Centers for Disease Control and Prevention

# The National Personal Protective Technology Laboratory (NPPTL)

NIOSH

# Considerations for Selecting Protective Clothing use in Healthcare for Protection against Microorganisms in Blood and Body Fluids

# Background

Healthcare workers can be exposed to biological fluids that are capable of transmitting diseases. Those diseases, whi are caused by a variety of microorganisms such as, Hepatitis B virus (HBV), Hepatitis C virus (HCV), Ebola Virus, and Human Immunodeficiency Virus (HIV) can pose significant risks to life and health. Healthcare workers wear protective clothing (e.g., surgical gowns, isolation gowns, and coveralls) to protect both patients and themselves from the transf microorganisms by blood and body fluids. A common misunderstanding among many end users is that they are protected from blood, body fluids, and other potentially infectious materials when they wear any type of fluid-resista garment. This document provides an overview of scientific evidence and information on national and international standards, test methods, and specifications for fluid-resistant and impermeable gowns and coveralls used in healthca This document focuses on selecting protective clothing primarily on the basis of their barrier properties; it does not address all aspects of garments related to their design, integrity, durability, comfort, and functionality.

# Classifying Worker Exposure to Bloodborne Pathogens

As with any type of personal protective equipment (PPE), the key to proper selection and use of gowns and coveralls understand the hazards and the risk of exposure. The Centers for Disease Control and Prevention (CDC) has categori three primary routes of transmission: (i) contact (direct and indirect), (ii) respiratory droplets, and (iii) airborne drople nuclei [Siegel 2007]. Contact transmission is generally the most common and direct contact occurs when microorgan transfer directly from one person to another. Airborne transmission occurs by dissemination of either airborne drop nuclei or small particles in the respirable size range containing infectious agents. Droplet transmission refers to respiratory droplets generated through coughing, sneezing, or talking. By using appropriate protective clothing, it is possible to create a barrier to eliminate or reduce contact and droplet exposure, and therefore prevent the transfer o microorganisms between patients and healthcare workers. This document provides information about protective clothing standard test methods and classification standards when the transmission of the microorganisms is through direct contact with blood or body fluids. Direct contact can occur through broken skin or mucous membranes located areas such as the eyes, nose, or mouth. In addition to blood, other body fluids can include (but are not limited to) urin saliva, sweat, feces, vomit, breast milk, and semen.

Employers should conduct a thorough risk assessment first to identify potential exposures to blood and body fluids. risk of exposure sometimes depends on the stage of the disease and severity of symptoms. For example, for Ebola vi disease, severe symptoms are strongly associated with high levels of virus production. In addition, close contact with patient and invasive medical care can increase opportunities for transmission. This should be considered during the assessment, such as in the case of Ebola virus disease, as Ebola patients can release large volumes (as much as 8 liters/day) of body fluids (vomit, diarrhea) [Kreuels 2014]. A complete assessment of the risks is outside the scope of t document, but resources are available. For example, the Association for the Advancement of Medical Instrumentatio (AAMI) published a guidance document on selection and use of protective apparel in healthcare facilities, Technical Information Report (TIR) 11 [AAMI 2005]. Some of the factors important to assessing the risk of exposure in he facilities include source, modes of transmission, pressures and types of contact, and duration and type of tasks.

# Selecting Protective Clothing

## Barrier Properties of Protective Clothing

Once the hazard and the risks of exposure are identified, gown and coverall selection can be guided by current scientific understanding of how protective clothing materials provide protection against microorganisms in blood a body fluids. A microorganism's movement through protective clothing materials depends upon several factors, including the following:

- **Physical and chemical properties of the fabric:** Includes factors such as thickness pore size, and repellency
- **Shape, size, and other characteristics of the microorganisms:** Includes factors such as morphology, motility, and adaptation to environmental extremes
- **Characteristics of the carriers:** Includes factors such as surface tension, volume, and viscosity
- **External factors:** Includes factors such as physical, chemical, and thermal stresses

Several different microorganisms have been found in healthcare settings, including bacteria, viruses, and some fur The shape and size of microorganisms varies, and this will affect their ability to move through a fabric structure. In general, fungi are larger than bacteria, and bacteria are larger than viruses. For instance, HIV virus is spherical and 100–120 nanometers (nm) in diameter. The Ebola virus is a single-stranded RNA virus with a filamentous shape, a median particle length ranging from 974 nm to 1,086 nm, and average 80 nm in diameter.

