosafety guidelines for handling SARS-CoV-2 specimens are provided below. For additional information on handling SARS-CoV-2 specimens, refer to the Laboratory Biosafety Frequently Asked Questions.

General Guidance

All laboratories should perform a site-specific and activity-specific risk assessment to identify and mitigate risks. Risk assessments and mitigation measures are dependent on:

- The procedures performed
- Identification of the hazards involved in the process and/or procedures
- The competency level of the personnel who perform the procedures
- The laboratory equipment and facility
- The resources available

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard Precautions include hand hygiene and the use of personal protective equipment (PPE), such as laboratory coats or gowns, gloves, and eye protection.

Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste.

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Routine Diagnostic Testing

Routine diagnostic testing of specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:

- Using automated instruments and analyzers
- Processing initial samples
- Staining and microscopic analysis of fixed smears
- Examination of bacterial cultures
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container)
- Using inactivated specimens, such as specimens in nucleic acid extraction buffer
- Performing electron microscopic studies with glutaraldehyde-fixed grids

Decentralized and Point of Care Testing

For diagnostic testing of specimens conducted outside of a BSL-2 laboratory, such as rapid respiratory testing performed at the point of care, use Standard Precautions to provide a barrier between the specimen and personnel during specimen manipulation. For additional information on specimen collection, handling, and testing refer to Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs).

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Procedures with a High Likelihood to Generate Droplets or Aerosols

For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols.

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Environmental Specimen Testing

Procedures that concentrate viruses, such as precipitation or membrane filtration, can be performed in a BSL-2 laboratory with unidirectional airflow and BSL-3 precautions, including respiratory protection and a designated area for donning and doffing PPE. The donning and doffing space should not be in the workspace. Work should be performed in a certified Class II BSC.

This guidance is intended for only those laboratories that perform virus concentration procedures, such as wastewater/sewage surveillance testing, not public health or clinical diagnostic laboratories that handle COVID-19 clinical specimens or laboratories that perform culture and isolation of SARS-CoV-2. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes or large volumes, and the likelihood to generate infectious droplets and aerosols.

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Virus Isolation

Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens should only be conducted in a Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs.

Decontamination

Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2 . Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

Laboratory Waste Management

Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs any additional packaging or disinfection procedures

Specimen Packing and Shipping

Pack and ship suspected and confirmed SARS-CoV-2 patient specimens, cultures, or isolates as UN 3373 Biological Substance, Category B, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations . Personnel must be trained to pack and ship according to the regulations and in a manner that corresponds to their function-specific responsibilities.

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Resources

- CDC Laboratory Biosafety Frequently Asked Questions
- EPA List N: Disinfectants for Use Against SARS-CoV-2

- Saf-T-Pak Packaging Checklist, see Category B
- IATA Packing Instructions 650 for UN 3373
    - Click on “Infectious substances” and there is an option to download the packing instructions.
- Labels for UN 3373
    - When using cold pack (CDC) – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
    - When using dry ice (CDC) – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- CDC Schematic for packaging, UN 3373 Category B
- WHO Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)
- APHL Risk Assessment Best Practices
- WHO Laboratory Biosafety Manual, 3rd
- WHO Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)-World Health Organization
- CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions

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Page last reviewed: March 31, 2020
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

APPENDIX B

WHO GUIDELINES ON LABORATORY BIOSAFETY FOR WORK WITH NOVEL CORONAVIRUS

Laboratory biosafety guidance related to coronavirus disease (COVID-19)

Interim guidance
13 May 2020

World Health Organization

Background

The purpose of this document is to provide interim guidance on laboratory biosafety related to the testing of clinical specimens of patients that meet the case definition of coronavirus disease (COVID-19).

This version is an update to the interim guidance adding recommendations on point of care (POC) or near-POC assays *(1)*.

Highlights of COVID-19 laboratory biosafety

- All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.
- Initial processing (before inactivation) of specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test [NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2).
- Point of care (POC) or near-POC assays can be performed on a bench without employing a BSC, when the local risk assessment so dictates and proper precautions are in place.
- Propagative work (for example virus culture or neutralization assays) should be conducted in a containment laboratory with inward directional airflow (BSL-3).
- Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds).
- Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance Category B". Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans".

Laboratory biosafety

It is essential to ensure that health laboratories adhere to appropriate biosafety practices. Any testing for the presence of SARS-CoV-2, the virus that causes COVID-19 or of clinical specimens from patients meeting the suspected case definition *(2)* should be performed in appropriately equipped laboratories, by staff trained in the relevant technical and safety procedures. National guidelines on laboratory biosafety should be followed in all circumstances. For general information on laboratory biosafety guidelines, see the WHO *Laboratory biosafety manual: third edition (3)* in the interim before the fourth edition is released.

Key points

- Each laboratory should conduct a local (that is, institutional) risk assessment to ensure it is competent to safely perform the intended testing with appropriate risk control measures in place as exemplified in Annex II.
- When handling and processing specimens, including blood for serological testing, laboratory practices and procedures that are basic to good microbiological practice and procedure (GMPP) should be followed.
- The handling and processing of specimens from cases with suspected or confirmed COVID-19 infection that are intended for additional laboratory tests, such as haematology or blood gas analysis, should follow standard guidelines without additional measures.
- Non-propagative diagnostic laboratory work, including sequencing and NAAT, on clinical specimens from patients who are suspected or confirmed to be infected with COVID-19, should be conducted adopting the practices and procedures of "core requirements",[1] as detailed in Annex I, and an appropriate selection of "heightened control measures",[2] as informed by the local risk assessment. In the interim, basic Biosafety Level 2 (BSL-2) suitable for diagnostic services in the WHO *Laboratory biosafety manual: third edition (3)* remains appropriate until the fourth edition replaces it.

[1] **Core requirements:** A set of minimum requirements defined in the 4th edition of the WHO *Laboratory biosafety manual* to describe a combination of risk control measures that are both the foundation for, and an integral part of, laboratory biosafety. These measures reflect international standards and best practice in biosafety that are necessary to work safely with biological agents, even where the associated risks are minimal.

[2] **Heightened control measures:** A set of risk control measures that may need to be applied in a laboratory facility because the outcome of a risk assessment indicates that the biological agents being handled and/or the activities to be performed with them are associated with a relatively high risk that cannot be acceptable solely with the core requirements.

- Handling of material with high concentrations of live virus (such as when performing virus propagation, virus isolation or neutralization assays) or large volumes of infectious materials should be performed **only by properly trained and competent personnel in laboratories meeting additional essential containment requirements and practices**, that is, BSL-3.
- Initial processing (before inactivation) of all specimens, including those for sequencing and NAAT, should take place in an appropriately maintained and validated BSC or primary containment device.
- The external lysis buffer of the listed common RNA extraction kits is effective in inactivating the COVID-19 virus without heat or other additional means (*4*).
- Appropriate disinfectants with proven activity against enveloped viruses should be used for the recommended contact time, at the correct dilution and within the expiry date after the working solution is prepared.
- All technical procedures should be performed in a way that minimizes the generation of aerosols and droplets *(5)*.
- Appropriate personal protective equipment (PPE), as determined by a detailed risk assessment, should be worn by all laboratory personnel handling these specimens.
- Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance Category B". Viral cultures or isolates should be transported as Category A UN2814, "infectious substance, affecting humans" *(6)*.

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

The additional recommendations provided in this section address the minimal/essential working conditions associated with specific manipulations in laboratory settings.

1. Risk assessment

Risk assessment is a systematic process of gathering information and evaluating the likelihood and impact of exposure to or release of workplace hazard(s), and determining the appropriate risk control measures to reduce the risk to an acceptable level. Hazards alone do not pose a risk to humans or animals. The types of equipment used and the procedure(s) performed with the biological agent also play a role.

It is highly recommended to start by conducting a local risk assessment for each process step, that is, from sample collection, sample reception, clinical testing, polymerase chain reaction (PCR) to virus isolation (only when and where applicable). Specific hazards will be identified for each process step, such as aerosol exposure during sample processing; eye splash during sample processing; infectious culture material spill; and leaking sample receptors. Each process step has its own assessed grade of risk. For each identified risk, appropriate risk control measures, including the following recommendations, should be selected and implemented, to mitigate the residual risks to an acceptable level.

