



Aerosol containment device design considerations and performance evaluation metrics

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ABSTRACT

Background: Spurred by the Coronavirus infectious disease 2019 pandemic, aerosol containment devices (ACDs) were developed to capture infectious respiratory aerosols generated by patients at their source. Prior reviews indicated that such devices had low evidence of effectiveness, but did not address how ACDs should be evaluated, how well they should perform, nor have clearly defined performance standards. Towards developing design criteria for ACDs, two questions were posed: 1) What characteristics have guided the design of ACDs? 2) How have these characteristics been evaluated?

Methods: A scoping review was performed consistent with PRISMA guidelines. Data were extracted with respect to general study information, intended use of the device, device design characteristics and evaluation.

Results: Fifty-four articles were included. Evaluation was most commonly performed with respect to device aerosol containment ($n = 31, 61\%$), with only 5 (9%), 3 (6%) and 8 (15%) formally assessing providing experience, patient experience and procedure impact, respectively. Nearly all of the studies that explored provider experience and procedure impact studied intubation. Few studies provided a priori performance criteria for any evaluation metric, or referenced any external guidelines by which to benchmark performance.

Conclusion: With respect to aerosol containment, ACDs should reduce exposure among HCP with the device compared with the absence of the device, and provide $\geq 90\%$ reduction in respirable aerosols, equivalent in performance to N95 filtering facepiece respirators, if the goal is to reduce reliance on personal protective equipment. The ACD should not increase awkward or uncomfortable postures, or adversely impact biomechanics of the procedure itself as this could have implications for procedure outcomes. A variety of standardized instruments exist to assess the experience of patients and healthcare personnel. Integration of ACDs into routine clinical practice requires rigorous studies of aerosol containment and the user experience.

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1. Introduction

Patients with respiratory infectious diseases, including pulmonary tuberculosis, influenza and Coronavirus Infectious Disease 2019

Abbreviations: ACD, Aerosol Containment Device; AIIR, Airborne Infection Isolation Room; APF, Assigned Protection Factor; COVID-19, Coronavirus Infectious Disease 2019; D, Drape Design; FD, Frame with Drape Design; FFR, Filtering facepiece respirator; HCP, Healthcare Personnel; M, Mask Design; NASA TLX, National Aeronautics and Space Administration Task Load Index; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; R, Rigid Box Design; SARS-CoV-2, Severe Acute Respiratory Syndrome Coronavirus 2.

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(COVID-19) can emit infectious aerosols into the environment, resulting in increased risk of disease transmission to susceptible patients and healthcare personnel (HCP). The primary strategies used in healthcare facilities to prevent the transmission of respiratory infectious diseases from patients are airborne precautions, consisting of a combination of the use of negative pressure airborne isolation rooms (AIIRs), use of surgical masks by patients, and the use of surgical masks or respirators by HCP; and droplet precautions, which consist of use of surgical masks by HCP [1]. In the first years of the COVID-19 pandemic, COVID-19 cases overwhelmed the available number of AIIRs, and resulted in shortages of respirators and surgical masks. These circumstances led to rapid innovation in infectious disease prevention strategies, including research into novel designs of personal protective equipment (PPE) to be worn by HCP [2], as well as devices intended to capture infectious

aerosols generated by patients and prevent pathogens from entering the environment.

Out of necessity, the development of aerosol containment devices (ACDs) during the COVID-19 pandemic has been rapid and widespread. For example, members of the University of Utah Center for Medical Innovation developed one such device for head-of-bed procedures like intubation and general respiratory aerosol containment patient transport, vent disconnection and noninvasive airway interventions [3]; this device was utilized in a number settings including the emergency department at University Hospital to reduce environmental contamination and the risk of HCP exposure. The broad adoption of ACDs is not particularly surprising because they offer a local control mechanism, and can be built at low cost using readily-available materials. Sorbello et al. [4] reviewed the literature through May 27, 2020 and found that while a wide variety of ACDs had been described, evidence for effectiveness of ACDs was lacking, with some studies suggesting the devices may hinder airway management. Saito and Asai [5] drew the same conclusions.

The goal of this review differs from prior reviews, in that the focus is on identifying a set of design criteria for ACDs with the purpose of guiding future device design and evaluation, and facilitating comparison between devices. That is, the review seeks to explore how ACDs should perform and how performance should be assessed. To achieve this goal, a literature review was performed guided by two questions: 1) What characteristics have guided the design ACDs? 2) How have these characteristics been evaluated? Findings from the literature review will be discussed in conjunction with best-practices for user-centered design to recommend design and evaluation criteria for current and future ACDs.

