

Disposable Isolation Device to Reduce COVID-19 Contamination During CT Scanning

Amel Amalou, MA, Baris Turkbey, MD, Sheng Xu, PhD, Evrim Turkbey, MD, Peng An, MD, Gianpaolo Carrafiello, MD, Anna Maria Ierardi, MD, Robert Suh, MD, Hayet Amalou, MD, Bradford J. Wood, MD

Rationale and Objectives: The use of chest computed tomography (CT) in the era of the COVID-19 pandemic raises concern regarding the transmission risks to patients and staff caused by CT room contamination. Meanwhile the Center for Disease Control guidance for air exchange in between patients may heavily impact workflows. To design a portable custom isolation device to reduce imaging equipment contamination during a pandemic.

Materials and Methods: Center for Disease Control air exchange guidelines and requirements were reviewed. Device functional requirements were outlined and designed. Engineering requirements were reviewed. Methods of practice and risk mitigation plans were outlined including donning and doffing procedures and failure modes. Cost impact was assessed in terms of CT patient throughput.

Results: CT air exchange solutions and alternatives were reviewed. Multiple isolation bag device designs were considered. Several designs were custom fabricated, prototyped and reduced to practice. A final design was tested on volunteers for comfort, test-fit, air seal, and breathability. Less than 14 times enhanced patient throughput was estimated, in an ideal setting, which could more than counterbalance the cost of the device itself.

Conclusion: A novel isolation bag device is feasible for use in CT and might facilitate containment and reduce contamination in radiology departments during the COVID Pandemic.

Key Words: Computed Tomography; Patient isolation / instrumentation; Infection control / standards.

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INTRODUCTION AND BACKGROUND

The use of chest computed tomography (CT) during the COVID-19 pandemic may introduce contamination risk to staff and nearby patients during imaging procedures. Chest CT in patients with COVID-19 may be of tremendous clinical and epidemiological value, however, this may put pressure on CT scanners to examine large numbers of patients without spreading the infection. Chest CT can provide valuable information but it often requires 30–90 minutes of CT room decontamination and passive air exchange, which takes a heavy toll on workflow and productivity. The exact decontamination time after CT of a patient with a diagnosis or suspicion

for Covid-19 depends upon air exchange rate per hour and passive airflow (1,2), ideally in a negative pressure setting. While advanced staff training, dedicated equipment and hallways, and pre-emptive standardized operating procedures may reduce risk to staff, a single infected patient or breach in technique can have profound implications. Risk can be mitigated by reducing the chance of viral spread by human to human transmission as well as direct transmission via imaging equipment (1) via detailed decontamination procedures, cleaning all surfaces in between patients, and having all patients wear masks, or in specific settings, other personal protective equipment (PPE)-like isolation devices. Some thoracic radiologists in less CT dense countries feared the risk of contamination of CT scanners (2). Designating CT scanners as either “Dirty” or “Clean” CT suites, does not resolve the fact that the “dirty” CT scanner needs a deep cleaning and a delay in between patients. One well-established strategy is to control the respiratory source of airborne or droplet transmission of infection with a face mask. An isolation bag provides a layer of security, in addition to a face mask.

The COVID-19 pandemic has the potential to completely stall radiology department throughput due to excessive delays in between patients for decontamination and airflow exchanges. In the setting of a pandemic from a droplet-transmitted novel virus and an immune-naïve population, there is a critical clinical need for cost-effective disposable PPE for the infected patient’s isolation while undergoing CT

Acad Radiol 2020; ■:1–7

From the Center for Interventional Oncology, Radiology and Imaging Sciences, NIH Clinical Center and National Cancer Institute, Center for Cancer Research, National Institutes of Health, Bethesda, MD 20892 (A.A., S.X., B.J.W.); Molecular Imaging Branch, National Cancer Institute, NIH, Bethesda, Maryland (B.T.); Radiology and Imaging Sciences, National Institutes of Health, Bethesda, Maryland (E.T.); Department of Radiology, Xiangyang No.1 People’s Hospital Affiliated to Hubei University of Medicine Xiangyang, Hubei, China (P.A.); Radiology Department, Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, University of Milan, Italy (G.C., A.M.I.); Department of Radiology, University of California Los Angeles, Los Angeles, California (R.S., H.A.). Received May 12, 2020; revised May 17, 2020; accepted May 18, 2020. **Address correspondence to:** B.J.W. e-mail: bwood@nih.gov

Published by Elsevier Inc. on behalf of The Association of University Radiologists.

