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Respiratory Protection for Exposures to the Influenza A (H1N1) Virus: Health Care and Laboratory Workers

Frequently Asked Questions (FAQs)

3M has received a number of inquiries regarding the selection of appropriate respirators for use against potential occupational exposures to the H1N1 influenza (previously referred to as "swine flu") virus in healthcare and laboratory settings. Following are responses to many of the most commonly asked questions. It is important to note this FAQ is not a substitute for the guidance of the Centers For Disease Control and Prevention (CDC) and World Health Organization (WHO). Please frequently consult their websites for the most current information and infection control procedures regarding H1N1 influenza.

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CDC: http://www.cdc.gov/h1n1flu/
WHO: http://www.who.int/en/

What does CDC recommend for Health Care workers regarding the use of respiratory protection against the virus that causes H1N1 influenza?

In their guidance "Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Healthcare Setting", May3, 2009, the CDC's current recommendation for respiratory protection is:

"All healthcare personnel who enter the rooms of patients in isolation for swine influenza should wear a fit-tested disposable N95 respirator or equivalent (e.g., powered air purifying respirator)*. Respiratory protection should be donned upon room entry."

"Note that this recommendation differs from current infection control guidance for seasonal influenza, which recommends that healthcare personnel wear surgical masks for patient care. The rationale for the use of respiratory protection is that a more conservative approach is needed until more is known about the specific transmission characteristics of this new virus. This recommendation is also outlined in the October 2006 "Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Healthcare Settings during an Influenza Pandemic" http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html."

"*Respirator use should be in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) regulations. Information on respiratory protection programs and fit test procedures can be accessed at www.osha.gov/SLTC/etools/respiratory. Staff should be medically cleared, fit-tested, and trained for respirator use, including: proper fit-testing and use of respirators, safe removal and disposal, and medical contraindications to respirator use."

A copy of the CDC documents can be accessed at http://www.cdc.gov/h1n1flu

What does CDC recommend for Laboratory Workers regarding the use of respiratory protection against the virus that causes H1N1 influenza?

On May 1, 2009 the CDC updated "H1N1 Influenza Virus Biosafety Guidelines for Laboratory Workers." Laboratory workers who may be processing or performing diagnostic testing on clinical specimens from patients with suspected H1N1 influenza virus infection, or performing viral isolation should wear respiratory protection, specified as a fit tested N95 respirator or higher level of protection.

A copy of the CDC documents can be accessed at http://www.cdc.gov/h1n1flu/

Do I need eye protection when exposed to patients with suspect or confirmed Influenza A(H1N1)?

Yes. The World Health Organization (WHO) has recommended protective eyewear for healthcare workers providing care for confirmed or suspected A(H1N1) influenza patients. Additionally, the U.S. Centers for Disease Control and Prevention (CDC) has issued multiple guidances which included recommendations for protective eyewear for healthcare and emergency medical services workers providing care for confirmed or suspected H1N1 influenza patients and laboratory workers. These guidances specify goggles or faceshields as appropriate eyewear for infection control and laboratory activities. The complete WHO and CDC guidance documents should be reviewed carefully to understand all recommendations. www.who.int and www.cdc.gov/h1n1flu/

Unvented and indirectly vented goggles when used properly, can help provide eye protection from splashes, sprays and droplets. Face shields should have crown and chin protection and wrap around the face to the point of the ear. If a faceshield is used, a primary means of eye protection, such as goggles is still required.

Can a European or Australian/New Zealand or other approved respirator be used for H1N1 influenza?

At the present time, the Centers for Disease Control and Prevention's (CDC) guidance states that a National Institute for Occupational Safety and Health (NIOSH)-certified N95 particulate respirator, or one with an equivalent or higher level of protection, should be used in health care settings and community settings in specific situations.

At this time the World Health Organization (WHO) is recommending European CE approved particulate respirators, EN149:2001 approved FFP2 or FFP3 disposable respirator or EN143:2000 P2 filters or respirators with higher levels of protection, for use outside the United States to help reduce health care worker's exposures to airborne organisms in certain situations such as during aerosol generating procedures.

The WHO has posted the following "interim guidelines" on their Influenza A(H1N1) website, under the area for guidance for Healthcare Management and Facilities, which lists examples of acceptable disposable particulate respirators. "Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care", June 2007.

