



The FDA and Personal Protection Equipment for the 2009 H1N1 Flu Virus Questions and Answers

Q: What are facemasks and N95 respirators?

Facemasks and N95 respirators are devices that when properly worn may help prevent the spread of germs (viruses and bacteria) from one person to another.

Facemasks and N95 respirators do not provide complete protection from airborne germs and other contaminants. They are one part of an infection-control strategy that should also include frequent hand washing, social distancing, and staying home when sick.

Facemasks and N95 respirators should not be shared. Facemasks and respirators may become contaminated with germs (viruses and bacteria) that can be spread between people.

It is important to understand that if you are exposed to infectious material while wearing a facemask or N95 respirator, it should be considered contaminated. After you remove it and dispose of it properly, wash your hands thoroughly.

Q: What's the difference between a facemask and an N95 respirator?

A facemask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.

If worn properly, a facemask is meant to help block large-particle droplets, splashes, sprays or splatter that may contain germs (viruses and bacteria) from reaching your mouth and nose. Facemasks may also help reduce exposure of your saliva and respiratory secretions to others.

While a facemask may be effective in blocking splashes and large-particle droplets, a facemask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes or certain medical procedures. Facemasks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the facemask and your face.

An N95 respirator is a respiratory protective device designed to achieve a very close facial fit and efficient filtration of airborne particles. In addition to blocking splashes, sprays and large droplets, the respirator is also designed to help prevent the wearer from breathing in small particles that may be in the air.

To work as expected, an N95 respirator requires a proper fit to your face. It is designed to fit tightly over your mouth and nose, with no gaps. And gaps will allow air to pass around and reach your nose, mouth, and lungs without being filtered.

The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of small test particles. If properly fitted, the filtration capabilities of N95 respirators

exceed those of face masks. However, even a properly fitted N95 respirator does not completely eliminate the risk of contracting illness through airborne viral particles.

N95 respirators are not designed for children or people with facial hair. **Because a proper fit cannot be achieved on children and people with facial hair, the N95 respirator may not provide the expected protection.** Also, people with chronic respiratory, cardiac, or other medical conditions that make it harder to breathe should check with their healthcare provider before using an N95 respirator because the N95 respirator can require more effort to breathe.

FDA has cleared the following N95 respirators for use by the general public in public health medical emergencies:

3M™ Particulate Respirator 8670F
3M™ Particulate Respirator 8612F
Pasture Tm F550G Respirator
Pasture Tm A520G Respirator

These devices are labeled "NOT for occupational use."

Q: Do N95 respirators reduce the chances of contracting the 2009 H1N1 flu virus?

When worn properly, N95 respirators help reduce your exposure to airborne germs. They do not provide complete protection from airborne germs and other contaminants, however. They are one part of an infection-control strategy that should also include frequent hand washing and staying home when sick.

Q: Is it OK to use one disposable N95 respirator for a long time?

Disposable N95 respirators are not intended to be used over long periods of time. If the respirator is damaged, torn or soiled, or if it becomes difficult to breathe while wearing it, remove it and replace it with a new one.

It is important to understand that if you are exposed to infectious material while wearing an N95 respirator, your respirator should be considered contaminated. After you remove it and dispose of it properly, wash your hands thoroughly.

Additional references on this can be found at the following:

U.S. Centers for Disease Control and Prevention
"Recommendations for Facemask and Respirator Use in Certain Community Settings Where H1N1 Flu Virus Transmission Has Been Detected"
<http://www.cdc.gov/swineflu/masks.htm>

"The Department of Health and Human Services Guidelines for the Use of Facemasks and Respirators in Non-Occupational Settings during an Influenza Pandemic"
<http://www.pandemicflu.gov/plan/community/maskguidancecommunity.html>

Q: Is it OK to re-use or share a disposable N95 respirator?

Disposable N95 respirators are not intended to be used more than once. They should also never be shared. Their protective capabilities cannot be assured when they are reused either by yourself or another person. Perhaps more importantly, by sharing, one may inadvertently be exposing another person to infectious material.

