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REPORTS OF ORIGINAL INVESTIGATIONS

A hood shield reduces postdoffing contamination during simulated COVID-19 airway management: an exploratory, simulation-based randomized study

Un capuchon de protection réduit la contamination post-retrait de l'équipement de protection individuelle pendant une simulation de prise en charge des voies aériennes en cas de COVID-19 : une étude exploratoire randomisée de simulation

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Abstract

Purpose *SARS-CoV-2 poses a significant occupational health threat to health care workers performing aerosol-generating medical procedures, with a threefold increased risk of a positive test and predicted infection compared with the general population. Nevertheless, the personal protective equipment (PPE) configuration that provides better protection with lower contamination rates is still unknown.*

Methods *We enrolled 40 practitioners with airway management training (anesthesiologists, anesthesia assistants/nurses) in an exploratory, simulation-based randomized study. We evaluated the performance of a novel, locally designed hood (n = 20) in terms of protection from surrogate contamination using an ultraviolet (UV) marker during a standardized urgent intubation procedure and a simulated episode of coughing in a high-fidelity simulation setting compared with standard PPE (n = 20). The primary outcome was the presence of residual UV fluorescent contamination on any base clothing or exposed skin of the upper body after doffing PPE assessed by a blinded evaluator.*

Results *The proportion of participants with residual contamination on any base clothing or exposed skin of the upper body after doffing was less than half in the hood PPE group compared with the standard PPE group (8/20 [40%] vs 18/20 [90%], respectively; P = 0.002).*

Conclusions *Compared with standard PPE, enhanced PPE with a locally designed prototype hood was associated with reduced contamination of the upper torso and fewer body areas being exposed to droplets after a simulated aerosol-generating scenario without designed airflow.*

Study registration *ClinicalTrials.gov (NCT04373096); registered 4 May 2020.*

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Résumé

Objectif *Le SRAS-CoV-2 représente une menace importante pour la santé au travail des travailleurs de la santé réalisant des interventions médicales générant des aérosols, avec un risque trois fois plus élevé de test positif au SRAS-CoV-2 et d'infection prédite au SRAS-CoV-2 par rapport à la population générale. Néanmoins, la configuration optimale des équipements de protection individuelle (EPI) offrant la meilleure protection avec des taux de contamination plus faibles est encore inconnue.*

Méthode *Nous avons recruté 40 praticiens ayant une formation en prise en charge des voies aériennes (anesthésiologistes, assistants en anesthésie/personnel infirmier) dans le cadre d'une étude exploratoire randomisée de simulation. Nous avons évalué la performance d'un nouveau capuchon conçu localement (n = 20) par rapport aux EPI standards (n = 20) en termes de protection contre la contamination de substitution à l'aide d'un marqueur ultraviolet (UV) au cours d'une procédure d'intubation urgente normalisée et d'un épisode simulé de toux dans un environnement de simulation haute fidélité. Le critère d'évaluation principal était la présence d'une contamination résiduelle par fluorescence UV sur les vêtements de base ou la peau exposée du haut du corps après le retrait des EPI telle qu'évaluée par un évaluateur en aveugle.*

Résultats *La proportion de participants présentant une contamination résiduelle sur les vêtements de base ou la peau exposée du haut du corps après le retrait des équipements de protection était de moins de la moitié dans le groupe ayant porté le capuchon par rapport au groupe EPI standard (8/20 [40 %] vs 18/20 [90 %], respectivement; P = 0,002).*

Conclusion *Par rapport aux EPI standards, les EPI améliorés avec un prototype de capuchon conçu localement étaient associés à une contamination réduite du haut du torse et à moins de zones du corps exposées aux gouttelettes après une mise en situation simulée de génération d'aérosols sans flux d'air préconçu.*

Enregistrement de l'étude *clinicaltrials.gov (NCT04373096); enregistrée le 4 mai 2020.*

