The Grand Challenges in the Design of Respiratory Protection Devices

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June 18, 2013

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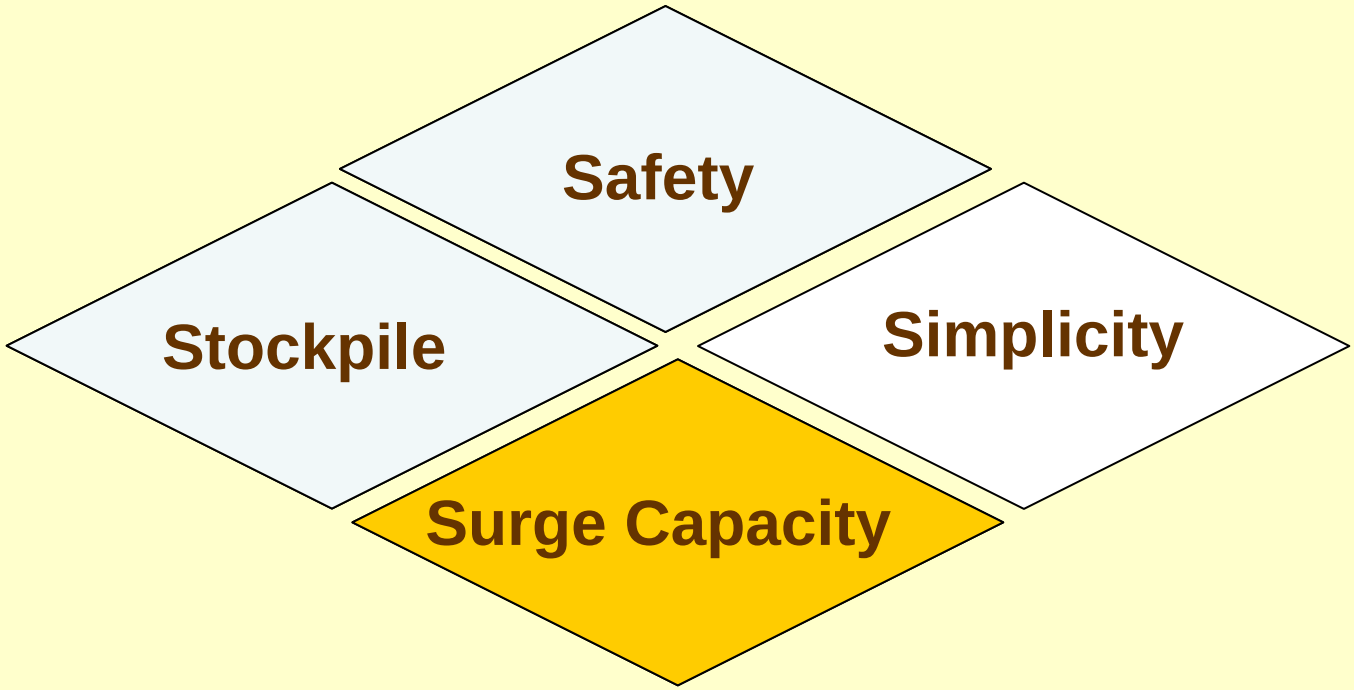
Overview of Presentation