<https://doi.org/10.1016/j.acra.2020.05.017>

procedures. This may be even more impactful for the clandestine infection which causes presymptomatic transmission of SARS-CoV-2 which may account for nearly half of all transmissions (3). Custom prototype isolation PPE devices for the patient were designed, test fit, and custom fabricated. Center for Disease Control (CDC) guidelines are reviewed as relevant to CT decontamination and isolation. A portable isolation bag device for patients with symptomatic or asymptomatic upper respiratory infectious diseases was designed to reduce contamination in imaging suites, which could facilitate containment during the COVID pandemic.

METHODS

The potential cost impact of a theoretical isolation device was assessed in terms of enhanced efficiency and patient throughput. The functional requirements and clinical and engineering features for a portable isolation bag device were reviewed and specifications were defined. Methods of practice and risk mitigation plans were outlined including donning and doffing procedures and failure modes. Alternatives methods such as portable CT anterooms or zippered plastic pseudo-walls are briefly reviewed for enhancing CT room safety and workflow efficiency. Air exchange rates and requirements dictate the length of time in between patients known or suspected to have COVID-19 to allow for passive air flow. CDC guidelines for air exchange and optimal airflow relevant to radiology and CT rooms are reviewed (Table 1), along with specific methods for enhancing those exchange rates or mitigating poor exchange rates.

RESULTS

Prototype Development, Engineering, Materials, Air Filtering, Methods of Practice, and Risk Mitigation

Multiple proof-of-concept prototypes were designed, custom fabricated, and test-to-fit on simulated adult and pediatric patients for testing of features intended to minimize droplet spread, while avoiding claustrophobia and risk of asphyxiation. A hypoallergenic plastic polymer (civflex, Civco Medical Solutions, Iowa) was used for the main component skin of the device. This is the same material as has been used for decades in radiology and surgery procedures, to protect ultrasound transducers, CT gantries, image detectors, surgical equipment or patients.

Several designs for oxygen or room air intake were built and tested, with an oxygen intake nozzle integrated with the bag, sealed along the outside of the bag (Fig 1). This included an integrated nasal cannula to deliver more dedicated oxygen to those patients in need. Another model had a one-way valve at the afferent nozzle for one-way entry of room air to the inside the bag. Oxygen connection with a standard oxygen nozzle was made with super low flow oxygen (0.5 lpm) to avoid aerosolization of infectious droplets, such as might occur with high flow oxygen, or without the bag. The air

TABLE 1. CDC Guidelines for Environmental Infection Control in Healthcare Facilities:I. Airborne Contaminant Removal

ACH *	Time (Mins) Required for Removal 99% Efficiency	Time (Mins) Required for Removal 99.9% Efficiency
2	138	207
4	69	104
6	46	69
8	35	52
10	28	41
12	23	35
15	18	28
20	14	21
50	6	8

* Air changes/hour (ACH) and time required for airborne contaminant removal by efficiency. Removal times will be longer in rooms or areas with imperfect mixing or air stagnation. Airborne Contaminant Removal. The time required for removal of airborne SARS-CoV-2 depends upon the air exchange rate (air changes per hour), and the clock starts after the aerosolizing source patient leaves the CT room. Reproduced from public references (2): <https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1>

flowed in to the patient compartment, then slowly through an integrated patch, made from N-95/FFP2 materials flush to the bag skin (Fig 2). In an alternate design, a second integrated nozzle for efferent flow was connected to an N-95/FFP2 mask sealed around the sub-centimeter nozzle with a

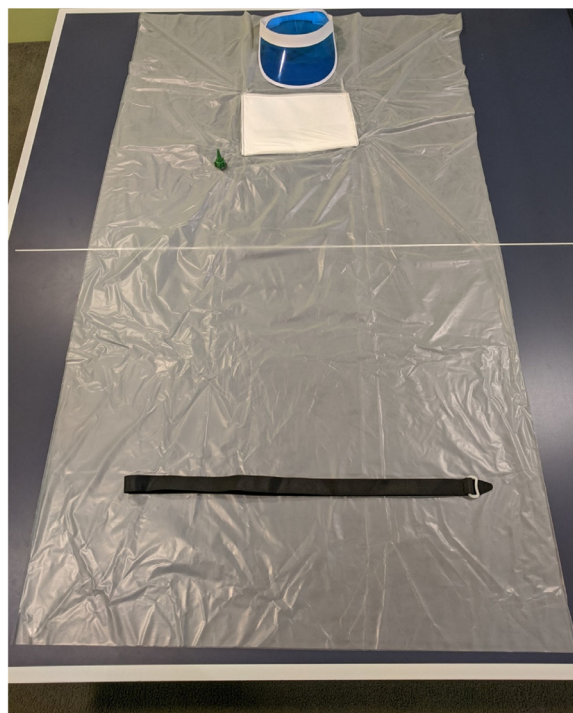


Figure 1. Final design disposable isolation device: integrated oxygen nozzle (green), integrated N-95 filter patch (white), internal visor (blue), and Velcro belt (black) on background torso bag with one open end. Color version of figure is available online.



