NPPTL Support for the Ebola Response: Research and Guidance on Gowns and Coveralls

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Photo Credit: NIOSH EPRO
Background

- Healthcare workers (HCW) can be exposed to body fluids that are capable of transmitting diseases
- HCW wear protective clothing to protect both patients and themselves from the transfer of microorganisms by blood and body fluids
- Translating disease-specific infection control recommendations into personal protective equipment (PPE) performance specifications can be challenging
Outline

• Protective clothing selection process
• Standard test methods for blood and viral penetration resistance
• Current healthcare protective clothing (gown and coverall) standards and specifications
• Ongoing NPPTL research projects for Ebola
• Summary
Protective Clothing Selection Process

Conduct Hazard Assessment
- Source
- Modes of transmission
- Pressure and type of contact
- Duration and type of tasks
- Stage of disease
- Severity of symptoms

Identify Standards or Specifications
- HCW gown and coverall classification standards, specifications, test methods
- National, international

Select Appropriate Protective Clothing
- Regulations
- Practices

Photo Credit: CDC PHIL 10816
Microorganism’s Movement through Protective Clothing Materials

- Pore characteristics (size, volume, geometry, and orientation)
- Repellency
- Thickness
- Thread count (woven)

Physical and Chemical Properties of the Fabric

- Surface Tension
- Volume
- Viscosity

Characteristics of Carriers

- Shape
- Size
- Morphology
- Polarity
- Motility
- Adaptation to Environmental Extremes

External Factors

- Physical, chemical, and thermal stresses

Characteristics of Microorganisms

- Shape
- Size
- Morphology
- Polarity
- Motility
- Adaptation to Environmental Extremes
**Bloodborne Pathogen Strikethrough**

- 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.

<table>
<thead>
<tr>
<th>Volume of strike-through (1)</th>
<th>100 µL</th>
<th>10 µL</th>
<th>1 µL</th>
<th>0.1 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>size</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><img src="image.png" alt="Image" /></td>
<td><img src="image.png" alt="Image" /></td>
<td><img src="image.png" alt="Image" /></td>
<td><img src="image.png" alt="Image" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of bloodborne pathogens (2)</th>
<th>HBV</th>
<th>HCV</th>
<th>HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10,000,000</td>
<td>100–100,000</td>
<td>6–700</td>
</tr>
<tr>
<td></td>
<td>1,000,000</td>
<td>10–100,000</td>
<td>0.6–7</td>
</tr>
<tr>
<td></td>
<td>100,000</td>
<td>1–1,000</td>
<td>0.06–7</td>
</tr>
<tr>
<td></td>
<td>10,000</td>
<td>0.1–100</td>
<td>0.006–0.7</td>
</tr>
</tbody>
</table>

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

Terminology

- Fluid-resistant
- Fluid-proof
- Fluid-repellent
- Impervious
- Moisture-resistant
- Moisture-proof
- Impermeable
- Liquid-proof
- Liquid-resistant
Considerations for Protective Clothing Selection

- **Design of protective clothing**
  - No clinical studies have been done to compare the efficacy of gowns vs. coveralls.
  - Coveralls: provide 360-degree protection.
  - Gowns: relatively easier to put on/remove, and more familiar to HCW, hence more likely to be used and removed correctly. The level of heat stress generated is also expected to be less compared to coveralls.

- **Critical fabric and clothing properties**
  - Strength properties of the fabric and seams (e.g., tensile strength and seam strength)
  - Barrier properties of seams/closures
  - Size of the garment

- **Donning and doffing features of protective clothing**
  - The ease or difficulty with which PPE is put on and removed may affect its effectiveness and the potential for self-contamination.

- **Other factors**
  - These include factors such as compliance with regulatory agencies, durability (abrasion resistance), comfort (breathability, air permeability), flammability, electrostatic properties, cost, availability, ergonomics/human factors, and integration with other types of PPE.

Photo credit: CDC PHIL 18351, 17843, 17842
# Standard Test Methods to Evaluate the Resistance of Fabrics to Synthetic Blood & Virus Penetration

<table>
<thead>
<tr>
<th>Barrier Property</th>
<th>ASTM Test Methods</th>
<th>ISO Test Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetic Blood Penetration</td>
<td><strong>ASTM F1670</strong>— Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood.</td>
<td><strong>ISO 16603</strong>— 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.</td>
</tr>
<tr>
<td>Viral Penetration</td>
<td><strong>ASTM F1671</strong>— 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.</td>
<td><strong>ISO 16604</strong>— 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.</td>
</tr>
</tbody>
</table>

Note: These tests are typically conducted on fabrics, but they can be conducted on the garment seams/closures as well.
Critical Parameters of Blood and Viral Penetration Resistance Tests