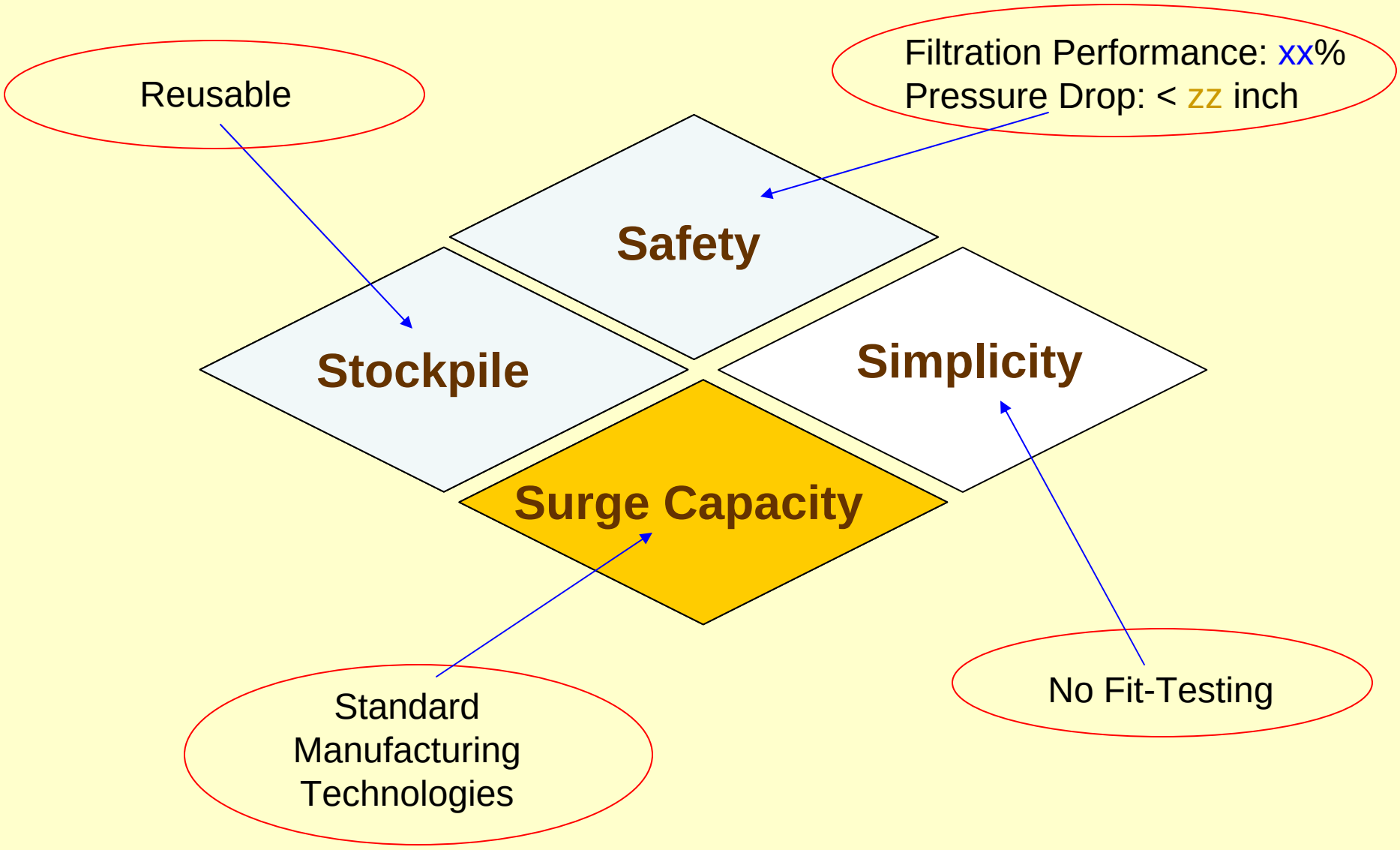
- National Pandemic Preparedness and PPE
- The Grand Challenges
- A Building Block Approach to the Grand Challenges
- Conclusions
- Acknowledgements

