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Major Article

Investigation of the barrier performance of disposable isolation gowns

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Liquid penetration
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Background: Recent epidemics and pandemics highlighted the need for effective personal protective equipment, including isolation gowns. The most critical property of an isolation gown is its ability to keep liquids and viruses from passing through the gown. Liquid and viral barrier penetration can be measured using laboratory test methods. Association for the Advancement of Medical Instrumentation (AAMI) PB70 standard defines isolation gown barrier performance levels and requirements. In this study, 22 disposable isolation gown models from 6 manufacturers were tested for liquid and viral penetration resistance.

Methods: Standard test methods were used to evaluate water and viral penetration. Test results were evaluated using AAMI PB70 barrier performance criteria for 4 protection levels.

Results: Seven of the 22 tested gown models did not pass liquid and viral penetration testing based on AAMI PB70 at the level claimed by the manufacturer. The majority of these failures occurred at the seam and/or tie attachment areas.

Conclusions: The study findings underscore the need for improved processes surrounding activities such as premarket testing and postmarket evaluation of gowns according to standardized test methods by third-party laboratories. This study also supports the recent Food and Drug Administration guidance document that clarified the characteristics of isolation gowns considered to be class II and subject to Food and Drug Administration premarket review. Infection preventionists, hospital purchasers, and safety professionals should seek isolation gowns demonstrating conformance to industry standards from manufacturers.

BACKGROUND

Isolation gowns are the second-most-used piece of personal protective equipment (PPE) in hospitals, after gloves.[1] Hospital isolation gowns are worn to protect health care workers (HCWs) when anticipating contact with infectious blood, body fluids, secretions, and excretions or when protecting of the skin or clothing from contamination with antibiotic-resistant organisms that pose a risk for transmission to other patients is needed. The 2014 Ebola epidemic, infected (>800) and killed (>500)[2] more HCWs, than any other outbreak in the history of this virus,[3] highlighted the need for effective PPE to protect both HCWs and their patients.

Testing of isolation gowns

Isolation gowns are defined by the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) ANSI/AAMI PB70 (AAMI PB70 hereafter) as protective apparel used to protect HCWs and patients from the transfer of microorganisms and body fluids in patient isolation situations.[4] Many different types of isolation gowns with varying protection levels are currently available to HCWs. The need for, and type of isolation gown selected, is based on the microorganisms properties, the nature of the patient interaction, including the anticipated degree of contact with infectious material and the potential for blood and body fluid penetration of the barrier.[5] For example, during the COVID-19 pandemic, isolation gowns that provide a low level of barrier resistance (AAMI PB70 Level 1) were acceptable while Level 3 or Level 4 gowns were recommended to use when managing patients with suspected or known Ebola Virus Disease. The gown selection and use decisions are based on a risk assessment generally made by the staff from various groups which typically include infection preventions, purchasing agents, and sometimes

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Table 1
ANSI/AAMI PB70:2012 classification of barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories.[4]

Level*	Test	Liquid challenge	Pass/fail criteria†	Expected barrier effectiveness
1	AATCC 42 impact penetration‡	Water	≤4.5 g	Minimal water resistance (some resistance to water spray)
2	AATCC 42 impact penetration	Water	≤1.0 g	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127 hydrostatic pressure§	Water	≥20 cm	
3	AATCC 42 impact penetration	Water	≤1.0 g	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127 hydrostatic pressure	Water	≥50 cm	
4	ASTM F1670 synthetic blood penetration Test (for surgical drapes)**	Synthetic Blood	No penetration	Blood and viral penetration resistance (59 min at ambient pressure and 1 min at 2 psi)
	ASTM F1671 viral penetration test (for surgical and isolation gowns)††	Bacteriophage Phi-X174	No penetration	

*In order to increase protection.
†The sampling requirement outlined in ANSI/AAMI PB70:2012 is to assure a 4% acceptable quality level (AQL) and 20% RQL per critical zone. ANSI/AAMI PB70′s current version was published in 2023.
‡American Association of Textile Chemists and Colorists (AATCC) 42 water resistance: impact penetration test determines the ability of a material to resist water penetration under spray impact.
§AATCC 127 water resistance: hydrostatic pressure test determines the ability of a material to resist water penetration under constant contact with increasing pressure.
**American Society of Testing and Materials International (ASTM) F1670 Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood evaluates the resistance of a material to synthetic blood penetration.
††ASTM 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 determines the resistance of a material to viral penetration.

