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Major Article

Evaluation of fluid leakage at the coverall and glove interface in single and double glove conditions

Zafer Kahveci PhD^a, F. Selcen Kilinc-Balci PhD^{a,*}, Patrick L. Yorio PhD^b^a US Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA^b US Centers for Disease Control and Prevention, Office of the Director (OD), Human Resources Office (HRO), Office of the Chief Operating Officer (OCOO), Atlanta, GA

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A B S T R A C T

Background: Fluid leakage through the glove-protective clothing interface is an area of concern for many health care personnel, including emergency medical service providers, who may wear coveralls to protect themselves from multiple types of hazards. There is currently no established standard test method to specifically evaluate the barrier performance of the glove-protective clothing interface region for any personal protective equipment ensemble.

Objective: This study quantifies the fluid leakage at the coverall and glove interface using single and double gloving.

Methods: A robotic arm, which can simulate upper extremity movements of health care personnel, was used to test 5 coverall models and an extended examination glove model in single and double glove conditions.

Results: The results show that there was a significant difference in fluid leakage amounts between some of the coverall models and the number of glove layers studied. Findings also highlight that there is a high correlation between basis weight and stiffness of the coverall fabrics and the fluid leakage amounts.

Conclusions: These results underline that coverall constructed from thin and less stiff fabrics can result in lower fluid leakage levels. Also, there was no significant difference in fluid leakage amounts between single and double gloves when tested with each of the coverall models, with the exception of the coveralls with the highest basis weight and stiffness.

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It is essential for health care personnel (HCP) to follow the basic principles of protection to ensure that infectious material does not reach unprotected skin or mucous membranes while patient care is being provided. Personal protective equipment (PPE) play a vital role in preventing contamination of clothing with blood and body fluids that may be contaminated with pathogens such as the Hepatitis B and Hepatitis C viruses, Ebola virus,^{1–5} and coronaviruses.⁶ Various types of PPE are used to protect HCP, including gloves, gowns, coveralls, masks, respirators, goggles, and face shields. Gowns are one of the main types of protective clothing items used in health care settings to protect HCP from the transmission of micro-organisms that

may be found in blood and body fluids; however, coveralls may also be recommended when greater coverage is required.

The movement of microorganisms through protective clothing depends on several factors, including the physical and chemical properties of the fabric, the shape and size of micro-organisms, the characteristics of the medium which carries the microorganisms, and various external factors such as pressure on the fabric.⁷ There are many different types of gowns and coveralls available in the marketplace with varying protection levels and design features. Therefore, selection of appropriate PPE depends on characteristics such as type and duration of the anticipated exposure, durability, fit, and relevance for the task.⁸ In high-risk exposure settings, the use of impermeable gowns or coveralls may be recommended.⁹ When the main transmission route of a highly infectious virus is through direct contact (such as through broken skin or mucous membranes in the eyes, nose, or mouth) with blood or body fluids, extreme PPE precautions should be applied by HCP. As an example, World Health Organization (WHO) and US Centers for Disease Control and Prevention (CDC)

* Address correspondence to F. Selcen Kilinc-Balci, PhD, US Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochran Mill Rd, Pittsburgh, PA 15236.

E-mail address: [jqc8@cdc.gov](mailto:jcq8@cdc.gov) (F.S. Kilinc-Balci).

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recommended the use of fluid-resistant or impermeable single-use gowns or coveralls in addition to other PPE elements that are necessary for full encapsulation when managing patients with Ebola Virus Disease.

Numerous properties can be used to characterize the level of protection clothing can offer. In Europe, 6 types of protection levels have been outlined in the standards based on many individual fabric properties, including tensile strength, puncture resistance, chemical permeation, flame resistance, and resistance to penetration by blood and body fluids. These “types” of protection levels are defined based on the intended protection against a variety of hazardous materials—namely, dust, liquids, or gases in variable pressure levels.^{10–13} In the United States, the National Fire Protection Association (NFPA) established and recognized several standards for coveralls that are intended to provide protection against multiple types of hazards, such as chemicals and biological contaminants. One of the standard test methods that NFPA used in the coverall specifications is the ASTM F1359 Standard Test Method for Liquid Penetration Resistance of Protective Clothing or Protective Ensembles Under a Shower Spray While on a Manikin, which may be similar with the testing methodology outlined in this paper. ASTM F1359 defines minimum performance requirements for each PPE component and requires the performance of a shower spray test, which measures the liquid penetration resistance of the construction and configuration of the overall protective clothing or protective ensemble, particularly of seams, closures, and interfaces along with other components such as gloves, boots, hoods, and respiratory protective devices.¹⁴ Some of the features of ASTM F1359 standard test method may not allow to measure fluid leakage through the glove and protective clothing interface for health care settings. First, it uses a stationary mannequin which does not allow for the simulation of different types of HCP movements. Second, it simulates only the spraying type of exposure, although soaking is also common in health care settings where HCP are exposed greater amount of fluids. The last, the pressure that can be applied during the performance of health care tasks was not considered in this standard and the fluid leakage is not quantified.