Pandemic Preparedness Initiative

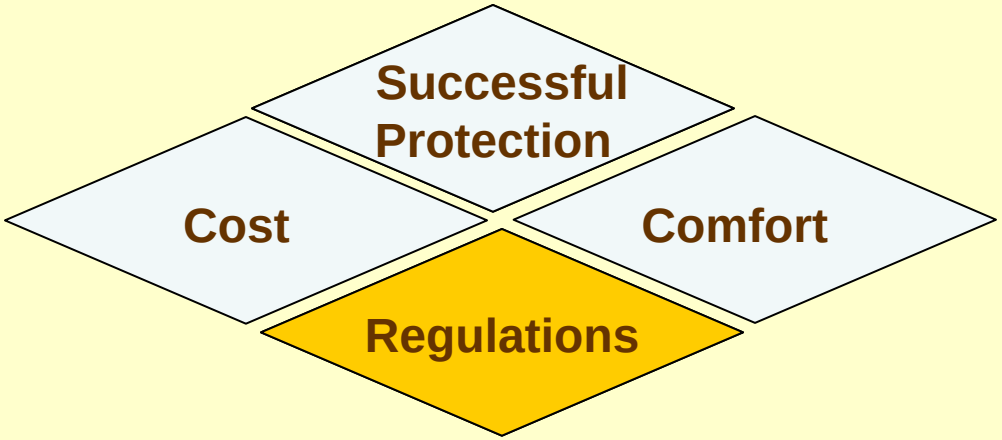


National Pandemic Influenza Implementation Plan (May 2005)
http://www.phe.gov/preparedness/mcm/enterprisereview/pages/default.aspx

