Filter Efficiency and Facial Fit of Health Care Masks

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Surgical Masks

- Developed in early 1900s
- Used to prevent contamination of the surgical field
- Uses have expanded to include protection of the wearer from:
  - Splashes and sprays of body fluids
  - Laser “plumes”
  - Dental aerosols
Are Masks Effective?

- Can reduce dispersal of organisms from the wearer and lower rate of bacterial contamination in operative field
- No correlation between wound contamination and airborne bacteria
- Clinical studies show no difference in surgical wound infection rates with or without masks
FDA Approval to Market

- Pre-market notification
- Approval for marketing – not certification
- Mask must be at least as good as anything currently on the market
- ASTM F2100-04 Standard Specification for Performance of Materials Used in Medical Face Masks
### TABLE 1 Medical Face Mask Material Requirements by Performance Class

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Low Barrier</th>
<th>Moderate Barrier</th>
<th>High Barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial filtration efficiency, %</td>
<td>( \geq 95 )</td>
<td>( \geq 98 )</td>
<td>( \geq 98 )</td>
</tr>
<tr>
<td>Differential pressure, mm H(_2)O/cm(^2)</td>
<td>(&lt; 4.0)</td>
<td>(&lt; 5.0)</td>
<td>(&lt; 5.0)</td>
</tr>
<tr>
<td>Sub-micron particulate filtration efficiency</td>
<td>Not required</td>
<td>( \geq 98 )</td>
<td>( \geq 98 )</td>
</tr>
<tr>
<td>at 0.1 micron, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resistance to penetration by synthetic blood, minimum</td>
<td>80</td>
<td>120</td>
<td>160</td>
</tr>
<tr>
<td>pressure in mm Hg for pass result</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flame spread</td>
<td>Class 1</td>
<td>Class 1</td>
<td>Class 1</td>
</tr>
</tbody>
</table>
Medical mask selection depends on exposure hazards

- General use masks
  - Minimal fluid resistance
  - Isolation settings
- Sub-micron masks
  - Laser or electrocautery surgery
- Fluid-resistant masks
  - Probability of exposure to blood or body fluids
ASTM 2100-04

- Does not evaluate medical face masks for regulatory approval as respirators.
- Only evaluates materials used in the construction of medical face mask -- not the seal against the wearer’s face or other design features that determine its effectiveness of preventing exposure to the wearer.
ASTM 2100-04

- Test Methods
  - *Bacterial Filtration Efficiency*—ASTM F 2101
  - *Differential Pressure*—paragraph 4.4.1.2 of MIL-M-36954C
  - *Sub-Micron Particulate Filtration*—ASTM F 2299
  - *Resistance to Penetration by Synthetic Blood*—ASTM F 1862
  - *Flammability*—16 CFR Part 1610
ASTM 2100-04

- **Submicron Particulate Filter Efficiency (PFE)**
  - F 2299 Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks for Penetration by Particulates Using Latex Spheres

- **Bacterial Filtration Efficiency (BFE)**
  - ASTM F2101-01 Standard Test Method for Evaluating Bacterial Filtration Efficiency of Surgical Masks Using a Biological Aerosol of *Staphylococcus aureus*
  - Also Mil-M-36954C and Modified Greene and Vesley Method
Sub-Micron Particulate Filtration Efficiency

- Uses 0.1 µm latex spheres (monodisperse)
- Flow rates from 0.5 to 25 cm/s
- Count particles upstream and downstream using light scattering photometer

**KEY POINTS:**
- Aerosol not neutralized
- No standard flow rate
Bacterial Filtration Efficiency

- *Staphylococcus aureus*, average diameter 0.8 μm (liquid dispersion)
- Aerosol size 3 ± 0.3 μm
- 6-stage Andersen impactor
- 1 CFM (28.3 L/min)
- Challenge concentration: 1700-2700 colony-forming units

**KEY POINTS:**
- Aerosol not neutralized
- Large particle size
- Counting colonies
Respirator Filter Performance (42 CFR 84)

- NIOSH certification tests use NaCl (solid) and DOP (liquid oil) aerosols (0.3 µm) charge neutralized at 85 L/min.
- 3 levels of filter efficiency:
  - 95 = at least 95% efficiency
  - 99 = at least 99% efficiency
  - 100 = at least 99.97% efficiency
- 3 categories of oil resistance (N, P, R)
- 9 classes of respirators
NIOSH Tests are “Worst Case”