other HCWs. Existing standard test methods can be used to evaluate the resistance of fabrics or seams and closures to water, synthetic blood, or viral penetration. In the United States, AAMI PB70 establishes a system of classification for protective apparel used in health care facilities (including surgical gowns and isolation gowns), based on their liquid barrier performance.[4] It also specifies labeling requirements and test methods for determining the compliance of protective apparel labeled with liquid barrier claims or liquid-borne microbial barrier claims. The AAMI PB70 standard was recognized by the Food and Drug Administration (FDA) in 2004. AAMI PB70 relies upon 4 existing standard tests to evaluate the barrier effectiveness of surgical gowns, isolation gowns, and surgical drapes. The 2023 edition of the AAMI PB70 also included additional protective apparel, such as decontamination gowns, open-back gowns, and surgical togas. 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. Table 1 summarizes the barrier performance requirements of ANSI/AAMI PB70:2012 for the classification of surgical gowns, isolation gowns, and surgical drapes.[4] The standard requires a maximum rejectable quality level (RQL) of 20% for rated gowns, which defines the relationship between the probability of acceptance by a consumer of a product compared to the possible percent of defectives within that lot.

Viral versus liquid penetration

Since viruses such as Ebola Virus, HBV, and HIV are found in high concentrations in some body fluids, the large number of microorganisms can be carried in a very minute volume of blood or body fluids.[4] The risk of transmission among these pathogens differs based on multiple factors in addition to viral load. Consequently, it is important to protect the HCW's skin or mucous membranes from very small volumes of blood or body fluids which may pass through a perforated seam and may not even be visible to the naked eye.[6,7] OSHA's 29 CFR 1910.1030 standard mandates that when there is occupational exposure, the employer shall provide to the employee, appropriate PPE that does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes.[8]

As indicated in Table 1, only Level 4 gowns are tested for viral penetration resistance, and therefore only Level 4 garments are considered impermeable to viral penetration using ASTM F1671. The gowns complying with the lower levels (Level 1, 2, and 3) are not considered impermeable to viruses. However, Level 1 to 3 gowns can provide increasing resistance to liquids. AAMI PB70 Level 1, 2, and 3 testing requirements for gowns only use water as a challenge. A common misunderstanding among many end users is that they are protected from body fluids, and other potentially infectious materials when they wear any type of fluid-resistant gown. As the surface tension of water is much higher than that of blood, blood typically penetrates through fabrics more readily than water, since liquids with higher surface tension are more likely to bead on a surface than liquids with lower surface tension, which are more likely to wet and penetrate through the garment.[9,10]

Medical device classification

The FDA categorizes medical devices into 1 of 3 classes—Class I, II, or III— based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. PPE used in health care is typically regulated as either a class I or class II device by the FDA. The FDA regulation at 21 CFR 878.4040[11] classifies surgical gowns and surgical masks as class II and apparel other than surgical gowns and surgical masks as class I. The class I devices are typically exempt from premarket notification requirements; therefore, they are not required to undergo FDA's extensive review process, unless they exceed the limitations of exemption under 21 CFR 878.9. The basic requirement for class I gowns is that the sponsor complies with general controls, such as registration and listing requirements and good manufacturing practices. Class II devices, such as surgical gowns, are considered intermediate risk by FDA. Such devices must be cleared through a premarket notification that demonstrates that the device to be marketed is at least as safe and effective as a legally marketed device. In determining whether a gown is intended for use as a "surgical gown," the FDA considers a number of factors, including, but not limited to, the terminology used in the gown's labeling, level of barrier protection claimed, and the device's technological characteristics. Under this regulatory framework, gowns (including isolation gowns) with moderate to high barrier protection claims (AAMI PB70 Level 3 and Level 4) may

be determined to be intended for use as "surgical gowns" that are subject to the premarket notification requirements.