Four Ss and PPE Performance



Design of PPE: The Drivers



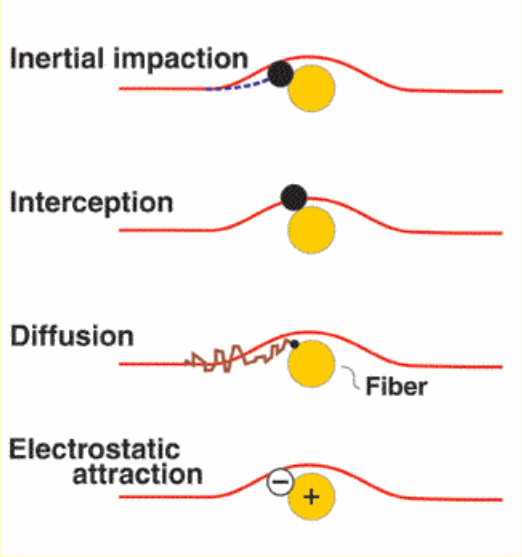
Preparing for an Influenza Pandemic:
Personal Protective Equipment for Healthcare Workers
-- IOM Report, September 2007

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
- *Trade-Offs – The Balancing Act*

Today's Reality

- Commercial Respirators
  - Nonwovens
  - Charged Polypropylene Filters



Mechanisms for Trapping Particulates

3M N95 Healthcare Particulate Respirator & Surgical Mask

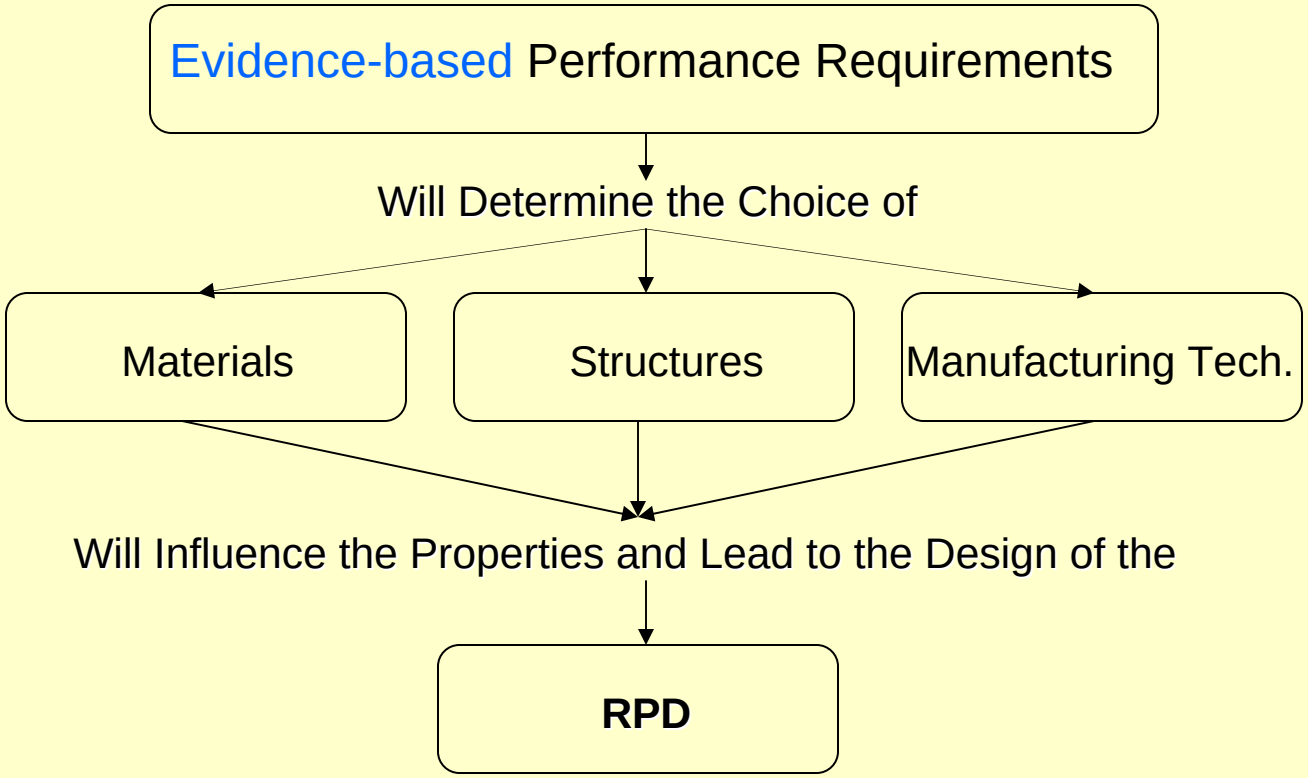
The Design Challenge

- Ensure Performance
  - Efficacy – Ensure Degree of Protection During Use
  - Avoid Leakage [Crutchfield et al., *Applied Occupational and Environmental Hygiene,* Volume 14(12):827-837,1999]
    - 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