"Examples of acceptable disposable particulate respirators in use in various parts of the world include:
−Australia/New Zealand: P2 (94%), P3 (99.95%)
−China: II (95%), I (99%)
−European Union: CE-certified filtering face-piece class 2 (FFP2) (95%), or class 3 (FFP3) (99.7%)
−Japan: 2nd class (95%), 3rd class (99.9%)
−Republic of Korea: 1st class (94%), special (99.95%)
−United States: NIOSH-certified N95 (95%), N99 (99%), N100 (99.7%)."

This document can be found at
http://www.who.int/csr/resources/publications/WHO_CDS_EPR_2007_6c.pdf

The WHO, the CDC and your local health authority should be referenced for the most current information and guidelines.

If the above listed certified respirators are not available then the facility's management must make an informed decision as to whether or not to use a respirator that is equivalent to those respirators specified in the CDC or any local guidance. Certain approved respirators, such as those approved as a European or Australian/New Zealand "P1" respirator, are not considered equivalent to those specified in the CDC guidances. Therefore, 3M does not recommend "P1" respirator use in health care or other settings to reduce exposures to the virus that causes H1N1 influenza. Respirator efficiency, fit of the respirator, and wear time all play a role in effectively reducing exposures but they cannot eliminate the risk of contracting infection, illness, or disease. It is anticipated that fitted and properly worn certified respirators will reduce the inhalation exposure to the virus that causes H1N1 influenza.

It is important to remember any government-approved respirators will help to reduce your exposure but will not eliminate exposure or the risk of contracting disease, illness or infection.

What is a type N95 respirator?
N95 is one of nine classifications for National Institute for Occupational Safety and Health (NIOSH) certified particulate respirators.

Can respirators protect you from biological agents such as bacteria or viruses?
It is probable that H1N1 influenza is spread from person to person in several ways. Therefore, a respirator is just one of several preventative measures that can be used to help reduce exposure to the virus that causes H1N1 influenza. Respirators are designed to reduce exposures of the wearer to airborne hazards. Biological agents, such as bacteria or viruses, are particles and can be filtered by particulate filters with the same efficiency as non-biological particles having the same physical characteristics (size, shape, etc.). However, unlike most industrial particles there are no exposure limits, such as Permissible Exposure Limit (PEL) or Threshold Limit Value (TLV), established for biological agents such as the H1N1 influenza virus. Therefore, respirators are not a guarantee that the user will not contract H1N1 influenza. Respirators may help reduce exposures to airborne biological contaminants, but they don't eliminate the risk of exposure, infection, illness, or death. For additional information regarding filtration of biological hazards, please refer to 3M Technical Data Bulletin #174 titled "Respiratory Protection Against Biohazards". The technical data bulletin can be accessed at the 3M websites provided at the end of the FAQs.

Can medical facemasks be used to help reduce exposures to biological agents?
Medical, surgical and patient care masks are not designed to protect the wearer from inhaling airborne hazards; therefore 3M recommends that they not be used for this purpose, or in place of an approved respirator.

What is the difference between a government-certified respirator and a surgical mask?
Respirators are designed to help reduce the wearer's exposure to airborne particles. The primary purpose of a surgical facemask is to help prevent biological particles expelled by the wearer from going into the environment. Surgical masks are also designed to be fluid resistant to splash and splatter of blood and other infectious materials.. Surgical facemasks are not necessarily designed to seal tightly to the face and therefore the potential of air leakage around the edges exists. Even those masks that appear similar to respirators have not been designed to protect the wearer from airborne hazards or tested to the same level of filtration efficiency; therefore they should not be considered an equivalent substitute to government-approved respirators. Some approved respirators are designed to have the characteristics of both an approved respirator and a surgical mask. In the U.S., these products are both approved by the National Institute for Occupational Safety and Health (NIOSH) and cleared by the U.S. Food and Drug Administration (FDA) as surgical masks.

Are there any medical restrictions for wearing a respirator?
Individuals with a compromised respiratory system, such as asthma or emphysema, or people with a history of heart disease should consult a physician before wearing a respirator. When personal protective equipment, including respirators, is used in a professional environment, its use must comply with applicable workplace standards, regulations and policies. In the United States, workers must receive medical clearance to wear a respirator from a licensed health care professional prior to using the respirator.

What are the limitations of using respirators for potential exposures to H1N1 influenza?
Respirators are not a guarantee that the user will not contract H1N1 influenza. The following items need to be carefully read and understood.

