U.S. Healthcare and Elastomeric Respirators

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AOHP National Conference

Baltimore, MD

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Key Topics

I. Regulation and Approval
II. Elastomeric Half-mask Respirators (EHMR) in Context
III. EHMR to Protect Against Infectious Diseases
IV. National Academy of Medicine Consensus Report about EHMR
V. Recent Developments with EHMR at CDC/NIOSH

Requirements and Regulations

- Title 42, Code of Federal Regulations Part 84
- In U.S. workplaces requiring the use of respiratory protective devices, the Occupational Safety and Health Administration (OSHA) requires the use of respirators approved by the National Institute for Occupational Safety and Health (NIOSH)
- The National Personal Protective Technology Laboratory (NPPTL), a Division of NIOSH, tests and approves respirators
- The Food and Drug Administration (FDA) regulates medical devices
  - including N95 filtering facepiece respirators (N95) in collaboration with NIOSH

OSHA® Occupational Safety and Health Administration

National Institute for Occupational Safety and Health NIOSH

FDA U.S. FOOD & DRUG ADMINISTRATION

OSHA requires the use of NIOSH-certified respirators in U.S. workplaces requiring RPDs

NIOSH has authority to approve respirators

- *Authority rooted in creation of the Bureau of Mines, 1910*
- *Occupational Safety and Health Act of 1970*
- *FCMSHA of 1977*
- 42 CFR 84 current

federal register

Part II

Department of Health and Human Services

Department of Labor

Department of Labor

Department of Health and Human Services

Infectious Occupational Hazards in Healthcare

- Healthcare Personnel (HCP) work in unique settings where they are routinely exposed to infectious diseases (virus, bacteria, fungi)
- HCP may be at increased risk for acquiring infections, compared to the general population
  - HCP ~ 2x odds of infection with H1N1 influenza (2009 pandemic) compared to non-HCP (Lietz et al)
  - HCP 21-32x more likely to be infected with ebola in 2014-15 than general population (www.who.int)
  - HCP ~ 44% of SARS cases in 2003 in Greater Toronto Area (McDonald *et al.*)
- Respirators are an important component of infection prevention and control: to protect HCP from aerosol-transmissible infections

Respirator Recommendations, Regulation, and Policies

- The Centers for Disease Control and Prevention (CDC) recommends HCP wear respiratory protection to protect against aerosol-transmissible infections in certain settings and when performing specific tasks placing them at risk (HICPAC 2007)
- The Occupational Safety and Health Administration (OSHA) requires employers to provide respiratory protection to HCP "where respirators are necessary to protect the health of the employee." (CFR 1910.134)
- Healthcare delivery organizations' policies and practices (e.g., hospitals, clinics) from across the nation call for respiratory protection to protect HCP from exposures to aerosol-transmissible infectious diseases

NIOSH Respirator Approvals

- NIOSH approves *'individual, completely assembled respirators';* 42 CFR 84.30(a)
- NIOSH will not issue approval of *'any respirator component or any respirator subassembly;* 42 CFR 84.30(b)
- Concept makes it easy to track actual configurations and identify critical performance characteristics

OSHA Required Fit Testing Process

Medical Evaluation → Fit Testing → Education & Training

Photo courtesy of NIOSH

Example Method: PortaCount® Quantitative Fit Testing

1. Normal Breathing
2. Deep Breathing
3. Head Side-to-Side
4. Head Up and Down
5. Talking
6. Grimace
7. Bending
8. Normal Breathing

For Respirators to be Effective, They Must Fit Correctly

- OSHA requires fit testing at least annually
- Cost ~ $200,000 per year per U.S. hospital

Qualitative Fit Testing

Photos courtesy of Veterans Health Administration

Sources:
(a) Kellerman et al Infect Control Hosp Epidemiol. 1998 Sep;19(9):629-34 (2017 dollars)
(b) CFR 1910.134; Occupational Safety and Health (OSHA) Respiratory Protection Regulation

Surgical Masks

- Disposable coverings, loose-fitting that leave gaps between the mask and the wearer's face through which infectious aerosols may pass
- Intended to prevent transmission of infection *from* the wearer to others (source control)
- Not respirators
- Worn with droplet precautions (not airborne precautions)
- Regulated/cleared by FDA

