



Major article

A simulation study to assess fluid leakage through the glove-gown interface in isolation settings

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Background: Isolation gowns are recommended to protect healthcare personnel, patients, and visitors from transfer of microorganisms and body fluids in patient isolation situations. Standards provide limited information about barrier performance of isolation gowns for possible exposure scenarios. One of the most vulnerable areas of the personal protective equipment ensemble is considered the glove-gown interface. However, current isolation gown classification standards do not consider the interface regions of the personal protective equipment system while assessing the level of protection. The purpose of this study was to quantitatively evaluate the fluid leakage through the glove-gown interface by simulating exposures and healthcare personnel arm movements in patient care for isolation settings.

Methods: We tested fluid leakage of two examination gloves with different cuff lengths and seven isolation gown models designed with varying levels of barrier resistance and multiple cuff types.

Results: Our results demonstrated that leakage through the glove-gown interface depends on multiple factors, including glove cuff length and gown cuff design. Gowns with the thumb loop design provided better protection than the elastic cuff design, and the elastic cuff design provided better protection compared to the knit cuff design for a given AAMI PB70 level. More importantly, a substantial penetration through gown fabrics was observed.

Conclusions: This research identifies a need to develop a standardized method to evaluate leakage at the glove-gown interface to improve worker protection.

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Isolation gowns are one of the most frequently used personal protective equipment (PPE) in healthcare settings. They serve a critical role in infection control by protecting arms and exposed body areas of healthcare personnel (HCP), visitors, and patients. They are also used to prevent contamination of clothing with blood, body fluids, and other potentially infectious material, specifically blood-borne pathogens, such as human immunodeficiency virus, hepatitis B and hepatitis C virus, and Ebola virus.^{1–6}

The Occupational Safety and Health Administration mandated the wearing of gowns and other protective apparel in 1991.⁷ According to the Occupational Safety and Health Administration rule, employers

must provide the appropriate PPE for their employees based on the type of exposure and the amount of body fluids that may be encountered during the task. There are multiple critical factors that may affect the PPE selection, including the type of the exposure (spray/splatter, droplet, aerosol); anticipated part of the body (face, hands, arm); the pressure, type, and duration of the exposure; the anticipated amount of the exposure of the blood or body fluid; and the type and the duration of the work.^{24,25} According to the CDC's isolation precautions guidelines, the need for and type of the isolation gown should be selected based on the nature of the patient interaction and anticipated degree of exposure with the infectious material.⁸

There are many studies, however, that point out the challenges related to selecting appropriate body protection in this context. For example, comparing the barrier effectiveness of the products on the market can be difficult as a result of the inconsistent methodology and terminology, inadequate description of fabrics, and variability in the test conditions.^{9,10} Also, recent technological advancements in textile technology resulted in the use of a wide range of fabrics, designs, and seams in gown construction.

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The American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) have established a standard (ANSI/AAMI PB70) for the classification of liquid-barrier performance of medical textiles which includes isolation gowns, and it is the only standard currently available for isolation gowns that classifies them based on the liquid barrier protection.¹¹ The ANSI/AAMI PB70 (AAMI PB70 hereafter) standard includes four standard test methods to assess the barrier effectiveness of isolation gowns, surgical gowns, and surgical drapes. Based on the results of these standardized tests, four levels of barrier performance are defined, with level 1 being the lowest level of protection and level 4 being the highest level of protection. AAMI PB70 also identifies certain areas of isolation and surgical gowns as critical zones, which include those areas where direct contact with blood, body fluids, and/or other potentially infectious materials is most likely to occur. According to the standard, the entire garment is considered to be a critical zone for isolation gowns. The entire isolation gown, including the seams, but excluding the cuffs, hems, and bindings, must achieve claimed barrier performance. In contrast, for surgical gowns the critical zone comprises at least the front panel and lower sleeves. Also, the standard does not consider open-back gowns as isolation gowns, although they are often referred to as such in marketplace terminology.