The Design Toolkit



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

Medical Device Design: FDA Guidelines

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 ➔ 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 → Porous, Comfortable
- Saran Wrap → Impermeable, Dangerous
- The Key: Achieving The Delicate Balance

The Fit-Test Barrier

- Fit-Testing → Critical for Efficacy and Safety
- Holy Grail of Respirator Research: Obviate Fit-Testing
- Pantyhose → Form-Fitting, But Not “Safe”
- The Key: Achieving a Pantyhose-Type Fit, but Safe!

The Reusability Paradigm

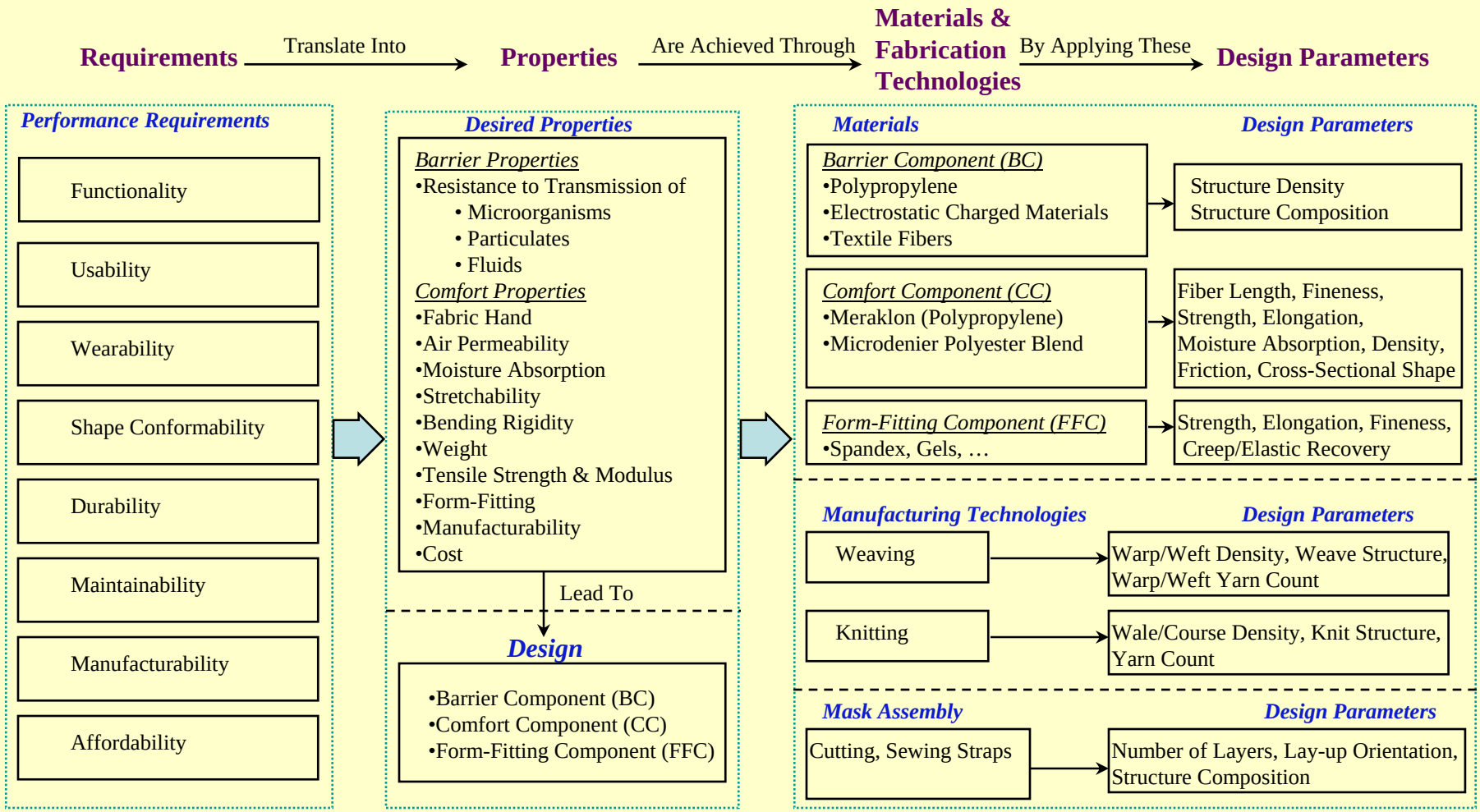
- Reusability → Stockpile, Surge Capability and Total Cost of Ownership
- Traditional Textile Structures → Reusable
- Nonwoven Structures → Disposable
- The Key: Balancing Safety With Operational Metrics

