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State of the science review

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

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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.

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

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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 al[56] and Belkin,[57] in which cover gowns were used).[32-35,56,57] Klein et al[33] 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 al[35] 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 al[60] 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 al[61] reported that gowns (no mention about the type of gown used) have a protective effect. Slaughter et al[60] 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 al[22] 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 al[72] 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 Weber[36] reviewed studies in regard to the strikethrough protection performance of disposable and reusable gowns