The AAMI PB70 endeavors to classify the strikethrough resistance of the fabric with water, synthetic blood, or virus. Barrier performance testing is a crucial part of the garment evaluation, since barrier protection is the critical function of gowns as well as being one of the most common gown failure areas as pointed out in the literature.^{12,13} However, AAMI PB70 excludes the interface regions, such as the glove-gown interface, due to the complexity of other factors that affect the barrier performance of this area²⁶, although the glove-gown area is considered to be one of the most vulnerable areas of PPE ensemble.¹⁴

The glove-gown interface can be described as the junction between the open end of a glove and the sleeve of a gown immediately underneath the glove. There is currently no established standard test method to specifically evaluate the barrier performance of the glove-gown interface region for PPE ensembles used in healthcare.

Generally, gown sleeves are constructed to be wide to provide comfort to the wearer; however, when gloves are donned, the extra portion of the gown sleeve typically creates channels^{15,16} underneath the extended cuff of the examination glove. A greater risk of exposure to arm and wrist areas arises when standard cuff examination gloves are used. The standard glove cuff barely covers the cuff of the gown and creates not only channels but also large gaps. Contaminated body fluid may travel through those channels or openings and thereby contaminate the skin of the wearer. Thus, fluid leakage

through the glove-gown interface can put both personnel and patients at risk for transmission of pathogens.¹⁷

This study examines quantitative evidence of fluid leakage through the glove-gown interface using a robotic arm, which can simulate HCP activities in isolation settings. The primary goal of the research is to compare fluid leakage at the glove-gown interface for seven isolation gown models, two examination glove models, and the combinations of isolation gown and examination glove configurations while upper extremity movements and exposure for isolation settings were simulated.

METHODS

A variety of isolation gown types are used in healthcare facilities, both with varying AAMI PB70 barrier protection ratings, as well as without any ratings. Seven disposable isolation gown models from three major manufacturers were selected from the most commonly used or ordered isolation gowns in the U.S. market by the U.S. Veterans Affairs Hospitals, U.S. Ebola Treatment Centers, and Centers for Disease Control and Prevention's Strategic National Stockpile at the time this study was started in 2018. Gown information was obtained from manufacturers' product data sheets. The suppliers included Cardinal Health, Halyard Health (formerly Kimberly Clark), and Medline. The gowns were denoted 2G, 3G, 6G, 10G, 11G, 12G, and 13G for the purpose of this study. Two of the gown models were labeled as AAMI PB70 Level 2, two other gown models were Level 3, and rest of the models (three) did not have any AAMI PB70 claims.¹¹ Six of the gown models were found to be primarily constructed with nonwoven fabrics and the seventh gown type, 13G, was made of polyethylene film. Additional gown characteristics are listed in Table 1. Fabrics cut from gowns were also measured for weight and thickness following ASTM D1777 (Standard Method for Measuring Thickness of Textile Materials) and ASTM D3776 (Standard Method for Mass per Unit Area of a Woven Fabric), with results included in Table 1. Variations in sizing between manufacturers necessitated individual determination of sizes appropriate for the robotic testing arm.

There were two examination glove models used in this study with different length measurements. Both glove models were purchased from Fisherbrand and were manufactured from non-latex and powder-free nitrile material. Fisherbrand-extended cuff nitrile examination gloves (Fisher Scientific catalog number 19-041-170B) were labeled as complying to ASTM F1671, ASTM F739, and ASTM D3578, and were FDA 510(k) cleared for medical use. The manufacturer claimed that these gloves were made with textured finish for a superior wet or dry grip, are nonsterile with a beaded cuff, and are tested for use with chemotherapy drug exposure. These extended cuff gloves, which were referred to as 1GLV, were 12 inches in length, and had 6-mil (palm), 7-mil (finger), and 4.5-mil (cuff) thickness measurements. The standard cuff Fisherbrand powder-free nitrile examination gloves with catalog number 19-130-1597C, referred to as 2GLV, were described as gloves with a textured surface for solid grip in wet or dry conditions, having 4-mil (palm), and 4.7 mil (finger) thickness, superior tactile sensitivity and dexterity, and were also described as being non-sterile, ASTM F1671 certified, and 9.5 inches in length.

