NPPTL Research on Healthcare Worker Personal Protective Equipment: Minimum Requirements for Isolation Gowns

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Building the Chain of Safety: Stakeholder Summit
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Overview

- OSHA, NIOSH and NPPTL
- NPPTL Healthcare Worker (HCW) Personal Protective Equipment (PPE) Research
- Highlights from Institute of Medicine (IOM) Report on PPE for HCWs
- HCW Protective Clothing Problems
- Relevant Standards & Regulations
- Isolation Gown Project
- Concluding Remarks
Occupational Safety & Health Act (1970) established OSHA & NIOSH - To assure safe and healthful working conditions for all working men and women.
Healthcare Workforce

- Fastest growing industry sector
- About **17 million workers** (11% of the U.S. workforce)
- Includes 12 of top 20 fastest growing occupations
NPPTL HCW PPE Research Program Summary

- Ensembles Research
  - Surgical/isolation gowns, EMS clothing

- Filtration Research
  - Nanoparticles / Bioaerosols (H1N1)

- Respirator Fit Research
  - Facial anthropometrics
  - Frequency of fit testing
  - Respirator fit test research (user seal check, novel methods, multiple donnings)

- Respirator Comfort Research
  - Physiology studies
  - Project BREATHE
• **Commit to Worker Safety and Appropriate Use of PPE**
  - Demo and Sentinel Surveillance
  - Public Health Practice studies
  - Best practices, outreach

• **Respirator Performance & Usability Research**
  - Performance against cough generated aerosols
  - PPE combinations
  - Respirator clinical effectiveness

• **Influenza Pandemic**
  - Risks of handling a contaminated respirator
  - Decontamination of filtering facepiece respirators
  - Assessing modes of transmission
Highlights from
Institute of Medicine (IOM) PPE for HCW Update Report
Personal Protective Equipment (PPE)

PPE: Specialized clothing or equipment worn by workers for protection against health and safety hazards. For HCWs, PPE may include:

- Respirators
- Face masks
- Gloves
- Eye protection
- Face shields
- Gowns
- Head and shoe coverings
National Academies Evaluations provide high level scientific input to PPT Program

- 2006 – IOM report examining issues related to the potential reuse of masks and N95 respirators in the event of an influenza pandemic

- 2007 – IOM report to assess the NIOSH anthropometric survey

- 2007 – IOM report on PPE for Healthcare Workers (HCW)

- 2010 – Certifying Personal Protective Technologies: Improving Worker Safety

- 2011 – IOM report - PPE for HCW Update
Criteria on PPE Selection & Use

According to IOM Report, HCW PPE should:

- Effectively reduce risks of disease or injury to HCWs
- Minimize negative interactions with or effects on patients and their families and caregivers
- Be acceptable and usable by HCWs in their daily tasks (including ease of communication and comfort)
- Be practical regarding issues of cost, time, and training
- Be appropriate to the occupational risk being encountered
Evidence-Based Performance Requirements

- Functionality
- Usability
- Comfort & Wearability
- Durability
- Maintenance & Reuse
- Aesthetics
- Cost
Evidence-Based Performance Requirements

**Functionality**
- Protect against influenza virus
- Guard against contact with contaminated fluids and aerosols

**Usability**
- Maintain biomechanical efficiency and sense of touch and feel
- Odor-free
- Hypoallergenic
- Accommodate wide range of users (face and body profiles)
- Compatibility across various elements of the PPE ensemble and with other equipment (e.g., stethoscope)
- Non-startling to patients and families
- Facilitate communication with others (verbal, facial)

**Comfort and Wearability**
- Comfortable—no skin irritation or pressure points
- Prolonged use without discomfort
- Breathable—air permeable
- Moisture absorbent—wickability
- Low bulk and weight
- Dimensional stability
- Easy to put on and take off (don and doff)

**Maintenance and Reuse**
- Easy to decontaminate and discard disposable elements
- Easy to clean and replace parts in reusable PPE
- Optimize