- Respirators may help reduce exposure to airborne biological contaminants, but they don't eliminate the risk of exposure, infection, illness, or death.
- For greatest effectiveness respirators need to be worn before and during the entire exposure period.
- Respirators may help protect your lungs, however, some biological contaminants may be absorbed through the skin or eyes and other protective equipment may be required.
- Fit of the respirator to the face is very important. If it does not fit properly, airborne contaminates will penetrate (enter underneath) the facepiece seal.
- 3M respirators are not designed for children.
- Anything that comes between the respirator and face will make the respirator less effective by interfering with its fit. Men should shave every day that they may use the respirator. Hair, jewelry and clothing should not be between the face and the respirator.
- Training on proper use and limitations, including practice putting the respirator on and wearing it is required for workers before they use the respirator.
- Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician before wearing a respirator. In the United States, workers must receive medical clearance to wear a respirator from a licensed health care professional prior to using the respirator.

Each facility or individual should use the best available information to determine appropriate respiratory protection for exposures to the virus that causes H1N1 influenza.

Are multiple sizes of respirators needed?
Multiple sizes of respirators are not mandatory. Multiple sizes or alternative facepiece designs can provide the individual with additional options for obtaining a good fit and seal. What is important is that the respirator fit the wearer.

How important is fit?
Fit is very important. If a respirator does not seal tightly to the face, airborne hazards can penetrate or enter underneath the facepiece seal and into the breathing zone. It is very important to always follow the donning instructions and do a user seal-check or fit-check before entering the contaminated environment. A good fit can only be obtained if the face is clean-shaven in the area where the respirator seals against the face. Beards, long mustaches, and stubble may cause leaks into the respirator. Many medical facemasks, not approved as respirators, do not seal tightly to the face allowing airborne hazards to enter the breathing zone. Even those medical facemasks that appear to seal tightly to the face have not been designed to protect the wearer from airborne hazards. Therefore, they should not be considered an equivalent substitute for government-approved respirators.

Some approved respirators are designed to have the characteristics of both an approved respirator and a surgical mask. In the U.S., these products are both approved by National Institute for Occupational Safety and Health (NIOSH) as a respirator and cleared by the U.S. Food and Drug Administration (FDA) as a surgical mask. Workplace environments, such as health care facilities, must follow local government standards and regulations concerning respirator use such as training and fit testing.

In U.S. workplaces, the Occupational Safety and Health Administration (OSHA) requirements for respiratory protection (1910.134) must be followed including medical evaluation, training, and fit testing for employees required to use respirators in the workplace. In the U.S., health care workers, and other employees that are required to wear respirators must do a fit test before wearing the respirator for the first time. This fit test must be performed before a new make or model of respirator is worn by the employee. For U.S. employees required to wear a respirator, a user seal check cannot be used as a substitute for the fit test.

In countries where the OSHA standards do not apply, health care workers and other employees required to wear a respirator should follow applicable national workplace standards, regulations and policies concerning use, fit-testing/checking and training. 3M recommends that fit testing and training always be conducted.

What if I have a beard or stubble and want to wear a respirator?
A tight sealing respirator, one where the sealing surface contacts the face, will not provide an adequate seal when placed over any amount of facial hair. A bearded worker will typically require a powered air-purifying respirator (PAPR) with a hood or helmet.

How do I put on the respirator and check for proper fit?
The *User Instructions* for a 3M respirator contain the proper procedures for putting on the respirator and checking for fit and seal. It is very important to read and follow the donning instructions very carefully and to conduct a fit check or user seal check every time the respirator is put on. The user instructions are provided with the original packaging of the respirator.

Donning Instructions for 3M Filtering Facepiece Respirators for Workers can be found at the following 3M websites as well:

Fit Instructions for Cup-Shaped Filtering Facepiece Respirators, Professionals - Bulletin

http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6lVs6EVs666vQFCOrrrrQ-

Respirador Libre de Mantenimiento en Forma de Copa, Profesionales - Boletín

http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6lVs6EVs666vQfCOrrrrQ-

Fit Instructions for Filtering Facepiece Three-Panel Respirator - Bulletin

http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6lVs6EVs666vQDCOrrrrQ-

Respirador Libre de Mantenimiento Plegable - Boletín

http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6lVs6EVs666vQdCOrrrrQ-

How is a user seal check/fit check performed on a disposable respirator?
The *User Instructions* for a 3M respirator contain the proper procedures for putting on the respirator and checking for fit and seal. It is very important to read and follow the donning instructions very carefully and to conduct a fit check or user seal check every time the respirator is put on. The user instructions are provided with the original packaging of the respirator. Additionally, the website links listed in the previous question contain the proper procedures for putting on the respirator and checking for fit and seal for 3M filtering facepiece respirators.