The surface tension for a number of human body fluids varies between 27 and 75 dyn/cm with an average of 40 dyn/cm at 20°C–25°C. ASTM F1670¹⁸ and ISO 16603¹⁹ specify the use of synthetic blood with a surface tension of 42 ± 2 dyn/cm to simulate most body fluids; therefore, in this study, a challenge fluid was prepared using deionized water and a surfactant as suggested in ASTM F903²⁰ (0.03% weight percent solution of Surfynol 104 H, Air Products, Vandalia, IL) to keep the surface tension at approximately 42 ± 2 dyn/cm, and this challenge fluid was used for all experiments. Fluorescent tracers were used in the early trials of the experiments as a visual aid. However, the use of tracers did not significantly affect the observed

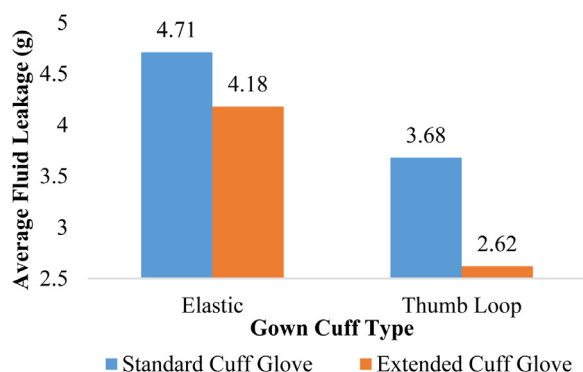


Fig 1. Interaction between gown cuff type and glove cuff length in Level 2 gowns.

Table 1
Gown specifications

ID #	Manufacturer	AAMI PB70 rating	Model #	Fabric type	Sleeve seam	Fabric weight (g/m ²)	Fabric thickness (mm)	Cuff type
2G	Cardinal Health	No Rating	7101PG	Laminated nonwoven	Stitched	42.6	0.25	Knit
3G	Cardinal Health	No Rating	5210PG	Polyethylene film	Heat sealed	23.4	0.08	Thumb loop
13G	Cardinal Health	No Rating	1100PG	Light nonwoven (Spunbond Polypropylene)	Stitched	20.3	0.13	Thumb loop
10G	Medline	Level 2	NONLV240	Medium weight multi-ply-nonwoven	Heat sealed	26.0	0.18	Thumb loop
12G	Medline	Level 2	NONLV200	Medium weight multi-ply-nonwoven	Heat sealed	20.8	0.17	Elastic
6G	Halyard Health	Level 3	54310	Heavy weight multi-ply-nonwoven	Heat sealed	38.5	0.24	Elastic
11G	Medline	Level 3	NONLV325	Medium weight multi-ply-nonwoven	Heat sealed	44.7	0.33	Knit

results. Therefore, due to the challenges with cleaning the experimental chamber and parts, this particular experimental setup did not involve any tracers or coloring.

This study used a published testing methodology to determine the barrier performance of glove-gown interface with the use of a robotic prosthetic limb to simulate HCP movements during the performance of healthcare tasks.¹⁶ This robotic arm is capable of mimicking almost all of the movements of a human arm. An experimental chamber, which houses the robotic arm, was designed and developed by the National Institute for Occupational Safety and Health (NIOSH). The testing includes four equidistant corner nozzles aimed at the glove-gown interface, which are used to introduce challenge fluids with precisely controlled volume and pressure to the glove-gown interface area.

The most commonly performed arm movements in isolation settings were selected based on the literature, as well as by communicating and reaching a consensus with HCP and experts in the field (see Table 2). In clinical settings, the procedure time may vary, but total test duration was kept constant at 15 minutes in this study due to the complexity of the testing and the large number of experiments. Previous studies also highlighted that, in general, the period of isolation gown use is very brief and less than 15 minutes.²¹ Moreover, our previous findings¹⁶ showed that test duration does not significantly affect the fluid leakage through the interface when exposure type, duration, and amount as well as number of movements are maintained constant. Studies designed to investigate the manner in which HCP are exposed to potentially contaminated body fluids and the duration of that exposure are scarce. The most common exposure type experienced in the isolation settings, as determined via the communication with subject matter experts, is brief spraying. Consequently, a one-time 5-second spraying exposure was simulated in each 15-minute testing duration.