Photo Courtesy of Shutterstock

Filtering Facepiece Respirators
(N95 is most common in healthcare)

- Standard N95: NIOSH-approved (Meets all requirements of 42 CFR 84 Subpart K). Designed to reduce inhalation of aerosolized particles. Fit testing is required.
- N95-F: Meets all requirements of Standard N95. Meets three additional performance requirements: 1) Biocompatibility (in vitro test, sensitivity, irritation), 2)Flammability, 3) Fluid Resistance. Fit-testing is required.
- Surgical N95: FDA-cleared as a medical device and NIOSH-approved. Designed to reduce inhalation of aerosolized particles. Fit testing is required.
  N95-F replaces this designation as of August 2018.
- Most N95s are disposable (single-use) and not designed for repeated or extended use.
  - However, limited reuse may be permitted under certain circumstances (e.g., extreme shortages during a pandemic)
  - EHMRs and PAPRs are designed for reuse

Photo Courtesy of 3M

Powered Air-Purifying Respirators (PAPRs)

- Reusable respirators that are typically loose-fitting, tight-fitting, hooded or helmeted
- Equipped with a battery-powered blower to force air through a particle filter for the wearer to breathe
- Capable of reducing airborne exposures at efficiencies that typically exceed the N95 and EHMR, using a high-efficiency particulate air (HEPA) filter
- NIOSH approved

Photo Courtesy of MaxAir

Photo Courtesy of North

Elastomeric Half-mask Respirators (EHMRs)

- Half-mask, tight-fitting respirators that are made of synthetic or rubber material permitting them to be repeatedly disinfected, cleaned, and re-donned
  - Equipped with exchangeable filter cartridges
  - May have disposable components
- NIOSH-approved
- OSHA assigned protection classification (APF) same as N95s

Photo Courtesy of MSA

Closing the national respirator gap with EHMRs: Why we need EHMRs during a Surge of Infectious Patients

- Nationwide projected N95 need for 1918-like influenza pandemic: 1.7 – 7.3 billion
  - Approximate cost to purchase: $1-5 billion every several years (shelf life ~ 5 years)
  - Approximate cost to store annually: $100 million (Veterans Health Administration)
- Gap in national surge needs:
  - ASTHO Report (2014): Total number of N95 held by U.S. acute care hospitals ≈ 60M
  - This means, hospitals have about 1% of expected national demand for a severe pandemic
- Shortages of N95 respirators occurred during SARS (2003) and H1N1 influenza (2009)
- Shortages pose substantial operational and policy challenges during public health emergencies
  - Approximate percentage of U.S. HCPs willing to work during moderate-severe influenza pandemic: 80%
  - Percentage of U.S. HCPs willing to work during a moderate-severe influenza pandemic in midst of a widespread respirator shortage: unknown
  - Recent studies: HCP willingness to work during a pandemic increases when their organizations have mature respiratory protection programs and adequate numbers of respirators in supply

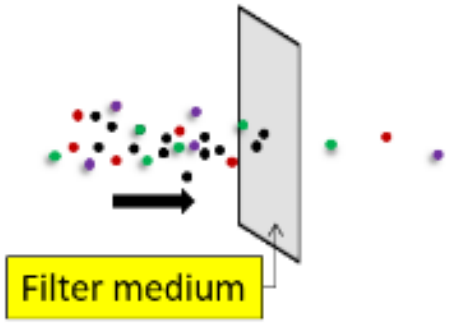
Using EHMRs during an Emergency

- During public health emergencies, healthcare systems may need EHMRs temporarily to fill a surge gap
- Rapidly fit-testing and training HCP may be necessary
- Validated methods to rapidly achieve fit and training have not been described
- NIOSH is engaged in efforts to fit, train and educate HCP to use EHMRs during a public health emergency

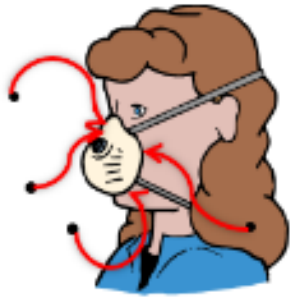
Assigned Protection Factor

- Established by OSHA
- A major difference between SMs and respirators
- The standard N95 and the N95-F/surgical N95 are assigned an APF of 10, meaning the N95 reduces the aerosol concentration by a factor of 10 (one-tenth the number of particles inside compared to outside the N95)