Keywords intubation · personal protective equipment · simulation training · SARS-CoV-2

The SARS-CoV-2 virus, which causes COVID-19,[1] poses a significant occupational health threat to health care professionals. There was at least a threefold increased risk of a positive SARS-CoV-2 test and predicted SARS-CoV-2 infection among frontline personnel compared with the general population.[2] High-infection rates pose a staffing challenge to already strained health care systems at a time of high demand. Inadequate use of personal protective equipment (PPE) due to shortage or unavailability is believed to have contributed significantly to the SARS-CoV-2 infection burden, especially in those performing aerosol-generating medical procedures (AGMPs).[3,4]

In the present study, we developed a new, locally designed, and locally produced hood and compared it with standard PPE in terms of the extent of ultraviolet (UV) fluorescence surrogate contamination and ease of use during the performance of an AGMP (endotracheal intubation) in a high-fidelity simulation laboratory. We hypothesized that PPE enhanced with the use of a hood would significantly decrease the incidence of contamination in the upper body after a simulated AGMP.

Methods

This study was approved by the University Health Network Research Ethics Board (Toronto, ON, Canada; 7 May 2020; Study ID 20-5448) and registered at ClinicalTrials.gov (NCT04373096; 4 May 2020). We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for the design and reporting of this study.[5]

Participants

After giving written-informed consent to participate, we enrolled 40 anesthesiologists, anesthesia fellows, and anesthesia assistants aged 20–75 yr and with an American Society of Anesthesiologists' Physical Status of I and II in an exploratory, simulation-based randomized study. Using an online randomization allocation system (Randomization.com), participants were randomized in a 1:1 ratio (20 participants per group) to either the standard PPE group (control) or the hood PPE (study) group to participate in an airway management simulation session using different PPE (two participants per simulation, ten simulation sessions in each group). Sealed opaque envelopes with sequential randomization allocation were prepared in advance and opened by the simulation lead on the morning of the study session. Participants unfamiliar with the institutional policies for donning/doffing PPE were excluded.

Primary outcome

The primary outcome was the presence of residual UV fluorescent contamination on any base clothing or exposed skin of the upper body after doffing PPE.

Secondary outcomes

Secondary outcomes were

A) Number of body areas contaminated. For the purpose of this outcome, the body was divided in the following ten areas: a) face, b) hair or posterior aspect of the head, c) right side of the neck, d) left side of the neck, e) right arm or forearm, f) left arm or forearm, g) left wrist or hand, h) right wrist or hand, i) torso, and j) lower extremities;
B) Total number of discrete contamination clusters (defined as discernible fluorescent contamination patches of variable sizes on a given surface);
C) Number of contamination clusters of < 5 cm^2 and > 5 cm^2;
D) Operator visibility during the simulated procedure rated by each participant on an 11-point numeric-rating scale from 0 (no visibility due to fogging or physical interference of the PPE, leading to inability to perform the required procedures) to 10 (perfect visibility, no fogging or physical interference with the required tasks);
E) Ease of intubation assessed using an 11-point numeric-rating scale from 0 = extremely difficult; PPE made it impossible to intubate to 10 = absolutely no obstruction or difficulty added by the PPE;
F) Ease of breathing while wearing PPE, assessed using an 11-point numeric-rating scale from 0 = felt suffocated, needed to remove the PPE before completing the task to 10 = no difficulty breathing;
G) Thermal comfort while wearing the PPE, reported on an 11-point numeric-rating scale from 0 = extremely hot, needed to remove the PPE before completing the task to 10 = no discomfort due to temperature; and
H) Ease of verbal communication while wearing the PPE during the performance of intubation.

Standard versus hood personal protective equipment

Standard PPE included surgical cap, fit-tested N95 face mask, Association for the Advancement of Medical Instrumentation (AAMI) level 2 gown, nonsterile vinyl double gloves, and face shield, as per current institutional Infection Prevention and Control recommendations for AGMPs (Fig. 1).