**Aesthetics**
- Variety of styles and colors
- Customizable

**Durability**
- Adequate wear life
- Strength—tear, tensile, burst
- Abrasion resistance
- Corrosion resistance

**Cost**
- Product cost
- Total life-cycle cost
- Minimal environmental impact
- Cost Benefit & Effectiveness
Phases of the Design & Engineering Process

1. **User requirements analysis** - understanding the work hazards and barriers to PPE use

2. **Design realization** - identifying the key characteristics and translating the evidence-based performance requirements into the specific design of the PPE

3. **Field use and evaluation** - new PPE is tested in the field in order to provide a realistic assessment of its performance and to identify unintended consequences of use
Considerations in Designing PPE

- Phase-change materials
- Antibacterial finishing treatments
- The impact of temperature and relative humidity in the work environment
- The use of multiple layers
- Changes that can result from laundering or cleaning that might impact the protective effects of the clothing (Laing, 2008)
- The industrial and home laundering both were effective in decontamination of healthcare clothing, including lab coats (Wilson et al., 2007)


HCW Protective Clothing Problems:
Compliance, Lack of Awareness &
End User Issues
Gown Wear Compliance

Manian, F. A., and J. J. Ponzillo. 2007. Compliance with routine use of gowns by healthcare workers (HCWs) and non-HCW visitors on entry into the rooms of patients under contact precautions. Infection Control and Hospital Epidemiology 28(3):337-340.
Lack of Awareness

- A recent survey by Kimberly-Clark Health Care of 300 purchasing managers, infection control professionals and registered nurses from facilities across the country showed that(*):
  - Only 38% of respondents were aware of AAMI guidelines
  - Those who were aware factored the guidelines into purchasing criteria for isolation gowns 73% of the time
  - Only 26% of respondents who use AAMI guidelines as a basis in purchasing gowns could identify a specific performance requirement in Level 2

Factors Affecting Opinions about Protective Gowns and Drapes

7 most important factors (out of 13)


N(RN)=208
N(MD)=108
Factors Affecting Opinions about Protective Gowns and Drapes


N(RN)=208
N(MD)=108
End User Problems

- According to Gallup poll(*) by a prominent surgical gown manufacturer, more than half of the surgeons and OR nurses wanted to provide input for the selection of the gowns they wear.

- Only 16% of surgeons and 26% of OR nurses involved in the selection of surgical apparel.

- Purchase is the responsibility of a hospital purchasing agent, or OR nurse supervisor, or other administrative personnel.

- Although 66% of surgeons and 90% of nurses involved in high fluid surgical procedures want to wear gowns that is liquid proof (instead of liquid resistant), far fewer actually wear such gowns even during high-fluid procedures.

Gallup poll, 1994

Standards and Regulations
• Medical devices are defined by FDA as devices “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or animals”.

• PPE devices used in HC environments are considered medical devices and are regulated as either Class I or Class II devices.

• FDA clears some types of PPE for sale as medical devices. Approval process relies on determining equivalence to predicate devices, and requires third-party testing only for respirators (NIOSH certification).
FDA regulations are designed to control the manufacture and sale of PPE. These regulations do not specifically apply to employers or employees. Requirements regarding the use of PPE in the HC workplace are overseen by OSHA, along with state and local agencies and employers.

### FDA Classification of PPE-Related Equipment

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk to Patient or Device Wearer</th>
<th>Requirements</th>
<th>Healthcare PPE and Related Devices</th>
</tr>
</thead>
</table>
| I     | Low                             | General standards for good manufacturing processes; most Class I devices are exempt from 510k submissions | • Surgeons’ gloves (510k required)  
• Examination gloves (510k required)  
• Other surgical apparel (isolation gowns, shoe covers, caps, caps, hoods, operating room shoes) (510k exempt) |
| II    | Intermediate                   | 510k submission | • Surgical gowns  
• Surgical masks  
• Surgical respirators |
| III   | High                            | Subject to pre-market approvals must submit clinical evidence of safety and efficiency | None |
• NIOSH is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness.

