

THE CLINICAL ISSUE



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INTRODUCTION

In 2007, the Centers for Disease Control and Prevention (CDC) published the **Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007** (2007 Isolation Guideline),¹ which builds upon a series of isolation and infection prevention documents that have provided clinical guidance since 1970. One of the most important and possibly understated components of the 2007 Isolation Guideline is the reaffirmation of Standard Precautions, initially recommended in the 1996 **Guidelines for Isolation Precautions in Hospitals**,² as the foundation for preventing infectious pathogen transmission during patient care in all healthcare settings. Also reaffirmed was the importance of implementing Transmission-Based Precautions based on the clinical presentation or syndrome and likely pathogens until the infectious etiology has been determined. The underpinnings of these precautions are the consistent, anticipatory performance of hand hygiene and donning of personal protective equipment (PPE), as well as careful removal and disposal after use.

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STANDARD PRECAUTIONS AND THE HEALTHCARE WORKER

The primary focus of Standard and Transmission-Based Precautions is the prevention of patient exposure to pathogens which may result in colonization and infection. Patients are the population at highest risk of infection acquisition in the healthcare setting; however, healthcare workers (HCWs) are susceptible to infections in the clinical environment as well. One has only to review data published after the Severe Acute Respiratory

Image 1.



The SARS outbreak in Toronto illustrated the critical importance of PPE use in healthcare facilities (Image Courtesy of University Health Network, Toronto, Canada).

Syndrome (SARS) outbreak in Toronto to appreciate that fact.^{3,4} PPE, when appropriately selected and used, does protect both the patient and the HCW. After gloves, the most commonly used PPE are gowns. As part of Standard Precautions, isolation gowns are to be worn to protect the HCWs' arms and exposed body areas during procedures and patient-care activities when anticipating contact with: clothing, blood, body fluids, secretions and excretions.¹ Contact Precautions, a component of the Transmission-Based Precautions, recommends routine use of gowns along with gloves for all patients infected with multi-drug resistant organisms (MDROs) and for patients who have been previously identified as being

colonized with methicillin-resistant **Staphylococcus aureus** (MRSA) or Vancomycin-resistant Enterococcus (VRE). The goal of Transmission-Based Contact Precautions in addition to Standard Precautions is to prevent cross-transmission of other potentially infectious materials (OPIM) that may contaminate the environment, common use equipment and HCWs' clothing. According to the 2007 Isolation Guideline, the need for and type of isolation gown selected should be based on the nature of the patient interaction including (1) the anticipated degree of contact with infectious material and (2) potential for blood and body fluid penetration of the barrier apparel. The likelihood of strike-through, leakage and soak-through of an isolation gown is procedure dependent.

Although the CDC's guidelines are almost uniformly recognized by U.S. healthcare institutions, they are in fact, recommendations without the force of law. However, the wearing of isolation gowns and other protective apparel is mandated by the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard⁶ and does carry the full weight of law and enforcement capability. According to the Code of Federal Regulations (CFR) 1910.1030(d) (3)(i), "Appropriate personal protective equipment (PPE) does not permit blood and other potentially infectious material (OPIM) to pass through to or reach the employee's work clothes, street clothes, skin, eyes, ...under normal conditions of use and for the duration of time which the PPE will be used." Both the CDC 2007 Isolation Guideline and the OSHA CFR 1910 emphasize the need for PPE selection based on anticipated exposure risk.

What really happens in the health care environment? Do HCWs usually get to choose the type of protective gown that they will wear based on the procedure and potential exposure risk to blood, body fluids and other OPIM? If so, on what criteria are those choices made? This Clinical Issue* will discuss the required characteristics of gowns used for Standard and Transmission-Based Contact Precautions, the Association for the Advancement of Medical Instrumentation (AAMI) Protective Barrier

(PB) 70 Standard⁵ as it relates to isolation gowns, the possible relationship of the AAMI gown levels to clinical procedures, potential barriers to gown selection in the clinical setting and opportunities to improve that situation.