This study was initiated by the National Personal Protective Technology Laboratory of the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), in collaboration with the American Society of Testing and Materials International (ASTM International) F23 committee on Protective Clothing and Equipment (a standard development organization that consists of representatives from manufacturers, laboratories, end users), to evaluate barrier and physical performance with a sample of isolation gowns in order to develop minimum performance requirements for an ASTM standard.[12] Twenty-two disposable isolation gown models from 6 manufacturers were evaluated using AAMI PB70 standard requirements for liquid and viral penetration resistance.

METHODS

In response to letters inviting manufacturers to participate in the isolation gown project and a Federal Register Notice,[13] manufacturers sent gowns to the National Personal Protective Technology Laboratory for evaluation. Only gowns labeled as "isolation gowns" were included in the testing performed by an ISO 17025-accredited laboratory (Nelson Laboratories). Gowns labeled as surgical gowns, cover gowns, protective gowns, comfort gowns, procedure or procedural gowns, and open-back gowns were not included due to the use and design differences. Hospital isolation gowns are used when anticipating contact with infectious blood and body fluids or when protection of the skin or clothing from contamination with antibiotic-resistant organisms that pose a risk for transmission to other patients is needed. However, the intent of this evaluation was not the ability of gowns to function for the latter purpose but solely for the former purpose, as the testing needs may be different. Twenty-two different single-use (disposable) isolation gown models from 6 manufacturers were voluntarily submitted. Twenty gown models were categorized and tested with respect to the manufacturers' labeling claims based on AAMI PB70 barrier levels and testing methodology shown in Table 1. Two gown models, which do not claim any AAMI PB70 protection level, were evaluated at Level 1 protection since Level 1 was defined as the minimum level of protection for isolation gowns by AAMI PB70. Based on the ASTM F23.40 Biological Subcommittee consensus and a minimum sample size practice in the industry at the time the study was started, for each gown model, 13 samples were cut from each of the 3 critical zones defined by AAMI PB70 (chest, sleeve seams, and tie attachments) using different garments. One tie attachment, one sleeve, and 1 chest sample were obtained from each gown. Three or more failures in a single location were defined as gown failures for the purpose of this study. Nineteen gown models were evaluated for liquid penetration resistance, whereas 3 gowns submitted in the AAMI Level 4 protection category were tested for only viral penetration resistance based on the AAMI PB70 requirements.

RESULTS

Testing was conducted on 6 isolation gown models submitted by 5 manufacturers at the AAMI PB70 Level 1, 6 models submitted by 6 manufacturers at Level 2, 7 models submitted by 5 manufacturers at Level 3, and 3 models submitted by 2 manufacturers at Level 4. Test results demonstrated that, despite the presence of a widely used industry standard (AAMI PB70), there are large variations in the barrier properties of isolation gowns in the marketplace. Also, 7 of the isolation gown models failed to meet the AAMI PB70 requirements for liquid barrier performance at the level specified by the manufacturer (see Table 2). In addition, 2 of the gown models that

Table 2
AAMI PB70 test results of 22 disposable isolation gowns

AAMI PB70 Level	Model ID#	AAMI PB70 test result	AATCC 42, AATCC 127, and ASTM F1671 test results*
1	1	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures
	2	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures
	3	Failed (no AAMI PB70 claims)	A1:5/13 Failures A2:0/13 Failures A3:2/13 Failures
	4	Failed (no AAMI PB70 claims)	A1:13/13 Failures A2:8/13 Failures A3:8/13 Failures
	13	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures
	21	Passed	A1:0/13 Failures A2:1/13 Failures A3:0/13 Failures
2	5	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:0/13 Failures B2:0/13 Failures B3:0/13 Failures
	6	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:0/13 Failures B2:0/13 Failures B3:0/13 Failures
	7	Failed	A1:0/13 Failures A2:0/13 Failures A3:5/13 Failures B1:0/13 Failures B2:0/13 Failures B3:6/13 Failures
	14	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:0/13 Failures B2:0/13 Failures B3:0/13 Failures
	18	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:0/13 Failures B2:0/13 Failures B3:0/13 Failures
	22	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:0/13 Failures B2:0/13 Failures B3:0/13 Failures
3	8	Failed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:1/13 Failures B2:3/13 Failures B3:2/13 Failures
	9	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:0/13 Failures B2:0/13 Failures B3:0/13 Failures
	10	Passed	A1:0/13 Failures A2:0/13 Failures A3:0/13 Failures B1:2/13 Failures B2:0/13 Failures B3:0/13 Failures

