# Novel Test Method for the Evaluation of Fluid Leakage at the Glove-Gown Interface and Investigation of Test Parameters

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## Abstract

**BACKGROUND:** Exposure to patients' blood/body fluids could be life-affecting, when providing care to patients with infectious diseases. Although the glove-gown interface is considered one of the weakest points of the protective ensemble system, there is a lack of research, and existing standards do not provide much guidance on strategies to minimize gaps between the gowns and gloves. Currently, there is no known standard test method to evaluate fluid leakage or assess performance improvements with new gowns/gloves.

**STUDY DESIGN:** A novel test method with a robotic arm, which has the capability to simulate health care personnel's arm movements during fluid exposure, was developed to determine the leakage at the glove-gown interface. This article explains the test method and investigates the effect of movement, exposure type, exposure duration, procedure duration, and existence of pressure on the amount of leaked fluid at the glove-gown interface.

**RESULTS:** Test results suggest that, with the exception of procedure duration, all parameters significantly affected the amount of fluid leaked at the glove-gown interface. Leakage was higher for soaking when compared to spraying, increased as the exposure duration increased, and was greater with the application of pressure.

**CONCLUSIONS:** The novel method developed in this study could be used by manufacturers of personal protective equipment to evaluate their products. Standard development organizations could adapt this test method in their specifications, testing standards, and guidelines.

Personal protective equipment (PPE) is worn by health care personnel (HCP) to protect against contamination by blood, body fluids, respiratory droplets, and aerosols. However, this protective barrier may be breached during the performance of activities by interaction of the HCP with the patient. The large number of HCP deaths during the 2014 Ebola epidemic (499 deaths out of 861 confirmed cases[1]) drew attention to ensuring the protection of HCP from patients' infectious diseases. Remarkable effort has been put into developing new materials and manufacturing techniques to meet consumers' design needs, and to improving barrier protection and quality of each PPE element. For example, many different gown models with a variety of neck closures, cuff types,[2] colors, and seaming techniques are now available. New fabrics for gowns with higher barrier resistance properties against viral penetration have been developed. Gloves are also designed with varying cuff lengths, materials with different grip and dexterity properties, and higher resistance to punctures, chemicals, and viruses, in addition to reduced risk of spontaneous tears. Along with these product improvement efforts, a number of standards for the quality and performance of gowns and gloves have been developed by standard development organizations.[3]

Despite the large amount of attention paid to improving materials used in these PPE elements, little attention has been given to the interface and interoperability of PPE. The interface between the sleeve of the gown and the glove, in particular, is an area of concern because blood and body fluids can flow through the protective system worn by HCP. Generally, gowns and gloves are produced by different manufacturers and are not necessarily made to function as a system. Currently, most of the elements of HCP PPE ensembles are selected and purchased separately, given that each PPE element is typically produced by a different manufacturer and not offered as a system. This results in many issues with interoperability between elements of HCP PPE ensembles.

Although the glove-gown interface is considered one of the weakest points in the protective ensemble system,[4] studies in this area are limited,[4–7] and existing standards do not provide much guidance on protection for HCP. Furthermore, strikethrough, the unintended penetration of a fluid, blood, or body fluid and the subsequent ability for the microorganisms in those fluids to get through the gown and onto the skin of the wearer, are also critical concerns for operating room personnel. There is a risk of infection posed by these fluid exposures. 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.

Gowns in health care are usually provided with sleeves cuffed at the outer end. The stretchable cuffs are usually made of knit or elastic material. In operating rooms, the gloves are typically pulled up over the cuff and sleeve of surgical gowns. However, due to a low frictional interface between the interior side of the glove and the surgical gown sleeve, glove

"roll-down," or slippage, occurs. When the glove rolls down or slips on the sleeve, the risk of exposure to blood or body fluids increases.

The more important problem associated with the glove-gown interface occurs when gloves are pulled up over the wide and baggy cuff and sleeve of the gown.[7] The sleeve of the gown is bunched up under the glove in folds and pleats, which develop a series of channels through the interface. These channels then allow body fluids running down the sleeves to track toward the inner surface of the glove. This phenomenon is known as "channeling" and poses great risk for surgeons in deep abdominal surgery or trauma cases, where they may reach deep into the incision site, resulting in significant exposure to body fluids around the glove-gown interface. The fluids may continue running down freely while the HCP's arm is moving and reach the gown cuff, which lies directly against the wearer's wrist. The gown cuffs are not required to be water resistant according to the commonly used gown liquid barrier classification standards, such as "American National Standards Institute/ Association for the Advancement of Medical Instrumentation (ANSI/AAMI) PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities"[8] and EN 13795 "Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment."[9] Therefore, the HCP's skin may become contaminated with the patient's body fluids.

Currently, there is no known standard test method to evaluate fluid leakage at the glove-gown interface or to assess the performance of new designs developed to eliminate this problem for HCP. The only available test method to assess leakage at the protective clothing and glove interface is the American Society for Testing and Materials (ASTM) F1359 "Standard test method for liquid penetration resistance of protective clothing or protective ensembles under a shower spray while on a manikin." However, ASTM F1359 was not developed for health care PPE and does not focus on the interface regions. Rather, it was designed to test the whole garment system. In addition, because it was not developed for health care protective clothing, this method does not represent the common exposure types in health care or common HCP movements. Therefore, there is a need for a test method to evaluate the interfaces to determine the degree of protection provided by health care PPE during performance of simulated HCP tasks.

Many attempts have been made to address concerns with the glove-gown interface previously, with several pros and cons.[10] For example, during 2014 Ebola epidemic, adhesive tapes or rubber bands were used to wrap around the glove end, where it meets the gown sleeve, to close the openings and prevent roll down of the glove. However, if adhesive tape is used, protective clothing or gloves can tear during doffing, which increases the risk of exposure to contaminated fluids. Furthermore, many of the common adhesives used in tapes may not be resistant to fluids, and the seal can be broken during a procedure. Also, surgeons often use an adhesive clear drape to secure the glove-gown interface when reaching into the abdomen in a hand port. This is also a concern for tearing during doffing. Given the lack of published research in this important area, there is a need to better understand the amount of exposure that HCP may face during the routine performance of occupational tasks and the factors that can influence the degree of fluid leakage.

