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Technical Data Bulletin

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#176

Pandemic Influenza Preparedness Planning: Practical Considerations for Respirator Use in a Health Care Setting

Description

On January 26, 2016, the Centers for Disease Control and Prevention (CDC) revised a guidance document titled "Interim Guidance for Infection Control Within Healthcare Settings When Caring for Confirmed Cases, Probable Cases, and Cases Under Investigation for Infection with Novel Influenza A Viruses Associated with Severe Disease".[1] The intent of the guidance is to provide recommendations for initial infection control in healthcare settings where patients who may be infected with a novel influenza A virus associated with severe disease may receive healthcare services. This includes confirmed cases, probable cases, cases under investigation for infection with a novel influenza A virus associated with severe disease, and other patients for whom available clinical and epidemiologic information strongly support a diagnosis of infection with a novel influenza A virus associated with severe disease. The CDC recommendations apply to settings where pandemic influenza patients may receive healthcare services including, but not limited to:

- acute care hospitals
- long-term care facilities, such as nursing homes and skilled nursing facilities
- physicians' offices
- urgent-care centers
- outpatient clinics
- home health care (i.e., care provided at home by professional healthcare providers)
- emergency medical services

Settings include specific sites within non-healthcare settings where healthcare is routinely delivered (e.g., a medical clinic embedded within a workplace or school).

The CDC guidance recommends a higher level of infection control measures than for seasonal influenza, as outlined in the CDC document "Prevention Strategies for Seasonal Influenza in Health Care Settings." Among the important differences from the seasonal influenza guidance are recommendations for Airborne Precautions, which includes a higher level of personal protective equipment for healthcare personnel, including the expanded use of respirators (i.e. for all patient-care activities).

IMPORTANT NOTE

Healthcare personnel (HCP) refers to all persons, paid or unpaid, working in healthcare settings whose activities place them as risk for transmission of respiratory infections from patients. Examples of such activities include those that require direct contact with patients and/or exposure to the patient care environment, including being in the patient room or in a triage or examination room or other potentially contaminated areas, and handling blood, body fluids, secretions, or excretions (except sweat) or soiled medical supplies, equipment or environmental surfaces.

The CDC guidance adds to existing infection control precautions (i.e. Standard Precautions) used every day in healthcare settings during the case of any patient.

According to the CDC, lack of immunity to a pandemic influenza strain and potential for a high case-fatality rate makes it advisable to take additional precautions beyond those typically recommended during a seasonal influenza outbreak. Use of respiratory protection during an influenza pandemic is one of those additional precautions. The primary consideration for use of respiratory protection in a healthcare setting during an influenza pandemic is the reduction in exposure needed or desired

for the situation. Airborne precautions include the use of respiratory protection that is at least as protective as a fit-tested NIOSH-certified disposable N95 filtering facepiece respirator upon entry to the patient room or care area.

However, the CDC recommends caution when performing Aerosol-Generating Procedures on patients with suspected or confirmed influenza as these procedures may be more likely to generate higher concentrations of infectious respiratory aerosols that coughing, sneezing, talking or breathing and indicates a higher level of respiratory protection may be considered.[1] Aerosol-Generating Procedures identified by the CDC include planned procedures such as bronchoscopy, sputum induction, elective intubation and extubation, and autopsies, and some procedures that often occur in unplanned, emergent settings and can be life-saving, such as cardiopulmonary resuscitation, emergent intubation and open suction of airways.

In the guidance document, several types of respiratory protection are referenced as potentially utilized by health care workers during a pandemic situation. The purpose of this technical data bulletin is to describe the types of respirators available and considerations for use in a healthcare setting during an influenza pandemic. It is important to remember that use of respirators is only one of many strategies to help reduce exposure to biological hazards. Since no respirator will completely prevent the inhalation of all particles, use of respirators may help reduce, but not eliminate, the risk of exposure, infection, illness or death. Reading and understanding the CDC guidance document prior to selecting and using respiratory protective equipment is recommended.

