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Personal Protective Equipment



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Please note:

- This course may not satisfy individual state requirements on CDC/Infection Control. Please check with your State Board to verify.
- **Iowa dental professionals**: This course complies with the Iowa Dental Board for recertification in the area of infection control standards, as established by the Centers for Disease Control and Prevention (CDC).

Conflict of Interest Disclosure Statement

- Dr. Terézhalmy has done consulting work for Procter & Gamble and has served on the dentalcare.com Advisory Board.
- Dr. Huber is a member of the dentalcare.com Advisory Board and has no relevant financial relationships to disclose.

Introduction - Personal Protective Equipment

Participants in Personal Protective Equipment will be introduced to (1) the concept of personal protective equipment (PPE), (2) federal agencies with advisory and regulatory/enforcement jurisdiction related to PPE, (3) the indication for and selection of PPE for use in oral healthcare settings, and (4) a hierarchy of steps to follow for putting on and safely removing PPE to prevent skin, mucosal, clothing, and environmental contamination.

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Overview

Participants in this course will be introduced to (1) the concept of personal protective equipment (PPE), (2) federal agencies with advisory and regulatory/enforcement jurisdiction related to PPE, (3) the indication for and selection of PPE for use in oral healthcare settings, and (4) a hierarchy of steps to follow for putting on and safely removing PPE to prevent skin, mucosal, clothing, and environmental contamination.

Learning Objectives

Upon completion of this course, the dental professional should be able to:

- Define PPE and identify those relevant to the safety of oral healthcare personnel.
- Discuss the roles of federal agencies with advisory or regulatory/enforcement jurisdiction related to the establishment of a safe and healthy working place.
- Discuss the regulatory role of the FDA as it relates to medical devices and the rationale for the classification of medical devices, e.g., PPE.
- Discuss the indication for and selection of PPE with reference to three key elements: anticipated exposure, barrier effectiveness, and fit.
- Demonstrate the steps to follow for putting on and safely removing PPE.

infectious material (OPIM) may contaminate skin and conjunctival, nasal, and oral mucosal tissues by direct or indirect contact transmission; and the respiratory epithelium by inhalation of airborne microorganisms in droplets or droplet nuclei suspended in air. To prevent or reduce the risk of disease transmission, the wearing of personal protective equipment (PPE) is mandated by Standard and Transmission-Based Precautions.^{1,2,3}

Standard Precautions represent the minimum standard required, regardless of the suspected or confirmed infection status of the patient, in healthcare delivery. Transmission-Based Precautions represent additional measures to be taken when Standard Precautions alone cannot prevent disease (e.g. tuberculosis, SARS-CoV-2)^{3,5} transmission through contact, droplet or airborne routes (e.g., skin contact, sneezing, coughing).

PPE are medical devices designed to protect healthcare personnel from acquiring healthcare-associated infections (HAIs). In oral healthcare settings PPE include surgical gowns, surgical masks, respirators, goggles, face shields, and gloves. The following sections highlight regulatory issues, uses and methods of selecting PPE, and a hierarchical strategy for putting on and removing PPE that will prevent skin, mucosal, clothing, and environmental contamination.

Advisory and Regulatory Federal Agencies

Federal agencies with advisory (i.e., nonregulatory) responsibilities related to PPE include the Centers for Disease Control and Prevention (CDC) and the National Institute for Occupational Safety and Health (NIOSH).^{6,7} The CDC is the nation's health protection agency. It makes evidence-based recommendations related to the prevention and control of disease, injury, and disability. NIOSH conducts research and makes evidence-based recommendations to prevent worker injury and illness. CDC and NIOSH set the standards of care.

Introduction

Pathogens in blood and other potentially

Federal agencies with enforcement (i.e., regulatory) responsibilities related to PPE include the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA).^{8,9} OSHA is responsible for setting and enforcing regulations to assure safe and healthy working conditions. The FDA is responsible for setting and enforcing public health regulations to assure the safety, efficacy, and security of the nation's food supply, drugs, biological products, cosmetics, and medical devices. OSHA and the FDA enforce compliance.

Medical Devices

The FDA categorizes medical devices into three classes.¹⁰ Class I medical devices pose minimal risk of injury or harm to patients and/or users. General regulatory controls, i.e., registering the device, proper branding and labeling, and proper manufacturing techniques assure their safety and effectiveness. Examples of Class I medical devices include tongue depressors, some dental instruments, dental floss, isolation gowns, examination and surgical gloves, and eye protection.