Microorganisms are transported by carriers such as body fluids, sloughed skin cells, lint, dust, and respiratory droplets. 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 (see Figure 1). For example, the number of infectious units of Hepatitis B a 0.1-microliter (µL) droplet is 10,000, which is why it is highly infectious and easily transferrable. Ebola virus RNA levels in blood also increase rapidly during the acute phase of the illness. One study reported an average peak titer $3.4 \times 10^5$ RNA copies per 0.1 µL (i.e., 34 times higher than the concentration of Hepatitis B) for cases associated with fatal outcome [Towner 2004]. Several studies [Brown 1992; Kotilainen et al. 1992; Shadduck et al. 1990; McCullough 1993] have also reported that when liquid containing microorganisms penetrate a material, microorganisms are carried with it, and penetration is possible without liquid being visible. Because of this, standardized test methods must be sensitive enough to detect microorganism penetration, since this is the only way to determine if microorganism penetration has occurred in any part of the garment, including the seams.

| Volume of strike-through[1] | 100 µL | 10 µL | 1 µL | 0.1 µL |
|---|---|---|---|---|
| *Approximate size* |  |  |  |  |
| Number of bloodborne pathogens[2] | | | | |
| HBV | 10,000,000 | 1,000,000 | 100,000 | 10,000 |
| HCV | 100–100,000 | 10–100,000 | 1–1,000 | 0.1–100 |
| HIV | 6–700 | 0.6–70 | 0.06–7 | 0.006–0.7 |

[1] Volume of red 40 dyne/cm synthetic blood delivered to white blotter paper.
[2] Based on documented whole blood concentrations of infected patients.

**Figure 1: Bloodborne pathogen strikethrough (penetration) conversion chart (This chart converts the amount of strikethrough to the amount of potential bloodborne pathogen contamination). The four spots at the top were formed from premeasured droplets of synthetic blood and marked in microliters**

**(µL) ranging from 100 µL to 0.1 µL. Adapted with permission from AAMI TIR 11:2005, "Selection and us of protective apparel and surgical drapes in health care facilities."**

**Terminology**

**Design of Protective Clothing: Gown vs. Coverall**

**Critical Fabric and Clothing Properties**

**Donning and Doffing Features of Protective Clothing**

**Other Factors**

**Review Protective Clothing Manufacturers Data/Information**

# Current Healthcare Protective Clothing Standards and Specificatior

Several fluid-resistant and impermeable protective clothing options are available in the market place for healthcare workers. These include isolation gowns, surgical gowns, and coveralls. When selecting the most appropriate protectiv clothing, employers should consider all of the available information on recommended protective clothing, including t potential limitations. Employers should consult protective clothing manufacturers as needed in regards to availability practicality for their facilities. A key step in this process is to understand the relevant standards and test methods. Descriptive information about each standard is provided in the body of this document.

## Standard Test Methods to Measure Blood and Viral Penetration Resistance

When the transmission route is defined as "direct contact transmission," such as in the case of Ebola and HIV, employers should consider gowns and coveralls that demonstrate resistance to synthetic blood, as well as passage virus. Standard test methods can be used to evaluate the resistance of fabrics or seams/closures to synthetic blood penetration and viral penetration, as described in Table 1.

The United States commonly uses American Society of Testing and Materials International (ASTM) methods, while Europe commonly uses International Organization for Standardization (ISO) methods.

**Table 1. Standard test methods to evaluate the resistance of fabrics to synthetic blood and virus penetration**

| Barrier Property (Type of Penetration) | ASTM Test Methods | ISO Test Methods |
|---|---|---|
| Synthetic Blood Penetration | ASTM F1670— *Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood.* | ISO 16603— *Clothing for protection against contact with blood and body fluids—Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood.* |

| | | |
|---|---|---|
| Viral Penetration | ASTM F1671— *Standard test method for resistance of materials used in protective clothing to penetration by bloodborne pathogens using Phi-X174 bacteriophage penetration as a test system.* | ISO 16604— *Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by bloodborne pathogens— Test method using Phi-X174 bacteriophage.* |

Note: These tests are typically conducted on fabrics, but they can be conducted on the garment seams as well. It is recommended that end users inquire from the garment manufacturers about seam barrier test results, in addition to the fabrics, in order to appropriately protect healthcare workers from blood and viral penetrations.

ASTM F1670 and ISO 16603 are “screening-tests” that evaluate the resistance of a material to synthetic blood penetration [ASTM 2003a; ISO 2004a]. The synthetic blood used for these tests is a mixture of cellulose, coloring, buffer solution, and stabilizing agents. Synthetic blood has a surface tension (0.042 ± 0.002 Newton per meter [N/m and viscosity representative of blood and some body fluids (see Table 2 for surface tension of the body fluids).

Within the context of gowns and coverall testing, the surface tension of the challenge liquid is critical. This is becau liquids with higher surface tension, like water (0.070–0.072 N/m), are more likely to bead on a surface than liquids with lower surface tension, which are more likely to wet and penetrate through the garment. Consequently, some test methods that use water as a challenge agent may not be representative for evaluating the barrier effectivenes of the healthcare PPE and may overestimate the effectiveness of the PPE for blood-borne pathogens. Test method evaluating the water resistance of garments will be discussed later in this document.

**Table 2: Surface tension values for water, synthetic blood, and human blood and body fluids**[1]

| | Surface Tension (N/m) | | | Temperature(°C) |
|---|---|---|---|---|
| | Average | Min. | Max. | |

The viral penetration resistance tests, namely ASTM F1671 and ISO 16604, are similar to ASTM F1670 and ISO 1660 but they use a bacteriophage (Phi-X174) challenge suspension instead of synthetic blood [ASTM 2003a; ISO 2004b]. the conclusion of the exposure period in the ASTM F1671 or ISO 16604 viral penetration tests, the opposing surfac of the material is rinsed with an assay fluid, and this fluid is then cultured in the presence of the host bacterium, E. coli. Plaques form when a bacteriophage is present, with the number of plaques indicating the number of penetrating bacteriophages. Materials pass the viral penetration test when no liquid is observed to penetrate the specimen and the E. coli bacteriophage is not detected in the assay fluid.