Types of Respiratory Protection

A **respirator** is a device designed to help provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.[2]

In a pandemic influenza scenario, the hazards are airborne infectious biological particles, or bioaerosols. For more information regarding respirator protection for bioaerosols in general consult 3M Technical Data Bulletin #174 - Respiratory Protection for Airborne Exposure to Biohazards. Bioaerosols can be filtered by respirators with particulate filters.[3-7]

Particulate respirators are available as:

1. A filtering half facepiece respirator, where the filter is the entire respirator.
2. An elastomeric (reusable) half mask with a particulate filter.
3. An elastomeric (reusable) full facepiece with a particulate filter.
4. A powered air purifying respirator (PAPR) that includes a particulate filter.

For use in the United States, respiratory protective equipment must be certified by the National Institute for Occupational Safety and Health (NIOSH), the federal agency tasked with testing and certification of respirators. NIOSH has nine approval categories for respirators designed to reduce exposure to particles.

The NIOSH approval categories for particulate filters include N95, N99, N100, R95, R99, R100, P95, P99 and P100 and, for powered air purifying respirators (PAPRs), a high efficiency (HE) filter designation similar in filter efficiency to the 100 level category. The 95, 99 and 100 (99.97) refer to the percentage of particle filtration efficiency when tested according to the NIOSH laboratory test methods.[2] An N-certified respirator can only be used in environments that do not contain oil aerosols. R and P-certified respirators can be used in both oil and non-oil containing environments.

Healthcare settings normally do not contain oil aerosols and in most healthcare applications respirators from any of the approval categories and filtration efficiencies could be selected to help reduce exposure to bioaerosols.

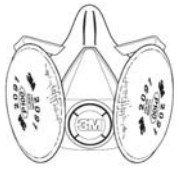
It should be noted that penetration of particles through the filter is only one of the possible sources of respiratory exposure. Other potential sources such as face seal leakage, improper maintenance, or not wearing the respirator when necessary may contribute more to exposure than filter penetration. Each of these must be addressed and controlled. Wearers must achieve

a proper fit, be trained how to properly maintain their respirators and the importance of wearing them during all times of exposure.

It is also important to emphasize that respirators only reduce exposure. Types or classes of respirators are given an "assigned protection factor" or APF. APF is the expected ability of the respirator to reduce exposure when used according to an effective respiratory protection program. For example, an APF of 10 means that a respirator is expected to reduce exposure by a factor of 10 (or 90%) when properly selected, maintained, fitted and worn. Therefore, even if a filter is 100% efficient, the expected amount of exposure reduction would be limited by the APF. Because no respirator will prevent the inhalation of all particles, they cannot eliminate the risk of exposure, infection and illness.

Use of respirators in the workplace, including healthcare facilities, is regulated by the Occupational Safety and Health Administration (OSHA) and requires a complete respiratory protection program including fit testing, training and medical evaluation.[8]

Table A. Examples of Respirator Types

3M™ Filtering Facepiece Respirator Without Exhalation Valve	3M™ Filtering Facepiece Respirator With Exhalation Valve	Half Facepiece Elastomeric Respirator	Full Facepiece Elastomeric Respirator	3M™ Loose-fitting Facepiece for Powered Air Purifying Respirator	3M™ Hood for Powered Air Purifying Respirator (PAPR)	3M™ PAPR Motor Blower with Filter
						

Following are some general features, advantages and disadvantages of different types of respirators.

Disposable Filtering Facepiece Respirator

- Disposable, no maintenance
- Lightweight
- Need separate eye and face protection
- Fit testing needed and required by regulation in certain countries (including the US) to ensure respiratory protection
- Some can be used as surgical masks. For more information on the differences between surgical masks and respirators, consult 3M Technical Data Bulletin #231 - Respirators and Surgical Masks: A Comparison
- OSHA APF of 10[9]

