Aerosols in Dentistry: The Continuing Story of Respiratory Protection
Support for this program provided by:

HALYARD

Part of the Owens & Minor Family
1. The State of the Pandemic
2. OSHA and CDC Updates
3. FDA Updates
5. Why Mask and Respirator Standards Matter
COVID-19 Pandemic Update

CDC COVID Data Tracker

*Historical cases are excluded from daily new cases and 7-day average calculations until they are incorporated into the dataset for the applicable date. Of 89,986 historical cases reported retroactively, 1,651 were reported in the current week and 1,649 were reported in the prior week.

Note: In the above table, historical data with missing report dates are excluded from current and prior 7-day averages, and the percent change in the 7-day average.

Source: CDC
COVID-19 Pandemic Update

State Profile Report

The State Profile Report (SPR) is generated by the Data Strategy and Execution Workgroup in the Joint Coordination Cell, in coordination with the White House. It is managed by an interagency team with representatives from multiple agencies and offices (including the United States Department of Health and Human Services, the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, and the Indian Health Service). The SPR provides easily interpretable information on key indicators for each state, down to the county level.

For each state, this report provides a weekly snapshot in time that:

- Focuses on recent outcomes in the last seven days and changes relative to the month prior
- Provides additional contextual information at the county level for each state, and includes national level information
- Supports rapid visual interpretation of results with color thresholds

Click here to download the State Profile Report

CDC COVID Data Tracker
M3 I will go to this website briefly during the webinar - just to give the viewers a taste of what info is available to them.
Mary, 4/21/2021
Updated CDC Guidance

Interim Public Health Recommendations for Fully Vaccinated People

Updated May 13, 2021  Languages  Print

Summary of Recent Changes

Updates as of May 13, 2021

- Update that fully vaccinated people no longer need to wear a mask or physically distance in any setting, except where required by federal, state, local, tribal, or territorial laws, rules, and regulations, including local business and workplace guidance.
- Update that fully vaccinated people can refrain from testing following a known exposure unless they are residents or employees of a correctional or detention facility or a homeless shelter.

Key Points

The following recommendations apply to non-healthcare settings. For related information for healthcare settings, visit [Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination](https://www.cdc.gov/coronavirus/2019-ncov/healthcare-professionals/).  

Fully vaccinated people can:

- Resume activities without wearing masks or physically distancing, except where required by federal, state, local, tribal, or territorial laws, rules and regulations, including local business and workplace guidance
- Resume domestic travel and refrain from testing before or after travel or self-quarantine after travel
- Refrain from testing before leaving the United States for international travel (unless required by the destination) and refrain from self-quarantine after arriving back in the United States
- Refrain from testing following a known exposure, if asymptomatic, with some exceptions for specific settings
- Refrain from quarantine following a known exposure if asymptomatic
- Refrain from routine screening testing if feasible

For now, fully vaccinated people should continue to:

- Follow CDC and health department travel requirements and recommendations
Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination

Updated Apr. 27, 2021

Summary of Recent Changes

Updates as of April 27, 2021

- Updated SARS-CoV-2 testing recommendations
- Updated visitation guidance to include recommendations for acute care facilities and to describe circumstances when source control and physical distancing are not required during visitation
- Added guidance for communal activities and dining in healthcare settings

Key Points

- CDC has updated select healthcare infection prevention and control recommendations in response to COVID-19 vaccination, which are summarized in this guidance.
- Updated recommendations on SARS-CoV-2 testing
- Updated recommendations will be added to this page regularly as new information becomes available.

5. Use of Personal Protective Equipment

- Recommendations for use of personal protective equipment by HCP remain unchanged.
Current CDC Guidance for Dental Settings

Guidance for Dental Settings
Interim Infection Prevention and Control Guidance for Dental Settings During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated Dec. 4, 2020
Print

Key Points
- Recognize dental settings have unique characteristics that warrant specific infection control considerations.
- Prioritize the most critical dental services and provide care in a way that minimizes harm to patients from delaying care and harm to personnel and patients from potential exposure to SARS-CoV-2 infection.
- Proactively communicate to both personnel and patients the need for them to stay at home if sick.
- Know the steps to take if a patient with COVID-19 symptoms enters your facility.

Additional Key Resources
- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
- Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic
- Information about managing school sealant programs during COVID-19 on CDC's Considerations for School Sealant Programs page.