Class II medical devices are those for which general regulatory controls alone cannot assure safety and effectiveness. These devices are subject to special labeling requirements, mandatory performance standards, premarketing FDA notification, and post-marketing surveillance. Examples of Class II medical devices include X-ray machines, infusion pumps, surgical needles, surgical drapes, surgical gowns, surgical masks, and particulate respirators.

Class III medical devices pose the greatest risk of injury or harm to patients and/or users and their safety and effectiveness cannot be assured solely through general or special regulatory controls. They must undergo scientific review by an expert panel and must obtain premarketing approval from the FDA. Examples of Class III medical devices include implantable pacemakers, heart valves, automated external defibrillators, and endosseous implants (e.g., dental implants). what, and how PPE should be used to prevent exposure to infectious pathogens.¹⁻⁵ OSHA issues and enforces workplace health and safety regulations. OSHA regulations require that employers provide their employees with appropriate PPE and to ensure that PPE is properly disposed of, or if reusable, that it is properly cleaned or laundered, repaired, and stored. The objective of the following sections is to provide information on the selection and use of PPE in oral healthcare settings.

When selecting PPE three key elements need to be considered. First, the type of anticipated exposure, e.g., direct contact with blood or OPIM; or exposure to splash, spatter, spray; or inhalation of airborne microorganisms in droplets or droplet nuclei suspended in air. Second, what is the durability and appropriateness of the PPE for the task, i.e., what is the barrier's effectiveness? The third is the fit. PPE must fit the individual user, and it is up to the employer to ensure that all PPE are available in sizes appropriate for the workforce to be protected.

Surgical Gowns

Surgical gowns must be worn by OHCP whenever splash, spatter, spray, and aerosols of blood or OPIM are anticipated during the clinical process.¹⁻⁵ Surgical gowns should have long sleeves to protect the wrists and forearms. They should also cover the torso from neck to knees and wrap around the back to prevent contamination of street the clothes. Scrubs, or clinical and laboratory coats or jackets worn for comfort and/or purposes of identity are NOT considered PPE.³

Surgical gowns, which are Class II medical devices, may be disposable or reusable. Repellency and pore size of the fabric affect blood and OPIM penetration of the barrier and contribute to gown performance. Regardless of the material used to manufacture surgical gowns, they must be resistant to liquid and microbial penetration. Several gown sizes should be available in oral healthcare settings to ensure appropriate coverage for all staff members.

Selecting and Using PPE

The CDC issues recommendations for when,

Surgical gowns should be changed between patients, as soon as possible when penetrated by blood or OPIM, and before leaving patient-care areas. Surgical gowns should be removed in a manner to avoid contamination of air, environmental surfaces, patients, and healthcare personnel. Designated containers for used disposable or reusable protective clothing should be placed in a location that is convenient to the point of use to contain contamination.

Surgical Masks

Surgical masks, that cover both the nose and the mouth, must be worn by all OHCP during clinical activities likely to generate splash, spatter, spray, and aerosols.¹⁻⁵ Masks also protect patients from exposure to infectious pathogens carried in the mouth or nose of OHCP. Finally, surgical masks should be worn by coughing patients to limit potential dissemination of infectious respiratory secretions to others, i.e., Respiratory Hygiene/ Cough Etiquette.

Surgical masks, which are Class II medical devices, are labeled according to their performance level on testing standards developed by the American Society for Testing and Materials (ASTM). This FDAaccepted testing method (ASTM 2100-11) takes into consideration fluid resistance, bacterial filtration efficiency (BFE), particulate filtration efficiency (PFE), breathability (P- Δ), and flammability of the mask material in determining barrier performance (Table 1).¹¹

Surgical masks are available with fluidresistant outer layers and tissue inner layers or fluid-resistant outer and inner layers. Fluid resistance helps protect the oral and respiratory mucosa of OHCP from splash, splatter, spray, and aerosols generated during patient care. A mask's resistance to penetration by synthetic blood under pressure at 80, 120, and 160 mmHg is tested on a pass/fail basis. Surgical masks with higher resistance provide for greater protection.

