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Brief Report

Reprocessing N95s with hydrogen peroxide vaporization: A robust system from collection to dispensing

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The SARS-CoV2 pandemic has created extreme shortages of N95 mask necessitating the need for rapid development of reuse and reprocessing plans. Our aim was to create a process to recapture, reprocess, and redistribute N95 masks using hydrogen peroxide vapor as a real time disinfection method within a large hospital system. We were able to recapture and reprocess 29, 706 N95 masks using hydrogen peroxide vapor with approximately 25% loss due to damage.

BACKGROUND

The US is estimated to need 3.9 billion N95 masks to care for patients with COVID-19. As of March 3, the number of N95 masks in the United States stockpile was 35 million, accounting for less than 1% of estimated need.[1] Hospitals are also limited in the number of N95 masks that can be purchased resulting in an unstable supply. In a response to the N95 shortage, the CDC released guidelines on limiting use, extended use, and alternatives to N95 masks.[2] These measures do not address decontamination of N95 masks which could harbor SARS-CoV-2 after use. Hydrogen peroxide vapor (HPV) is an automated decontamination technology that has been proven by multiple studies to be highly effective at reducing pathogens within the hospital environment.[3-5] This technology was first deployed in several Singapore hospitals during the 2002 outbreak of SARS. In 2016, Duke University tested this technology on N95 masks with results showing HPV could decontaminate the mask without damaging the integrity or performance.[6]

In anticipation of high demand for N95 masks within our health care system, we embarked on a plan to use HPV to sustain our N95 supply.

METHODS

We first validated our HPV process with a small pilot program using post cycle visual inspection and quantitative fit testing using Portacount TM Pro+ (TSI Instruments) after each cycle for 15 HPV cycles. The Portacount machine was calibrated daily using the calibration cycle and fit testing was administered by employees in environmental health who are trained to perform this process. A total of 24 masks, representing 7 different N95 models, underwent the validation process using both employee heath personnel and health care workers for fit testing. A fit factor of greater than 100 was considered acceptable for both control and reprocessed masks. Of the reprocessed masks, 2 masks failed fit testing. One failing mask was a 3M 1860s, representing 1 of 8 3M 1860s tested, and one was a Moldex 1510 XS, the only model tested in this category. Of the 22 masks that passed fit testing, the fit factor did not differ from the control masks. Masks were worn in between reprocessing and fit validation cycles.

Mask decontamination was validated using Apex Geobacillus *stearothermophilus* biological indicator discs placed in the room during a HPV cycle and then transferred to growth media under aseptic conditions and incubated at 55°C for 48 hours. No growth was seen on the plates containing the discs that underwent an HPV cycle.

Next, we proceeded with designing the recapture, reprocessing, and redistribution phase. The recapturing phase encompasses collection of N95 masks after use for return to the reprocessing location,

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the reprocessing phase encompasses the Bioquell decontamination, and the return phase is the process of returning masks to central supply or the original uses. These 3 phases constitute one cycle of N95 salvaging.

Recapture phase

Information was sent out to all staff on the reprocessing program including the medical evidence supporting HPV decontamination of N95 masks. Instructions on the recapture process were included with pictures of the plastic bins designated for N95 collection. Collection bins were placed at convenient locations on each unit within the hospital and made easily identifiable by color and signage. Daily number of masks distributed versus recaptured from all areas of the hospital were tracked to determine the recapture rate.

Reprocess phase

The reprocessing phase represents one of the components of a N95 salvage cycle and includes loading the used N95s in the Bioquell room, completing the Bioquell run, environmental cleaning of "hot zone" where contaminated masks were stored, mask removal from the Bioquell room to the designated "clean zone" where masks are inspected, marked, and counted by type and location. A reprocessing station was set up within the hospital in an area repurposed for this project. The addition of ceiling barriers was added to the Bioquell room. The ventilation system was not changed. The reprocessing area was divided in zones identified as Hot, Warm, and Clean. Contaminated bins and masks are stored in the hot zone until ready for reprocessing. The warm zone encompasses the reprocessing room where the masks are decontaminated via 35% HPV emitted from BioQuell, a decontamination system produced and sold by Ecolab. Room set up includes metal storage racks to hang masks, aerators to increase air circulation, and three Bioquell systems. Duration of aeration is calculated for each cycle by the Bioquell machine using the room size and amount of masks present. Masks are hung by straps to a PVC rod that is then inserted into the storage rack. Each mask is positioned so that it remains suspended with all surfaces exposed. After closing the door to the reprocessing room, the Bioquell machines are activated via a wall switch. Off-gassing after a cycle is measured via hydrogen peroxide monitoring badges on personnel and on surfaces closest to the processing room. Results have all been below the level of detection.