Table 2
Body part movements in 15-min isolation simulation

Body part	Movement	Number of activities in 15 min
Shoulder	Flexion (90°)	3 times (each movement)
	Flexion (180°)	
	Abduction (90°)	
	Abduction (max)*	
	Internal Rotation	
Elbow	Hyperextension*	3 times (each movement)
	Flexion (45°)	
	Flexion (90°)	
	Flexion (Max)*	
Wrist	Pronation	2 times (each movement)
	Supination	
	Flexion	
	Extension	
	Ulnar deviation	
	Radial deviation	

*Modified movements for the purpose of this study.

Each 15-minute testing procedure started with introduction of test fluid by spraying. A 5-second spray was employed from four corner nozzles at the beginning of the testing procedure (minute zero). The total fluid amount applied from four nozzles to the glove-gown interface was 187 ml. The robotic arm was automated to perform a series of pre-programmed movements after the exposure (Table 2). The evaluation of the total fluid leakage in grams was done by calculating the amount of fluid absorbed by the inner cotton sleeve (93/7% Cotton/Spandex, Medline, NONSLEEVE) and knit cuff of the gown (if applicable) through weighing the dry (pre-test) and wet conditions (post-test). The scale used in the measurements was Symmetry by Cole-Parmer model # S-PT 413E with 0.001 g sensitivity. Each test was repeated 10 times for each condition.

A series of experiments were conducted in which the amount of fluid leakage (g) was assessed as a function of gown AAMI PB70 level, cuff type, and glove type. Forty experiments were conducted using Level 2 gowns, and 40 experiments were conducted using Level 3 gowns. Between the two Level 2 gown models used in this study, one had a thumb loop cuff and the other incorporated an elastic cuff. Two Level 3 gown models were also used—one had a knit cuff and the other incorporated an elastic cuff. Two different glove types were included in the analysis of each Level 2 and Level 3 gown—an extended and a standard glove type. Given that thumb loop and knit cuff types were unique to Level 2 and Level 3 gowns, respectively, a separate analysis of variance with properly adjusted, post-hoc, pairwise comparisons was conducted for each AAMI PB70 level gown individually. For this purpose, the IBM SPSS Statistics version 23 (IBM, Armonk, NY) was utilized.

RESULTS

Table 3 lists the research design, the number of experiments, and the descriptive statistics corresponding to each cell in the design. Unexpectedly, fluid penetration (striethrough) through the fabric itself was observed after exposures with most of the gown models. In the case of the use of extended gloves, fabric striethrough was observed for all but one of the observations with the knit cuff glove, 11G, and for all 10 observations with the 3G model, which was constructed from polyethylene film and designed with thumb loop cuffs. The other 59 experiments with the extended cuff glove resulted in fabric striethrough.

The cases in which the fluid was collected on the inner cotton sleeve material and fluid leakage occurred only through the glove-gown interface were denoted as “2” in Table 3. Since there was a large opening between the glove and gown cuffs when the standard glove length was used, there were more observations noted with only glove-gown interface leakage. This result could be attributed to the quick movement of fluid through the opening, thereby reducing the amount of fluid available for the gown fabric to absorb. When the fluid collected on the sleeve was partially due to fabric striethrough and partially due to leakage through the glove-gown interface; this was denoted as “1.” Finally, if the collected fluid was due to the fabric