Bacterial and particulate filtration efficiency reflects the effectiveness of a fabric to filter out bacteria or particles, respectively. The results are expressed as the percentage (%) of bacteria or particles filtered by the fabric. However, even with high filtering efficiency, some inhaled and/or exhaled air can pass unfiltered around the edges of the mask. The greater the edge leakage of a surgical mask, the lower its in-use BFE and PFE.

P- Δ measures the pressure change (in mm H2O/cm2) across the mask, i.e., the resistance to air flow. It is expressed numerically on a scale of 1 to 5. Resistance relates directly to the degree of protection provided by the mask, i.e., greater the resistance to air flow, the

ASTM level	Fluid resistance (mmHg)	BFE (1-5 microns)	PFE (0.1- 1.0 microns)	Breathability (P- Δ in mm H ₂ O/cm ²	Flammability	Barrier effectiveness level in the presence of splash, spatter, spray, and aerosols
1	80	≥ 95%	_	< 4	Class 1	Low
2	120	≥ 98%	—	< 5	Class 1	Moderate
3	160	≥ 98%	_	< 5	Class 1	High
Particulate respirator	160	_	≥ 95%	> 5	Class 1	Airborne Precautions

Table 1. Surgical mask performance levels (ASTM 2100-11).¹¹

better the protection. Unfortunately, resistance relates inversely to breathability. Flammability measures the rate of flame spread in the mask fabric. Minimum acceptable burn rate is 3.5 seconds (Class 1 rating).¹²

Masks come in various shapes (e.g., molded and non-molded), sizes, and method of attachment (e.g., ties, elastic, ear loops). Several different types of masks should be available in healthcare settings to meet individual needs of personnel. A new surgical mask must be used for each patient. When a mask becomes wet intra-operatively, it must be changed as soon as possible. Surgical masks should not be confused with particulate respirators described below.

Particulate Respirators

When Airborne Precautions are necessary (i.e., Transmission-based Precautions), a National Institute for Occupational Safety and Health (NIOSH)-certified, fit-checked particulate-filter respirator, a Class II medical device, must be worn.^{1-3,5} OSHA guidelines further require (1) medical clearance for healthcare personnel to wear a respirator, (2) education on respirator use, and (3) periodic re-evaluation of the respiratory protection program in each healthcare setting.¹³

Airborne Precautions require that healthcare personnel wear NIOSH-certified N95, N99, or N100 particulate-filter respirators, which have the ability to filter particles in the range of 0.1 to 1.0 micron with a filtration efficiency of 95, 99, and 99.8%, respectively.¹³ A user sealcheck ("fit-check") must be performed by the wearer of a respirator each time a particulate respirator is donned to confirm that there is no air leakage around the facepiece.¹³

Currently, the CDC recommends the use of a N95 or higher level respirator by OHCP exposed to patients with suspected or confirmed tuberculosis or SARS-CoV-2.^{5,14} Although Airborne Precautions are recommended for preventing airborne transmission of influenza, measles, varicellazoster, and SARS viruses, there are no data upon which to base a recommendation beyond Standard Precautions for respiratory protection of susceptible OHCP against these pathogens.

Goggles and Face Shields

Goggles must be worn by OHCP and patients to prevent the transmission of pathogens through the conjunctival mucosa either directly (e.g., splash, spatter, spray, or aerosols) or by touching the eyes with contaminated hands or other objects.^{1-5,15} Goggles, which are Class I medical devices, must fit snugly from the corners of the eyes across the brow. Indirectlyvented goggles with anti-fog coating provide the most reliable eye protection.

Personal eyeglasses and contact lenses are NOT considered adequate eye protection.¹⁵ Several different types, styles, and sizes of goggles should be made available to meet individual needs. Goggles that fit comfortably over prescription glasses are available and contact lenses may be worn with recommended eye protection devices. Contact lens users should vigorously adhere to hand hygiene guidelines when inserting, adjusting or removing contact lenses.¹⁶

While goggles provide effective eye protection, they do not protect other parts of the face. Face shields with high crowns and chin protection that wrap around the face to the point of the ears are recommended for infection control purposes.¹⁵ They should fit snugly and the foam brow-band contoured to the wearer. Since face shields are open from below, they are to be worn with surgical masks. Disposable face shields attached to masks do not provide optimal protection.