The glove-protective clothing interface (hereinafter “the interface”) can be described as the junction between the open end of a glove and the sleeve of a protective clothing immediately underneath the glove. There is currently no established standard test method to quantify the barrier performance of the interface region for any PPE ensembles. The coverall sleeves are constructed wide to provide comfort to the wearer; however, when gloves are donned, the extra portion of the coverall sleeve typically creates channels underneath the extended cuff of the glove.^{15,16} A greater risk of exposure to the arm and wrist areas arises when standard cuff examination gloves are used. The standard glove cuff barely covers the cuff of the coveralls and creates not only channels but also large gaps. Body fluid may travel through those channels or openings and thereby contaminate the skin of the wearer. Thus, fluid leakage through the interface can put both HCP and patients at risk for transmission of pathogens.¹⁷

This study examines quantitative evidence of fluid leakage through the interface using a robotic arm that simulates HCP movements during patient care activities. The primary goal of the

research is to compare the fluid leakage at the interface for 5 coverall models—each paired with an extended examination glove model in single and double glove conditions while upper extremity movements and fluid exposures for isolation settings were simulated. An examination of the fluid leakage that can occur at the interface can help end users to make informed PPE selection and support future standard development processes. Although the main focus is health care exposures, the findings are applicable to other occupational settings such as agriculture, construction, and chemical manufacturing, where coveralls are also used against similar exposure routes.

METHODS

Five disposable coverall models from four major manufacturers were selected from the most used coveralls in the US market by the US Veterans Affairs Hospitals, US Ebola Treatment Centers, and the Strategic National Stockpile in 2016. The model information was obtained from our partners. Coverall information was collected from manufacturers’ product data sheets. The manufacturers were DuPont, Kimberly Clark, Medline, and Enviroguard. The coveralls were denoted 1C, 2C, 3C, 4C, and 5C, respectively, for the purpose of this study. [Table 1](#) lists the properties of the coveralls used in this study.

There are several fabric types used for manufacturing disposable coveralls. One of the methods to manufacture a specific type of fabric is flash spinning of polymers, such as polyethylene, and polypropylene. The “flashspun” term comes from when solvent vaporizes rapidly (flashes) during the extrusion of the polymer solvent mixture through fine holes with high pressure and temperature. This process produces fine fibers, which are then compressed into dense sheets of fabric-like materials. The fabric produced using this method has many superior properties such as liquid resistance, softness, strength, and breathability. A microporous film sheet is another material type used for the construction of disposable coveralls. These coverall fabrics usually consist of additional microporous polyethylene film as a second layer on top of a standard spunbonded polymer layer. The film layers are expected to increase the liquid resistance and strength of the materials; however, end products may suffer from reduced breathability and thus cause discomfort to the user due to heat retention. Similarly, laminated fabrics also provide excellent liquid barrier resistance but may cause comfort issues due to reduced breathability.

The fabric types of the coveralls selected for this study varied depending on the model. The 1C DuPont Tyvek 800 and 2C DuPont Tyvek 600 garments are composed of flash-spun high-density polyethylene nonwoven material. The 3C KleenGuard A60 coveralls have 3-layer fabric construction with a middle layer of microporous film. The 4C Medline NONCV300XL was described as from microporous breathable material that passes ASTM F1670. The 5C Enviroguard Viroguard 2 is made from a proprietary laminated nonwoven material. The physical properties including thickness, weight, stiffness, and sleeve cuff width for each of the coveralls are shown in [Figure 1](#) and [Table 2](#).

