

New Mexico Medical Advisory Team (MAT) Assessment

Workgroup Name: Clinical Care PPE Subgroup

Date: 4/3/2020

Question or task for assessment or Protocol name/description

What Directive could the Governor give to hospitals to apply recycling strategies for PPE?

DIRECTIVE

To maximize the supply of PPE, especially N95-type respirators, the workgroup recommends the Governor to issue the following directive:

New Mexico acute care and ambulatory facilities should implement structures and policies for the recycling of N95-type respirators.

Elements to consider:

We recommend the use of Ultraviolet (UV) Light, Vaporized Hydrogen Peroxide (VHP), as well as manufacturer's instructions for reusable PPE (respirators, gowns) for recycling. All solutions are commercially available and have already been implemented to various degrees in New Mexico acute care facilities.

Recommendations

Re-Use Strategies

UV and VHP

No PPE items may be sterilized in the traditional sense of steam autoclaving (temperatures required degrade materials beyond usability in a single cycle). However, UV and VHP (e.g. Halosil brand) have been demonstrated to sanitize disposable N95 respirators. By extension, face masks (surgical/procedural) and face shields would be expected to achieve similar sanitization results from the same two methods.

UV has a distinct drawback of requiring line of sight, so "shadowing" can result in incomplete sanitization. VPH has the advantage of permeating materials and not requiring line of sight, rendering it the more reliable and effective process.

Manufacturer's Instructions

Reusable N95 (or greater) half-face or full-face respirators may be topically disinfected or batch-sanitized with disinfectants approved by the manufacturer. Cloth gowns may be laundered per industry standards for sanitization for reuse.

Not Re-Useable

Disposable isolation gowns and nitrile examination gloves are not amenable to sanitization due to recommended methods for removal (balling gown up inside-out) and cavitary design (gloves difficult to treat inner and outer surfaces without increasing exposure risk of sanitization operator).

Protocols Available for Reference (How to Implement)

- **University of Nebraska Medicine N95 UVGI Protocols:** To extend the stockpile of N95 Filtering Facepiece Respirator (FFR)s, University of Nebraska developed a decontamination procedure involving the delivery of ultraviolet germicidal irradiation (UVGI) to used N95 FFRs. The evidence base supporting this program includes: 1) UVGI has been shown to effectively inactivate a wide range of human pathogens including coronaviruses and other human respiratory viruses; 2) UVGI

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has been demonstrated to inactivate human respiratory viruses, including coronaviruses, on various models of N95 FFRs; 3) levels of UVGI needed to inactivate human respiratory viruses are well below the level of irradiation that adversely affects the fit and filtration characteristics of N95 FFRs; and 4) UVGI can be safely administered when appropriate safeguards are in place.

- **Duke Medicine Decontamination Process:** Duke Health research and clinical teams have confirmed a way to use existing vaporized hydrogen peroxide methods to decontaminate the masks so they can be reused. The process uses specialized equipment to vaporize hydrogen peroxide, which permeates the layers of the mask to kill germs, including viruses, without degrading the mask material. Additionally, Duke Health confirmed consistent fit of VPH processed N95 respirators after multiple processing cycles without any detectable product degradation.

Analysis, including triggers and thresholds if applicable

Concepts that are essential to a Hospital PPE recycling plan

- Communication to develop awareness and desire among the workforce:
 - To participate
 - To locally disinfect or sanitize (as available)
 - To assess for soiling prior to collection of disposable items
 - To routinely and reliably disinfect reusable items in between periodic batch-sanitization
 - Reassurance to staff about the effectiveness of sanitization
 - Reassurance to staff that conservation is not a lack of leadership/organizational concern for their wellbeing but a carefully executed strategy to ensure PPE for the Surge

Currently Available to New Mexico Health Systems

UV and VHP room sanitizers (various manufacturers), table top UV sanitizers, steam autoclave (no acceptable use cases for PPE), topical surface disinfectants, hypochlorite (bleach) solution and wipes.

