

Current Issues in the Assessment of Respiratory Protective Devices: Non - Traditional Workers and Public Use

National Academies Webinar, August 4 – 5, 2020

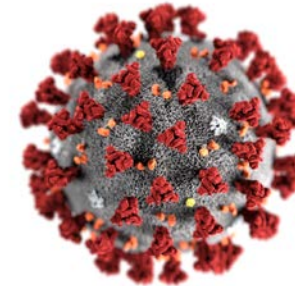
Session 4B

Assessment Pathways for Respiratory Protective Devices and Other Options for the Public (Non-Occupational Use)

“The Challenge”

Critical Questions???

- Who do we provide protection?
 - General public
 - Children
 - At risk population
- What is the hazard?
 - Chemicals
 - Air Pollution
 - Biological agents
- How will we provide protection?
 - Engineering controls
 - Administrative controls
 - Personal protective equipment (PPE)



What is a Respiratory Protective Device (RPD)?

- An RPD can be a type of PPE
- An RPD is a device that is designed to provide the wearer with a specified level of respiratory protection against a defined hazard
- RPDs can be divided into three types based on design and performance
- Respirators (recognized type of PPE)
 - NIOSH and FDA define the CA and OSHA defines the elements of the respirator program for use by management
- Masks (Can be a type of PPE)
 - FDA defines the performance of surgical and non-surgical face masks
 - Face masks for non-medical use by the general public have no FDA requirements
- Facial Coverings (Not a type of PPE)
 - A new designation currently being defined with specific performance requirements being identified and developed

Examples of RPD (All NIOSH approved half facepiece respirators)



Elastomeric half facepiece



Filtering half facepiece



Surgical N95



Elastomeric half facepiece



Filtering half facepiece



Surgical N95

Examples of Masks and Facial Coverings



Face mask, surgical (FDA)



Comfort mask



Facial covering



Face mask, non-surgical (FDA)
Procedure mask



Facial covering

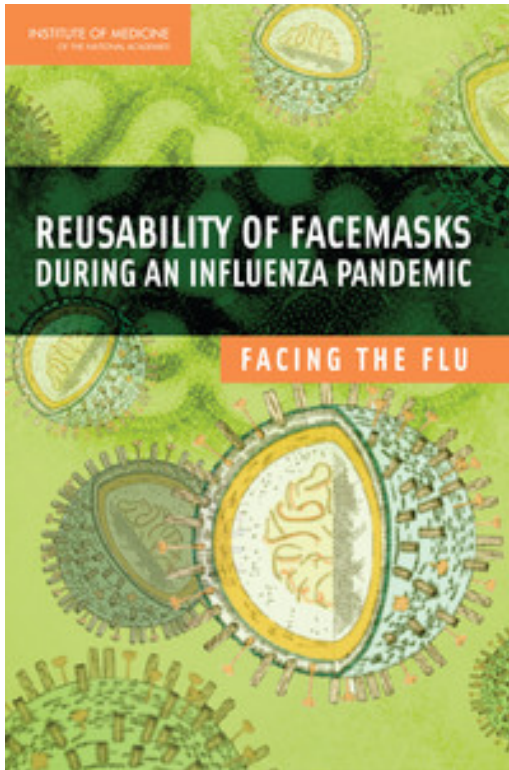


Facial covering

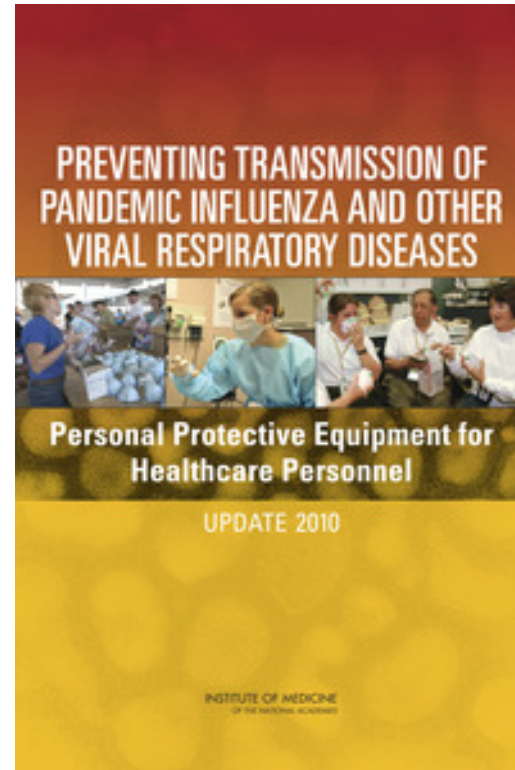
What is needed for effective RPD (facial coverings) Use by the Public ?