- Most penetrating particle size
  - Particles larger and smaller than 0.3 µm will be collected with HIGHER efficiency
- Charge neutralized aerosols collected with lower efficiency than non-neutralized aerosols
- High flow rate (85 L/min)
- Pre-conditioning at 85±5% RH and 38±2.5°C for 25±1 hr
Evaluation of Fit

- Health care masks:
  - Not part of FDA approval or ASTM filter testing methods

- Respirators:
  - QLFT and QNFT methods
  - Protection factor of 10 for filtering facepiece respirators
Study Goal

Measure filter efficiency and facial fit for representative health care masks
Methods

- Nine health care masks used in hospital and dental settings
- Range of uses (surgical, laser, procedure)
- Range of mask types (cup, flat, duckbill)
- Range of fastenings (1 or 2 ties, ear loops)
Filter Efficiency Methods

- Three sizes monodisperse latex spheres (0.895, 2 and 3.1 μm)
- 6 L/min
- Neutralized aerosol
- Masks sealed to metal plate
- Upstream and downstream concentrations measured with laser photometer
- 3 replicates of each mask
- Also tested 3 replicates of each mask using NIOSH test conditions (84 L/min, 0.3 μm NaCl) with TSI Automated Filter Tester
Facial Fit Methods

- Only masks with less than 0.6% filter penetration
- 20 subjects (10 male, 10 female)
- Medical screening; informed consent
- Each subject wore 1 mask, 4 tests
  - 2 QLFT (Bitrex) assisted, unassisted
  - 2 QNFT (Portacount) assisted, unassisted
# Health Care Masks

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Protection (BFE%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Medical, cone, one strap</td>
<td>(Not reported)</td>
</tr>
<tr>
<td>B</td>
<td>Medical, 3-ply, ear loops</td>
<td>(BFE 95%)</td>
</tr>
<tr>
<td>C</td>
<td>Medical, 3-ply, 2 ties</td>
<td>(BFE 95%)</td>
</tr>
<tr>
<td>D</td>
<td>Procedure, fluid resistant, splashguard visor, pleated, ear loops</td>
<td>(99%, 99%)</td>
</tr>
<tr>
<td>E</td>
<td>Surgical, 3-ply, pleated, 2 ties</td>
<td>(96%, 97%)</td>
</tr>
<tr>
<td>F</td>
<td>Surgical, pleated, 2 ties</td>
<td>(96%, 97%)</td>
</tr>
<tr>
<td>G</td>
<td>Sub-micron, fluid resistant, splashguard visor, pleated, 2 ties</td>
<td>(99%, 99%)</td>
</tr>
<tr>
<td>H</td>
<td>Sub-micron, pleated, 2 ties</td>
<td>(99%, 99%)</td>
</tr>
<tr>
<td>I</td>
<td>Sub-micron, duckbill, 2 ties</td>
<td>(99%, 97%)</td>
</tr>
</tbody>
</table>
Dental Masks

- Penetration (%) vs. Particle Size (µm)

- Graph showing penetration percentages for different particle sizes.

- Three lines represent different materials A, B, and C.

- Material A shows the highest penetration.

- Material B and C show decreasing penetration with increasing particle size.

- Y-axis ranges from 0 to 100.

- X-axis ranges from 0.895 to 3.1.
Fit Tests

- Included only the 5 hospital masks (D, F, G, H and I) with less than 0.6% penetration for all three test particle sizes
Qualitative Fit Test Results

- All subjects failed the Bitrex aerosol qualitative fit test on the first exercise when donning without assistance.
- Only 2 male subjects passed QLFT with assistance.
  - 60% failed on first exercise.
Quantitative Fit Test Results

- Fit factor = 2.5 – 6.9 for unassisted donning
- Fit factor = 2.8 – 9.6 for assisted donning
- Average fit factor for all masks, unassisted donning = 4.4 ± 0.9
- Average fit factor for all masks, assisted donning = 5.7 ± 0.8
Quantitative Fit Test
Results

- Some masks showed improvement after assisted donning, others did not
- Gender had no effect on fit factor with either donning protocol
Conclusions

- Health care mask filters exhibit wide range of filter efficiency
- Filter efficiency is not predictive of fit
  - Mask with one of the best filter efficiencies had lowest fit factor
- BFE and PFE results are not predictive of filter performance
- Health care masks do not fit and do not meet even minimum expectations for respiratory protection