Materials In Medicine
Advances in Gowns & Gloves

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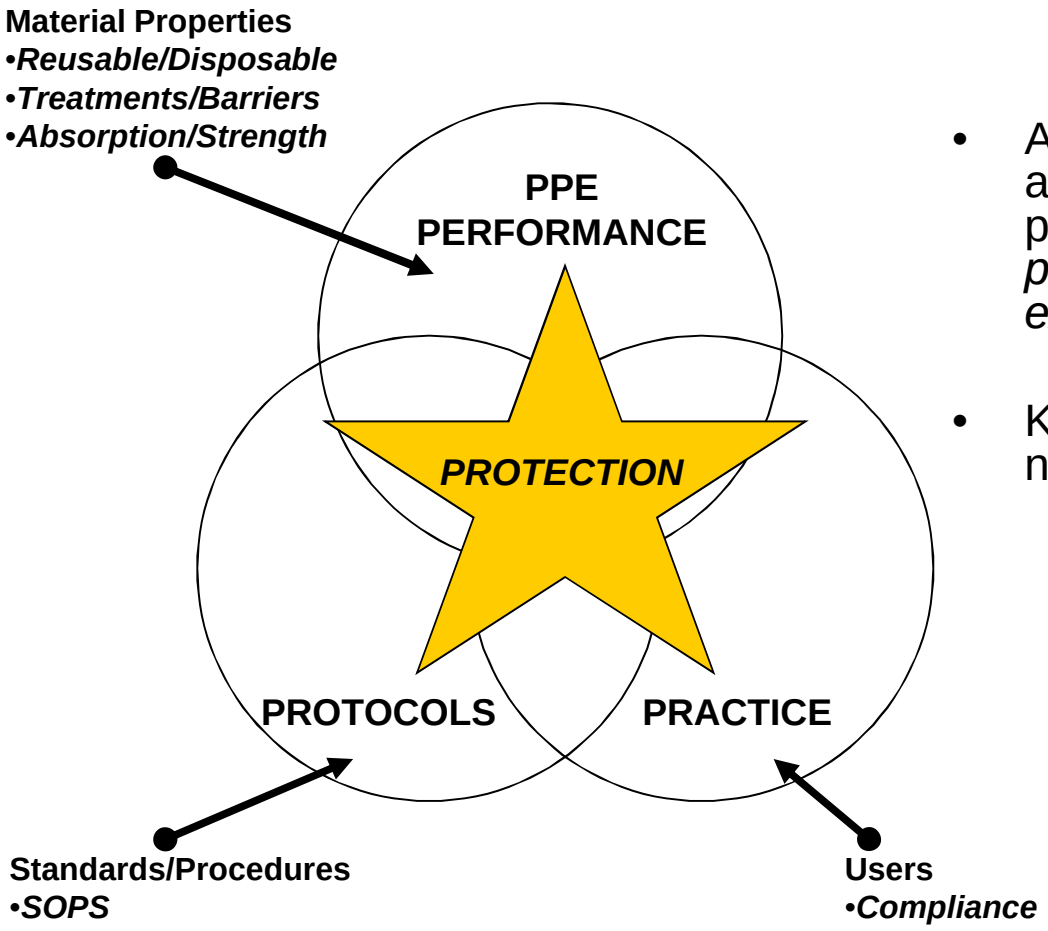
Technologies for PPE – State of the Art



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 p*ractice*, namely:
  - Standard Operating Procedures (SOPs) in place
  - Routine use of PPE
  - Right PPE for the job
  - Wear length of PPE
  - Disposal of PPE

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Technologies for PPE – State of the Art

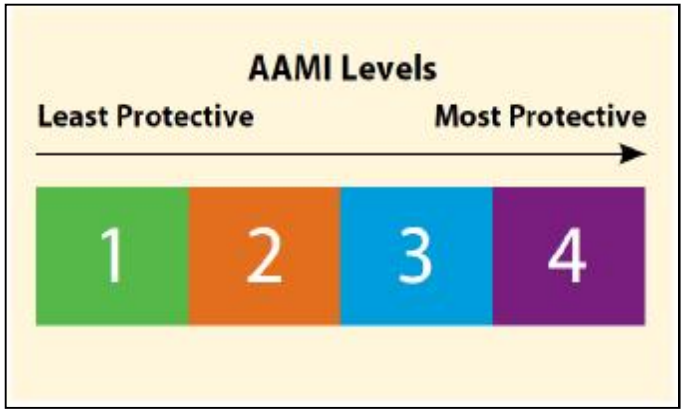
Key PPE necessitates HIGH PERFORMANCE MATERIALS as seen in:

