Catalyst Innovations in Care Delivery

CASE STUDY

Global Collaboration on a UV-C Cabinet to Decontaminate and Reuse N95 Respirators in Low- and Middle-Income Environments

Nichole Starr, MD, MPH, Natnael Gebeyehu, MD, Anderson S. L. Gomes, PhD, E. Rosas, PhD, Tyler N. Chen, MS, Dawit Assefa, PhD, Jared Shless, Jit Bhattacharya, PhD, Arnab Bhattacharya, PhD, David Robinowitz, MD, MHS, MS, Martin Purschke, PhD, Thomas Baer, PhD

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The Covid-19 pandemic has caused worldwide shortages in N95 respirators, surgical masks, and other respiratory personal protective equipment, particularly for hospitals in low-income settings. Treatment with ultraviolet-C (UV-C) light is an affordable technology for the decontamination and reuse of N95 respirators in times of critical shortage. Optical engineers, physicists, and clinicians collaborated to develop an affordable, enclosed cabinet to decontaminate N95 respirators with UV-C irradiation in hospital sterile processing areas; units were constructed and implemented locally at 21 hospitals in low- and middle-income countries. Along with this practical grassroots approach to deliver a simple and locally accessible technology, the team's experience in developing relevant clinical workflows resulted in a rapid and effective implementation of a decontamination process that provided hundreds of thousands of additional N95 respirators for health care provider protection.

KEY TAKEAWAYS

- » Personal protective equipment (PPE) shortages were, and continue to be, a challenge both in the United States and abroad during the Covid-19 pandemic.
- » Decontamination and reuse of N95 respirators with UV-C irradiation was one crisis-mitigation strategy for PPE shortages, but information regarding delivery and implementation of this technology was limited.

- » This global collaborative of engineers, physicists, and clinicians developed implementation guidance, produced training materials, and provided mentorship for the construction and use of UV-C cabinets to decontaminate respirators during the pandemic.
- » Working in multidisciplinary, interprofessional teams can leverage varied skill sets to enhance innovation and implementation in crisis situations.

The Challenge

In the initial weeks and months of the Covid-19 pandemic, personal protective equipment (PPE) shortages, particularly of N95 respirators, were profound and widespread throughout the globe.¹ Scenes of improvised PPE solutions, such as garbage bags and ski masks, and stories of scarce PPE, such as N95s being used for days to weeks at a time, were omnipresent in the media. Health care systems scrambled to devise strategies to obtain new PPE, as well as for the extended use, reuse, and decontamination of N95 respirators.^{2–4} Even worse, N95 masks were — and still are — being reused a few times without any decontamination process in some countries.

By early summer 2020, the worst of the PPE shortages in high-income countries such as the United States and those in Europe had eased, and surging prices of N95 and surgical masks ensured that the wealthiest nations had more access to contracts for newly manufactured N95s. Low- and middle-income countries, however, continued to experience chronic and severe shortages of respiratory PPE, which still persist.^{5,6} Generally accepted N95 decontamination and reuse strategies for Covid-19 include hydrogen peroxide vapor,⁷ humid heat,^{8,9} room temperature wait and reuse,¹⁰ and ultraviolet-C (UV-C) irradiation for up to five reuse cycles.¹¹⁻¹⁵ Some groups in the United States adopted whole-room decontamination of N95 respirators using preexisting UV-C towers or laboratory setups^{16,17}; however, these towers are expensive, on the order of \$80,000 per unit, and were not generally available in low-income environments.

The Goal

To ameliorate the severe global PPE shortages, our team aimed to use UV-C cabinets for the decontamination and reuse of N95 respirators in low-income settings. This process included: (1) design, testing, and validation of a robust, easy-to-fabricate UV cabinet for N95 decontamination; (2) identifying engineering teams to construct and test cabinets in their local environments; (3) partnering with interested health care facilities that had a need for N95 decontamination and developing clinical implementation guidance; and (4) supporting the staff training and implementation of new workflows in hospitals.