Grand Challenges and The Pandemic Preparedness Initiative

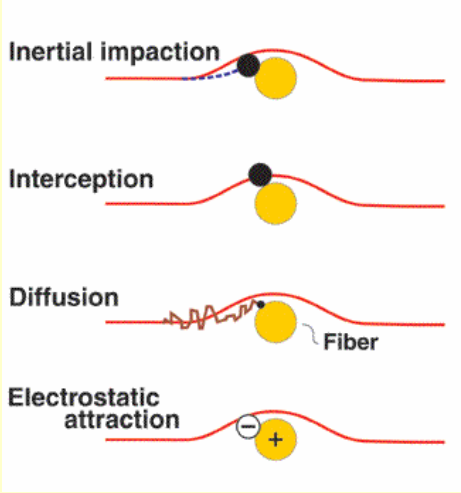
- Addressing the Identified Grand Challenges Will Contribute to Enhancing the Nation's Pandemic Preparedness – the Four Ss

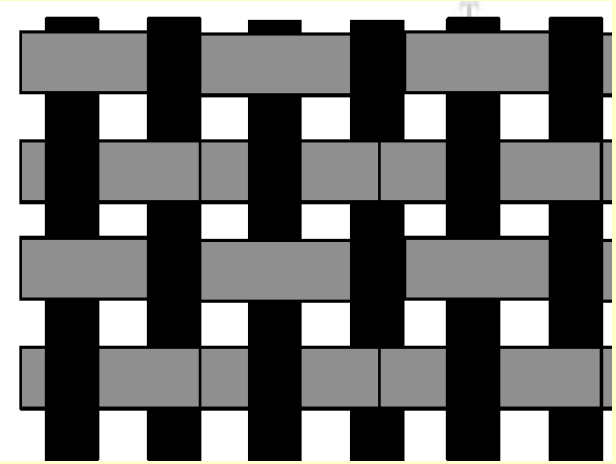
- A Building Block Approach

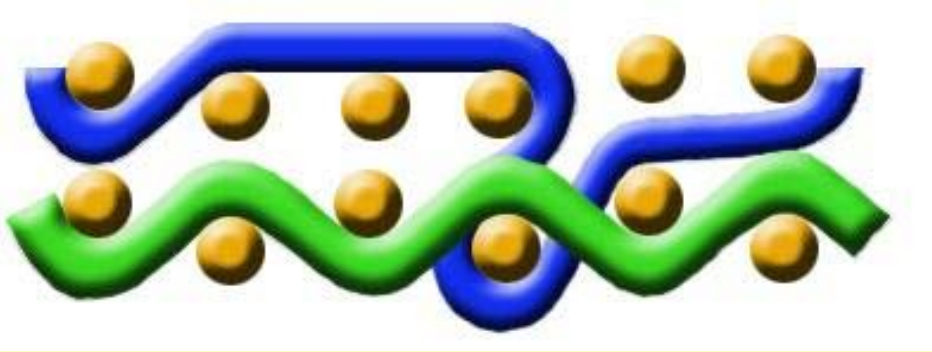
Framework Adopted for Design and Development

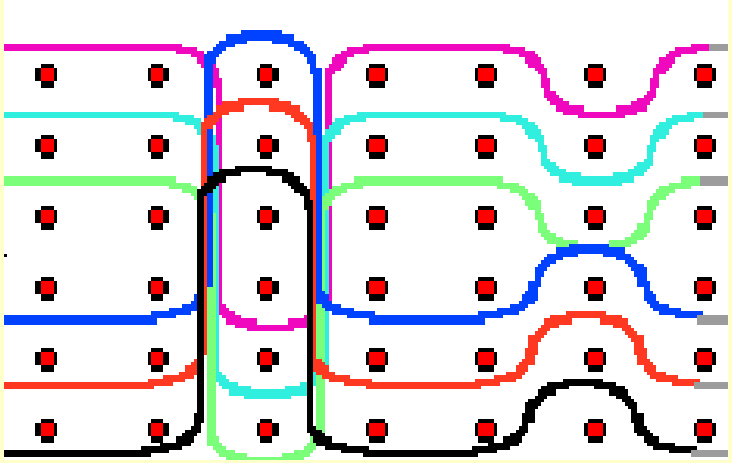


Structural Variations









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, 52, 45, 55, 48, 53, 47, 50, 60, 58, 56, 59, 61, 57					
Test Sample Number	Filtration Efficiency (%)	No. of Tests	Standard deviation	CV %	Delta-P (")
44	5.54	4	0.673661	12.19735	0.275
45	21.04	4	1.520997	7.221211	0.278
46	25.54	4	2.17806	8.553634	0.332
47	33.44	4	4.510725	13.58246	0.455
48	53.43	4	3.786785	7.095632	0.24
49	60.73	4	1.464161	2.411527	0.28
50	63.17	4	2.139324	3.387139	0.35
51	61.22	4	1.139747	1.862725	0.405
52	59.28	5	2.572115	4.357083	0.44
53	64.94	4	2.91516	4.501624	0.46
54	74.95	4	0.729021	0.973029	0.34
55	74.37	4	1.922781	2.590572	0.358
56	79.75	4	2.203062	2.764829	0.375
57	80.67	4	1.759917	2.182362	0.4
58	80.47	4	3.051267	3.805744	0.36
59	87.37	4	0.689111	0.788852	0.335
60	99.65	4	0.101339	0.101698	0.465
61	79.56	4	3.231939	4.082988	0.405

Sampling of Results (Cont'd)