Figure 2. Final design disposable isolation device. (a) Bag device is deployed on upright patient with integrated oxygen input nozzle (green) with integrated N-95 filter patch (white square) and Velcro belt (black) that seals the air in the patient isolation chamber. (b) Oxygen is directly connected to the oxygen input nozzle, and the patient has on a mask, for source control as well as to prevent airway obstruction by the bag material. A hat visor keeps the bag polymer away from face and airway. Figure 2b reproduced with permission (6). Color version of figure is available online.

tight redundant elastic band, or even connected to a negative flow high-efficiency particulate air filter device.

A tight seal is maintained between the patient compartment (enclosing the head and chest) and the outside room air, via a wide elastic band or a disposable Velcro belt around waist and the bag, just proximal to its open end (Fig 1). All patients must wear an N-95/ FFP2 or standard surgical mask as an added measure of protection against droplet formation as well as a prophylactic against asphyxiation, by preventing airway obstruction by the bag material. In addition one early prototype used a flat cardboard hat integrated with the bag, to avoid the bag falling in the face (Fig 3). A simpler later design use a disposable plastic visor that sits like an independent cap on the head, under the bag, for the same purpose (Fig 1).

Doffing and Donning the Device

It is important to educate and implement training modules for standard operating procedures for all staff and patients well before device implementation. Training videos may be reviewed by staff before use, and instructive menus should

be posted with sequential steps. Failures modes must be understood and avoided, such as might occur with PPE breach, or with contamination of patients or staff from inadvertently touching the dirty inside of a bag device or mask, from incomplete rolling of the open edge. A loose belt might also result in contaminated air from droplet leakage out an incomplete seal from a ruffled piece of clothing or pannus with a crevice. A standardized protocol must be implemented with extensive staff training in order to avoid contamination of staff or patients due to risky or incorrect doffing or donning processes. The same dedicated space must be used for all doffing and donning, ideally a special contaminated ante-room. Two staff optimally assist, one on each side of an upright or supine patient (Fig 3). All staff don their own PPE prior to the patient arrival, including an N-95/ FFP2 mask, hat, gown, gloves, shoe covers, and eye protection. Each side is supported as the bag is rolled over the head first, then carefully rolled open from head to waist, without touching the patient. The CT technologist stays in the control room as much as possible with verbal cues and visual monitoring from outside the room.



Figure 3. Early prototype isolation bag donning by two staff: An upright patient is assisted by 2 staff members for careful donning. Reproduced with permission reference (6).

Bag removal (doffing) is accomplished with slow lifting of the bag from the head, by lifting the visor towards the ceiling, without rolling the bag so as to minimize exposure to the inner surface of the bag. This technique minimizes contamination from the dirty inside of the bag (which was exposed to droplets) to avoid inner bag touching staff or nearby surfaces. The opening of the bag is cinched tightly by tightening the belt, to seal the contaminated air inside and the air is expressed out the filter exit by slowly squeezing and rolling the bag like a toothpaste tube (Fig 2), from lower open side towards the head and filter patch. Removal of the bag is done in the same contaminated location, away from the CT scanner, possibly outside, or in a special contaminated ante room nearby. Bag disposal requires a contaminated trash bin, after the air has been squeezed out and completely removed through the filter patch, by staff still wearing N-95 level PPE. Strict attention to donning and doffing could minimize the risk for additional exposure to staff or environmental contamination, although this is not yet proven.

Air Exchange and Radiology Rooms with Diagnostic CT Scanners

The CDC recommends a specific time requirement for contaminant removal out to a certain efficiency or percentage

TABLE 2. CDC Guidelines for Environmental Infection Control in Healthcare Facilities: Ventilation Specifications for Healthcare Facilities: Ancillary/Radiology

Area Designation	Air Movement Relationship to Adjacent Area	Minimum air Changes of Outdoor Air Per Hour	Minimum Change Per Hour	All Air Exhausted Directly to Outdoors	Recirculated by Means of Room Units	Relative Humidity <-%	Design Temperature (Degrees F [C])
X-ray (surgical/critical care and catheterization)	Out	3 (replacement air from the outside is necessary)	15	Air with contamination shall be exhausted to the outside and not recirculated.	No	30–60	70–75(21–24)
X-ray (diagnostic & treatment)	-	-	6	-	-	-	75 (24)

Whereas interventional radiology is generally designed as positive pressure, (like an operating theatre), on the other hand, a diagnostic CT room has no guideline for air movement to outside and minimal guidelines for air exchange per hour. Reproduced from public reference (5): <https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1>

(Table 1) (4,5). The CDC does not however specifically require a negative pressure room for imaging of patients with COVID-19, however, the recommendations for delay after such an imaging exam will vary according to the native air exchange rate for the room. As the passive air exchange rate slows down, the delay between patients goes up (Table 1) (4,5).