- Virus morphology
- Time of exposure
- Pressure of the challenge
- Surface tension
Virus Morphology

Phi-X174: spherical, ~27 nm in diameter

HCV: spherical, ~30 nm in diameter

HIV: spherical, 100-120 nm diameter

Ebola Virus: filamentous, ~80 nm in diameter

Photo Credit: CDC PHIL 8153, 11279, 10815
# Surface Tension of the Challenge Liquid

<table>
<thead>
<tr>
<th>Fluid Type</th>
<th>Surface Tension (N/m)</th>
<th>Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Water</strong> [Randall and Calman 1954]</td>
<td>0.072</td>
<td>25</td>
</tr>
<tr>
<td><strong>Synthetic Blood</strong></td>
<td>0.042 ± 0.002</td>
<td>25</td>
</tr>
<tr>
<td><strong>Blood</strong> [Attinger et al. 2013] (review)</td>
<td>—</td>
<td>0.027</td>
</tr>
<tr>
<td><strong>Blood</strong> [Hrncir et al. 1997]</td>
<td>0.056</td>
<td>—</td>
</tr>
<tr>
<td><strong>Saliva</strong> [Kazakov et al. 2009]</td>
<td>0.042</td>
<td>—</td>
</tr>
<tr>
<td><strong>Saliva</strong> [Geigy Scientific Tables, 1984]</td>
<td>0.015-0.026</td>
<td>—</td>
</tr>
<tr>
<td><strong>Gastric juices</strong> [Spychal et al. 1990]</td>
<td>0.047</td>
<td>—</td>
</tr>
<tr>
<td><strong>Gastric juices</strong> [Aburub et al. 2008]</td>
<td>—</td>
<td>0.035</td>
</tr>
<tr>
<td><strong>Duodenal and Jejunal fluids</strong> [Fuchs and Dressman 2014]</td>
<td>—</td>
<td>0.028</td>
</tr>
<tr>
<td><strong>Sweat</strong> [Bothorel et al. 1992]</td>
<td>0.0383</td>
<td>—</td>
</tr>
<tr>
<td><strong>Sweat</strong> [Bothorel et al. 1992]</td>
<td>0.0418</td>
<td>—</td>
</tr>
<tr>
<td><strong>Sweat</strong> [Geigy Scientific Tables, 1984]</td>
<td>0.069-0.070</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) Vomit is usually gastric juice, although in extreme cases intestinal juices can be included. Diarrhea is just the opposite—it is predominantly intestinal juices.
Pressure Type and Level

- Pressures exerted on surgical gowns during pressing and leaning in surgery can range from 1 psi to 60 psi (1)
- 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) (2)
- Most pressures applied to the front of surgical gowns are 2.9 psi or less for a duration of 15 seconds or less (3)
- Representative abdominal pressures during surgical procedures is estimated to be 0.25 - 2.0 psi (2)
- ASTM F1670 and ASTM F 1671 use 2 psi (13.8 kPa) hydrostatic pressure
- ISO 16603 and ISO 16604 use incremental hydrostatic pressure levels, 0 kPa up to 20 kPa
- Hydrostatic vs. mechanical pressure

• Time of exposure to pressurized liquid challenge is also another factor that might affect the results. This time is now set as 1 minute at the ASTM F1670 and ASTM F1671 test methods.
Current Healthcare Protective Clothing Standards and Specifications
Standards and Classifications for Gowns

- **ANSI/AAMI PB70**—Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities
  - Applies to surgical gowns and isolation gowns

- **EN 13795**—Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment. General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels.
  - Applies to surgical gowns

- **ASTM F2407**—Standard specification for surgical gowns intended for use in healthcare facilities
  - Applies to surgical gowns
# ANSI/AAMI PB 70:12 Classification Requirements

<table>
<thead>
<tr>
<th>Level</th>
<th>Test</th>
<th>Liquid Challenge</th>
<th>Result</th>
<th>Expected Barrier Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AATCC 42 Impact Penetration</td>
<td>Water</td>
<td>≤ 4.5 g</td>
<td>Minimal water resistance (some resistance to water spray)</td>
</tr>
<tr>
<td>2</td>
<td>AATCC 42 Impact Penetration</td>
<td>Water</td>
<td>≤ 1.0 g</td>
<td>Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)</td>
</tr>
<tr>
<td></td>
<td>AATCC 127 Hydrostatic Pressure</td>
<td>Water</td>
<td>≥ 20 cm</td>
<td>Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)</td>
</tr>
<tr>
<td>3</td>
<td>AATCC 42 Impact Penetration</td>
<td>Water</td>
<td>≤ 1.0 g</td>
<td></td>
</tr>
<tr>
<td></td>
<td>AATCC 127 Hydrostatic Pressure</td>
<td>Water</td>
<td>≥ 50 cm</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ASTM F1670 Synthetic Blood Penetration Test (for surgical drapes)</td>
<td>Surrogate Blood</td>
<td>no penetration at 2 psi (13.8 kPa)</td>
<td>Blood and viral penetration resistance (2 psi)</td>
</tr>
<tr>
<td></td>
<td>ASTM F1671 Viral Penetration Test (for surgical and isolation gowns)</td>
<td>Bacteriophage Phi-X174</td>
<td>no penetration at 2 psi (13.8 kPa)</td>
<td></td>
</tr>
</tbody>
</table>
ANSI/AAMI PB70 Critical Zones for Gowns