It is important to understand that if you are exposed to infectious material while wearing an N95 respirator, your respirator should be considered contaminated. After you remove it and dispose of it properly, wash your hands thoroughly.

Q: What other personal protective equipment does FDA regulate?

Personal protective equipment (PPE) is any type of face mask, glove, eye shield, or specialized clothing that acts as a barrier between infectious materials and the skin, mouth, nose, or eyes (mucous membranes). When used properly, PPE can help prevent the spread of infection from blood, body fluids, or respiratory secretions.

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) requires employers to provide appropriate PPE for workers who could be exposed to blood or other infectious materials (bloodborne pathogens). OSHA may also require employers to provide PPE to protect against other hazards at work. Although OSHA requires the use of specific equipment, it does not regulate the marketing of these devices nor grant claims of disease prevention. For more information, go to <http://www.OSHA.gov>.

The U.S. Centers for Disease Control and Prevention (CDC) gives recommendations for protecting yourself from infection, including swine flu. For more information, go to <http://www.cdc.gov/h1n1flu/>.

The National Institute for Occupational Safety and Health (NIOSH) has established certification requirements for various respiratory PPE, which are found at 42 CFR part 84. NIOSH tests products for compliance with these regulations and issues a certification for products that comply. NIOSH certification evaluates the performance of respiratory protection equipment in functional terms and not in terms of claims for use in preventing disease. Employers subject to OSHA and the Mine Safety and Health Administration (MSHA) regulation may be required to provide NIOSH-certified respiratory protection equipment to satisfy their OSHA and MSHA requirements.

Q: Where can I find additional information on personal protective equipment (PPE)?

For more information on Personal Protective Equipment (PPE), go to: <http://www.fda.gov/cdrh/ppe/>

Q: What is the purpose of the FDA's Emergency Use Authorization for certain N95 disposable respirators?

A: The FDA issued an Emergency Use Authorization (EUA) for certain disposable respirators known as N95 respirators. This EUA permits the deployment of these products, accompanied by fact sheets with information for use during the 2009 H1N1 flu virus emergency, from the Strategic National Stockpile for use by the general public to help reduce wearer exposure to airborne germs during this emergency. The term "general public" in this EUA is broad and includes people performing work-related duties.

Q: Does the FDA's Emergency Use Authorization for certain disposable N95 respirators cover only products in the Strategic National Stockpile?

A: The FDA's EUA for certain disposable N95 respirators for use by the general public during the 2009 H1N1 flu emergency is limited to only those products deployed from the Strategic National Stockpile (SNS) before or after the signing of the EUA on April 27, 2009. The specific products

covered by the EUA are identified by manufacturer and model number (see <http://www.fda.gov/cdrh/emergency/N95-authorization.html>).

Q: Does the FDA's Emergency Use Authorization for certain disposable N95 respirators permit them to be re-used in health care settings?

A: The FDA's EUA for certain disposable N95 respirators for use by the general public does not permit the re-use of N95 respirators.

Q: Does the FDA's Emergency Use Authorization for certain disposable N95 respirators cover health care employees?

A: Yes, the term "general public" in this EUA is broad and includes people performing work-related duties, for example in occupational health care settings. However, this EUA does not affect Occupational Safety and Health Administration (OSHA) requirements. If respirators are used for people in occupational settings, employers must comply with the OSHA Respiratory Protection Standard, (29 CFR 1910.134), which can be found at <http://www.OSHA.gov>.

Q: Does the FDA's Emergency Use Authorization for certain disposable N95 respirators lift the fit-testing requirements?

A: No, the EUA does not waive fit testing and other OSHA requirements that apply when respirators are used for people performing work-related duties.

The FDA's EUA and accompanying fact sheet can be found on the FDA's Web site at: <http://www.fda.gov/cdrh/emergency/h1n1influenza.html>. For further information on OSHA requirements, go to <http://www.OSHA.gov>.
