NIOSH Recommendations for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings

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NIOSH Recommendations for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings

Edward Fisher, MS  Debra Novak, PhD, RN  Ronald E. Shaffer, PhD
Webinar Objectives

- Inform professionals who manage respiratory protection programs in healthcare settings about the benefits and risks of implementing extended use and limited reuse of N95 FFRs during both emergency and non-emergency situations

- Describe best practices for healthcare facilities to implement extended use and limited reuse of N95 FFRs to minimize the risks of reduced protection and self-inoculation via contact transmission
Why Healthcare Respiratory Protection is a Priority

- Healthcare is the fastest-growing sector of the U.S. economy, employing over 18 million workers
- Healthcare personnel (HCP) are at higher risk of exposure to infectious respiratory pathogens than workers in non-healthcare settings
- Preferred methods of reducing exposure (elimination, substitution, administrative, and engineering controls) are often not possible or practical to implement, especially during an emerging outbreak or pandemic
When should a respirator be worn?

- Respirators are often recommended to be used when in close contact with patients suspected of having an aerosol transmitted disease. Some *possible examples include:
  - Influenza (Avian strains capable of causing serious disease in humans or during certain medical procedures)
  - Varicella disease (chickenpox, disseminated shingles)
  - Measles
  - Monkeypox
  - Severe acute respiratory syndrome (SARS)
  - Smallpox
  - Tuberculosis (TB)
  - *Note: Infection control guidance for specific pathogens can vary by jurisdiction and for different medical procedures
Respiratory Protection in Healthcare

- N95 Filtering Facepiece Respirators (FFRs) are the most commonly used type of respirator in healthcare
  - NIOSH 42 CFR Part 84
  - FDA “Surgical N95 respirator”

![Image of healthcare workers wearing N95 masks]
Respirator Supply Concerns

- N95 FFRs are often discarded after each patient contact (‘single-use’)
- Healthcare facilities experienced increased usage of FFRs and shortages during previous public health emergencies
  - 25% of respondents that worked at a facility that treated one or more possible/confirmed SARS patients experienced FFR shortages (Srinivasan et al., 2004)
  - Hospitals in Vancouver reported that the use of N95 FFRs doubled during the 2009 H1N1 flu pandemic (Mitchell et al. 2010)
  - 50% of California hospital managers reported they had experience shortages of respirators during the 2009 H1N1 flu pandemic (Beckman et al. 2013)
Options

1. Pre-emergency planning:
   - Purchase excess supplies of respirators and “stockpile” them until needed

2. During the event:
   - Minimize # of individuals who need to use respirators through the preferential use of engineering and administrative controls
   - Use alternatives to N95 FFRs (e.g., other classes of FFRs, elastomeric half-mask and full facepiece air purifying respirators, powered air-purifying respirators)
   - Implement practices allowing extended use and/or limited reuse of N95 FFRs
   - Prioritize the use of N95 FFRs for those personnel at the highest risk of contracting or experiencing complications of infection
Background

- Historically, N95 FFRs have been used in industrial settings to reduce worker exposure to harmful dusts and aerosols
  - Reuse & continuous use over several hours is common
- More recently, N95 FFRs have been recommended for use in healthcare settings
  - Because of infection control concerns, decisions regarding reuse & long-term use require additional considerations
Limited FFR Reuse in Healthcare

- Reuse is the practice of the same healthcare worker using the same FFR for multiple patient encounters (‘close contacts’)
- The FFR is removed (‘doffed’) after each encounter, stored between uses, and then put on again (‘donned’) for the next encounter
- Even when FFR reuse is practiced or recommended, restrictions are in place which limit the # of times the same FFR is reused
  - FFR reuse is often called “limited FFR reuse”
Extended FFR Use in Healthcare

- Extended use is the practice of wearing the same FFR for repeated encounters with several patients, **without** removing the FFR between patient encounters
- Can result in several hours of continuous wear
Concerns Expressed by Stakeholders with Extended Use and Limited Reuse of FFRs

- **Self-inoculation** (e.g., used FFR = fomite?)
- **Reduction in protection provided by the FFR** (e.g., over time, # of donnings)
- **Human factors** (e.g., comfort, tolerability, psychological, aesthetics)
- **Secondary exposures** (e.g., reaerosolization)
Scientific Assessment

- 2006: IOM report recommended that “avoiding contamination [of FFRs] will allow for limited reuse” and identified key research gaps
- 2006-2012: NIOSH and others conducted laboratory and human subject studies
- 2013: NIOSH working group established to reexamine recommendations
### CDC FFR Limited Reuse and Extended Use Recommendations – Historical Perspective

<table>
<thead>
<tr>
<th>Respiratory Pathogen</th>
<th>Contact Transmission Possible(*)?</th>
<th>FFR Shortage Likely?</th>
<th>Extended Use/Limited Reuse Allowed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB [1994]</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>SARS [2003]</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>H5N1 Influenza [2004]</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>H1N1 pandemic [2009]</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Seasonal Influenza (AGP#) [2013]</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>H7N9 Influenza [2013]</td>
<td>Yes</td>
<td>No</td>
<td>No†</td>
</tr>
</tbody>
</table>

**Notes:**

(*) Some debate exists in the scientific community regarding the primary mode(s) of transmission for many respiratory viruses; however, most experts cannot rule out contact transmission

(#) Aerosol Generating Procedures (AGP)

(†) Interim recommendations, subject to change
Fomite  fo·mite n. –
An inanimate object or substance that is capable of transmitting infectious organisms from one individual to another.