Although not designating CT rooms specifically, the CDC describes Airborne Infection Isolation Rooms, “as single-patient rooms at negative pressure relative to the surrounding areas, and with a minimum of 6 air changes per hour (12 air changes per hour are recommended for new construction or renovation). Air from these rooms should be exhausted directly to the outside or be filtered through a high-efficiency particulate air filter directly before recirculation. Room doors should be kept closed except when entering or leaving the room, and entry and exit should be minimized. Facilities should monitor and document the proper negative-pressure function of these rooms” (4,5).

Regular air exchange measurements should be made by institutional or designated facilities management experts or safety officers. Negative pressure can be monitored with alarms and differential pressure monitors, which alert when door openings make negative pressure change to positive pressure. Negative pressure means the air in the room is removed and exhausted elsewhere. Positive pressure (like surgical theatres) brings clean air into the surgical room, but may blow this air to the hallways or under the doors, as well as to an exhaust. The American Society of Health Care Engineering also has design parameters for ventilation of healthcare facilities. These guidelines for ventilation requirements for radiology were modified March 2, 2020 regarding minimum air exchanges per hour (<https://www.ashrae.org/technical-resources/standards-and-guidelines/standards-addenda/ansi-ashrae-ashe-standard-170-2017-ventilation-of-health-care-facilities>).

The CDC COVID-19 guidelines include consideration to provide portable x-ray equipment in patient cohort areas to reduce the need for patient transport (4,1). Thus, methods are needed for protection during inpatient transport to radiology for CT, as the CDC recommends simple mask coverage during transport (4). In order to benefit from any added value of CT over chest X-ray, risk reduction during transport could occur with a disposable bag isolation device. Then, after the patient leaves CT, all radiology and environmental cleaning staff should refrain from entering the CT room until sufficient time has elapsed for enough air changes to remove potentially infectious particles (4,5).

There are minimal ventilation specifications from the CDC for construction of diagnostic CT rooms (Table 2) (5). However, best practices might include an attempt to mitigate risk via extra delays between patients, allowing for more passive air exchange, or alternatively temporary negative pressure isolation via portable anterooms (Fig 5), or plastic curtains with zippers, as commonly used in healthcare facility construction (Fig 6) (7). These may be used in conjunction with the portable isolation bag. Facilities personnel in charge of

ventilation and air handling may also assess for recirculating air versus “one-pass air,” as well as percent air from outside. For patients with COVID-19 or persons under investigation for COVID-19, these issues become more relevant for aerosolizing procedures, common in interventional radiology.

DISCUSSION

Previous use of similar containment devices in CT, magnetic resonance imaging, and positron emission tomography (PET), have focused on either a high-tech, complex, bulky, and expensive high-level containment chamber or isolation pod (Fig 4) (8), or a super low-tech medical waste bag (6). The former was designed for critical care use or transport in field or military settings, whereas the latter was used to reduce risk in the COVID-19 outbreak in Hubei Province to



Figure 4. High-level containment isolation pod. Designed originally for critical care and emergency transport, previously reported isolation pods have been described in CT, MRI, and PET imaging, but are bulky, costly, not disposable and may thus be more challenging to use for outpatient or multiple inpatient imaging exams. Reproduced with permission reference (8).



Figure 5. Temporary negative pressure isolation: although not as suitable as permanent ventilation solutions, a portable anteroom may be installed and connected to portable air ducts. Reproduced from public reference (7).



Figure 6. Temporary negative pressure isolation: like a clinical construction set-up, a plastic curtain is connected to ceiling and wall with a zippered entry, and an in-circuit HEPA filtration system for one-pass air. Reproduced from public reference (7). HEPA, high-efficiency particulate air.

enhance CT in screening in fever clinics. The ability of such devices to contain infectious agents such as Ebola, severe acute respiratory syndrome (SARS), MERS, multidrug resistant tuberculosis or SARS-CoV-2 requires arresting contact, fomite, droplet, and respiratory aerosols. However, the bulky isolation chamber is not as ergonomic nor conveniently portable as the bag. SARS-CoV-2 requires such droplet and aerosol precautions, and a disposable cost-effective device could augment patient and staff safety, although this is speculative. Although also not directly proven, the prototype device described herein may have less risk for contaminated air escaping into the CT room or surrounding environment, compared to using simply a standard medical waste bag. Any more substantial non-disposable device or chamber might also cause more artifacts on CT or MRI than a thin disposable plastic material, and may reduce the signal to noise ratio more than the simple low-profile plastic bag. The plastic bag should also not influence radiation dose to the patient, compared to the isolation chamber, which causes increased radiation (via scatter or dose modulation) (5).