Reusable Half mask or Full Facepiece Respirator

- Often available in multiple sizes
- Facepieces can be disinfected and reused
- Full facepieces may provide eye and face protection
- Fit testing needed and required in certain countries (including the US) to ensure respiratory protection
- Facepieces must be maintained
- Half mask respirators have an OSHA APF of 10
- Full Facepiece respirators have an OSHA APF of 10 when qualitatively fit tested and an OSAH APF of 50 when quantitatively fit tested[9]

Powered Air Purifying (PAPR) Respirator

- Some elements can be disinfected and reused

- Higher assigned protection factor depending on headgear used, a PAPR can have an OSHA APF of 25 or 1000. For more information consult 3M Technical Data Bulletin #175 - Assigned Protection Factors (APF) for Hoods and Helmets
- Less prone to fogging
- No fit testing required for systems with loose fitting head covers
- May not need separate eye and face protection depending on the head covering
- Batteries need to be charged and entire unit maintained
- Higher initial cost

Additional Considerations for Use

Fit Testing

Respirators which rely on a face to facepiece seal require fit testing per OSHA regulations. This requirement includes the filtering facepiece respirators as well as the half and full facepiece elastomeric respirators.

IMPORTANT NOTE

Respirators which do not rely on a seal to the face, such as PAPRs with loose-fitting facepieces and hoods, do not require fit testing.

Fit test methods that are acceptable to OSHA are listed in Appendix A of 29 CFR 1910.134. These include qualitative fit test methods such as the saccharin or bitter aerosol methods or quantitative fit test methods where a device gives a numerical measurement of the fit.

Employees with facial hair cannot wear respirators which rely on a face to facepiece seal, such as the filtering facepiece respirators and the half and full facepiece elastomeric respirators. This needs to be considered during respirator selection. For loose fitting facepieces and hoods with an elasticized faceseal 3M recommends users are clean shaven where the faceseal contacts the wearers face. For hoods and helmets with an inner neck collar or an inner shroud that form a partial seal in the neck region of the wearer, 3M suggests that beards and facial hair should not extend into the sealing surface area of the hood or helmet.[10]

The need to fit test individuals also involves logistical considerations. During a pandemic event, it may be necessary to utilize staff that may not have been previously fit tested on filtering facepiece or elastomeric respirators. From a preparedness perspective, the preferred scenario is that all potentially affected employees will have been properly fit tested and trained in preparation for such an event well in advance of a potential occurrence. If this has not transpired, logistical considerations could include a plan to fit test these employees at the time of an event (prior to use of the respirator) as well as potential use of PAPRs with loose fitting facepieces or hoods. Training, medical evaluation and all other requirements of the respirator standard are, however, required for use of PAPRs.

It is also important to note that the CDC encourages measures to minimize the number of personnel who come into contact with suspected or confirmed pandemic influenza patients in order to minimize the number of workers exposed as well the demand for respirators.

Reuse of Respiratory Protection

Filtering Facepiece Respirators

If disposable respirators are used, they should be removed and discarded after leaving the patient room or care area and closing the door.[1]

Elastomeric Facepiece Respirators and PAPRs

If reusable respirators are used, they must be cleaned and disinfected according to manufacturer's reprocessing instructions prior to re-use. Used filters should be discarded. Filters and cartridges cannot be washed and reused.

Cleaning of 3M elastomeric respirators is often accomplished by removing the filters and then immersing the facepiece, loose-fitting facepiece, or hood in warm water with a neutral detergent and scrubbing with a soft brush if needed.

IMPORTANT NOTE

Solvents and strong detergents may damage 3M respirators and respirator components and should not be used for cleaning.

3M half and full facepieces can be sanitized by soaking in a quaternary ammonia disinfectant, sodium hypochlorite, or other disinfecting agent. Hoods and loose-fitting facepieces can be wiped with similar disinfecting agents. The sodium hypochlorite solution used to sanitize respirators, 1 ounce (30ml) of household bleach in 2 gallons (7.5L) of water, may be less concentrated than the sodium hypochlorite solution used in a health care setting. The directions that accompany the quaternary ammonia solutions or other disinfecting agents should be followed, including mixing instructions and the appropriate contact time. Contact times of disinfecting agents may be several minutes in duration and should be included in the logistics of cleaning and maintenance.