Particular consideration should be given to risks related to human factors. The likelihood of errors and incidents are higher when staff training is insufficient and staff members are under pressure to produce rapid results.

A risk assessment template is provided in Annex II; this is intended to serve as an example and to facilitate the process.

2. Routine laboratory procedures, including non-propagative diagnostic work and PCR analysis

Non-culture-based diagnostic laboratory work and PCR analysis on clinical specimens from patients who are suspected or confirmed to be infected with the virus responsible for COVID-19 should be conducted adopting practices and procedures described for conventional clinical and microbiology laboratories as described in the "core requirements" (see Annex I).

However, all manipulations of potentially infectious materials, including those that may cause splashes, droplets, or aerosols of infectious materials (for example, 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 BSCs or primary containment devices, by personnel with demonstrated capability.

Examples of routine laboratory procedures include:

- diagnostic testing of serum; blood (including haematology and clinical chemistry); respiratory specimens such as nasopharyngeal and oropharyngeal swabs, sputum and/or endotracheal aspirate or bronchoalveolar lavage; stool; or other specimens;
- routine examination of mycotic and bacterial cultures developed from respiratory tract specimens. When handling and processing specimens, "core requirements" (see Annex I), including GMPP, should be followed at all times, including but not limited to those under the following subheadings. More details are explained and demonstrated in the WHO Biosafety video series *(7)*.

3. Point of care (POC) or near-POC assay

Point of care or near-POC assays, including those using polyvalent platforms such as GeneXpert, were recently released for COVID-19 testing of samples such as nasopharyngeal swab, nasal wash and aspirate. Each POC molecular platform uses different procedures to process samples and it is difficult to generalise the safety recommendations. There still are chances of spills, especially when staff are not adequately trained and at the same time are under immense pressure to deliver rapid results.

It is deemed, however, that sample manipulation and the level of aerosol generation would be minimal *(8)*. The United States Food and Drug Administration has authorized the use of the GeneXpert tests outside of BSL-2 laboratories and patient care settings (*1*).

They could be performed on a bench without employing a BSC, when the local risk assessment so dictates and the following conditions are fully met:

- performed on a diaper or large paper towel **in a well-ventilated area** free of clutter, where there are no documents, computers or personal stuff
- appropriate PPE worn similar to other manual testing, such as but not limited to a full-length long (elastic) sleeved lab coat, safety goggles or glasses, and suitable disposable gloves
- risk assessment should inform the use of respiratory protection as a supplementary precaution
- staff well trained in GMPP
- no rush or increased pressure for test turnaround time
- a validated infectious waste process including excess specimens

If the existing GeneXpert or similar platform of the tuberculosis programme is to be temporarily shared for COVID-19 testing, the equipment should be already installed in a suitable area with sufficient ventilation (*9*). In this case, there is no particular need to relocate it. Should the equipment have been in use for non-respiratory disease programmes, such as HIV/AIDS, it is important to ensure proper ventilation before starting the test for COVID-19.

4. Use of appropriate disinfectants

While little is known about this novel virus, the comparable genetic characteristics between the virus responsible for COVID-19 and MERS-CoV suggest that the COVID-19 virus may be susceptible to disinfectants with proven activity against enveloped viruses, including sodium hypochlorite (bleach; for example, 1000 parts per million [ppm] (0.1%) for general surface disinfection and 10 000 ppm (1%) for disinfection of sample spills); 62–71% ethanol; 0.5% hydrogen peroxide; quaternary ammonium compounds; and phenolic compounds, if used according to the manufacturer's recommendations. Other biocidal agents such as 0.05–0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate can be less effective.

Particular attention should be paid not only to the selection of the disinfectant but also the contact time (for example, 10 minutes), dilution (that is, concentration of the active ingredient), shelf-life and expiry date after the working solution is prepared.

COVID-19 virus and human coronaviruses in general are known to persist on inanimate surfaces such as metal, glass or plastic for up to 7 and 9 days, respectively *(10, 11)*.

5. Viral isolation

Unless the country decides otherwise, viral isolation on clinical specimens from patients who are suspected or confirmed to be infected with the virus responsible for COVID-19 should be performed only in laboratories capable of meeting the following additional containment criteria:

- a controlled ventilation system maintains inward directional airflow into the laboratory room;
- exhaust air from the laboratory room is not recirculated to other areas within the building. Air must be HEPA (high-efficiency particulate air) 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 should be discharged through HEPA filters;
- a dedicated hand-wash sink is available in the laboratory;
- all manipulations of infectious or potentially infectious materials must be performed in appropriately maintained and validated BSCs;
- 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; and eye protection (goggles or face shield). Risk assessment should inform the use of respiratory protection (fit-tested particulate respirator, for example, EU FFP2, US 6 NIOSH-certified N95 or equivalent, or higher protection);
- 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.

6. Additional risks associated with virus isolation studies

Certain experimental procedures may carry additional risks of virus mutations with possible increased pathogenicity and/or transmissibility, or viruses with altered antigenicity or drug susceptibility. Specific risk assessments should be conducted, and specific risk-reduction measures adopted, before any of the following procedures are conducted:

- coinfection of cell cultures with different coronaviruses, or any procedures that may result in a coinfection and in turn recombination;
- culture of viruses in the presence of antiviral drugs;
- deliberate genetic modification of viruses.

7. Work with animals infected with the virus responsible for COVID-19

The following activities require an animal facility – BSL-3 facilities and work practices, as detailed in the WHO *Laboratory biosafety manual*, 3rd edition *(3)*:

- inoculation of animals for potential recovery of the virus responsible for COVID-19;
- any protocol involving animal inoculation for confirmation and/or characterization of the COVID-19 virus.

8. Referral of specimens to laboratories with appropriate risk control measures in place

Laboratories that are not able to meet the above biosafety recommendations should consider transferring specimens to national, regional, or international referral laboratories with COVID-19-detection capacity that can meet the biosafety requirements.

Packaging and shipment

All materials transported within and between laboratories should be placed in a secondary packaging, to minimize the potential for breakage or a spill. Specimens leaving the BSC should be surface decontaminated. Detailed guidance is provided in the WHO Biosafety video series *(7)*, in particular, *Good microbiological practices and procedures (GMPP) 7: transport*.

Transport of specimens within national borders should comply with national regulations. Cross-boundary transport of specimens of the virus responsible for COVID-19 should follow the United Nations model regulations, *Technical instructions for the safe transport of dangerous goods by air (Doc 9284)* of the International Civil Aviation Organization *(12)*, for airlifted transport, and any other applicable regulations depending on the mode of transport being used. More information may be found in the WHO *Guidance on regulations for the transport of infectious substances 2019-2020* (applicable as from 1 January 2019) *(6)*. A summary on transport of infectious substances can also be found in Tool box 4 of the WHO handbook, *Managing epidemics: key facts about deadly diseases (13)*.

Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance Category B", when they are transported for diagnostic or investigational purposes. Viral cultures or isolates should be transported as Category A UN2814, "infectious substance, affecting humans" *(6)*. All specimens being transported (whether UN3373 or UN2814) should have appropriate packaging, labelling, and documentation, as described in the documents mentioned earlier.

References

1. US Food and Drug Administration (FDA). Emergency Use Authorization (EUA) information, and list of all current EUAs. (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization, accessed 3 May 2020).

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Annex I: Core requirements

1. Good microbiological practice and procedure (GMPP)

Best practice

• Never store food or drink, or personal items such as coats and bags in the laboratory. Activities such as eating, drinking, smoking, and applying cosmetics are only to be performed outside the laboratory.

• Never put materials, such as pens, pencils or gum in the mouth while inside the laboratory, regardless of having gloved hands or not.

• Wash hands thoroughly *(14)*, preferably with warm running water and soap, after handling biological material and/or animals, before leaving the laboratory or when hands are known or believed to be contaminated.

• Ensure open flames or heat sources are never placed near flammable supplies and are never left unattended.

• Ensure that cuts or broken skin are covered before entering the laboratory.

