



State of the science review

Isolation gowns in health care settings: Laboratory studies, regulations and standards, and potential barriers of gown selection and use



F. Selcen Kilinc Balci PhD *

National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Pittsburgh, PA

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Although they play an important role in infection prevention and control, textile materials and personal protective equipment (PPE) used in health care settings are known to be one of the sources of cross-infection. Gowns are recommended to prevent transmission of infectious diseases in certain settings; however, laboratory and field studies have produced mixed results of their efficacy. PPE used in health care is regulated as either class I (low risk) or class II (intermediate risk) devices in the United States. Many organizations have published guidelines for the use of PPE, including isolation gowns, in health care settings. In addition, the Association for the Advancement of Medical Instrumentation published a guidance document on the selection of gowns and a classification standard on liquid barrier performance for both surgical and isolation gowns. However, there is currently no existing standard specific to isolation gowns that considers not only the barrier resistance but also a wide array of end user desired attributes. As a result, infection preventionists and purchasing agents face several difficulties in the selection process, and end users have limited or no information on the levels of protection provided by isolation gowns. Lack of knowledge about the performance of protective clothing used in health care became more apparent during the 2014 Ebola epidemic. This article reviews laboratory studies, regulations, guidelines and standards pertaining to isolation gowns, characterization problems, and other potential barriers of isolation gown selection and use.

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Many items, including gowns, drapes, masks, sheets, towels, and blankets, used in health care settings are composed of textile materials. These are known to be suitable substrates for bacterial and fungal growth under appropriate moisture and temperature conditions. Several studies showed that textiles play an important role in infection prevention and control, whereas others highlighted the dissemination of microorganisms through textiles or personal protective equipment (PPE).^{1–21}

Microorganisms' movement through isolation gown fabrics depends on several factors, including the physical and chemical properties of the fabric, the shape and surface characteristics of the microorganisms, and the characteristics of carriers, and other factors such as physical and chemical stresses. A number of fabric and

design characteristics, such as fabric and seam strength, pore size, repellency, size, fit, thermal comfort, mobility, and interfaces, can also contribute to the effectiveness of isolation gowns. Isolation gowns offer varying performance depending on all of this cited properties.^{22–24} Several clinical studies that show the effectiveness of gown use (isolation gown, cover gown, or surgical gowns) have reached mixed conclusions. Although some studies show no benefit of the routine use of isolation gowns,^{25–31} others demonstrated that the infection rate is reduced by use of protective apparel.^{32–35} This article reviews laboratory studies, regulations, guidelines and standards pertaining to isolation gowns, characterization problems, and other potential barriers of isolation gown selection and use.

LABORATORY STUDIES

Gowns have been used for years in hospital settings to reduce cross-transmission and the risk of disease acquisition by health care workers (HCWs). There are several studies that deal with the

* Address correspondence to F. Selcen Kilinc Balci, PhD, National Personal Protective Technology Laboratory (NPPTL/NIOSH/CDC), 626 Cochran Mill Rd, T-403-107, Pittsburgh, PA 15236.

E-mail address: [jqc8@cdc.gov](mailto:jcq8@cdc.gov).

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effectiveness of gown use, and past findings have shown that gowns offer varying resistance to blood and that the effectiveness in preventing blood contact varied according to the type of material, its impermeability-permeability, and its wear and tear.²²⁻²⁴ In these studies, several methods have been used to assess barrier effectiveness, including visual penetration of blood and other body fluids, monitoring the occurrence of hospital-acquired infections (HAIs), attaching agar plates to the inside or outside of the gown and then evaluating for the presence of microorganism growth caused by transmission, and standardized and nonstandardized laboratory tests.