The CDC issues guidelines for patients with infectious diseases such as measles, varicella, pneumonias due to resistant bacteria, and multidrug resistant tuberculosis, SARS CoV-1, MERS, Ebola, and now COVID-19 (1,2). Radiology departments traditionally try to accommodate the uncertainties from imaging such patients by performing imaging at the end of the workday, in order to allow for longer air exchange. However, this delays the CT, and also CT in some

hospitals has a 24-hour workday. The CDC has issued guidelines for length of time to allow for passive air exchange after imaging a patient with COVID-19 (2). Whatever the time recommended for passive air exchange, this can become cumbersome and inefficient during a pandemic outbreak, when there may be too many patients to let them all wait until the end of the workday, or to wait in between patients.

Broad use of CT has impacted patient isolation in outbreak settings, however only a few patients can be done per shift depending upon air exchanging rates (1,2). The goal of using disposable personal protective isolation devices in this setting would be to try to enhance patient safety and staff protection, while avoiding major slowdowns of any COVID-1-specific CT scanner in cost-effective fashion (3).

Assuming a 2-hour delay for decontamination and ventilation and a 10-minute fast low-dose scan, a single emergency COVID-19-specific CT scanner might be able to scan about 10 patients in a 24-hour working day. Let's assume the isolation bag enables a fast and safe low-dose chest CT every 10 minutes (with preprocedure and postprocedure preparations taking place next door). This would allow 144 patients to be scanned in the same 24-hour period. This translate into over 14 times greater patient throughput per day, with the addition of the bag PPE in a continuously running COVID-19 dedicated CT. Nearly 15-fold enhanced productivity is far greater than any expected cost for a disposable device made from inexpensive and easily sourced materials. The population impact and cost-effectiveness of the enhanced use of CT as a result of bag use during a COVID-19 outbreak is reviewed elsewhere (3).

In addition to reducing contamination of imaging rooms and radiology departments, the disposable isolation bag may meet an urgent clinical need brought about by unprecedented pandemic. Such a cost-effective device might prove useful in any situation where the CT might not reside in a negative pressure setting, which may be common in both inpatient and outpatient imaging centers. Such issues may have added relevance in countries without resources requisite for construction of negative pressure ventilation in radiology or interventional radiology departments. The especially contagious SARS-CoV-2 virus potentially remains viable for several days on surfaces after nebulization (10), such as may occur in contaminated CT rooms. Future analysis may assess the ability to successfully contain nebulized virus in vitro with this disposable and cost-effective isolation device. Such a device might address an unmet practical need during a pandemic, such as for nebulized medications, outpatient doctor office visits, or acute care settings. Given the wide concern for asymptomatic viral contagiousness, such a device could also be used uniformly to enhance cleanliness in a standard health-care setting such as radiology, magnetic resonance imaging, PET, nuclear medicine, interventional radiology, outpatient surgery, endoscopy, plastic surgery, or even tattoo parlors, salons, or other back to work settings. This brief description of a prototype isolation device for reduction in contamination requires clinical translation. The limited overview of ventilation for radiology related to COVID-19 is a superficial introduction for the clinician

that requires more in-depth communications and a multidisciplinary understanding involving facilities management, hospital epidemiology, environmental safety officers, and clinical leadership. Given the benefits of ongoing COVID-19 awareness, radiology department pandemic preparations (9,11,12) should be attentive to airflow in CT rooms, and should consider all options for risk mitigation for staff and patients.

OFF LABEL USE

Devices discussed may not be cleared for any indication by the CE Mark or the US Food and Drug Administration.

ACKNOWLEDGMENTS

The opinions are those of the authors in their personal capacity and do not necessarily represent the opinions of the National Institutes of Health nor the US Government. Supported in part by the NIH Center for Interventional Oncology and the Intramural Research Program of the National Institutes of Health. Thanks to Brad Dunlap, Robin Therme, and team at Civco Medical Solutions for rapid and pro-active prototyping and thoughtful discussions. NIH may have intellectual property in the area.

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