Although elastomeric facepieces and components can be submerged, this is not true for many PAPR components such as motor blowers, batteries and breathing tubes that have a "muffler" inside for sound dampening. Submersion of these components in any liquid will likely result in damage and instead should be wiped with a disinfecting solution. One exception is the motor blower of the 3M GVP PAPR, which is designed to be sealed or capped and then submerged for cleaning. Another exception is the motor blower unit and batteries for the TR-600 PAPR which can also be sealed and then submerged for cleaning with the TR-653 Cleaning and Storage Kit according to the instructions in 3M Technical Data Bulletin #222. Filters and cartridges should not be submerged or washed.

In an industrial setting, once an elastomeric respirator or a PAPR with a loose-fitting facepiece or hood has been cleaned and sanitized per the user instructions, it is returned to inventory and can be used by another person. Although sharing disinfected respirators between employees is not specifically addressed by the CDC, it is an additional factor for consideration in the event of an influenza pandemic.

Inspection

All respirators, including brand new respirators, and components must be inspected prior to each use and any damaged or deteriorated components replaced. Refer to the User Instructions provided with each respirator system for specific cleaning, sanitizing, inspection and maintenance procedures.

Storage

The CDC did not provide guidance regarding storage; however, OSHA requires that respirators be stored in an area free from potential contamination and in a method that will not cause any damage. Elastomeric respirators and PAPRs dedicated to specific individuals should be identifiable to the person (e.g. write name on headband of respirator, store in a specified location, etc.).

Maintenance

Filtering facepieces respirators have no replaceable parts and are considered disposable. Elastomeric facepiece respirators and PAPRs, however, do have parts and filters that need to be available when a replacement is needed. Planning for a pandemic event should include not only the respirator system, but any replacement parts and filters that may be required. In addition, PAPR systems operate on a battery which requires a battery charging and maintenance program be in place or

detailed in preparedness plans. For guidance on battery charging and maintenance of 3M PAPRs refer to 3M Technical Data Bulletin #151 - PAPR Management and Planning for First Responders, and the specific User Instructions for the PAPR.

Infection Control

CDC's guidance indicates if a respirator that provides protection from splashes of blood or body fluids is needed, an FDA-cleared surgical respirator should be selected. Currently, only certain filtering facepiece respirators have been cleared by the FDA as surgical respirators.

An additional infection control consideration is that PAPRs and respirators with exhalation valves allow the air, including the person's exhaled breath, to be released into the environment. If worn by an infected person, these respirators would not prevent transmission of a virus from the wearer. PAPRs and respirators with exhalation valves should not be used in healthcare environments requiring a sterile environment such as the operating room.

Ability to Perform Job Duties

Selection criteria may also include which style respirator will be least likely to affect the person's ability to perform job duties. The ability to communicate to co-workers and patients is perhaps least affected by filtering facepiece respirators. Speaking while wearing elastomeric facepiece respirators may sound slightly more muffled.

PAPRs also have some noise associated with the motor blower which may interfere with the ability to hear while using a stethoscope. It is not recommended to use a stethoscope with a hood as the stethoscope tubing may interfere with the sealing area.

Summary

Many aspects of respirator use and selection must be considered while planning for the possibility of a pandemic influenza event. Table B is a summary of the considerations described in this document. Preparedness planning may require a combination of approaches and perhaps even selection of a variety of respiratory protection products. Respirator use in a healthcare setting, as in any occupational setting, must be in compliance with a complete respiratory protection program in accordance with OSHA regulations (29 CFR 1910.134).

