SURGICAL MASK PERFORMANCE

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Surgical Mask History

- Developed in early 1900s
- Proposed when research showed that bacteria from nose and mouth are present in droplet nuclei (Flugge, 1897)
- 1926 study showed that wearing gauze masks in OR reduced streptococcal infections
  - “Despite the attention surgical masks received during this period, many... staff... were not using them often or correctly.” (Belkin, 1996)
- 9-year study suggested surgical masks would reduce surgical wound infections (Meleny, 1935)
  - “The practice of surgical masks was hindered by surgeons’ dissatisfaction with the poor quality and discomfort of two-ply gauze masks.” (Belkin, 1996)
Surgical Mask History

- **1940s & 50s** - new materials & designs; new testing methods (Spooner, 1967)
  - Gauze masks have ineffective filters
  - Wetting lowered efficiency
  - Improper fitting allowed leakage around the sides
  - Multiple layers uncomfortable

- **1960s** - exploration of UV light, laminar air, more air changes, surgical masks showed little improvement in surgical wound infection rates

- **1970s** - surgical masks deflect droplet nuclei around sides of mask but do not lower levels of airborne contamination (Ritter 1975)
Masks Show No Clinical Effectiveness

® First randomized controlled trial (6 mos) finds no difference in wound infection rates with and without surgical masks (Orr, 1981)

® Second randomized controlled trial in new OR also found no difference with and without masks (Mitchell and Hunt, 1991)

§ “... with the exception of high risk surgery, the wearing of surgical masks by the surgeon and scrubbed assistants is an unproven value.”

® Third randomized controlled trial (2 yr) & 3 different surgical masks in OR found similar rates of infection with and without masks (Tunevall, 1991)
"The Tunevall study is a landmark in giving us proof that a costly device commonly used in the OR may be another ‘sacred cow’ and could be eliminated. Its elimination would help surgical team members by giving them more energy and, if some form of ‘splash shield’ is made available, would offer comfort and greater protection for the surgical team."

"The latest CDC guidelines admit that the role of face masks in reducing the risk of surgical site infections may be more uncertain than previously thought. The same guidelines support the use of surgical face masks as personal protective equipment." (Romney, 2000)
Surgical Mask Filter Performance

- **Pre-1980s measured with microbial aerosols (generated from people or artificially)**
  - Aerosols are large and polydisperse
  - Sampled with agar plates (later Andersen impactor)
  - Counted colony forming units
  - Very imprecise (high standard deviation)

- **Post-1980s measured with inert, artificially-generated, spherical particles**
  - Aerosols are monodisperse and can be made in broad range of sizes
  - Sampled with direct reading instrument (laser photometer)
  - Count concentrations in air
  - Much more precise
Surgical Mask Filter Performance

Many studies from 1985-present (see list at end of presentation)

Key findings:

- Surgical mask filter efficiency is extremely variable
  - Generally ranges from 20-80%
  - Much lower efficiency than any respirator filter

- Bacterial efficiency tests (ASTM F2100-04 required by FDA) are not predictive of performance with monodisperse inert aerosols (Oberg & Brosseau, 2008)

- Well-controlled experiments using biological organisms (single organisms) produce the same results as inert aerosols of similar aerodynamic diameter (McCullough et al., 1997)
Study with Kimberly Clark Tecnol PCM 2000 masks (0.1 µm fluid shield) showed 80% penetration of 3 to 14 µm latex powder aerosols (generated by gloves) INTO the facepiece (Mitakakis, 2000)

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
Surgical Mask Fit

- **Qualitative Fit Tests (Bitrex)**
  - All subjects failed on first exercise when masks donned without assistance with fit
  - All but 2 male subjects failed when donning with assistance (60% on first exercise)

- **Quantitative Fit Tests (Portacount)**
  - **Unassisted Donning**
    - Average Fit Factor = 4.4 ± 0.9 (2.5 – 6.9)
  - **Assisted Donning**
    - Average Fit Factor = 5.7 ± 0.8 (2.8 – 9.6)

- Some masks improved with assistance, some didn’t
- Gender had no effect on fit with donning protocol
Surgical Mask Fit

- Recent study of total leakage through a surgical mask worn by 25 subjects (Grinshpun et al., 2009) using particles < 1 µm
- Contribution to total leakage into the mask was
  - 5-8% from filter leakage
  - 25-38% from faceseal leakage
- For N95 respirator contribution to total leakage was
  - < 1% from filter leakage
  - 3-5% from faceseal leakage
Surgical Masks Not Approved or Certified

- FDA gives “clearance for marketing”
- FDA requirements do not ensure adequate levels of filter efficiency
  - Filter test conditions are not standardized
  - FDA does not specify a minimum level of performance
- Manufacturers must demonstrate that mask is as good as a mask already on the market
- No assessment of fit is required
- Healthcare settings are not required to purchase FDA-cleared surgical masks (many do not)
Conclusions

- Surgical masks are not clinically effective for original purpose, i.e. reduction of surgical wound infection.
- Surgical masks are ineffective at preventing ILI or lab-confirmed influenza in HCWs [MacIntyre 2009].
- Filter performance with well-controlled aerosol experiments is highly variable (20-80%) and cannot be predicted from FDA required tests.
- Faceseal leakage ranges from 15-40%.
- FDA does not approve or certify:
  - Tests are not useful in discerning “good” from “bad” masks.
  - Hospitals not required to use masks cleared by FDA.
Surgical Mask Filter Studies

® Tuomi, AIHAJ, 1985
® Chen and Willeke, AJIC, 1992
® Weber et al., AJIC, 1993
® Willeke et al., J Aerosol Sci, 1994
® Chen et al., AJIC 1994
® McCullough et al., Annals Occup Hyg, 1997
® Brosseau et al., Appl Occup Env Hyg, 1997
® Wake et al., Annals Occup Hyg, 1997
® Balazy et al., AJIC, 2006
® Lawrence et al, JOEH, 2006
® Oberg and Brosseau, AJIC, 2008
® Grinshpun et al, JOEH, 2009