User seal checks (fit checks) are to be performed in non-contaminated or clean areas only. If, during the *user seal check* (fit check), you notice air leakage around the edges of the respirator you should readjust the respirator. If you still notice air leakage, you should remove the respirator (in a clean area only). Review the instructions, if necessary, to make sure that you are putting it on correctly. Inspect the respirator to make sure that there is no damage to the respirator. You must be clean-shaven. Be sure that there is no hair, clothing or jewelry between your skin and the edge of the respirator. Put the respirator on again, according to the manufacturer's directions. Do a *user seal check* (fit check). If you still cannot achieve a proper seal, do not enter the contaminated area. You may need to obtain a different size, make or model respirator. In the U.S. and certain other countries, workers need to pass a fit test before wearing a respirator for the first time. If you do not pass a fit test on the first try, you should remove the respirator. Reread the instructions and put it on again. Conduct a *user seal check* (fit check). If you do not feel any air leakage around the respirator edges, then you should try the fit test again. If you fail the fit test on the second try, do not enter the contaminated area. You should obtain a different size, make or model of respirator. Follow local regulations regarding fit testing.

What is the shelf life of 3M's filtering facepiece respirators?

In the U.S. there is currently no regulatory requirement for manufacturers of respiratory protection devices to include storage or shelf life information. In their Respiratory Protection standard, 29 CFR

1910.134, OSHA does require that respirators be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and that they be stored to prevent deformation of the facepiece and exhalation valve. OSHA also requires respirators be stored in accordance with any applicable manufacturer instructions and that the wearer inspect the product prior to use. If a user finds a respirator that has damage to a component they should discard it and get a different respirator of the same model.

Although there is currently no shelf life stated on most 3M NIOSH approved filtering facepiece respirators, respirator shelf life will benefit from controlled storage conditions. 3M recommends filtering facepiece respirators be stored in their original packaging within climatic conditions ranging from -4°F (-20°C) to +86°F (+30°C) and not exceeding 80% RH.. Always inspect product and conduct a user seal check before use as specified in the *User Instructions*. Examine all the respirator parts for signs of damage including the headbands, nose foam and staples, If a user finds a respirator that has damage to a component they should discard it and get a different respirator of the same model. **If you cannot achieve a proper seal, do not use the respirator.**

Outside the United States shelf life ("use by" dates) and/or storage conditions are commonly required by country respirator certification standards. Such statements are found on many of the products manufactured to other requirements, including European standards (CE marked), where the end of shelf life and storage conditions (temperature and humidity) are required by the regulation to be communicated on the packaging. Typical use by dates for filtering facepiece respirators are in the three to five year range for product stored in the conditions specified on the packaging.

Can disposable respirators be shared between people?
Disposable respirators should never be shared.

What is BFE, and what does it measure?
BFE stands for Bacterial Filtration Efficiency. This test evaluates how well a surgical mask can prevent biological particles expelled by the wearer from entering into the environment. Some approved respirators are designed to have the characteristics of both an approved respirator and a surgical mask and they will also have been tested for BFE. Bioaerosol particles generated during the BFE test are “large,” on the order of 1 to 5 microns in size. For comparison, particles used for respirator filter efficiency tests are much smaller, approximately 0.3 microns in size. The BFE test is a relative indicator of the performance of a medical, surgical or patient care mask but the results are not comparable to respirator certification filtration efficiency.

Are government-certified respirators tested for BFE?
They are not necessarily tested for Bacterial Filtration Efficiency (BFE). The BFE result has little meaning for government-certified respirators. More stringent filter efficiency tests are used for certification testing of respirators. The manufacturers of combination approved respirator/surgical masks will publish BFE results. BFE results are not necessarily useful for applications outside of the health care industry.

Can a valved respirator be used for protection from the virus that causes H1N1 influenza?
A valved respirator is designed to allow for easy exhalation through a one-way exhalation valve. If a person is wearing a respirator to help reduce his or her exposure to airborne viruses, a respirator with an exhalation valve would be acceptable. It would not be acceptable for someone to wear a valved respirator if they have a are suspected/probable/confirmed case of H1N1 influenza, as they may be exhaling airborne viruses into the environment.

For other situations where healthcare workers are required to wear a respirator the use of a valved respirator must be in accordance with national guidelines. For example, in some regions of the world such as the U.S. and Canada, it is not acceptable for a healthcare worker to wear a valved respirator in a situation requiring a sterile environment, such as the operating room.