Hood PPE included surgical cap, fit-tested N95 face mask, AAMI level 2 gown, nonsterile vinyl double gloves, and an intubation hood (Fig. 1).

Hood prototypes were jointly developed by the investigators and a local engineering company (Lake Harbour Co. Ltd., Markham, ON, Canada) in an iterative process between May and December 2020. The final prototype was a T5 Medical Protection Hood (designed to be used with a T5^{TM} medical helmet [Stryker; Kalamazoo, MI, USA]) with a clear window and adjustable head band. The hoods are intended for single use. They were manufactured using a three-layer Spunbound Meltblown Spunbound fabric with polypropylene, polyethylene, and polyethylene terephthalate (PET), to meet AAM1 level 3 protection standards. The clear window was made from PET material with dimensions of 37 cm by 23 cm. The headband was made from polypropylene material with an integrated front hoop and one-handed operation for size adjustability. Velcro was used at the front and the top of the headband to attach the hood to enhance thermal management and visibility.

Study sessions and simulation scenario

The study sessions took place between December 2020 and May 2021 in a high-fidelity simulation laboratory without designed airflow at Toronto Western Hospital (Toronto, ON, Canada). Sessions comprised the following seven consecutive steps: 1) briefing (introduction to simulation laboratory, materials, correct donning and doffing PPE technique, correct use of PPE (standard *vs* hood according to randomization), video laryngoscope and mannequin; 2) baseline UV scan to rule out any baseline contamination; 3) donning of PPE; 4) simulated intubation scenario with an episode of coughing; 5) doffing of PPE; 6) final UV scan of base layer scrubs after doffing of PPE; and 7) completion of feedback questionnaire filled out immediately after the activity by participants. Two participants (one intubating operator and one intubation assistant) were enrolled per session, and the two participants in any given session wore the same type of PPE. The duration of each study session was approximately one hour.

A baseline UV light (UVL 1007; Marlatek Inc., Brockville, ON, Canada) examination was conducted before donning PPE to rule out pre-existing "stains" or fluorescence. All traces of pre-existing fluorescence were removed before donning PPE. The research assistant then left the room to remain blinded to group allocation.

Following this, the two participants donned PPE under supervision as per randomization results. Participants then attended to the mannequin simulating an adult patient positive for COVID-19 with pneumonia and respiratory failure requiring urgent endotracheal intubation. The intubating team performed an emergent rapid sequence induction and intubation using a GlideScope® videolaryngoscope (Verathon Inc., Bothell, WA, USA). During laryngoscopy, an episode of cough was simulated with Glo Germ^{TM} sprayed twice towards both participants using the manufacturer's spray bottle (Glo Germ Mist Kit,