Adapted with permission from ANSI/AAMI PB70:2012, “Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities”
# Overview of Some of the EN 13795 Surgical Gown Performance Requirements

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Test Method</th>
<th>Unit</th>
<th>Standard Performance</th>
<th>High Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance to liquid penetration</td>
<td>EN 20811</td>
<td>cm H₂O</td>
<td>≥20</td>
<td>≥10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>≥100</td>
</tr>
<tr>
<td>Resistance to microbial penetration—dry</td>
<td>EN ISO 22612</td>
<td>CFU</td>
<td>N/A</td>
<td>≤300(1)</td>
</tr>
<tr>
<td>Resistance to microbial penetration—wet</td>
<td>EN ISO 22610</td>
<td>Iₜ</td>
<td>≥2.8</td>
<td>N/A</td>
</tr>
</tbody>
</table>

(1) Test conditions: challenge concentration $10^8$ CFU/g talc. and 30 min vibration time.  
(2) $I_B = 6.0$ for the purpose of this European Standard means: no penetration. $I_B = 6.0$ is the maximum achievable value.
Standards and Classifications for Coveralls

• EN 14126—“Performance requirements and test methods for protective clothing against infective agents”

• NFPA 1999—“Standard on Protective Clothing for Emergency Medical Operations”
EN 14126—Performance Requirements & Test Methods for Protective Clothing against Infective Agents

- EN 14126 defines performance requirements for materials in protective clothing used to protect from infectious agents.
- Due to the heterogeneity of microorganisms (in terms of size, shape, infectious dose, survival abilities, etc.), the EN 14126 standard does not define performance criteria for specific types of microorganisms. The test methods specified in this standard focus on the medium containing the microorganism, such as liquid, aerosol, or solid dust particle.

<table>
<thead>
<tr>
<th>Classification according to EN 14126 of resistance to penetration by blood and body fluids using ISO 16603 and ISO 16604 test methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

Photo Credit: NIOSH EPRO
NFPA 1999—Standard on Protective Clothing for Emergency Medical Operations

• Developed to address a range of different clothing items worn by emergency medical service first responders, but also applies to medical first receivers

• Includes design criteria, performance criteria, labeling requirements, and test methods that address both single-use (disposable) and multiple-use (reusable) emergency medical garments, which can be coveralls, multi-piece clothing sets, or partial body clothing

• Uses ASTM F1671 to demonstrate the viral penetration resistance of materials and seams, which is supplemented with an overall liquid integrity test for full body clothing

• There are also testing requirements applied to materials and seams for setting minimum criteria such as strength and physical hazard resistance
Commonly Used Test Methods to Determine Barrier Effectiveness of Protective Clothing

<table>
<thead>
<tr>
<th>Test</th>
<th>Challenge</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AATCC 42 Impact Penetration</td>
<td>Water</td>
<td>Determines the ability of a material to resist water penetration under spray impact</td>
</tr>
<tr>
<td>AATCC 127 Hydrostatic Pressure</td>
<td>Water</td>
<td>Determines the ability of a material to resist water penetration under constant contact with increasing pressure</td>
</tr>
<tr>
<td>EN 20811 Hydrostatic Pressure</td>
<td>Water</td>
<td>Determines the ability of a material to resist water penetration under constant contact with increasing pressure</td>
</tr>
<tr>
<td>EN ISO 22612 Resistance to microbial penetration—dry</td>
<td>Contaminated (Bacillus Subtilis) talcum powder</td>
<td>Determines the ability of dry fabric to resist penetration of particles carrying microorganisms</td>
</tr>
<tr>
<td>EN ISO 22610 Resistance to microbial penetration—wet</td>
<td>Staphylococcus aureus suspension</td>
<td>Determines a fabric's resistance to penetration of bacteria in a liquid while being subjected to mechanical rubbing</td>
</tr>
<tr>
<td>ASTM F1670 Synthetic Blood Penetration Test</td>
<td>Surrogate Blood</td>
<td>Determines the ability of a material to resist the penetration of synthetic blood under constant contact</td>
</tr>
<tr>
<td>ASTM F1671 Viral Penetration Test</td>
<td>Bacteriophage (Phi-X174) challenge suspension</td>
<td>Determines the ability of a material to resist the penetration of a microorganism under constant contact</td>
</tr>
</tbody>
</table>
Ongoing NPPTL Research Projects