There is no study found which reviews isolation gowns specifically; however, several excellent reviews of surgical gowns and drapes have been published recently.^{24,36,37} There have been many clinical studies in regard to the barrier effectiveness of protective clothing in health care^{25,27,28,38-46} and laboratory studies evaluating the barrier effectiveness under various conditions.⁴⁷⁻⁵¹

There are studies that examined the effectiveness of cover or isolation gowns demonstrating no benefit to their routine use.^{25-31,37,52-55} Multiple studies have also failed to demonstrate that the routine use of cover gowns decreased bacterial colonization of infants or overall nosocomial infection rates.²⁹⁻³¹ Cover gowns were not well-defined in the articles; however, it is believed that isolation gowns, with or without barrier claims, were used for these studies. In fact, a cover gown and isolation gown are 2 different types of garments; however, because of the confusion in the marketplace over the terminology of gowns, sometimes the term cover gown is used for defining an isolation gown. Isolation gowns are defined by the Association for the Advancement of Medical Instrumentation (AAMI) as "the protective apparel used to protect HCWs and patients from the transfer of microorganisms and body fluids in patient isolation situations." However, a cover gown is an article of clothing worn over an operating room (OR) scrub suit-dress when OR personnel leave the OR suite (eg, to go to lunch) to prevent soiling of the OR scrubs outside of the OR.

Other studies found that, by use of gowns, the infection rate was reduced (there is no mention of the gown type except in Srinivasan et al⁵⁶ and Belkin,⁵⁷ in which cover gowns were used).^{32-35,56,57} Klein et al³³ reported a reduction in nosocomial infection during pediatric intensive care when protective, high-barrier gowns and gloves were used. Both glove and gown use compliance have been reported to reduce the rate of nosocomial respiratory syncytial virus (RSV) infection among children by Leclair et al.³⁴ Madge et al³⁵ found that, combined with rapid laboratory diagnosis and cohort nursing, the wearing of gowns and gloves for all contacts with RSV-infected children can significantly reduce the risk of nosocomial RSV infection. They also found that neither the use of gowns and gloves alone nor the cohort nursing alone produced a significant reduction in cross-infection. Using cover gowns (disposable polypropylene gown) showed a significant benefit for the routine use of gowns and gloves over gloves alone.⁵⁶

There are studies that show that control of vancomycin-resistant enterococci (VRE) outbreaks has been achieved by use of disposable gowns when entering the rooms of patients with known or suspected colonization (no mention of the type of the gown used).^{58,59} However, Slaughter et al⁶⁰ found that isolation gowns (a disposable polypropylene gown which can withstand 11.5 cm of hydrostatic pressure) do not offer added protection against VRE infection over glove use alone in an intensive care unit of a hospital with endemic VRE; however, Puzniak et al⁶¹ reported that gowns (no mention about the type of gown used) have a protective effect. Slaughter et al⁶⁰ also suggested that gown use might provide enhanced awareness of transmission dynamics and increase compliance with infection prevention and control procedures. Additional studies have shown that enhanced infection prevention and control strategies were associated

with increased compliance without mention of the gown type used.⁶¹⁻⁶³ There were other studies that showed that use of protective clothing (gowns, nurse uniforms, surgical gowns, and surgical scrubs) was effective in infection control.⁶⁴⁻⁶⁷ Because limited information was provided about the type of the gown used in these studies, it is difficult to make a clear conclusion about the gown performance especially for the studies that were conducted before 1995.

Some researchers have identified factors related to barrier properties of surgical gowns, such as amounts and durations of pressure exerted on gowns, the period of time that the gown was worn, and prewetting of the fabric with blood or other liquids.^{43,68,69} It is apparent that the conditions of use greatly influence the performance of any gown; however, the limited information provided regarding specific gown characteristics in these references makes it difficult to identify gown characteristics that relate to barrier efficiency.

Reusable versus disposable gowns

Hospital isolation gowns are fabricated from either reusable (multiuse) or disposable (single use) materials. These 2 basic types of products each have advantages and disadvantages in terms of protection, maintenance, comfort, cost, and environmental impact.⁷⁰ Within each of these categories, there is considerable variation in design and performance characteristics.