FFRs as fomites?
FFR doffing and transfer of pathogens

- FFR fomite hazard can be minimized with use of proper doffing techniques

http://www.cdc.gov/HAI/pdfs/ppe/ppeposter1322.pdf
How contaminated are FFRs in the field?

Using a simple mathematical model (Fisher et al. 2014)

Pathogens on FFR \((C_a) = C_v \times IR_a \times T \times E_r\)

and inputs from the literature for influenza in healthcare settings we can estimate contamination levels

<table>
<thead>
<tr>
<th>Scenario</th>
<th>(C_v^*) viruses/m(^3)</th>
<th>(IR_a) m(^3)/hr</th>
<th>(E_r) %</th>
<th>(T) hr</th>
<th>(C_a^*) viruses/mask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low value inputs</td>
<td>168</td>
<td>0.780</td>
<td>0.900</td>
<td>0.160</td>
<td>19</td>
</tr>
<tr>
<td>High value inputs</td>
<td>16,000</td>
<td>1.920</td>
<td>0.999</td>
<td>6.600</td>
<td>202,549</td>
</tr>
<tr>
<td>Likely</td>
<td>12,000</td>
<td>1.140</td>
<td>0.991</td>
<td>0.330</td>
<td>4,473</td>
</tr>
</tbody>
</table>

\((C_v)\) airborne virus concentration  
\((IR_a)\) inhalation rate  
\((T)\) time of FFR/SM use or patient interaction  
\((E_r)\) virus retention of FFR/SM

*Includes both viable and nonviable viruses
Factors that influence pathogen transfer efficiency

- Fomites may occur as porous or nonporous surfaces
- Porous surfaces demonstrate lower transfer rates than nonporous surfaces

<table>
<thead>
<tr>
<th>Substrate</th>
<th>% transferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lego</td>
<td>65</td>
</tr>
<tr>
<td>Vinyl</td>
<td>66</td>
</tr>
<tr>
<td>Ceramic</td>
<td>55</td>
</tr>
<tr>
<td>Wood</td>
<td>17</td>
</tr>
<tr>
<td>Shoulder pad</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Towel</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Bed sheet</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Desai et al. American Journal of Infection Control April 2011
Transfer efficiency of viruses & bacteria from porous surfaces to skin is poor

- Respirators contaminated with *Bacillus atrophaeus*

\[
\approx 0.1\%
\]

- Other findings reported in the literature have similar results

<table>
<thead>
<tr>
<th>Porous surface</th>
<th><em>E. coli</em></th>
<th><em>S. aureus</em></th>
<th><em>B. thuringiensis</em></th>
<th><em>MS-2</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotton</td>
<td>&lt;6.8 ± 7.0</td>
<td>&lt;1.0 ± 0.6</td>
<td>&lt;0.6 ± 0.1</td>
<td>0.03 ± 0.02</td>
</tr>
<tr>
<td>Polyester</td>
<td>&lt;0.37 ± 0.28</td>
<td>&lt;0.37 ± 0.48</td>
<td>&lt;0.6 ± 0.6</td>
<td>0.3 ± 0.2</td>
</tr>
<tr>
<td>Paper currency</td>
<td>&lt;0.05 ± 0.04</td>
<td>0.2 ± 0.1</td>
<td>&lt;0.1 ± 0.1</td>
<td>0.4 ± 0.4</td>
</tr>
</tbody>
</table>

Modeling can be used to estimate the # of pathogens that will actually make it to the finger/hand per touch

Pathogens/touch = $C_a \times$ transfer efficiency $\times$ fingertip/FFR ratio

• Using typical values found in the literature the model estimates that only a few viruses should get transferred to a finger ($<1 - 8$ viruses/touch)

$C_a = \text{pathogens on the mask}$
# Contact with the contaminated surface of FFRs

<table>
<thead>
<tr>
<th>Event</th>
<th>Single Use</th>
<th>Extended Use</th>
<th>Reuse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper doffing technique **#</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Random touching **#</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Adjusting **#</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Redonning #</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>User seal check</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

(*) Can be mitigated with proper training and education
(###) Contact with entire surface of the FFR is not anticipated
Regulatory and Policy Consideration

- **NIOSH**: Service life of filters on NIOSH-approved respirators is limited by considerations of hygiene, damage, and breathing resistance; the filter should be replaced if it becomes damaged, soiled, or causes noticeably increased breathing resistance.

- **OSHA**: For TB, FFRs can be reused by the same healthcare worker as long as the functional and structural integrity of the FFR is maintained.

