Methods

Background

- PPE is a critical component in the hierarchy of controls used to protect HCW from infectious hazards.
- HCW PPE may include gowns, respirators, face masks, gloves, eye protection, face shields, and head & shoe coverings.
- Institute of Medicine’s (IOM) recent reports and NPPTL Implementation Plan highlight the need for more research on HCW PPE.
- Important research has been conducted in certain areas, such as respirators, masks, and gloves but studies in other areas, particularly gowns, drapes are scarce. This research will initially focus on gowns & drapes.
- Understanding the issues related to the design and development of gowns & drapes, as well as the factors that impact their use, such as barrier effectiveness, comfort, cost, durability, testing, standards, maintenance, care, and awareness, are critical to ensuring HCW's are adequately protected.

Results

Existing Regulations, Standards & Guidelines

- FDA clears some types of PPE for sale as medical devices. The approval process relies on determining equivalence to predicate devices and requires manufacturer/supplier declaration of conformity, except for respirators which require NIOSH approval.
- 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>
<tbody>
<tr>
<td>I</td>
<td>Low</td>
<td>General standards for good manufacturing processes; most Class I devices are exempt from 510k submissions</td>
<td>Surgeons’ gloves (510k required)</td>
</tr>
<tr>
<td>II</td>
<td>Intermediate</td>
<td>510k submission</td>
<td>Surgical gowns</td>
</tr>
</tbody>
</table>

Existing standards and guidelines for surgical gowns and drapes are listed below:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAMI</td>
<td>TIR No.11 Selection &amp; Use of Protective Apparel &amp; Surgical Drapes in Health Care Facilities ANSI/ AAMI PB70 Liquid Barrier Performance &amp; Classification of Protective Apparel &amp; Drapes Intended for Use in Health Care Facilities AAMI/ANSI ST65 Processing of Reusable Surgical Textiles for Use in Health Care Facilities</td>
</tr>
<tr>
<td>AORN</td>
<td>Recommended Practices for Selection and Use of Surgical Gowns &amp; Drapes</td>
</tr>
</tbody>
</table>

PPE Selection & Use

According to the 2010 IOM report, HCW PPE should:
- Effectively reduce risks of disease or injury
- Be practical regarding issues of cost, time, and training
- Be appropriate to the occupational risk being encountered
- Minimize negative interactions with or effects on patients and their families & caregivers
- Be acceptable and usable by HCW in their daily tasks (including ease of communication & comfort)

Conclusions/ Future Work

Numerous research gaps were identified:
- Lack of awareness regarding standards & classifications of PPE
- Test Procedures & standards do not match HCW expectations or needs
- Research on evidence-based performance requirements for PPE
- Clinical research that evaluates the use, effectiveness, and failures of HCW PPE
- Innovation in gown design & engineering (with particular attention to interfaces, repellent finishes, fabric technology, functionality, wearability, and other factors)
- In-depth analysis of level of protection & cost effectiveness of single-use vs. reusable PPE
- Determination of the role of PPE in reducing the transmission of diseases
- Identifying clinical situations that require certain types of gowns or other PPE
- Identifying the physiological impact of PPE

Next Step: From the list of research gaps, identify priority projects most suitable for future NPPTL research.