Recent Study on COVID-19 and Aerosols


Only 28 individuals in the study – may not be statistically significant

Were patients COVID-19+
Current Guidance from OSHA on Respiratory Protection

<table>
<thead>
<tr>
<th>Recommended PPE ensembles for dentistry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Care of patients in areas where community transmission of COVID-19 has subsided in the local area</strong></td>
</tr>
<tr>
<td><strong>Dental procedures not involving aerosol-generating procedures</strong></td>
</tr>
<tr>
<td>- Work clothing, such as scrubs, lab coat, and/or smock, or a gown</td>
</tr>
<tr>
<td>- Eye protection (e.g., goggles, face shield)</td>
</tr>
<tr>
<td>- Face mask (e.g., surgical mask)</td>
</tr>
</tbody>
</table>

COVID-19 - Control and Prevention - Dentistry Workers and Employers | Occupational Safety and Health Administration (osha.gov)
OSHA and the CDC

March 12, 2021

MEMORANDUM FOR: REGIONAL ADMINISTRATORS
STATE PLAN DESIGNEES

THROUGH AMANDA EDENS
Deputy Assistant Secretary

FROM: PATRICK J. KAPUST, Acting Director
Directorate of Enforcement Programs

SUBJECT: Updated Interim Enforcement Response Plan for Coronavirus Disease 2019 (COVID-19)
Attachment 1
Specific Guidance for COVID-19 Enforcement

1. Workplace Risk Levels: To prioritize OSHA enforcement activities during the Coronavirus Disease 2019 (COVID-19) pandemic, the following guidance is provided to help CSHOs identify workplaces and job tasks with a risk-based potential for COVID-19 exposures. The risk of worker exposures to SARS-CoV-2, the virus that causes COVID-19, depends on numerous factors, including: the extent of community transmission; the type of work activity; the ability of workers to wear face coverings and appropriate personal protective equipment (PPE); the extent to which the employer follows OSHA standards and current guidelines from OSHA and the Centers for Disease Control and Prevention (CDC); and the need to work in close contact with other people, hereafter defined as within 6 feet for a total of 15 minutes or more over a 24-hour period, per the CDC.[3] Potential for worker exposures could also depend on medical or other measures present to control the impact of the virus and the implementation of those measures. For example, vaccinations are becoming increasingly available to certain groups of workers and others in the general population. Information on classifying risk of worker exposure is available on the Hazard Recognition page on OSHA’s COVID-19 website. OSHA has also prepared guidance that employers should use for planning purposes - Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace.
Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace

OSHA will update this guidance over time to reflect developments in science, best practices, and standards.

Guidance posted January 29, 2021

On this Page

Executive Summary
Purpose
About COVID-19
What Workers Need To Know about COVID-19 Protections in the Workplace
The Roles of Employers and Workers in Responding to COVID-19
Additional Detail on Key Measures for Limiting the Spread

https://www.osha.gov/coronavirus/safework
OSHA launches program to protect high-risk workers from coronavirus, focuses on employers that retaliate against workers with safety concerns | Occupational Safety and Health Administration
Important Dates for the COVID-19 National Emphasis Program

- **MARCH 12, 2021**
  - NEP becomes effective
  - Complaints/referrals and follow-up inspections begin

- **MARCH 26, 2021**
  - (2 weeks after NEP)
  - NEP targeting/programmed inspections begins

- **MAY 12, 2021**
  - (60 days after NEP)
  - State Plans inform OSHA of their intent

- **AFTER MAY 12, 2021**
  - (open-ended)
  - If a State Plan adopts the NEP, they must submit documentation of their policy to OSHA within 60 days of adoption

Legend:
- Light gray circle: Federal OSHA
- Black circle: State Plans
FDA Emergency Use Authorizations for Disposable Respirators
Recommendations

The FDA recommends that health care personnel and facilities:

- Limit decontamination of disposable respirators. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new FFRs or if you are unable to obtain any new respirators.

- Transition away from a crisis capacity strategy for respirators, such as decontamination of N95 and other FFRs.

