Eye Protection, Face Mask and Contingency Planning for Doctors of Optometry and Staff During COVID-19 Pandemic

According to the U.S. Centers for Disease Control and Prevention (CDC), all health care personnel working in facilities located in areas with moderate to substantial community transmission are more likely to encounter asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection.

WITH HIGH COMMUNITY SPREAD THROUGHOUT THE U.S. (INCLUDING NEW COVID-19 VARIANTS DISCOVERED IN MANY STATES) AND HIGH RATES OF ASYMPTOMATIC COVID-19 DISEASE, DOCTORS OF OPTOMETRY AND STAFF (INCLUDING THOSE VACCINATED) ENGAGED IN CLOSE PATIENT CONTACT (LESS THAN 5 FEET) SHOULD WEAR EYE PROTECTION (FACE SHIELD OR GOGGLES) AS MUCH AS IS PRACTICABLE DURING AN EXAMINATION IN ADDITION TO N95 MASKS.

If SARS-CoV-2 infection is not suspected in a patient presenting for care (based on symptom and exposure history), health care personnel should follow Standard Precautions and Transmission-Based Precautions if required based on the suspected diagnosis (*e.g. asymptomatic disease*). At least 50% of new SARS-CoV-2 infections was estimated to have originated from exposure to individuals with infection but without symptoms.[i] Health care personnel should also wear eye protection in addition to their facemask to ensure the eyes, nose, and mouth are all protected from exposure to respiratory secretions during patient care encounters. (Guidance—Added February 10, 2021)

For health care personnel, the potential for exposure to SARS-CoV-2 is not limited to direct patient care interactions. Transmission can also occur through unprotected exposures to asymptomatic or pre-symptomatic co-workers in breakrooms or co-workers or visitors in other common areas.

Examples of contingency planning and how physical distancing can be implemented for health care personnel include:

- Reminding health care personnel that the potential for exposure to SARS-CoV-2 is not limited to direct patient care interactions.
- Emphasizing the importance of source control and physical distancing in non-patient care areas.

- Providing family meeting areas where all individuals (e.g., visitors, health care personnel) can remain at least 6 feet apart from each other.
- Designating areas and staggered schedules for health care personnel to take breaks, eat, and drink that allow them to remain at least 6 feet apart from each other, especially when they must be unmasked.
- Provide human and fiscal resources to meet occupational health needs related to infection control (e.g., health care personnel immunization, post-exposure evaluation and care, evaluation and management of health care personnel with communicable infections.
- Provide supplies and equipment necessary for the consistent observance of standard precautions, including hand hygiene products and personal protective equipment *(e.g., gloves, gowns, face and eye protection*).
- Develop and implement policies and procedures to ensure that reusable patient care equipment is cleaned and reprocessed appropriately before use on another patient.
- Develop and implement processes to ensure oversight of infection control activities appropriate to the health care setting and assign responsibility for oversight of infection control activities to an individual or group within the health care organization that is knowledgeable about infection control.
- Develop and implement systems for early detection and management (e.g., use of appropriate infection control measures, including isolation precautions, personal protective equipment [PPE]) of potentially infectious persons at initial points of patient encounter in **outpatient settings** (e.g., **triage areas, emergency departments, outpatient clinics, physician offices**).

Properly manage anyone with suspected or confirmed SARS-CoV-2 infection or who has had contact with someone with suspected or confirmed SARS-CoV-2 infection:

  - Health care personnel should be excluded from work and should notify occupational health services to arrange for further evaluation.
  - Visitors should be restricted from entering the facility and be referred for proper evaluation.

Face Masks

N95 respirators and surgical masks are examples of personal protective equipment that are used to protect the wearer from airborne particles and from liquid contaminating the face. The Food and Drug Administration (FDA), CDC, National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) together regulate N95 respirators.

It is important to recognize that the optimal way to prevent airborne transmission is to use a combination of interventions from across the hierarchy of controls, not just PPE alone.