The front and sides of goggles and face shields are likely to be contaminated. However, the ties, ear-loops, and/or head-bands used to secure these devices to the head are considered "clean" and, therefore, safe to touch with bare hands. Following use, eye protection devices should be placed in a designated receptacle. Wearing gloves, these devices should then be cleaned with soap and water, disinfected with a hospital level disinfectant, rinsed with water, and air dried before reuse.

Gloves

Task-specific gloves (Table 2) should be worn by all OHCP to prevent contamination of the hands when (1) anticipating direct contact with blood, mucous membranes, nonintact

Glove Type	Comments	Common Materials
Patient examination gloves	Class I medical device • Sterile and nonsterile • Single use disposable	Natural rubber latex Nitrile Vinyl (PVC)
Surgeon's gloves	Class I medical device Sterile Single use disposable No lubricating or dusting powder used in these glove Subject to the design control requirements Gloves for dental surgery may be thicker than standard surgeon's gloves 	Natural rubber latex Nitrile Combinations of latex and/or synthetics

Table 2. Task-specific gloves for use in oral healthcare settings.¹⁷

skin, and OPIM; (2) having direct contact with patients who are colonized or infected with pathogens transmitted by the contact route, or (3) handling visibly or potentially contaminated patient care items and environmental surfaces.¹⁻⁵

Gloves have been reported to reduce the volume of blood on the external surfaces of sharps by 46.86% (residual blood in the lumen of a hollow-bore needle is not affected).³ The extent to which gloves will protect OHCP from transmission of bloodborne pathogens (e.g., HIV, HBV, and HCV) following a needlestick or other sharps injury that penetrates the glove barrier has not been determined.³

Patient examination gloves, classified as Class I medical devices, should be worn during dental preventive, restorative, and other nonsurgical dental procedures.¹⁷ Sterile surgeon's gloves are intended for use during surgical procedures to protect the provider and the wound from contamination. Surgeon's gloves, subject to design control requirements, are classified as Class I medical devices. Surgeon's gloves must also be sterile when offered for sale to end-users.¹⁷

Patient examination gloves and surgeon's gloves are made primarily of latex, nitrile, or vinyl.¹⁷ While there is little difference in the barrier properties of unused intact gloves; vinyl gloves have higher failure rates than latex or nitrile gloves.³ For this reason latex or nitrile gloves are preferable for procedures that involve extensive patient contact. To reduce the risk of latex-related allergies, powdered gloves were banned by the FDA in December of 2006¹⁸ and low-allergen latex gloves or nitrile gloves should be used.

Patient examination gloves and surgeon's gloves are single-use patient-care items.

They may not be washed for subsequent reuse because microorganisms cannot be removed reliably and continued glove integrity cannot be guaranteed. Washing gloves can lead to wicking (penetration of liquids through undetectable holes in the gloves) and subsequent hand contamination. Glove reuse has been associated with transmission of MRSA and gram-negative bacilli.³

When gloves are torn or punctured, they must be changed as soon as possible. To prevent transmission of infectious pathogens, it is also necessary to change gloves when during the course of treatment radiographs, dental charts, computer keyboards, or other equipment are touched. When donning and removing gloves, strict adherence to hand hygiene guidelines is imperative.¹⁴ Double-gloving is acceptable for extensive surgical procedures.

Gloves that fit snugly around the wrist are preferred for use because they will cover the gown cuff and provide a more reliable continuous barrier for the arms, wrists, and hands. When gloves are worn in combination with other PPE, they are to be put on last (Figure 1). Following glove removal, hand hygiene further ensures that the hands will not transmit pathogens that might have penetrated the gloves through small tears or contaminated the hands during glove removal.

The FDA does not regulate cleaning (utility or general purpose) gloves used for routine janitorial functions in healthcare facilities and it is illegal for manufacturers to label or suggest that such gloves are suitable for medical use.¹⁷ Gloves used for cleaning patients, or cleaning or handling surfaces or items contaminated with patient waste or fluids and patientcare devices contaminated with blood or OPIM should meet requirements for patient examination gloves.¹⁷

Putting on and Safely Removing PPE

The CDC recommends a hierarchical sequence of steps for putting on PPE and for the safe removal of PPE that will prevent skin, mucosal, clothing, or environmental contamination (Figures 1, 2 and 3).¹⁹ Designated containers for used disposable or reusable PPE should be placed in a location convenient to the site of removal to facilitate containment of contaminants. Hand hygiene is always the final step after the removal and disposal of PPE.

