[High Priority] - S0394 : [COVID-19] Disinfection of N95 Respirators: UV Light May Be Considered for Limited Reuse Situations [ECRI Exclusive User Experience Network]

Medical Device Special Report

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UMDNS Terms:

- Respirators, Air-Purifying, Particulate [20359]

Geographic Regions: Worldwide

Suggested Distribution: Infection Control, Risk Management/Continuous Quality Improvement, Materials Management

Problem:

1. Healthcare facilities dealing with COVID-19 are facing shortages of single-use N95 respirators.
2. Following CDC recommendations for extended use and reuse of single-use N95 respirators may increase healthcare worker exposure to the virus, as compared to using new N95 respirators for each patient interaction.
3. Facilities may attempt to decontaminate single-use N95 respirators using various methods, including UV disinfection.
4. Disinfection of single-use N95 respirators using methods that have not been validated may:
    1. Have limited efficacy
    2. Degrade fit and performance
    3. Increase risk to healthcare workers

ECRI Recommendations:

1. If your facility is facing shortages of N95 respirators:
    1. Follow CDC and NIOSH guidelines for optimizing your N95 respirator supply, including extended use and limited reuse of respirators as appropriate (CDC 2020 [1], NIOSH 2018 [2]).
2. If your facility chooses to disinfect N95 respirators between reuses:
    1. Continue to follow CDC guidelines for limited reuse of respirators:
        1. Discard N95 respirators following use during aerosol generating procedures.
        2. Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
        3. Perform hand hygiene before and after touching or adjusting the respirator.
        4. Store used respirators properly, according to CDC guidelines, such as in a breathable paper bag.
        5. Assign only one wearer per respirator to reduce the risk of secondary exposure.
    2. Consider developing a policy for implementation of UV disinfection. The policy may include:
        1. Before first use, label the respirator strap with the wearer's name.
        2. After use of a respirator, follow protocol for doffing. Avoid touching the internal surface.
        3. Place the respirator in a paper bag, marked to identify the wearer, for transport to a UV disinfection location.
        4. UV disinfection device operators should wear appropriate PPE (i.e., gloves, gown, respirator) when handling respirators.
        5. For disinfection using countertop UV disinfection systems:
            1. Place the respirator in the device. Conical (duckbill) respirators that fold flat should be propped open to enable sufficient surface exposure.
            2. Follow the UV device manufacturer's recommendations for disinfection cycle time, which ranges from 30 seconds to 2 minutes. Aim to achieve a UV dose of at least 18 mJ/cm^2 (most devices will achieve this within the manufacturer-specified disinfection cycle time); doses over 59 mJ/cm^2 are preferred.
        6. For disinfection using UV room disinfection systems:
            1. Hang respirators in the center of a clean, empty storage area. Place a UV room disinfection device 5 feet in front of the respirators.
                1. Space respirators appropriately. Do not allow them to touch one another.
                2. Be aware of the distance between each respirator and the UV device. If the distance increases beyond about 7 feet (about a 45° angle from the UV device), longer cycle times may be required to achieve the desired dose. Required cycle time varies by device.
                3. Ensure that each respirator has a clear line of sight to the UV device. Conical (duckbill) respirators that fold flat should be propped open to enable sufficient surface exposure. Attempt to limit shadowing, which may reduce the UV dose that reaches the surface of the respirator.
            2. When enough respirators are present, run a disinfection cycle for 5 minutes, or as recommended by the UV

device manufacturer.

3. Move the device to the opposite side of the respirators, and repeat the cycle to ensure that both the inside and outside of the respirator are disinfected.

7. Follow protocol for donning reused respirators. Wear gloves, and perform hand hygiene before and after donning.
8. Inspect respirators before UV disinfection and before each reuse. Discard respirators that:
    1. Are soiled
    2. Are damaged (e.g., torn, discolored)
    3. Do not fit properly
    4. Are difficult to breathe through
    5. Have reached the maximum number of uses recommended by the N95 respirator manufacturer or were used a maximum of 5 times (NIOSH 2018).