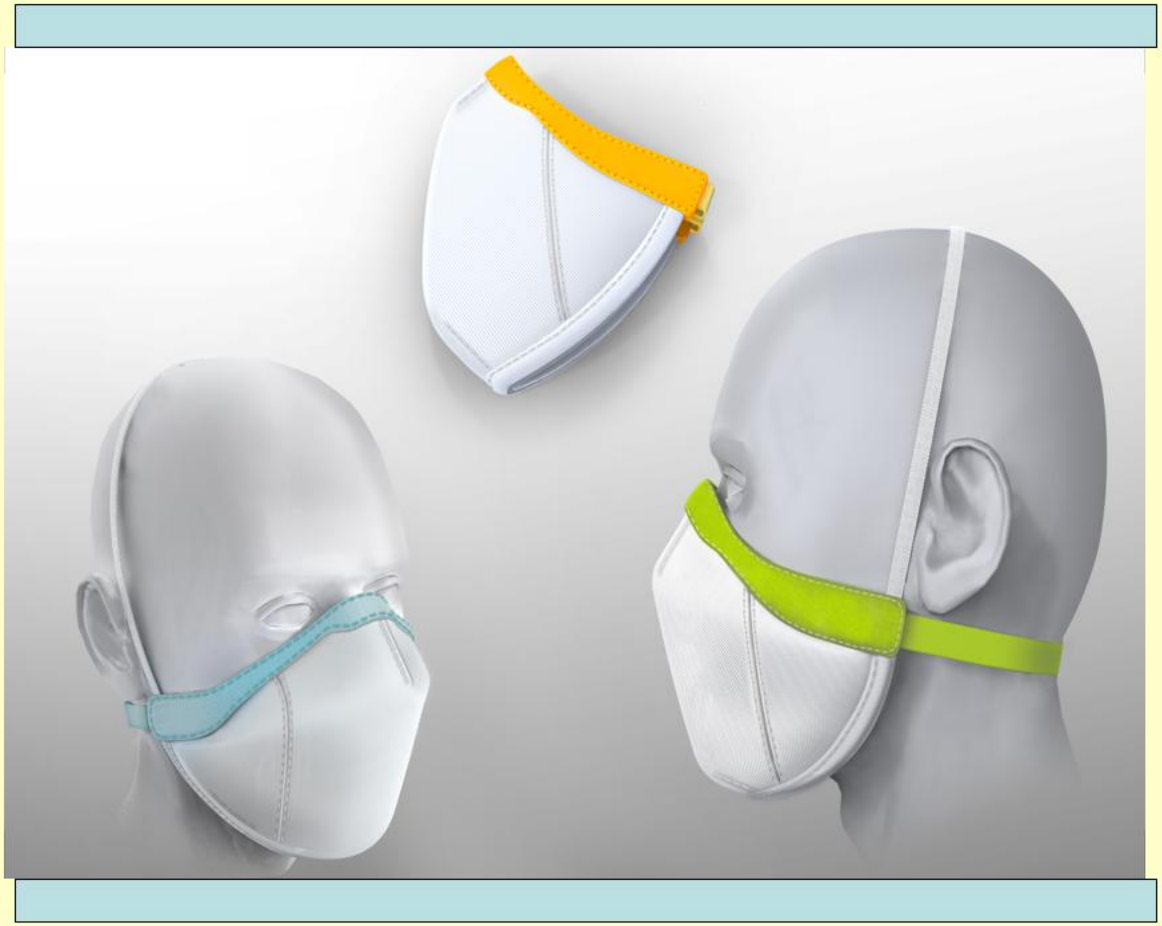
Test Sample Number	Filtration Efficiency (%)	Number of Tests	Standard deviation	CV %	Delta-P (")
62	99.58	3	0.024648	0.024751	0.45
63	99.56	3	0.08597	0.086346	0.495
64	74.61	3	0.482642	0.646846	0.37
65	77.59	3	0.248357	0.320041	0.40
66	85.27	3	0.642242	0.753112	0.34
67	78.90	3	0.438411	0.555655	0.332
68	98.99	3	0.164563	0.166235	0.48
69	99.35	3	0.020285	0.020417	0.155
70	99.13	3	0.068999	0.069601	0.30
71	99.57	3	0.064016	0.064287	0.36
72	99.28	3	0.148825	0.149882	0.39