Disposable isolation gowns are designed to be discarded after a single use and are typically constructed of nonwoven materials alone or in combination with materials that offer increased protection from liquid penetration, such as plastic films. Various forms of synthetic fibers (eg, polypropylene, polyester, polyethylene) are used for the construction of disposable isolation gowns. Reusable (multiuse) isolation gowns are laundered after each use and typically made of 100% cotton, 100% polyester, or polyester-cotton blends. Several studies made comparisons of different materials (eg, reusable, disposable), and with different wearers and produced mixed results. A consistent finding is that, although impermeable materials are effective in reducing transfer of microorganisms, the thermal comfort of the wearer is compromised.²⁴ Also, several studies have evaluated penetration of blood, other fluids, and bacteria through surgical gowns and coats; results showed penetration occurs in some of the clothing.^{23,40,42-46,71}

A limited number of studies have compared the performance of reusable and disposable isolation gowns. Lovitt et al²² assessed the resistance to penetration by human blood of 11 types of disposable isolation gowns and 1 type of reusable isolation gown (new and washed 40 and 80 times) at 5 different pressures (0.25-2 psi) and 6 durations (1 second-2 minutes). Their testing showed significant differences in the amount of strikethrough (the extent of liquid penetration) allowed by the gowns and demonstrated important differences in the gowns' protective capabilities. Granzow et al⁷² evaluated 6 gown types used in hospitals (1 disposable cover or isolation gown, 3 disposable surgical gowns, and new and washed reusable surgical gowns). Gowns were evaluated for dry spore and *Staphylococcus aureus* filtration efficiencies and were subjected to 20 time-pressure combinations with methicillin-resistant *S aureus*-spiked blood to evaluate blood strikethrough and passage of methicillin-resistant *S aureus*. They found that disposable surgical gowns made of polypropylene, spunbonded-meltblown-spunbonded laminate offered higher fluid resistance than gowns made of polyester-wood pulp blend and that disposable cover gowns made of polypropylene only allowed passage at pressures >1 psi. They concluded gowns therefore should be chosen according to the task performed and conditions encountered.

Rutala and Weber³⁶ reviewed studies in regard to the strike-through protection performance of disposable and reusable gowns

(both surgical and isolation gowns). However, because development of a new standard⁷³ led to the introduction of gowns that comply with that standard, it is accepted by researchers that studies conducted before 2000 may not reflect the performance of currently available products.^{36,70}

Several researchers have also considered the effects of laundering on the barrier effectiveness of reusable protective clothing and reached mixed conclusions.^{24,36,44,48,50,72,74} These studies mostly used surgical gown samples. In general, researchers have reported that laundering reduces the ability of the fabric to prevent the transmission of microorganisms through the fabrics as a result of abrasion and damage during wearing and the breakdown of the fabric during laundering. Gowns reinforced with other layers were generally reported to remain protective to a defined point (ie, launderings).

Both disposable and reusable gowns have an environmental impact, which was evaluated by researchers.^{36,70} Based on an evaluation of the functional requirements, environmental impact, and economics of gowns, clear superiority of either reusable or single-use gowns and drapes cannot be demonstrated.

REGULATIONS FOR ISOLATION GOWNS

Food and Drug Administration

PPE devices intended for use in preventing disease in health care are considered medical devices in the United States and are subject to regulation under the device provisions of the Federal Food, Drug, and Cosmetic Act. This includes surgical gowns and isolation gowns. The Food and Drug Administration (FDA) is the principal agency for approving PPE for use by HCWs.^{75,76}

PPE used in health care is regulated as either class I or class II devices by the FDA. The 21 CFR 878.4040⁷⁷ classifies surgical gowns as class II (special controls) and apparel other than surgical gowns (including isolation gowns) as class I (general controls). The class I devices, including isolation gowns, are considered low risk to the wearers and normally exempt from the premarket notification requirements. Premarket notification procedures require manufacturers to demonstrate that the device to be marketed is substantially equivalent (at least as safe and effective) to a legally marketed device (a device which was approved by the FDA previously). The basic requirement for isolation gowns is that the manufacturer meets general standards for good manufacturing processes. Class II devices, such as surgical gowns, are considered intermediate risk and must be cleared through the premarket notification process [or 510(k) process] to demonstrate that the device meets specific voluntary standards and is substantively equivalent to a similar predicate device before it is allowed to be marketed by the FDA. Although the FDA does not have any specific PPE requirements for protection against infectious diseases, its regulations are designed to control the manufacture and sale of PPE.^{75,76} In the United States, requirements regarding the use of PPE in health care are overseen by the Occupational Safety and Health Administration (OSHA) along with state and local agencies and employers. There are no mandatory standards that drive device selection and use, and certification is not mandatory either.