This article describes a novel test method to assess the leakage at the glove and protective clothing interface using a robotic arm, which has the capability to simulate HCP arm movements during performance of health care tasks. It also evaluates the effect of movement, exposure type and duration, procedure duration, and existence of pressure on the amount of leaked fluid, which is collected at the glove-gown interface area.

## METHODS

A robotic arm, the modular prosthetic limb (MPL), developed by the Johns Hopkins University Applied Physics Laboratory, with the support of the Defense Advanced Research Projects Agency (DARPA), was used (Fig. 1).[11] The MPL was built in response to the growing number of military personnel injured by improvised explosive devices, to improve upper extremity prosthetics by providing a replacement device that would mimic human performance in terms of appearance, function, and natural control. It is capable of effectuating almost all of the movements of a human arm and hand. The MPL has a lifelike appearance and high resolution tactile and position sensing. The MPL has joints at the shoulder, elbow, and wrist that enable it to simulate human arm and hand movements. It also has more than 100 sensors in the hand and upper arm. The movement of finger joints were not included in this study because the movements of shoulder, elbow, and wrist joints clearly showed greater impact on the glove-gown interface compared with finger movements.

An experimental chamber, which houses the MPL, was designed and developed by the National Institute for Occupational Safety and Health (NIOSH) (Fig. 1). Four spraying nozzles equidistant from the robotic wrist were placed in the corners of the chamber. The nozzles were designed and printed precisely using 3D printers to better control the fluid flow, rather than using off-the-shelf shower heads (Fig. 2).

### Parameters that may affect the leakage

The four main parameters that affect the fluid leakage were identified as: PPE, task, exposure type, and environment (Table 1). The type of protective clothing and the type and number of gloves are some of the main PPE-related parameters. The gown/coverall design, material, barrier properties, fit, sleeve, and cuff diameter are some of the important protective clothing-related parameters. The design, grip, elasticity, material, fit, barrier properties, cuff diameter, and cuff length are some of the glove-related parameters. In terms of the task-related parameters, activity, wear duration, and physical stresses are important variables. Furthermore, exposure-related parameters are the type of the exposure, duration of the exposure, and type of exposed fluid. In terms of environmental factors, humidity and temperature are important considerations.

This study investigated the task and exposure-related parameters. These parameters included PPE wear duration, exposure type (spray, soak, and combination), exposure duration, and existence of physical stresses (pressure and movement). The hypotheses of the study are listed below:

> Hypothesis #1: More rigorous activity level leads to more fluid leakage compared to less rigorous activity.

Hypothesis #2: Longer wear/test duration leads to larger fluid leakage compared with shorter wear/test duration.

Hypothesis #3: Soaking leads to larger leakage compared with spraying.

Hypothesis #4: Longer exposure duration leads to larger fluid leakage compared with shorter exposure duration.

Hypothesis #5: Application of pressure leads to more fluid leakage compared with no pressure application.

The importance of these parameters, and how they were selected, are explained below. The PPE and environment-related factors were held constant in this study.

## Exposure types

Health care personnel are exposed to different fluids, including patients' blood, during the performance of tasks. The type of fluid exposure is one factor that can affect leakage at the glove-gown interface. Studies have shown that exposure to potentially infectious blood or body fluids could occur with varying pathways and rates. Tokars and colleagues,[12] in a survey of 3,420 surgeons, reported that 87.4% cases had blood-to-skin contact. Willy and associates[13] reported, in a national survey among nurse midwives, that 74% had blood exposure to their hands and arms, 51% experienced facial splashing of blood or amniotic fluid, and 24% had at least one needle stick injury during the previous 6 months.

The technical information report published by AAMI (TIR 11:2005) identifies two different types of liquid exposures occurring in surgery; spraying/splashing and soaking with pressing and leaning.[14] Therefore, these two types of exposure settings were applied in this study: spraying/splashing and soaking/dipping with the selected fluid. Soaking exposure is encountered mostly during operations (trauma, deep abdominal procedures, or wound management, especially when the abdominal cavity is large and while reaching into a basin filled with irrigation fluid), during labor and delivery, and in the course of decontamination procedures. Spray exposures are mostly encountered when there is arterial bleeding or episodes of vomiting or diarrhea during patient care.

Each exposure was simulated independently in this study. For soaking/dipping, the robotic arm was immersed in a container filled with the selected fluid. For spraying/splashing, 4 nozzles from facing corners were used to introduce a measured amount of fluid inside the chamber, at a regulated flow rate. If there was pressure in the experiment, a certain amount of pressure was applied on the arm to simulate leaning/kneeling or pressing after the fluid exposure. The variables, such as flow rate, exposure duration, exposure distance, and duration and region of the pressure application could be altered depending on the type of the simulated health care tasks. The distance between the exposure source (nozzle) and the exposed area (glove-gown interface) was set to 21.5 inches, based on communications with HCP and experts in the area (Fig. 1).

## Simulation of arm movements

The type of movement and the joints involved in the movement are other critical test conditions. Health care personnels' most common arm movements during delivery of patient

care were selected for the testing procedure of this study. These movements were determined by current literature and communication with experts in the field. Two studies were found in the literature demonstrating the most common HCP movements. Nguyen and coauthors[15] studied surgeons' body postures and upper extremity movements when performing laparoscopic and open procedures. They videotaped 5 surgeons performing 8 laparoscopic and 8 open operations, and they reviewed all videotapes and analyzed the number of neck, trunk, shoulder, elbow, and wrist movements. A similar study was conducted by McAtamney and colleagues[16] to investigate work-related upper limb disorders. The MPL was programmed based on these two studies and through communication with HCP and HCP organizations.

## Test fluid

The choice of the challenge fluid and the surface tension of the fluid in the testing methods are critical test conditions because increased wettability, or lower surface tension of fluids, is more likely to lead to HCP exposures. Many factors can affect the wetting and penetration characteristics of body fluids, such as surface tension, viscosity, and polarity of the fluid, as well as the structure and relative hydrophilicity or hydrophobicity of the materials. In order to simulate body fluids, different types of fluids could be tested with varying surface tension, considering the wide range of surface tension of the body fluids (15 to 70 dynes/cm).[17] In this study, a solvent was prepared using water and surfactant (0.1 weight % solution of Surfynol 104H [Air Products, Vandalia, IL] with deionized water) to simulate body fluids with low surface tension. The surface tension of the simulated body fluid was measured by du Noüy Ring Method and set as $32 \pm 2$ dynes/cm, similar to the fluid specified in ASTM F1359. The surface of the barrier (fabric and glove) was accepted as constant by using the same models of gowns and gloves.