2. Methods

Consistent with PRISMA guidelines for scoping literature review performance and reporting, a multi-step approach was used that involved: forming the question, defining inclusion/exclusion criteria and search terms, selecting studies, and extracting data [6,7]. Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) was used to manage the review process. The primary research questions were: 1) What characteristics have guided the design ACDs? 2) How have these characteristics been evaluated? The devices of interest are those intended to contain aerosols generated from the airways or medical procedures involving the head and respiratory tract. Two databases were identified for the literature search: PubMed and Web of Science. PubMed comprehensively covers the medical literature, and the Web of Science comprehensively covers the aerosol science literature. The search strategy shown in Table 1 was implemented on April 22, 2021, and was repeated on August 30, 2021 and May 15, 2022 to identify subsequently published articles. In the last search in Web of Science, the phrase “healthcare OR ‘health care’” was inadvertently omitted from the query, yielding a larger number of articles than in prior searches. Identified literature was exported into Covidence. Studies published prior to 2010 were excluded because ACDs have not historically been a research priority, and preliminary search strategy tests identified few articles to have been published on this topic prior to this date.

Table 1
Search strategy implemented in PubMed and Web of Science

Connection	Terms
	aerosol OR airway OR intubation OR particles
AND	box OR tent OR drape OR barrier OR enclosure OR sheet
AND	containment OR control
AND	healthcare OR “health care”
NOT	respiratory distress” OR “noninvasive ventilation” OR “respiratory failure” OR “airway pressure”
NOT	review
AND	publication since 1/1/2010
AND	English language

Titles and abstracts were independently reviewed by two of five investigators (BH, JB, RMJ, NA and TD) using a priori inclusion and exclusion criteria; disagreements were resolved through discussion. The inclusion criterion used was that the study describes the design or evaluation of a device intended to contain aerosols generated from the patient head and airways. Among the exclusion criteria were: 1) that an article is a review or commentary, 2) that the device is not intended to contain aerosols generated from the head or airways (e.g., for other sources of aerosols), 3) the device studied is intended for dental procedures, and 4) that the study is not about a device intended to contain aerosols, such as PPE for HCP. Full texts were screened by the two of five investigators (BH, JB, RMJ, NA and TD) using the inclusion and exclusion criteria, and differences in selection were resolved through discussion.

Consistent with the approach of a scoping review, included literature was not formally assessed for quality. A custom template was developed in Covidence for data extraction. Data extraction was organized into the following categories:

1. general study information, including study design and participant characteristics;
2. intended use of the device;
3. device design characteristics (e.g., structure type, materials, ventilation, etc.);
4. assessment of provider experience with the device (e.g., cognitive demands, posture and biomechanics, user perception);
5. assessment of device aerosol containment performance;
6. assessment of patient experience with the device, including with participants in experimental simulation setting; and
7. impact of device on the medical procedure or other intended use.

Categories 1–3 were selected to capture general information about the study and device, while categories 4–7 reflect components of user-centered design.

Study designs were classified as experimental simulation, field trials, or descriptive studies. Experimental simulation involved evaluation of the device under controlled conditions in the laboratory or patient care areas using task trainers or participants who were not actually receiving or delivering clinical care. Field trials involved use of the device with patients during clinical care, and included case reports. Descriptive studies only described the device.

For categories 4–7, assessments were considered to have been performed when their methods and results were formally described; otherwise, outcomes were classified as anecdotal. For example, a statement to the effect that providers said the device was easy to use was considered anecdotal unless the methods section identified the systematic use of a survey or interview to collect provider experiences and the results of this data collection are provided, including the number of participants and a descriptive summary of results.

3. Results

The literature searches identified 1144 articles, of which 117 were duplicates. Title and abstract screening excluded 962 articles, leaving 65 for full-text review; 54 articles were included in the review (Fig. 1). All included studies were published in 2020 or later. Thirty-three studies (61%) had corresponding authors from North America (Table S1). There were six studies (11%) that had corresponding authors from South Asia, and nine (17%) from East Asia; other studies had corresponding authors from Australia, Africa and Europe.

Table 2 summarizes the device types and device evaluation components of the included studies, by study design. The devices studied fall into four broad categories: 1) rigid box (R), which has rigid materials (e.g. acrylic sheets) forming the sides of the primary structure but may have drape on the side over the patient's torso, 2) frame with drape (FD), which has a rigid or semi-rigid frame to which one or

