Sterilization of N95 respirators: The time for action is upon us!

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ABSTRACT

Re-processing of primary protective equipment is the need of the hour with healthcare systems all over the world strained due to the shortage precipitated by severe acute respiratory syndrome coronavirus 2. The common methods of re-sterilization do not hold well for filtering facepiece respirators (FFRs) as they affect their structure and function. We propose the validation and eventual use of gamma irradiation, an already existing method of re-sterilization, to disinfect FFRs in bulk.

KEY WORDS: Coronavirus, coronavirus disease-19, decontamination, filtering facepiece respirator, gamma irradiation, N95, pandemic, personal protective equipment, re-sterilization, reuse

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INTRODUCTION

Devices for protection of the respiratory tract are one of the key factors that can mitigate the impact of pandemics due to airborne pathogens. In the context of the ongoing pandemic due to the novel severe acute respiratory syndrome coronavirus 2 (SARS-COV2), these respiratory protection devices have been advocated by all global health authorities to reduce transmission of the infection. This not only effects patients and respiratory physicians but also has an impact on physicians from other specialties which cater to patients with comorbidities such as chronic liver or kidney disease, who have a higher mortality rate as compared to their healthy peers. The N95 filtering facepiece respirators (FFRs) have been recommended to good effect in the past during outbreaks related to influenza, SARS, and other emerging pathogens, where aerosol transmission is considered possible.[1] N95 FFRs are capable of capturing ≥95% of 0.3 μm airborne particles and are generally disposed after a single use. Past experience with the H5N1 epidemic of 2005 and the H1N1 pandemic of 2009 has resulted in healthcare systems' stockpiling protective equipment including respirators. No single stockpile can ever meet the acute massive demand for such devices by a global pandemic like the one that we are currently battling. In addition, supply chain disruptions, trade embargo, and limited movement of goods during lockdowns can seriously impact a nations' ability to re-stock rapidly dwindling supplies. It is imperative to note that the demand of medical supplies during a pandemic needs to be addressed not just by quantity but also by quantity

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as a function of time. Experience in the ongoing COVID pandemic in countries such as Italy, the United States of America, and Spain is a testament to the fact that acute shortages of personal protective equipment (PPE) have resulted in a high incidence of infections among healthcare workers (HCWs).

DISCUSSION

An important approach to mitigate a shortage of equipment is to adopt FFR re-sterilization and reuse strategies. Re-sterilization of FFRs needs to be accomplished without significantly affecting the reliability of protection against infection. Various strategies have been proposed with the Centers for Disease Control and Prevention recommending mainly two types of conservation strategies namely: extended use and limited reuse. Extended use refers to the use of the same N95 FFR for multiple patients without doffing by the same HCW. Limited reuse refers doffing the respirator after each encounter with restrictions in place to limit the number of times the same FFR is reused.[2] One of the major concerns in the adoption of FFR extended use or limited reuse policy is the potential for self-infection following contamination of the respirators. Past experiences of self-infection by contaminated respirators, during the Ebola outbreak, have made public health officials wary of implementing such strategies.[3,4]

Implementation of a reuse policy requires strict validation with regard to cleaning, sterilization, and functional performance. Cleaning refers to processes that eliminate soiling organic material that can potentially interfere in the re-sterilization of the respirator. Cleaning of respirators is difficult because it is an exposed filter and generally not compatible with standard laundering techniques. However, it can be argued that in the context of a public health emergency, reliable and safe elimination of any viable pathogens from the respirator through validated re-sterilization strategies may offset the need to rid other organic material.[5]

Multiple studies have documented effective re-sterilization of respirators using microwave-generated steam (MGS), moist heat incubation (MHI), and ultraviolet germicidal irradiation (UVGI). All methods have shown a reduction of >4 log reduction of H1N1 influenza on contaminated respirators.[5,6] Combination strategies using a solution of sodium hypochlorite with either MGS or UVGI have also shown effective re-sterilization with multi-log reduction in MS2 virus from respirators. There are currently no guidelines for effective re-sterilization which can also be suited to meet the singular requirements of a pandemic.[7,8]