## Exposed test fluid amount

The amount of fluid that the surface comes into contact with is another essential testing condition. The amount of fluid used in this study was selected based on the current literature. Panlilio and associates[18] identified high risk factors as being exposed to possible infectious blood when patient loss is greater than 250 mL blood and operation time is greater than 1 hour. Therefore, the fluid amount was set as 560 mL/minute from each nozzle. The total fluid amount reaching the wrist area was calculated as approximately 37.5 mL/second. In 10 seconds, which is the longest exposure duration used in this study, the total fluid amount was approximately 375 mL to simulate common exposure types. Each nozzle placed in the NIOSH experimental chamber has 9 holes with 0.5 mm diameters, allowing a large area for fluid movement (Fig. 2).

## Investigation of pressure effect

External force acting against clothing is another critical testing condition because there is evidence of initiation of penetration generated by external pressure,[19] such as from a pressing or leaning motion. These pressures may pose a risk to HCP when they lean or press on a surface that may be wet with blood or body fluids, such as in the case of leaning against a patient's bed or lifting a patient who is releasing or has released body fluids, a surgeon pressing his or her wrist or arm on a surface covered with the patient's fluids

during a surgical procedure, or an emergency medical responder kneeling on a contaminated roadway. Studies have documented a range of pressures to which protective clothing is subjected during clinical use. Altman and coworkers[20] reported that the pressures exerted on surgical gowns during pressing and leaning in surgery can range from 1 pound per square inch (psi) to 60 psi. Also, blood penetration has been shown to increase with increasing pressure.[19,21]

Even though some studies reported high pressures, other studies have found that many common movements during surgery (including leaning, reaching, and arm resting) result in less than 2-psi pressure. For example, Smith and Nichols[22] showed that leaning against the operating room table caused a pressure of 0.52 psi. The greatest pressure seen during any maneuver was 1.84 psi (12.7 kPa) while reaching. Smith and Nichols[22] estimated representative abdominal pressures (ie pressure on the surgeon's abdomen from leaning) during surgical procedures to be between 0.25 and 2.0 psi. Smith and coauthors[23] also studied the effect of magnitude and duration of the pressure on passage or strikethrough of liquids. Fifteen surgeons performed 20 procedures with a 32-sensor mat placed on their abdominal area, and more than 87.8% of 16 procedures involved 2.9 psi or less pressure contacts. In addition, 80% of the contacts were 15 seconds or less during the 13 procedures. Furthermore, current blood and viral penetration test methods used for fabrics by the industry (ASTM F1670[24] and ASTM F1671[24,25]) also use 2 psi as the pressure level based on the literature. Therefore, 2 psi was selected as the pressure level used in this study. However, it should be noted that ASTM F1670 and ASTM F1671 tests use 2 psi of hydrostatic pressure as opposed to mechanical pressure used in this study. Instead of hydrostatic pressure, which is applied in the existing standards (American Association of Textile Chemists and Colorists [AATCC] 127,[26] ASTM F1670, and ASTM F1671), mechanical pressure effect[19] (similar to ASTM F1819[27]) was investigated in this study. Pressure was applied to the wrist area after the fluid exposures (spray, soak, or combination).

### Evaluation of the fluid leakage

A liquid absorptive inner sleeve made of 93/7% cotton/spandex (Medline, NONSLEEVE) was used to cover all interested areas of the robotic arm, which was protected using a liquid-proof fabric. The donning sequence of the inner sleeve and PPE is presented in Figure 3. Fluid collected on the sleeve and surgical gown cuff are referred to as "liquid penetration or fluid leakage" in this study, and are accepted as equal to the fluid amount leaked through the glove-gown interface. The fluid amount was determined by weighing the fluid collected on the inner sleeve and gown cuff.

### Test procedure

The robotic arm was programmed using the most commonly performed arm movements (Fig. 4), which were selected based on the current literature[15,16] and communications with HCP. Exposures were performed by spraying the simulated body fluid from 4 nozzles simultaneously (to simulate spraying/splashing) or immersing the arm into a container (to test soaking/dipping). Absorptive inner sleeve, gown, and glove were donned in a sequence. The arm followed the programmed movements for each period of time. At the end of the testing period, excess liquid from the surface of the gown was gently removed without

pressing. After carefully removing the gown, the inner sleeve was weighed to determine the fluid leakage amount (ie liquid penetration). Special attention was paid to see if there was any fluid strikethrough due to the failure of gown fabric, gown seams, or gloves. Additionally, the knit cuff was cut, weighed, and dried. After drying, the amount of fluid absorbed by the cuff was also determined. Fluid absorbed by inner sleeve and fluid absorbed by the knit cuff were added to calculate the total amount of absorbed fluid in grams. The temperature and relative humidity vary according to the zones in the hospital settings and range between 68°F and 75°F (21°C and 24°C) and 30% and 60% relative humidity.[28] The temperature and humidity of the experimental chamber and temperature of testing fluid were monitored and recorded for each experiment. The average temperature for the duration of the tests was 72°F, and average humidity was 50%.

**Materials**

The highest level of protection for gowns and extended gloves were selected to minimize the penetration through the PPE material in this study. An appropriate size of extended (12-inch cuff length) examination gloves, declared by the manufacturer as passing the ASTM F1671 viral penetration test, and the AAMI PB70 Level 4 surgical gowns, featuring knit cuffs and heat sealed sleeves, were used as PPE for the experiments. Gown and glove sizes were selected based on the best fit to the manikin. Gown and glove types were selected among the most commonly used PPE during the 2014 Ebola epidemic in the United States based on information received from US Ebola Treatment Centers, Centers for Disease Control and Prevention's Strategic National Stockpile, and Veterans Affairs Hospitals. Selected surgical gowns were sold with laminated sleeves to provide high barrier resistance. This laminated surface is also a smoother surface that provides less friction with the inner surface of the glove.