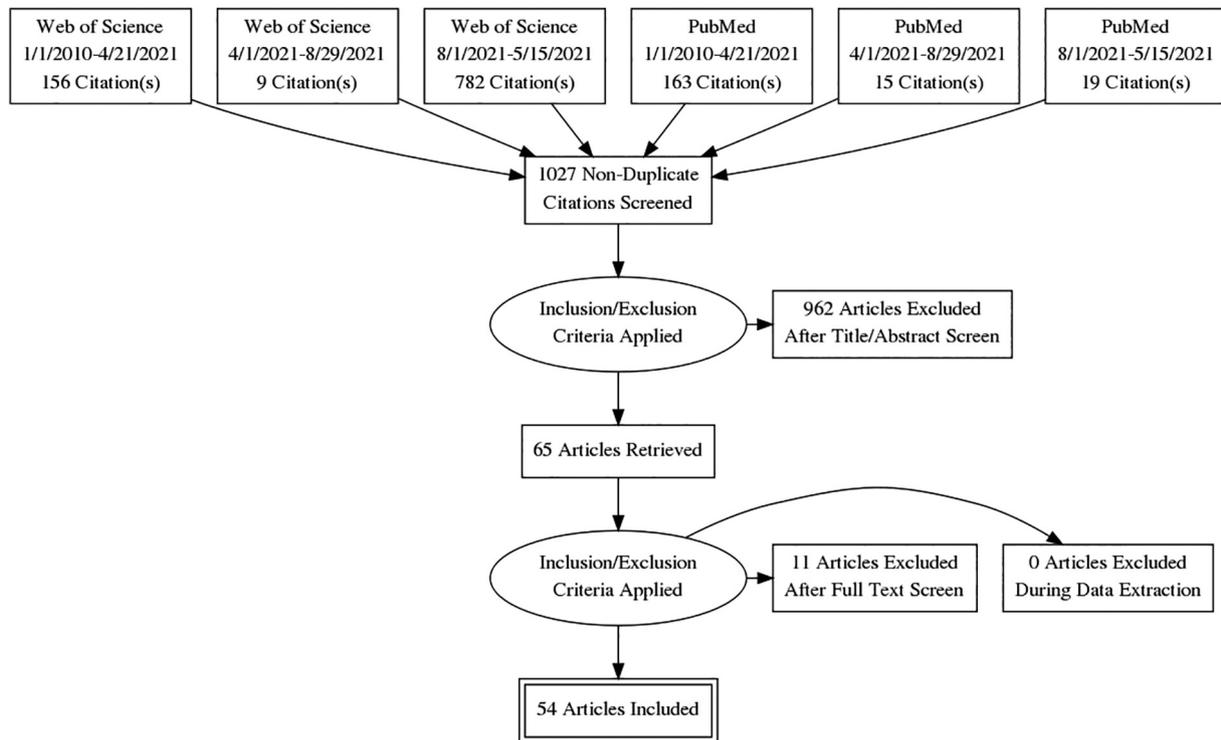


Fig. 1. PRISMA flow diagram.

more drapes were affixed, 3) drape only (D), which has one or more drapes attached to a piece of medical equipment (e.g., microscope) or laid across the patient's body, and 4) masks (M), which were devices worn by the patient to contain aerosols (Table 2). Some studies evaluated more than one device design; two studies were by the same authors and evaluated the same design [8,9]. Experimental simulation was used in the majority of the reviewed studies ($n = 35$, 65%). Field trials were used in 24% of studies ($n = 13$). Eleven percent ($n = 6$) of studies consisted of a description of the device [10–14] only, and therefore are not discussed further. Supplementary Table 1 provides additional details about the device designs and study characteristics.

Four areas of device performance evaluations were identified a priori based on principles of user-centered design, including 1) provider experience with the device, 2) aerosol containment performance, 3) patient experience with the device and 4) impact of device on the medical procedure or other intended use. Table 2 provides an overview of which references performed evaluations in these four areas using formal or anecdotal methods, with latter involving statements reported by the authors in the absence of described structured data collection methods and formal result reporting. Evaluation was most commonly performed with respect to device aerosol containment ($n = 33$, 61%). Only five (9%) studies formally evaluated provider experience, while three (6%) evaluated patient experience. Eight (15%) studies evaluated the impact of the device on some aspect of the intended use, such as ability of providers to perform a medical procedure on a task trainer, or provide a medical procedure to a patient.

Seven of the studies that evaluated device impact on procedure performance studied adult intubation, while one studied endoscopy [15]. Three of the intubation studies assessed procedure performance in patients [16–18], while the others utilized an experimental simulation method with task trainers. Table 3 summarizes the performance metrics used in studies involving intubation procedures. Time to completion of intubation was the most commonly used metric. To assess the device's impact on performance, two studies [11,14] used an a priori threshold (a larger than 10 s increase in time to intubation compared to intubation

procedures without the device present as control condition) whereas one study [19] used a statistical test (noninferiority) as a decision criterion. Two studies measured ease of intubation using the Cormak-Lehane grading system [16,17], while other studies used Likert scales about perceived difficulty. Colman et al. [20] did not directly assess procedure performance, but identified through a simulation-based user-centered design approach a number of design factors with potential impact on procedure performance. Among these factors were device size and set-up requirements potentially delaying patient care, impeding positioning the device, or limiting the use of equipment inside the device. In the study about device impact on endoscopy, the outcomes were mean difference in procedure duration and image quality grade [15].