• Elbow-Lean Test
  – Objective: To quickly evaluate blood penetration under mechanical pressure that demonstrates actual use conditions

• ASTM F1670/ASTM F1671
  – Objective: To better understand the factors affecting barrier performance of protective clothing materials against blood and bloodborne pathogens and improve current test methods

• Isolation Gown Project
  – Objective: To define minimum performance and design requirements for isolation gowns

• Heat Stress Evaluation
  – Objective: To evaluate the added heat stress caused by the most commonly used protective garment combinations in West Africa for Ebola
Elbow-Lean Test

- A rapid qualitative screening process
- Originally developed by W. L. Gore and Assoc. Inc., serves as the basis for ASTM F1819 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood Using a Mechanical Pressure Technique
- Represents a simple way to demonstrate blood strikethrough
- Ink pad is saturated with synthetic blood, the test material is placed over the saturated pad, followed by a blotter, and then an individual leans on the blotter to see if the synthetic blood will penetrate onto the blotter
- Simulates actual use conditions

Photo Credit: NIOSH NPPTL
Elbow-Lean Test (Continued)

• Unconfined blood can move away from the pressure point taking the path of least resistance rather than being contained as in ASTM F1670 or ISO 16603 test methods. Uses mechanical forces of a human elbow.

• We evaluated 8 different fabrics from isolation gowns, coveralls and 1 fabric from an apron (both body and seams/zippers) (ANSI/AAMI PB70 Level 1, 2, 3, and 4 isolation gowns, 3 different types of coveralls and an apron)

• Pressure Range: 2-44 PSI

• Only ANSI/AAMI PB70 Level 4 gowns, one coverall and apron passed the test at both low and high pressure levels at the continuous regions

• At the seams/closures, only Level 4 isolation gown passed the test at both low and high pressure levels for both water and synthetic blood challenges except one shoulder sample

• This method demonstrated the ability to offer a quick and visual assessment of performance, which suggests that it may have additional value as a training aid for infection control and safety professionals
Objective: To better understand the factors affecting barrier performance of materials against bloodborne pathogens and improve current test methods.

**ASTM/ISO Test Methods**

- **Phi-X174:** spherical, ~27 nm in diameter, no lipid envelope
- **Ebola Virus:** filamentous, ~80 nm in diameter, with a lipid envelope
- **Phi-6:** spherical, ~75-86 nm in diameter, with a lipid envelope

**Virus Type:** Phi-X174 vs. Phi-6

**Pressure:** Hydrostatic vs. mechanical, and increasing levels

**Surface tension:** 0.042 N/m vs. lower surface tensions (similar to the surface tension of vomit and diarrhea)

**Time:** Duration of the exposure to challenge liquid
Development of Performance and Design Criteria for Isolation Gowns

• Work with ASTM F23.40 to develop standard specification that defines minimum performance and design requirements for isolation gowns

• Existing gowns are now being tested by NPPTL and Nelson Laboratories to identify the current performance. Currently, 22 models of isolation gowns from 6 different manufacturers were evaluated for a variety of performance requirements. Reusable gown part is underway.

Photo Credit: NIOSH EPRO

CDC Workplace Safety and Health

NIOSH

NPPTL Research to Practice through Partnerships
NIOSH/NPPTL evaluated the added heat stress caused by the most commonly used protective clothing combinations in West Africa for Ebola for using thermal manikin and human subject testing.
Other NIOSH/NPPTL Support

- NIOSH/NPPTL created a webpage about the protective clothing selection considerations for healthcare workers for protection against microorganisms in blood and body fluids
  
  http://www.cdc.gov/niosh/npptl/topics/protectiveclothing/

- NIOSH/NPPTL also provides support to CDC for updating PPE recommendations for Ebola
Summary

• Several fluid-resistant and impermeable protective clothing options are available in the market place for HCWs

• When selecting the most appropriate protective clothing, employers should consider all of the available information on protective clothing (performance data, availability, practicality), including the potential limitations

• A key step in this process is to understand the relevant standards and test methods

• Multiple test methods and classification standards exist to determine the barrier effectiveness of gowns and coveralls

• There is room for improvement in some of the test methodologies
Summary (Continued)

• NPPTL plans to continue research to better understand the factors affecting barrier performance of protective clothing materials against bloodborne pathogens and use that information to validate/improve current test methods

• NPPTL plans to expand its work for determination of the minimum performance requirements for other PPE elements, such as hoods, aprons, and footwear covers

• NPPTL will continue supporting CDC by generating technical documents for all types of PPE used by HCW and emergency responders to protect against microorganisms in blood and body fluids
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