Summary

A Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care was published by the CDC in 2016. This guide is based on elements of Standard Precautions and represents a summary of basic infection prevention expectations for safe care in oral healthcare setting as recommended in the Guidelines for Infection Control in Dental Health-Care Setting – 2003.^{2,4} However, this document includes an Infection Prevention Checklist for Dental Settings (Appendix A). The Infection Prevention Checklist, Section *I: Policies and Practices provides a tool* to monitor and document institutional compliance with issues related to Personal Protective Equipment Safety (Section I.6). In addition, Section II.2 of the checklist provides a tool to document the correct use of PPE by direct observation of personnel.

The Centers for Disease Control and Prevention. Guidance for Dental Settings: Interim Infection Prevention and Control Guidance for Dental Settings During the COVID-19 Response⁵ is a dynamic document addressing the Transmission-Based Precautions necessary to provide safe dental care to the patient infected or potentially infected with SARS-Co-V-2.

Wearing PPE is an important component of Standard and Transmission-based Precautions. PPE should not permit blood or OPIM to pass through it and reach street clothes, undergarments, skin or mucous membranes of the eyes, nose, and mouth. Surgical gowns should protect the wrists, forearms, and torso from neck to knees. Masks and goggles should protect the mouth, nose and eyes. Face shields should provide protection to other parts of the face. Task-specific gloves should protect the hands. However, wearing gloves does not eliminate the need for hand hygiene. It is further mandated that an Infection Prevention Checklist be used to document institutional compliance with issues related to PPE and that personnel compliance with the proper use of PPE be documented by direct observation.

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

1. GOWN

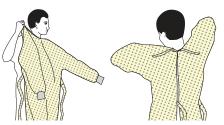
- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist

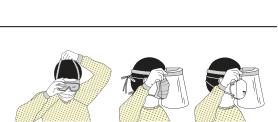
2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator

3. GOGGLES OR FACE SHIELD

· Place over face and eyes and adjust to fit





4. GLOVES

• Extend to cover wrist of isolation gown



- Keep hands away from face
- Limit surfaces touched
- · Change gloves when torn or heavily contaminated
- Perform hand hygiene

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Figure 1. Sequence for putting on PPE.¹⁹

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container

2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

3. GOWN

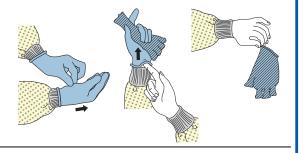
- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- · Fold or roll into a bundle and discard in a waste container

4. MASK OR RESPIRATOR

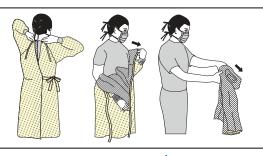
- Front of mask/respirator is contaminated D0 NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
 Grasp bottom ties or elastics of the mask/respirator, then the ones at
- the top, and remove without touching the front • Discard in a waste container
- 5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE

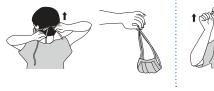
PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

Figure 2. How to safely remove PPE (Option 1).¹⁹

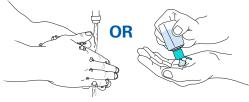














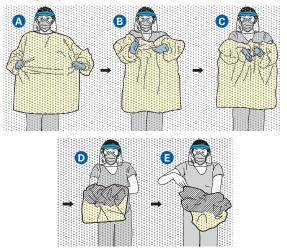
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HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container



2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated D0 NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container

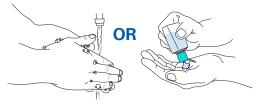
4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE

PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

Figure 3. How to safely remove PPE (Option 2).¹⁹









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Course Test Preview

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1. All of the following statements regarding personal protective equipment (PPE) are correct, except for one. Which one is the exception?

- A. The wearing of PPE is mandated by Standard and Transmission-Based Precautions.
- B. Transmission-Based Precautions represent the minimum standard required, regardless of the suspected or confirmed infection status of the patient, in healthcare delivery.
- C. PPE are medical devices designed to protect healthcare personnel from acquiring healthcare-associated infections (HAIs).
- D. In healthcare settings PPE include the use of surgical gowns, surgical masks, respirators, goggles, face shields, and gloves.