The Execution

The collaboration to implement UV-C decontamination units for N95 respirators began in April 2020, with the construction and validation of a prototype UV-C cabinet in the United States by

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the lead project engineers.^{18,19} This prototype was constructed using a metal office storage cabinet lined with household aluminum foil, with 16 UV-C bulbs (fluorescent tube lights, delivering 254-nm wavelength) arranged in equally spaced arrays at the front and back of the cabinet. A rack capable of suspending 28–36 N95 respirators is placed in the middle of the cabinet. When cabinet doors are closed and the bulbs switched on, the respirators are irradiated uniformly, meeting the required minimum decontamination dose of 1 J/cm² in less than 10 minutes.¹⁸

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The entire cabinet is constructed for approximately \$500-\$1,500 (depending on location) and can reprocess nearly 5,000 masks per day at maximum capacity, or about 1,500 masks per day in a standard 8-hour workday."

At these irradiation doses, microbiological testing showed a higher than 3-log reduction in the highly UV-C-resistant *Bacillus pumilus*, which is within the required values for decontamination purposes for severe acute respiratory syndrome coronavirus 2 and without damaging the mask.²⁰ The entire cabinet is constructed for approximately \$500-\$1,500 (depending on location) and can reprocess nearly 5,000 masks per day at maximum capacity, or about 1,500 masks per day in a standard 8-hour workday. A photodiode sensor that can measure UV-C dose is placed in the cabinet at a certain position and can be used to both validate the dose delivered by new cabinets and measure relative power over time, monitoring for bulb outages or other losses in power (see <u>Appendix</u> for details).

During construction and validation of the prototypes, initial communications were made with engineering and clinical teams in Brazil, Mexico, Kenya, India, Ethiopia, and other countries (Figure 1). These engineering groups expressed both interest and the ability to construct their own UV-C cabinets to aid in alleviating the PPE shortages in their own countries, and clinical teams verified the need for mask reprocessing and guaranteed that staff and physical space could be allocated for cabinet use. Information on the cabinet construction, materials needed, and a portal for communicating with engineering mentors was made publicly available on a website as well.

As with any new technology, end users must be familiar with, comfortable with, and well trained in the safe and effective use of the UV-C cabinets. Educational materials to support training and implementation were developed by the clinical portion of the team and were vetted through internal peer revision of all collaborative members (Figure 2).²¹

The recommended workflow of N95s through the decontamination process drew on existing workflows for surgical instrument reprocessing, in which a one-way flow from dirty to clean materials is emphasized, and management of contamination is essential. Infographic materials and videos were developed to educate clinical staff and hospital administrators on the mechanism

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Locations of Engineering and Clinical Teams in Ultraviolet-C Cabinet Collaborative

Each of the 18 stars represents a location of team members with engineering and/or clinical roles.



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of UV-C decontamination, the basics of the cabinet design, important principles of operation, and safety considerations, and on the recommended workflow for mask decontamination (Figure 3).

A worksheet for implementation was provided to help teams determine the best setup for their facility (Figure 4).

A process mapping template and guiding questions were also created to facilitate the hospitalbased planning and customization of the implementation process. These educational materials were created with human-centered design principles in mind; they were reviewed and iteratively improved with input from both engineering and clinical perspectives from six countries with variable resource environments. These materials and others were also developed into a short <u>online course</u> with multiple-choice questions that can check for understanding during staff training. Educational and course materials were translated into Spanish and Portuguese for use by our teams in Brazil and other countries in Central and South America. Additional details and factors that hospital teams should consider prior to implementation are provided in the <u>Appendix</u>.

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Ultraviolet-C Cabinet Educational Infographic

This infographic was developed to serve as an overview of the ultraviolet-C (UV-C) cabinet effort, emphasizing basic scientific and design principles and use and safety directions that would be most important to the end user. (For a larger version of this figure, please consult the Appendix.)



C. Diff = *Clostridioides difficile*, MRSA = methicillin-resistant *Staphylococcus aureus*, PPE = personal protective equipment, RNA = ribonucleic acid, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, VRE = vancomycin-resistant enterococci.

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For wider adoption of the UV-C cabinets, regulatory approval, rather than off-label and pilot testing use, will be required."

Multiple team meetings were arranged over the course of the 8-month implementation period, with engineers and clinicians sharing their experiences, challenges, and major learning points throughout the process from multiple locations across the globe. Most meetings were held over Zoom; however, in-person mentorship visits were made in Brazil, Kenya, and Ethiopia.