Filter penetration



Face seal leakage



Respirator	SM	N95	EHMR	PAPR
APF	N/A	10	10	25-1000

EHMRs: Examples

Photo courtesy of Gershon

Photo courtesy of JSP

Photo courtesy of Honeywell

Photo courtesy of Moldex

Photo courtesy of Moldex

Photo courtesy of SAS

Photo courtesy of North

Photo courtesy of Gershon

Elastomeric Half-mask Respirators

- Most equipped with removable filter(s)

Photo Courtesy of SEA

Photo Courtesy of North

Elastomeric Half-mask Respirators (EHMRs)

- May have
  - Cartridge cover

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)

- May have a pre-filter

  (large particulates)

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)

- Particulate filter

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)

- May have a charcoal filter

  (Chemicals/gasses)

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)

- May have an exhalation valve

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)

- Facepiece

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)

- Head harness

Photo Courtesy of SEA

Elastomeric Half-mask Respirators (EHMRs)
Hybrid/combination models

Combination EHMR and PAPR

Photo Courtesy of Draeger

Combination EHMR and Filtering Facepiece

Photo Courtesy of North

Elastomeric Full-Facepiece Respirators

- Equipped with a clear lens that covers the eyes, nose and mouth
- Rarely used for infection prevention in civilian sector, including healthcare

Photo Courtesy of North

Photo Courtesy of Draeger

Key Benefits of EHMRs

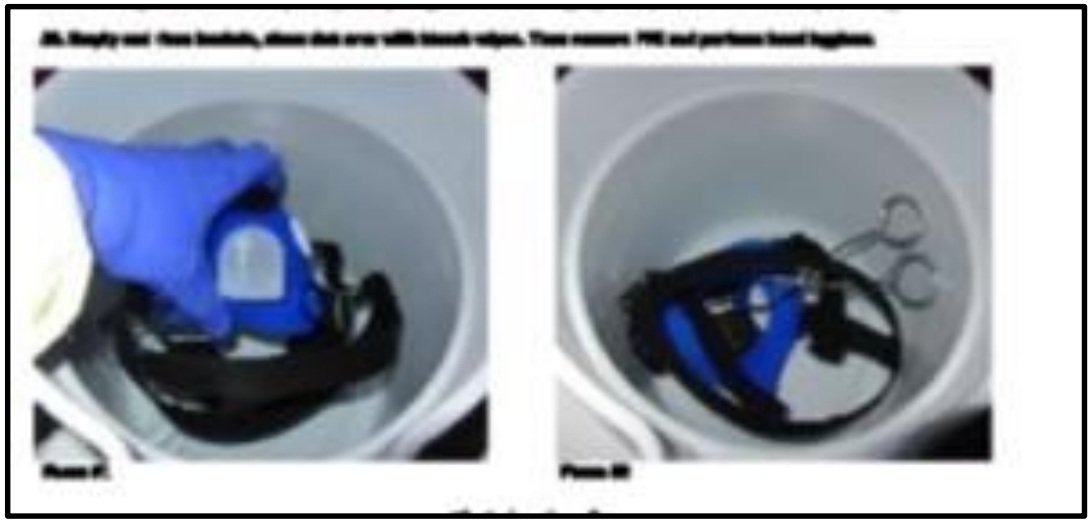
- Reusable
- One EHMR assigned to each worker
- Potential cost savings
- Close the national RPD surge gap

Photo Courtesy of Shutterstock

Photo Courtesy of Gerson

Benefit: Reusability

- Can be reused after
  - Disinfection
  - Cleaning
- Durable
  - Maintain fit over time
  - Stand up to repeated manipulation and storage between uses



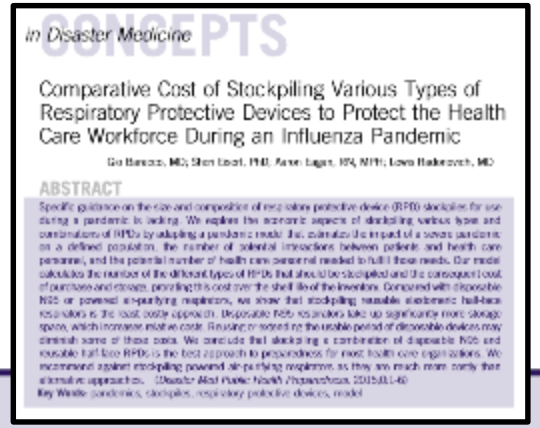
Adapted from Bessesen *et al.* (2015)