The total experiment time was divided into 4 identical movement cycle routines in order to create an equal distanced exposure or pressure pattern (Fig. 5). The exposure (spray or soak) or pressure was applied at the beginning of each cycle. Three procedure (wear) durations (15, 30, and 60 minutes) and three exposure durations (2, 5, and 10 seconds) were investigated using full movement cycles, as shown in Figure 5. To investigate the effect of the one distinct parameter, other experiment parameters were maintained constant. For instance, the effect of movement was examined by repeating the experiments with or without movements while all other experimental conditions were kept identical. Also, the impact of the number of movements of certain wear duration on the leakage amount was investigated by running one-quarter of the arm movements vs full movements. The experimental design of the study and the total number of experiments are shown in Table 2.

Given the large number of independent variables and their associated levels, 5 experiments were conducted for each unique condition. Table 2 shows that across the entire experimental research program, 195 total trials were conducted corresponding to 39 different experiments. Five trials for each of the 39 different experiments allowed for sufficient statistical power to detect the main effects for each primary independent variable while allowing a reasonable amount of statistical power to examine the interaction effects.

Possible activity scenarios were planned by changing exposure types and application of pressure, as illustrated in Table 3. Pressure was either applied at 2 psi for 30 seconds or was not applied. For example, for the first activity scenario listed in Table 3, assuming 15-minute procedure duration and 2-second exposure with full movement cycle, the nozzles spray the fluid for 2 seconds, the robotic arm simulates the HCP's movements for 3 minutes and 45 seconds, the nozzles again spray the fluid for 2 seconds, and movements were repeated. The protocol continued until 4 cycles were completed, with 1 exposure at the start of each cycle. In addition, combinations of exposure scenarios were studied by adding spray, soak, and pressure into the procedures. When there was a second type of exposure in the procedure (eg soak), that type of exposure was applied after the first exposure (eg spray) between each cycle. When there was pressure, it was applied after the second and third exposures for 30 seconds. SPSS version 23 by SPSS Inc was used to examine the main effects of each variable along with the applicable interactions.

## RESULTS AND DISCUSSION

A number of experiments were conducted in an effort to determine the most important factors that affect the fluid leakage through glove-gown interfaces, while HCP movements were simulated and the factors and their levels were varied as shown in Table 2.

### Effect of the arm movement on the liquid penetration

In order to examine the potential effect of movement of the HCP on the dependent variable (amount of fluid leaked through the glove-gown interface), a series of experiments were conducted in which simulated movement was varied between no movement, minimal movement, and moderate movement, while holding all other independent variables (exposure type, exposure duration, procedure duration, and pressure) constant within the experiments. In the first investigation, the difference between no movement and moderate movement on liquid penetration was examined in the 4-spray exposure type condition. Also, the difference between minimal and moderate movement on fluid leakage was examined within the 1-spray condition. Given that the dependent variable (liquid penetration or fluid leakage) was a non-negative, noninteger, positively skewed outcome that significantly differed from normality (Shapiro-Wilk < 0.05), the efficacy of a gamma regression estimation approach was formally assessed (through Akaike's Information Criterion, Bayesian Information Criterion, and Log Likelihood values), and found to fit the data significantly better than a normal distribution. Therefore, a generalized linear model assuming a gamma distribution approach was used to test the relative risk and mean difference of liquid penetration between 0 and 4 movement cycles and 1 and 4 movement cycles. Considering the difference between no movement and moderate movement in the 4 spray, 5-second exposure type condition, there was an overall significant difference in liquid penetration among the levels of movement cycle, Wald chi-square = 145.12, $p < 0.001$. The estimated mean liquid penetration for no movement was 0.83 g (SD 0.45), standard error was 0.13, while the estimated mean liquid penetration for the moderate movement cycle condition was 5.54 g (SD 1.11), standard error 0.45. These means were significantly different at $p < 0.001$. The relative risk associated with moderate movement when compared with no movement was also significant (B = 2.00, standard error 0.16, $p < 0.001$, Exp

[B] = 6.65), where B is the regression coefficient from the generalized linear model. This finding suggests that, with exposure type (4 sprays) and exposure duration (5 seconds) held constant, moderate movement during a simulated medical procedure is expected to be associated with 6.65 times the amount of potential liquid penetration when compared to no movement. This could be expected and explained as while the arm is moved, the fluid finds its way to move through channels. Because there is no manipulation of the fluid when there is no movement of the arm, fluid penetration is less compared with the moderate movement condition. However, it is important to note that there was still fluid (0.83 g) leaking through the glove-gown interface with the no-movement condition with the type of gown and glove selected during the 4-spray, 5-second exposure.

Considering the difference between minimal movement and moderate movement in the 1-spray exposure type condition in 2, 5, and 10 seconds of exposures, there was no overall significant difference in liquid penetration among the levels of movement cycle, (Wald chi-square = 0.01, p = 0.91) opposite to what was hypothesized (Hypothesis #1). The estimated mean liquid penetration for the minimal movement condition was 0.97 g (SD 0.39), standard error 0.13, while the estimated mean liquid penetration for the moderate movement condition was 0.99 g (SD 0.66), standard error 0.13. Consistent with the omnibus test, these means were not significantly different, nor were the regression coefficient and the associated relative risk. As explained earlier, minimal movement was performed by conducting experiments by only moving the robotic arm for 1 cycle, while the moderate movement was performed while moving for 4 cycles. Each cycle is identical and represents the combination of several shoulder, elbow, and wrist joint movements. Considering these differences, one could expect that there will be more leakage with the moderate movement. However, test results suggest that most of the leakage occurred when the first cycle of movement was completed and that adding other cycles of movements did not significantly affect the leakage through the interface. In other words, most of the liquid sprayed at the beginning of the procedure had already moved through the channels of the interface after the first cycle of movements, and addition of other movement cycles did not change the liquid penetration significantly because there is not much liquid left after the first movement cycle.

Taken together, these results suggest that a sizable difference in liquid penetration can be expected between no movement and moderate movement (approximately 85% more), while no difference is expected between minimal and moderate simulated movement. Given these findings, the experimental program used a consistent experimental condition of some degree of movement across the remaining experiments. This experimental condition also more accurately simulates actual conditions present during performance of health care activities—zero movement would not be expected from the HCP during any medical tasks.