The examination glove model used in this study was manufactured from nonlatex and powder-free nitrile material. The Fisher-brand extended cuff nitrile examination gloves (Fisher Scientific

Table 1
Properties of the coveralls

ID#	Manufacturer	Model number	Seam			Cuff type
			Shoulder	Sleeve	Hood	
1C	DuPont	TJ198TWHLG0025PI	No seam	Serged and taped	Serged and taped	Elastic, thumb hook
2C	DuPont	TY198TWHLG002500PI	No seam	Serged and taped	Serged and taped	Elastic
3C	Kimberly Clark	KleenGuard A60 45003	No seam	Serged, no tape	No hood	Elastic
4C	Medline	NONCV300XL	Serged	Serged, no tape	No hood	Plain
5C	Enviroguard	Viroguard 2	No seam	Serged and taped	No hood	Elastic, thumb hook, tape

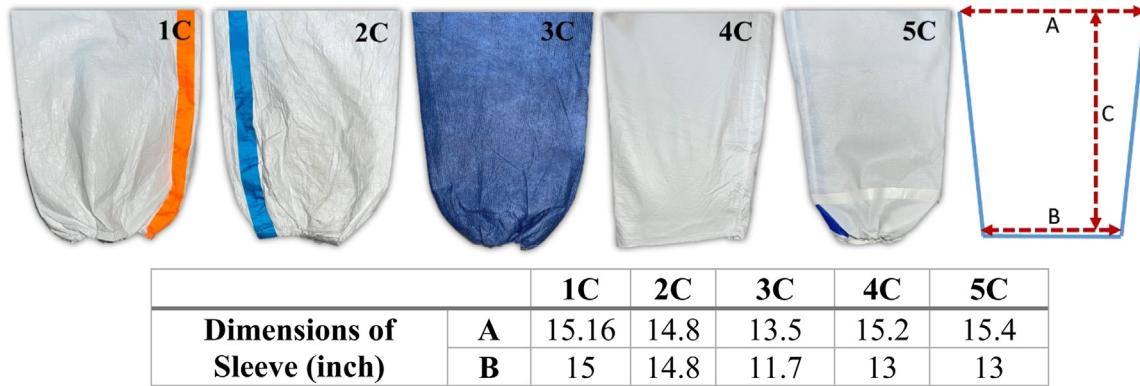


Fig 1. Sleeve designs and circumference measurements of overall models. C represents the sleeve length covered by glove cuff and equal to 6 inches.

catalog number is 19-041-170B) were labeled as complying with ASTM F1671, ASTM F739, and ASTM D3578 and were FDA 510(k)-cleared for medical use. The manufacturer claimed that these gloves are nonsterile with a beaded cuff, were made with textured finish for a superior wet or dry grip and were tested for use with chemotherapy drug exposure. These extended cuff gloves, which are 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 surface tension of the exposed fluid plays an important role in the penetration through fabric, as higher values are expected to have less penetration and vice versa. The challenge fluid was prepared using deionized water and a surfactant as suggested in ASTM F903¹⁸ (0.03% weight percent solution of Surfynol 104H, Air Products) to keep the surface tension at approximately 42±2 dyn/cm. This fluid was used for all of the experiments. A surface tension of 42±2 dyn/cm was selected for two main reasons: (1) the surface tension of 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 and (2) ASTM F1670¹⁹ and ISO 16603²⁰ specify the use of synthetic blood with a surface tension of 42±2 dyn/cm to simulate body fluids. The synthetic blood was not used due to reported stability issues and difficulty with the cleaning stains from the chamber.

This study used a published testing methodology to determine the barrier performance of the interface with the use of a robotic prosthetic limb to simulate HCP movements during the performance of health care tasks.¹⁶ This robotic arm is capable of mimicking nearly all the movements of a human arm. The testing includes 4 equidistant corner nozzles aimed at the interface, which are used to introduce challenge fluids in the chamber.

The type of movement and the joints involved in the movement are the critical parameters that directly affect the fluid leakage at the interface. The most common arm movements by HCP during patient care were selected for the arm movements procedure of this study. These movements were determined by current literature as well as by researchers communicating and reaching a consensus with HCP and subject matter experts in the field^{21,22} (Table 3).

