CDC Props Up Unproven "Cleaning" Methods for N95 Respirators

CDC GOES TO THE "LAUNDROMAT"

On April 1, 2020 the CDC posted guidance that endorses the unproven, and potentially dangerous, practice of what they call "decontaminating" disposable N95 respirators.

An array of business interests has backed the concept of cleaning N95 respirators for some time. Because federal and state officials have refused to order PPE manufacturers to hand over existing stockpiles and start producing large numbers of N95s, the idea of cleaning disposable respirators has been gaining traction.

There is **no credible evidence that it is possible to disinfect disposable N95 equipment and retain the protective effectiveness of the respirator.** In fact, one of the largest producers of filtering face piece respirators (FFP), 3M, has stated:

> **"As of March 27, 2020 no disinfection method has met all four of these key criteria, and without all four, the method is not accceptable."**
>
> **— Statement from 3M Corporation**

According to 3M, in order to effectively decontaminate and reuse a disposable respirator four criteria would have to be met.

3M's criteria for any decontamination process includes the following:

- Be effective against the target organism, such as the virus that causes COVID-19;
- Not damage the respirator's filtration;
- Not affect the respirator's fit; and
- Be safe for the person wearing the respirator (e.g. no off-gassing of chemicals into the breathing zone).

BIASED "SCIENCE"

Unfortunately, the CDC has shown how deeply it's willing to cave in to business interests during this crisis, citing flawed and biased "studies" to prop up the idea of decontamination.

Their main piece of evidence is a 2016 study from Battelle, a multi-billion-dollar research institute based in Columbus, Ohio. Battelle's study heavily touts disinfection equipment manufactured by Bioquell Corporation, but it turns out that Battelle is also getting into the "decontamination" business.

Bioquell and other manufacturers of hydrogen peroxide vapor machines are angling to make a fortune from "decontaminating" single-use N95 respirators.

On March 29th the company announced that it had been authorized by the FDA to market its "Critical Care Decontamination

System™" to hospitals and other healthcare facilities.

Unfortunately, the CDC fails to mention the many shortcomings of Battelle's 2016 analysis of hydrogen peroxide vapor decontamination methods. For example, it did not focus on coronavirus, or other pathogens likely found in the healthcare setting, and it did not verify that the cleaning agent they used was cleared from the entire respirator mask.

In fact, **Battelle's own fact sheet for healthcare workers lists the following potential risks** from their newly launched Critical Care Decontamination System™, including:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Another recent report cited by the CDC comes from Duke University. But the researchers provide no actual evidence that the cleaning process eliminated of the SARS CoV-2 virus. Instead, they cited Battelle's 2016 study as proof that decontamination is safe.

Upon closer examination, it turns out the Duke study did not meet the four standards laid out by respirator manufacturer 3M, either, and **the fit testing component involved all of two subjects**!

And on April 9th, the FDA stated that they have approved use of equipment from another corporation – the STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems.

Once again, the science is inconclusive at best. A recent French study reported that "Only the 92°C-15min protocol was able to inactivate totally the virus (>6 Log10 decrease)". In order to reduce damage to the N95 material, the Steris process uses lower heat that may not completely deactivate the virus.

> **"No current data exists supporting the effectiveness of these decontamination methods specifically against SARS-CoV-2 on an FFR [filtering face piece respirator]. Other pathogens may also be present on FFRs and there is only limited data available for other pathogens. Further work is needed to assure SARS-CoV-2 and other pathogens are inactivated. Therefore, even after decontamination, these FFRs should be handled carefully."**
>
> ***Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies***
> **Centers for Disease Control, April 1, 2020**

In the end, the CDC tries to have it both ways—promoting unreliable studies, tainted by self-interest, and then covering themselves by admitting there's no evidence that disposible respirators can be safely cleaned.

So where does that leave healthcare workers?

The CDC admits the data don't exist. NIOSH doesn't endorse any N95 cleaning method. 3M says no effective method exists. **Then why the push for bogus cleaning of N95s?**

REAL SOLUTION=GET US PPE!

The challenges in the N95 supply chain could be solved. **NYSNA is calling on President Trump to unleash the Defense Production Act** and ordering corporations to make them. They are extremely straight forward technology and can be cranked out by the millions.

In New York, Governor Cuomo has signed an executive order authorizing the state to commandeer respirators and other protective equipment. **Now he needs to actually use this authority to get additional PPE to the frontlines!**

And hospitals need to immediately deploy real reusable equipment like elastomeric half-face respirators and Powered Air Purifying Respirators (PAPRs).