• Before entering the laboratory, ensure that there are adequate supplies of laboratory equipment and consumables, including reagents, PPE and disinfectants, and that these items are suitable for the activities envisaged.

• Ensure that supplies are stored safely and according to storage instructions to reduce accidents and incidents such as spills, trips and falls.

• Ensure proper labelling of all biological agents and chemical and radioactive material.

• Protect written documents from contamination using barriers (such as plastic coverings), particularly those that may need to be removed from the laboratory.

• Ensure that the work is performed with care and without hurrying. Avoid working when fatigued.

• Keep the work area tidy, clean and free of non-essential objects and materials.

• Prohibit the use of earphones, which can distract personnel and prevent equipment or facility alarms from being heard.

• Cover or remove any jewellery that could tear gloves, easily become contaminated or become fomites. Cleaning and decontamination of jewellery or spectacles should be considered, if such items are worn regularly.

• Refrain from using portable electronic devices (for example, mobile telephones, tablets, laptops, flash drives, memory sticks, cameras, or other portable devices, including those used for DNA/RNA sequencing) when not specifically required for the laboratory procedures being performed.

• Keep portable electronic devices in areas where they cannot easily become contaminated or act as fomites that transmit infection. Where close proximity of such devices to biological agents is unavoidable, ensure the devices are either protected by a physical barrier or decontaminated before leaving the laboratory.

Technical procedures

• Avoid inhalation of biological agents. Use GMPP techniques to minimize the formation of aerosols and droplets when manipulating specimens.

• Avoid ingestion of biological agents and their contact with the skin and eyes.

• Always wear disposable gloves when handling specimens.

• Avoid gloved hands coming into contact with the face.

• Shield or otherwise protect the mouth, eyes and face during procedures where splashes may occur.

• Wherever possible, replace any glassware with plasticware.

• If required, use scissors with blunt or rounded ends rather than pointed ends.

• Handle any sharps, syringes or needles with care in order to prevent injury and injection of biological agents.

• Use ampoule openers for safe handling of ampoules.

• Never re-cap, clip or remove needles from disposable syringes.

• Dispose of any sharps materials (for example, needles, needles combined with syringes, blades, broken glass) in puncture-proof or puncture-resistant containers fitted with sealed covers.

• Preventing dispersal of biological agents:
  – discard specimens and cultures for disposal in leak-proof containers with the tops appropriately secured before disposal in dedicated waste containers;
  – consider opening tubes with disinfectant-soaked pad/gauze;
  – decontaminate work surfaces with a suitable disinfectant at the end of the work procedures and if any material is spilled or obviously contaminated;
  – ensure that the disinfectant is efficacious against the pathogen being handled and is left in contact with infectious waste materials long enough for complete inactivation.

2. Personnel competence and training

General familiarization and awareness training
General training should include an introduction to laboratory layout, codes of practice, local guidelines, safety manuals, risk assessments, legislative requirements, and emergency response procedures.

Job-specific training
• Training requirements may vary depending on the job functions.

• However, in general, all personnel involved in the handling of biological agents must be trained on GMPP.

• Competency and proficiency assessment must be used and verified before working independently, followed by regular review and refresher training.

• Relevant information such as new procedures must be updated and communicated to applicable personnel.

Safety and security training
• All personnel must be aware of the hazards present in the laboratory and their associated risks as well as safe working procedures, security measures, and emergency preparedness and response.

3. Facility design

• Ample space and a designated hand-washing basin must be provided, with appropriate restriction of access.

• Doors must be properly labelled, and laboratory walls, floors, and furniture must be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory.

• Laboratory ventilation, where provided (including heating/cooling systems and especially fans/local cooling split-system air-conditioning units – specifically when retrofitted) should ensure airflows do not compromise safe working. Consideration must be made for resultant airflow speeds and directions, and turbulent airflows should be avoided; this applies also to natural ventilation.

• Laboratory space and facilities must be adequate and appropriate for safe handling and storage of infectious and other hazardous materials, such as chemicals and solvents.

• Facilities for eating and drinking must be provided outside the laboratory, and first-aid-facilities must be accessible.

• Appropriate methods for decontamination of waste, for example disinfectants and autoclaves, must be available close to the laboratory.

• The management of waste must be considered in the laboratory design. Safety systems must cover fire, electrical emergencies, and emergency/incident response facilities, based on risk assessment.

• There must be a reliable and adequate electricity supply and lighting to permit safe exit.

• Emergency situations must be considered in the design, as indicated in the local risk assessment, and should include the geographical/meteorological context.

4. Specimen receipt and storage

• A specimen received by the laboratory must be accompanied by sufficient information to identify what it is, when and where it was taken or prepared, and which tests and/or procedures (if any) are to be performed.

• Consider unpacking the items in the BSC. Personnel unpacking and receiving specimens must be adequately trained on the hazards involved; how to adopt necessary precautions according to GMPP described earlier; how to handle broken or leaking containers; and how to handle spills and use disinfectants to manage any contamination.

• Specimens must be stored in containers with adequate strength, integrity, and volume to contain the specimen, and that are leakproof when the cap or stopper is correctly applied. Use plastic containers whenever possible that are free of any biological material on the outside of the packaging. In addition, containers should be correctly labelled, marked and recorded to facilitate identification, and made of an appropriate material for the type of storage required

• Inactivation methods must be properly validated whenever an inactivation step is used, before transferring the specimens to other areas for further manipulation, such as PCR analysis.

5. Decontamination and waste management

• Any surface or material known to be, or potentially be, contaminated by biological agents during laboratory operations must be correctly disinfected to control infectious risks.

• Proper processes for the identification and segregation of contaminated materials must be adopted before decontamination or disposal.

• Where decontamination is not possible in the laboratory area, or onsite, contaminated waste must be packaged in a leakproof fashion, for transfer to another facility with decontamination capacity.

6. Personal protective equipment

• Laboratory coats must be used in laboratories to prevent personal clothing from getting splashed or contaminated by biological agents. Laboratory coats must have long sleeves, preferably with elasticated or fitted cuffs, and must be

fastened when worn in the laboratory. Sleeves should never be rolled up. Coats must be long enough to cover the knees, but not trail on the floor. Where possible, the fabric of the laboratory coat should be splash-resistant. Laboratory coats must only be worn in designated areas. When not in use, they should be stored properly; they should not be hung on top of other laboratory coats, or kept in lockers or on hooks with personal items.

• Appropriate disposable gloves must be worn for all procedures that may involve planned or inadvertent contact with blood, body fluids or other potentially infectious materials. They must not be disinfected or reused, as exposure to disinfectants and prolonged wear reduces the integrity of the glove and decreases protection to the user. Gloves should always be inspected before use, to check that they are intact.

• Safety glasses or goggles, face shields (visors) or other protective devices must be worn whenever necessary to protect the eyes and face from splashes, impacting objects or artificial ultraviolet radiation. Eye protection devices can be re-used but must be cleaned each time after use. If splashed, devices must be decontaminated with an appropriate disinfectant.

• Footwear must be worn in the laboratory and must be of a design that minimizes slips and trips and reduces the likelihood of injury from falling objects and exposure to biological agents.

• Respiratory protection is generally not among the core requirements. In the present COVID-19 context, however, a local risk assessment should be conducted to determine whether the use of respiratory protection is needed, especially when procedures that may create aerosols and droplets will be performed outside the BSC, for example, centrifugation and handling leaking samples. These also include procedures that can cause splashes, such as: 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.

7. Laboratory equipment

When used effectively together with GMPP, the safe use of laboratory equipment will help to minimize the likelihood of exposure of personnel when handling or manipulating biological agents.

• To effectively reduce any associated risks with using laboratory equipment, the laboratory management must ensure that ample space is provided for its use. An adequate budget must also be available to operate and maintain the equipment. All staff working in the laboratory or who are responsible for maintaining equipment must be adequately trained and be able to demonstrate proficiency.

8. Emergency/incident response plan

• Even when carrying out low-risk work and following all core requirements for biosafety, incidents can still occur. To reduce the likelihood of exposure to/release of a biological agent, or to reduce the consequences of such incidents, a contingency plan must be developed that provides specific standard operating procedures (SOPs) to be followed in possible emergency scenarios that apply to the work and local environment. Personnel must be trained on these procedures and have periodic refresher training to maintain competency.

