Emerging Practice Summary: Reprocessing of N95 masks during severe shortages

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The CDC has recommended strategies for hospitals to optimize their supply of N95 masks stratified by the severity of their shortage. Contingency and crisis capacity strategies include options for extended use and limited reuse as well as use of other types of respirators, expired respirators and other controls.

The CDC has also provided guidance on the decontamination and reuse of respirators as a crisis strategy for hospital's experiencing severe shortages. Mask rotation using a minimum of 5 days under proper storage conditions is recommended as a passive decontamination strategy. Other promising methods noted by the CDC included ultraviolet germicidal irradiation (UVGI), hydrogen peroxide vapor (HPV) and moist heat. It is suggested that hospitals may want to primarily focus current efforts on these technologies because they have the most experience to-date. Many other decontamination technologies, however, have also been proposed and trialed.

Vizient has collected polling data from hospitals regarding N95 mask strategies. As of April 15, 78 hospitals reported reprocessing of N95 respirators. Forty-two respondents (54%) indicated they were using UVGI technology, 19% were using HPV, 8% were using heat, 6% were using ethylene oxide and 13% reported other unspecified methods. Reprocessing is being performed both in-house and through third-party reprocessors.

Ideally, the selection of disinfection technology should be provided by the respirator manufacturer after validation on their specific products, but third-party guidance may also be used in the absence of manufacturer recommendations according to CDC. At least one manufacturer of respirators has begun testing and approving various disinfection methods.

Important considerations for mask decontamination technologies include:

- efficacy of viral load deactivation
- maintenance of filtration efficiency
- no compromise of fit or weakening of any mask component

At this time, there are limitations in the evidence for each method. Most have not been tested directly against the SARS-CoV-2 virus; thus, they often extrapolate conclusions from use against different pathogens. Studies have also been conducted on only a limited number of mask types and using limited sample numbers. Since there are many versions of N95 masks, with different materials, layers, thicknesses and shapes, one method may work well for one mask type and not for another. Filtration efficiency will be affected by material degradation, but is also a function of induced changes in the electrostatic charge of the polypropylene strands. The number of decontamination cycles will also undoubtedly affect efficacy outcomes.

Further description of the pros and cons of the various mask decontamination technologies can be found at the N95decon consortium website and in the CDC guidance. A bibliography is included at

the end of this document listing much of the primary evidence from published clinical studies derived from a search of the PubMed database. MedRxiv is another resource for some of the most recent, albeit non peer-reviewed, clinical evidence.

Findings from the reviewed evidence suggest UVGI has been studied on masks against various pathogens for more than 10 years and there is a fair amount of evidence in the clinical literature for its safety, efficacy and acceptance under controlled conditions. University of Nebraska Medical Center has published extensively on their technique using UVGI. Applied Research Associates has also published an FDA-sponsored study of UVGI for use on masks during public health emergencies that was conducted prior to the current pandemic.

Similarly, HPV had also undergone previous study by the Battelle Institute for use on respirators during public health emergencies. Duke University has also published their guidance on HPV disinfection of N95 respirators. The published research suggests HPV can be safely used specifically on N95 respirators with good viral deactivation and little compromise of materials over many cycles. In addition, the FDA has reviewed and granted emergency use authorization (EUA) for 4 different HPV-based technologies.

The number of cycles that a mask can be reprocessed is not well-established and will be highly dependent on the specific decontamination technology, operating parameters, mask model and findings from the quality assurance process conducted after every cycle. In general, for some specific regimens of UVGI and HPV there is data in the literature that support reprocessing up to 20 times without compromising filtration efficiency, straps or fit. FDA EUA labeling for select HPV technologies suggests a maximum between 2 and 20 cycles and anecdotal reports from some hospitals suggest they do not expect to reprocess masks more than about 5 to 7 times.

Conclusions

Reprocessing is a crisis strategy reserved for severe shortages when preferable alternatives are not available.

A number of hospitals have reported reprocessing strategies for masks due to crisis conditions.

The optimal reprocessing strategy has not been established due to limitations in the evidence.

There are a variety of options available that hospitals should consider based on their unique situations.

The selected decontamination method should effectively reduce the pathogen burden, maintain function and not affect the fit of the respirator.

Organizations should validate their process and outcomes to ensure safety.

Close inspection should be made after each decontamination cycle and affected masks should be discarded.

The number of reprocessing cycles should be minimized.

Due to fast-moving developments during this pandemic, efforts should be made to review any new evidence and recommendations regarding reprocessing when they become available.

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