REQUIRED PROTECTIVE APPAREL CHARACTERISTICS

The most important consideration when choosing protective apparel is its functionality.⁷ Does the product demonstrate the necessary attributes required by the purchasers and users and purported by its manufacturer to possess? Barrier fabrics, at a minimum, should perform three basic functions. The fabric needs to be resistant to liquid and microbial penetration under various in-use conditions where impact under pressure may occur and should also be moisture-vapor permeable for wearer comfort. Not all barrier fabrics used for protective apparel are equally protective.

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Image 2.



The most important consideration when choosing protective apparel is its functionality.⁷

Consider isolation gowns as an example. It is impossible to tell which gown would provide the most protection based solely on visual or tactile inspection. There are different types and characteristics of barrier fabrics and it is important to understand the barrier protection inherent in the product being purchased and provided to the HCW. Another important point worth noting is that contrary to surgical gowns, where the majority of exposures to blood and body fluid are frontal, gowns used for cover and isolation applications need to be protective not only in the front but also in the back due to the more unpredictable types of potential contact with blood, body fluids, and OPIM associated with general patient care. Additionally, isolation gowns need to protect the patient from microbial contamination which can be present on all sides of the HCW's body and work clothing.

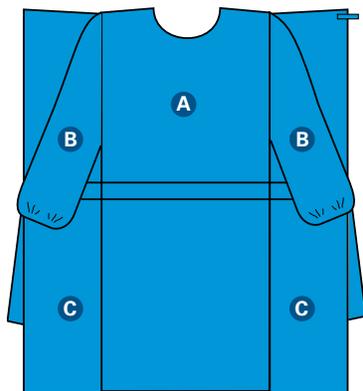
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AAMI PB70 STANDARD

AAMI is an independent non-governmental organization that in 2003 developed the **Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities** or AAMI PB70 Standard. This standard, a Federal Drug Administration (FDA)-recognized consensus, provides stratification of protective apparel based on liquid barrier performance and is the material industry standard by which barrier gowns and drapes are judged.⁵ Because an isolation gown must provide both front and back protection,

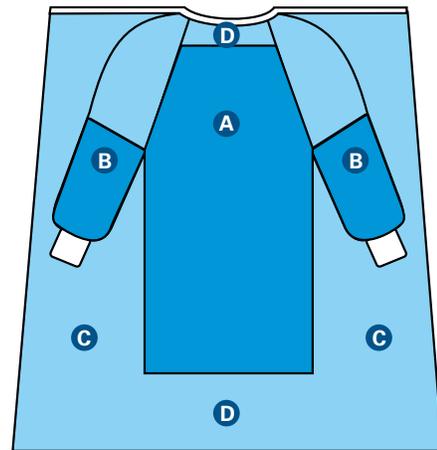
the protective performance of the entire gown is critical, including the seams. Figure 1 is a schematic drawing of an isolation gown and its critical zones. By contrast, Figure 2, a schematic drawing of a surgical gown, notes that its critical zones are very different. Only the critical zones of the front of the surgical gown and sleeves are required to be protective according to the AAMI BP70 Standard. The non-critical zone areas of the surgical gown may be non-protective, but a warning label stating that fact must be prominently displayed on the garment.

Figure 1. Isolation Gown Critical Zones



- Critical Zones
- A – Front
 - B – Sleeve
 - C – Back

Figure 2. Surgical Gown Critical Zones



- Critical Zones
- A – Front
 - B – Sleeve
 - C – Back (non-critical zone)
 - D – Front (non-critical zone)

AAMI CLASSIFICATION LEVELS OF BARRIER PERFORMANCE

How exactly does one know how protective an isolation gown is? This is where the AAMI PB70 Standard becomes relevant. This standard classifies performance criteria for isolation gowns with fabric testing challenge levels ranging from 1 through 4 and specifies that general use cover or isolation gowns must meet, at a minimum, AAMI Level 1 barrier performance to be classified as protective. Table 1 lists the four AAMI Classification Levels and applicable tests utilized at each testing stage. Additionally, a minimum acceptable quality level (AQL) of 4% is required of all four AAMI Levels.