### Effect of exposure type, exposure duration, procedure duration, and pressure

Initially, 150 experiments were conducted to examine the effects of exposure type, exposure duration, procedure duration, and pressure on liquid penetration. Exposure type was varied between spray and soak to simulate the most common liquid exposures in health care. Exposure duration was varied between 2, 5, and 10 seconds. Pressure was applied on the inner 6-square-inch wrist area for 30 seconds using 12 pounds of weight, and it varied

between 0 psi and 2 psi. Procedure duration (PPE wear duration) was defined as the time that the medical procedure was applied using the PPE, and it varied between 15, 30, and 60 minutes. The main effects of each variable, along with the 2 and 3-way interactions were examined. Consistent with the previously reported process used to select an appropriate statistical estimation technique, a gamma distribution within a generalized linear modeling approach was found to be most appropriate to perform this analysis.

The 2- and 3-way interactions were found to be not significant. The main effect of procedure duration was also not significant (Wald chi-square = 1.13, degrees of freedom [df] = 2, p = 0.57), suggesting there were no significant differences in the resulting liquid penetration between 15 minutes, 30 minutes, and 60 minutes of procedure durations (PPE wear durations) averaged across the other variables in the study, as opposed to Hypothesis #2. However, it should be noted here that the number of movements performed during each procedure duration investigated (15 minutes, 30 minutes, 60 minutes) was selected as identical due to the fact that the number of movements will affect the resultant leakage amounts. Therefore, the result of the analysis should be interpreted with this consideration. In the real wear experiences, however, it might be expected to have more movements when PPE is worn for longer periods. Also, other factors, such as prewetting of the fabric due to perspiration, repeated exposures, and repeated exertion of stresses, would change the barrier performance of the gown and glove-gown interface. The main effects for exposure type, exposure duration, and pressure on the liquid penetration were, however, significant: exposure type, Wald chi-square = 1235.42, df = 1, p < 0.001; exposure duration, Wald chi-square = 364.51, df = 2, p < 0.001; pressure, Wald chi-square = 34.83, df = 1, p < 0.001.

Regression coefficients and relative risk for the model are reported in Table 4. For exposure type there was an approximate 5 times the amount of liquid penetration expected for the soak exposure type (M = 30.44 g) when compared with the spray exposure type (M = 6.08 g), where M defines the mean value; B = 1.61, p < 0.001, Exp(B) = 5.01, as hypothesized (Hypothesis #3), where B defines the regression coefficient from the generalized linear model. This result suggests that HCP should avoid the soaking types of exposures as much as possible because the expected exposure risk (fluid leakage) is clearly much higher than a spray type of exposure (average 30.44 g of liquid penetration vs 6.08 g). Table 4 also shows that both a 2-second and a 10-second exposure duration were significantly different from a 5-second exposure duration. A 2-second exposure duration (M = 7.67 g) resulted in significantly lower liquid penetration when compared with 5-second exposure duration (M = 14.89 g): B = −0.66, p < 0.001, Exp (B) = 0.52. A 10-second exposure duration (M = 22.07 g) resulted in significantly higher liquid penetration when compared to a 5-second exposure duration: B = 0.39, p < 0.001, Exp (B) = 1.48. These findings suggest that 2 seconds of exposure can be expected to result in approximately 50% less liquid penetration when compared to a 5-second exposure. This further suggests that a 10-second exposure can be expected to result in approximately 50% greater liquid penetration when compared with the 5-second exposure duration reference group as hypothesized (Hypothesis #4). In terms of pressure applied at the glove-gown interface, Table 4 further shows that 0 psi (M = 11.70 g) resulted in significantly lower resulting liquid penetration when compared with the 2 psi condition (M = 15.82 g): B = −0.30, p < 0.001, Exp (B) = 0.74. This result is in agreement

with Hypothesis #5 and suggests that HCP should minimize/eliminate the pressure on the glove-gown interface area.

Given the large effect associated with exposure type, additional experiments were undertaken to examine the effects of additional types of possible exposure scenarios on resulting liquid penetration through the glove-gown interface. Two exposure types were examined in addition to the 4 sprays and 4 soaks exposure types previously reported: an exposure scenario with a decreased level of spray (1 spray), and an exposure scenario with a combination of spray and soak (4 sprays/4 soaks).

A total of 45 experiments were executed, and the differences in mean liquid penetration levels were examined between the 4 exposure types. Within this set of experiments, the exposure duration was held constant at 2 seconds and pressure was held constant at zero psi. Similar to the previous set of experiments, a moderate level of movement that simulated common HCP tasks was included. The results of this model are reported in Table 5 and illustrated in Figure 6. Within the model, the newly introduced exposure type of 4 sprays/4 soaks was used as the referent groups. The results suggest that both 1 spray (M = 0.49 g) and 4 sprays (M = 3.11 g) exposure types were significantly lower than the 4 sprays/4 soaks exposure type (M = 11.65 g): 1 spray, B = −3.17, p < 0.001, Exp(B) = 0.04; 4 sprays, B = −1.32, p < 0.001, Exp(B) = 0.27. Table 5 also shows that the 4 soaks exposure type (M = 12.67 g) was not significantly different from the 4 sprays/4 soaks exposure type. This result could indicate that spraying contributes minimally to the liquid penetration compared with soaking.

Within the generalized linear model framework, follow-up pairwise comparisons were examined between the gamma regression estimated mean liquid penetration levels for all exposure types. For these, significance levels were adjusted using the most conservative estimates between Bonferroni and Sidak adjustments. The results suggest that the means associated with each of the exposure types were significantly different from each other at the p < 0.001 level except for the comparison between 4 soaks and 4 sprays/4 soaks (p = 0.56).

