Update on Respirators and Surgical Masks
Review of Literature (2007-2010)

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IOM Recommendations for Healthcare PPE

- Products that balance cost, comfort and protection while enhancing compliance and use
- Use systems approach for design, development, testing and certification
  - Measures for comparing effectiveness
  - Collaboration between users, mfrs, researchers and regulators
  - Consensus-based transparent process for standard setting
  - More pre-market testing prior to approval
  - Reevaluate FDA medical device classification for healthcare PPE
Literature Review

- Approximately 50 publications from 2007-present (not exhaustive)
- Selected those most appropriate to healthcare settings.
- Organized findings into four categories:
  - Filtration and Fit
  - Antimicrobial Filters
  - Comfort
  - Visualization Techniques
Filtration and Fit

- **Big research questions:**
  - Do current respirator filters provide adequate protection against nanoparticles (individual viral particles)?
  - Which particles leak around the facepiece?
  - How do respirator and surgical mask filtration and fit compare?

- **Other questions:**
  - Is cyclic flow necessary for testing filter performance?
  - What happens to filter performance after long storage periods?
Inert Nanoparticle Filtration – N95 Filters

- The most penetrating particle size (MPPS) occurs at 40-60 nm.
- Penetration at the MPPS ranges from 2-10% at 85 L/min.

Figure from Shaffer & Rengasamy, J Nanoparticle Research, 2009
Inert Nanoparticle Filtration – Surgical Mask Filters

- MPPS for most surgical masks = 200-300 nm (mechanical collection mechanisms)
- A few surgical masks have a lower MPPS = 40 nm (electrostatic filters)
- Collection efficiency highly variable -- ranges from 30-95%

3 Surgical Masks, 85 L/min, Room Air
Biological Nanoparticle Filtration

- Respirator filters collect inert and biological aerosols of similar aerodynamic size and distribution with the same level of efficiency.
- Inert aerosols are much easier to generate and measure.

**N95 Respirator Filters**

![Graphs showing penetration of N95 filters for NaCl, B. Subtilis bacteriophage, and T4 bacteriophage at different flow rates.](Figures adapted from Eninger et al., Ann Occup Hyg, 2008)
Recent studies with surgical masks show the same results as previous studies:

- Results using high-quality laboratory techniques demonstrate that FDA-required test results do not discern “good” filters from “bad”
- FDA needs to adopt a more aggressive standard for filtration performance that specifies the use of a charge-neutralized submicron inert aerosol and a single, high face velocity (worst case test)
Other Filtration Findings

- Cyclic flow is not necessary for testing filter performance.
- Should test filters with a relatively high flow (40-85 L/min) to ensure good performance at lower flows.
- N99 and P100 filters collect nanoparticles with very high efficiency.
- Non-certified dust masks show as much variability in filter performance as surgical masks. Should not be used for exposures to nanoparticles (e.g. welding).
- Long-term storage (up to 6 years) does not adversely impact filter performance of N95 filters.
One recent study sheds new light on faceseal performance (Grinshpun et al, 2009). Measured contribution of filter penetration and faceseal leakage to N95 FFR and surgical mask performance, using subjects and manikins. 25 subjects matching the NIOSH bivariate panel OSHA fit test exercises. Filter and faceseal leakage measured continuously for different particle sizes.
Faceseal Leakage Study – Key Findings

- Leakage around the face seal greatly exceeds penetration through the filter.
- Face seal leakage is particle size dependent.
- MPPS for face seal leakage = 100-200 nm
  - Suggests that mechanical filtration collection mechanisms play important role
- N95 filtering facepiece respirator had:
  - 5% leakage at 120 nm (leakage was lower at sizes smaller and larger than this)
  - ≤ 1% filter penetration at particle sizes ranging from 80-200 nm
Faceseal Leakage

- Surgical mask had:
  - 40% faceseal leakage at 120 nm (lower leakage at smaller and larger particle sizes)
  - 5% filter penetration at all tested sizes

- Variability in ratio of faceseal and filter leakage
  - 70% variability due to differences among subjects
  - 30% due to differences in individual donning practices

- No relationship found between subjects’ facial measurements and penetration for either leakage pathway.

- Penetration differed significantly across the different exercises.
Authors conclude that between-subject variability is due to -
- Differences in facial and body movements during different exercises (esp. head movements and bending over)
- Differences in breathing pattern

Results suggest that faceseal leakage (fit) is a dynamic process that cannot be captured with static measurements of facial dimensions.
- 3-dimensional measurements are not likely to yield useful information
- Ensuring a range of facial dimensions in a fit test panel will not yield a representative picture of respirator fit
Surgical Mask Fit

- Study of 5 surgical masks with < 0.6% filter penetration (0.9 µm latex spheres) and 20 subjects (10 male, 10 female) (Oberg and Brosseau, 2008)
  - Qualitative & quantitative fit tests
  - Assisted and un-assisted donning

- Qualitative fit testing – all subjects failed on first exercise without assistance; 90% of subjects failed fit test (60% on first exercise) with assistance

- Quantitative fit testing – Average ±SD (range)
  - No assistance – 4.4 ± 0.9 (2.5 – 6.9)
  - Assistance – 5.7 ± 0.8 (2.8 – 9.6)
Big question (it appears):
- Do antimicrobial treatments ensure higher levels of wearer protection from hazardous biological organisms?