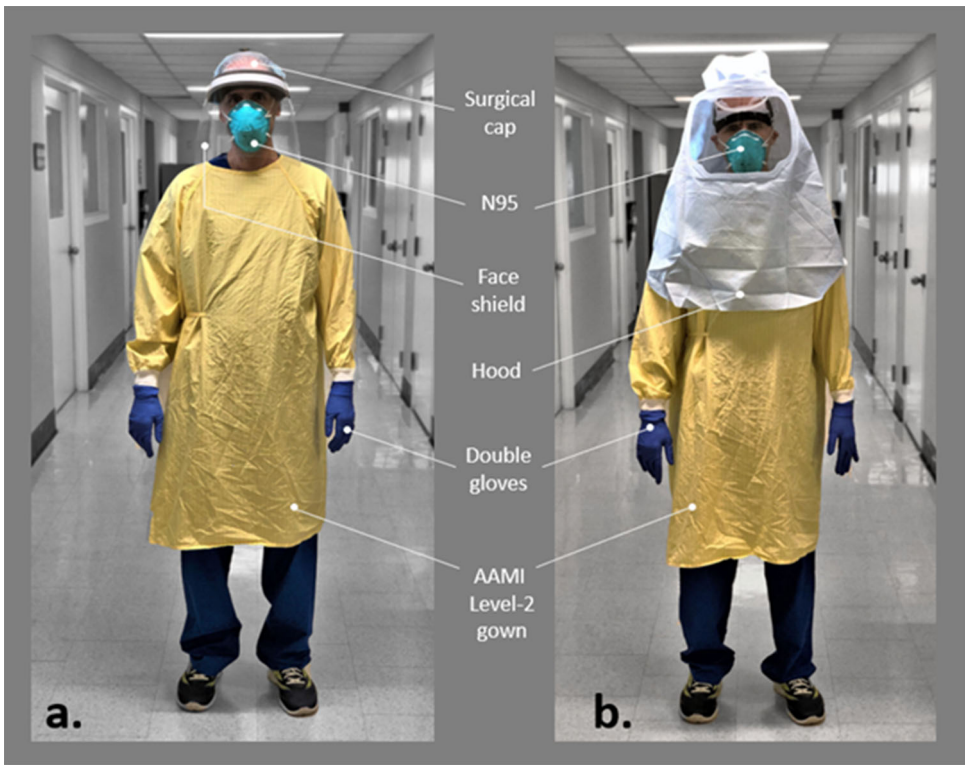

Fig. 1 Standard and hood personal protective equipment (PPE) configurations. a) Standard PPE (control) group and b) hood PPE (study) group

Marlatek Inc, Brockville, ON, Canada) positioned adjacent to the mannequin's jaw and pointing upwards in a 45° angle towards both the right and left of the mannequin. For each study session, the bottle was half-full and manually pressurized 12 times as per manufacturer's recommendations. Both participants were exposed to the same product (Glo Germ), although they were sprayed individually, twice per participant. The participants then doffed PPE under supervision. After doffing, the blinded research assistant entered the simulation room and performed a visual inspection of each subject under UV light and documented the primary and all remaining secondary outcomes on a standardized data collection sheet.

Data collection

Both UV scans for this study were carried out in a dark room. Given the nature of the study, it was not possible to blind neither the participants nor the simulation-lead investigator. Nevertheless, the research assistant documenting all primary and secondary outcomes was blinded to group allocation. The presence of UV fluorescent contamination for each anatomical region and the number of contamination clusters present after doffing were documented using a size scale (< 5 cm^2 and > 5 cm^2). After each simulation, the participants filled out a questionnaire consisting of five 11-point numeric-rating scale survey questions assessing the participant's overall perception of the PPE used.

Sample size estimate

We hypothesized that PPE that includes the use of a hood would significantly decrease the incidence of any contamination of the upper body from 90% to 50%. This is based on a previous study that suggests that with the use of standard PPE, the incidence of any contamination after doffing, following a simulated patient cough is approximately 90% (mostly affecting the neck and head areas).[6] To show that difference using comparison of proportions with a Chi square test, for a type I error of 0.05 and a power of 80%, we estimated that 17 participants would be required per group (34 participants total) to appropriately reject the null hypothesis. Since intubating teams consist of two members per study session, we ran 20 simulations for 40 participants to account for possible withdrawals or incomplete data.

Statistical analysis

Participant characteristics and primary and secondary outcomes were summarized using counts and percentages for continuous variables and means and standard deviations or medians and interquartile ranges for continuous variables, depending on the shape of the distributions.

Outcomes were compared between the standard and hood PPE groups using either Wilcoxon Rank Sum tests or Chi square tests. Whenever counts lower than 10 were encountered, Fisher's exact test was used for comparison. Feedback questionnaire answer scores were summarized with medians and interquartile ranges and were compared using Wilcoxon rank-sum tests. Bonferroni correction was used to account for multiple comparisons for the eight secondary outcomes. The corrected significance threshold was $\alpha = 0.05/8 = 0.006$.