Wherever possible, optometry offices should continue to use FDA-cleared face masks and NIOSH-approved and/or FDA-cleared N95 respirators or better. In response to the COVID-19 pandemic, the FDA has also issued EUAs that authorize certain N95 FFRs, including NIOSH-approved disposable FFRs (see description below) and imported non-NIOSH-approved disposable FFRs, for use in health care settings by

health care personnel and are intended to help increase availability of these devices to front-line personnel during the public health emergency.

The FDA provides guidance to support response efforts to the COVID-19 pandemic: Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency.

This FDA guidance should be instructive for optometry offices attempting to acquire additional face masks, to reuse and sterilize face masks or use non-medical N95 masks to fulfill PPE requirements for health care providers examining patients in a medical setting of an optometry office during this COVID-19 pandemic. Additionally, it will provide useful information on face masks that you can provide patients and the general public.

Highlights include:

1. Informed descriptions of the various types of face masks:
    a. **Face Mask.** A mask that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels.
    b. **Surgical Mask**. A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.
    c. **Filtering Facepiece Respirator.** A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.
    d. **N95 Respirator.** A disposable half-mask FFR that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level and when used in a health care setting is a Class II device, regulated by FDA.
    e. **NIOSH approved N95 respirator.** An N95 respirator, approved by the National Institute for Occupational Safety and Health (NIOSH) that meets an approved filtration efficiency level.
    f. **Surgical N95 respirator.** A disposable FFR used in a health care setting that is worn by HCPs during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at a predetermined N95 filtration efficiency level. A surgical N95 respirator is a Class II device, regulated by FDA.

2. Optometry offices should note that face masks originally intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease are regulated by the FDA. Other face masks and filtering facepiece respirators marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications, are not regulated by the FDA.

3. In general, FDA recommends that health care providers, like doctors of optometry, follow current CDC guidance regarding PPE that should be used during the COVID-19 outbreak. To ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, for the duration of the public health emergency the FDA does not intend to object to the distribution and use of face masks (not including respirators) that

are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency; prior submission of a premarket notification is not required.

   a. HPI notes that with community spread of COVID-19 variants unregulated face masks may create undue risk.

4. Optometry offices should also note that there are FDA PPE requirements for personnel reprocessing respirators, as follows:

   FDA is responsible for the oversight of reprocessed single use medical devices and generally requires the submission of a 510(k) from entities performing these activities. To facilitate the safe reuse and conservation of PPE for the duration of the public health emergency, FDA is working with manufacturers on the reprocessing of otherwise disposable N95 particulate filtering facepiece respirators (and other FFRs) to facilitate marketing authorization through an emergency use authorization (EUA) for reprocessed devices. The FDA will assess the description of the process and validate bioburden reduction/disinfection and approve protocols and acceptance criteria for scale-up of the process. Optometry offices should thus beware of purchasing reprocessed face masks without an FDA label saying the process used was approved. For example:

   i. The FDA will also evaluate mask materials compatibility with methods of reprocessing. For example, cellulose-based materials are incompatible with hydrogen peroxide as hydrogen peroxide will degrade cellulose.
   ii. The FDA will evaluate evidence to demonstrate that repeated exposure to reprocessing cycles does not interfere with the filtration ability or breathability of the masks.
   iii. The FDA will evaluate evidence to demonstrate that repeated exposure to the reprocessing cycle steps does not decrease the ability of the mask to form a tight fit to the wearer's face. This includes evidence to demonstrate that the reprocessing cycle steps do not compromise the integrity of the elastic bands to maintain an appropriate fit to the wearer.

Additional resources for HCP and facilities:

Considerations for Selecting Respirators for Your Health Care Facility

Surgical Mask and Gown Conservation Strategies - Letter to Health Care Providers

Wear Face Masks with No Metal During MRI Exams: FDA Safety Communication

Global concern remains high due to the rapid spread of the disease internationally including alarmingly high numbers of cases identified throughout the U.S. This information is evolving as public health organizations track and learn more about SARS-CoV-2 and its variants. It is important to monitor for changes in information from the FDA, CDC and WHO to best protect against infection.

[i] JAMA Network Open. 2021;4(1): e2035057. doi:10.1001/jamanetworkopen.2020.35057 (Reprinted) January 7, 2021