The racks are then moved into a clean area for inspection. Each mask undergoes 2 independent visual inspections by reprocessing staff trained to identify damage including visible stains, stretched or broken straps, or other defects. Stretched straps are determined by visual inspection of the strap material and by subjective measurement of the strap tension as compared to a new mask. Masks are discarded if damaged or if the number of reprocessing cycles exceeds 15. After inspection, a small tally mark using a black marker is made at the bottom of the exterior portion of the mask to denote a reprocessing cycle has occurred. Tally marks are placed on the exterior to avoid transfer of ink to the user's skin and the bottom of the mask was chosen as it was less visually distracting. Tally marks are made after reprocessing to limit contact with contaminated masks. Clean gloves are used during the process to avoid contamination of the mask. Of note, penetration of HPV into the area of the mask containing the tally mark has not been studied. Masks that pass inspection are placed into a clean bin for reuse. A small number of masks are fit tested after each reprocessing cycle for quality assurance. Multiple models of N95 masks are reprocessed daily, with the most common models being made by 3M (1860, 1870, 9205, 8210, 8110), Moldex (22115, 22126G, 2217G), and San Huei (SH2950). The only masks excluded are those containing cellulose.

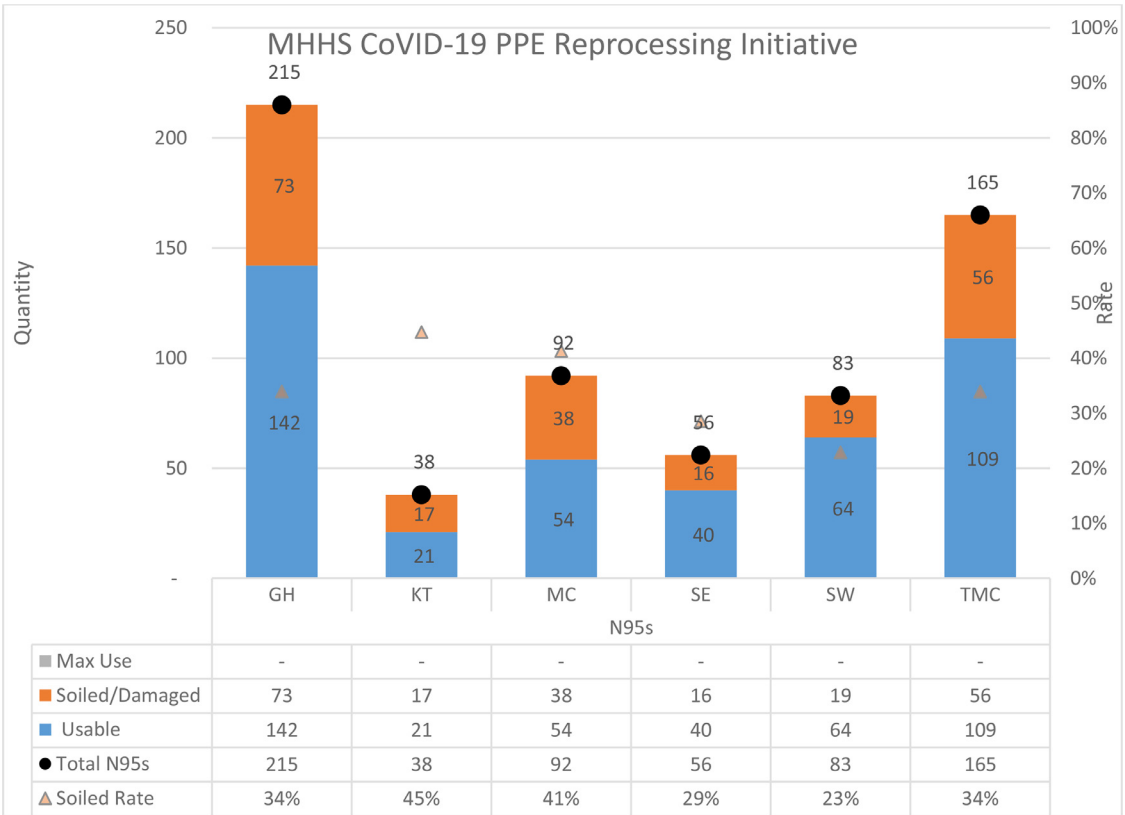

Fig 1. Example of daily recapture data.