Results

From December 2020 to May 2021, 40 participants were randomized in the study: 20 in the standard PPE group and 20 in the hood PPE group. There were no crossovers. Participant characteristics are shown in Table 1, and the CONSORT flow diagram is shown in Fig. 2.

Primary outcome

The proportion of participants with residual contamination on base clothing or exposed skin of the upper body (head/neck, forearms, arms, wrists, hands, or torso) after doffing was less than half in the hood PPE group compared with the standard PPE group (8/20 [40%] *vs* 18/20 [90%], respectively; $P = 0.002$) (Table 2, Figs 3 and 4).

Secondary outcomes

The total number of body areas with contamination was lower in the hood PPE group than in the standard PPE group (one *vs* five body areas, respectively; $P < 0.001$). Similarly, the number of contamination clusters of any size was six times lower in the hood PPE group (Table 2).

At the Bonferroni-corrected significance threshold of 0.006, there were no statistically significant differences in ratings of visibility (9.0 *vs* 8.5; $P = 0.70$), ease of intubation (10.0 *vs* 8.5; $P = 0.33$), ease of breathing (7.5 *vs* 9.0; $P = 0.09$), ease of verbal communication (9.0 *vs* 9.0; $P = 0.99$), or thermal comfort (6.0 *vs* 9.0; $P = 0.04$) between the hood and standard PPE groups, respectively.

No participants had to remove their PPE to complete the assigned simulation tasks, and all endotracheal intubations were successful on the first attempt. There were no breaches in donning or doffing procedures in either group.

Discussion

The main finding of this study is that enhanced PPE with the prototype hood significantly reduced contamination rates of the upper body and the total number of body areas contaminated compared with standard PPE during a simulated scenario of an urgent endotracheal intubation and coughing. Similar to previous studies, our results suggest that the head and neck regions are particularly vulnerable to droplet contamination during AGMPs using standard PPE (Fig. 4).

SARS-CoV-2 is found in sputum and upper airway secretions of infected patients in very high concentrations.[7] Respiratory droplets (> 5–10 μm in diameter) and droplet nuclei or aerosols (≤ 5 μm in diameter) account for viral contact and airborne transmission.[8,9] Viral transmission is complex and exposure occurs in three principal ways:

Table 1 Participant characteristics

	Standard PPE *N* = 20	Hood PPE *N* = 20
Age (yr), median [IQR]	38 [34–50]	40 [34–46]
Sex, *n*/total *N* (%)		
Female	11/20 (55%)	4/20 (20%)
Male	9/20 (45%)	16/20 (80%)
Weight (kg), mean (SD)	78 (14)	74 (14)
Height (cm), mean (SD)	174 (9)	174 (9)
BMI ($kg \cdot m^{-2}$), mean (SD)	25.7 (3.7)	24 (3)
Training level, *n*/total *N* (%)		
Staff anesthesiologist	3/20 (15%)	6/20 (30%)
Anesthesia fellow	9/20 (45%)	12/20 (60%)
Anesthesia assistant	5/20 (25%)	1/20 (5%)
Nurse	3/20 (15%)	1/20 (5%)

BMI = body mass index; IQR = interquartile range; PPE = personal protective equipment; SD = standard deviation

