Position Statement in the Age of COVID-19
Real Time Information to Support Policy Decisions
Published 06/16/20

Benefits, Costs, and Risks of Vaporized Hydrogen Peroxide for Disinfecting N95 Respirators: Beware of the Hype

Alfredo Penzo-Mendez PhD – Senior Research Analyst, Health Technology Assessment
Chris Lavanchy, BSME – Engineering Director, Device Evaluations

Vaporized hydrogen peroxide: a “rising star” amid the COVID-19 pandemic

With the persistent short supply of N95 masks during the COVID-19 pandemic, many hospitals are decontaminating and reusing single-use N95 respirators to alleviate shortages. An ideal decontamination process should reduce viral loads to safe levels without damaging the mask materials, fit, or their filtering effectiveness. Also, decontamination procedures should be fast and cost-effective enough to be feasible at a hospital scale. Though several decontamination methods have been quickly developed for N95s, none have been ideal. Heat, chemical disinfectants, and ultraviolet radiation can damage single-use N95 masks. Chemicals may also leave toxic residue behind. Gamma irradiation, while effective at disinfecting, is typically too costly to be practical, and repeated gamma sterilization can degrade elastomeric materials, such as mask straps, causing them to crack or fall prematurely.

Vaporized hydrogen peroxide (VHP) has garnered much attention because it offers potentially unique advantages for N95 decontamination compared with other methods. As of June 6, FDA has granted Emergency Use Authorization (EUA) to seven VHP systems for N95 decontamination, and interest from hospitals is growing rapidly. However, these EUAs are based on limited bench validation research that may not translate to real-world use or be sufficient for comparing the effectiveness of VHP and other disinfection methods.

ECRI urges caution and careful consideration of all available options to identify the N95 decontamination process that best meets a hospital’s operative needs and budget.

VHP: attractive option, but a complex process with toxicity risks

In principle, hydrogen peroxide is well-suited for decontaminating N95s because it has potent germicidal activity and low reactivity with synthetic polymers. Hydrogen peroxide is effective against all microorganisms given sufficient contact and time, and degrades over time, leaving no toxic residue. However, to be useful on porous materials such as those in the N95 masks, hydrogen peroxide must be maintained as a vapor at close to room temperature, which is technically challenging. The two VHP processes available for decontaminating rooms and reusable devices were developed by AMSCO (now Steris) in the 1980s. Both use vacuum to enhance VHP penetration and cyclic gas purging and injection to ensure a minimum exposure at the effective VHP concentration.

Despite technology advances, VHP manipulation is not without safety risks. Hydrogen peroxide degradation releases pure...
Disinfection capability, mask integrity over multiple decontamination cycles, turnaround time, and cost are all factors that hospitals need to consider.

oxygen, which is a fire and explosion hazard. VHP can cause lung and airway irritation at concentrations as low as 75 ppm and serious injury at higher concentrations. Thus, accidental worker exposure is a significant risk. Residual hydrogen peroxide on hard surfaces poses little risk, but residue in porous N95 filters may pose a risk to healthcare workers using them.

Vendors of VHP systems that FDA has granted EUA have looked at the residual hydrogen peroxide and concluded that the levels remaining on masks after decontamination are safe. Thus, residue should be a concern only if the user introduces shortcuts in the process. Some users may also be decontaminating N95 models that the VHP vendor has not tested before obtaining the EUA, and differences in mask composition could potentially result in higher levels of residue. For example, on June 7, 2020, FDA issued a change to standing N95 disinfection EUAs to exclude non-NIOSH respirators manufactured in China because initial NIOSH testing may not have covered the full range of designs and materials seen in these devices.

Preliminary evidence: safe and effective, but other methods may work as well and may cost less

A recent ECRI Clinical Evidence Assessment, Safety of Extended Use and Reuse of N95 Respirators, identified no clinical studies on N95 decontamination. However, we reviewed a large literature base of bench studies on N95 decontamination. In the absence of clinical data, these studies provide at least a rationale for considering potential N95 decontamination processes.