(*continued on next page*)

Table 2 (*continued*)

AAMI PB70 Level	Model ID#	AAMI PB70 test result	AATCC 42, AATCC 127, and ASTM F1671 test results*
	11	Passed	A1:0/13 Failures
			A2:0/13 Failures
			A3:0/13 Failures
			B1:2/13 Failures
			B2:0/13 Failures
			B3:0/13 Failures
	15	Failed	A1:0/13 Failures
			A2:1/13 Failures
			A3:0/13 Failures
			B1:3/13 Failures
			B2:3/13 Failures
			B3:4/13 Failures
	19	Failed	A1:0/13 Failures
			A2:0/13 Failures
			A3:6/13 Failures
			B1:13/13 Failures
			B2:0/13 Failures
			B3:2/13 Failures
	23	Passed	A1:0/13 Failures
			A2:0/13 Failures
			A3:0/13 Failures
			B1:1/13 Failures
			B2:0/13 Failures
			B3:0/13 Failures
4	16	Failed	C1:3/13 Failures
			C2:2/13 Failures
			C3:13/13 Failures
	17	Failed	C1:1/13 Failures
			C2:0/13 Failures
			C3:7/13 Failures
	20	Failed	C1:4/13 Failures
			C2:3/13 Failures
			C3:7/13 Failures

NOTE. 1, 2, 3 describe the tested gown location (1: sleeve seam, 2: chest, 3: tie attachment). Three or more sample failures from 13 samples in each critical zone were considered a failure. The sampling requirement outlined in ANSI/AAMI PB70:2012 is to assure a 4% AQL and 20% RQL per critical zone. The sampling done in this study characterizes the performance using only the RQL requirement.

*A: AATCC 42 test results B: AATCC 127 test results C: ASTM F1671 test results.

did not meet the AAMI PB70 Level 1 requirements did not have any claims from the manufacturer. One gown from the Level 4 category was a prototype that was not sold commercially at the time that the study was conducted. 67% (4 out of 6 models) of the Level 1 models passed the AAMI PB70 liquid barrier testing requirement. 80% (4 out of 5 models) of the Level 2 models passed the AAMI PB70 liquid barrier testing requirements. 57% (4 out of 7 models) of the Level 3 models passed the AAMI PB70 liquid barrier testing requirements and 0% (0 out of 3 models) of the Level 4 models passed the AAMI PB70 viral penetration resistance requirements, meaning that 100% (3 out of 3 models) of the Level 4 gowns failed to meet AAMI PB70 viral penetration resistance requirement at the sample number used for this study. Two gowns evaluated in the Level 1 category (no AAMI PB70 claims) failed the American Association of Textile Chemists and Colorists (AATCC) 42 water impact resistance testing requirement, one gown in the Level 2 category failed both the AATCC 42 water impact resistance and AATCC 127 hydrostatic pressure testing requirements, 2 gowns in the Level 3 category failed the AATCC 127 testing requirement, 1 of the gowns in the Level 3 category failed both the AATCC 42 and AATCC 127 testing requirements, and all 3 gowns submitted in the Level 4 category failed the ASTM F1671 viral penetration tests. In the Level 1 category, while only samples cut from the sleeve seam area failed for one of the gown models (Model #3), the other gown model failed (Model #4) in all 3 critical regions, namely; sleeve seams, chest, and tie attachment. In the Level 2 category, the failure was only at the tie attachment area (Model #7). In the Level 3 category, there were failures in all 3 critical zones (Model #8 chest, Model #15 all 3 zones, Model #19 tie and sleeve seam). In the Level 4 category, 1 of the gown model's (Model #16) both sleeve and tie attachment samples failed testing requirement, while the other gown's (Model #17) tie attachment area samples failed. Samples taken from all 3 critical zones failed AAMI PB70′s ASTM F1671 viral penetration resistance criteria for the other Level 4 gown model (Model #20).