To achieve AAMI Level 1 liquid barrier class, protective apparel material shall be tested for water resistance in accordance with the American Association of Textile Chemists and Colorists (AATCC) 42 impact penetration test (See Glossary for explanation).

The AAMI Level 2 criteria are more stringent, utilizing the AATCC 42 impact penetration test from Level 1 and the AATCC 127 hydrostatic pressure test. Not only is the allowable amount of water absorbed reduced, but the water is placed under 20 centimeters (cm) of water pressure as well.

For fabrics to be certified at an AAMI Level 3, the AATCC 42 impact penetration test remains the same as in Level 2; however, the AATCC 127 hydrostatic pressure test requirement is increased (50 cm).

The AAMI Level 4 tests challenge surgical drapes and gowns using the American Society for Testing and Materials International – ASTM F1670 test, the most commonly used and standardized industry test method for assessing resistance of materials used in protective clothing to penetration by synthetic blood (See Glossary for explanation). This is a pass/fail screening test for drapes and gowns. Protective apparel that pass this first test are then challenged using the ASTM F1671 test, the standard method for assessing resistance of materials used in protective clothing to penetration by bloodborne pathogens.

Therefore, products that do not meet, at a minimum, the AAMI Level 1 performance challenge shall be considered non-protective and shall not receive any classification or assurance of performance. Apparel that has not been classified by AAMI criteria shall also be considered non-protective.

Table 1. AAMI Classification Levels of Barrier Performance

Level	Test	Result	Exposure Risk
1	Impact Penetration	≤4.5 g	Minimal
2	Impact Penetration Hydrostatic Pressure	≤1.0 g ≥20 cm	Low
3	Impact Penetration Hydrostatic Pressure	≤1.0 g ≥50 cm	Moderate
4	ASTM F1670 (Drapes) ASTM F1671 (Gowns)	Pass Pass	High

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AAMI PB70 STANDARD AND REUSABLE APPAREL

Reusable or multiple-use products can receive AAMI classification if they meet a few additional criteria. Processing instructions must be provided by the manufacturer and must be followed. The number of times the article can be processed while maintaining its performance properties must be known and traced using a verifiable tracking system such as manual check off, bar code, or radio frequency (RF) chip. The product must be routinely inspected for maintenance of barrier quality. If barrier performance cannot be verified, the product is to be downgraded to non-protective. Another important point to remember is that gowns protect patients and staff, but can also be a mode of pathogen transmission if not used only once then removed and discarded or reprocessed appropriately.

RELATIONSHIP OF AAMI LEVELS TO CLINICAL PROCEDURES

The AAMI PB70 Standard provides criteria for classifying protective apparel but does not specify the appropriate clinical procedures or environments for each AAMI Level. In order to provide that relational information, in January 2008 an independent research organization conducted an on-line U.S. survey of 300 infection control professionals, registered nurses and materials purchasing managers who had to either wear isolation gowns within or have responsibility for purchasing isolation gowns for their facilities.⁸ Table 2 displays possible relationships between gown barrier performance and clinical procedure exposure risks based on those data.