All five of the studies that evaluated provider experience with the device involved adult intubation as the procedure (Table 2). Colman et al. [20] evaluated provider experience using a facilitated debriefing session after simulation, and identified a number of device design issues related to provider safety, including: loss of negative pressure when opening the device, tearing of device materials, and potential need to initiate procedure before device was in place. Other studies used investigator-developed surveys to assess provider experience, with the topics listed in Table 3. No studies assessed cognitive demands on providers, although Jen et al. [16] reported participant comments to the effect that the device increased cognitive demands during intubation. Further, no studies formally assessed posture nor biomechanics among participants using the devices, though related participant comments – both positive and negative – were noted in several studies [11,16,21–25]. One study reported anecdotally that the participating laryngoscopists noted glare from the device [19].

Patient experience with device use was assessed in three studies. Workman et al. [26] assessed patient satisfaction with wearing a ventilated mask during an ear, nose and throat (ENT) procedure on a 10-point Likert scale. Jen et al. [16] assessed patient perception of comfort and acceptability of a rigid device during intubation on a 5-point Likert scale. Puthenveettil et al. [17] assessed orodental injuries and hemodynamic variables among patients.

Table 2
Device design and study characteristics of included references, sorted by study design.

Reference	Device Design ¹	Device Ventilation ²	Target Patient Pop.	Target Procedure ³	Evaluation			
					Provider Experience	Aerosol Containment	Patient Experience	Procedure Performance
Description Only								
Babazade et al. [11]	D	None	AD	INT	Anec.	N	N	N
Fox et al. [14]	FD	Suction	AD	General	N	Anec.	N	N
Gupta et al. [42]	FD	Suction	AD	General	N	N	Anec.	N
Motara et al. [13]	R	None	AD	INT	Anec.	N	N	N
Rehm et al. [12]	D	None	AD	INT	N	N	N	N
Ueno et al. [52]	R	Suction	AD	General	N	N	N	N
Field Trials								
Bianco et al. [53]	R	None	AD	INT	N	N	N	N
Chow et al. [27]	FD	Suction	AD	ENT Surg	N	Y	N	N
Das et al. [54]	D	Suction	AD	ENT Surg	N	N	N	N
Ghaly et al. [55]	FD	Suction	AD	INT	Anec.	N	Anec.	N
Gonzales-Ciccarelli et al. [56]	FD	Suction	AD	ENT Surg	Anec.	N	N	N
Jen et al. [16]	R	None	AD	INT	Y	N	Y	Y
Leow et al. [57]	D	None	AD	Endoscopy	N	N	N	N
Luk et al. [58]	D	None	AD	INT	Anec.	Y	N	N
Nair et al. [59]	R	Suction	AD	ENT Surg	Anec.	N	N	N
Putthaveetil et al. [17]	R	None	AD	INT	N	N	Y	Y
Sen et al. [18]	R	Suction	PED	PED, RET	N	N	N	Y
Workman et al. [26]	M	Suction	AD	Endoscopy	N	Y	Y	N
Yamamoto et al. [60]	R	None	AD	Bronchoscopy	N	N	N	N
Simulation Experiments								
Abi Karam et al. [47]	M	Fan	AD	General	N	Y	N	N
Blood Jr. et al. [48]	FD	Suction	AD	General	N	Y	N	N
Brant-Zawadzki et al. [3]	FD	Fan	AD	INT	N	Y	N	N
Bryant et al. [39]	FD	Suction	AD	INT	N	Y	N	N
Burnett et al. [38]	R	None	AD	INT	N	Y	N	N
Chari et al. [40]	R	Suction	AD	ENT Surg	N	Y	N	N
Chen et al. [50]	D	None	AD	ENT Surg	Anec.	Y	N	N
Colman et al. [20]	R, FD	None	PED	INT	Y	N	N	Y
Cottrell et al. [23]	D	None	AD	ENT Surg	Anec.	Y	N	N
Daniel et al. [31]	R	Suction	AD	HFNC	N	Y	N	N
Fennelly et al. [41]	FD	Fan	AD	NDT	N	Y	N	N
Fidler et al. [28]	R, FD, D	Suction	AD	General	N	Y	N	N
Fried et al. [29]	D, R	None	AD	INT	N	Y	N	N
Garzona-Navas et al. [61]	FD	Fan	AD	Exercise	N	Y	N	N
Gopesh et al. [51]	R	Suction	AD	NDT & General	N	Y	N	N
Hsu et al. [33]	R	Vaccum	AD	INT	N	Y	N	N
Ibrahim et al. [22]	R, D	None	AD	INT	Anec.	Y	N	N
Issa et al. [43]	R	Suction	AD	INT	N	Y	N	N
Jamaludin et al. [32]	R	None	AD	CPR	N	Y	N	N
Jazuli et al. [36]	R	None	AD	INT	N	Y	N	N
Kikuchi et al. [15]	M	Suction	AD	Endoscopy	N	Y	N	Y
Laack et al. [21]	R	Suction	AD	INT	Y	N	N	Y
Le et al. [35]	R	Suction	AD	General	N	Y	N	N
Lederer et al. [62]	D	None	AD	CPR	Anec.	N	N	N
Lee-Archer et al. [19]	D, FD, R	None/Suction	AD	INT	Y	Y	N	Y
Lumlertgul et al. [24]	R	None	AD	CPR	Anec.	Y	N	N
Maloney et al. [10]	FD	None	AD	INT	N	Y	N	N
Matsui et al. [37]	FD	None	AD	HFNC	N	Y	N	N
Mousavi et al. [9]	FD	Suction	AD	General	N	Y	N	N
Nayak et al. [63]	R	None	PED	RET	N	Y	N	N
Phu et al. [34]	R	Fan	AD	General	N	Y	Anec.	N
Querney et al. [64]	R, FD	None	AD	INT	Y	N	N	Y
Rose et al. [65]	D, R	None	AD	INT	Anec.	Y	N	N
Roth et al. [8]	FD	Suction	AD	General	N	N	N	N
Seger et al. [30]	R	Suction	AD	General	Anec.	Y	N	Anec.
TOTAL WITH ASSESMENT (YES)					5 (9%)	33 (61%)	3 (6%)	8 (15%)