Benefit: one per worker

- Each worker is assigned his/her own device
- Name or ID number may be applied

Photo Courtesy of Texas Center for Infectious Diseases

Benefit: potential cost savings


in Disaster Medicine

Comparative Cost of Stockpiling Various Types of Respiratory Protective Devices to Protect the Health Care Workforce During an Influenza Pandemic

ABSTRACT

TABLE 4

Annual RPD[a] Pandemic Stockpiling Costs for a Population of 1 Million, per Strategy

	N95[b] Single Use[c]	Elastomeric[d]	PAPR[e]	Mixed[f] Single Use	Extended Use[g] N95	Extended Use[g] Mixed
Number of RPDs	6 112 500	10 612	2653	N95: 2 791 500 Elastomeric: 5766	1 222 500	N95: 558 300 Elastomeric 5766
RPD acquisition cost, per year (thousand US$)	306–800	69–122	17 889–18,048	177–429	61–159	65–139
Warehouse[h] and management[i] cost, per year (thousand US$)	207	5	455	97	42	22
Annual cost of RPD stockpile (thousand US$)	512–1001	74–127	18 343–18,502	274–526	87–160	103–201

Baracco *et al.* (2015)

Benefit: closing the gap

EHMRs during a Surge of Infectious Patients

- Nationwide projected N95 need for 1918-like influenza pandemic: 1.7 – 7.3 billion
- ASTHO Report (2014): Total number of N95 held by U.S. acute care hospitals ≈ 60M
- Shortages of N95 respirators occurred during SARS (2003) and H1N1 influenza (2009)

Key Challenges with EHMRs

- Lack of familiarity/experience among healthcare and first responders/receivers
- Interference with duties
- Carried by healthcare personnel during workday
- Storage between work shifts
- Disinfection/cleaning process
- Fit testing is required

Challenge: Lack of Familiarity and Experience

- EHMRs are rarely used in U.S. health care delivery
- Two known U.S. healthcare systems using EHMRs for patient care
  - Texas Center for Infectious Diseases (TB-only facility)
  - University of Maryland, Baltimore
- Used by maintenance workers in healthcare organizations

ARTICLE IN PRESS

American Journal of Infection Control ■■ (2017) ■■-■■

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journal homepage: www.ajicjournal.org

Brief Report

Evaluation of 9 health care organizations' respiratory protection programs and respiratory protective device practices: Implications for adoption of elastomerics

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[c] PCIH, Emerald Isle, NC

Challenge: interference with duties

- Speech intelligibility: ~10% decrease

TABLE III. Speech Intelligibility Associated with Half-Face Elastomeric Respirators Equipped with and without Speech Augmentation Devices

Manufacturer	Model	Filter Type	Filter Model	Voice Augmentation Device	MRT % Mean [SD] 3 ft	MRT % Mean [SD] 7 ft	MRT % Mean [SD] 3 and 7 ft
Control (none)	N/A	N/A	N/A	N/A	98 [2.4]	97 [2.2]	97 [2.3]
Scott	Xcel	P100	7422-FP2	Mechanical vibration membrane	91 [5.2]	89 [4.4]	90 [4.9][a]
Sundström	SR100	P100	SR510	Electronic voice amplifier	87 [6.2]	91 [5.5]	89 [6.0][a]
Survivair	Blue1	P100	1050	Mechanical vibration membrane	90 [4.7]	88 [5.8]	89 [5.3][a]
North	5500	P100	7580P100	None	88 [4.6]	86 [4.1]	87 [4.5][a]
3M	7500	P100	7093	None	86 [6.8]	87 [7.1]	86 [6.9][a]
Survivair	2000	P100	1050	Computer-aided acoustical design	83 [8.5]	85 [5.2]	84 [7.0][a]

Radonovich *et al.* (2009)

Challenge: interference with duties

- Downward visual gaze

Photo courtesy of MSA

Resuscitation (2007) 74, 310–316

ELSEVIER

RESUSCITATION

www.elsevier.com/locate/resuscitation

MANIKIN AND SIMULATION PAPER

Influence of air-purifying respirators on the simulated first response emergency treatment of CBRN victims☆

