Updated Eye Protection, Face Mask and Contingency Planning for Doctors of Optometry and Their Staff in Response to the 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.

NEW CDC RECOMMENDATIONS FOR WEARING A MASK OR PHYSICALLY DISTANCING TO PROTECT INDIVIDUALS FROM COVID-19 DISEASE ARE INTENDED TO HELP INDIVIDUALS MAKE DECISIONS ABOUT DAILY ACTIVITIES AFTER BEING FULLY VACCINATED BUT THEY ARE NOT INTENDED FOR HEALTH CARE SETTINGS.

DOCTORS OF OPTOMETRY AND STAFF (INCLUDING THOSE VACCINATED) SHOULD CONTINUE TO WEAR FACE MASKS AND WHEN ENGAGED IN CLOSE PATIENT CONTACT (LESS THAN 5 FEET) WEAR EYE PROTECTION (FACE SHIELD OR GOGGLES) AS MUCH AS IS PRACTICABLE DURING AN EXAMINATION.

On May 13, 2021, the CDC updated guidance for wearing a mask or physically distancing to protect individuals from COVID-19 disease among individuals who have been fully vaccinated.

These new CDC recommendations are intended to help individuals make decisions about daily activities after being fully vaccinated, but they are *not* intended for health care settings.

CDC guidance was most recently updated on April 27, 2021 for settings where health care is delivered which includes, but not limited to; physician offices including optometry offices and other professions, remains in effect. Of utmost importance, the CDC recommends for the increased use of personal protective equipment by health care personnel to remain unchanged and in effect. If you are a health care provider in any capacity and work directly with patients or handle material that could spread infection, it is strongly advised by the CDC to obtain appropriate and recommended vaccines to reduce the likelihood that you will contract or spread vaccine-preventable diseases.[i] Because of the potential for asymptomatic and pre-symptomatic transmission, face masks are recommended for everyone in a health care facility, even if they do not have symptoms of COVID-19.

All health care personnel should continue to implement universal prevention measures.[ii]

These prevention measures include well-fitting cloth masks, surgical style facemasks, or respirators to cover a person's mouth and nose to prevent spread of respiratory droplets and secretions when they are breathing, talking, sneezing, or coughing. This can continue to help prevent the transmission of SARS-CoV-2, the virus that causes COVID-19, by an individual that may not be aware that they are infected and/or contagious. As the material used in these devices varies person to person, these personal protective devices also offer varying levels of protection for the wearer against exposure to infectious droplets and particles produced by other surrounding infected people. It is important for the wearer to remember that a proper mask fit is critical to viral spread transmission and infection.

Patients and visitors of all health care facilities should wear their own well-fitting face mask upon arrival to and throughout their stay in the facility. If they do not bring their own, they should be provided an appropriate and disposable mask that is as consistent as possible with CDC specifications.

Guidance on recommended face masks for health care personnel.

Health care personnel should wear well-fitting face masks at all times while they are in the healthcare facility, including office breakrooms or other spaces where they might encounter co-workers.

To reduce the number of times health care personnel must touch their face and potential risk for self-contamination, health care personnel should consider continuing to wear the same respirator or well-fitting face mask (extended use) throughout their entire work shift.

Health care personnel should remove their respirator or face mask (and properly dispose or clean it) , perform hand hygiene, and put on their community face mask when leaving the facility at the end of their shift.

Communal activities within a health care setting (new update).[iii]

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.

In general, fully vaccinated health care personnel should continue to wear face masks while at work. If unvaccinated health care personnel are present, everyone should wear face masks and unvaccinated health care personnel should continue to physically distance from others.

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 were estimated to have originated from exposure to individuals with infection but without symptoms.[iv] 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 droplets and secretions during patient care encounters. (Guidance—Added February 10, 2021)

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 face masks 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.
- 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.

Prevention of transmission and protection of the unvaccinated and/or those under 12 years of age

Doctors of optometry should be aware that in addition to a large population of Americans still unvaccinated, and large patient and patient dependent population below the age of 12, significant risk is still present for infection, serious illness and death. According to the FDA EUA, both the Pfizer and Moderna vaccines are not effective in preventing COVID-19 among their respective clinical trial participants 100% of the time. That means, while unlikely, a vaccinated person can still become infected and become quite ill or die. Additionally, they can also transmit the virus as well. Below are efficacy results of the clinical trials showing that there is not 100% prevention of acquiring the virus after vaccination.

Pfizer Efficacy

“The data to support the EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who completed the two-dose vaccination regimen and did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received saline

placebo. The vaccine was 95 percent effective in preventing COVID-19 disease among these clinical trial participants with 8 COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group. Of these 170 COVID-19 cases, one in the vaccine group and three in the placebo group were classified as severe. Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if the Pfizer-BioNTech COVID-19 vaccine will reduce such transmission." [v]

Moderna Efficacy

"COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38 degrees C), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS- CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee. The median length of follow up for efficacy for participants in the study was nine weeks post dose two. There were 11 COVID-19 cases in the Moderna COVID-19 vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%)." [vi]

This means that while the Pfizer and Moderna vaccines are highly effective, those vaccinated may still contract and express signs and symptoms of varying degrees of COVID-19 illness, including serious illness, hospitalization and death, however, as previously stated, it is significantly less likely. Additionally, vaccinated persons that contract COVID-19 can still infect others, both vaccinated and unvaccinated. Unvaccinated persons, including those 12 and under, can still become unwell, seriously ill or fatally ill even if they contract the virus from a vaccinated person.

Doctors of optometry are advised: 1.) Educate their patients and patient dependents on the limitations of the vaccines and masks and 2.) Educate their patients and patient dependents to wear a face mask and implement other customary methods of COVID-19 precaution in any type of health care environment. Additionally, specific precautions should especially be taken with populations age 12 and under and those that are in contact with those under age 12 as there is complete certainty that they are unvaccinated, unprotected and still just as vulnerable to COVID-19 transmission as before the vaccines became available within the United States.

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, settings in which clinical optometric care is delivered to the public 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 clinical optometric care settings 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 during this COVID-19 pandemic. Additionally, it will provide useful information on face masks that health care personnel 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-facepiece 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 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. Settings in which clinical optometric care is delivered to the public 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. Settings in which clinical optometric care is delivered 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. 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] https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html
[ii] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
[iii] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html#anchor_1619116573222

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

[v] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions

[vi] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html