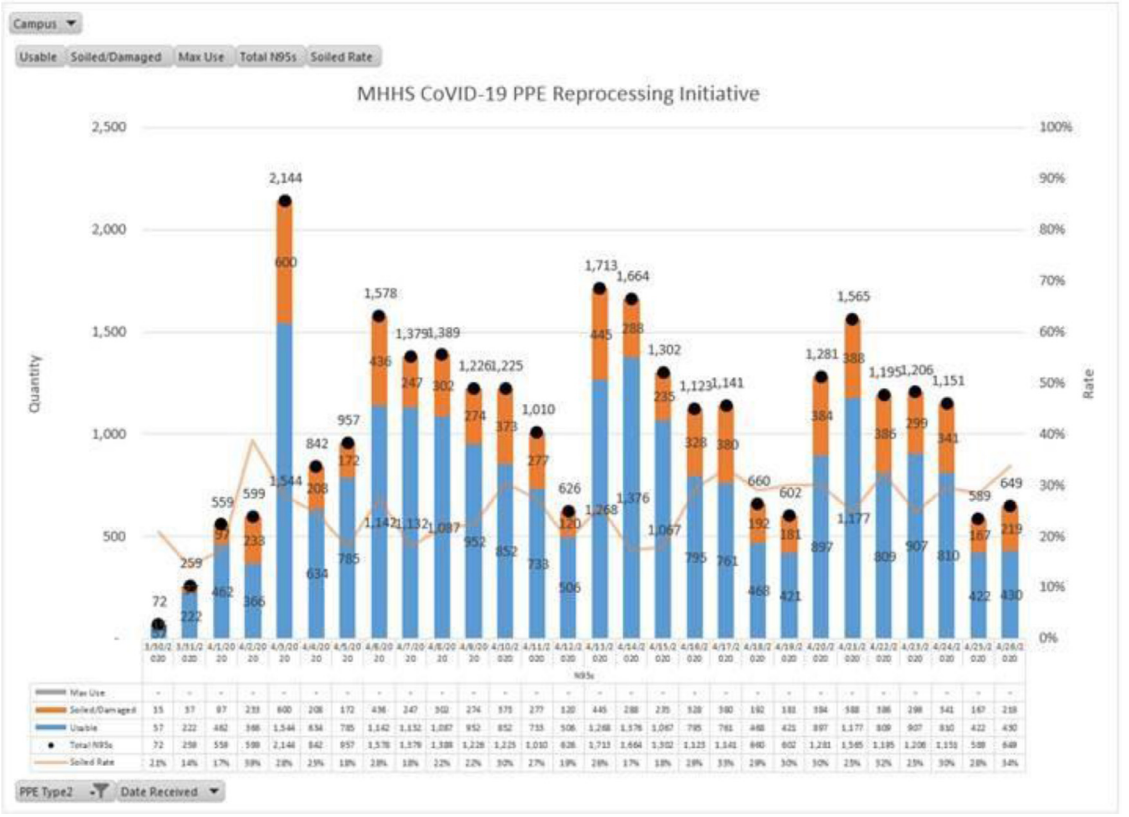

Fig 2. Reprocessing volumes. Data as of April 26, 2020.

Return phase

Clean masks are sorted by size for our institution or by location for hospitals within our system. The reprocessed masks then go back to the original user at some campus locations or to central supply for redistribution. For masks redistributed randomly, end users are instructed to visually inspect the mask prior to donning and complete a validation seal check after donning. Masks are obtained by individual units via order forms to help predict future N95 use per area.

RESULTS

Recapture outcomes

Overall recapture rate is approximately 86%. Most common reasons for not returning were inconvenient location of return bins. This has been addressed with smaller bins placed outside patients' rooms and throughout the units (Fig 1).

Reprocess outcomes

Across all the hospitals within the system, total count of reprocessing cycles as counted by discrete number of reprocessed masks, is 45,554. Approximately 25% (average over multiple cycles) are soiled or damaged after visual inspection. Soiled masks are primarily due to staining with make-up. The communication department developed a "Bare to Spare" campaign which encouraged no make-up use below the eyes. Make-up remover wipes are also now included in the bag containing the N95 (Fig 2).

Return outcomes

Across the hospital system, 34,125 masks have been returned for reuse. At our campus, 8,995 masks have been returned to central supply to be allocated for reuse.

Cost and savings

Reprocessing cost per mask is approximately $1.47. The cost decreases as volume of masks to be reprocessed increases and at capacity would be 0.57-0.61 cents per mask. Commercial companies are now offering a similar service and cost to send masks out for reprocessing averages $1.65-$3.25 per mask. Cost savings for in house processing versus send out calculated by the numbers of masks reprocessed to date is $8,200-81,000.

CONCLUSIONS

Our study is the first to use HPV technology on a large scale to reprocess N95s within a health care system. Previous studies have reported this method of reprocessing on a smaller scale with similar results.[7,8] Commercial companies are now offering HPV services for N95 masks. Hospitals must ship the masks to the company and then wait for mask return. Having the ability to reprocess masks within our facility allows us to return masks back in to circulation more rapidly. The success of the program hinged on collaboration across multiple hospital departments, and is an example of the collaboration needed to respond to an ever-changing environment. The SARS-CoV2 pandemic has created unprecedented challenges to the health care system which can only be overcome with unique and innovative solutions.

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