It is well known that a significant number of microorganisms can be carried in a very minute volume of blood or body fluids, which may not be visible to the naked eye.[17] Therefore, when all of the fluid leakages obtained in this study are considered (>0.49 g), the results can be interpreted as significant. The ANSI/AAMI PB70 standard[8] requires samples taken from all 3 critical zones (chest, sleeves, and points of attachments) should be tested for water resistance using the AATCC 42 testing for classifying gowns as level 1 through level 3. The AATCC 42 Impact Penetration Test[29] assesses the resistance of materials to penetration of water by spray impact, as measured by weight gain of a blotter. A lower number represents higher resistance. One of the criteria for classifying gowns as level 1 is to have equal or less than 4.5 g of water penetration and for level 2 and level 3 gowns, equal or less than 1 g of water penetration using the AATCC 42 test method. Results obtained in this study were compared with the ANSI/AAMI PB70 requirements. When all of the test results obtained in this study are considered, it will be seen that the resultant fluid leakages are above the ANSI/AAMI PB70 minimum performance requirements using the AATCC 42 water resistance test method except for 1-spray (M: 0.49 g) and 4-sprays (M: 3.11 g) conditions.

It should be noted here that the test methods and tested PPE locations used in this study were different. Also, level 4 gowns, for which the ASTM F1671 viral penetration resistance testing is required for the ANSI/AAMI PB70 classification, were used in this study as test samples.

## CONCLUSIONS

The new test method explained in this study introduces a novel approach to examine concerns about potential leakage at the glove-gown interface that is frequently raised by HCP. The novel test method has been used successfully to measure the fluid leakage through the glove-gown interface. This study also investigated the use of this new method to evaluate the extent of the fluid leakage problem. This novel test method uses a state of the art robotic arm, which can simulate HCP movements and experimental setup to mimic the most common exposures encountered in health care settings.

This study investigated the effect of a number of parameters, namely, degree of the movement, exposure type, exposure duration, procedure duration, and existence of pressure on the fluid leakage at the glove and protective clothing interface using an AAMI level 4 surgical gown and extended examination gloves. Test results suggest that except for the procedure duration (or test duration) (Hypothesis #2), all four parameters significantly affect the amount of fluid leaked at the glove-gown interface, as hypothesized. However, this can be interpreted as a result of selecting an equal number of movements for each procedure duration for comparison purposes. In real hospital settings, because more movement is expected when PPE is worn for longer periods, larger fluid leakages might be experienced. Also, other factors, such as prewetting of the fabric due to perspiration, repeated exposures, and repeated exertion of stresses would change the barrier performance of the gown and the glove-gown interface. As opposed to what was presented in Hypothesis #2, longer procedure duration did not significantly result in larger fluid leakages at the glove-gown interface. However, as hypothesized, soaking led to larger fluid leakages as longer exposure, more rigorous activity, and application of pressure.

Results also suggest that HCP should avoid soaking types of exposures as much as possible because the expected exposure risk (fluid leakage) is clearly much higher compared to spray types of exposure. The amount of leakage also increases with the duration of exposure and application of pressure. Test results suggest that a sizable difference in liquid penetration can be expected between no movement and moderate movement, while no difference is expected between minimal and moderate simulated movements. As a follow-up to this study, custom designed testing procedures could be developed and analyzed separately for each health care setting activity (eg, surgical, patient isolation, and decontamination) using the appropriate PPE for each activity. Although the 2014 Ebola outbreak dramatically heightened awareness about the limitations of currently available PPE products, it should be acknowledged that self-contamination during use or doffing of PPE remains as one of the risk factors for HCP as well as patients, and may defeat the purpose of using PPE.

This study limits the control of temperature and humidity in the experimental chamber and the temperature of the challenge fluid. This novel test method could be used by

manufacturers of coveralls, gowns, and gloves to evaluate their products. Health care personnel can have a better understanding of what increases the skin exposure risks and how they can mitigate the skin exposures. Furthermore, standard development organizations could also adapt this test method in their standard specifications, testing standards, and guidelines.

## Acknowledgment:

## Abbreviations and Acronyms

| | |
|---|---|
| **AATCC** | American Association of Textile Chemists and Colorists |
| **ANSI** | American National Standards Institute |
| **ASTM** | American Society of Testing and Materials |
| **df** | degrees of freedom |
| **HCP** | health care personnel |
| **MPL** | modular prosthetic limb |
| **NIOSH** | National Institute for Occupational Safety and Health |
| **PPE** | personal protective equipment |
| **psi** | pounds per square inch |

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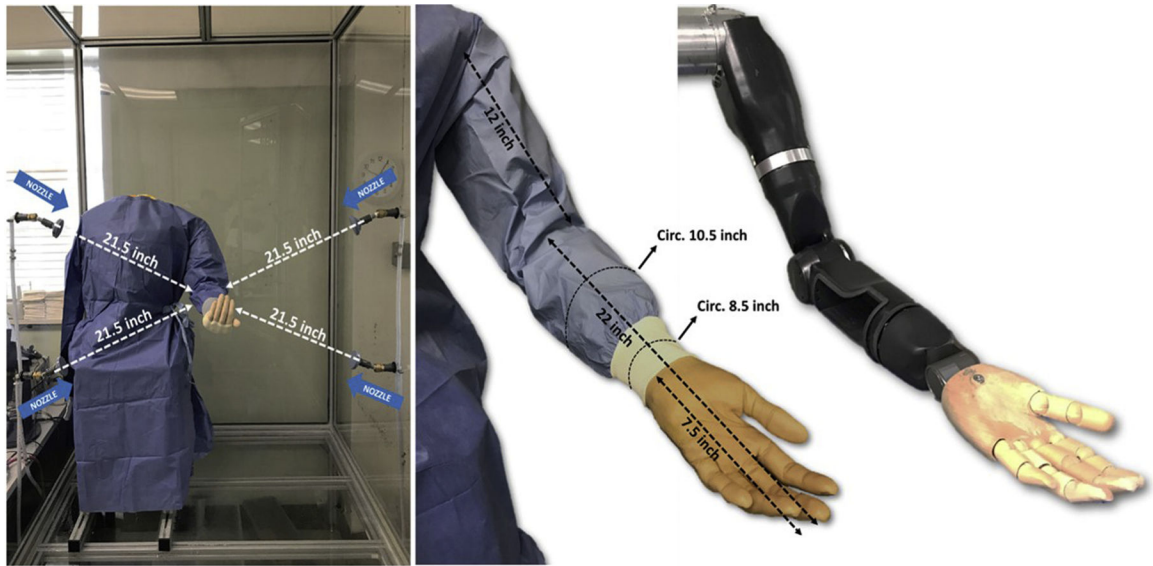
**Figure 1.**
The experimental chamber and modular prosthetic limb.

