

Health Systems Corporate Liaisons Meeting: IC Update

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Disinfection of Ophthalmology Equipment

Quick Safety 49

Quick Safety

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Disinfection of tonometers and other ophthalmology devices

Editorial Note: Please direct this Quick Safety to your organization's infection control and ophthalmology leadership.

Issue:

Health care organizations and providers that use tonometers and other devices that touch eyes need to be aware of an infection risk to patients. The American Academy of Ophthalmology has reported that transmission of adenovirus and herpes simplex virus HIV, hepatitis C virus (HCV), enterovirus 70, *Pseudomonas aeruginosa*, methicillin-resistant *Staphylococcus aureus*, *Acanthamoeba*, and prions (transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease) could occur from failure to adequately disinfect ophthalmology devices, such as tonometers.¹

Despite this information, a review of Joint Commission survey data identified either a lack of awareness of the requirements or misinterpretation of manufacturer's instructions — combined with lack of staff training and leadership oversight — related to the disinfection of ophthalmology devices. This has resulted in multiple declarations of an immediate threat to health and safety of patients.

Lack of compliance with reprocessing has been observed with the following items:

- Tonometers
- YAG laser lens
- Eye specula

Tonometer tips are particularly problematic because disinfectants can dissolve the glue that holds the hollow tip together, causing the tip to swell and crack. It's important to note that tonometer tips have been identified as sources of ophthalmic nosocomial outbreaks commonly linked to adenovirus types 8 and 19. Desiccated virus remains viable and can be recovered after 49 days on dried plastic or metal surfaces.¹

Surveyor Feedback

- No or outdated instructions
- Manufacturers
 - No longer in business
 - Sold to new company
 - Not aware of updated FDA guidance for device manufacturers
- Users do not understand the instructions
- Users have implemented Quick Safety Guidance



Example of Instructions*

Touches eye (mucous membrane) – requires high level disinfection

Cleaning	
Rinse:	Immediately upon removal from patient's eye, thoroughly rinse in cool or tepid water.
Wash:	Place a few drops of mild soap on a moistened cotton ball. Gently clean with a circular motion.
Rinse:	Thoroughly rinse in cool or tepid water, then dry carefully with a <i>non-linting</i> tissue.
Then:	Proceed with either disinfection or sterilization instructions.

Disinfection			
Soak In:	GLUTARALDEHYDE	OR	BLEACH
	2% or 3.4% aqueous solution		10% solution mixed at: 1 part bleach to 9 parts cool tepid water
	Temperature per manufacturer instructions		
	Minimum exposure time = 20 minutes		Recommended exposure time = 20 minutes
Caution <i>To avoid damage to the lens, do not exceed recommended exposure time.</i>			
Then:	Rinse <i>thoroughly</i> to remove disinfection solution. 3 cycles of 1 minute, with cool or tepid water is recommended. Dry carefully and place in a dry storage case.		

Only FDA approved High Level Disinfectants in this list

NOTE **known to be compatible with:** Asepti-Wipe, Cavi-cide, **Cidex, Cidex OPA**, DisCide Wipe, Enviro-cide, H₂O₂ - 3%, and Opti-Cide

Caution *If used on an ulcerated cornea, must be **STERILIZED** before next procedure.*

*dated 2001 but most current provided by manufacturer

FDA Position*

- Instructions for older, legally-marketed, reusable devices may not be consistent with state-of-the-art science
 - Labeling may not ensure device is clean, disinfected or sterile
 - Device may be misbranded
 - Labeling may not bear adequate directions for use and therefore the device is dangerous to health

*Adapted from FDA OSAP Conference Presentations June 23,2017 and June 1, 2019

FDA Resources

- Manufacturers: FDA Issued “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff” on March 17, 2015

Available at <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/working-together-improve-reusable-medical-device-reprocessing>
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>

FDA Guidance for Users

1. Check the label for date of issuance or the date of the latest revision
2. Contact the manufacturers technical service representatives for new instructions that comply with 2015 FDA Reprocessing Guidance
3. Search the FDA 510(k) database
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfp/mn/pmn.cfm>

FDA Guidance for Users

4. Seek assistance from the FDA

- Contact the FDA
 - Division of Industry and Consumer Education (DICE)
 - 800-638-2041 or DICE@fda.hhs.gov
- File a voluntary report of a medical device problem
 - <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>
- File an Allegations of Regulatory Misconduct
 - Use for complaints such as misleading or incomplete instructions

FDA Allegations of Regulatory Misconduct

- Available to anyone
 - May be submitted anonymously
 - Must identify device, identify issue, provide supporting documents
- Submit by
 - Email: CDRHDeviceAllegations@fda.hhs.gov
 - Online form: <https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form>
 - Mail

*Adapted from FDA OSAP Conference Presentations June 1, 2019
FDA Website: <https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct>