Background:

1. N95 respirator manufacturers state that their products are intended for single use. Manufacturers have not validated the effectiveness or safety of disinfecting respirators.
2. Disinfection of N95 respirators before reuse is not required, according to CDC guidelines for contingency and crisis strategies.
    1. Extended use is preferred over limited reuse, because it provides a lower risk of self-inoculation or transmission caused by touching of the respirator (CDC[1], Fisher[3]).
    2. Disinfection may reduce the risk of self-inoculation when limited reuse is required. Risk factors for self-inoculation include (Fisher 2014[3]):
        1. Number of pathogens on the surface of the respirator
        2. Pathogen survival on the respirator
        3. Transfer efficiency of pathogens from the respirator surface to the hands or skin of a healthcare worker
    3. CDC has recently posted guidelines on Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies .
        1. As a first strategy, CDC recommends issuing each healthcare worker five N95 respirators, to be used in a 5-day rotation cycle. This cycle allows about 4 days of downtime, exceeding the expected 3-day persistence of SARS-CoV-2 on surfaces.
        2. CDC states that: "If supplies are even more constrained and five respirators are not available for each worker who needs them, FFR decontamination may be necessary. Decontamination and subsequent reuse of FFRs should only be practiced as a crisis capacity strategy." (CDC[4])
3. Effectiveness of UV disinfection:
    1. Studies have shown that UV disinfection may be effective against influenza strains on the surface of N95 respirators (Mills[5], Heimbuch[6], Lore[7]). These studies did not test all models of N95 respirators, but included many common models.
    2. Based on data available for other coronaviruses (Walker[8], Weiss[9], Duan[10], Kariwa[11]), ECRI has calculated (Kowalski book[12]) that a dose of 18.4 mJ/cm^2 at 254 nm wavelength may be sufficient to achieve a 3-log reduction of SARS-COV-2 on smooth surfaces.
    3. Based on data from Fisher[13], UV light reaching the internal filter layers of N95 respirators, where airborne viruses are likely to be caught, may be dramatically reduced.
        1. Depending on the respirator model, 0.25% to 31% of UVC light may penetrate to the filter layers.
        2. A surface-dose of 59 mJ/cm^2 to 7,000 mJ/cm^2 may be sufficient to achieve a 3-log reduction in SARS-COV-2 at the internal filter layers. To ECRI's knowledge, this has not been empirically validated.
    4. Because of practical considerations, ECRI does not recommend a UV dose of 7,000 mJ/cm^2.
        1. Not all respirators required such a high dose to reach the internal layers.
        2. Viruses caught in the internal filter layers are unlikely to re-aerosolize.[14]
        3. Applying a dose of 7,000 mJ/cm^2 could require up to 100 times as long as ECRI's current recommended doses. UV devices are typically not designed to provide doses this high, and therefore repeated cycles would likely be required.
        4. Repeatedly treating N95 respirators at a dose of 7,000 mJ/cm^2 would increase the likelihood of physical degradation of the respirator.
    5. At a distance of 5 feet, most UV room disinfection devices can achieve a dose of 58 mJ/cm^2 within 1 to 2 minutes. ECRI recommends 5-minute cycles (150 to 450 mJ/cm^2) per side to account for variations in distance, dose requirements, and to provide an additional margin of safety.
    6. Respirator shape may block the UV light from reaching certain areas of the respirator; for example, folds or pleats may interfere with consistent coverage.
4. Respirator Degradation:
    1. Studies have shown that high doses of UV exposure may degrade N95 respirators.
        1. The first signs of meaningful degradation are likely to be visible are the weakening of materials (e.g., tears) and loss of elasticity of straps that may lead to poor fit (Lindsley[15]).

    2. Filtration effectiveness and air flow resistance were slightly degraded, but typically not to a meaningful level. Most N95 respirators were still able to pass NIOSH requirements for 95% filtration after exposure to very high UV doses (Lore[7] 1800 mJ/cm^2, Lindsley[15] 120,000 mJ/cm^2).
2. The UV dose that ECRI recommends is unlikely to cause meaningful degradation, even after repeated cycles (Lindsley[15]).
3. Each respirator model is composed of different materials, and some models may be more susceptible to damage than those previously studied.
4. When UV disinfecting and reusing N95 respirators, users should inspect the respirator for signs of damage or poor fit before each use.

5. Consider the limitations of UV disinfection:
    1. Each UV disinfection cycle increases the likelihood of material degradation.
    2. Each reuse increases the likelihood of exposure (e.g., through touching a contaminated respirator) and poor fit (e.g., caused by physical damage or stress).
    3. Each subsequent reuse of a respirator provides diminishing returns.
        1. A single disinfection-and-reuse approximately doubles your supply of N95 respirators.
        2. A second disinfection-and-reuse gives you 50% more supply than a single reuse.
        3. A third disinfection-and-reuse gives you 33% more supply than reusing twice.
    4. Weigh the risks and benefits of disinfection-and-reuse.
6. The University of Nebraska has developed a protocol for UV disinfection of N95 respirators. This protocol has been widely publicized by news media.
    1. This protocol originally recommended a UV dose of 60 mJ/cm^2, but has since been updated to a UV dose of at least 300 mJ/cm^2.
    2. The protocol also recommends use of white (“clean") paper bags for returning N95 respirators to service, and brown (“dirty") paper bags for used N95 respirators.

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Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Apr 2. ECRI researched report