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

2 **Spunsper -SFS™ Surgical Gown**
- Breathable, fully reinforced surgical gown
- AAMI Level 4* F1670/F1671
- 180 cm hydrostatic pressure

3 ***SFS Bodygard*™ Surgical Gown**
- Breathable fully reinforced comfortable surgical gown
- AAMI Level 3* 180cm hydrostatic pressure

4 **SMS Surgical Gown**
- AAMI Level 1 and 2, (task-dependent)
- AAMI Level 3 is available with upto 55cm hydrostatic pressure



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*

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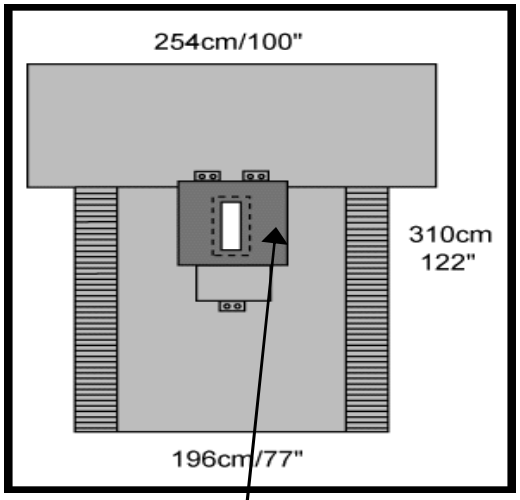
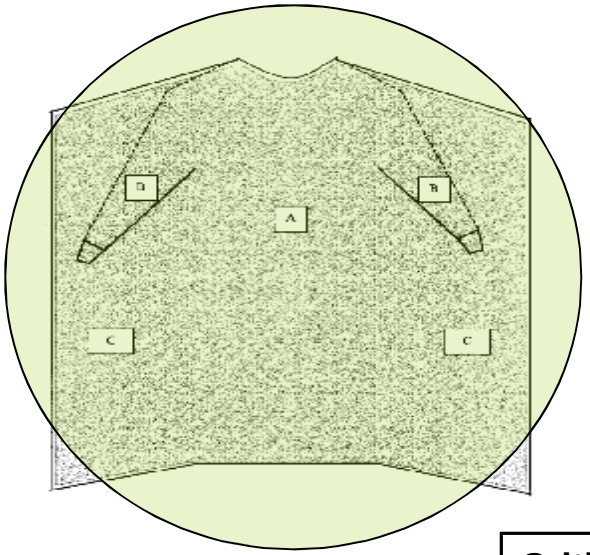
Technologies for PPE – State of the Art

- 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

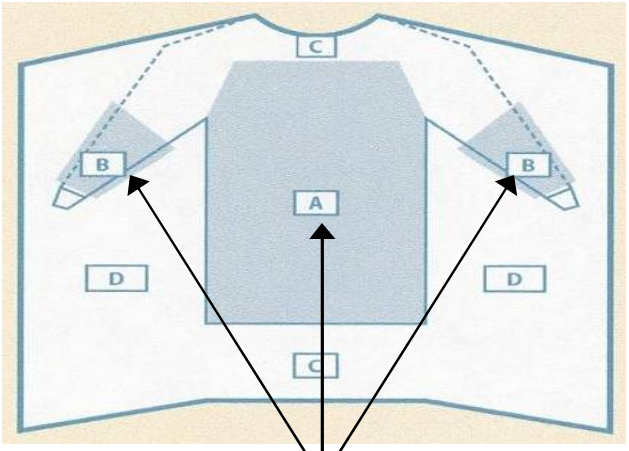
- Critical areas include material as well as areas of construction - e.g., seams



Drape Reinforcement



Isolation Gown / Fully reinforced surgical gown(entire gown)