Table 2. Possible Relationship Between Gown Barrier Level and Clinical Exposure Risks

AAMI Barrier level	Exposure Risk Level	Fluid Amount	Fluid Spray or Splash	Pressure on Gown	Example of Procedures with Anticipated Exposure Risks	
Level 1	Minimal	Minimal	Minimal	Minimal	Basic Cover Gown Standard Isolation Nursing Care Cover Gown for Visitors Laundry/Housekeeping	
Level 2	Low	Low-to-Moderate	Low-to-Moderate	Low-to-Moderate	Radiology SPD/CS Dialysis GI/GU Labs Laundry/Housekeeping	Nursery Phlebotomy Cath Labs IV Procedures
Level 3	Moderate	Moderate	Moderate	Moderate	OB/GYN Laboratory Decontamination ER/ICU/Trauma Burn Units	
Level 4	High	High	High	High	Surgery	

SPD (Sterile Processing Department)/CS (Central Services)
OB (Obstetrics)/GYN (Gynecology)

GI (Gastrointestinal)/GU (Genitourinary) Labs
ER (Emergency Room)/ICU (Intensive Care Unit)

POTENTIAL BARRIERS TO PROTECTIVE APPAREL SELECTION AND USE

Observations of Standard and Transmission-Based Contact Precautions compliance have identified significant lapses in optimal adherence, especially with protective apparel gown use. As noted in a compliance evidence review conducted by Gammon et al., “the reality of adopting Standard Precautions within the clinical setting is far from what is recommended and has proved to be somewhat problematic.”⁹ Interestingly, lack of compliance has been linked to higher education levels and longer years of experience.^{10,11} System issues such as lack of supplies and staff time; education issues including inadequate understanding of Standard Precautions and isolation practices; as well as clinical staff issues such as low risk perception or mentors who model non-compliant behavior have been cited as causative factors.^{12,13}

LACK OF SAFETY CULTURE

This non-adherence to basic safety standards has been linked to a lack of a shared organizational culture of safety. As noted in the CDC 2007 Isolation Guidelines, “safety culture (or safety climate) refers to a work environment where a shared commitment to safety on the part of management and the workforce is understood and maintained.”¹ When the value of a safe environment (safety culture) is not shared, cost rather than HCW safety or patient care concerns may be the primary driver of gown choice. Compliance with Standard Precautions in such a setting may not be viewed as essential but rather a choice that purchasers and HCWs can make according to price or convenience. The authors of the Institute of Medicine’s report entitled **To Err Is Human** acknowledged that causes of medical error are multifaceted but emphasized the pivotal role of system failures and the benefits of a safety culture.¹⁴ A safety culture does not happen by accident. It is created through the intentional actions of management to improve patient and worker safety.

To be effective, workers must participate in safety planning, program implementation, evaluation and the process improvement cycle. The influence of group norms regarding acceptable safety practices must be understood and if necessary, intentionally changed to the expected safety behavior. Most critically, the organization’s orientation and socialization process

Image 3.



Ensuring a consistent supply of PPE is critical to overcoming potential barriers to selection and use.

for new personnel must be extensive, consistent and pervasive. One telling statistic may be the percentage of orientation time allotted to patient safety and infection prevention education. Safety and improved patient outcomes, including healthcare-associated infection reduction, can be enhanced by improving or creating organizational characteristics within the board rooms and the Chief-suites as well as on patient care units.

SYSTEM FACTORS

There may also be system factors which pose as obstacles to appropriate gown selection and use – such as who makes the system level choices on gown types and the selection criteria used. Are there storage space issues at the warehouse, SPD or on the unit that impede the ability for HCWs to have a choice in gowns? Is there a mechanism embedded in the system to ensure that gown supply is never an issue regardless of day of week, time of day or unexpected needs such as a **Clostridium difficile** or Influenza outbreak?

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LACK OF KNOWLEDGE

At the purchasing, unit and worker levels, there may be a lack of knowledge about the CDC 2007 Isolation Guideline, OSHA worker protection mandate and the AAMI PB70 Standard. The relationship of AAMI Levels for gown selection and the types of clinical procedures for which they may or may not provide adequate protection may also not be understood. Some criteria for isolation

gown selection and use which have been found essential to ensuring and improving compliance with protective apparel use include: adequate size choices, bacterial and viral filtration efficacy of the chosen fabric, fluid barrier adequacy, perceived comfort, ability to remove gown without self-contamination, single-use and ease of disposal as well as assurance of adequate supply on all shifts.

