The Grand Challenges in the Design of Respiratory Protection Devices

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Overview of Presentation

• National Pandemic Preparedness and PPE
• The Grand Challenges
• A Building Block Approach to the Grand Challenges
• Conclusions
• Acknowledgements
Pandemic Preparedness Initiative

National Pandemic Influenza Implementation Plan (May 2005)
Four SSs and PPE Performance

- Reusable
- Safety
- Stockpile
- Simplicity
- Surge Capacity

- Filtration Performance: $xx\%$
- Pressure Drop: $< zz$ inch
- Standard Manufacturing Technologies
- No Fit-Testing
Design of PPE: The Drivers

The Three Perspectives

• End Users
  • Successful Protection
  • Comfort

• Administrators/Providers
  • Successful Protection
  • End User Acceptance
  • Cost
  • Regulations (e.g., OSHA)

• Manufacturers
  • End Users
  • Administrators
  • Regulations

Prepared for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers
– IOM Report, September 2007

• Trade-Offs – The Balancing Act
Today’s Reality

- **Commercial Respirators**
  - Nonwovens
  - Charged Polypropylene Filters

![Mechanisms for Trapping Particulates](image)

3M N95 Healthcare Particulate Respirator & Surgical Mask
The Design Challenge

• Ensure Performance
  – Efficacy – Ensure Degree of Protection During Use
    • Fundamental Leakage – Occurs When Donned
    • Transient Leakage – Occurs during Use

• Maintain or Reduce Total Cost of Ownership (TCO)
  – TCO = Respirator Cost + Fit-Testing Cost + Disposal Cost + Inventory Management Cost + Disinfecting Cost + ....

• Cost of *Non-Availability* Cannot be Computed: No Protection
Research Objective

- Design And Develop Innovative Cost-effective, User-friendly, Reusable Respiratory Protection Device (RPD) For Healthcare Workers

- The Next Generation Healthcare RPD

- The PanFlu Initiative: CDC Funding
Evidence-based Performance Requirements

Will Determine the Choice of

Materials  Structures  Manufacturing Tech.

Will Influence the Properties and Lead to the Design of the

RPD

Gather Evidence from Users …
User Requirements: The Survey Instrument

Design and Development of Innovative Medical Masks

End-User Survey

In a Nutshell: The research project at Georgia Tech is aimed at developing the next generation respirator mask for healthcare workers that is comfortable and easy to use by eliminating the “fit-test” that is typically required for such devices. This survey is designed to obtain your valuable input – as an end-user of an N95 respirator mask – in a healthcare setting. Rest assured, all the information you furnish will be used only in the research and none of your input will be traced back to you. We thank you for your time and valuable input.

***

1. USER PROFILE
   a. Occupation: Doctor, Nurse, Researcher, ____________
   b. Work Environment: Hospital, Research Lab, ____________
   c. Typical Type of Hazard: Patients, Lab Animals, ____________
   d. Device Availability
      i. Is a device always available to you (yes/no)?
   e. Usage Statistics
      i. Device Type:
         1. N95 Respirator
         2. Surgical Mask
         3. N95 Surgical Mask
         4. Other: ____________
      ii. Regularly using Device for the past _________ [months/years]
      iii. Brand Name / Model: ____________
      iv. Duration of Continuous Use: ____________ [e.g., 2 hours/day]
      v. Number of Devices Used/Day: ____________
   vi. Reason for Changing Device during Day (Please circle all that apply and rank order in frequency of occurrence with Most Often – 1 and so on):
      1. Moving from Patient to Patient
      2. Fear of contamination & Device becoming ineffective
      3. Difficulty of Breathing