Table 2
Overall fabric properties, with standard deviations shown in parentheses

ID	Average thickness (mm)	Average basis weight (g/m ²)	Average circular bending stiffness (lbf)
1C	0.196 (0.017)	62.362 (2.598)	0.5192 (0.099)
2C	0.184 (0.017)	47.291 (2.174)	0.3052 (0.049)
3C	0.408 (0.023)	73.223 (3.340)	0.8592 (0.099)
4C	0.284 (0.061)	48.175 (1.418)	0.2928 (0.044)
5C	0.376 (0.009)	91.464 (5.882)	1.466 (0.149)

In terms of the duration of exposure, previous studies highlighted that, in general, the period of isolation gown use is very brief and less than 15 minutes.²³ In clinical settings, the procedure time (wear time) may vary^{24,25}; however, total test duration was kept constant at 15 minutes. Moreover, previous findings by NIOSH researchers 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.¹⁶ Regarding the type of exposure, the most common exposure type experienced in the isolation settings, as determined via the communications with subject matter experts, may be best characterized as brief spraying. Consequently, a one-time 5-second spraying exposure was simulated in each 15-minute testing duration. The testing procedure started with introduction of test fluid by spraying, and a 5-second spray was employed directly to the interface from 4 corner nozzles at the beginning of each testing procedure. The challenge fluid amount was decided upon through literature research and discussions with subject matter experts, and the total fluid amount applied from 4 nozzles to the interface was measured as 187 mL at 10 psi outlet pressure of the pump.^{16,24} The robotic arm was automated to perform a series of preprogrammed movements after the exposure. An additional inner cotton sleeve (93/7% Cotton/Spandex, Medline, NONSLEEVE) was used to collect the penetrated fluid. The evaluation of the fluid leakage in grams was done by calculating the amount of fluid absorbed by the inner cotton sleeve, which was done by weighing its dry and wet states and calculating the difference. The scale used in the measurements was a Symmetry by Cole-Parmer model # S-PT 413E with 0.001-g sensitivity. The fabric stiffness was measured using the SASD-672 pneumatic fabric stiffness tester by J.A. King (Whitsett, NC) and following ASTM D1388. The stiffness test was performed by a plunger forcing a flat, folded swatch of fabric through a circular opening. The test method measures the force required to push the fabric through the orifice.

Table 3
Body part movements in 15-minute isolation simulation

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

Each of the coverall models was coupled with an extended examination glove and both single and double glove layer conditions were examined. Each of the ten test configurations (5 coveralls x 2 glove conditions) was tested ten times, thus 100 data points were collected. Analysis of variance (ANOVA) was used to examine the fluid exposure at the interface for each of the ten coverall and glove configurations individually. Within the ANOVA, the main effect of coverall, the main effect of the number of gloves, and their interaction were considered as the effects of interest. Following the factorial model, follow-up, Bonferroni-adjusted, post hoc multiple comparisons were conducted to further examine the pattern of differences within the effects. The correlation analysis was conducted between leakage and fabric thickness, basis weight, and stiffness values. IBM SPSS Statistics version 23 (IBM) was utilized.

RESULTS

The descriptive statistics for each test configuration in the experimental design are shown in Table 4. The mean fluid leakage (M) for both single and double gloved conditions for each of the coveralls included in the study are included in Table 4 and depicted in Figure 2. As shown, there was variability in fluid leakage between the single and double glove conditions and across the coveralls studied. As also depicted, 5C had the highest overall fluid leakage for each of the glove conditions.

Each of the effects within the ANOVA (ie, the main effect of coverall model, the main effect of the number of gloves, and their interaction) were significant at the $P < .001$ level. Ignoring the number of gloves, the main effect of coverall model was significant ($F = 49.73$, $df = 4$, $P < 0.001$, $\eta_p^2 = 0.69$). The mean fluid leakage in grams for 1C = 0.82, 2C = 0.95, 3C = 1.06, 4C = 0.68, and 5C = 2.59. Follow-up, adjusted, post hoc multiple comparisons showed that fluid leakage for 5C was significantly higher than for the remaining coveralls ($P < 0.001$) and that 4C was significantly lower than 3C ($P < 0.02$). Fluid leakage for the remaining coveralls was not significantly different. The main effect of the number of gloves was also significant ($F = 24.06$, $df = 2$, $P < 0.001$, $\eta_p^2 = 0.21$). Across coverall models, when a single glove was worn the mean fluid leakage was 1.46 g, while double gloves resulted in a mean fluid leakage of 0.98 g.