• First-aid kits, including medical supplies, such as bottled eye washes and bandages, must be available and easily accessible to personnel. These products must be checked routinely to ensure that they are within their use-by dates and are in sufficient supply.

• All incidents must be reported to the appropriate personnel promptly. Accidents and incidents must be documented, in line with national regulations where applicable. Any incident must be reported and investigated in a timely manner and taken into consideration when updating laboratory procedures and emergency response plans.

• Laboratory staff should have immediate access to spill kits, including those containing disinfectant. Depending on the size, location, concentration or volume of the spill, different protocols may be necessary. Written procedures for cleaning and decontaminating spills must be developed for the laboratory and followed by adequate training of personnel.

9. Occupational health

• The employer, through the laboratory director, must take responsibility for ensuring that the health of laboratory personnel is adequately monitored.

• Medical examination or health status information of the laboratory personnel may be required to verify whether it is safe for them to work in the laboratory.

Annex II: Risk assessment template

Although a qualitative approach to combining likelihood and severity parameters in a risk matrix is provided as a method for risk evaluation here, it is important to note that quantitative (for example, from simple numerical scoring schemes to complex mathematical models) and hybrid (semi-quantitative) methods can also be used for risk evaluation. Laboratories should use a risk-evaluation/assessment method that best meets their unique needs, including customized evaluation approaches, scoring methods and definitions of the parameters.

Although this template was primarily developed for biosafety risk assessment, it can also be used for general safety risk assessment of laboratory activities, especially when the biosafety and general safety risks are interlinked, for example, sample collection and transport.

Personnel on the risk assessment team may include but are not limited to, principal investigators, laboratory and quality managers, laboratory technicians and biosafety officers. Active involvement of the laboratory and/or organizational leadership is important in the risk assessment process.

Institution/Facility name	
Laboratory name	
Laboratory manager/Supervisor	
Project titles/Relevant standard operating procedures (SOPs)	
Date	

If using this template, complete all sections following the instructions in the grey boxes. The instructions and bullet points in the grey boxes can be copied into the text boxes beneath the instructions and used as prompts to gather and record the necessary site-specific information. The grey instruction boxes can then be deleted, and the text remaining will form a risk assessment draft. This draft must be carefully reviewed, edited as necessary, and approved by the members of the risk assessment team.

STEP 1. Gather information (hazard identification)

Instructions: *Provide a brief overview of the laboratory work and summarize the laboratory activities to be conducted that are included in the scope of this risk assessment.*	
Describe the biological agents and other potential hazards (for example, transmission, infectious dose, treatment/preventive measures, pathogenicity).	
Describe the laboratory procedures to be used (for example, culturing, centrifugation, work with sharps, waste handling, frequency of performing the laboratory activity).	
Describe the types of equipment to be used (PPE, centrifuges, autoclaves, biological safety cabinets [BSCs]).	
Describe the type and condition of the facility where work is conducted.	
Describe relevant human factors (for example, competency, training, experience and attitude of personnel).	
Describe any other factors that may affect laboratory operations (for example, legal, cultural, socioeconomic).	

STEP 2. Evaluate the risks

Instructions: *Describe how exposure and/or release could occur.*	
What potential situations are there in which exposure or release could occur?	
What is the likelihood of an exposure/release occurring? • Unlikely: to occur in the near future • Possible: to occur in the near future • Very likely: to occur in the near future	
What is the severity of the consequences of an exposure/release (negligible, moderate, severe)?	

Instructions: *Evaluate the risk and prioritize the implementation of risk control measures. Circle the initial (inherent) risk of the laboratory activities before additional risk control measures have been put in place.*
Note:
- *When assigning priority, other factors may need to be considered, for example, urgency, feasibility/sustainability of risk control measures, delivery and installation time and training availability.*
- *To estimate the overall risk, take into consideration the risk ratings for the individual laboratory activities/procedures, separately or collectively as appropriate for the laboratory.*

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequence of exposure/release	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium
Laboratory activity/procedure		**Initial risk (very low, low, medium, high, very high)**	**Is the initial risk acceptable? (yes/no)**	**Priority (high/medium/low)**

Select the overall **initial** risk.	☐ Very low	☐ Low	☐ Medium	☐ High	☐ Very high
Should work proceed without additional risk control measures?	☐Yes ☐No				

STEP 3. Develop a risk control strategy

Instructions: *List any requirements that have been prescribed by international and national regulations, legislation, guidelines, policies, and strategies on biosafety and biosecurity.*	
Describe the measures required by national legislation or regulations (if any).	
Describe the measures advised by guidelines, policies and strategies (if any).	

Instructions: *Describe the resources available for risk control and consider their applicability, availability, and sustainability in the local context, including management support.*	
Are resources sufficient to secure and maintain potential risk control measures?	
What factors exist that may limit or restrict any of the risk control measures?	
Will work be able to proceed without any of the risk control measures; are there alternatives?	

STEP 4. Select and implement risk control measures

Instructions: *Describe where and when risk control measures are needed, the level of **residual** (remaining) risk when these risk control measures are in place, and an assessment of the availability, effectiveness, and sustainability of the risk control measures.*

Laboratory activity/procedure	**Selected risk control measure(s)**	**Residual risk (very low, low, medium, high, very high)**	**Is the residual risk acceptable? (yes/no)**	**Are risk control measures available, effective, and sustainable? (yes/no)**

Instructions: *Evaluate the **residual** risk that remains after risk control measures have been selected, to determine whether that level of risk is now acceptable and whether work should proceed.*
*Circle the **residual** risk of the laboratory activities after risk control measures are in place.*

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequence of exposure/release	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium

Overall **residual** risk:	☐ Very low	☐ Low	☐ Medium	☐ High	☐ Very high

If the residual risk is still acceptable, further action is necessary, such as additional risk control measures, based on the initial risk evaluated in STEP 2, redefining the scope of work such that it is acceptable with existing risk control measures in place, or identifying an alternative laboratory with appropriate risk control strategies already in place that is capable of conducting the work as planned.

Should work proceed with selected risk control measures?	☐Yes ☐No
Approved by (name and title)	
Approved by (signature)	
Date	

Instructions: *Describe how to communicate risks and risk mitigation strategies to personnel. Provide a mechanism of communication within the laboratory. Describe the process and timeline for ensuring all identified risk control measures and that associated SOPs and training have been completed before starting the laboratory work.*	
Communication of the hazards, risks and risk control measures	
Implementation of risk control measures	
Training of personnel	
Operational and maintenance procedures	

STEP 5. Review risks and risk control measures

Instructions: *Establish a periodic review cycle to identify: changes in laboratory activities, biological agents, personnel, equipment or facilities; changes in knowledge of biological agents or processes; and lessons learnt from audits/inspections, personnel feedback, incidents, or near misses.*	
Frequency of the review	
Person to conduct the review	
Describe updates/changes	
Personnel/procedures to implement the changes	
Reviewed by (name and title)	
Reviewed by (signature)	
Date	

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

WHO reference number: WHO/WPE/GIH/2020.3

APPENDIX C

WHO GUIDELINES ON CLEANING AND DISINFECTION OF ENVIRONMENTAL SURFACES IN THE CONTEXT OF COVID-19

Cleaning and disinfection of environmental surfaces in the context of COVID-19

Interim guidance

15 May 2020

World Health Organization

Background

Coronavirus disease 2019 (COVID-19) is a respiratory infection caused by SARS-CoV-2 (COVID-19 virus). The COVID-19 virus is transmitted mainly through close physical contact and respiratory droplets, while airborne transmission is possible during aerosol generating medical procedures.[1] At time of publication, transmission of the COVID-19 virus had not been conclusively linked to contaminated environmental surfaces in available studies. However, this interim guidance document has been informed by evidence of surface contamination in health-care settings[2] and past experiences with surface contamination that was linked to subsequent infection transmission in other coronaviruses. Therefore, this guidance aims to reduce any role that fomites might play in the transmission of COVID-19 in health-care[3] and non-health care settings.[4]

Environmental surfaces in health-care settings include furniture and other fixed items inside and outside of patient rooms and bathrooms, such as tables, chairs, walls, light switches and computer peripherals, electronic equipment, sinks, toilets as well as the surfaces of non-critical medical equipment, such as blood pressure cuffs, stethoscopes, wheelchairs and incubators.[5] In non-healthcare settings, environmental surfaces include sinks and toilets, electronics (touch screens and controls), furniture and other fixed items, such as counter tops, stairway rails, floors and walls.