OSHA

The OSHA has the primary responsibility for enforcing the proper use of PPE in health care facilities in the United States. The main regulation relevant to isolation gown (protective clothing) use by HCWs relevant to infectious diseases is 29 CFR §1910.1030.⁷⁸ The OSHA proposed the document in 1991, and it is a standard designed to eliminate or minimize occupational exposure to bloodborne

pathogens when it is determined that HCWs have a significant health risk as a result of occupational exposure to blood and other potentially infectious materials (OPIM), which may contain blood-borne pathogens. This regulation mandates the principles of universal precautions and allows employers to specify what PPE is required and when it must be used. Although the OSHA requires the use of specific equipment, it does not regulate the marketing of isolation gowns or grant claims of disease prevention.⁷⁵

STANDARDS, GUIDELINES, AND PRACTICES

Many organizations have published guidelines for the use of PPE, including isolation gowns, in U.S. health care settings. These organizations include the Centers for Disease Control and Prevention (CDC), Association of periOperative Registered Nurses, OSHA, and AAMI.

The OSHA does not have specific standards covering the use of PPE by HCWs and does not require that such PPE be cleared by the FDA. For isolation gowns, there is no standard that considers not only the barrier resistance but also a wide array of end user attributes to guide infection preventionists to select the most appropriate gown. There is only one standard available currently for isolation gowns,⁷³ and it establishes a system of classification based on liquid barrier protection. Recently, a new task group (ASTM International WK33313 - New specification for non-sterile isolation gowns intended for use in health care facilities⁷⁹) was formed in the ASTM's F23 Committee on Protective Clothing and Equipment, with FDA and CDC's participation, to develop a standard specification for nonsterile isolation gowns. Development of a standard is intended to improve users' understanding of levels of protection to be provided.

A brief summary of the current guidelines, recommended practices, and standards related to isolation gowns follows.

CDC

In 2007 the CDC published an update entitled *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings*.⁸⁰ According to the CDC guideline, isolation gowns are used to protect HCWs' arms and exposed body areas and prevent contamination of clothing with blood, body fluids, and OPIM. The need for and type of isolation gown selected is based on the nature of the patient interaction, including the anticipated degree of contact with infectious material and potential for blood and body fluid penetration of the barrier. The CDC recommends that HCWs should wear gowns that are appropriate to the task to protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities when contact with blood, body fluids, secretions, or excretions is anticipated.⁸⁰

American National Standards Institute/AAMI

ANSI/AAMI:PB70, which was revised in 2012, establishes a system of classification for protective apparel used in health care facilities, based on their liquid barrier performance.⁷³ It also specifies labeling requirements and test methods for determining the compliance of protective apparel labeled with liquid barrier claims or liquidborne microbial barrier claims, including single- and multiple-use isolation gowns, surgical gowns and other garments that are regulated by the FDA as medical devices. The standards were published and accepted by the FDA in 2004 and revised in 2009 and 2012.⁷³ Additionally, AAMI published a technical information report (a guidance document) that covers the selection and use of protective apparel and surgical drapes in health care facilities.⁸¹ It is developed to guide infection preventionists, safety

officers, and other product committee members for consideration of many other attributes related to the safety and efficacy of protective clothing during selection. Some of the safety and performance characteristics of protective clothing identified by the technical information report are barrier effectiveness, abrasion resistance, strength, comfort, staining, discoloration, electrostatic properties, flammability, lint generation, shrinkage, sustainability, and biocompatibility. Other factors to be taken into consideration are compliance with regulatory guidelines, efficiency, cost-effectiveness, and environmental concerns.