In addition, the interaction between coverall model and the number of gloves ($F = 7.27$, $df = 4$, $P < 0.001$, $\eta_p^2 = 0.24$) was significant. In order to compare the differences between single and double gloves for each gown model individually, follow-up adjusted, post hoc multiple comparisons were conducted. The use of double gloves instead of single glove resulted in a decrease in fluid leakage values. Although the overall difference between single glove and double gloves across the different coverall models was significant, when coverall models 1C, 2C, 3C, and 4C were considered individually, the fluid leakage

was not significantly different between 1 and 2 gloves. There was a significant difference in fluid leakage between single ($M = 3.36$ g) and double gloves ($M = 1.82$ g) when coverall model 5C was considered ($P < 0.001$). Note that due to the seam design (serged and no taped seams), 2 of 10 observations for each of the 3C and 4C models involved visible fluid penetration through sleeve seams when tested with single gloves. Similarly, 5 and 4 out of 10 observations with 3C and 4C models, respectively, included seam failures when these coveralls were tested with double gloves. Although the penetration through the seams slightly increased the mean leakage values, these observations were not excluded in the analysis since they also contributed to the overall penetration values.

The bi-variate correlations between leakage, fabric thickness, basis weight, and stiffness are shown in Table 5. The correlations were computed between the mean fluid leakage and physical properties after aggregation. Stiffness and basis weight shared the strongest association with fluid leakage. The association between thickness and leakage was the weakest and was not significant. Figure 3 provides a depiction of how the average fluid leakage and physical properties vary across the different coveralls. Within the figure, each of the measures were entered untransformed but the log of mass was used in order to better depict the associations.

DISCUSSION

In general, fluid leaked through all the coverall and glove interfaces tested and reached to the inner sleeve where it was collected, which represents a failure in the fluid resistance of the interface, although fluid exposure was only 5 seconds. This is probably because of the large and baggy design of the coverall sleeves and use of stiff fabrics, since large channels and voids were created when the glove was donned due to the pleats and folds.²⁶ However, less stiff fabrics could be better compressed with the pressure applied by the elastic glove cuff, which reduces the voids and channel size. This effect was more noticeable when double gloves were worn, perhaps because the double glove cuff exerts greater pressure on the coverall fabric. The fabric used in the construction of 5C has the greatest stiffness values compared to the other coverall models, which may explain why 5C resulted in higher leakage values, and the leakage declined relatively when the double layer glove was worn. Also, 3C, which was constructed from a fabric with the second greatest stiffness value, resulted in the second greatest leakage value, although smaller sleeve width was used compared to all other coveralls. The same correlation could also be found with the basis weight value (Table 5). An increase in fabric basis weight and stiffness is expected to contribute to worker fatigue due to movement restrictions, additional weight, and heat stress. Stiffness may also result in discomfort; therefore, these properties could be considered by the HCP when selecting a coverall.

Table 4
Descriptive statistics

Coverall Models	Number of gloves	N	Mean fluid leakage (g)	Std. deviation	Std. error of mean	95% Confidence interval	
						Lower	Upper
1C	1	10	0.88	0.16	0.05	0.56	1.19
	2	10	0.76	0.12	0.04	0.45	1.07
2C	1	10	1.03	0.17	0.05	0.72	1.34
	2	10	0.86	0.12	0.04	0.55	1.17
3C	1	10	1.22	0.13	0.04	0.91	1.53
	2	10	0.90	0.17	0.05	0.59	1.21
4C	1	10	0.82	0.26	0.08	0.51	1.13
	2	10	0.54	0.23	0.07	0.23	0.85
5C	1	10	3.36	1.41	0.45	3.05	3.67
	2	10	1.82	0.45	0.14	1.51	2.13

