FDA Regulation of Surgical Masks and Respirators

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Presentation Topics

- Background
- 510(k) submission of surgical mask
- FDA recommendation on device reuse
- Conclusions
IOM ISSUES

- Measures that would allow cost-effective reuse of N95 respirators in healthcare settings.
- Developing cost-effective reusable face masks for the public to reduce person-to-person spread of influenza.
**REUSE**

- Reuse between patients with adequate reprocessing
  - Ex: Endoscopes

- Reuse by the same person with adequate reprocessing/decontamination
  - Ex: Contact lenses

- Repeat use by the same person over extended use time (with or without reprocessing)
  - Ex: “Reusable” Surgical masks??
    - One wearer vs. multiple wearers
    - One HCW to one pt. vs. multiple pts.
Center for Devices and Radiological Health, FDA (CDRH)

- CDRH/FDA regulates devices – including articles that are intended for use in preventing diseases.
- Most N-95 respirators are not labeled or promoted for any such use.
- If any article, including an N95 respirator, is marketed with claims for use in preventing transmission of avian flu, it falls under FDA purview.
CDRH RESPONSIBILITIES

- Evaluate and approve/clear medical devices for marketing to ensure they are **safe** and **effective**
- Inspect manufacturing facilities to ensure the quality of devices
- Take corrective actions to remove devices from commercial distribution when they are unsafe, misbranded, or adulterated
- Educate consumers
Three Regulatory Classes of Medical Devices

Class I: Low risk - General Control – 510(k) exempt (mostly)

Class II: Intermediate risk - Special & General Control – 510(k)

Class III: High risk - Premarket Approval (PMA)
GENERAL CONTROLS

- ESTABLISHMENT REGISTRATION
- UNITED STATES AGENT (*new requirement*)
- LIST DEVICE
- GOOD MANUFACTURING PRACTICES (QSR)
- PREMARKET NOTIFICATION [510(k)]
- LABELING
- MEDICAL DEVICE REPORTING
SPECIAL CONTROLS

- Regulatory performance standards
- Special labeling requirements
- Special user education and training
- Patient registries
- Postmarket surveillance
- FDA guidance documents
Benefits of FDA Regulations

- Premarket review – Ensure the device is **SAFE** and **EFFECTIVE**.
- GMP – Assure the quality of device that actually reaches users
- Good labeling, including adequate directions for use (**Important aspect for mass distribution of masks to the public during pandemic**)
Personal Protective Equipment (PPE)

- **Eye Protection**
  - goggles, face shields

- **Masks**
  - Surgical masks, N-95 respirators
  - Surgical N-95 respirators

- **Gowns**
  - surgical & isolation

- **Gloves**
  - examination & surgical
FDA PPE WEB SITES

● PPE and Avian Flu
  • www.fda.gov/cdrh/ppe/fluoutbreaks.html

● General discussion of PPE
  • www.fda.gov/cdrh/ppe/index.html
Surgical Masks

- Classified under 21 CFR 878.4040 – A general classification for apparel intended to protect both patients and persons in contact with patients from transfer of microorganisms, body fluids, and particulate materials.

- Class II devices – Subject to Premarket Notification [510(k)]
  - General Control & Special Control
Surgical Masks

- FDA 2004 Guidance document on 510(k) submissions for surgical masks, including N95 respirators, lays out recommendations for how to establish *substantial equivalence (as safe and as effective)* to existing devices (predicate devices)

http://www.fda.gov/cdrh/ode/guidance/094.html
PREMARKET NOTIFICATION 510(K)

A marketing application submitted to FDA to demonstrate that the subject device is as safe and as effective (substantially equivalent) to an existing legally marketed (predicate) device.
Surgical Masks

● Also known as:
  • Laser masks
  • Isolation masks
  • Dental masks
  • Medical procedure masks
Performance Characteristics of Surgical Masks

- Fluid resistance
  - ASTM F 1862-00a: Standard test method for resistance of surgical mask to penetration by synthetic blood

- Filtration efficiency
  - (1) Particulate filtration efficiency (PFE) – 0.1 µ polystyrene latex sphere
  - (2) Bacterial filtration efficiency (BFE) - ASTM F 2101-01: Standard test method for evaluating the bacterial filtration efficiency (BFE) of surgical mask using a biological aerosol of *Staphylococcus aureus*
Performance Characteristics of Surgical Masks (Cont’d)

- **Air exchange (differential pressure, Delta -P)**
  - Measure breathability and comfort of surgical masks

- **Flammability**
  - Class 1 and Class 2 flammability rating material for use in the operating room (O.R.)
  - Class 4 flammability rating is not appropriate for use in O.R. (Would be labeled as **NOT FOR OR USE**)

- **Biocompatibility**
In some healthcare settings, healthcare workers (HCWs) may be at risk to inhalation of droplets of TB (*M. tuberculosis*) and exposure to body fluids that may contain blood-borne pathogens.

*Surgical N-95 respirator*, which combines both NIOSH certified N-95 respirator and surgical mask in one single product, is designed for this purpose.

Require NIOSH certification as N-95 respirator and cleared through 510(k) by FDA as surgical mask.
N-95 Respirators Certified by NIOSH

- For industrial uses
  - Not considered as medical devices

- For medical uses
  - Considered as medical devices subject to FDA oversight
FDA Reprocessing Guidance


- Labeling instructions for users on how to prepare the reusable device for reuse

Reusable Device Labeling

● Labeling for a reusable device that contacts the patient must include reprocessing instructions.

● The instructions must indicate the appropriate microbicidal endpoint for the recommended reprocessing method.
  • Critical Device ---Sterilization
  • Semicritical Device ---High level disinfection
  • Noncritical Device ---Intermediate or low level disinfection

● Surgical mask and N-95 respirator may be considered “Non-Critical Device” (intact skin contact and non-sterile) for the purpose of reprocessing, especially if used by the same person.
Reusable Device Labeling (Cont’d)

- The reprocessing method must be feasible considering the intended location of reprocessing (e.g., hospital vs home use).
- Reprocessing instructions must be validated.
- After reprocessing, the device must still meet the established performance specifications of the original device, after X number of times of repeated reprocessing.
Validation

- Reusable devices requiring cleaning, disinfection, or sterilization between use must be designed in a manner that enables the necessary steps to be performed adequately.

- Manufacturers must establish that devices can be reprocessed effectively after repeated use and must establish and validate procedures for reprocessing.
Reusable Surgical Masks or N-95 Respirators

- Instructions for preparing for reuse?
  - Home vs. hospital?
  - Need autoclaving or other disinfection method to remove contaminating microorganism, including virus?
  - Would material withstand reprocessing?

- How long or how many times the mask or respirator can be “reused”?

- After reprocessing, does the mask or respirator still perform?
CONCLUSIONS

● FDA thus far has not cleared any surgical mask or respirator as “reusable” device.

● FDA is committed in working with manufacturers to develop this type of device.

● If such device is available, FDA will perform an expedited review of premarket submission to meet the public health need.