Respirators should not be worn by a person whose respiratory system has been compromised or who may have trouble breathing through a respirator, unless otherwise advised by your personal physician.

Should an influenza patient wear a respirator?
The CDC's "Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Healthcare Setting" updated on May 3, 2009 states that an "*ill person should wear a surgical mask when outside of the patient room*,". Additionally the CDC recommends frequent hand washing, following good respiratory hygiene practices, not sharing cups and utensil and applying routine cleaning and disinfection practices used during influenza season.

The CDC is not recommending the use of respirators by influenza patients at this time. 3M recommends that patients, and any individual, whose respiratory system has been compromised or who may have trouble breathing through a respirator, consult with their personal physician before donning a respirator.

Is fluid resistance important?
The health care facility must determine the need to provide fluid resistant respirators to their health care workers and for which tasks fluid resistant respirators are necessary. In the U.S., the Occupational Safety and Health Administration (OSHA) has specific provisions under the Bloodborne Pathogen Standard that specifically details the "appropriateness" of personal protective equipment used by health care workers. Fluid resistance is the ability of a respirator's or mask's material construction to minimize a high pressure stream of fluid from traveling through the material and potentially coming in contact with the user of the facemask. If the mask or respirator comes in contact with blood or body fluids of a suspected or confirmed influenza patient, it is recommended the respirator be changed as soon as possible. Respirators should only be removed when the wearer is in an area that is considered free of airborne hazards, including confirmed or suspected influenza patients.

What precautions should visitors take when visiting facilities with H1N1 influenza patients?
Prior to entering a health care setting, visitors should consult with the facility's Infection Control Practitioner regarding visitor policies.

Can I clean or wash a disposable respirator?
Under no circumstances should an attempt be made to clean or wash a disposable respirator.

If I use a disposable respirator in areas (i.e. healthcare settings) with suspected or confirmed H1N1 influenza patients, should I discard the respirator after use?
The recommendations of the local health authority and the facilities infection control practitioner should be followed.

Can a disposable respirator be reused if worn in an area where there have been no suspected or confirmed patients with H1N1 influenza?
The recommendations of the local health authority and the facilities infection control practitioner should be followed. Respirators may be used according to local guidelines, until they become damaged, or contaminated with blood or body fluids. Otherwise a respirator should be stored in a clean environment to protect it from damage, contamination, dust, sunlight, extreme temperatures, and damaging chemicals. Respirators must also be properly stored to prevent their deformation. Wearers should remove their respirator only when they are in an area that is considered free of airborne hazards, including confirmed or suspected H1N1 influenza patients.

How should respirators be disposed of after use?
The recommendations of the respirator manufacturer, the local health authority and the facilities infection control practitioner should be followed.

What is the risk of inhaling biological particles that have been collected by the respirator filter?
The risk of inhaling particles that have been collected by the filter is very low, particularly in very clean areas (such as a patient care setting or a home). When particles are collected on a filter they are strongly held to the filter. Breathing through a filter has not been shown to dislodge the particles collected in that filter. However, it is important to understand that proper use of respirators only reduces your exposure to particles and does not prevent the risk of some exposure.

Can particles, such as bacteria or viruses, be reaerosolized from the respirator filter?
When particles are collected on a filter they are strongly held to the filter. Proper and normal use of a respirator has not been shown to reaerosolize the particles collected in that filter. Just because particles may not reaerosolize, does not mean that a respirator can be reused. The recommendations of the local health authority and the facilities infection control practitioner regarding reuse should be followed.

Do 3M disposable respirators contain natural rubber latex? None of 3M's National Institute for Occupational Safety and Health (NIOSH) approved N95, N100, R95, P95, or P100 disposable respirators contain components made from natural rubber latex. This is stated on each original packaging of these respirators. Many 3M respirators sold outside the U.S. do not contain components made from latex. However, there are some that contain natural rubber latex components and these respirators carry a statement on the primary packaging similar to the following: "This product contains components which contain natural rubber latex which may cause allergic reaction." If you require information on which 3M products contain natural rubber latex components, please contact your local 3M office.

What do N, R, and P stand for?
For the following National Institute for Occupational Safety and Health (NIOSH) filter designations N stands for Not Resistant to oil; R stands for Resistant to oil; and P stands for oil Proof.

Do any of 3M's disposable respirators contain fiberglass material?
No. All 3M disposable respirators have filter media made from polypropylene and coverings typically made from a combination of polypropylene, polyester.

For more information, visit www.3M.com/OccSafety or www.3M.com/swineflu .