Table 3
Descriptive statistics for Level 2, Level 3, and non-rated gowns

AAMI PB70 level	Gown cuff type	Seam type	Glove cuff type	Fluid leakage region (N)*	Mean fluid leakage (g)	Std. deviation	Std. error of mean
No rating	Knit	Stitched	extended	1(10)	2.84	0.87	0.27
			standard	1(8); 2(2)	4.05	0.86	0.27
	Thumb loop	Heat sealed	extended	2(10)	0.76	0.14	0.04
			standard	2(10)	1.85	0.28	0.09
			Stitched	0(10)	6.37	1.23	0.39
Level 2	Elastic	Heat sealed	extended	0(10)	13.68	1.87	0.59
			standard	0(9), 1(1)	4.18	0.96	0.30
	Thumb loop	Heat sealed	extended	0(2), 1(8)	4.71	0.63	0.20
			standard	0(10)	2.62	0.31	0.10
			standard	0(1), 1(9)	3.68	0.78	0.25
Level 3	Elastic	Heat sealed	extended	0(7), 1(3)	1.79	0.49	0.15
			standard	0(1), 1(9)	2.65	0.40	0.13
	Knit	Heat sealed	extended	1(9), 2(1)	2.49	0.63	0.20
			standard	1(8), 2(2)	4.32	0.57	0.18

*0: No fluid observed through glove-gown interface; 1: Partial fluid observed through glove-gown interface; 2: All the penetration is through the glove-gown interface.

strikethrough only, the observation was denoted as “0.” Based on the results provided in Table 3, the statistical analysis used the assumption that each AAMI PB70 Level had similar fabric properties and were therefore combined.

The analysis of this study was conducted with the assumption of similar fabric barrier properties in each AAMI PB70 level based on the results provided on Table 3. Also, the total fluid collected on the sleeve was analyzed regardless of the type or reason for the fluid passage (fabric strikethrough or leakage).

Follow-up testing was conducted on the Level 2 and Level 3 gown fabrics to confirm the manufacturers' AAMI PB70 barrier claims. AATCC 42²² and AATCC 127²³ results were found to be in alignment with the manufacturers' claims for all Level 2 and Level 3 gowns (see Table 4). AAMI PB70 requires AATCC 42 and AATCC 127 tests to be conducted using water as a fluid challenge; however, we repeated the testing protocol with the challenge fluid used in this study to understand the change in barrier performance with different challenge fluids (see Table 4). In the meantime, the glove-gown interface testing was repeated with water. Since fabrics allowed the penetration of a similar amount of water, the testing was continued with the challenge fluid with reduced surface tension in order to better simulate exposure scenarios. Given the inherent barrier performance differences between gowns rated as AAMI PB70 Level 2 and Level 3, the

analysis focused on the comparison of gown cuff types and glove types within each AAMI PB70 Level.

Analysis on AAMI PB70 level 2 gowns

Each of the main effects (gown cuff type and glove cuff type/length) was statistically significant at a 5% confidence level. Ignoring glove cuff length, the elastic cuff type gown had a significantly higher leakage (Mean (M) = 4.44 g) than the gown with the thumb loop cuff type (M = 3.15 g), $F = 33.00$, $df = 1$, $P < .001$, partial eta squared (η_p^2) = 0.48. Ignoring gown cuff type, standard gloves (M = 4.19 g) had a significantly higher leakage than extended gloves (M = 3.40 g), $F = 12.38$, $df = 1$, $P < .001$, $\eta_p^2 = 0.26$. Therefore, 48% of the variance in leakage was accounted for by gown cuff type, and 26% of the variance was accounted for by glove cuff length. The interaction between glove and gown cuff types did not meet our significance test with a $P = 0.25$, with the interaction plot (which also visually captures the main effects) displayed in Figure 1. The R^2 for the model was 0.57 and the adjusted R^2 was 0.53.