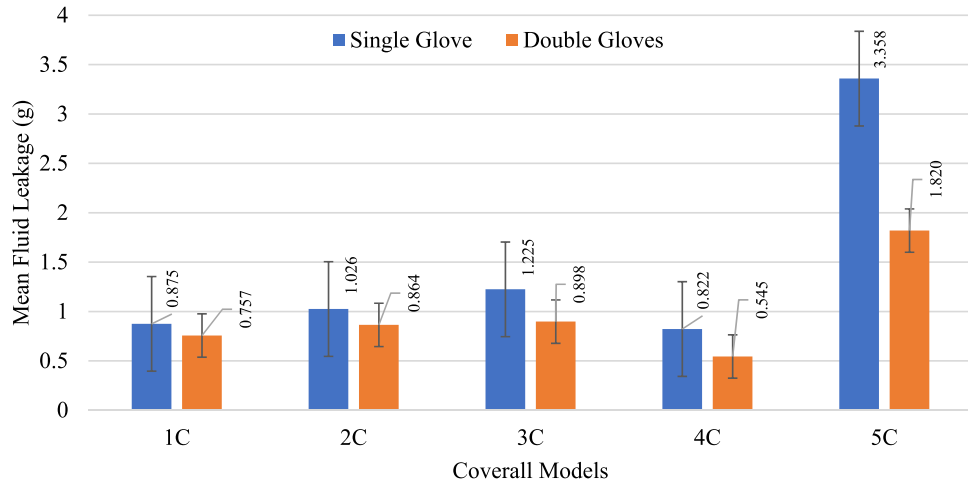


Fig 2. Mean fluid leakage for all coverall models in single and double glove conditions.

Table 5
Bi-variate correlations between leakage, fabric thickness, basis weight, and stiffness

	Leakage	Thickness	Basis weight
Thickness	0.48		
Basis Weight	0.77*	0.73*	
Stiffness	0.83*	0.73*	0.98*

*Correlation with a P value less than .05 level (2-tailed) were considered significant.

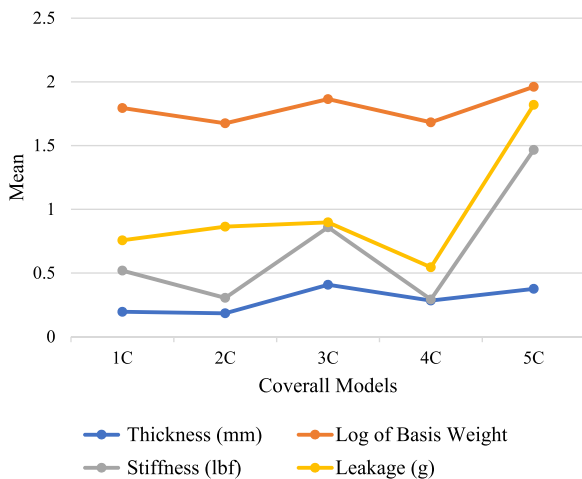


Fig 3. Mean leakage, thickness, stiffness, and log of basis weight for each coverall model.

CONCLUSIONS

Fluid leakage through the glove-protective clothing interface is an area of concern for many HCP, including emergency medical service personnel, who may wear coveralls to protect themselves from multiple types of hazards and under unexpected conditions. In contrast to the significant risks posed to HCP, there are limited research studies devoted to understanding the degree of fluid leakage through the glove-protective clothing interface. This study represents one of the first efforts to compare the amount of fluid leakage for 5 coverall models, 1 examination glove model, and single vs double gloving. A unique and state-of-the art robotic arm was utilized in this study to simulate the arm movements of HCP while the most frequent types of exposures were introduced.

The results showed that there was a significant difference in fluid leakage amounts between some of the coverall models and the number of glove layers. The trend was maintained when the number of gloves was increased. Some of the differences in the fluid leakage amounts were attributed to fabric basis weight and fabric stiffness. Also, the results demonstrated that although the overall difference between single glove and double gloves across the different coverall models was significant, when coverall models 1C, 2C, 3C, and 4C were considered, the fluid leakage was not significantly different between single and double glove conditions. Findings highlighted that there was a high correlation between basis weight and stiffness of the fabrics that coveralls were constructed from and the fluid leakage amounts. These results underline that coveralls constructed from low basis weight and less stiff fabrics can result in lower fluid leakage levels. However, the glove-protective clothing interface represents only one of the potential exposure routes; therefore, penetration properties of the gloves and fabric as well as seams need to be considered. As a follow-up to this study, the results could be confirmed with human subject testing for validation and to explore and address the limitations of the testing system. In addition, the impact of the common solutions developed on the field (eg, taping) on the leakage amounts could be investigated.

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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