The ANSI/AAMI:PB70⁷³ standard includes 4 standard tests to evaluate the barrier effectiveness of protective gowns (including surgical gowns and isolation gowns) and drapes. These test methods are as follows:

- Impact Penetration Test, which measures the resistance of fabrics to penetration of water by spray impact (at 1 psi), as measured by weight gain of a blotter. A lower number represents higher resistance.⁸²
- Hydrostatic Pressure Test, which measures the resistance of fabrics to penetration of water under constantly increasing hydrostatic pressure (0.25-2.0 psi), measured as hydrostatic resistance (cm). A higher number represents higher resistance.⁸³
- Synthetic blood penetration resistance, which is used to evaluate the resistance of materials to penetration by synthetic blood under conditions of continuous liquid contact and only applies to surgical drapes. Results are reported on a pass or fail basis.⁸⁴
- Bloodborne pathogens penetration resistance, which measures the resistance of materials used in protective clothing to penetration by bloodborne pathogens, using a surrogate microbe under conditions of continuous liquid contact. Results are reported on a pass or fail basis.⁸⁵

Based on the results of these standardized tests, 4 levels of barrier performance are defined, with level 1 being the lowest level of protection and level 4 being the highest level of protection.⁸¹

ANSI/AAMI:PB70⁷³ identifies certain areas of surgical and isolation gowns as critical zones. According to the standard, the whole garment is considered a critical zone for isolation gowns because of the unpredictable types of potential contact with blood, body fluids, and OPIM, whereas for surgical gowns the critical areas are listed as torso and sleeves. The fabrics, areas of construction within the critical zones and critical points of attachment and seams are required to be tested. The entire isolation gown, including the seams, but excluding the cuffs, hems, and bindings, must achieve a barrier performance of at least level 1. Open-backed isolation gowns do not meet the critical area parameters and therefore cannot be rated.^{81,86}

It is recommended in the AAMI technical information report⁸¹ that when choosing products, anticipated volume of blood, body fluids, OPIM, or other liquids and the type and duration of procedure or activity being performed should be considered. End users are recognized as the best judges of the barrier level required, based on experience and the potential of known exposure risks.

Because ANSI/AAMI:PB70⁷³ does not specify the appropriate clinical procedures or environments for each AAMI level, in order to provide that information, in 2008, an independent organization conducted a survey of people who had to either wear isolation gowns or have responsibility for purchasing isolation gowns for their facilities.⁸⁶ Accordingly, possible relationships between gown barrier performance and clinical procedure exposure risks were displayed in a table in the AAMI technical information report.⁸¹ For example, AAMI level 2 classified isolation gowns may be suitable for the types of procedures with anticipated exposures as those

usually performed in radiology, cardiac catheterization and endoscopy laboratories, medical-surgical supply areas, depending on degree of anticipated exposures.

Other agencies and organizations

A number of other organizations, such as the Joint Commission and Association for Professionals in Infection Control and Epidemiology, also impact the use of PPE by HCWs.

Table 1 summarizes the relevant standards for HCWs' protective clothing used in the United States.

POTENTIAL BARRIERS TO PROTECTIVE APPAREL SELECTION AND USE

Lack of knowledge, compliance, and end user issues

The medical and financial complications associated with nosocomial infections have had a significant impact on hospitals.⁹⁹⁻¹⁰¹ Although several practices have been demonstrated to be effective controls, the success of infection control depends on compliance by HCWs. Given the potential for the transfer of infectious diseases among patients in isolation, HCWs, other patients, and visitors, the proper use of PPE and compliance are critical.