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Ultraviolet-C Cabinet Workflow Infographic

This infographic outlines the workflow related to loading contaminated N95 masks for disinfection in the ultraviolet-C (UV-C) cabinet and the handling and distribution of the reprocessed masks. (For a larger version of this figure, please consult the Appendix.) HCW = health care worker, PPE = personal protective equipment.



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The Team

The <u>N95DECON consortium</u>, which formed in March 2020, was the virtual meeting place of the project collaborators and the nidus for innovation of the UV-C cabinet. The N95DECON consortium brought together more than 100 clinicians, scientists, and engineers to review the available literature and provide evidence-based guidance on the decontamination and reuse of N95 respirators at the start of the Covid-19 pandemic. UV-C irradiation was one of these technologies, along with humid heat treatment and hydrogen peroxide vapor.

After the core team assembled, some outside professional affiliations of team members enabled the funding and widespread implementation of the UV-C cabinet, from both a technical and a

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Planning and Implementation Worksheet

This infographic outlines hospital-level preimplementation planning and decision-making regarding ultraviolet-C (UV-C) cabinet use, as well as workday processes for both the clinical staff and the reprocessing staff in the handling of the N95 masks. (For a larger version of this figure, please consult the Appendix.)



Decon = decontamination, PPE = personal protective equipment. Source: The authors

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clinical implementation perspective. The <u>Optica Foundation</u> (formerly Optical Society of America) mobilized student engineering chapters and mentors around the globe and provided much of the seed funding for constructing and testing chambers. The <u>Addis Ababa Institute of Technology</u> and <u>Factor[e] Ventures</u> in Nairobi led engineering and construction teams in their respective locations. The Pernambuco State Foundation for Science & Technology (<u>FACEPE</u>) in Brazil also supported the project. <u>Lifebox Foundation</u>, Inc., a charity organization that works to improve the safety of surgery and anesthesia worldwide, is experienced in training clinical providers in sterile processing techniques and infection prevention. Clinical teams associated with Lifebox were engaged to pilot the UV-C cabinets in hospitals and provided input on

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training materials during their creation. Over the 8-month period, approximately 75 individuals were involved in some way.

Hurdles

For wider adoption of the UV-C cabinets, regulatory approval, rather than off-label and pilot testing use, will be required. As of January 2022, FDA application processes are ongoing in Brazil and Ethiopia; however, significant delays in processing time and bureaucratic procedures have hindered the FDA approval process to date. While one Emergency Use Authorization was granted (and since revoked)²² by the U.S. FDA for a commercial UV-C system to decontaminate N95 respirators, the larger cabinets and whole-room decontamination strategies that were temporarily used in the United States¹⁶ are no longer being used, as severe PPE shortages in high-income settings have abated, for the most part.

Additionally, the negative connotations associated with PPE reuse, even as a crisis mitigation strategy, disincentivized some locations from using UV-C cabinets in clinical settings. Some clinicians viewed adoption of the UV-C cabinet as a sign that the health care infrastructure would not invest in optimal, single-use respiratory PPE for all necessary encounters and did not want to encourage this practice. Other locations viewed the cabinets as a necessary stop-gap measure during a time of crisis and were more willing to adopt the strategy as a short-term solution.

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While selected clinical sites agreed to provide physical space, staff, and follow-up of the cabinets in the selection process, it was difficult to enforce these agreements and impossible to know a priori which sites would follow through."

Furthermore, specific follow-up of each engineering team, hospital, and cabinet use was challenging given the crisis nature of the pandemic, the difficulties with Internet connectivity, and competing priorities. In some instances, a long testing and validation process was required by local regulatory procedures before cabinets could be used in a clinical setting; in others, after delivery to hospitals, further follow-up was not possible, leaving us with only approximately 50% of the cabinets being fully deployed in clinical settings with follow-up from the sites. While selected clinical sites agreed to provide physical space, staff, and follow-up of the cabinets in the selection process, it was difficult to enforce these agreements and impossible to know a priori which sites would follow through. Some may have used the cabinet but not reported any use to us because they were overwhelmed with other pandemic-related matters, but some sites that did not respond may never have used a delivered cabinet.