Follow-up Bonferroni-adjusted, post-hoc multiple comparisons were conducted to statistically compare each of the means depicted in Figure 1. When standard cuff gloves were used, leakage was significantly higher for the gown with the elastic cuff (M = 4.71 g) than for

Table 4
Barrier performance of Level 2 and Level 3 gowns

Gown model	AATCC 127 Hydrostatic resistance (cm H ₂ O)*,†				AATCC 42 Impact resistance (g)*,‡			
	Deionized water		Fluid with reduced surface tension		Deionized water		Fluid with reduced surface tension	
	Seam	Chest	Seam	Chest	Seam	Chest	Seam	Chest
10G	35.5 (3.3)§	36.6 (8.5)	18.5 (2.2)	21.5 (1.6)	0.3 (0.09)	0.3 (0.08)	17.4 (0.43)	19.1 (0.35)
12G	28.3 (2.7)	34.4 (6.9)	8.7 (2)	18.2 (2)	2 (4.9)¶	0.7 (0.49)	18.4 (0.62)	19.5 (0.78)
6G	56.6 (6.3)	63 (6.2)	23.1 (2)	25.9 (1.4)	0.1 (0.02)	0.1 (0.02)	4.6 (3.42)	16.8 (1.26)
11G	60.2 (8.6)	68.7 (19.8)	27.7 (3.5)	28.7 (1.6)	0.1 (0.02)	0.2 (0.37)	0.4 (0.9)	16.9 (0.63)

*Average of 13 test measurements.

†American Association of Textile Chemists and Colorists (AATCC) 127 Water resistance: hydrostatic pressure test determines the ability of a material to resist water penetration under constant contact with increasing pressure.

‡AATCC 42 Water resistance: impact penetration test determines the ability of a material to resist water penetration under spray impact

§Standard deviations depicted in parentheses.

¶Due to a visible hole on the sleeve seam, one of the measurements was 18.26 g, and when the outlier was excluded, the standard deviation becomes 0.4.

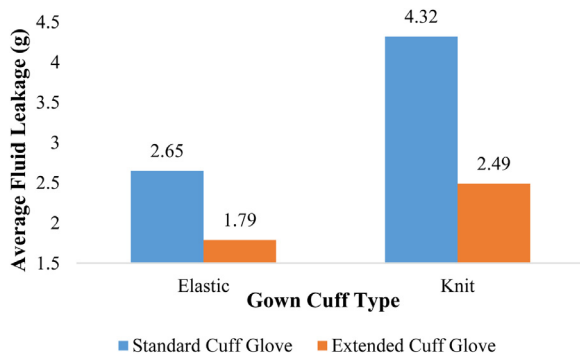


Fig 2. Interaction between gown cuff type and glove cuff length in Level 3 gowns.

the gown with a thumb loop ($M = 3.68$ g), ($P = .003$). This result might be attributed to the length of the gown arm from shoulder to the cuff end. Since the gown with the thumb loop had longer arm design (24-inch) compared to the elastic cuff design (23-inch), the gown with the elastic cuff design was 1 inch closer to the glove end. Therefore, in the elastic cuff design, the fluid travelled a shorter path to reach the inner sleeve (skin), which resulted in higher fluid accumulation. When extended cuff gloves were used, leakage was significantly higher for the gown with the elastic cuff ($M = 4.18$ g) compared to the gown with the thumb loop ($M = 2.62$ g) ($P < .001$). For the gown with the elastic cuff, leakage did not meet our significance test between standard ($M = 4.71$ g) and extended ($M = 4.18$ g) cuff gloves ($P = 0.11$). For the gown with the thumb loop cuff, leakage was significantly higher with standard cuff gloves ($M = 3.68$ g) when compared to extended cuff gloves ($M = 2.62$ g) ($P = .002$).

Analysis on AAMI PB70 level 3 gowns

Similar to AAMI PB70 Level 2 gowns, each of the main effects (gown cuff type and glove cuff type/length) was significant. Ignoring glove cuff type, leakage associated with the Level 3 gown with the elastic cuff ($M = 2.22$ g) was significantly lower than for the gown with the knit cuff ($M = 3.41$ g), $F = 50.35$, $df = 1$, $P < .001$, $\eta_p^2 = 0.58$. Ignoring gown cuff type, leakage associated with standard cuff gloves ($M = 3.49$ g) was significantly higher than leakage associated with

extended cuff gloves ($M = 2.22$ g), $F = 64.40$, $df = 1$, $P < .001$, $\eta_p^2 = 0.64$. Therefore, 64% of the variance in leakage was accounted for by glove cuff length, and 58% of the variance was accounted for by gown cuff type. The interaction between glove and gown cuff types (Fig 2) was also significant, $F = 8.46$, $df = 1$, $P = .006$, $\eta_p^2 = 0.19$. The R^2 for the model using level 3 gowns was 0.77 and the adjusted R^2 was 0.76.