Environmental surfaces are more likely to be contaminated with the COVID-19 virus in health-care settings where certain medical procedures are performed.[6-8] Therefore, these surfaces, especially where patients with COVID-19 are being cared for, must be properly cleaned and disinfected to prevent further transmission. Similarly, this advice applies to alternative settings for isolation of persons with COVID-19 experiencing uncomplicated and mild illness, including households and non-traditional facilities.[9]

Transmission of the COVID-19 virus has been linked to close contact between individuals within closed settings, such as households, health facilities, assisted living and residential institution environments.[10] In addition, community settings outside of health-care settings have been found vulnerable to COVID-19 transmission events including publicly accessible buildings, faith-based community centres, markets, transportation, and business settings.[10,11] Although the precise role of fomite transmission and necessity for disinfection practices outside of health-care environments is currently unknown, infection prevention and control principles designed to mitigate the spread of pathogens in health-care settings, including cleaning and disinfection practices, have been adapted in this guidance document so that they can be applied in non-health care setting environments.* In all settings, including those where cleaning and disinfection are not possible on a regular basis due to resource limitations, frequent hand washing and avoiding touching the face should be the primary prevention approaches to reduce any potential transmission associated with surface contamination.[21]

Like other coronaviruses, SARS-CoV-2 is an enveloped virus with a fragile outer lipid envelope that makes it more susceptible to disinfectants compared to non-enveloped viruses such as rotavirus, norovirus and poliovirus.[22] Studies have evaluated the persistence of the COVID-19 virus on different surfaces. One study found that the COVID-19 virus remained viable up to 1 day on cloth and wood, up to 2 days on glass, 4 days on stainless steel and plastic, and up to 7 days on the outer layer of a medical mask.[23] Another study found that the COVID-19 virus survived 4 hours on copper, 24 hours on cardboard and up to 72 hours on plastic and stainless steel.[24] The COVID-19 virus also survives in a wide range of pH values and ambient temperatures but is susceptible to heat and standard disinfection methods.[23] These studies, however, were conducted under laboratory conditions in absence of cleaning and disinfection practices and should be interpreted with caution in the real-world environment.

The purpose of this document is to provide guidance on the cleaning and disinfection of environmental surfaces in the context of COVID-19.

This guidance is intended for health-care professionals, public health professionals and health authorities that are developing and implementing policies and standard operating procedures (SOP) on the cleaning and disinfection of environmental surfaces in the context of COVID-19. †

* The topics of current WHO interim guidance documents for non health care setting environments, including environmental cleaning and disinfection recommendations, include faith-based community settings,[12] funerary services,[13] workplaces,[14] food sector,[15] accommodation sector,[16] aviation sector,[17] maritime sector,[18] schools,[19] prisons and other places of detention.[20]

† This document is not intended to be comprehensive guidance on the practice of environmental cleaning and disinfection, which is covered in other relevant guidelines

Principles of environmental cleaning and disinfection

Cleaning helps to remove pathogens or significantly reduce their load on contaminated surfaces and is an essential first step in any disinfection process. Cleaning with water, soap (or a neutral detergent) and some form of mechanical action (brushing or scrubbing) removes and reduces dirt, debris and other organic matter such as blood, secretions and excretions, but does not kill microorganisms.[25] Organic matter can impede direct contact of a disinfectant to a surface and inactivate the germicidal properties or mode of action of several disinfectants. In addition to the methodology used, the disinfectant concentration and contact time are also critical for effective surface disinfection. Therefore, a chemical disinfectant, such as chlorine or alcohol, should be applied after cleaning to kill any remaining microorganisms.

Disinfectant solutions must be prepared and used according to the manufacturer's recommendations for volume and contact time. Concentrations with inadequate dilution during preparation (too high or too low) may reduce their effectiveness. High concentrations increase chemical exposure to users and may also damage surfaces. Enough disinfectant solution should be applied to allow surfaces to remain wet and untouched long enough for the disinfectant to inactivate pathogens, as recommended by the manufacturer.

Training in health-care settings

Environmental cleaning is a complex infection prevention and control intervention that requires a multipronged approach, which may include training, monitoring, auditing and feedback, reminders and displaying SOPs in key areas.

Training for cleaning staff should be based on the policies and SOPs of the health-care facility and national guidelines. It should be structured, targeted, and delivered in the right style (e.g. participatory, at the appropriate literacy level), and it should be mandatory during staff induction to a new workplace. The training programme should include instructions on risk assessment and ensure demonstrative competencies of safe disinfectant preparation, mechanical cleaning and equipment use, standard precautions and transmission-based precautions. Refresher courses are recommended to encourage and reinforce good practice. In health-care facilities and public buildings, posters or other guidance should be visible to cleaning workers and others to guide and remind them about the proper procedures on disinfectant preparation and use.

Cleaning and disinfection techniques and supplies

Cleaning should progress from the least soiled (cleanest) to the most soiled (dirtiest) areas, and from the higher to lower levels so that debris may fall on the floor and is cleaned last in a systematic manner to avoid missing any areas. Use fresh cloths at the start of each cleaning session (e.g., routine daily cleaning in a general inpatient ward). Discard cloths that are no longer saturated with solution. For areas considered to be at high risk of COVID-19 virus contamination, use a new cloth to clean each patient bed. Soiled cloths should be reprocessed properly after each use and an SOP should be available for the frequency of changing cloths.

Cleaning equipment (e.g. buckets) should be well maintained. Equipment used for isolation areas for patients with COVID-19 should be colour-coded and separated from other equipment. Detergent or disinfectant solutions become contaminated during cleaning and progressively less effective if the organic load is too high; therefore, the continued use of the same solution may transfer the microorganisms to each subsequent surface. Thus, detergent and/or disinfectant solutions must be discarded after each use in areas with suspected/confirmed patients with COVID-19. It is recommended that fresh solution be prepared on a daily basis or for each cleaning shift. Buckets should be washed with detergent, rinsed, dried and stored inverted to drain fully when not in use.[28]

Products for environmental cleaning and disinfection

Follow the manufacturer's instructions to ensure that disinfectants are prepared and handled safety, wearing the appropriate personal protective equipment (PPE) to avoid chemical exposure.[26]

The selection of disinfectants should take account of the microorganisms targeted, as well as the recommended concentration and contact time, the compatibility of the chemical disinfectants and surfaces to be tackled, toxicity, ease of use and stability of the product. The selection of disinfectants should meet local authorities' requirements for market approval, including any regulations applicable to specific sectors, for example health-care and food industries.[‡]

The use of chlorine-based products

Hypochlorite-based products include liquid (sodium hypochlorite), solid or powdered (calcium hypochlorite) formulations. These formulations dissolve in water to create a dilute aqueous chlorine solution in which undissociated hypochlorous acid (HOCl) is active as the antimicrobial compound. Hypochlorite displays a broad spectrum of antimicrobial activity and is effective against several common pathogens at various concentrations. For example, hypochlorite is effective against rotavirus at a concentration of 0.05% (500 ppm), however, higher concentrations of 0.5% (5000 ppm) are required for some highly resistant pathogens in the health-care setting such as *C. auris* and *C. difficile*.[30,31]

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including the WHO's *Essential environmental health standards in health care*[25] and the joint U.S. Centers for Disease Control and Prevention & Infection Control Africa Network's document *Best practices for environmental cleaning in healthcare facilities in resource-limited settings.*[26] This guidance does not address the procedures for decontamination of instruments and semi-critical and critical medical devices, which can be found in the WHO document on *Decontamination and reprocessing of medical devices for health-care facilities.*[27]