Twenty-two single-arm and comparative laboratory studies (synthesized in 3 systematic reviews) reported on N95 decontamination using various bacterial and viral pathogens: 13 reported on ultraviolet-C (UV-C) irradiation, 11 on heat-based methods (autoclaving, steaming, dry ovens), 9 on bleach, 8 on VHP, 5 on ethylene oxide, and 3 on 70% alcohol. Three recent studies also compared VHP, UV irradiation, alcohol, and peracetic acid fogging using N95s and active SARS-CoV-2-2019 particles. The studies reported effective pathogen inactivation with all methods and minimal effects on N95 performance with VHP, although this varied by mask model and number of decontamination cycles. Nonetheless, this evidence should be considered with caution because bench studies reflect ideal operating conditions that are seldom realized in a real clinic. While the studies covered many common N95 models, the findings also need validation on other models on a case-by-case basis.

More importantly, bench studies are not sufficient to compare VHP and other disinfection methods. Bench studies cannot demonstrate superiority beyond sterilization, which was achieved not only with VHP, but also with other chemicals, heat, and UV-C irradiation. VHP caused less damage to N95s than autoclaving, chemical disinfectants, and UV-C, but whether the difference matters in real-world use depends on the specific N95 models and number of decontamination cycles they are subjected to.

For example, Battelle (the first company to receive an EUA for VHP of N95s) reported that its process had minimal effect on N95 performance after 20 decontamination cycles. However, our evidence review of bench studies found that >20% of N95s become unusable without decontamination cycles of any kind because of mechanical wear and tear after doffing and donning just five times.

Furthermore, no published data are available to assess potential costs of different N95 decontamination methods.

The need for specialized equipment makes the VHP per-run cost likely higher than that of most heat-based methods, although many hospitals have in-house VHP sterilizers to preprocess temperature-sensitive medical instruments, which could mitigate costs.

With external vendors, the cost may come down as processes are optimized for N95s. The Wall Street Journal reported in a June 1, 2020, article that Battelle estimates its process currently costs about $110 per mask—an expense currently incurred by the Federal government, which funds N95 reprocessing at this time. Battelle stated that it expects the cost to come down to about $7 per mask “within a few months.”

VHP also offers rapid turnaround compared with other low-temperature methods. The size and number of equipment loads at each facility also factor in the relative financial impact of different N95 disinfection methods.

Hospitals: assess needs and options, and beware the emphasis on VHP

VHP decontamination is an important development that addresses particular sterilization and disinfection needs, especially for room and reusable supplies for which other methods are unfeasible or difficult. VHP has features of an “ideal” N95 decontamination process, and preliminary evidence is somewhat favorable. However, even an ideal method may not always be the most appropriate to address a particular
facility’s needs and constraints, and the available evidence is too preliminary to inform which decontamination method is best. What is best in a given facility may be driven in large part by what is readily available. Disinfection capability, mask integrity over multiple decontamination cycles, turnaround time, and cost are all factors that hospitals need to consider.

Media focus on VHP is useful to raise awareness on this N95 decontamination adoption but may obscure other viable alternatives. Thus, hospitals may want to take a step back when considering VHP. Careful value analysis and tools such as ECRI’s PriceGuide may help hospitals minimize both the clinical and financial impact of N95 shortages by choosing the most appropriate decontamination processes.

**Policy Statement**

The information contained in this Position Paper is highly perishable and reflects ECRI's position at the time this document was prepared. This Position Paper is not intended to provide specific guidance for the care of individual patients. ECRI makes no express or implied warranties regarding the products discussed herein, including any implied warranty of merchantability or fitness for a particular use.

ECRI assumes no liability or responsibility for how members use the information, comments, or opinions contained in Position Papers. All material in this Position Paper is protected by copyright, and all rights are reserved under international and Pan-American copyright conventions. Subscribers may not copy, resell, share, or reproduce information (except to print or email single report copies for authorized use within the member institution), or transfer it to third parties without prior written permission from ECRI.

**About ECRI**

ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on patient safety, evidence-based medicine, and health technology decision solutions, ECRI is the trusted expert for healthcare leaders and agencies worldwide. The Institute for Safe Medication Practices (ISMP) is an ECRI affiliate. Visit ecri.org and follow @ECRI_Org.