Big misunderstandings:
- Biological particles in healthcare settings will not grow or migrate through the filter once they are captured.
- Biological (and all other) particles will stick once they are captured. Even short high velocity bursts of air are unlikely to dislodge them.
- Overloading is highly unlikely to become overloaded in healthcare settings. Respirators will become un-wearable before they are overloaded.
Antimicrobial Filters

- Reviewed 5 papers, but only 1 was properly conducted.
  - Eninger et al. 2008 concluded that antimicrobial treatment was not responsible for enhanced filter performance.

- Problems with other papers involved comparisons of “apples with oranges”:
  - Did not measure both total and viable particle penetration using methods with similar collection efficiency in the same particle size range.
  - Did not compare inert and biological aerosols having similar median sizes and size distributions.
  - Did not assess whether the treatment changed the mechanical collection properties of the filter.
  - Did not compare the same filter with and without treatment.
  - Did not assess whether the antimicrobial treatment was responsible for loss of cell viability after filter liquid extraction.

- Particle transit time through filter = milliseconds
Comfort

- HCW want respirators that are: (Baig, 2010)
  - More comfortable
  - Interfere less with breathing
  - Diminish heat buildup
  - Permit wearer to have facial hair

- Such a respirator exists.
  - Interview with respirator designer identified a simple PAPR design (sold in Japan) that could be used in healthcare settings (Brosseau, 2009)
  - Problem: Would not meet stringent NIOSH certification criteria for industrial PAPRs.
Other Comfort Issues

- Wearing a surgical mask over an N95 FFR does not have a significant effect on physiologic variables, comfort or exertion.
  - My opinion – wearing a faceshield would be a better method for preventing exposure to splashes
Two studies of communication interference:
- Surgical masks in dental settings (Mendel 2008)
- Surgical masks and half-mask respirators in ICU (Radonovich 2010)

- Surgical masks and filtering facepiece respirators do not decrease speech intelligibility.
- Elastomeric respirators with speakers are better than those without.
- PAPRs decrease speech intelligibility by about 10%.
- Medical settings can be noisy and interfere with understanding speech – without masks or respirators.
Visualization Techniques

- Flow visualization using Schlieren photography and video.
  - Demonstrate differences in airflow around surgical masks and respirators.
  - Tracking turbulent jets from coughs – can also measure distance, velocity and profile.
  - Effect of masks and respirators on air jets from coughs.
Profile of a Cough

Air jets from unprotected coughs and coughs covered by surgical mask and N95 FFR

Images from Tang et al., J Royal Society Interface, 2010
Visualization Techniques

- Thermal imaging with IR camera can be used to compare surface temperature of respirators with and without exhalation valves (Monaghan et al., 2009)
- No difference with & without exhalation valves because flow rate too low to activate valve (need at least 30 L/min)

Images from Monaghan et al., JISRP, 2009
Encouraging Innovation

- Toward Better Fitting Respirators (NIOSH workshop and research roadmap)
  - Evaluate barriers and incentives for innovations in respirator design and fit test methods
  - Develop recommendations for activities that could lead to improvements in respirator fit

- High potential for innovation exists – success will depend on --
  - specialized knowledge about materials and technology
  - preliminary and supporting research
  - significant financial support
  - regulatory assistance and flexibility
  - health and safety professional and user acceptance.
Тowards Better Fitting Respirators

- Research should focus on:
  - Clarifying how respirator fit is influenced by respirator design and facial characteristics.
  - User seal check methods and their role in establishing initial and long term fit.

- Key stakeholders need to be more involved in setting and evaluating research directions:
  - Respirator users
  - Respirator program managers
  - Inventors
  - Researchers
  - Manufacturers

- More formal support is needed for inventors and small businesses to assist with research, development and commercialization of innovations.
Conclusions

- No more research needed on nanoparticle filtration or filtration in general, for either respirator or surgical mask filters.
- Surgical masks do not fit and will not adequately protect the wearer from aerosol exposures.
- Changes are needed in FDA requirements for marketing clearance of surgical masks, using more prescriptive and “worst case” filter test criteria.
- Need much more research about faceseal leakage and respirator fit.
  - Especially need creative approaches that capture the dynamic relationship between fit and facial and body movements.
Conclusions

- No studies have yet demonstrated utility of antimicrobial filter treatments.
- Innovative powered air purifying respirator designs could be responsive to issues of comfort, facial hair, heat buildup.
  - May require changes in NIOSH certification tests.
  - Need to address interferences with speech communication.
- Visualization techniques using Schleiren and IR photography should be explored further.
- More efforts is needed to support innovative approaches to respirator design and fit testing.