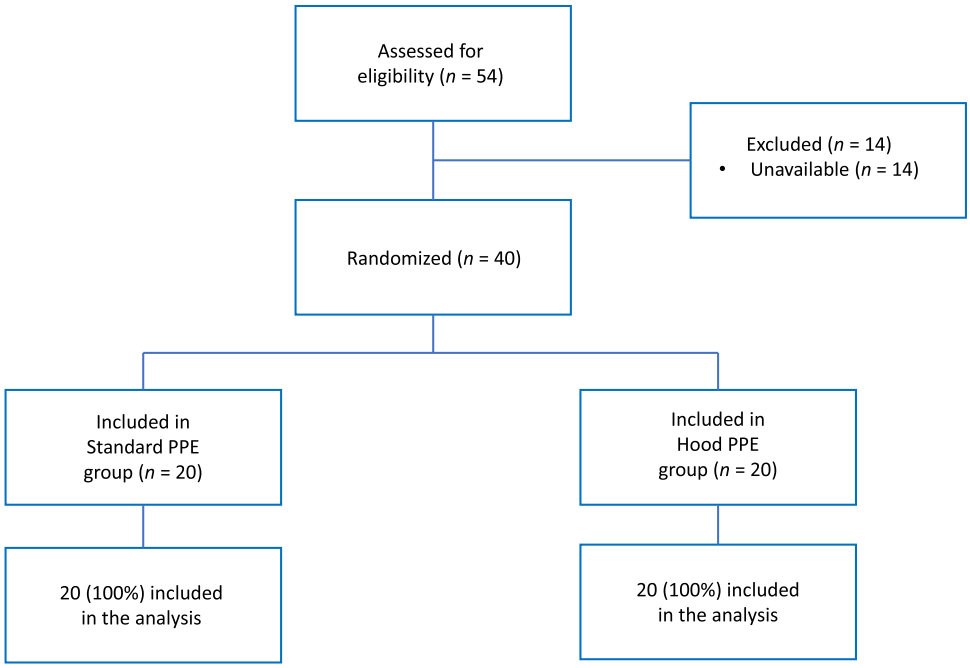

Fig. 2 CONSORT flow diagram

Table 2 Primary and secondary (contamination) outcomes after doffing

Outcomes	Standard PPE *N* = 20	Hood PPE *N* = 20	*P* value
Primary outcome, *n*/total *N* (%)			
Presence of contamination of any area in the upper body	18/20 (90%)	8/20 (40%)	0.002[a]
Secondary outcomes, median [IQR]			
Number of body areas∫ contaminated	5 [3–5]	1 [0–2]	< 0.001[b]
Total number of contamination clusters	9 [3–14]	2 [0–3]	0.002[b]
Number of contamination clusters < 5 cm^2	6 [2–12]	1 [0–3]	0.007[b]
Number of contamination clusters > 5 cm^2	1 [0–3]	0 [0–0]	0.004[b]

∫Out of ten possible body areas of contamination. The body was divided into 10 areas = a) face, b) hair or posterior aspect of the head, c) right side of the neck, d) left side of the neck, e) right arm or forearm, f) left arm or forearm, g) left wrist or hand, h) right wrist or hand, i) torso, and j) right or left lower extremity

[a] Chi square test

[b] Wilcoxon test

IQR = interquartile range; PPE = personal protective equipment

1) inhalation of very fine respiratory aerosol particles; 2) deposition of respiratory droplets and particles onto exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays; and 3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them. The importance of these three modes of transmission is also reflected in current Centers for Disease Control and Prevention guidelines for the sequence of donning and removing PPE.[10]

Concern has been raised that contamination of ears, neck, hair, face mask, and eyeshield during AGMPs can occur with the use of standard PPE alone.[1,11,12] This has prompted recommendations to upgrade standard PPE for AGMPs and has led to the development of various barrier devices attempting to enhance health care worker protection.[1,3,13–17] Unfortunately, controlled studies comparing standard PPE with these alternative enhanced devices (such as hood PPE) are currently lacking. Thus, PPE configuration that provides better protection with the lowest contamination rates is still unknown.