Nine holes
Diameter=0.5mm

**Figure 2.**
Nozzles for spraying.
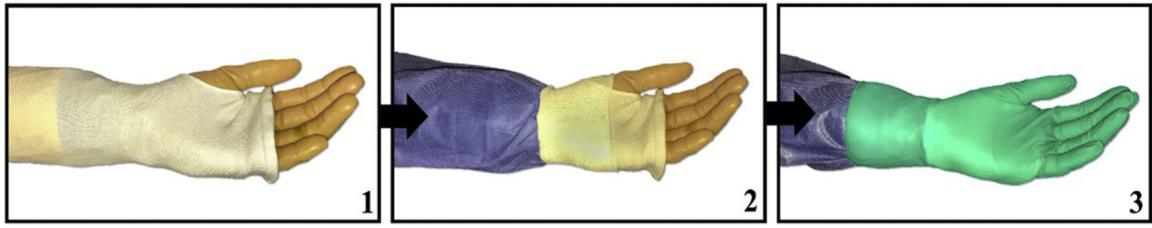
**Figure 3.**
Sequence of donning (1) inner sleeve, (2) gown, and (3) glove.
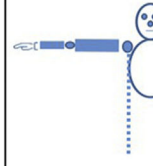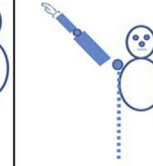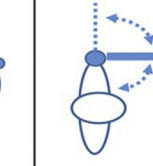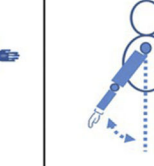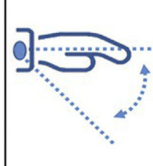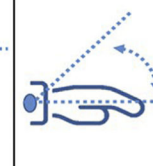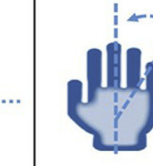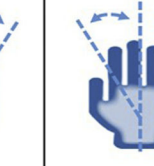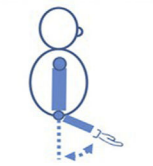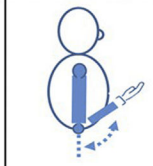
**Figure 4.**
Joint movements used in the testing protocol.
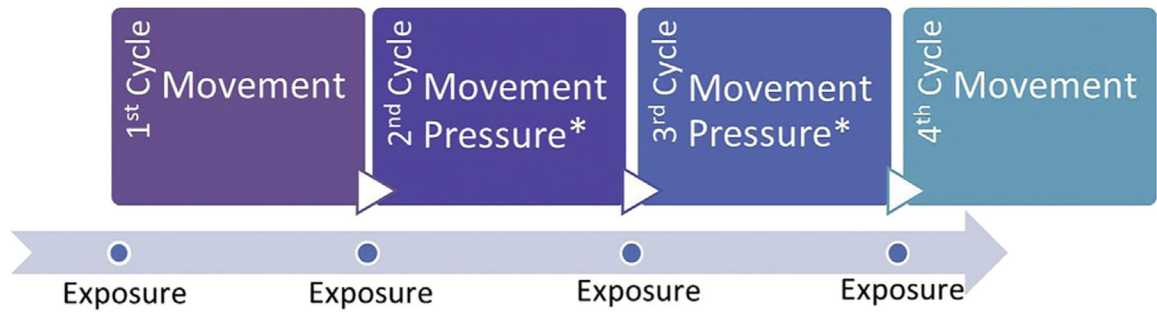
**Figure 5.**
Test activity procedures.

**Figure 6.**
Average liquid penetration at the glove-gown interface with different exposure types.

**Table 1.**

Factors That May Affect the Fluid Leakage at the Glove and Protective Clothing Interface

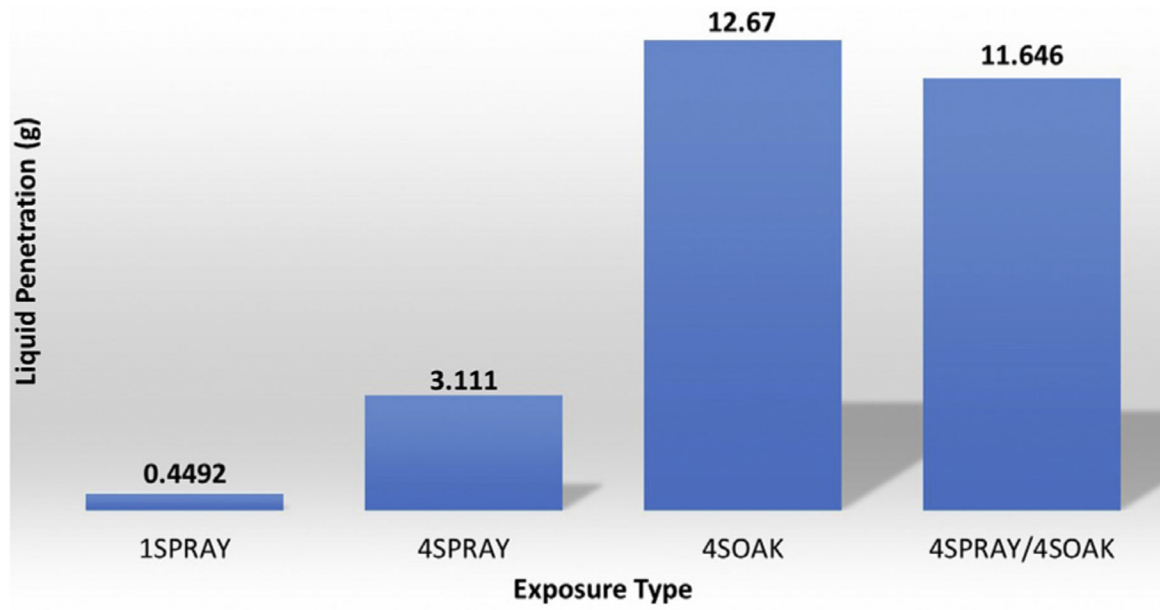| PPE-related parameter | | | | |
|---|---|---|---|---|
| **Glove** | **Clothing** | **Task-related parameter** | **Exposure-related parameter** | **Environment-related parameter** |
| Glove type<br>Surgical<br>Examination | Clothing type<br>Surgical gown<br>Isolation gown<br>Coverall | Task type<br>Surgical<br>Isolation<br>Decontamination | Exposure type<br>Spray<br>Soak<br>Combination | Temperature<br>Humidity |
| Cuff design<br>Standard<br>Extended | Cuff design<br>Knit<br>Elastic<br>Thumbn loop | Wear duration | Exposure duration | |
| Protection<br>Pass ASTM<br>F1670/1671<br>Fail ASTM<br>F1670/1671 | Protection<br>AAMI level 1–4<br>Pass ASTM<br>F1670/1671<br>Fail ASTM<br>F1670/1671 | Physical stresses<br>Pressure<br>Extension | Exposed fluid type<br>Blood<br>Urine<br>Amniotic fluid<br>Vomit | |
| Material<br>Latex<br>Synthetic | Material<br>Woven<br>Non-woven<br>Film | Degree of movement | | |
| Surface property | Surface property | | | |
| Fit | Fit | | | |