• NIOSH is the principal governmental agency with responsibility for testing and certifying respirators and NPPTL establishes the testing requirements and performs tests on respirators submitted by manufacturers.

• The NIOSH certification process does not certify antiviral claims for respirators.

• NIOSH does not certify other forms of PPE.

• NIOSH staff do participate in the development of voluntary consensus standards for other PPE and perform research in these areas.
OSHA has the primary responsibility for enforcing the proper use of PPE in the healthcare facilities.

Main regulations relevant to HCW PPE relevant to viral respiratory diseases:
- 29 CFR 1910.134, which governs the use of respirators
- 29 CFR 1910.132, which governs the use of PPE other than respirators

All respirators used by HCWs must be NIOSH certified and their use must be part of a respiratory protection program that includes attention to issues regarding medical clearance, fit testing, and training.

OSHA requires that some types of PPE (e.g., eyewear) meet specified voluntary consensus standards. However, gaps in the standards and proper use for HCW PPE exist.

OSHA does not have specific standards covering the use of PPE by HCWs and does not require that such PPE be cleared by the FDA.

Other Agencies and Organizations

- **CDC** provides infection control guidance, including guidance on the use of respirators and masks by HCWs for protection against influenza.

- **The Joint Commission** provides accreditation for many hospitals and a variety of other employers of HCWs. The use of PPE is included in the Joint Commission’s requirements for employers.

- **State and local health agencies** provide guidance and licensing to employers of HCWs.

- **Standards development organizations** (ANSI, AAMI, and ASTM International) work through professional organizations and standards development committees to develop voluntary consensus standards that specify testing methods and performance expectations.

- **Professional organizations** (AORN, APIC, AST) provide guidance for the selection and use of HCW PPE.
## Example of Relevant Protective Clothing Standards/Guidelines

<table>
<thead>
<tr>
<th>Organization</th>
<th>Standard</th>
</tr>
</thead>
</table>
| **ASTM**     | F1670 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood  
                F1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System  
                F2407 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities |
| **AAMI/ANSI**| TIR No.11 Selection & Use of Protective Apparel & Surgical Drapes in Health Care Facilities  
                ANSI/ AAMI PB70 Liquid Barrier Performance & Classification of Protective Apparel & Drapes Intended for Use in Health Care Facilities  
                AAMI/ANSI ST65 Processing of Reusable Surgical Textiles for Use in Health Care Facilities |
| **NFPA**     | 702 Standard for Classification of Flammability of Wearing Apparel  
                1999 Standard on Protective Clothing for Emergency Medical Operations |
| **AORN**     | Recommended Practices for Selection and Use of Surgical Gowns and Drapes |
| **AATCC**    | AATCC 42: 2007 Water Resistance: Impact Penetration Test  
                AATCC 127: 2008 Water Resistance: Hydrostatic Pressure Test |
| **AST**      | Recommended Standards of Practice for Gowning and Gloving |
| **CDC**      | Guideline for Infection Control in Hospital Personnel 1998  
                Guideline for the Prevention of Surgical Site Infection, 1999 |
Isolation Gowns Project
HAI & Infection Control Facts

Proper use of PPE is a crucial step in controlling of HAIs

- HAIs are the sixth leading cause of death nationally
- ~1 in 10 hospitalized patients will acquire an infection after admission
- At any given time, 1.4 million people worldwide suffer from HAIs
- The Agency for Healthcare Research and Quality (AHRQ) reports that patients diagnosed with MRSA infections rose from 1,900 in 1993 to 368,600 in 2005
- 1.7 million HAIs occurred in U.S. hospitals in 2002 and were associated with 99,000 deaths. CDC estimates 2 million people contact an HAI and over 90,000 people die as a result of complications in the U.S.
- $6.7 billion annual impact on healthcare facilities in U.S.
- The additional cost to treat a single MRSA infection can be as high as $35,000
- 97% of HAIs are caused by medical materials

References are listed at the end of the presentation.
Background

- The threat of emerging infectious diseases has highlighted the need for effective PPE for HCW to protect both HCWs and patients.