2. Which of the following federal agencies is the nation's health protection agency that makes evidence-based recommendations related to the prevention and control of disease, injury, and disability?

- A. CDC
- B. NIOSH
- C. OSHA
- D. FDA

3. Which of the following federal agencies is responsible for setting and enforcing regulations to assure safe and healthy working conditions?

- A. CDC
- B. NIOSH
- C. OSHA
- D. FDA

4. A medical device for which general regulatory controls alone cannot assure safety and effectiveness is categorized by the FDA as a _____.

- A. Class I medical device
- B. Class II medical device
- C. Class III medical device
- D. All of the above are correct.
- 5. All of the following statements regarding PPE are correct, except for one. Which one is the exception?
 - A. The CDC issues recommendations for when, what, and how PPE should be used to prevent exposure to infectious pathogens.
 - B. OSHA regulations require that employers provide their employees with appropriate PPE.
 - C. Key elements to consider when selecting PPE include the type of anticipated exposure, the durability and appropriateness of the PPE for the task, and the fit.
 - D. The NIOSH regulates the pricing of PPE

6. All of the following statements related to protective clothing are correct, except for one. Which one is the exception?

- A. Surgical gowns must be worn by OHCP whenever splash, spatter, spray, and aerosols of blood or OPIM are anticipated during the clinical process.
- B. Scrubs, or clinical and laboratory coats or jackets worn for comfort and/or purposes of identity are considered appropriate PPE.
- C. Surgical gowns should have long sleeves to protect the wrists and forearms.
- D. Surgical gowns should cover the torso from neck to knees and wrap around the back to prevent contamination of street the clothes.

7. All of the following statements are correct with respect to surgical gowns, except for one. Which one is the exception?

- A. Disposable and reusable surgical gowns are Class I medical devices.
- B. Repellency and pore size of the fabric affect blood and OPIM penetration of the barrier and contribute to gown performance.
- C. Regardless of the material used to manufacture surgical gowns, they must be resistant to liquid and microbial penetration.
- D. Several gown sizes should be available in oral healthcare settings to ensure appropriate coverage for all staff members.

8. All of the following statements regarding surgical gown use are correct, except for one. Which one is the exception?

- A. Disposable surgical gowns should undergo sterilization prior to disposal in general trash.
- B. Surgical gowns should be changed between patients.
- C. When penetrated by blood or OPIM, even intra-procedure, surgical gowns should be changed as soon as possible.
- D. Surgical gowns should be changed before leaving patient-care areas.

9. All of the following statements regarding surgical masks are correct, except for one. Which one is the exception?

- A. Surgical masks must be worn by all OHCP during clinical activities likely to generate splash, spatter, spray, and aerosols.
- B. Surgical masks, which are Class II medical devices, are labeled according to their performance level on testing standards developed by the American Society for Testing and Materials (ASTM).
- C. Fluid resistance, bacterial filtration efficiency (BFE), particulate filtration efficiency (PFE), breathability (P-Δ), and flammability of the mask material determine surgical mask performance.
- D. The higher the breathability number, the easier it is to breathe through a surgical mask.

10. Which of the following ASTM level surgical face mask has a high level of barrier effectiveness in the presence of splash, spatter, spray and aerosols?

- A. Level 1
- B. Level 2
- C. Level 3
- D. Particulate respirator

11. All of the following statements are correct with respect to particulate respirators, except for one. Which one is the exception?

- A. When Airborne Precautions are necessary (i.e., Transmission-based Precautions), NIOSHcertified, fit-checked particulate-filter respirator, a class II medical device, must be worn.
- B. NIOSH-certified N95, N99, or N100 particulate-filter respirators, which have the ability to filter particles in the range of 0.1 to 1.0 micron, have a filtration efficiency of 95%, 99%, and 99.8% respectively.
- C. Fit testing is required on a weekly basis.
- D. Currently, the CDC recommends the use of a N95 or higher- level respirator by OHCP exposed to patients with suspected or confirmed tuberculosis or SARS-CoV-2.