Desired

A large-scale processing center for economy of scale and access to UV or VHP methods for smaller facilities/systems, dedicated supply chain for reusable and disposable PPE, dedicated units/facilities for COVID-19 confirmed patients (cohorting allows HCPs to continuously wear PPE across multiple patients with less donning/doffing and consumption).

Minority Report: Dry heat, Ethylene Oxide (EtO) and gamma rays were suggested as possible decontamination mechanisms; dry heat is in use in at least one facility. However, during research review these methods were found to be not consistently viable. See this 3M document for additional detail (note there is bias due to their retail Conflict of Interest):

<https://multimedia.3m.com/mws/media/18165760/disinfection-of-disposable-respirators-technical-bulletin.pdf>

Current Methods to Store/Bank for Reuse

Presbyterian Healthcare Services (PHS) is beginning to collect non-soiled/functional disposable surgical masks, face shields, and N95 respirators from hospital nursing stations in biohazard containers/bags, transporting when 50% full as biohazardous materials to an internal hospital reprocessing location, arranging items on horizontal racks or hanging racks (as appropriate to the item type), exposing to VHP (Halosil brand) per manufacturer's instructions, allowing indicated rest time for off-gassing, then collecting in clean storage containers for return to central supply followed

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by distribution. Independent assessment of research on VHP and UV accompanied by assessment of University of Nebraska's UV protocol led to development of a solution that would not require individual tracking and return of items. VHP was determined to meet that requirement.

Other methods include:

- Segregation of PPE
- Focused retrieval
- Short time storage and daily processing and packaging
- Placement of items (N95s) in a special container for regular pickup and reprocessing

Potential Future Re-Use Strategies for New Mexico

- **Battelle Memorial Institute Decontamination System:** U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (“the Battelle Decontamination System”) for use in decontaminating compatible N95 or N95-equivalent respirators (“compatible N95 respirators”) for reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic resulting from the Coronavirus Disease 2019 (COVID-19) pandemic. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Battelle Decontamination System may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms. Battelle is authorized to decontaminate up to 10,000 compatible N95 respirators per chamber load, consistent with the data provided to FDA.

Note: The Duke Medicine and Battelle solutions offer the opportunity to process far more devices than Ultraviolet and without the “shadowing” risk.

Red flags, major concerns and recommendation sunset

Absolute conditions that would prohibit potential re-use:

- Visible soiling
- Material degradation
- Material failure, gross contamination (especially with bodily fluids)
- Damage resulting from material failure or from inappropriate use

Relative conditions that would prohibit potential re-use:

- Expiration date of product
- Exceeding recommended reuse/extended use limits
- Manufacturer’s instructions for use
- Accepted practices
- Clarity following multiple sanitation cycles (face shield-specific)
- The University of Nebraska Medicine N95 UVGI Protocols have not been approved by CDC or FDA at this time.

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Gaps in knowledge or science related to topic

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Level of consensus within workgroup

Total	Moderate	Limited
X		

Contributors

PPE Subgroup:

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References or resources for further information

- CDC Decontamination and Reuse of Filtering Facepiece Respirators : <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>
- Duke Medicine: <https://corporate.dukehealth.org/news-listing/duke-starts-innovative-decontamination-n95-masks-help-relieve-shortages?h=nl>
- University of Nebraska: <https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf>
- Instructions for Use for Repurposing N95 Mask in STERRAD Sterilization Systems: [https://www.asp.com/sites/default/files/covid-19/AP-2000011-Instructions for Use for Reprocessing N95 Masks in STERRAD Sterilization Systems.pdf](https://www.asp.com/sites/default/files/covid-19/AP-2000011-Instructions%20for%20Use%20for%20Reprocessing%20N95%20Masks%20in%20STERRAD%20Sterilization%20Systems.pdf)
- FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: <https://www.fda.gov/media/136533/download>

Attachments:

- [Duke Medicine] Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor (policy/procedure)
- [Battelle Memorial Institute] FDA Approval for N95 Disinfection