Critical Zones

Surgical Gown

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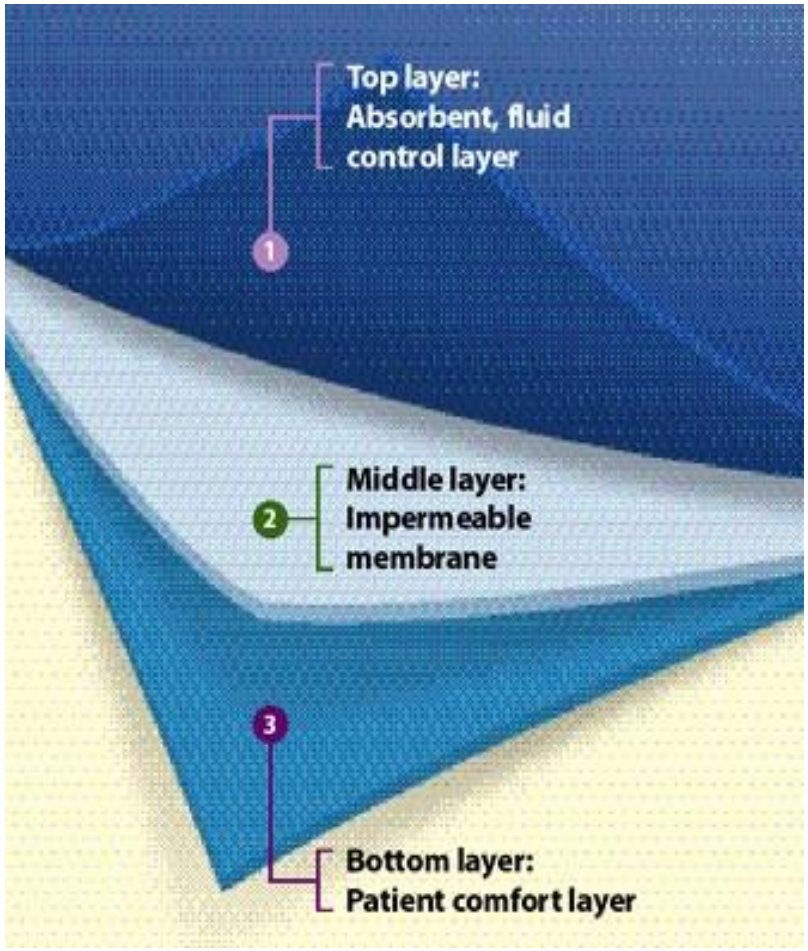

- **Three-layer micro-fiber composite:**
  - Absorbent top layer
  - Impervious middle membrane
  - Patient comfort layer