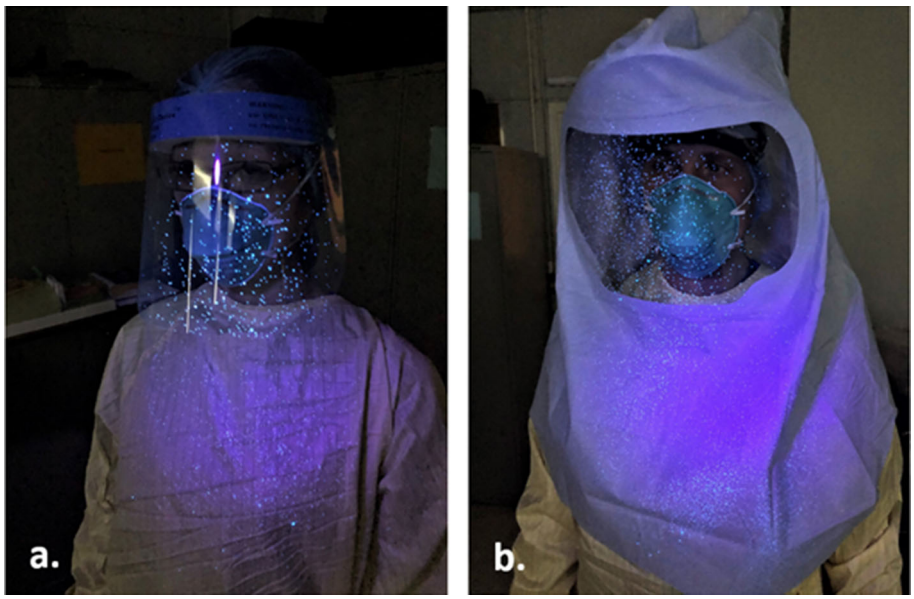

Fig. 3 Droplet contamination patterns under UV light scanning before doffing. a) Standard PPE and b) hood PPE

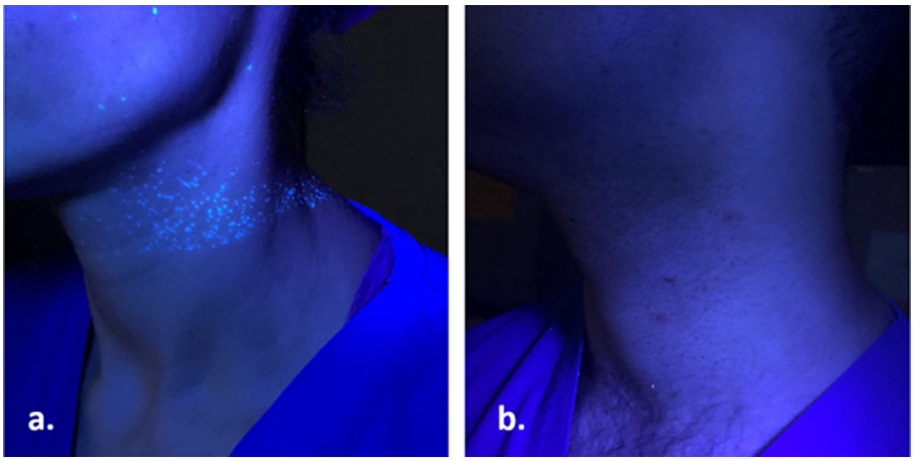

Fig. 4 Contamination patterns under UV light scanning after doffing. a) Standard PPE and b) hood PPE

Powered air-purifying respirators (PAPR) are an alternative to PPE; they use a battery-powered blower that provides positive airflow through a replaceable filter, cartridge, or canister to a hood.

In a simulation-based study, Zamora *et al.*[6] found that participants using standard PPE were more likely to experience larger total areas of contamination, particularly at the anterior neck, than those using PAPR. Coupling PAPR PPE with Tyvek coveralls, hoods, boot covers, and HEPA filters adds longer donning/doffing procedures with greater cross-contamination rates during doffing.[6,18,19] Nevertheless, these extra protection elements are optional, and PAPR units with hoods or helmets with face shields can be used with gowns instead of coveralls. In addition, the recent use of easily decontaminated PAPRs by paramedics during the COVID-19 pandemic, including reusable filters in units that only require surface decontamination, have made the use of PAPRs more practical. Nevertheless, PAPRs are less readily available and are not part of routine PPE at most institutions.

