Materials In Medicine
Advances in Gowns & Gloves

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What is necessary?

• A simple and cost effective portfolio of apparel and protective products that is proven to provide the highest level of protection and comfort whilst offering exceptional ease of use

• Key to success for protection is practice, namely:
  • Standard Operating Procedures (SOPs) in place
  • Routine use of PPE
  • Right PPE for the job
  • Wear length of PPE
  • Disposal of PPE

Material Properties
• Reusable/Disposable
• Treatments/Barriers
• Absorption/Strength

PPE PERFORMANCE

PROTECTION

PROTOCOLS

PRACTICE

Standards/Procedures
• SOPS

Users
• Compliance
Key PPE necessitates HIGH PERFORMANCE MATERIALS as seen in:

- **Tiburon® Surgical Drapes**
  - Fully impervious surgical drape
  - Absorbent top layer for fluid management
  - AAMI Level 4*

- **SmartGown™ Surgical Gown**
  - Breathable, fully impervious surgical gown
  - AAMI Level 4*

- **RoyalSilk™ Surgical Gown**
  - Most comfortable surgical gown
  - AAMI Level 3*

- **SMS/PE Isolation Gown**
  - AAMI Level 1, 2, 3 or 4* (task-dependent)

* AAMI Standard PB70:2003 (Association for the Advancement of Medical Instrumentation)

Liquid Barrier Performance Classification of Protective Apparel & Drapes Intended for Use in Health Care Facilities
AAMI defines critical zones as those areas where direct contact is likely to occur with:
- Blood
- Body Fluids
- Other potentially infectious material (OPIM) including influenza virus - e.g., H1N1, HCV

Critical areas include material as well as areas of construction - e.g., seams
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Technologies for PPE – State of the Art

Top Layer: Durable, Heavy Wt, Repellent

Middle Layer: 3 Layers, Maximum Breathability and Adhesion

Bottom Layer: Soft, Comfortable

Water Vapor Transmission Rate (WVTR)

Superior protection against bacteria & viruses (H1N1, HCV)

Product Performance - Smartgown™
RoyalSilk™ Surgical Gowns

- Soft, silky material makes it a **most** comfortable gown
- AAMI Level 3 protection
- *Lighter material helps reduce surgical glove roll down*
• **Three-layer micro-fiber composite:**
  - Absorbent top layer
  - Impervious middle membrane
  - Patient comfort layer

• **Key attributes:**
  - Impervious (AAMI Level 4)
  - Flame-resistant
  - Absorbent
  - Abrasion resistant and low lint
  - Puncture resistant
Isolation Gowns

- Frequently used form of PPE
- Requires FDA* approval if it provides enhanced barrier protection – e.g., antimicrobial, antiviral
- Disposable – single-use
- Intended for short-term use or procedures when there is a risk of exposure to blood, body fluids, OPIM (e.g., H1N1), chemicals, or chemotherapy drugs
- Four common types:
  - PE Film
  - Spunbond
  - SMS Film
  - SMS + PE Film
- 2004 – 2009: Year-on-Year Growth is 5%

* Draft Guidance for Industry and FDA Staff: Premarket Notification (510K) submissions for medical devices that include antimicrobial agents – July 19, 2007
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### Technologies for PPE – Current & Future