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

1-Bodygard® Surgical Drapes

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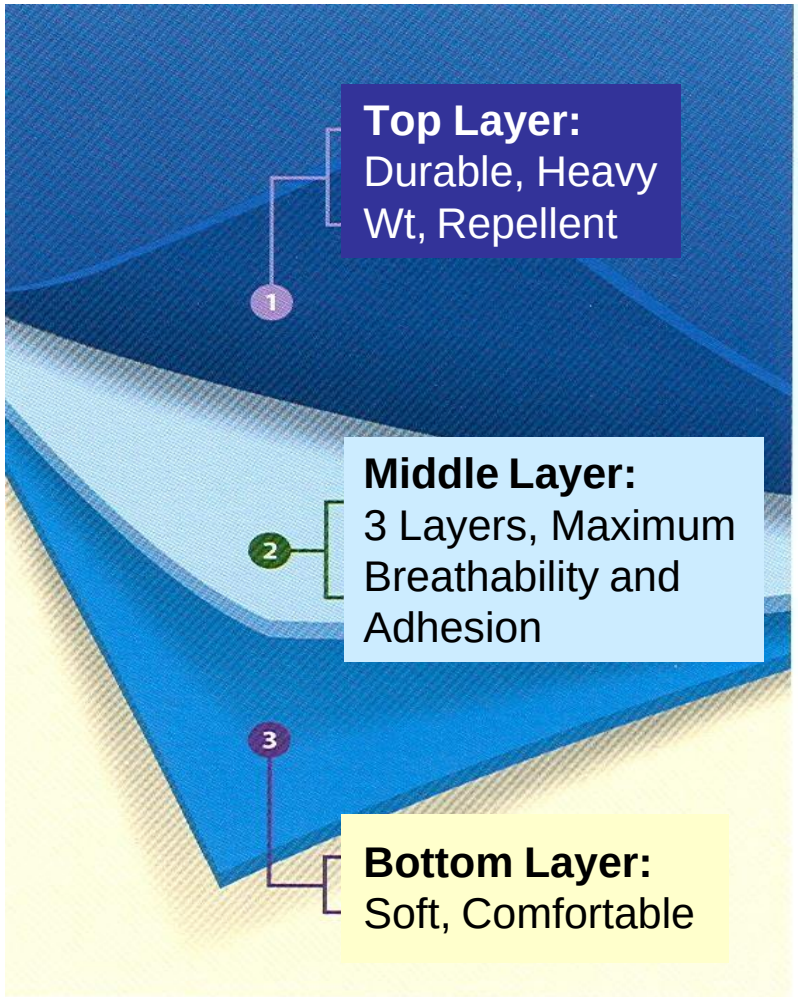
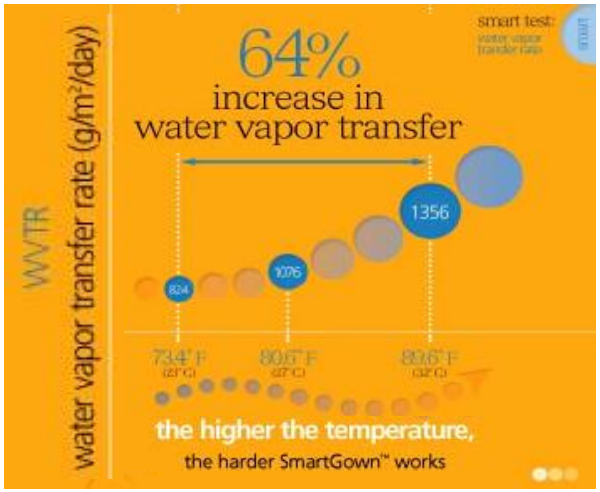
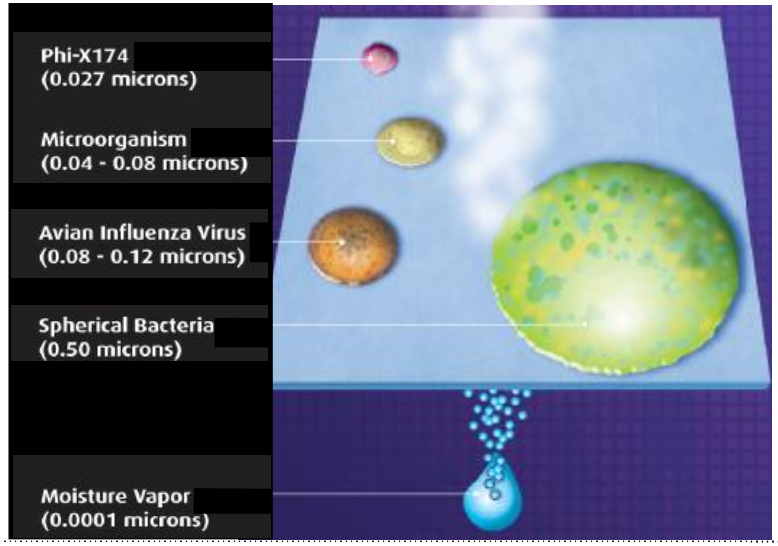


Water Vapor Transmission Rate (WVTR)





Superior protection against bacteria & viruses (H1N1, HCV)

2-Product Performance - Spunsper-SFS Bodygard™

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3-SFS ***Bodygard*™ Surgical Gowns**

- Soft, silky material makes it a comfortable gown
- AATC 127 upto 180cm hydrostatic pressure
- AAMI Level 3 protection
- ***60gsm Lighter material helps reduce surgical glove roll down***