¹ R = Rigid box, RD = rigid box with drape, FD = frame with drape, D = drape only, and M = mask.
² Suction refers to wall suction or portable suction device, including smoke evacuator, surgical waste management system or vacuum; Fan refers to use of a fan to remove air from the device via a duct, typically with filtration.
³ Population is AD (AD) or PED (PED) patients; Procedures include: Intubation/Extubation (INT), general containment or airway procedures, including patient transport (General); ear, nose and throat surgery such as mastoidectomy or tracheostomy (ENT Surg); nebulized drug therapy (NDT); high-flow oxygen nasal cannula (HFNC); and cardiopulmonary resuscitation (CPR).

Among the 33 studies that performed aerosol containment, 19 (58%) involved ventilated devices and 14 (42%) involved unventilated devices (Table 4). In 61% of the studies, a procedure was always ($n = 17$) or sometimes ($n = 3$) performed or simulated by a participant acting as a HCP to some extent during the containment testing. Among the

studies that visually assessed contamination on surfaces outside the device, all of the studies utilized fluorescent material as the tracer except for one study, which used spray paint [10]. Among the studies that visually assessed contamination on participants performing the procedure, all utilized fluorescent materials except for two studies, which used

Table 3
Metrics used to evaluation impact of device on procedure and patient experience for studies involving endotracheal intubation.

Metric	Objective	Subjective	Assess In Patients	Reference
Procedure Performance Metrics				
Time to intubation	X			[16,17,19,21,64]
Proportion of first-pass successful intubation (failed intubations)	X			[16,17,21]
Number of intubation attempts	X			[16]
Total time of airway manipulation	X			[16,19]
Intubation difficulty: Perceived		X		[16,17,21]
Intubation difficulty: Cormak-Lehane Grading	X		X	[16,17]
Proportion with airway loss	X		X	[17]
Hemodynamic variables	X		X	[16,17]
Patient Cough	X		X	[17]
Patient Experience Metrics				
Orofacial injury to patient	X		X	[17]
Perception of comfort of device		X	X	[16]
Perception of acceptability of device		X	X	[16]
Provider Experience Metrics				
Perception of intubation difficulty		X	X	[16,17,21]
Interest in using the device		X		[16,17,21]
Effect on communication		X	X	[64]
Able to perform all required patient care		X		[64]
Effect on ability see what was required		X		[64]
Effect on movement		X		[21,64]
Ease of assembly		X		[64]
Perception of improved safety		X		[64]
Ease of use		X		[19,64]

tissue aerosolized during the procedure [27] and indigo pigment [15]. The studies that visually assessed aerosol containment utilized a variety of materials, including: water vapor generated from fog machines [28–31]; fluorescent dye emitted by a humidifier [32]; smoke generated from smoke powder, smoke tubes or candles [19,33–35]; scented vapor from e-cigarettes [36]; India ink [15]; and denatonium benzoate [35]. Two studies used 2-dimensional laser sheets to look for emission of aerosol from devices [31,37]. Visual assessment results were typically described qualitatively, though Burnett et al. [38] tabulated the number of a priori locations with tracer contamination (Table 4). No studies specified a priori criteria for the impact of the device on surface contamination outside the device or on participants' exposure while performing the procedure.