12. All of the following statements are correct with respect to goggles, except for one. Which one is the exception?

- A. Goggles must be worn by OHCP and patients to prevent the transmission of pathogens through the conjunctival mucosa either directly (e.g., splash, spatter, spray, or aerosols) or by touching the eyes with contaminated hands or other objects.
- B. Goggles, which are Class I medical devices, must fit snugly from the corners of the eyes across the brow.
- C. Indirectly-vented goggles with anti-fog coating provide the most reliable eye protection.
- D. Personal eyeglasses and contact lenses are considered adequate eye protection.

13. All of the following statements are correct with respect to face masks, except for one. Which one is the exception?

- A. Face shields with high crowns and chin protection that wrap around the face to the point of the ears are recommended for infection control purposes.
- B. Face masks should fit snugly and the foam brow-band contoured to the wearer.
- C. Face shields can be worn without surgical masks.
- D. Eye protective devices should be cleaned with soap and water, disinfected with a hospital level disinfectant, rinsed with water, and air dried before reuse.

14. All of the following statements regarding task specific gloves are correct, except for one. Which one is the exception? Task-specific gloves should be worn by all OHCP to prevent contamination of the hands when _____.

- A. accomplishing administrative activities
- B. anticipating direct contact with blood, mucous membranes, nonintact skin, and OPIM.
- C. having direct contact with patients who are colonized or infected with pathogens transmitted by the contact route.
- D. handling visibly or potentially contaminated patient care items and environmental surfaces

15. All of the following statements are correct with respect to gloves, except for one. Which one is the exception?

- A. Patient examination gloves, classified as Class I medical devices, should be worn during dental cleaning, restorative, and other non-surgical dental procedures.
- B. Sterile surgeon's gloves are intended for use during surgical procedures to protect the provider and the wound from contamination.
- C. Surgeon's gloves are subject to design control requirements and are classified as Class II medical devices.
- D. Surgeon's gloves must be sterile when offered for sale to end-users.

16. All of the following statements are correct with respect to patient examination and surgeon's gloves EXCEPT which one?

- A. Patient examination gloves and surgeon's gloves are made primarily of latex, nitrile, or vinyl.
- B. There are significant differences in the barrier properties of unused intact gloves.
- C. Vinyl gloves have higher failure rates than latex or nitrile gloves.
- D. To reduce the risk of latex-related allergies, low-allergen latex gloves or nitrile gloves should be used.

17. All of the following statements regarding medical gloves are correct, except for one. Which one is the exception?

- A. Patient examination gloves and surgeon's gloves may not be washed for subsequent reuse because microorganisms cannot be removed reliably and continued glove integrity cannot be ensured.
- B. Washing gloves can lead to wicking (penetration of liquids through undetectable holes in the gloves) and subsequent hand contamination.
- C. Powder is often added to gloves to ease glove donning.
- D. To prevent transmission of infectious pathogens, it may be necessary to change gloves when during the course of treatment radiographs, dental charts, computer keyboards, or other equipment are touched.

18. All of the following statements regarding cleaning (utility or general-purpose gloves) are correct, except for one. Which one is the exception?

- A. The FDA does not regulate cleaning (utility or general purpose) gloves used for routine janitorial functions in healthcare facilities.
- B. It is illegal for manufacturers to label or to suggest that such gloves as suitable for medical use.
- C. Gloves used for cleaning patients, or cleaning or handling surfaces or items contaminated with patient waste or fluids and patient-care devices contaminated with blood or OPIM should meet the requirements for patient examination gloves.
- D. Utility gloves used in healthcare must be appropriately labeled as such by the manufacturer.

19. All of the following statements regarding the putting on and removal of PPE are correct, except for one. Which one is the exception?

- A. The CDC recommends a hierarchical sequence of steps for putting on PPE and for the safe removal of PPE that will prevent skin, mucosal, clothing, or environmental contamination.
- B. Designated containers for used disposable or reusable PPE should be placed in a location convenient to the site of removal to facilitate containment of contaminants.
- C. Putting on PPE begins with the gown and progresses sequentially to the mask or respirator, goggles or face shield, and, finally, the gloves.
- D. In the hierarchal sequence of PPE removal, the last item PPE removed are the gloves.

20. To safely remove PPE begins with

the gloves and progresses sequentially to goggles or face shield, gown, mask or respirator, and concludes with hand hygiene immediately after removing all PPE

OR

the gown and gloves and progresses sequentially to goggles or face shield, mask or respirator, and concludes with hand hygiene immediately after removing all PPE. A. True

B. False

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