- Assign the responsibility for the overall program to one responsible organization with authority to delegate as appropriate
 - E.g., Government or private sector??
- Develop an education program for the general public
 - E.g., Differences between respirator, mask, and face-covering
- Evaluate, quantify, and communicate the hazards and risks clearly and accurately
 - E.g., Are droplets or particles the major COVID-19 inhalation hazard
- Develop and implement consensus standards that define the RPD performance that also include a conformity assessment program
 - Emiel DenHartog and Jon Szalajda's presentations

IOM reports provide a wealth of information on RPDs and other PPE topics



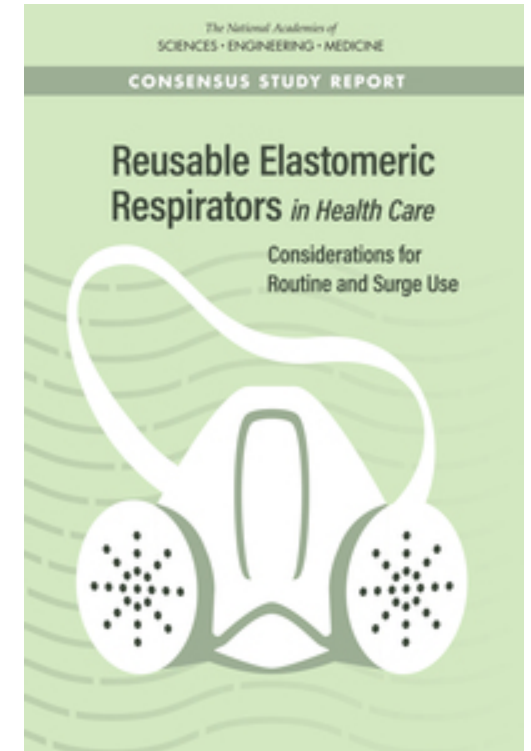
2006



2008/2010



2011



2019

IOM publication recommendations

Many of the IOM recommendations are still very relevant for today topic!

- **2006 “Reusability of Facemasks During an Influenza Pandemic”**
 - “Determine routes of transmission and risks of disease for an influenza pandemic ”
 - “Short-term research opportunities e.g.: evaluate effective use of various forms of respiratory protection including by the general public
- **2008/2010* “Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases”**
 - “Examine the effectiveness of face masks and face shields as PPE”
 - “Improve fit test methods and evaluate user seal checks”
 - “Move forward on better fitting respirators”
 - “Standards and certifications for face masks and face shields”

IOM publication recommendations (cont.)

- 2011 “Certifying Personal Protective Technologies”
 - “Develop and implement risk-based conformity assessment (CA) processes for non-respirator personal protective technologies (PPT)”
 - “Enhance research, standards development, and communication”
- 2019 “Reusable Elastomeric Respirators in Health Care”
 - Efficacy of reusable elastomeric respirators has been demonstrated
 - Routine use of elastomeric respirators could be a viable option for respirator programs for routine use in healthcare
 - Surge use of elastomeric respirators could be a viable option
 - Health care respirator needs will require the design of an innovative reusable respirators and robust respirator programs

“The Challenge”

- The development of a conformity assessment (CA) program for RPD and other PPE for civilian use needs to be assigned to one organization with authority to delegate as appropriate
- This separate or integrated CA program for RPD and other PPE used by the public should follow the successful NIOSH and OSHA model
- A major challenge is the development of systems for the identification and characterization of the hazards and quantification of the risks encountered by the public when using the RPD or other PPE