Quantitative measurement of aerosols occurred predominantly with ventilated devices (Table 4). Supplemental Table 1 summarizes the details of the experimental procedures used for containment testing, including the aerosols used and aerosol sampling equipment. Two studies supplemented experiments with modeling: Le et al. used modeling to determine overall containment, outflow rate from ventilation and leak rate from the device [35], while Mousavi et al. used modeling to calculate the equivalent leakage area for the device [9]. Only one study identified an a priori performance criterion for quantitative aerosol containment, which was a 90% or larger reduction in transmission of airborne particles measured by pragmatic testing [10]. Unfortunately, this study did not use methods to assess aerosol containment quantitatively consistent with definitions in this review. The reviewed studies reported the quantitative aerosol containment in a variety of ways (Table 4). Most commonly, the aerosol concentration outside the device was compared to that within the device [3,34,35,39]; or the aerosol concentration measured at a location outside the device was compared to that measured at the same location without the device [26,28,40,41]. Another metric reported was the time required to evacuate the device of aerosol [3,30,35].

Several studies described the need to maintain negative pressure within the device relative to the outside room [8,31,42,43]. For ACDs, maintenance of negative pressure requires that the airflow into the device that occurs through oxygen or other sources must be exceeded by the exhaust airflow of the ventilation system or suction. Daniel et al.

[31] found that when airflow out of the device from suction was less than airflow into the device aerosol visibly leaked from the device.

4. Discussion

The COVID-19 pandemic spurred interest in the development of engineering controls, such as ACDs, to prevent environmental contamination and occupational exposures to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). In the hierarchy of controls, engineering controls are prioritized over the use of PPE to protect the health and safety HCP and other workers owing to the potential high reliability and effectiveness of engineering controls [44], but use of engineering controls is strongly influenced by whether the design and function is acceptable to users. Devices must also meet safety and regulatory requirements, and through increasingly complex testing demonstrate usability for patients and HCP [45]. This review identified that ACD performance evaluation methods varied widely between investigators, indicating a lack of consensus about how performance should be evaluated, and about appropriate performance targets.

If an ACD is to be used consistently by HCP, it must result in at least a neutral, if not more positive experience for HCP relative to standard practice with respect to user perception, cognitive demands, posture and biomechanics, among other possible factors. Among the literature reviewed, provider or patient experience was assessed in some way in only a minority of studies (Table 2), most of which considered use of the device with endotracheal intubation. With respect to the provider experience metrics assessed measures for intubation (Table 3), it is less of a concern that subjective measures were used than that the investigators did not utilize standardized instruments. Standardized instruments like the NASA TLX or the System Usability Scale that can be informative and allow for direct comparison of study results. These types of assessments are a primary subject of research among Human Factors Engineers, and involvement of these experts in device development increases the likelihood of the development of a successful and user-acceptable or even user-friendly device. With respect to posture and biomechanics assessment, when conducted, it was focused on participants' self-reported ability to perform the necessary tasks or move. While such subjective information is helpful, motion capture studies

Table 4
Aerosol containment testing and performance metrics.