The choice of virus challenge agent in the standard methods is a critical test condition. For these test methods, the bacteriophage serves as a surrogate to simulate viruses that are pathogenic to humans. Phi-X174 bacteriophage ha nearly spherical morphology similar to HIV, Hepatitis B, and Hepatitis C. At 27 nm in diameter, it is similar in size an shape to Hepatitis C (30 nm in diameter), which is the smallest-known bloodborne viral pathogen.

As mentioned earlier, the size and shape of a virus are believed to affect viral penetration, and thus selecting a sma virus (27 nm in diameter) would serve as a “worst-case” scenario for the barrier material. Smaller particles are expected to more easily pass through pores in the fabrics used in barrier materials. Some of the other viruses, such

as Ebola virus, are larger in diameter compared to Phi-X174. Currently, there is no scientific evidence to suggest the Ebola and other larger viruses would be more likely to penetrate through protective clothing than a smaller virus.

The amount of pressure applied in the standard methods is another critical test condition. The biggest difference between the ASTM and ISO test methods is the pressure levels used when conducting test procedures. In ASTM F1670 and ASTM F1671, tests are conducted using 13.8 kilopascal (kPa) (2 pounds per square inch [psi]), and the criterion is that no penetration should occur. Whereas, in ISO 16603 and ISO 16604, the maximum pressure level before any penetration occurs is found by applying increasing pressure levels (0 kPa to 20 kPa)—14 kPa is the most equivalent pressure to that of the ASTM tests. Note that ISO 16603 and ISO 16604 are used to classify and rank materials, and they do not relate the classification of material barrier performance to any specific circumstances of use.

Penetration (often called strikethrough) can be initiated by an external force acting against clothing. The force generated by an external pressure, such as from a pressing or leaning motion, is likely one of the major routes of blood penetration, especially in the chest and sleeves of protective clothing. These pressures arise when individual wearing protective clothing lean or press on a surface that may be wet with blood or body fluids, such as in the cas of a healthcare worker leaning against a patient's bed 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 et al. 1991] reported that the pressures exerted on surgical gowns during pressing and leaning in surgery can range from 1 psi to 60 psi. Blood penetration has been shown to increase with increasing pressure [Granzow et al. 1998].

Although high pressures have been reported, other studies have found that many common surgical movements (including leaning, reaching, and arm resting) result in less than 2 psi pressure. For example, [Smith et al. 1995] evaluated the pressures generated during a variety of surgical procedures and found that most pressures applied the front of surgical gowns are 2.9 psi or less for 15 seconds or less. Another study showed that leaning against the operating table caused a pressure of 0.52 psi (3.6 kPa), while reaching for an instrument showed the greatest (0.70 psi, which equals 4.8 kPa) [Smith and Nichols 1991]. The greatest pressure seen during any maneuver was 1.84 psi (12.7 kPa) while reaching. Smith and Nichols estimated representative abdominal pressures during surgical procedures to be between 0.25 and 2.0 psi.

Others have looked at the areas where blood/body fluid penetration occurs through the garment. One study found that blood penetration was most common on the chest, forearm, and abdomen, and was correlated with the areas highest exposure and pressure [Quebbeman et al. 1992]. Others have noted that the cuff, forearm, thigh, chest, an abdomen are most vulnerable to blood strikethrough [Pissiotis et al. 1997]. Studies suggest that if a liquid is in prolonged contact with a fabric, prewetting can occur, and this can result in the fabric's decreased resistance to penetration [Flaherty et al. 1993; Olderman 1984].

The viral penetration of surgical gowns by HIV has been compared with the soak-through point (the point at which fluid visibly soaks through the fabric) by multiple investigators [Tyler et al. 1989; Shadduck et al. 1990]. It was reported that HIV could penetrate some surgical gown materials in common use at the time of the studies, and HIV penetration was sometimes noted in the absence of visible soak-through. This is important to remember, because endusers can often have a false sense of security when they see no visible penetration in their garments.

The conditions of the ASTM F1671 test require subjecting barrier material specimens in a special test cell to the vira challenge for one hour, with the sixth minute of the exposure at 13.8 kPa (2 psi) for one minute. These conditions were selected because they are used in a related method, "ASTM F903 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Liquids," which assesses liquid chemical penetration throug

protective clothing materials. Research at Kansas State University [McCullough and Schoenberger 1992] was performed to show how these test conditions best correlated with a human factors evaluation where visible blood strikethrough occurred. This is referred to as the elbow lean test.

**Performance Requirements for Protective Clothing**

**ANSI/AAMI PB70:2012—"Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities"**

**NFPA 1999—"Standard on Protective Clothing for Emergency Medical Operations"**

**Comparison of Test Methods and Classification Standards for Gowns and Coveralls**

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## Additional Reading

## Appendix

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