AAMI, Association for the Advancement of Medical Instrumentation; ASTM, American Society for Testing and Materials International; PPE, personal protective equipment.

**Table 2.**

Experimental Design of the Study

| Exposure type | Movement cycle | Exposure duration, s | Procedure duration, min | Pressure, psi | Total number of experiments, n |
|---|---|---|---|---|---|
| 1 spray | 1, 4 | 2, 5, 10 | 15 | 0 | 30 |
| 4 sprays | 0 | 5 | 15 | 0 | 5 |
| 4 sprays | 4 | 2, 5, 10 | 15, 30, 60 | 0 | 45 |
| 4 soaks | 4 | 2, 5, 10 | 15, 30, 60 | 0 | 45 |
| 4 sprays and 2 pressures | 4 | 2, 5, 10 | 15, 60 | 2 | 30 |
| 4 soaks and 2 pressures | 4 | 2, 5, 10 | 15, 60 | 2 | 30 |
| 4 sprays and 4 soaks | 4 | 2 & 2 | 60 | 0 | 5 |
| 4 sprays, 4 soaks and 2 pressures | 4 | 2 & 2 | 60 | 2 | 5 |

psi, pounds per square inch.

**Table 3.**

Possible Activity Scenarios

| Possible activity scenario | Spray | Soak | Pressure |
|---|---|---|---|
| 1 | 1 | 0 | 0 |
| 2 | 0 | 1 | 0 |
| 3 | 1 | 1 | 0 |
| 4 | 1 | 0 | 1 |
| 5 | 0 | 1 | 1 |
| 6 | 1 | 1 | 1 |

The number "1" shows the application of the exposure or pressure and "0" shows no application.

**Table 4.**

Liquid Penetration Regressed on Exposure Type, Exposure Duration, Pressure, and Procedure Duration

| Variable, parameter | Mean, g | B | SE | 95% Wald confidence interval | | Wald Chi-square | p Value | Exp(B) | 95% Wald confidence interval for exp(B) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Lower | Upper | | | | Lower | Upper |
| **Exposure type** | | | | | | | | | | |
| 4 soaks | 30.44 | 1.611 | 0.0458 | 1.521 | 1.70 | 1235.42 | <0.001 | 5.01 | 4.58 | 5.48 |
| 4 sprays | 6.08 | – | – | – | – | – | – | 1 | – | – |
| **Exposure duration** | | | | | | | | | | |
| 10 s | 22.07 | 0.39 | 0.056 | 0.28 | 0.50 | 49.26 | <0.001 | 1.48 | 1.33 | 1.66 |
| 2 s | 7.67 | −0.66 | 0.056 | −0.77 | −0.55 | 139.58 | <0.001 | 0.52 | 0.46 | 0.58 |
| 5 s | 14.89 | – | – | – | – | – | – | 1 | – | – |
| **Pressure** | | | | | | | | | | |
| 0 psi | 11.70 | −0.30 | 0.051 | −0.40 | −0.20 | 34.83 | <0.001 | 0.74 | 0.67 | 0.82 |
| 2 psi | 15.82 | – | – | – | – | – | – | 1 | – | – |
| **Procedure duration** | | | | | | | | | | |
| 15 min | 19.13 | 0.046 | 0.051 | −0.05 | 0.15 | 0.82 | 0.37 | 1.05 | 0.95 | 1.16 |
| 30 min | 17.88 | 0.058 | 0.068 | −0.07 | 0.19 | 0.75 | 0.39 | 1.06 | 0.93 | 1.21 |
| 60 min | 20.43 | – | – | – | – | – | – | 1 | – | – |

Mean values represent the regression estimated average liquid penetration in grams corresponding to each condition of the study. Maximum likelihood estimation assuming a gamma distribution. Each predictor is categorical with the reference group listed as the last row for each variable. Exp(B) is the relative risk for each level of the variable when compared to the reference group.

B, regression coefficient from the generalized linear model; psi, pounds per square inch.

**Table 5.**

Total Liquid Penetration Regressed on Exposure Type with Expanded Categories

| Variable, parameter | Mean, g | B | SE | 95% Wald confidence interval | | Wald Chi-square | p Value | Exp(B) | 95% Wald confidence interval for Exp(B) | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | | Lower | Upper | | | | Lower | Upper |
| Exposure type | | | | | | | | | | |
| 1 spray | 0.49 | −3.17 | 0.16 | −3.48 | −2.87 | 406.64 | <0.001 | 0.04 | 0.03 | 0.06 |
| 4 soaks | 12.67 | 0.08 | 0.15 | −0.21 | 0.38 | 0.32 | 0.57 | 1.09 | 0.81 | 1.46 |
| 4 sprays | 3.11 | −1.32 | 0.15 | −1.61 | −1.03 | 80.36 | <0.001 | 0.27 | 0.20 | 0.36 |
| 4 sprays/4 soaks | 11.65 | – | – | – | – | – | – | 1 | – | – |

Mean values represent the regression estimated average liquid penetration corresponding to each condition of the study. Maximum likelihood estimation assuming a gamma distribution. The exposure type predictor is a categorical with the reference group listed in the last row–4 Sprays/4 Soaks. Exp(B) is the relative risk for each the level of the variable when compared to the reference group.

B, regression coefficient from the generalized linear model.