IMPROVING PPE SELECTION AND USE OF COMPLIANCE

Successfully enabling compliance at the unit level requires commitment from all organizational stakeholders. A systematic process must also be in place which enables the HCW to do the right thing. Compliance must become the system, unit and HCW norms. Appropriate PPE must be readily available where and whenever needed. The critical program components must be embedded within the system and cannot be person dependent. If there is a system of supply replenishment, PPE supplies must be included. The process requires a system level strategy and a way to make it work all the time. An on-going process of system barrier identification and correction must be set into place where compliance is monitored and feedback provided to all critical departments and personnel. When that performance improvement cycle is completed, the process must begin again. This is not a fix it once and forget it issue!

Image 4.



Improving PPE selection and use compliance relies on having a systematic process in place which enables the HCW to do the right thing.

CONCLUSION

Standard Precautions practices protect patients, HCWs and healthcare organizations when understood and used correctly and consistently by clinicians and ancillary staff. It is important to remember that OSHA regulations are federal law. This makes Standard Precautions compliance mandatory within all U.S. healthcare facilities. However, HCWs need education, guidance, support and ongoing compliance monitoring to improve and maintain behavior that protects patients, themselves and their co-workers. They must work within a culture of safety that provides the resources of adequate staffing, supplies and other critical support measures required to ensure the removal of system, unit and worker level obstacles to protective apparel selection and use. These changes take time, persistence and an unflagging commitment to patient and HCW safety. By doing this, everyone wins in the final analysis – the institution, the HCW and most importantly, the patient.

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GLOSSARY

AATCC 42 Impact Penetration Test:

The AATCC 42 Impact Penetration Test is conducted as follows: a piece of blotter paper is weighed in grams; the fabric to be tested is placed on top of it and then water is sprayed on the fabric. The blotter is then weighed again and the water gain weight is calculated, which determines the amount of water that has penetrated the test fabric and soaked into the blotter on the other side. For AAMI Level 1, all critical zone components shall have a blotter weight gain of no more than 4.5 grams (g); for AAMI Level 2, that weight gain is reduced to 1.0 g. Therefore, the less water absorbed the better.

Acceptable Quality Level (AQL):

For a continued series of lots, the quality level that for the purpose of sampling inspection is the limit of a satisfactory process average. The AAMI PB70 Standard uses this to address and assure the overall quality of the manufactured product by allowing no more than 4% of the product tested to fail test criteria. An AQL of 4% is required of all four AAMI Levels.

AATCC 127 Hydrostatic Pressure Test:

This test method measures the resistance of a fabric to the penetration of water under hydrostatic pressure. It is applicable to all types of fabrics, including those treated with a water resistant or water repellent finish. Level 2 tests at 20 cm of water pressure while Level 3 increases the requirement to 50 cm of water pressure.

ASTM F1670 - 08 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood:

This test determines the ability of a material to resist the penetration of synthetic blood under constant contact. The test sample is mounted on a cell separating the synthetic blood challenge liquid and a viewing port. The time and pressure protocol specifies atmospheric pressure for 5 minutes, 2.0 psi for 1 minute and atmospheric pressure for 54 minutes. The test is terminated if visible liquid penetration occurs before or at 60 minutes.

ASTM F 1671 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:

This test determines the ability of a material to resist the penetration of a microorganism under constant contact using a method which has been specifically designed for modeling penetration of HBV, HCV, and HIV. Because these organisms are difficult to use, the test uses a bacteriophage, Phi-X174, one of the smallest known viruses, at 0.027 microns (μ) in diameter, similar in size and shape to Hepatitis C Virus (HCV), the smallest known bloodborne viral pathogen. A bacteriophage is a virus that attacks bacteria.



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