Reference	Device Design ¹	Procedure Performed	Visual Assessment			Quantitative Aerosol	Performance Measures
			Surfaces	HCPs	Aerosol		
Ventilated Devices							
Abi Karam et al. [47]	M	N	N	N	N	Y	Maximum particle concentrations outside device reported, compared with and without aerosol generation.
Blood Jr. et al. [48]	FD	N	N	N	N	Y	Particle concentrations inside and outside device compared at several time points using <i>t</i> -test.
Brant-Zawadzki et al. [3]	FD	Y	NR	Y	N	Y	Time to clear the device of aerosol; Particle concentration measured inside and outside device over time.
Bryant et al. [39]	FD	Y	N	N	N	Y	Maximum particle concentrations inside and outside device compared.
Chari et al. [40]	R	Y	N	N	N	Y	Particle concentrations measured outside device, compared between device and no device conditions with Wilcoxon test.
Chow et al. [27]	FD	Y	N	Y	N		Droplet size inside device and on participants' face shields.
Daniel et al. [31]	R	N	N	N	Y	Y	Tracer concentration measured outside the device, compared between device and no device conditions as percent reduction; Aerosol passing through laser sheet.
Fennelly et al. [41]	FD	N	N	N	N	Y	Particle concentrations inside and outside device compared
Fidler et al. [28]	R, FD, D	N	N	N	Y	Y	Time to clear device of aerosol; top 15% of particle concentrations in each minute outside the device compared between device and no device conditions.
Garzona-Navas et al. [61]	FD	N	N	N	N	Y	Particle concentrations measured in device compared with and without ventilation as percent reduction; time to clearance of 99.9% of particles
Gopesh et al. [51]	R	N	N	N	Y	Y	Mean intensity of pixels in images inside the device over time.
Hsu et al. [33]	R	N	N	N	Y	N	Time to clear device of aerosol.
Issa et al. [43]	R	N	N	N	N	Y	Particle concentrations measured inside device with over time, compared with and without ventilation by ANOVA; particle concentrations over time outside device compared to no device.
Kikuchi et al. [15]	M	Some	N	Y	Y	Y	Percent area of gloved hands contaminated; average particle number concentrations outside device compared with and without device.
Le et al. [35]	R	Some	N	N	Y	Y	Detection of taste of tracer; vapor escaping device; time to clear device of aerosol; estimated overall containment, leak rate and ventilation outflow rate
Mousavi et al. [9]	FD	Some	N	N	N	Y	Calculated equivalent leakage area; particle concentrations as percent of the concentrations inside the device.
Phu et al. [34]	R	Y	Y	Y	Y	Y	Vapor escaping device; particle concentrations inside and outside device compared
Seger et al. [30]	R	Y	Y	Y	Y	N	Locations of tracer contamination; vapor escaping device; time to clear device of aerosol
Workman et al. [26]	M	Y	N	N	N	Y	Particle concentrations outside the device compared between baseline and with device.
Unventilated Devices							
Burnett et al. [38]	R	Y	Y	Y	N	N	Presence on tracer at a priori locations on participants, equipment and surfaces outside the device.
Chen et al. [50]	D	Y	Y	Y	N	N	Percent surface area contaminated with tracer; tracer concentration.
Cottrell et al. [23]	D	Y	Y	Y	N	N	Distance of tracer contamination from surgical site, and on PPE and bodies of participants.
Fried et al. [29]	D, R	N	Y		Y	N	Locations of tracer; vapor escaping device
Ibrahim et al. [22]	D, R	Y	Y	Y	N	N	Locations of tracer
Jamaludin et al. [32]	R	Y	Y	N	Y	N	Locations of tracer; tracer aerosol escaping device
Jazuli et al. [36]	R	N	N	N	Y	N	Detection of odiferous tracer; vapor escaping device
Lee-Archer et al. [19]	D, FD, R	Y	Y	Y	Y	N	Locations of tracer contamination; vapor escaping device
Luk et al. [58]	D	Y	N	N	Y	N	Vapor escaping device
Lumlertgul et al. [24]	R	Y	Y	Y	N	N	Locations of tracer contamination.
Maloney et al. [10]	FD	N	Y	N	N	N	Surface area of exterior containment chamber contaminated.
Matsui et al. [37]	R	N	N	N	Y	Y	Percent change in particle concentrations relative to background; aerosol escaping device
Nayak et al. [63]	R	Y	N	Y	N	N	Locations of tracer contamination.
Rose et al. [65]	D, R	Y	N	Y	N	N	Score of tracer contamination at different locations.

offer a way to quantitatively assess the impact of the ACD on posture and biomechanics. Given that many healthcare activities, such as intubation, are of relatively short duration and performed only periodically by HCP, there is limited concern that the use of an ACD for this procedure increases the risk of musculoskeletal disorders. However, the ACD should not increase awkward or uncomfortable postures or adversely impact biomechanics of the procedure itself in such a way that it limits the ability of HCP to perform tasks using their “usual” or “preferred” motions and body positions, as this could have implications

for the procedure outcomes due to interference with automaticity while performing the procedure.

Of the four domains, patient experience was the most infrequently assessed, and was evaluated in only 6% of the reviewed studies (Table 2). This finding is not particularly surprising given that only 24% of the reviewed studies utilized field trials that could allow for the evaluation of patient experience. These studies, however, considered patients undergoing intubation and endoscopy, procedures which typically involve sedation. Sedation limits the information that can be

gathered from patients about the experience. ACDs may have much broader applications, including applications in which patients are alert and within the device for prolonged times, such as during patient transport or to provide respiratory isolation. For such applications, additional assessments of the patient experience need to be explored. While there are some instruments available that permit assessment of general patient experience and comfort, these instruments may not be applicable to the specific experience of patients undergoing procedures with the newly developed devices. As a result, simple Likert-type scales that are developed for the specific purpose of assessing patient comfort and experience in these settings would allow more structured and standardized data collection and quantification of patient's experience.

Among studies that evaluated the impact of devices on the medical procedure, all studied intubation (Table 2), which is a procedure amenable to objective measures of performance that are clinically relevant, such as time to procedure completion and frequency of success on the first attempt (Table 3). Further research is needed to explore the impact of the devices on a broader range of procedures and contexts in which ACDs are anticipated to be used. While other procedures and contexts may be less sensitive to the speed of procedure completion, they may require greater dexterity, visual acuity or other attributes to perform. Impact of a device on procedure performance is closely related to the user experience and patient experience as impediments to timely, successful procedure performance will frustrate users and patients, and potentially diminish the quality of care.