Table B. Summary of Consideration

Consideration	Filtering Facepiece Respirator	Elastomeric Half Facepiece Respirator	Elastomeric Full Facepiece Respirator	PAPR with Loose-fitting Facepiece	PAPR with Hood
Reduction in Exposure Desired (US OSHA Assigned Protection Factors)	APF of 10	APF of 10	APF of 50 (if quantitatively fit tested) APF of 10 (if qualitatively fit tested)	APF of 25	APF of 25 or 1000 (consult manufacturer)
Requires Fit Testing	Yes	Yes	Yes	No	No
Can be Used with Facial Hair	No	No	No	Limited facial hair	Yes
Reusable	No	Yes, with cleaning and disinfection. Dispose of used filters.	Yes, with cleaning and disinfection. Dispose of used filters.	Yes, with cleaning and disinfection. Dispose of used filters.	Yes, with cleaning and disinfection. Dispose of used filters.
Maintenance Required	No	Yes	Yes	Yes	Yes
Batteries to Charge	No	No	No	Yes	Yes
Exhaled Breathe Released into Environment	No (without valve), Yes (with valve)	Yes	Yes	Yes	Yes
Compatibility with Stethoscope	Yes	Yes	Potentially	Potentially	No

References

1. Centers for Disease Control and Prevention. Interim Guidance for Infection Control Within Healthcare Settings When Caring for Confirmed Cases, Probably Cases, and Cases Under Investigation for Infection with Novel Influenza A Viruses Associated with Severe Disease; Updated January 26, 2016.
2. "Approval of Respiratory Protective Devices," Code of Federal Regulations Title 42, Part 84, 1996. p.533.
3. Chen, S.K., Vesley, D., Brosseau, L.M., and J.H. Vincent. Evaluation of single-use masks and respirators for protection of health care workers against mycobacterial aerosols. Am. J. Infect. Control 22:65-74; 1994.
4. Brosseau, L.M., McCullough, N.V. and D. Vesley. Mycobacterial aerosol collection efficiency of respirator and surgical mask filters under varying conditions of flow and relative humidity. Appl. Occup. Environ. Hyg. 12(6):435-445; 1997.
5. McCullough, N.V., Brosseau, L.M. and D. Vesley. Collection of three bacterial aerosols by respirator and surgical mask filters under varying conditions of flow and relative humidity. Ann. Occup. Hyg. 41(6):677-690; 1997.
6. Qian, Y., Willeke, K., Grinshpun, S.A., Donnelly, J. and C.C. Coffey. Performance of N95 respirators: Filtration efficiency for airborne microbial and inert particles. AIHA Journal 59: 128-132; 1998.
7. Willeke, K., Qian, Y., Donnelly, J., Grinshpun, S.A. and V. Ulevicius. Penetration of airborne microorganisms through a surgical mask and a dust/mist respirator. AIHA Journal 57; 348-355; 1996.
8. "Respiratory Protection," Code of Federal Regulations Title 1910, Part 134. 2005. pp. 419-444.
9. "Assigned Protection Factors," Federal Register 71:164 (August 24, 2006) pp. 50122-50192.
10. 3M Technical Data Bulletin #218 - 3M™ Versaflo™ Loose Fitting Facepieces Hoods and Helmets: Use with Facial Hair. July 2013.

3M Technical Data Bulletins

- 3M Technical Data Bulletin #151 - PAPR Management and Planning for First Responders
- 3M Technical Data Bulletin #174 - Respiratory Protection for Airborne Exposure to Biohazards
- 3M Technical Data Bulletin #175 - Assigned Protection Factors (APF) for Hoods and Helmets
- 3M Technical Data Bulletin #218 - 3M™ Versaflo™ Loose Fitting Facepieces Hoods and Helmets: Use with Facial Hair
- 3M Technical Data Bulletin #222 - Cleaning, Inspection, and Storage of the 3M™ Versaflo™ PAPR TR-600
- 3M Technical Data Bulletin #231 - Respirators and Surgical Masks: A Comparison

Additional Resources

- CDC Website: www.cdc.gov
- OSHA Website: www.osha.gov

Bulletin Change Summary

For the most current 3M Technical Information available, please view this Bulletin electronically and click on the blue underlined links to view the relevant documents. Please read the entire Bulletin thoroughly.

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- Updated content throughout document.
- Updated hyperlinks throughout document.
- Updated format.

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