Findings: Complaints / Dislikes with Device

- Breathing is Impaired – Discomfort
- Fear of Suffocation – Hyperventilating
- Hot and Damp due to Condensation of Breath in Device
- Fogging of Glasses
- Scratchy
- Skin Breaks Down
- Bruises to Nose due to “Fitting” Tightly – Marks
- Multiple Straps – Difficult to adjust, significantly hurts hair and “messes” it up.
- Interferes with Stethoscope
- Communication Impaired
  - Need to speak at least 20% louder
  - Elderly patients who rely on lip reading to augment hearing loss have greater difficulty comprehending words.
- Heavy
- Thick
- Duckbill Design contributes to shifting of device during talking and increases potential for leakage.
- Difficult to fit individuals with narrow cheekbones.
- Facial hair interferes with use
Use-related hazards occur for one or more of the following reasons:

- Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user;
- The use environment affects operation of the device and this effect is not recognized or understood by the user;
- The particular use environment impairs the user’s physical, perceptual, or cognitive capabilities when using the device to an extent that negatively affects the user’s interactions with the device;
- Device use is inconsistent with user’s expectations or intuition about device operation;
- Devices are used in ways that were not anticipated; or
- Devices are used in ways that were anticipated but inappropriate and for which adequate controls were not applied.”

“Applying Human Factors and Usability Engineering to Optimize Medical Device Design”
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm
Current Devices and Guidelines

• Survey Findings Illustrate the Challenges of Current Generation of Devices vis-à-vis the FDA Design Guidelines for Medical Devices

• Design \( \Rightarrow \) **Optimal** Set of “Compromises” and Trade-offs

• No Such Thing as a “Perfect” Design
  – Technology is Constantly Evolving …
Value of the Findings

• Identification of the “Grand” Challenges in The Design of Respiratory Protection Devices

• Addressing the Grand Challenges: Design of Solutions
The Grand Challenges

• Solving The Comfort-Safety Conundrum
  – The Porosity-Permeability Balance

• Enhancing Ease-of-Use
  – Overcoming The Fit-Test Barrier

• Creating Reusable Devices
  – Maintaining The Performance for Reuse
The Porosity-Permeability Balance

- Bandage / Mosquito Net $\rightarrow$ Porous, Comfortable

- Saran Wrap $\rightarrow$ Impermeable, Dangerous

- The Key: Achieving The Delicate Balance
The Fit-Test Barrier

• Fit-Testing \(\rightarrow\) Critical for Efficacy and Safety

• **Holy Grail** of Respirator Research: Obviate Fit-Testing

• Pantyhose \(\rightarrow\) Form-Fitting, But Not “Safe”

• The Key: Achieving a Pantyhose-Type Fit, but Safe!
The Reusability Paradigm

• Reusability $\Rightarrow$ Stockpile, Surge Capability and Total Cost of Ownership

• Traditional Textile Structures $\Rightarrow$ Reusable

• Nonwoven Structures $\Rightarrow$ Disposable

• The Key: Balancing Safety With Operational Metrics
Grand Challenges and The Pandemic Preparedness Initiative

- Addressing the Identified Grand Challenges Will Contribute to Enhancing the Nation’s Pandemic Preparedness – the Four Ss

- A Building Block Approach
Framework Adopted for Design and Development

**Performance Requirements**
- Functionality
- Usability
- Wearability
- Shape Conformability
- Durability
- Maintainability
- Manufacturability
- Affordability

**Desired Properties**
- **Barrier Properties**
  - Resistance to Transmission of
    - Microorganisms
    - Particulates
    - Fluids
- **Comfort Properties**
  - Fabric Hand
  - Air Permeability
  - Moisture Absorption
  - Stretchability
  - Bending Rigidity
  - Weight
  - Tensile Strength & Modulus
  - Form-Fitting
  - Manufacturability
  - Cost

**Materials & Fabrication Technologies**
- **Barrier Component (BC)**
  - Polypropylene
  - Electrostatic Charged Materials
  - Textile Fibers
- **Comfort Component (CC)**
  - Meraklon (Polypropylene)
  - Microdenier Polyester Blend
- **Form-Fitting Component (FFC)**
  - Spandex, Gels, …