With respect to aerosol containment, a very wide variety of methods and metrics were utilized in the reviewed studies (Table 4). While qualitative assessment provides a general indication of device performance, the approach is inadequate for assessment of containment performance because visual detection of fluorescent material or smoke is less sensitive a method than quantitative methods for fluorescent material or aerosol concentrations. Given that a single pathogen can initiate infection [46], it is necessary to have a robust quantitative measure of containment performance, including variability in performance, so as to enable informed decision making about the performance of the control relative to other strategies, such as respiratory protection. From the perspective of protection of HCP from inhalation exposures to respiratory aerosols, the best metric would be the percent reduction in the time-averaged concentration in the breathing zone of the HCP with the device relative to normal practice without the device, as this metric most directly reflects the exposure reduction achieved by the device, if any. It is not sufficient that the concentration be statistically significantly different at the same location with and without the device [40], nor that the peak concentrations decrease with the device [28,47], because it is the cumulative number of inhaled pathogens that drives the risk of infection [46]. Comparing the aerosol concentration inside the device to outside the device can provide information on leakage [3,34,39,41,48], but this ratio is not equivalent to the reduction in exposure that the use of the device would provide to the HCP.

Based on the literature reviewed, it is not clear exactly what the aerosol containment performance target should be, other than as high as possible. The standard practice in healthcare to prevent inhalation of airborne-transmissible pathogens in the U.S. has been to wear N95 filtering facepiece respirators (FFRs), which are assumed by the Occupational Safety and Health Administration to reduce exposure by 90% when used in the context of an effective respiratory protection program. Specifically, N95 FFRs have an Assigned Protection Factor (APF) of 10, which means the aerosol concentration inside the facepiece is 1/10th the concentration outside the facepiece; powered air-purifying respirators of the type used in U.S. healthcare facilities have APF = 25, offering a 96% reduction in exposure [49]. Should the aerosol device be intended to decrease reliance on PPE, it would seem that performance should meet or exceed that exposure reduction offered by respiratory protection. Data from the reviewed articles and preliminary testing of similar devices by our research team indicate that such a performance target should be readily attained with a ventilated ACD.

Negative pressure is general principle in ventilation, and is used to control the direction of airflow between two spaces (e.g., from the room into the ACD). Roth et al. [8] utilized the negative pressure guideline of -2.5 Pa recommended for AIIRs by the Centers for Disease Control and Prevention as a benchmark for evaluation of their ACD. It's not clear that this AIIR guideline is appropriate for ACDs. In particular, a lower pressure difference may be adequate. Negative pressure alone, however, is not sufficient to demonstrate aerosol containment, as the pressure gradient can be disrupted by human activities, such as opening or closing ports, allowing aerosols to leak. Thus, while maintaining a target negative pressure may be a reasonable performance goal, the device should also be evaluated to ensure aerosol containment occurs under realistic use conditions.

Though this review did not specifically evaluate the quality of the studies, as the focus was on the types of evaluations performed and their metrics rather than on the specific results obtained, many studies had significant limitations in their experimental design. Types of limitations included: few or no experimental replicates [22,41,50,51], incomplete reporting of experimental replicates [32,40,43], lack of or inappropriate statistical analyses [43,47,48,50], and lack of methodology for some reported results (e.g., anecdotal information, Table 3). While many of the studies reviewed may be considered exploratory, rigorous study designs and methods are required to demonstrate efficacy and effectiveness of ACDs if they are to be incorporated into routine practice as a control system.

While the use of ACDs in U.S. hospitals has diminished with the reduction of COVID-19 hospitalizations and existence of adequate PPE supplies, other applications for ACDs, including patient transport and settings where patient isolation in AIIRs is infeasible, warrant continued research and development of ACDs. Further, the reliance of healthcare facilities on PPE to prevent infection transmission to HCP and susceptible personnel should be reconsidered in light of well-known limitations with PPE compliance and performance. ACDs are an engineering control that can have myriad benefits for infection prevention.

5. Conclusion

ACDs are a novel, promising control strategy to reduce the environmental contamination and the risk of exposure of HCP and patients to infectious respiratory aerosols. As illuminated by this review, assessment of the performance of these devices have been limited in scope and by experimental methods and study design. Beyond aerosol containment performance, device development would benefit from a comprehensive user-centered design approach that incorporates the multiple dimensions of the HCP and patient experience, as well as implementation research studies to explore how these devices can be effectively incorporated into routine clinical practice. Devices that seek to reduce utilization of PPE should reduce HCP exposures to aerosols equivalent to or better than the protection offered by respiratory protection.

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Rachael M. Jones: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Niles Andrus:** Writing – original draft, Methodology, Formal analysis, Data curation. **Thomas Dominguez:** Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. **Jeremy Biggs:** Writing – review & editing, Investigation, Formal analysis. **Brian Hansen:** Writing – review & editing, Project administration, Formal analysis, Data curation. **Frank A. Drews:** Writing – review & editing, Methodology, Conceptualization.

Declaration of Competing Interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ajem.2022.11.007>.

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