Bottom Line

- If the item should be high level disinfected and a facility cannot do so for any reason it should not be used
 - Puts patients at risk
 - Puts the facility at risk

Use of Personal Protective Equipment (PPE): Keeping Employees Safe

Personal Protective Equipment

- First case of HIV in a healthcare worker was from contact with non-intact skin
 - 1986, Barbara Fassbinder, RN: not wearing gloves and was infected through cuts in her hands
- 2014, Ebola transmission occurred
 - Thought to be related to PPE removal procedures
- Multiple studies on contamination of healthcare workers with infectious agents outline key risks
 - Failure to use
 - Use of the wrong PPE
 - Unsafe removal

Key Risks

- Failure to use PPE
 - Employees may be willing to accept high risk of infection based on the disease perception: Ebola versus common cold ¹
- Use of the wrong PPE for the exposure
 - Aerosols created during dental procedures ²

¹ Branch-Elliman W, et al. Protecting the Frontline: Designing an Infection Prevention Platform for Preventing Emerging Respiratory Viral Illnesses in Healthcare Personnel. *Infect Control Hosp Epidemiol* 2015;36(3):336–345

² Harrell SK Molinari J. Aerosols and splatter in dentistry A brief review of the literature and infection control implications. *JADA*, Vol. 135, April 2004

Implications of Incorrect Removal

- Incorrect removal

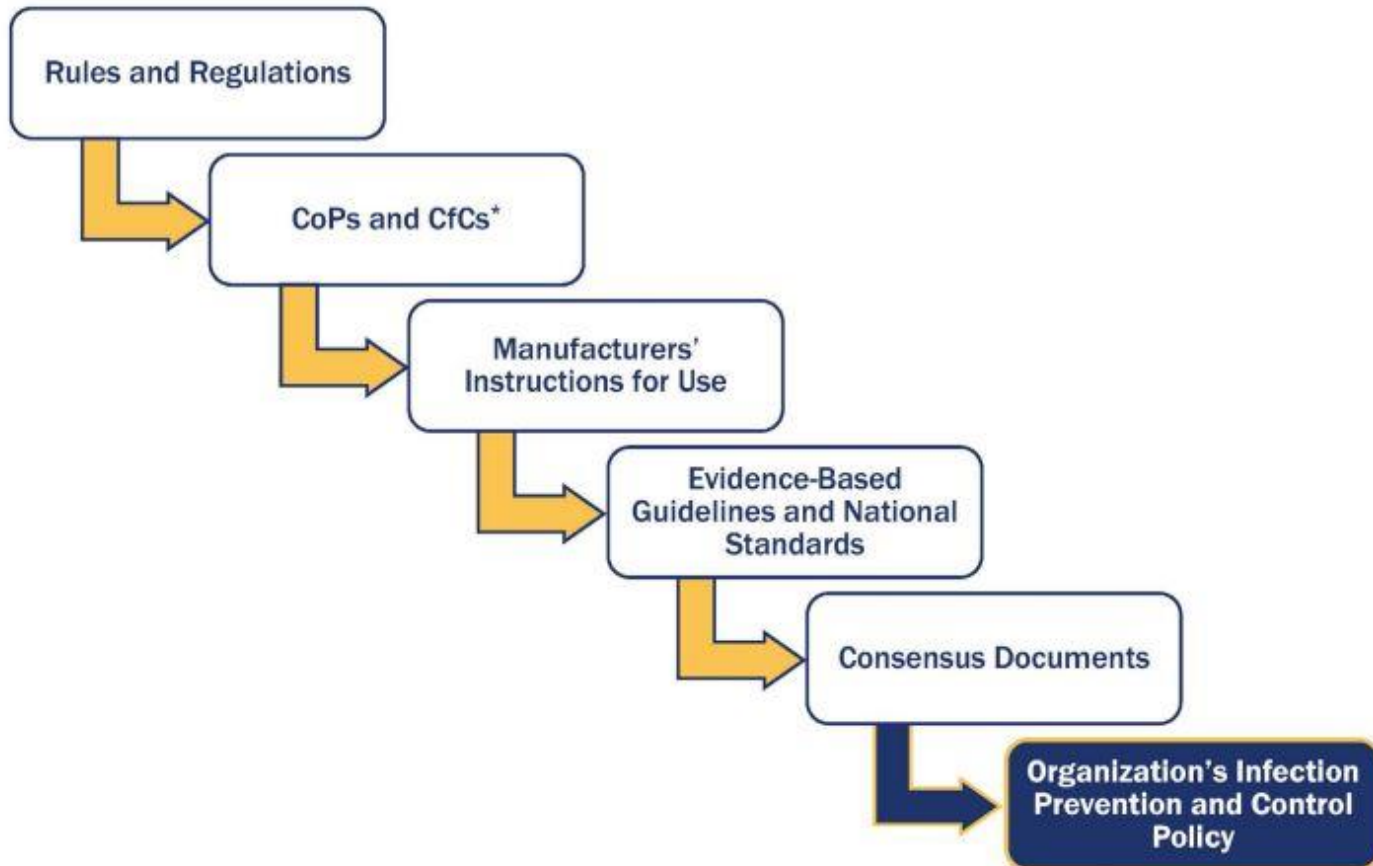
- 42.5%-50.3% self contamination with multi-drug resistant organisms at 4 hospitals *