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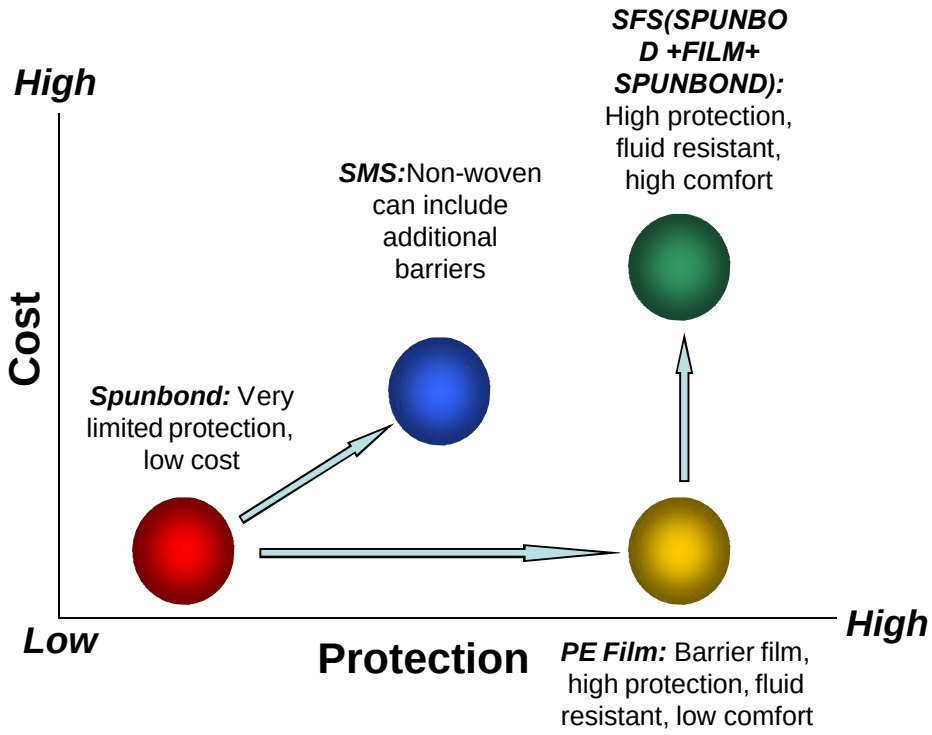
Isolation Gowns



- 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
  - SFS (Spunbond+film+Spunbond)
- 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

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

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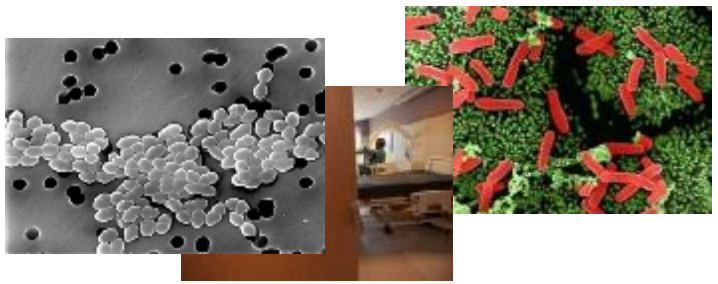
Technologies for PPE – Evidence Basis for PPE

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



*** Estimating HAIs and Deaths in US Hospitals, 2002** – Klevens, R.M. et al – Public health Reports, 2007, Vol. 122

****A cost benefit analysis of Gown use in controlling VRE transmission; is it worth the price?** - Puzniak, L.A., Gillespie, K.N., Leet, T., Kollef, M. and Mundy, L.M. – Infection Control & Hospital Epidemiology, 2004, Vol 25, no.5, p 418-424

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Design & Engineering Breakthroughs on Horizon

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

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Design & Engineering Breakthroughs on Horizon

Time Zone	Performance Materials	Products Protocols	Systems Practice
1-3 years **'SMART'**	•Lower basis weight •Move to bi-laminates •Odor elimination •Maintain/lower cost	•Improved fit, comfort •Enhanced barriers - antimicrobial, antiviral •Minimize cross-contamination •Maintain/lower cost	•Connectivity - gowns to gloves •Support compliance for effective protection
3-5 years **'SMARTER'**	•Move to 'green' materials •Improved additive technology •Monitoring capabilities - temperature, blood pressure and other vital signs •Maintain/lower cost	•Include more sensor technologies, feedback and alerts •Tear-proof/puncture resistant gown and gloves	•Easy to don/doff •Dual purpose products - gown **è** wipe •Combo products - Gown + Glove •Support compliance via RFID tracking systems
5-10 years **'SMARTEST'**	•Fibers and shapes for performance vs. cost •Functionalization of surfaces – electrical and chemical activity and responsiveness	•Self-cleaning •Maintain/lower cost	•New technologies for improved cleaning in hospitals •Reduced bio-burden on PPE for infection control

Ultimate Goal: Make PPE Obsolete

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Thank you!