DISCUSSION

Test results indicated that seam and/or tie construction might not be adequate for some isolation gowns to provide sufficient protection. It is an AAMI PB70 requirement that manufacturers evaluate the technique used in the construction of these critical areas. Not surprisingly, it was also found that overall, the continuous regions of tested gowns provide better protection compared to the non-continuous regions (seams, tie attachment areas). AAMI PB70 is designed to allow a manufacturer to evaluate production quality in a continuous manner, and quality assurance is specifically excluded in this standard (Section 1.3 Exclusions, J). Periodic postmarket evaluation of isolation gowns is needed to validate that isolation gowns continue to meet the performance requirements indicated by manufacturers.[14,15] Additionally, it should be validated that manufacturers of the gowns whose products failed to meet the AAMI PB70 requirements in this study have resolved issues.

Study findings support FDA's use of barrier protection claims as a factor in determining the intended use of, and premarket regulatory requirements for, gowns used in health care settings, including isolation gowns.[16] Isolation gowns used in this study were not FDA-cleared at the time of testing. Study findings are also in alignment with and provide support for the CDC's August 2015 Ebola PPE recommendations,[17] which recommended selecting and using PPE that has been tested by an ISO 17025-certified third-party laboratory.

The project findings also suggest that isolation gowns on the market should be evaluated periodically to determine their continued adherence to performance requirements. AAMI PB70 is primarily designed to be used by gown manufacturers in qualifying, classifying, and labeling the performance of their products so HCWs can make informed decisions when selecting the appropriate product for the anticipated task at hand, and quality assurance is specifically an exclusion of this standard. This standard allows a manufacturer to evaluate production quality in a continuous manner. In light of the results obtained from this research and the current needs identified by end users, the ASTM F3352 standard specification for isolation gowns, which defines the minimum physical performance criteria such as tensile strength, tear resistance, and seam strength in addition to the barrier resistance, has also incorporated particular conformity assessment criteria, including the utilization of ISO 17025-accredited laboratories. Because no consensus standard currently exists that enables third-party postmarket evaluation and quality interpretation of isolation or surgical gowns to provide purchasers confidence in their expected performance, it is suggested that members of the PPE community engage with standards development organizations to elevate the need to resolve this issue within these organizations.

The findings in this report are subject to at least 3 limitations. First, data represented in this report demonstrate only the performance of the gown models tested. Although the testing of the gowns was completed in 2015, no substantial changes in the technology, fabric structure, expected performance, or the design of isolation gowns were noted on the marketplace. In general, the samples included in this study were taken from only one production lot. It is not known whether the lots received were previously tested by the manufacturers. Findings are limited to the samples received as there was no attempt at random sampling to select gowns for testing. Second, conclusions from

these study findings are limited to the variability of the test methods (eg, screen type and surface tension of the carrier fluid in the ASTM F1671 viral penetration test). Third, only a limited number of samples were analyzed. A greater sample size randomly taken from multiple production lots would be preferred.

CONCLUSIONS

The study found that 7 (excluding 2 gown models without any AAMI PB70 claims) of the 22 tested disposable isolation gown models (32%) exceeded the RQL failure rate (maximum 20%) and would be unlikely to meet the requirements of their claimed AAMI level. These results emphasize the need for improved conformity assessment processes, such as third-party testing, as stated in the CDC's August 2015 Ebola PPE recommendations and now required by the ASTM F3352.[12] AAMI PB70 does not provide guidance for determining whether a new gown will perform as expected, it is recommended that AAMI PB70 be expanded to include guidance for postmarket quality assurance sampling and data interpretation for third-party entities.

This study also provides scientific support for the FDA's recent guidance, which describes the premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use during surgery or sterile procedures, or gowns intended to provide medium or high-level barrier protection. Infection preventionists, hospital purchasers, and safety professionals should seek isolation gowns demonstrating conformance to industry standards from manufacturers. The project findings also suggest that isolation gowns on the market should be evaluated periodically to determine their continued adherence to performance requirements.

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DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Mention of any company or product does not constitute endorsement by NIOSH, CDC.

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