[‡] A list of disinfectants for use against the COVID-19 virus is currently being actively updated by the U.S. Environmental Protection Agency (EPA) with caution that inclusion of a disinfectant within this list does not constitute endorsement by their agency.[29]

The recommendation of 0.1% (1000 ppm) in the context of COVID-19 is a conservative concentration that will inactivate the vast majority of other pathogens that may be present in the health-care setting. However, for blood and body fluids large spills (i.e. more than about 10mL) a concentration of 0.5% (5000 ppm) is recommended.[26]

Hypochlorite is rapidly inactivated in the presence of organic material; therefore, regardless of the concentration used, it is important to first clean surfaces thoroughly with soap and water or detergent using mechanical action such as scrubbing or friction. High concentrations of chlorine can lead to corrosion of metal and irritation of skin or mucous membrane, in addition to potential side-effects related to chlorine smell for vulnerable people such as people with asthma.[32]

Commercial sodium hypochlorite products with different levels of concentration may be readily available for use in a variety of settings. In Europe and North America chlorine concentrations in commercially available products vary between 4% and 6%.[34] Concentration may also vary according to national regulations and manufacturers' formulations. To achieve the desired concentration, it is necessary to prepare sodium hypochlorite by diluting the basic aqueous solution with a given proportion of clean, non-turbid water to produce the final desired concentration (Table 1).[34]

Table 1. Calculation of sodium hypochlorite concentrations

[% chlorine in liquid sodium hypochlorite / % chlorine desired] − 1 = Total parts of water for each part sodium hypochlorite.
Ex: [5% in liquid sodium hypochlorite/ 0.5% chlorine desired] -1 = 9 parts of water for each part sodium hypochlorite

Solid formulations of hypochlorite (powder or granules) may also be available in a variety of settings. Solid formulations are available as concentrated, high-test hypochlorite (HTH) (65-70%) and as chlorine or calcium hypochlorite powder (35%). To produce the final desired concentration, the weight (in grams) of calcium hypochlorite that should be added per litre of water can be determined based on the calculation in Table 2.

Table 2. Calculation of chlorine solutions from calcium hypochlorite

[% chlorine desired / % chlorine in hypochlorite powder or granules] × 1 000 = grams of calcium hypochlorite powder for each litre of water.
Ex: [0.5% chlorine desired / 35% in hypochlorite powder] × 1 000 = 0.0143 × 1 000 = 14.3
Therefore, you must dissolve 14.3 grams of calcium hypochlorite powder in each litre of water used to make a 0.5% chlorine solution.

Chlorine can decay rapidly in solutions depending on the source of chlorine and environmental conditions, for example ambient temperature or UV exposure. Chlorine solutions should be stored in opaque containers, in a well-ventilated, covered area that is not exposed to direct sunlight.[35] Chlorine solutions are most stable at high pH (>9) but the disinfectant properties of chlorine are stronger at lower pH (<8). Solutions of 0.5% and 0.05% chlorine have been shown to be stable for more than 30 days at temperatures of 25-35°C when the pH is above 9. However, chlorine solutions at lower pH have much shorter shelf lives.[36] Thus, ideally chlorine solutions should be freshly prepared every day. If this is not possible and the chlorine solution must be used for several days, they should be tested daily to ensure that the chlorine concentration is maintained. Several tests can be used to gauge chlorine strength, and these include chemical titration, chemical spectrometry or colorimetry, colour wheels and test strips, in order of decreasing accuracy.[37]

Spraying disinfectants and other no-touch methods

In indoor spaces, routine application of disinfectants to environmental surfaces by spraying or fogging (also known as fumigation or misting) is not recommended for COVID-19. One study has shown that spraying as a primary disinfection strategy is ineffective in removing contaminants outside of direct spray zones.[38] Moreover, spraying disinfectants can result in risks to the eyes, respiratory or skin irritation and the resulting health effects.[39] Spraying or fogging of certain chemicals, such as formaldehyde, chlorine-based agents or quaternary ammonium compounds, is not recommended due to adverse health effects on workers in facilities where these methods have been utilized.[40,41] Spraying environmental surfaces in both health-care and non-health care settings such as patient households with disinfectants may not be effective in removing organic material and may miss surfaces shielded by objects, folded fabrics or surfaces with intricate designs. If disinfectants are to be applied, this should be done with a cloth or wipe that has been soaked in disinfectant.

Some countries have approved no-touch technologies for applying chemical disinfectants (e.g. vaporized hydrogen peroxide) in health-care settings such as fogging-type applications.[42] Furthermore, devices using UV irradiation have been designed for health-care settings. However, several factors may affect the efficacy of UV irradiation, including distance from the UV device; irradiation dose, wavelength and exposure time; lamp placement; lamp age; and duration of use. Other factors include direct or indirect line of sight from the device; room size and shape; intensity; and reflection.[5] Notably, these technologies developed for use in health-care settings are used during terminal cleaning (cleaning a room after a patient has been discharged or transferred), when rooms are unoccupied for the safety of staff and patients**.** These technologies supplement but do not replace the need for manual cleaning procedures.[44] If using a no-touch disinfection technology, environmental surfaces must be cleaned manually first by brushing or scrubbing to remove organic matter.[44]

Spraying or fumigation of outdoor spaces, such as streets or marketplaces, is also not recommended to kill the COVID-19 virus or other pathogens because disinfectant is inactivated by dirt and debris and it is not feasible to manually clean and remove all organic matter from such spaces. Moreover, spraying porous surfaces, such as sidewalks and unpaved walkways, would be even less effective. Even in the absence of organic matter, chemical spraying is unlikely to adequately

cover all surfaces for the duration of the required contact time needed to inactivate pathogens. Furthermore, streets and sidewalks are not considered to be reservoirs of infection for COVID-19. In addition, spraying disinfectants, even outdoors, can be harmful for human health.

Spraying individuals with disinfectants (such as in a tunnel, cabinet, or chamber) **is not recommended under any circumstances**. This could be physically and psychologically harmful and would not reduce an infected person's ability to spread the virus through droplets or contact. Moreover, spraying individuals with chlorine and other toxic chemicals could result in eye and skin irritation, bronchospasm due to inhalation, and gastrointestinal effects such as nausea and vomiting.[40, 45]

Health-care settings environment

Environmental cleaning and disinfection in clinical, non-traditional facilities and home-based health-care settings should follow detailed SOPs with a clear delineation of responsibilities (e.g. housekeeping or clinical staff), regarding the type of surfaces and frequency of cleaning (Table 3). Particular attention should be paid to environmental cleaning of high-touch surfaces and items, such as light switches, bed rails, door handles, intravenous pumps, tables, water/beverage pitchers, trays, mobile cart rails and sinks, which should be performed frequently. However, all touchable surfaces should be disinfected. Cleaning practices and cleanliness should be routinely monitored. The number of cleaning staff should be planned to optimize cleaning practices. Health workers should be made aware of cleaning schedules and cleaning completion times to make informed risk assessments when performing touch contact with surfaces and equipment, to avoid contaminating hands and equipment during patient care.[46]

Table 3. Health-care setting: Recommended frequency of cleaning of environmental surfaces, according to the patient areas with suspected or confirmed COVID-19 patients.

Patient area	Frequency [a]	Additional guidance
Screening/triage area	At least twice daily	• Focus on high-touch surfaces, then floors (last)
Inpatient rooms / cohort – occupied	At least twice daily, preferably three times daily, in particular for high-touch surfaces	• Focus on high-touch surfaces, starting with shared/common surfaces, then move to each patient bed; use new cloth for each bed if possible; then floors (last)
Inpatient rooms – unoccupied (terminal cleaning)	Upon discharge/transfer	• Low-touch surfaces, high-touch surfaces, floors (in that order); waste and linens removed, bed thoroughly cleaned and disinfected
Outpatient / ambulatory care rooms	After each patient visit (in particular for high-touch surfaces) and at least once daily terminal clean	• High-touch surfaces to be disinfected after each patient visit • Once daily low-touch surfaces, high-touch surfaces, floors (in that order); waste and linens removed, examination bed thoroughly cleaned and disinfected
Hallways / corridors	At least twice daily [b]	• High-touch surfaces including railings and equipment in hallways, then floors (last)
Patient bathrooms/ toilets	Private patient room toilet: at least twice daily Shared toilets: at least three times daily	• High-touch surfaces, including door handles, light switches, counters, faucets, then sink bowls, then toilets and finally floor (in that order) • Avoid sharing toilets between staff and patients

[a] Environmental surfaces should also be cleaned and disinfected whenever visibly soiled or if contaminated by a body fluid (e.g., blood); [b] Frequency can be once a day if hallways are not frequently used.