In an effort not to overburden hospital teams with project-related paperwork, we requested estimates only of mask decontamination totals, not detailed record keeping after cabinet delivery. Therefore, the total number of masks decontaminated is a rough estimate based on

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daily and monthly averages reported by hospital teams, and given the allowance of masks being decontaminated and reused up to five times, individual masks may have been counted more than once.

Metrics

Chapters Engaged and Cabinets Constructed

A total of 20 Optica student chapters and three additional independent engineering organizations were engaged in the effort to construct and test UV-C cabinets; 18 engineering teams participated through the end of the project. These engineering groups were located in 12 countries across four continents (Table 1).

The engineering teams constructed a total of 41 UV-C cabinets between July 2020 and May 2021. Because these were pilot constructions, each of the teams innovated different safety or efficiency improvements to the original design, including external light-emitting diode lights that indicated if each UV-C bulb was functional inside the cabinet, glass windows in the cabinet walls that block UV-C escape from the cabinet but allow visualization of the internal chamber

Country	Engineering teams	Total cabinets	Hospitals receiving cabinets	Reported cabinets used in clinical setting*	Estimation of masks decontaminated (as of May 2021)	Updated estimation of masks decontaminated (as of January 2022)
Bangladesh	1	2	2	0	N/K	N/K
Brazil**	5	3	2	3	75,000	N/A
Chile	1	2	2	0	N/K	N/K
Ethiopia	1	8	1	1	25,000	70,000
Ghana**	1	4	4	3	75,000	N/A
India**	2	3	3	3	75,000	N/A
Kenya** ^{,#}	1	5	2	2	50,000	N/A
Mexico	5	8	8	8	150,000	560,000
Peru	1	3	3	0	N/K	N/K
Somaliland**	—	1	1	1	25,000	N/A
Zambia	—	1	1	0	N/K	N/K
Zimbabwe	-	1	1	0	N/K	N/K
Totals	18	41	30	21	475,000	930,000

Table 1. Engineering Team, UV-C Cabinet, and Mask Decontamination Totals

Given the nature of limited communication networks and infrastructure, robust information collection was not possible after the cabinets left the engineering teams. We describe "reported" cabinets used in a clinical setting; a zero indicates only that we have no report of cabinets in use. UV-C = ultraviolet-C, N/K = not known (after cabinets were delivered to hospitals, direct continuing communication was not established), N/A = not available: unable to secure updated information.*The reported number represents a minimum based on best available information. **Updated information was not available from these sites. #The Engineering team in Kenya supported efforts in Somaliland, Zambia, and Zimbabwe. Source: The authors.

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Local Team Adaptations and Implementation Workspace

In this figure, design adaptations by engineering teams include: members of the Ethiopia team discussing plans for a cabinet-top unit (A), the finished cabinet during site supervision topped with lights to indicate process status and bulb functionality (B), a red light bulb to indicate process status by the Brazil team (C), a hospital decontamination workspace in Ethiopia (D), and a foil-lined mask rack being fitted into the cabinet by the Mexico team (E).



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when on, and built-in timers that could be set to measure cycle length and sound an alarm to notify operators when a cycle ended. Each engineering team also performed validation for UV-C dose delivery and uniformity for their specific cabinet construction using either photochromic strip indicators at different positions in the cabinet^{23,24} or a photodiode unit for dose validation (<u>Appendix</u>). Engineers also added different types of interlocks or external locks on the doors to prevent accidental opening of the chamber when UV-C bulbs were turned on. Some photos of the engineering innovations and hospital implementation settings are shown in Figure 5.

We estimate that 475,000 masks were decontaminated for reuse between December 2020 and May 2021, with that total increasing to 930,000 or more by January 2022. With the cost of N95 respirators ranging from \$1 to \$4 during the pandemic, this resulted in a savings of \$930,000 to \$3.7 million for the clinical sites."

