Solutions for PPE Shortages –

CoVID-19 Decontamination Strategies and In-House Production Options
Presenters:

• Moderator:
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    • Associate Professor of Medicine, Division of Infectious Diseases; Emerging Pathogens Unit

• Panelists:
  • Dr. Matthew Stiegel, PhD
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  • Dr. Antony Schwartz, PhD
    • Assistant Director, Occupational & Environmental Safety, Duke
    • Director, Biological Safety Division, OESO | Biosafety Officer
  
  • Ms. Nicole Greeson, MS, CIH
    • Director, Occupational Hygiene and Safety, Duke
  
  • Dr. Becky Smith, MD, MS
    • Associate Professor of Medicine, Division of Infectious Diseases; Duke Infection Control Network
Some Background:

- Duke University Health System:
  - Duke University Hospital: 979 beds, Duke Regional Hospital: 369, Duke Raleigh Hospital: 186
  - Patient service area of approx. 1.94 million people in NC

- Duke University:
  - Approx. 6994 undergraduates; 8898 graduates and professional students
  - Active biomedical research presence, including Biosafety Level (BSL) 3 laboratory with expertise in Infection Disease response training; lead coordinating center, funded by NIEHS, to teach biohazard response.
Previous Experience with HPV/VHP (Hydrogen Peroxide Vapor)

- Ebola Preparedness 2014/2015:
  - Ambulance decon
  - Inpatient Emerging Pathogen Unit decon:

- But no PPE decon and reuse data at that time...
Validated the decontamination of N95 respirators with Hydrogen Peroxide Vapor for 50 cycles (complete inactivation without affecting air flow resistance or aerosol collection efficiency)

Reuse limiting factor was elastic straps that started to show degradation after 30 cycles

Parameters:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Duration (min)</th>
<th>Rate of HPV Injection (g/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditioning</td>
<td>10</td>
<td>NA</td>
</tr>
<tr>
<td>Gassing</td>
<td>20</td>
<td>2.0</td>
</tr>
<tr>
<td>Dwell</td>
<td>150</td>
<td>0.5</td>
</tr>
<tr>
<td>Aeration</td>
<td>300</td>
<td>NA</td>
</tr>
</tbody>
</table>

Available at: [https://www.fda.gov/media/136386/download](https://www.fda.gov/media/136386/download)
VHP Equipment
VHP Parameters

- Dosing 30-35% H2O2
- Range of H2O2 in room depending on vaporizer: 480ppm; 300 – 750ppm
Overview of the Decon Process

- Conditioning – 10 minutes
- Pre-gassing – 25 minutes
- Gassing - 25 minutes
- Gassing Dwell - 20 minutes
- Aeration – 240 minutes minimum
- Total time – 320 minutes minimum

- Ensure H2O2 < 1ppm (OSHA PEL, ACGIH TLV, NIOSH REL, Cal/OSHA PEL)
- <0.1ppm after ~4 hours
Testing Setup

- N95s were placed on racks in various configurations; face up was best configuration
- **Geobacillus stearothermophilus** 1x10^6
- ATCC12980 is a non-pathogenic strain
- Enclosed in a high porosity Tyvek pouch
Testing Results: Run Parameters
Testing Results: Fit Testing

Fit tested close to 400 N95s post-decon using the quantitative fit testing process for employees; all N95s passed!
Logistics and Workflow of Process

Healthcare Worker

Healthcare Worker

Staff label paper bag with:
Name, Date & Time

Place N95 in paper bag during shift.
Re-use N95 per latest guidance. At end of shift put N95s in collection bins.

Only N95s are placed in bin; NO Bags

Collection bins are consolidated at the unit level

Remove N95 from bins and place on racks. Place Bls for validation.

Decon Facility

To Decon

Central Holding Location

Central Packing and Warehouse

DukeHealth

Re-use N95

VHP Decon Process

Biological Indicators (Bls) incubated in growth media

Hold for Aeration

Release for use when Bls are Negative

Discard if there is: Wear & Tear Makeup Elastic Degradation Nose clip issues

Transfer to clean white bins

Back to Supply Chain

Only N95s are placed in bin; NO Bags

Latched

Disinfect by wipe-down on the outside
Collection at the Unit Level

• We’re all experiencing a shortage of PPE
• Many ways to exercise PPE conservancy
• Collect non-soiled masks (N95, loops) and face shields
PPE for Decon Set Up / Safety Measures

- Staff Handling N95 in Decon Room:
  - Scrubs
  - Nitrile gloves
  - Gown
  - Hair bonnet
  - N95 respirator
  - Face shield

- Staff Packaging N95 Post-decon:
  - Disposable lab jacket
  - Hair bonnet
  - Ear loop masks
  - Nitrile gloves
Placement of N95s: Interior Up for Effective Off-Gassing
Quality Assurance and Packaging

• Checking for degradation of the masks—wear and tear
• Checking for makeup and soiling
• Checking for elastic band integrity and degradation
• Checking nose clip

• Any N95s that fail QA check, get stored in their decontaminated form for potential later use.
What about 3M Technical Bulletin on Disinfection of Filtering Facepiece Respirators?

- [https://multimedia.3m.com/mws/media/1816576O/disinfection-of-disposable-respirators-technical-bulletin.pdf](https://multimedia.3m.com/mws/media/1816576O/disinfection-of-disposable-respirators-technical-bulletin.pdf)

- Four criteria of successful disinfection:
  1. Be effective against the target organism, such as the virus that causes COVID-19;
     - We used biological indicators showing 6 log reduction of spores, which arguably are harder to inactivate than enveloped viruses. Others have done viral testing. Battelle conducted droplet/aerosol spray and recovery study.
  2. Not damage the respirator’s filtration;
     - 3M bulletin provides data that the filtering efficiency was not affected by VHP decon. This data is available.
  3. Not affect the respirator’s fit; and
     - We showed this via repeated quantitative fit testing on humans. We’ve done ~400 at this point.
  4. Be safe for the person wearing the respirator (e.g. no off-gassing of chemicals into the breathing zone).
     - We showed this by measuring H2O2 until it dropped below 0.1ppm (LOQ). Due to necessary time for biological indicators, the respirators sit even longer (~24 hrs).
How Can Others Do This?

• Purchase the equipment (e.g., vaporizer, wire racks, clamshell containers, bins, etc.).

• Find a room where you can shut off HVAC or find ways to seal using caulk and other means so the high levels of H2O2 don’t leak out.

• Ability to monitor H2O2 levels to assure it is below relevant OELs (typically 1 ppm).

• Biological indicators to validate each cycle.

• Manage logistics of getting the used N95s to the decon room/facility and then back to users for reuse after decontamination.

• Adequately protect the employees who will be handling the contaminated N95s
Other Options for Decontamination?

• UV- Data seems to indicate no more than 2-3 cycles. Concerns with complete surface coverage due to curvature of respirator and with degradation. (3M Bulletin notes straps on 1870 lost elasticity; strong burnt odor; nosefoam compressed on 1860)

• Ethylene Oxide – concern about exposure to respirator wearer after reprocessing due to off-gassing
Communications/Messaging

• Communication to respirator users about reprocessing/decontamination

• This is only one piece of our PPE conservation effort
  • N95 extended use during a shift
  • N95 reuse during a shift
  • Used in conjunction with face shield to prolong usage.