- PPE is a critical component in the hierarchy of controls used to protect HCWs from infectious hazards.

- Gowns are determined as the second-most-used piece of PPE, following gloves in the healthcare setting(*).

- According to the CDC’s Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Setting 2007, isolation gowns should be worn to protect the HCWs’ arms and exposed body areas during procedures and patient-care activities when anticipating contact with clothing, blood, bodily fluids, secretions and excretions.

Background

- Important research has been conducted in certain areas, such as respirators and masks, but studies in other areas, particularly gowns are scarce.

- Many organizations (e.g., CDC, OSHA, APIC) have published guidelines for the use of PPE, including isolation gowns in healthcare settings.

- AAMI published guidance documents in the selection of the gowns as well as a standard on liquid barrier performance and classification for both surgical and isolation gowns, which was approved by ANSI and accepted by FDA in 2004.

- There is currently no existing standard on the isolation gowns which includes performance and design criteria and addresses the interface problems.
Motivation

- Recent feedback from stakeholders has indicated a strong need for performance requirements for isolation gowns.

- IOM recommended increased research on gowns for HCWs, especially in the area of effectiveness, integration, and interface with HCW PPE.

- A new Task Group was formed in March 2011 in ASTM’s F23 Committee on Protective Clothing and Equipment to work on a new specification standard on isolation gowns with FDA’s participation.

- The implementation of this project will help in establishing the performance and design criteria for isolation gowns and assist end users in correct PPE selection, resulting in higher levels of protection than currently provided.
Goals

- Provide the basis for and to recommend appropriate minimum design and performance requirements for isolation gowns which also addresses the interface problems
- Ultimately improve isolation gown selection & use compliance
- Evaluate currently used isolation gowns to determine existing performance, performance & design limitations, and interface issues
- Specifically,
  - determine the protection, comfort level, tolerability and interface issues with the most common isolation gowns currently in use
  - define performance and design requirements based on the results and end user feedback
AAMI Selection & Use Guidelines

General relationships between the barrier performance of isolation gowns, mode of disease transmission, and anticipated risk of exposure

<table>
<thead>
<tr>
<th>Mode of Transmission</th>
<th>Anticipated Risk of Exposure to Etiological Agent or Body Fluids</th>
<th>Appropriate Barrier Performance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defined</td>
<td>Low</td>
<td>Level 1 or 2</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Level 2 or 3</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Level 2, 3 or 4</td>
</tr>
<tr>
<td>Undefined</td>
<td>Not applicable</td>
<td>Level 2, 3 or 4</td>
</tr>
</tbody>
</table>

TIR No.11 Selection & Use of Protective Apparel & Surgical Drapes in Health Care Facilities
### Possible Relationship b/w Gown Barrier Level and Clinical Exposure Risks

<table>
<thead>
<tr>
<th>AAMI Barrier Level</th>
<th>Exposure Risk Level</th>
<th>Fluid Amount</th>
<th>Fluid Spray or Splash</th>
<th>Pressure to Gowns</th>
<th>Example of Procedures with Anticipated Exposure Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Minimal</td>
<td>Minimal</td>
<td>Minimal</td>
<td>Minimal</td>
<td>Basic Cover Gown&lt;br&gt;Standard Isolation&lt;br&gt;Nursing Care&lt;br&gt;Cover Gown for Visitors&lt;br&gt;Laundry/Housekeeping</td>
</tr>
<tr>
<td>Level 2</td>
<td>Low</td>
<td>Low-to-Moderate</td>
<td>Low-to-Moderate</td>
<td>Low-to-Moderate</td>
<td>Radiology&lt;br&gt;SPD/CS&lt;br&gt;Dialysis&lt;br&gt;GI/GU Labs&lt;br&gt;OR/GYN&lt;br&gt;Decontamination&lt;br&gt;ER/ICU/Trauma&lt;br&gt;Burn Units</td>
</tr>
<tr>
<td>Level 3</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>OR/GYN Laboratory&lt;br&gt;Decontamination&lt;br&gt;ER/ICU/Trauma&lt;br&gt;Burn Units</td>
</tr>
<tr>
<td>Level 4</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Surgery</td>
</tr>
</tbody>
</table>