Selecting a disinfectant product for environmental surfaces in health-care settings should consider the logarithmic (decimal order of magnitude) reduction for the COVID-19 virus, and also for other health care-associated pathogens, including *Staphylococcus aureus*, *Salmonella sp*, *Pseudomonas aeruginosa*, *Acinetobacter baumannii,* and hepatitis A and B viruses. In some contexts, environmentally persistent organisms, such as *Clostridioides difficile* and *Candida auris*, that are resistant to certain disinfectants, should also be considered when selecting a disinfectant. Thus, appropriate disinfectants need to be carefully selected for health-care facilities.[47]

After cleaning, the following disinfectants and defined concentrations can be used on environmental surfaces to achieve a >3 $\log^{10}$ reduction of human coronavirus,[33] and they are also effective against other clinically relevant pathogens in the health-care setting.[22]

- Ethanol 70-90%
- Chlorine-based products (e.g., hypochlorite) at 0.1% (1000 ppm) for general environmental disinfection or 0.5% (5000 ppm) for blood and body fluids large spills (See section: The use of chlorine-based products)
- Hydrogen peroxide ≥0.5%

Contact time of a minimum of 1 minute is recommended for these disinfectants[21] or as recommended by the manufacturers. Other disinfectants can be considered, provided the manufacturers recommend them for the targeted microorganisms, especially enveloped viruses. Manufacturers' recommendations for safe use as well as for avoiding mixing types of chemical disinfectants should always be considered when preparing, diluting or applying a disinfectant.

Non-health care settings environment

There is no evidence for equating the risk of fomite transmission of the COVID-19 virus in the hospital setting to any environment outside of hospitals. However, it is still important to reduce potential for COVID-19 virus contamination in non-healthcare settings, such as in the home, office, schools, gyms or restaurants. High-touch surfaces in these non-health care settings should be identified for priority disinfection. These include door and window handles, kitchen and food preparation areas, counter tops, bathroom surfaces, toilets and taps, touchscreen personal devices, personal computer keyboards, and work surfaces. The disinfectant and its concentration should be carefully selected to avoid damaging surfaces and to avoid or minimize toxic effects on household members or users of public spaces.

The environmental cleaning techniques and cleaning principles should be followed as far as possible. Surfaces should always be cleaned with soap and water or a detergent to remove organic matter first, followed by disinfection. In non-health care settings, sodium hypochlorite (bleach) may be used at a recommended concentration of 0.1% (1000 ppm).[5] Alternatively, alcohol with 70%-90% concentration may be used for surface disinfection.

Personal safety when preparing and using disinfectants

Cleaners should wear adequate personal protective equipment (PPE) and be trained to use it safely. When working in places where suspected or confirmed COVID-19 patients are present, or where screening, triage and clinical consultations are carried out, cleaners should wear the following PPE: gown, heavy duty gloves, medical mask, eye protection (if risk of splash from organic material or chemicals), and boots or closed work shoes.[48]

Disinfectant solutions should always be prepared in well-ventilated areas. Avoid combining disinfectants, both during preparation and usage, as such mixtures cause respiratory irritation and can release potentially fatal gases, in particular when combined with hypochlorite solutions.

Personnel preparing or using disinfectants in health care settings require specific PPE, due to the high concentration of disinfectants used in these facilities and the longer exposure time to the disinfectants during the workday.[49] Thus, PPE for preparing or using disinfectants in health care settings includes uniforms with long-sleeves, closed work shoes, gowns and/or impermeable aprons, rubber gloves, medical mask, and eye protection (preferably face shield)[§].

In non-health care settings, resource limitations permitting, where disinfectants are being prepared and used, the minimum recommended PPE is rubber gloves, impermeable aprons and closed shoes.[34] Eye protection and medical masks may also be needed to protect against chemicals in use or if there is a risk of splashing.

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WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication

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APPENDIX D

CDC GUIDELINES ON EXTENDED USE AND RE-USE OF N95 RESPIRATORS

Workplace Safety and Health Topics

Pandemic Planning

Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare

Promoting productive workplaces through safety and health research NIOSH

PANDEMIC PLANNING

For information about Coronavirus Disease 2019, visit https://www.cdc.gov/coronavirus/2019-ncov/index.html.

Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings

On This Page

Background

This document recommends practices for extended use and limited reuse of NIOSH-certified N95 filtering facepiece

respirators (commonly called "N95 respirators"). The recommendations are intended for use by professionals who manage respiratory protection programs in healthcare institutions to protect health care workers from job-related risks of exposure to infectious respiratory illnesses.

Supplies of N95 respirators can become depleted during an influenza pandemic (1-3) or wide-spreadoutbreaks of other infectious respiratory illnesses.(4) Existing CDC guidelines recommend a combination of approaches to conserve supplies while safeguarding health care workers in such circumstances. These existing guidelines recommend that health care institutions:

- Minimize the number of individuals who need to use respiratory protection through the preferential use of engineering and administrative controls;
- Use alternatives to N95 respirators (e.g., other classes of filtering facepiece respirators, elastomeric half-mask and full facepiece air purifying respirators, powered air purifying respirators) where feasible;
- Implement practices allowing extended use and/or limited reuse of N95 respirators, when acceptable; and
- Prioritize the use of N95 respirators for those personnel at the highest risk of contracting or experiencing complications of infection.

This document focuses on one of the above strategies, the extended use and limited reuse of N95 respirators only; please consult the CDC or NIOSH website for guidance related to implementing the other recommended approaches for conserving supplies of N95 respirators.

There are also non-emergency situations (e.g., close contact with patients with tuberculosis) where N95 respirator reuse has been recommended in healthcare settings and is commonly practiced.(5-9) This document serves to supplement previous guidance on this topic.

Definitions

Extended use refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters. Extended use may be implemented when multiple patients are infected with the same respiratory

pathogen and patients are placed together in dedicated waiting rooms or hospital wards. Extended use has been recommended as an option for conserving respirators during previous respiratory pathogen outbreaks and pandemics.(10, 11)

Reuse[1] refers to the practice of using the same N95 respirator for multiple encounters with patients but removing it ('doffing') after each encounter. The respirator is stored in between encounters to be put on again ('donned') prior to the next encounter with a patient. For pathogens in which contact transmission (e.g., fomites) is not a concern, non-emergency reuse has been practiced for decades.(7) For example, for tuberculosis prevention, CDC recommends that a respirator classified as disposable can be reused by the same worker as long as it remains functional[2] and is used in accordance with local infection control procedures.(9) Even when N95 respirator reuse is practiced or recommended, restrictions are in place which limit the number of times the same FFR is reused.Thus, N95 respirator reuse is often referred to as "limited reuse". Limited reuse has been recommended and widely used as an option for conserving respirators during previous respiratory pathogen outbreaks and pandemics.(2, 3, 10-12)

Implementation

The decision to implement policies that permit extended use or limited reuse of N95 respirators should be made by the professionals who manage the institution's respiratory protection program, in in consultation with their occupational health and infection control departments with input from the state/local public health departments. The decision to implement these practices should be made on a case by case basis taking into account respiratory pathogen characteristics (e.g., routes of transmission, prevalence of disease in the region, infection attack rate, and severity of illness) and local conditions (e.g., number of disposable N95 respirators available, current respirator usage rate, success of other respirator conservation strategies, etc.). Some healthcare facilities may wish to implement extended use and/or limited reuse before respirator shortages are observed, so that adequate supplies are available during times of peak demand. For non-emergency (routine) situations, current CDC recommendations (6, 9) specific to that pathogen should also be consulted.