- Increase inventory of available NIOSH-approved respirators—including N95s and other FFRs, elastomeric respirators, including new elastomeric respirators without an exhalation valve that can be used in the operating room, and powered air-purifying respirators (PAPRs). Even if you are unable to obtain the respirator model that you would prefer, the FDA recommends that you obtain and use a new respirator before decontaminating or bioburden reducing a preferred disposable respirator.
FDA Recommends Transition from Use of Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities

Recommendations

The FDA recommends that health care personnel and facilities:

- Limit decontamination of disposable respirators. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new FFRs or if you are unable to obtain any new respirators.

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CONCERNS ABOUT INFECTIOUS AEROSOLS ARE NOT LIMITED TO COVID-19!
Aerosol Transmitted Disease Risks in Dentistry

- SARS
- SARS-CoV-2
- Influenza
- Measles
- Rubella

- M. tuberculosis
- Ebola
- Varicella (chicken pox)
- Pertussis
- Group A strep


The Basics on Face Masks, Surgical Masks, and Respirators

Q: Is there a difference between a face mask, a surgical mask, and a respirator?
A: Face masks, surgical masks, and respirators all cover a wearer's nose and mouth, but they differ in several aspects.

- **Face masks**: A mask, with or without a face shield, that covers the user’s nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks that are not intended for a medical purpose are not considered medical devices. Face masks may be used by the general public and health care personnel as source control in accordance with CDC recommendations on Interim Infection Prevention and Control.

- **Surgical masks**: A mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks intended for medical purposes are considered medical devices. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests. Surgical masks are also tested for biocompatibility and are considered personal protective equipment (PPE). While a surgical mask may be effective in blocking splashes and large-particle droplets, they do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the mask and your face. Surgical masks are not respiratory protective devices such as respirators.

- **Respirators, known as filtering facepiece respirators (FFRs)**, including N95s and surgical N95s, filter at least 95 percent of airborne particles. They are PPE that tightly fit the face and provide certain filtration efficiency levels to help reduce wearer exposure to pathogenic airborne particles in a health care setting. They provide a higher level of protection against viruses and bacteria when properly fit-tested.

This CDC infographic (PDF - 227KB) explains the differences between surgical masks and N95 respirators.
# Understanding the Difference

## Surgical Mask vs. N95 Respirator

<table>
<thead>
<tr>
<th>Feature</th>
<th>Surgical Mask</th>
<th>N95 Respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing and Approval</strong></td>
<td>Cleared by the U.S. Food and Drug Administration (FDA)</td>
<td>Evaluated, tested, and approved by NIOSH as per the requirements in 21 CFR Part 84</td>
</tr>
<tr>
<td><strong>Intended Use and Purpose</strong></td>
<td>Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer’s respiratory emissions.</td>
<td>Reduces wearer’s exposure to particles including small particle aerosols and large droplets (only non-aerosol)</td>
</tr>
<tr>
<td><strong>Face Seal Fit</strong></td>
<td>Loose-fitting</td>
<td>Tight-fitting</td>
</tr>
<tr>
<td><strong>Fit Testing Requirement</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>User Seal Check Requirement</strong></td>
<td>No</td>
<td>Yes. Required each time the respirator is donned (put on)</td>
</tr>
<tr>
<td><strong>Filtration</strong></td>
<td>Does NOT provide the wearer with a suitable level of protection from inhaling smaller airborne particles and is not considered respiratory protection</td>
<td>Filters out at least 95% of airborne particles including large and small particles</td>
</tr>
<tr>
<td><strong>Leakage</strong></td>
<td>Leakage occurs around the edge of the mask when user inhales.</td>
<td>When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales.</td>
</tr>
<tr>
<td><strong>Use Limitations</strong></td>
<td>Disposable. Discard after each patient encounter.</td>
<td>Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.</td>
</tr>
</tbody>
</table>

[Infographic - Understanding the Difference, Surgical Mask, N95 Respirator (cdc.gov)]
Standards for Masks and Respirators

- NIOSH – National Institute for Occupational Safety and Health
  - www.cdc.gov/niosh

- FDA – Food and Drug Administration
  - www.fda.gov

- ASTM – American Society for Testing and Materials
  - www.astm.org
Medical Masks – Procedure or Surgical

- Cleared by FDA for medical use – indicated on packaging
- May be procedure mask vs. surgical mask
  - Surgical masks have ties, not earloops
    - for tighter fit
    - to fit over hair coverings
- ASTM levels should be indicated on packaging
5 Factors in respiratory protection
ASTM Standard F2100-11