- Tomas ME, Kundrapu S, Thota P, et al. Contamination of Health Care Personnel During Removal of Personal Protective Equipment. *JAMA Intern Med.* 2015;175(12):1904–1910. doi:10.1001/jamainternmed.2015.4535
- Podcast: <https://edhub.ama-assn.org/jn-learning/audio-player/11849091>

What do we see on survey?



What are the Requirements?



** For organizations that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive, Conditions of Participation (CoPs) and/or Conditions for Coverage (CfCs) should be reviewed for applicable mandatory requirements.*

Regulations

- Bloodborne Pathogens Standard (1991)
 - Applies to PPE deemed necessary to protect from exposure to blood and other potentially infectious materials linked to transmission of bloodborne pathogens
- Personal Protective Equipment for General Industry (1994)
 - Applies to PPE deemed necessary to protect workers from infectious disease that does not fall under coverage of the BBP standard (e.g., implementation of isolation)

How do we reduce risk?

- Perform a “hazard assessment”
- Develop an exposure control plan and update annually
- Identify, provide and maintain appropriate PPE
- Train employees in the use and care of the PPE
- Enforce use



Training should include:

- When PPE is necessary.
- What PPE is necessary.
- How to properly put on, take off, adjust and wear the PPE.
- The limitations of the PPE.
- Proper care, maintenance, useful life and disposal of PPE.

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
- 4. GLOVES**
 - Extend to cover wrist of isolation gown

USE SAFE WORK PRACTICES TO PREVENT AND LIMIT THE SPREAD OF COVID-19


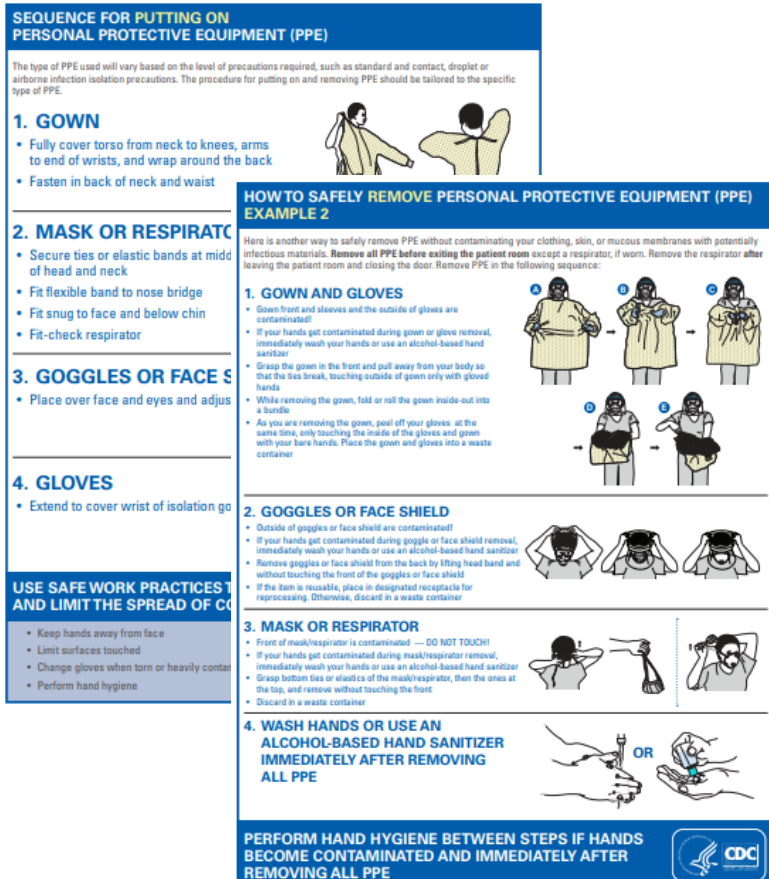
- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

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 goggles 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! — DO 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 elastic 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



Example: Each Facility Should Establish and Train

Will it work?

- Education and training resulted in a reduction in skin and clothing contamination during glove and gown removal (60.0% before the intervention vs 18.9% after, $P < .001$) that was sustained after 1 and 3 months (12.0% at both time points, $P < .001$ compared with before the intervention).

- Tomas ME, Kundrapu S, Thota P, et al. Contamination of Health Care Personnel During Removal of Personal Protective Equipment. *JAMA Intern Med* 2015; 175(12): 1904–1910. doi:10.1001/jamainternmed.2015.4535

Questions and Comments