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

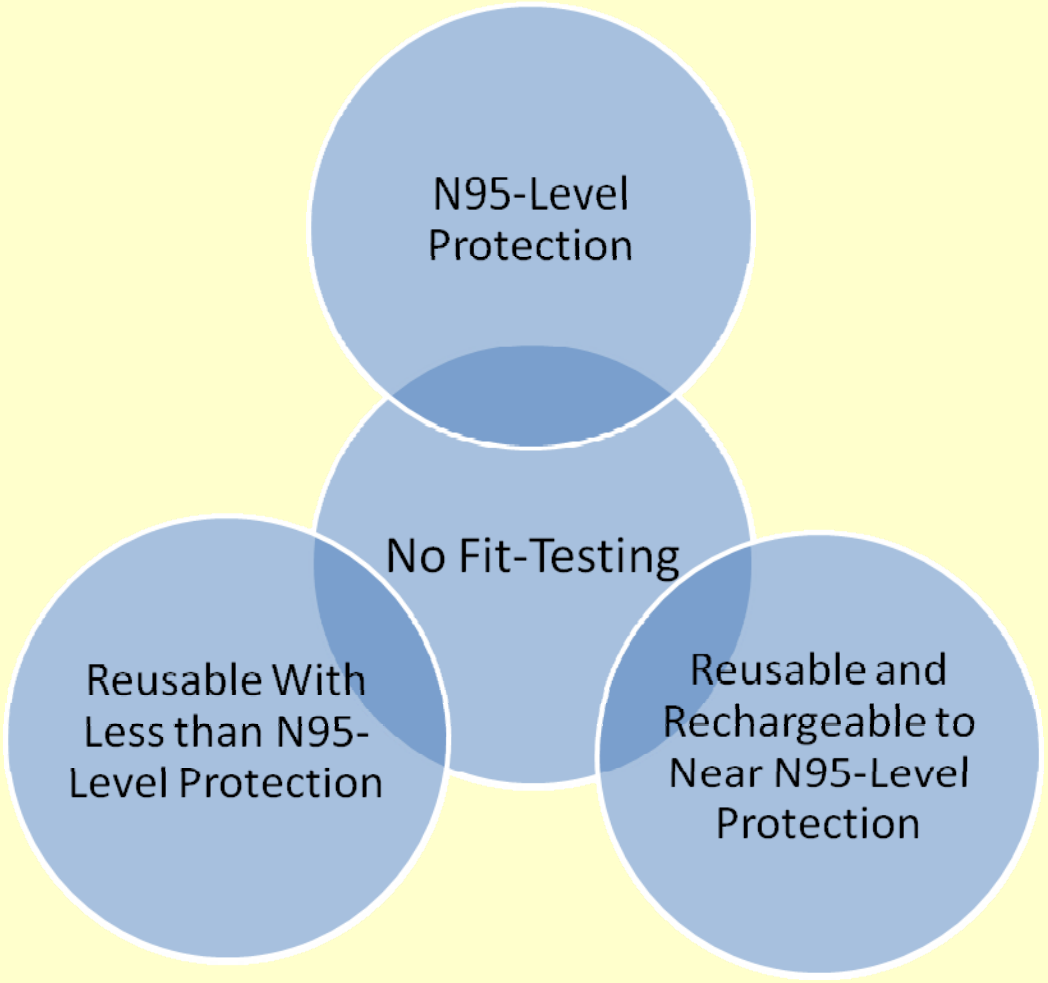
Prototype Masks

Mapping for Samples Delivered	Resistance	AVG	AVG	AVG	Penetration	AVG	AVG	Filtration Efficiency
	mmH_2O	mmH_2O	mmH_2O	(") H_2O	%	%	%	(%)
Sample #1	13.5	13.9	13.1	0.515	4.2	4.3	4.23	95.768
	14.3				4.4			
	11.9	12.3			4.1	4.2		
	12.6				4.3			
Sample #2	12.3	12.8	14.1	0.554134	4.1	4.2	4.56	95.4375
	13.2				4.3			
	15.0	15.4			4.9	5.0		
	15.8				5.1			
Sample #3	10.2	10.6	10.4	0.410433	8.0	8.3	7.57	92.435
	11.0				8.6			
	9.9	10.3			6.6	6.8		
	10.6				7.0			
Sample #4	12.7	12.8	12.3	0.485236	49.3	49.7	51.95	48.05
	12.8				50.0			
	11.8	11.9			54.1	54.3		
	12.0				54.4			

Another Structure for Sample #4 Configuration:
Filtration Efficiency: 60.3%; Pressure Drop: 0.285”

Results To-date

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
  - The Design Framework: Materials + Manufacturing Methods + Structures – Valuable for Further Research
- 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.*"

--The HHS Public Health Emergency Medical Countermeasures Enterprise Review, https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf,

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