Significant compliance issues have been identified in health care, especially with protective gown use. Manian and Ponzillo¹⁰² examined compliance of gown wear for HCWs and visitors to general wards and an intensive care unit. Overall compliance by HCWs was 76%, whereas visitors complied 65% of the time. It was pointed out in this study that educational efforts should be increased. Gammon et al¹⁰³ reviewed the compliance of HCWs to standard-universal infection control precautions and concluded that it is far from what is recommended. Some studies pointed out that the lack of compliance is linked to higher education levels and longer number of years of experience.^{104,105} Other issues have been noted as lack of supplies and staff time, educational issues, including inadequate understanding of standard precautions and isolation practices, and clinical staff issues, such as low-risk perception or mentors who model noncompliant behavior. Those responsible for purchasing may have a lack of knowledge about current isolation guidelines,⁸⁰ relevant standards, types of protective clothing, degree of protection provided, relationship of AAMI levels for gown selection, and types of clinical procedures for which they may provide adequate protection. Some criteria for isolation gown selection and use, which have been found critical to improve compliance with protective clothing use, have been identified and include the following: adequate size choices, microbial filtration efficacy of the fabric, liquid barrier adequacy, perceived comfort, ability to remove gown without self-contamination, ease of disposal (if single use), and assurance of adequate supply.⁸⁶

A survey conducted by a manufacturer among HCWs that wear isolation gowns or have responsibility for purchasing protective apparel for their facilities reported that 38% of respondents were aware of AAMI guidelines and that AAMI guidelines were factored into purchase decisions on isolation gowns 73% of the time. Only 26% of the respondents who use AAMI guidelines as a basis in purchasing gowns could identify a specific performance requirement in level 2.^{106,107} ASTM's Work Group⁷⁷ also reached similar results in a survey conducted in 2011.¹⁰⁸

In a Gallup poll by a surgical gown manufacturer, it was determined that more than half of the surgeons and OR nurses wanted to provide input for the selection of the gowns they wear. Although 66% of surgeons and 90% of nurses involved in high fluid surgical

Table 1
Example of relevant protective clothing standards and guidelines

Organization	Standard
ASTM	F1670 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood ⁸⁴ F1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System ⁸⁵ F2407 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities ⁸⁷ F1819 Standard Test Method for Resistance of Materials Used in Protective Clothing for Penetration by Synthetic Blood Using a Mechanical Pressure Technique ⁸⁸
AAMI/ANSI	F903 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Liquids ⁸⁹ TIR No.11 Selection & Use of Protective Apparel & Surgical Drapes in Health Care Facilities ⁸¹ ANSI/AAMI:PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Healthcare Facilities ⁷³ AAMI/ANSI ST65:2008/R(2013) Reprocessing of Reusable Surgical Textiles for Use in Health Care Facilities ⁹⁰
NFPA	NFPA: 1999 Standard on Protective Clothing for Emergency Medical Operations ⁹¹
AORN	Recommended Practices for Selection and Use of Surgical Gowns and Drapes ⁹²
AATCC	AATCC 42 Water Resistance: Impact Penetration Test ⁸² AATCC 127 Water Resistance: Hydrostatic Pressure Test ⁸³
AST	Standards of Practice for Gowning and Gloving ⁹³
CDC	1998 Guideline for Infection Control in Hospital Personnel ⁹⁴ 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007 ⁸⁰ Guideline for the Prevention of Surgical Site Infection, 1999 ⁹⁵ Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing) ⁹⁶ Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids ⁹⁷
Healthcare Laundry Accreditation Council	Accreditation Standards for Processing Reusable Textiles for Use in Healthcare Facilities ⁹⁸

AAMI, Association for the Advancement of Medical Instrumentation; AATCC, American Association of Textile Chemists and Colorists; ANSI, American National Standards Institute; AORN, Association of periOperative Registered Nurses; AST, Association of Surgical Technologists; CDC, Centers for Disease Control and Prevention; NFPA, National Fire Protection Association.

procedures want to wear gowns that are liquid proof (instead of liquid resistant), far fewer actually wear such gowns, even during high-fluid procedures.¹⁰⁹