**Design Parameters**
- Structure Density
- Structure Composition
- Fiber Length, Fineness,
  - Strength, Elongation,
  - Moisture Absorption, Density,
  - Friction, Cross-Sectional Shape
- Strength, Elongation, Fineness,
  - Creep/Elastic Recovery

**Manufacturing Technologies**
- Weaving
  - Warp/Weft Density, Weave Structure,
    - Warp/Weft Yarn Count
- Knitting
  - Wale/Course Density, Knit Structure,
    - Yarn Count

**Mask Assembly**
- Cutting, Sewing Straps
  - Number of Layers, Lay-up Orientation,
    - Structure Composition
Structural Variations
Designed a Series of Building Blocks

A Systems Approach . . .
Using the Building Blocks . . .

• Created Series of “Filtration Systems” with Various Combinations of Building Blocks

• Tested the Filtration Efficiency and Pressure Drop Using ASTM F-2299-03 Standard for N95 Respirators

• Designed, Produced and Tested Masks From these Building Blocks
## A Sampling of Results

### Second Series of Tests

Test Sequence: 51, 46, 54, 49, 44, 45, 55, 48, 53, 47, 50, 60, 58, 56, 59, 61, 57

<table>
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<th>Test Sample Number</th>
<th>Filtration Efficiency (%)</th>
<th>No. of Tests</th>
<th>Standard deviation</th>
<th>CV %</th>
<th>Delta-P (&quot;)</th>
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## Sampling of Results (Cont’d)

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<th>Test Sample Number</th>
<th>Filtration Efficiency (%)</th>
<th>Number of Tests</th>
<th>Standard deviation</th>
<th>CV %</th>
<th>Delta-P (%)</th>
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</table>
The Filtration Facet (Safety) → Identified Potential Solutions
Mask Design: Parameters

• **Shape**
  – Duckbill
  – Round
  – Positioning of Darts

• **Periphery**
  – Tight Fit to Prevent Leakage
  – Comfortable to Avoid Pressure Points

• **Straps**
  – Number
  – Orientation/Position

• **Developed a Series of Designs**
Prototype Designs
The Mask Design (Simplicity) → Identified Potential Solutions
Bringing The Building Blocks Together: The Final Designs and Prototypes
## Prototype Masks

### Mapping for Samples Delivered

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<tr>
<th>Mapping for Samples Delivered</th>
<th>Resistance mmH₂O</th>
<th>AVG mmH₂O</th>
<th>AVG mmH₂O</th>
<th>AVG ((&quot;) H₂O) %</th>
<th>Penetration AVG %</th>
<th>AVG %</th>
<th>AVG Filtration Efficiency (%)</th>
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Another Structure for Sample #4 Configuration:
Filtration Efficiency: 60.3%; Pressure Drop: 0.285"
Reusable Device:
Situations where high-level exposures (e.g., bronchoscopy) are not expected, but wherein a large number of individuals need or desire a device. Reusability → Lower TCO
Contributions of the Project

• The Grand Challenges: Solid Foundation
  – Building Blocks for Innovative Structures

• Design Prototypes
  – Designed, Developed, Tested, Refined and Delivered
A Step Closer to HHS Goals . . .

• “Improve medical countermeasure technologies and move towards a nimble, flexible capacity to produce MCMs in the face of any attack or threat.”

Build on the Solid Foundation

• Commercialization of Technology
  – Create Samples for Field Testing
  – Assemble Test Panel
  – Test and Refine Design
  – Certification – FDA and NIOSH
  – Bring to Market
Utilize this Work to Effectively Address the Grand Challenges in Respirator Design and Enhance the Quality of Life for Individuals
Acknowledgments

- Dr. Michael Bell, Associate Director for Infection Control, CDC
  - For Funding and Technical Interactions
  - An Exciting Opportunity

- Research Team Members
  - Georgia Tech
  - Kolon Glotech, Inc.

- NPPTL – For Periodic Confirmatory Testing
  - Dr. Maryann D’Alessandro
  - Dr. Samy Rengasamy