<table>
<thead>
<tr>
<th>Gown Type</th>
<th>Usage</th>
<th>PROS</th>
<th>CONS</th>
<th>FUTURE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spunbond</strong> - most appropriate for low-risk procedures that require limited barrier protection.</td>
<td>• Visitors&lt;br&gt;• Zero fluid contact&lt;br&gt;• Used in various wards&lt;br&gt;• Patient care &gt; 5+ min</td>
<td>• High comfort and durability&lt;br&gt;• Inexpensive</td>
<td>• Single-use&lt;br&gt;• Limited protection</td>
<td>• Very basic educate on protection to move users to SMS based gowns</td>
</tr>
<tr>
<td><strong>SMS</strong> - most appropriate for mid-risk procedures that require some additional barrier protection.</td>
<td>• Changing bed linens&lt;br&gt;• Nursing/Administering an injection&lt;br&gt;• Used in ICU’s/NICU’s/PACU’s&lt;br&gt;• AAMI Level 1, 2, or 3&lt;br&gt;• Patient care &gt; 15+ min</td>
<td>• Improved comfort and durability&lt;br&gt;• Medium Cost</td>
<td>• Single-use&lt;br&gt;• Mid-Level protection</td>
<td>• Include additional barrier protection to impact frequency/transmission of HAIs, OPIM (H1N1) &amp; MRDOs&lt;br&gt;• ‘Green’ for disposal</td>
</tr>
<tr>
<td><strong>PE Film</strong> - used for procedures that require high levels of barrier protection.</td>
<td>• Janitors/Auxiliaries&lt;br&gt;• One time use&lt;br&gt;• Sterile Processing Dept&lt;br&gt;• Patient care &lt; 15 min</td>
<td>• Inexpensive&lt;br&gt;• High Barrier</td>
<td>• Non-breathable&lt;br&gt;• Uncomfortable&lt;br&gt;• Flimsy</td>
<td>• Very basic – move to SMS +PE gown</td>
</tr>
<tr>
<td><strong>SMS+PE</strong> - best for procedures requiring a high level of barrier protection</td>
<td>• Preparation &amp; administrations of chemotherapeutic agents&lt;br&gt;• AAMI level 4&lt;br&gt;• Patient care &gt; 15+ min</td>
<td>• Excellent barrier protection&lt;br&gt;• Good chemical resistance</td>
<td>• Costly</td>
<td>• Barrier improvements for aggressive agents and additional chemodrugs&lt;br&gt;• ‘Green’ for disposal</td>
</tr>
</tbody>
</table>
Exam Gloves

- Most frequently used form of PPE
- Considered a class I medical device – requires FDA approval
- Disposable, usually ambidextrous & non-sterile
- Intended for short-term use or procedures when there is a risk of exposure to blood, body fluids, OPIM (e.g., H1N1), chemicals, or chemotherapy drugs
- Three common types:
  - Vinyl
  - Latex
  - Nitrile

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Technologies for PPE – State of the Art
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## Technologies for PPE – Current & Future

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<th>Glove Type</th>
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<th>CONS</th>
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<tr>
<td><strong>Vinyl</strong></td>
<td>- most appropriate for low-risk procedures that require little barrier protection.</td>
<td>• Changing bed linens</td>
<td>• Poor elasticity – stiff &amp; uncomfortable</td>
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<tr>
<td></td>
<td></td>
<td>• Administering an injection</td>
<td>• Minimal protection</td>
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<td></td>
<td></td>
<td>• Starting/discontinuing an IV line</td>
<td>• NOT for chemo</td>
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<td></td>
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<td>• Managing a urinary drainage bag</td>
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<td></td>
<td></td>
<td>• Emptying an emesis basin</td>
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<td></td>
<td>• Patient care &lt; 15 minutes</td>
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<tr>
<td><strong>Latex</strong></td>
<td>- used for procedures that require moderate to high levels of barrier protection</td>
<td>• Direct patient care in ICU, ER, LDRP, OR</td>
<td>• Allergy/Sensitization</td>
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<tr>
<td></td>
<td></td>
<td>• Handling of laboratory specimens</td>
<td>• Dry, irritated skin</td>
</tr>
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<td></td>
<td></td>
<td>• Patient care &gt; 15 minutes</td>
<td></td>
</tr>
<tr>
<td><strong>Nitrile</strong></td>
<td>- best for procedures requiring a high level of barrier protection</td>
<td>• Preparation &amp; administrations of chemotherapeutic agents</td>
<td>• Costly</td>
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<td>• Direct patient care in ICU, ER, LDRP, OR</td>
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Technologies for PPE – Evidence Basis for PPE

- Year-on-Year growth in total units – 8%
- Q4 2009 – 16.5B units sold

GHX Data, Q4 2009
HAI’s - Isolation Gowns & Gloves

- 1.7M acquire & some 100,000 die from nosocomial infections each year*

- Bacteria responsible for spread of such infections: Staphylococci & E-coli.