SPD (Sterile Processing Department/CS (Central Services)<br>OB (Obstetrics) GYN (Gynecology)<br>GI (Gastrointestinal/GU (Genitourinary)<br>ER (Emergency Room) ICU (Intensive Care Unit)

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Investigate HCW needs to determine specific hazards

Identify current products in use or products that could be used

Determine the specific properties that can be assessed

Evaluate “acceptable” and “unacceptable” products to aid in setting recommended requirements

Select the appropriate test methods

Carry out the test plan and analyze the test results

Prepare recommended design assessment and performance criteria

Document study findings, publish and present

Method
Properties Considered for Evaluation

- **Barrier Properties**
  - Impact Penetration
  - Hydrostatic Resistance
  - Blood Penetration Resistance (before and after washing)
  - Viral Penetration Resistance (before and after washing)

- **Strength Properties**
  - Tensile Strength
  - Tear Resistance
  - Burst Strength
  - Seam/Closure Strength
  - Abrasion Resistance

- **Other**
  - Staining

- **Comfort Properties**
  - Fabric Weight
  - Evaporative Resistance
  - Water Vapor Transmission Rate
  - Total Heat Loss
  - Air permeability
  - Dimensional Stability

- **Spread of Material and Microorganisms**
  - Lint Generation
  - Pilling Resistance

- **Safety**
  - Flame Spread
  - Biocompatibility
  - Electrostatic properties
Expected Outcomes

- New isolation gown standard will provide guidelines
- Appropriate barrier protection
- Help reduce the risk of contamination and transmission of infectious organisms which lead to HAIs
- Allow end user to select the right gown for the procedure
- Increase compliance
- Manufacturers develop and/or improve protective ensembles using new guidelines
National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory

Request Your Assistance

Our Need
The National Personal Protective Technology Laboratory (NPPTL) is interested in learning more about the potential barriers to the proper selection and use of Personal Protective Equipment (PPE) (surgical/isolation gowns, scrubs, gloves, respiratory protection, eye protection, facial protection) by healthcare workers (HCWs).

How You Can Help
Tell us your PPE concerns related to the selection and use in the following areas:
- Problems when selecting PPE
- Ability to access and acquire the proper PPE
- Identifying the comfort and burden of PPE
- Selecting appropriate PPE for different procedures and length of exposures
- Ability to perform work tasks while wearing PPE
- Multi-tasking and the need for changing or removing PPE between activities and/or patients
- Maintenance of PPE
- Other barriers to selection & use of appropriate PPE

How Will NIOSH Use This Information?
Your assistance will help NIOSH improve workplace safety and health practice for healthcare workers.

Contact: National Personal Protective Technology Laboratory
Toll free: 1-888-654-2294
E-mail: PPEConcerns@cdc.gov
Concluding Remarks

NPPTL
Research

User Compliance
Practice Guidelines
Standards
Procurement
New Product Development

NPPTL Research to Practice through Partnerships
Concluding Remarks

• NPPTL has an active research program, involving numerous partners, with current and planned projects related to filtration, respirator fit, comfort/tolerability, understanding barriers to proper use, performance, and specific issues related to Pandemic Influenza.

• NPPTL is expanding protective clothing and ensembles research and laboratory capabilities.

• Next steps – continue with the isolation gown research project towards development of a specification standard, identify gaps in HCW PPE, and barriers to proper use.

• End-user input is important!
  • Sign up to learn of future opportunities to collaborate and/or provide input on NPPTL activities
  • Look for "NPPTL self-subscribe list serve" under Spotlights at: http://www.cdc.gov/niosh/npptl/default.html
References

7. http://www.cdc.gov/eid/content/13/12/1840.htm
Thank you

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