Follow-up Bonferroni-adjusted, post-hoc multiple comparisons were conducted to statistically compare each of the means depicted in Figure 2. When standard cuff gloves were used, leakage was significantly higher for the gown with the elastic cuff ($M = 2.65$ g) than for the gown with a knit cuff ($M = 4.32$ g), ($P = .003$). Similarly, when extended cuff gloves were used, leakage was significantly higher for the gown with the elastic cuff ($M = 1.79$ g) compared to the gown with the knit cuff ($M = 2.49$ g), ($P < .001$). As with the Level 2 gowns, gown arm length could have impacted the results. Although the gown with the knit cuff was longer (24.5 inch) compared to the gown with the elastic cuff (23.5 inch), the knitted portion of the cuff was 2.25 inch; therefore, the knit cuff gown was 1.25 inch closer to the glove end where fluid travelled easier, resulting in higher leakage. For the gown with the elastic cuff, leakage was significantly different between standard ($M = 2.65$ g) and extended ($M = 1.79$ g) gloves ($P < .001$). For the gown with the knit cuff, leakage was significantly higher with standard cuff gloves ($M = 4.32$ g) when compared to extended cuff gloves ($M = 2.49$ g), ($P < .001$).

Figure 3 illustrates the average fluid leakage values with all the gowns. As shown, fluid leakage varied between gown models. In general, it can be seen that the use of extended cuff gloves resulted in lower fluid leakage values compared to standard cuff glove use. Although the fluid leakage values for Level 3 gown models were smaller compared to Level 2 gowns, this result could be attributed to the difference in the barrier performance of gown fabrics, as most of the fluid leakage was due to the fabric's liquid absorption. However, when the comparison was made within each AAMI PB70 level, some trends could be found. For example, when two Level 2 gowns were compared for the standard cuff gloves, it can be seen that the thumb loop cuff design resulted in lower fluid leakage, assuming that both of these gown fabrics penetrated the fluid similarly. Also, when two Level 3 gowns were compared for the standard cuff gloves, it can be seen that elastic cuff gown design resulted in lower fluid leakage through the interface. When a thumb loop design was used, it was observed visually that smaller channels were formed when the

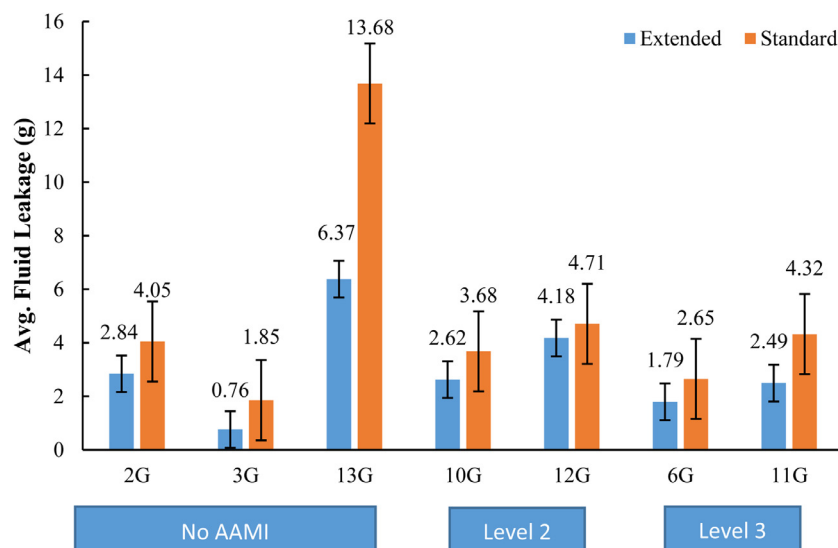


Fig 3. Varying fluid penetration values of gowns with extended and standard cuff gloves.

gloves were donned on top of the gowns. Our previous studies showed that smaller channels are associated with lower fluid leakage values.^{15,16} Also, a similar observation was also made for the elastic versus knit cuff designs. However, fabric stiffness as well as fabric thickness and weight also affect the formation of these channels.