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Masks Decontaminated

A total of 21 cabinets had been set up in clinical settings as of May 2021, including hospitals and clinics, with updates provided by some sites through January 2022 (Table 1). Others are in the process of testing, delivery, and staff training with plans to implement in the future. With an average of 30 masks per cycle and approximately 10 minutes per cycle, each cabinet can decontaminate approximately 1,440 masks per workday if running during normal working hours (8 hours); however, hospital staff reported that the number of masks decontaminated averaged approximately 200 masks per day or 5,000 per month.

We estimate that 475,000 masks were decontaminated for reuse between December 2020 and May 2021, with that total increasing to 930,000 or more by January 2022. With the cost of N95 respirators ranging from \$1 to \$4 during the pandemic, this resulted in a savings of \$930,000 to \$3.7 million for the clinical sites, not to mention the shortages that made N95s impossible to procure at times regardless of cost. There were no safety events reported from any site regarding the cabinet function or UV-C exposure; however, with incomplete follow-up from some of the clinical sites, we cannot be absolutely sure no safety events occurred, which is one of the limitations of a grassroots initiative such as ours.

Looking Ahead

During times of crisis, multidisciplinary innovations can solve problems that would be difficult, if not impossible, should we stay in our siloed professions. In this case, the collaboration of optical engineers, an academic consortium, clinicians, and a global nongovernmental organization was able to provide a unique solution that expanded the available supply of N95 respirators by up to five times through use of a simple, affordable decontamination strategy. By sharing expertise and drawing upon similar experiences, our team was able to innovate a device to respond to one of the critical challenges of the Covid-19 pandemic.

In the future, should another respiratory viral pandemic arise, this device will be simple to recreate and, with training materials already in place, could be rapidly deployed to assist in the response. UV-C is effective against a number of pathogens, making this a versatile technology should it be validated for decontamination with respect to other organisms.

With the large amount of health care-associated waste in mind, a solution such as this may also be explored for the decontamination and reuse of other suitable medical items that might be disposed of or damaged by other disinfectant methods, such as patient monitoring equipment or plastic items, although optical modeling and validation of the cabinet would be required prior to deployment for other uses. Furthermore, the overall structure of this collaboration, drawing upon multiple disciplines and across diverse geographic and income environments, is one that might be replicated in the future to rapidly innovate low-cost, practical solutions to challenges in health care.

Nichole Starr, MD, MPH

General Surgery Resident, Department of Surgery, University of California, San Francisco, San Francisco, California, USA

Resident Member, Center for Health Equity in Surgery and Anesthesia, University of California, San Francisco, San Francisco, California, USA

Senior Fellow 2020–2021, Fellowship Advisor 2021-present, Lifebox Foundation, Inc., London, United Kingdom

Natnael Gebeyehu, MD Resident Physician, Addis Ababa University, Addis Ababa, Oromia, Ethiopia

Anderson S. L. Gomes, PhD

Professor, Physics Department, Universidade Federal de Pernambuco, Recife, Brazil

E. Rosas, PhD President, Clúster Mexicano de Fotónica, Toluca de Lerdo, Mexico

Tyler N. Chen, MS PhD Candidate, Stanford University, Stanford, California, USA

Dawit Assefa, PhD

Professor, Addis Ababa Institute of Technology, Addis Ababa, Oromia, Ethiopia

Jared Shless

Undergraduate student, Department of Bioengineering, University of California Berkeley, Berkeley, California, USA

Jit Bhattacharya, PhD

Principal, Factor[e] Ventures, Nairobi, Kenya

Arnab Bhattacharya, PhD Professor, Tata Institute of Fundamental Research, Mumbai, Maharashtra, India

David Robinowitz, MD, MHS, MS

Health Sciences Clinical Professor, Anesthesia & Perioperative Care, University of California, San Francisco, San Francisco, California, USA

Martin Purschke, PhD

Former Instructor in Dermatology, Wellman Center for Photomedicine, Massachusetts General Hospital, Boston, Massachusetts, USA

Thomas Baer, PhD

Executive Director, Stanford Photonics Research Center, Stanford University, Stanford, California, USA

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Consulting Professor, Applied Physics Department, Stanford University, Stanford, California, USA

Associate Member, Stem Cell Institute, Stanford University, Stanford, California, USA

Appendix

UV-C Cabinet Assembly, Testing, and Implementation

Acknowledgments

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