The following sections outline specific steps to guide implementation of these recommendations, minimize the challenges caused by extended use and reuse, and to limit risks that could result from these practices.

Respirator Extended Use Recommendations

Respirator Extended Use Recommendations

Extended use is favored over reuse because it is expected to involve less touching of the respirator and therefore less risk of contact transmission. Please see the section on Risks of Extended Use and Reuse of Respirators for more information about contact transmission and other risks involved in these practices.

A key consideration for safe extended use is that the respirator must maintain its fit and function. Workers in other industries routinely use N95 respirators for several hours uninterrupted. Experience in these settings indicates that respirators can function within their design specifications for 8 hours of continuous or intermittent use. Some research studies (14, 15) have recruited healthcare workers as test subjects and many of those subjects have successfully worn an N95 respirator at work for several hours before they needed to remove them. Thus, the maximum length of continuous use in non-dusty healthcare workplaces is typically dictated by hygienic concerns (e.g., the respirator was discarded because it became contaminated) or practical considerations (e.g., need to use the restroom, meal breaks, etc.), rather than a pre-determined number of hours.

If extended use of N95 respirators is permitted, respiratory protection program administrators should ensure adherence to administrative and engineering controls to limit potential N95 respirator surface contamination (e.g., use of barriers to prevent droplet spray contamination) and consider additional training and reminders (e.g., posters) for staff to reinforce the need to minimize unnecessary contact with the respirator surface, strict adherence to hand hygiene practices, and proper Personal Protective Equipment (PPE) donning and doffing technique.(16) Healthcare facilities should develop clearly written procedures to advise staff to take the following steps to reduce contact transmission after donning:

- Discard N95 respirators following use during aerosol generating procedures.
- Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Discard N95 respirators following close contact with, or exit from, the care area of any patient co-infected with an infectious disease requiring contact precautions.
- Consider use of a cleanable face shield (preferred[3]) over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls) to reduce surface contamination.

- Perform hand hygiene with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).

Extended use alone is unlikely to degrade respiratory protection. However, healthcare facilities should develop clearly written procedures to advise staff to:

- Discard any respirator that is obviously damaged or becomes hard to breathe through.

Respirator Reuse Recommendations

There is no way of determining the maximum possible number of safe reuses for an N95 respirator as a generic number to be applied in all cases. Safe N95 reuse is affected by a number of variables that impact respirator function and contamination over time.(18, 19) However, manufacturers of N95 respirators may have specific guidance regarding reuse of their product.The recommendations below are designed to provide practical advice so that N95 respirators are discarded before they become a significant risk for contact transmission or their functionality is reduced.

If reuse of N95 respirators is permitted, respiratory protection program administrators should ensure adherence to administrative and engineering controls to limit potential N95 respirator surface contamination (e.g., use of barriers to prevent droplet spray contamination) and consider additional training and/or reminders (e.g., posters) for staff to reinforce the need to minimize unnecessary contact with the respirator surface, strict adherence to hand hygiene practices, and proper PPE donning and doffing technique, including physical inspection and performing a user seal check.(16) Healthcare facilities should develop clearly written procedures to advise staff to take the following steps to reduce contact transmission:

- Discard N95 respirators following use during aerosol generating procedures.
- Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Discard N95 respirators following close contact with any patient co-infected with an infectious disease requiring contact precautions.
- Consider use of a cleanable face shield (preferred[3]) over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), when feasible to reduce surface

contamination of the respirator.

- Hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.
- Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).
- Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene as described above.
- Use a pair of clean (non-sterile) gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.

To reduce the chances of decreased protection caused by a loss of respirator functionality, respiratory protection program managers should consult with the respirator manufacturer regarding the maximum number of donnings or uses they recommend for the N95 respirator model(s) used in that facility. If no manufacturer guidance is available, preliminary data(19, 20) suggests limiting the number of reuses to no more than five uses per device to ensure an adequate safety margin. Management should consider additional training and/or reminders for users to reinforce the need for proper respirator donning techniques including inspection of the device for physical damage (e.g., Are the straps stretched out so much that they no longer provide enough tension for the respirator to seal to the face?, Is the nosepiece or other fit enhancements broken?, etc.). Healthcare facilities should provide staff clearly written procedures to:

- Follow the manufacturer's user instructions, including conducting a user seal check.
- Follow the employer's maximum number of donnings (or up to five if the manufacturer does not provide a recommendation) and recommended inspection procedures.
- Discard any respirator that is obviously damaged or becomes hard to breathe through.
- Pack or store respirators between uses so that they do not become damaged or deformed.

Secondary exposures can occur from respirator reuse if respirators are shared among users and at least one of the users is infectious (symptomatic or asymptomatic). Thus, N95 respirators must

only be used by a single wearer. To prevent inadvertent sharing of respirators, healthcare facilities should develop clearly written procedures to inform users to:

- Label containers used for storing respirators or label the respirator itself (e.g., on the straps(11)) between uses with the user's name to reduce accidental usage of another person's respirator.

Risks of Extended Use and Reuse of Respirators

Although extended use and reuse of respirators have the potential benefit of conserving limited supplies of disposable N95 respirators, concerns about these practices have been raised. Some devices have not been FDA-cleared for reuse(21). Some manufacturers' product user instructions recommend discard after each use (i.e., "for single use only"), while others allow reuse if permitted by infection control policy of the facility.(19) The most significant risk is of contact transmission from touching the surface of the contaminated respirator. One study found that nurses averaged 25 touches per shift to their face, eyes, or N95 respirator during extended use.(15)Contact transmission occurs through direct contact with others as well as through indirect contact by touching and contaminating surfaces that are then touched by other people.

Respiratory pathogens on the respirator surface can potentially be transferred by touch to the wearer's hands and thus risk causing infection through subsequent touching of the mucous membranes of the face (i.e., self-inoculation). While studies have shown that some respiratory pathogens (22-24) remain infectious on respirator surfaces for extended periods of time, in microbial transfer (25-27) and reaerosolization studies (28-32) more than ~99.8% have remained trapped on the respirator after handling or following simulated cough or sneeze.

Respirators might also become contaminated with other pathogens acquired from patients who are co-infected with common healthcare pathogens that have prolonged environmental survival (e.g., methicillin-resistant Staphylococcus aureas, vancomycin-resistant enterococci, Clostridium difficile, norovirus, etc.). These organisms could then contaminate the hands of the wearer, and in turn be transmitted via self-inoculation or to others via direct or indirect contact transmission.

The risks of contact transmission when implementing extended use and reuse can be affected by the types of medical procedures being performed and the use of effective engineering and administrative controls, which affect how much a respirator becomes contaminated by droplet sprays or deposition of aerosolized particles. For example, aerosol generating medical procedures

such as bronchoscopies, sputum induction, or endotracheal intubation, are likely to cause higher levels of respirator surface contamination, while source control of patients (e.g. asking patients to wear facemasks), use of a face shield over the disposable N95 respirator, or use of engineering controls such as local exhaust ventilation are likely to reduce the levels of respirator surface contamination.(18)

While contact transmission caused by touching a contaminated respirator has been identified as the primary hazard of extended use and reuse of respirators, other concerns have been assessed, such as a reduction in the respirator's ability to protect the wearer caused by rough handling or excessive reuse.(19, 20) Extended use can cause additional discomfort to wearers from wearing the respirator longer than usual.(14, 15) However, this practice should be tolerable and should not be a health risk to medically cleared respirator users.(19)

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[1] The term "reuse" is used in a variety of settings in healthcare. For example, FDA defines 3 kinds of reuse: (1) between patients with adequate reprocessing (e.g., as with an endoscope), (2) reuse by the same person with adequate reprocessing/decontamination (e.g., as with contact lenses), and (3) repeated use by the same person over a period of time with or without reprocessing.(12, 13)

[2] Functional means that the N95 respirator has maintained its physical integrity and when used properly provides protection (exposure reduction) consistent with the assigned protection factor for this class of respirator.

[3] Use of a cleanable face shield is strongly preferred to a surgical mask to reduce N95 respirator contamination. Concerns have been raised that supplies of surgical masks may also be in limited supply during a public health emergency and that the use of a surgical mask could affect the function of the N95 respirator.(17)

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