DISCUSSION

In general, fluid unexpectedly penetrated most of the isolation gown fabrics, although the fluid exposure was brief (5 seconds) and the gowns' actual barrier performance aligned with the claimed barrier performance. Our previous test results did not report any fabric strikethrough when AAMI PB70 Level 4 surgical gowns were used.¹⁶ When the standard cuff gloves were used, since there was a visible opening between the glove cuff and the wrist, the fluid collected on the undersleeve was partially due to fabric strikethrough and partially due to leakage through the glove-gown interface. When the extended cuff gloves were used with fabric that does not provide superior barrier protection, all of the fluid reaching to the wrist area penetrated through the gown fabric and no fluid was left to reach to the glove-gown interface, where it can possibly leak through.

In the gown category without any AAMI PB70 claims, gowns provided varying levels of protection. Light nonwoven fabric (13G) provided the least barrier protection in this category. Since sleeves of 2G gown model were sewn, although the gown fabric provided superior barrier protection due to its laminated nonwoven structure, some of the fluid penetrated through the seam holes. The film gown (3G) with heat-sealed seams and the thumb loop design provided the best barrier protection of all the gown models. This result can be attributed to superior fabric (film) barrier performance, thumb loop cuff design, and the thinner fabric, which could have led to the formation of smaller channels underneath the glove cuff compared to all other fabrics tested. However, this fabric type along with the laminated model could have thermal comfort issues due to the closed fabric structure, with no air permeability. Assuming that gowns provide similar barrier protection within each AAMI PB70 level (see Table 4), gowns with the thumb loop design provided better protection than those with the elastic cuff design, and the elastic cuff design provided better protection at the glove-gown interface compared to the knit cuff design. Additionally, examination gloves with extended cuff length provided better protection compared to the standard cuff gloves.

CONCLUSIONS

The glove-gown interface is an area of concern as blood and body fluids can flow through the protective system worn by HCP and contaminate the skin of the wearer during the performance of healthcare tasks, such as lifting the patients, giving bed baths. Exposure to blood or body fluids could be life-affecting, when providing care to patients with infectious diseases, such as Hepatitis B virus, Hepatitis C virus and human immunodeficiency virus. In addition, patients with certain diseases, such as Ebola Virus Disease, can release large volumes of body fluids, which can put HCP at considerable risk. There is currently no established standard test method to evaluate the barrier performance of the glove-gown interface region for healthcare PPE ensembles, although the glove-gown area is considered to be one of the most vulnerable areas of PPE ensemble.

This study demonstrated that fluid leakage through the glove-gown interface depends on multiple factors including glove cuff length and gown cuff design. Gowns with the thumb loop design provided better protection than those with the elastic cuff design, and the elastic cuff design provided better protection compared to the knit cuff design for a given AAMI PB70 level. Furthermore, examination gloves with extended cuff length provided better protection

than standard cuff gloves in the glove-gown interface area. More importantly, a significant amount of strikethrough was exhibited with AAMI PB70 Level 2 and Level 3 gowns. This study identifies the need for a standardized method to evaluate leakage at the glove-gown interface to improve worker protection. Also, our study results underline that, as gowns and gloves are intended to function together, they should be designed as a system in order to minimize or eliminate fluid leakage through the interface areas.

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, Centers for Disease Control and Prevention. Mention of product names does not imply endorsement by NIOSH. This research was supported through Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), and the National Center for Emerging and Zoonotic Infectious Diseases.

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