The details of each re-sterilization technique are beyond the scope of this current communication; however, it might be worthwhile discussing possible strategies that can be pursued in the context of the COVID pandemic. The ideal method of re-sterilization for our immediate requirements needs to have the following characteristics:

- Effective against the target organism (SARS-COV2)
- No damage to the respirator's filtration
- No effect on the physical characteristics of the respirators that eventually governs the fit
- Safe for the person wearing the respirator (e.g., no release of chemicals into the breathing zone).

In addition, quick turnaround with low contact time, re-sterilization by bulk, and safety of the operators are also crucial to ensure that the supply chain is maintained and the requirements are met at the right time.

Unfortunately, currently, none of the strategies mentioned earlier have met these requirements. The MHI method requires a long contact time (30 min) and the use of an oven set to 160°F. The MGS method had a short contact time (2 min), but there may be concerns over wattage variability among microwave ovens. UVGI method can provide effective re-sterilization of the surface, but possible deep contamination of the respirator remains a serious concern before recommending this technique for reuse strategies. Hydrogen peroxide (HP) sterilization has shown some promise in clearing viral load on N-95 respirators. In a study by Kenney *et al.*, the masks had complete viral clearance and were "as good as new" after five cycles of treatment with HP.[9] However, the possibility of breathing in HP from the re-processed masks have to be further evaluated. To that end, there is an option that has not been explored and can potentially address most of the concerns raised by the current methods.

Proposal

Ionizing radiation with gamma irradiation has been extensively used in the medical devices, food, and pharmaceutical industry as a safe, effective, and quick mode of disinfection for the past 40 years.[10,11] The potential advantages of this method are summarized as:
The advantages of gamma radiation are:[10,11]

- Ease of application to any material with minimal damage
- Short contact times
- Maintenance of performance over a wide range of temperatures and physical conditions
- High penetration with homogenous effect, potentially providing uniform and reliable disinfection.

Preliminary work to assess the decontamination capacity of gamma irradiation for parasites and virus has been documented.[12,13] Gamma irradiation has been investigated as a specific inactivation technique for BSL-4 pathogens such as negative-sense RNA viruses.[13] The effect on viruses is both direct and indirect. Direct effect is by radiolytic cleavage or crosslinking of genetic material and proteins forming the viral envelopes. Indirect effects are by the effects of free radicals and ozone on the viral nucleic acids and proteins. Single-stranded viruses are more susceptible than double-stranded viruses.[10,12,13]

SARS-COV-2 is an enveloped, positive single-stranded RNA virus with a nucleocapsid. The virus is fragile with susceptibility to commercially available disinfectants,[14,15] thereby indicative of susceptibility to gamma irradiation. Moreover, the high penetration of gamma rays allows for bulk disinfection with good penetration into all the layers. However, there are some obvious limitations to the use of ionizing radiation for mass sterilization of respirators. A major drawback is that for practical reasons, gamma irradiators cannot be located within hospitals. This necessitates transport of infective materials such as respirators to the nearest facility, which inherently carries a safety hazard despite strict standard operating procedures. Safety concerns of personnel also impose the need for approval from the local biosafety panel and appropriate regulatory authorities.

CONCLUSIONS

The data on re-sterilization strategies are scarce and do not address major concerns that allow for mass application. However, throughout history, nothing has invoked the beast of survival in human beings more than the desperation. Let this be the stimulus that can inspire us to explore new avenues such as gamma irradiation that can provide reliable decontamination of respirators, thereby bridging the gap of shortage of protective equipment for our HCWs who are fighting the battle on the frontlines. It needs to be stressed, in no uncertain terms, that re-sterilization techniques, such as gamma irradiation in this context need validation which if performed on a war footing, may just be of vital importance in these times.

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Conflicts of interest
There are no conflicts of interest.

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