Fogging and visibility reduction is a potential limitation of PPE that incorporates hoods for AGMPs. In a retrospective case series involving 202 intubations during the COVID-19 pandemic, Yao *et al.* found that 80% of intubators using a hood without PAPR reported fogging and reduced technical efficiency during AGMPs, despite using antifogging products.[20] In our study, visibility ratings and ease of breathing during intubations were equally satisfactory in both groups. In contrast to other hoods, the hood used in the present study was not conceived to confer protection against aerosolized particles because it lacked an air-tight seal/positive pressurization and the use of lighter materials and breathing orifices in the occiput region. These design characteristics likely contributed to the reduced fogging and improved visibility reported by our participants compared with previously available hoods.

This study has some limitations. Extrapolation of these results to real clinical scenarios involving exposure to AGMPs in patients with COVID-19 requires caution. The total time that participants wore PPE in our simulations was relatively short (< 30 min). Although both PPE configurations were tolerated in terms of breathability, fogging, and thermal comfort, this may not be transferable to clinical situations requiring longer procedure times and greater psychological stress. The role of alternative materials (e.g., polyurethane or polyester) used in microporous elastic membranes that enhance breathability and comfort without compromising fluid protection should be further explored in future prototype hood PPE designs.

We treated each participant as an independent participant in the study, even though two participants took part in each study session. It is possible that the study may have been stronger if the methodology would have allowed randomized order of the two different types of PPE within the same subjects to control for individual differences in doffing procedures.

It is unclear if existing methods used to simulate cough and viral-loaded droplets during AGMPs adequately represent real-life exposures.[21] Representative calculations of the average adult human cough profile have an air volume of approximately 4.16 L and peak flow rates of 11.1 L·sec.[22] There is no standardized method for simulating a human cough. Glo Germ contains ingredients formulated to be the same size as many microorganism-loaded droplets (5 μm), theoretically making it comparable to SARS-CoV-2 transmission droplets for AGMP simulation purposes.[23] Nevertheless, it is possible that other AGMPs (e.g., accidental ventilator disconnections in critical care, sneezing during nasal swab, extubation cough episodes) could have different droplet and aerosol contamination patterns, and these findings may not be easy to extrapolate to all types of AGMPs.

An additional limitation is that there may be no obvious advantage in the locally developed hood over commercially available options. The main advantage of locally developed PPE alternatives such as this one is likely during the early phase of a pandemic in which commercially available options are typically in short supply because of a steep increase in global demand.

Finally, whether reduced rates of contamination translate to reduced infections is unclear, and depends on many factors including the pathogen involved and any additional measures taken by clinicians to further decontaminate (such as washing hands, removing clothing worn during the airway event, shower).

In conclusion, compared with standard PPE, enhanced PPE with a locally designed hood was associated with reduced droplet contamination rates of the upper torso and fewer body areas exposed to surrogate contamination after a simulated AGMP scenario. Future studies are needed to determine the performance of this device in clinical practice and the impact of these results may have on the burden of occupational infections on health care professionals during the current and future pandemics.

Author contributions *Felipe Muñoz-Leyva*, *Anahi Perlas*, and *Vincent Chan* contributed to hood prototype design. *Felipe Muñoz-Leyva*, *Anahi Perlas*, *Vincent Chan*, and *Ki Jinn Chin* contributed to study design. *Felipe Muñoz-Leyva*, *Anahi Perlas*, and *Mehdi Soheili* contributed to data collection. *Qixuan Li* and *Ella Huszti* contributed to data analysis. *Felipe Muñoz-Leyva* and *Anahi Perlas* contributed to the first draft of the manuscript. All authors contributed to the revision and approval of the manuscript.

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Prior conference presentations This study was presented as an abstract at Sim Expo, on 17 October 2022 in Toronto, Ontario, Canada.

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