- Pathogenic agents transmitted via the skin (hands), through droplets (from mouth and throat) and, last but not least, by textiles.

- Critical for spread are nurses’ and orderlies’ tunics and physicians’ coats (especially the coat pockets). (AJIC, Aug 07, vol 35)

- End-Users (Patient Providers) - points to value of antimicrobial agents as a defense against HAI’s & antiviral coatings against H1N1

VRE - Isolation Gowns & Gloves

- Recent study showed routine use of isolation gowns & gloves prevented more than 58 VRE cases during an 18 month period**

- Cost of treating a patient with infection is some $60K dollars

- Cost of providing gowns/gloves to prevent is approx. $2K per patient


Materials

- Non-wovens for disposable products
  - with new additives – lighter, more absorbent
  - ‘green’ sustainable – PLA, corn, non-petroleum based resin, algae-based resin
  - with barriers – hydrophobic, antimicrobial, antiviral, radiation, self-sealing, repellency
- Alternative fibers
  - Bamboo
  - Carbon nanotubes (SWCNT)
  - Other cellulosic

Products

- System solutions – e.g., combination device
- Advocate for single-use, disposable
- Trends match automation
- Improved comfort – softer, more breathable
- Easy to don/doff - minimize contamination

Other Technologies

- Indicators
- Sensors
- Smart, Smarter, Smartest
## Materials in Medicine
### Design & Engineering Breakthroughs on Horizon

<table>
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<tr>
<th>Time Zone</th>
<th>Performance Materials</th>
<th>Products Protocols</th>
<th>Systems Practice</th>
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<tbody>
<tr>
<td>1-3 years</td>
<td>• Lower basis weight</td>
<td>• Improved fit, comfort</td>
<td>• Connectivity - gowns to gloves</td>
</tr>
<tr>
<td>‘SMART’</td>
<td>• Move to bi-laminates</td>
<td>• Enhanced barriers - antimicrobial, antiviral</td>
<td>• Support compliance for effective protection</td>
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<tr>
<td></td>
<td>• Odor elimination</td>
<td>• Minimize cross-contamination</td>
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<tr>
<td></td>
<td>• Maintain/lower cost</td>
<td>• Maintain/lower cost</td>
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<tr>
<td>3-5 years</td>
<td>• Move to ‘green’ materials</td>
<td>• Include more sensor technologies, feedback and alerts</td>
<td>• Easy to don/doff</td>
</tr>
<tr>
<td>‘SMARTER’</td>
<td>• Improved additive technology</td>
<td>• Tear-proof/puncture resistant gown and gloves</td>
<td>• Dual purpose products - gown + wipe</td>
</tr>
<tr>
<td></td>
<td>• Monitoring capabilities - temperature, blood pressure and other vital signs</td>
<td></td>
<td>• Combo products - Gown + Glove</td>
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<td></td>
<td>• Maintain/lower cost</td>
<td></td>
<td>• Support compliance via RFID tracking systems</td>
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<tr>
<td>5-10 years</td>
<td>• Fibers and shapes for performance vs. cost</td>
<td>• Self-cleaning</td>
<td>• New technologies for improved cleaning in hospitals</td>
</tr>
<tr>
<td>‘SMARTTEST’</td>
<td>• Functionalization of surfaces – electrical and chemical activity and responsiveness</td>
<td>• Maintain/lower cost</td>
<td>• Reduced bio-burden on PPE for infection control</td>
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Ultimate Goal: Make PPE Obsolete
• **Assessing the Performance of Textiles incorporating phase change materials** - Ying, B., Kwok, Li Y., Zhu, Q. and Yengy, C., Polymer Testing 23, 5 2004 p541-9

• **Dressing to Kill** - Sun, G. and Williams, J.F., Chemistry and Industry, 17, 1999, p658-661


• **Smarter Textiles** - Holme, I., Future Materials, 2009, p13-25

• **Development of medical textile market** – Czajka, R., Fibers and Textiles in Eastern Europe, 13, 2005, p13-15


Acknowledgements

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