- Fluid Resistance (FR) – measures the ability of mask’s material and construction to minimize fluids from traveling through (penetrating) the material measured in mmHg

Source: Nelson Labs
M9 Need to insert measurement for fluid resistance pressure/time
Mary, 5/14/2021
5 Factors in respiratory protection
ASTM Standard F2100-11

- Bacterial Filtration Efficiency (BFE) – measures the percentage of bacteria larger than 3µ filtered out by the mask.
  - SARS-CoV2 is much smaller - ~.12µ

- Particle Filtration Efficiency (PFE) – measures the percentage of particles larger than 1µ
5 Factors in respiratory protection
F2100-11

- Delta P (Differential Pressure) – resistance to air flow - breathability

- Flame spread – measure of the material’s ability to burn rapidly and spread flames.

Source: Halyard Health
ASTM Level 1
Low Barrier
FR 80mmHg
BFE ≥95% 3µ
PFE @0.1µ
Delta P < 4.0
Flame Spread Class 1

ASTM Level 2
Moderate Barrier
FR 120 mmHg
BFE ≥98% 3µ
PFE @0.1µ
Delta P < 5.0
Flame Spread Class 1

ASTM Level 3
High Barrier
FR 160 mmHg
BFE ≥98% 3µ
PFE @0.1µ
Delta P < 5.0
Flame Spread Class 1
Studies show fluid strikes the face area of OR staff on average 45-51% of the time. Over 70% of masks are not ASTM F2100-11 rated for fluid resistance at all.

ASTM F2100-11 is the recognized consensus standard for medical face masks. Masks are measured on 5 performance metrics:

- Fluid Resistance
- Breathability
- Flammability
- Particulate Filtration (PFE)
- Biological Filtration (BFE)

MASKS ARE RATED ACCORDING TO PERFORMANCE LEVELS:

- Level 1: 60 mm Hg
- Level 2: 120 mm Hg
- Level 3: 160 mm Hg

LOW: Fluid Resistance
MODERATE: Fluid Resistance
HIGH: Fluid Resistance

Halyard Health

All HALYARD® fluidsHIELD® Surgical and Procedure Masks are available in Levels 1, 2, and 3 and are fluid-resistant.

Questions your protection. Get the full story and see the demo video at HalyardHealth.com/ASTMFaceMasks

Source: Halyard Health
What is the critical difference? Why should I care?

• Greatest difference is **Fluid Resistance**
  – 80mmHg (Level 1)
  – 160mmHg (Level 3)
  – Fluid penetrating the mask can carry infectious microbes

Source: Microsoft Creative Commons
Respirators

- **N95 Filtering Facepiece Respirators (FFRs)**
  - Commonly referred to as N95s
  - Medical grade vs. manufacturing grade

- Differ from masks in both fit, seal and particle filtration size
  - Some brands come in multiple sizes for better fit

- Designed for single use
  - Reuse allowed (temporarily) under FDA EUA

- Respirators with exhalation valves not appropriate for use in health care settings.

Source: Halyard Health
Respirators in health care settings

- Surgical respirators are Class II devices regulated by the FDA
  - 21CFR 878.4040

- Certified by CDC/NIOSH
  - 42 CFR Part 84

- Manufactured in the Americas vs. overseas
  - Less wait time to replenish inventory
  - Not all respirators are created equal...

Buyer Beware!
Summary of the current state of respiratory protection requirements for dentistry

- OSHA bases respiratory protection guidance on:
  - The incidence of disease in your area
  - Type of procedure being performed
    - Aerosol generating vs. non-aerosol generating

- OSHA has cited practices for not utilizing N95s and not fit testing those respirators prior to use.

- OSHA is reviewing current guidance for update and has stated that aerosol-transmitted hazards are not addressed in the BBPS.
Summary of the current state of respiratory protection requirements for dentistry

- CDC has not updated guidance for dental settings since 12/20.

- CDC has updated guidance for health care settings on 4/27/21
  - Vaccination of HCW is not an indicator for discontinuing use of recommended respiratory protection
  
  - Vaccinated HCW’s do not need to quarantine if exposed to COVID-19
  
  - Vaccinated HCW’s do not need to be screened daily for COVID-19
    - Unvaccinated workers do need to quarantine and require daily screening
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