- **FDA**: Some surgical N95 FFRs are not intended to be used more than once.
## Qualitative Assessment of Increased Risks of FFR Extended Use and Limited Reuse Compared with Single Use

<table>
<thead>
<tr>
<th>Issue</th>
<th>FFR Extended Use</th>
<th>Limited FFR Reuse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-Inoculation</strong></td>
<td>• Minimal risk for typical patient encounters, but can be mitigated by limiting touches</td>
<td>• Moderate risk for typical patient encounters, but can be mitigated by limiting unnecessary touches</td>
</tr>
<tr>
<td></td>
<td>• Risks can increase from AGP and can be reduced by limiting contamination</td>
<td>• Risks can increase from AGP and can be reduced by limiting contamination</td>
</tr>
<tr>
<td><strong>Protection</strong></td>
<td>• Negligible increased risk</td>
<td>• Minimal risk, but can be mitigated through limited # of reuses</td>
</tr>
<tr>
<td><strong>Human Factors</strong></td>
<td>• Increased discomfort, but no additional health risk to a medically cleared FFR user</td>
<td>• No additional health risk to a medically cleared FFR user</td>
</tr>
<tr>
<td><strong>Secondary Exposures</strong></td>
<td>• Negligible for typical patient encounters</td>
<td>• Negligible for typical patient encounters</td>
</tr>
<tr>
<td></td>
<td>• Risks can increase from AGP and can be reduced by limiting contamination</td>
<td>• Risks can increase from AGP and can be reduced by limiting contamination</td>
</tr>
</tbody>
</table>
Key Findings of NIOSH Working Group

- Policy makers need to weigh increased risks for disease transmission from FFR extended use and limited reuse vs. the alternatives

- Research largely supports past CDC recommendations on FFR Extended Use and Limited Reuse
  - Additional cautions and limitations should be used
  - Extended use is preferred over limited reuse
  - Decontamination for purposes of reuse should not be recommended at this time
Updated Recommendations Published March 2014

http://www.cdc.gov/niosh/topics/hcwcontrols/RecommendedGuidanceExtUse.html
Who Makes the Decision to Implement?

- Decisions to permit FFR extended use and/or limited reuse should be made at the local level by professionals who manage the institution's respiratory protection program in consultation with state/local public health departments, infection control, and relevant federal agencies (CDC, OSHA), etc.

- Planning is critical
Implementation During Emergency Situations

- **Case by case decision:**
  - Consult current CDC for that pathogen for general infection control guidance
  - Consider respiratory pathogen characteristics (e.g., routes of transmission, prevalence of disease in the region, infection attack rate, and severity of illness)
  - Consider local conditions (e.g., number of disposable N95 respirators available, current respirator usage rate, success of other respirator conservation strategies, etc.)

- **Some healthcare facilities may wish to implement extended use and/or limited reuse before respirator shortages are observed, so that adequate supplies are available during times of peak demand**
Implementation in Non-Emergency Situations

- Current CDC recommendations for that pathogen should be consulted
  - TB: limited FFR reuse permitted
  - Other pathogens: extended use or limited FFR reuse not recommended at this time
General Recommendations When Implementing FFR Extended Use and Limited Reuse

- Healthcare facilities should develop clearly written procedures to advise staff to:
  - Follow the FFR manufacturer’s user instructions
  - **Discard the FFR:** (1) if contaminated with blood, respiratory or nasal secretions, or other body fluids from patients, (2) if damaged or hard to breathe through, (3) following aerosol generating procedures, (4) exiting the care area of a patient co-infected with an infectious disease requiring contact precautions
  - Perform hand hygiene before and after touching or adjusting the FFR (if necessary for comfort, to maintain fit, or redon)
  - Limit FFR surface contamination, whenever feasible
Additional Recommendations for Limited FFR Reuse

• Healthcare facilities should develop clearly written procedures to advise staff to:
  – Follow the FFR manufacturer’s maximum number of donnings (or up to 5 if none is provided) and recommended inspection procedures
  – Hang used FFRs in a designated storage area or keep them in a clean, breathable container between uses
  – Pack or store used FFRs between uses so they do not become damaged or deformed or touch each other
  – Avoid sharing used FFRs
  – Label containers used for storing FFRs or label the FFR directly (e.g., on the straps) with the user’s name
Creative strategies are needed to educate healthcare workers......tools, templates, online resources

California Respirator Program Administrators go to- http://www.cdph.ca.gov/programs/ohb/Pages/RespToolkit.aspx
Summary
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References/Sources

- Example lists of aerosol transmitted diseases
  - https://www.dir.ca.gov/title8/5199a.html
  - http://www.cdc.gov/niosh/topics/ryanwhite/

- References:
References (continued)


References (continued)


- California Respirator Program Administrators Toolkit: [http://www.cdph.ca.gov/programs/ohb/Pages/RespToolkit.aspx](http://www.cdph.ca.gov/programs/ohb/Pages/RespToolkit.aspx)
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