Rucker et al determined perceptions of HCWs about potential sources of HAI by a survey that included questions about perceptions of 10 potential sources of HAI and any instances of surgical gown failures (critical incidents) and reported that strikethrough was one of the most common problems.¹¹⁰ They also found that patient and HCW safety and availability were the 3 most important factors when using protective gowns.¹¹¹

Characterization problems

Although HCWs are personally interested in the differences in protective ability between gowns, comparisons have been difficult because of varied testing procedures, standards, and lack of information. The primary performance characteristic of an isolation gown is its effectiveness in providing the appropriate level of protection against penetration of liquids and microorganisms. An effective microbial barrier must resist both wet and dry penetration of microorganisms. Several studies reported that when liquid containing microorganisms penetrates a material, microorganisms are carried with it, and they can penetrate a material without liquid being visible.^{71,112} However, end users generally associate the lack of visible strikethrough with the lack of microbial transfer.

Other important safety and performance properties may include abrasion resistance, strength, softness, drapeability, breathability, stain resistance, flammability, propensity for linting and electrostatic charge, pilling, toxicity, sizing, and color. Even though the methods developed to evaluate these properties are accepted and widely used in the industry, there is still ongoing disagreement on the effectiveness of barrier performance evaluation methods. Multiple difficulties have been described in the literature regarding the evaluation of the barrier effectiveness of isolation gowns. The problems determined by the researchers were summarized as follows:

- Only the AAMI highest level requires testing for bacterial penetration.⁸⁵ However, most of the end users think that they

are protected from blood, other body fluids, and OPIM when they wear any type of isolation gown.

- Laboratory testing may not mimic actual in-use testing,^{37,68,113} and it has been suggested that gowns should be tested both under conditions of use and in the laboratory settings.^{45,114} Additionally, no study has been found that investigates the stresses generated during patient care activities with isolation gowns.
- Because the surface tension of water is much higher than that of blood, blood can penetrate fabrics more readily than water. Therefore, no correlation can be made between different AAMI levels.
- ASTM tests (F1670 and F1671) used for testing barrier effectiveness are rated on a pass or fail basis, which prevents determining the performance capability of a product for the “degree of exposure anticipated” and identifying material that can resist penetration at varying pressure levels.¹¹⁵
- Hydrostatic pressure is applied in the ASTM tests (F1670⁷⁷ and F1671⁷⁹) for assessing barrier effectiveness. Mechanical pressure, which might be applied by HCWs during patient care (eg, bending, leaning, kneeling), was not considered in the test methods.
- The shape, size, and polarity of the virus might greatly affect the viral penetration properties of fabrics. The bacteriophage used in ASTM F1671/F1671M-13 viral penetration resistance test method (phi-X174) may not be applicable to characterize the penetration properties of all types of viruses with different morphology (eg, Ebola virus).

SUMMARY

Isolation gowns offer varying resistance to blood depending on the type of the material, its impermeability-permeability, its wear and tear, and its processing conditions. Although laboratory studies have produced mixed results for the effectiveness of gown use, appropriate gowns are recommended to prevent or reduce exposure to bloodborne pathogens of HCWs.

Many organizations have published guidelines for the use of PPE in medical settings. In addition, the AAMI published a standard on

liquid barrier performance classification protective clothing used in health care. However, there is currently no existing standard on isolation gowns which includes performance and design criteria and addresses the interface problems. As a result, several difficulties are faced in the selection process. Furthermore, end users have limited or no information on the gown they use during isolation conditions. It was determined that there is an urgent need to establish performance and design requirements for isolation gowns that guide HCWs in selecting the appropriate isolation gown. Recently, a Task Group was formed in ASTM to develop a specification standard for isolation gowns. In collaboration with ASTM and FDA, the National Personal Protective Technology Laboratories of the National Institute for Occupational Safety and Health under the CDC has started a research project to understand the effectiveness of current isolation gowns and determine performance and design requirements. A new standard document, which explains critical performance and design properties, can aid HCWs in the selection process, improve end users' understanding of the levels of protection provided by isolation gowns to select the right gown for the procedure, and can increase compliance.

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