Andrea Brinker[a], Stuart A. Gray[b], Jan Schumacher[c,*]

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[c] Department of Anaesthetics, Guy's, King's and St Thomas' School of Medicine, St Thomas' Campus, King's College, London, UK

Challenge: carried from room to room

- During work shift, typically carried in belt pack (fanny pack) or satchel with shoulder harness
  - Ideally rigid to protect device from damage
- Sometimes stored temporarily at nurses station, personal locker, or utility cart
- Typically do not fit in coat pockets
- Generally viewed as a nuisance

Photo Courtesy of Texas Center for Infectious Diseases

Challenge: storage

- Must be stored between work shifts
- Typically stored in personal locker
  - Sometimes in utility room(s)
  - Sometimes taken home (unpublished data)
- Long-term storage/stockpiling
  - Some materials, such as rubber, may become brittle or degrade if stored for 12+ months and may need to be replaced
  - Replacement parts necessary for on-site for emergency and routine maintenance
  - All components must be NIOSH approved for use with respirator

Challenge: Fit-testing

- Fit-testing required with EHMRs

Photos courtesy of Veterans Health Administration

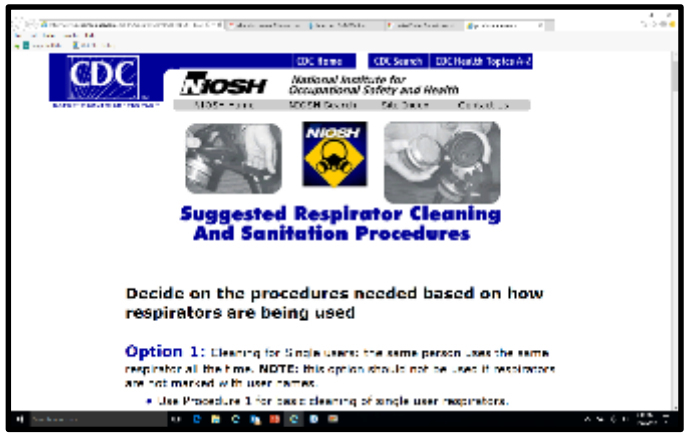
- Fit-testing not required with loose fitting PAPRs

Photo Courtesy of North

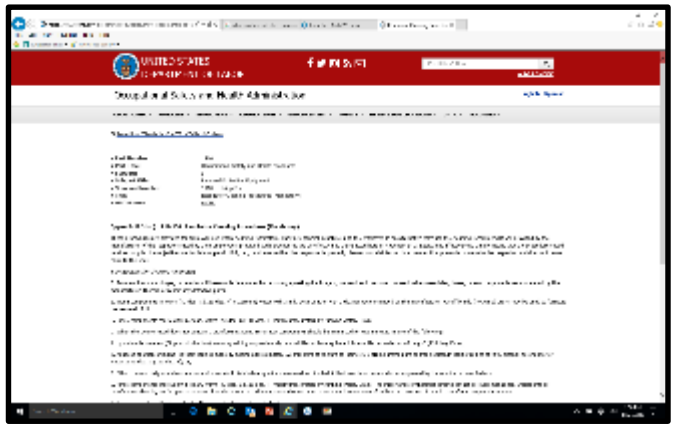
Challenge: Disinfection and Cleaning Required

- Terminology
  - Disinfection: destroying, inactivating, or removing potentially infectious microorganisms
  - Cleaning: removing non-infectious dirt or debris
- Sources of Information and Recommendations
  - Manufacturers' instructions
  - Healthcare Infection Control Practices Advisory Committee (HICPAC)
  - CDC/NIOSH
  - OSHA
  - Peer-reviewed publications

Bessesen *et al.* (2015)



NIOSH.gov



OSHA.gov

Challenge: Disinfection and Cleaning of EHMRs

- Disinfection and cleaning issues under study and discussion
  - Disinfectant materials
  - Cleaning materials
  - Frequency (e.g., end of work shift, between uses, between patient interactions)
  - Location (e.g., central processing, dirty utility room)
  - Avoidance of self-contamination
  - Duration of filter cartridge use
  - Duration of exposed filter use
  - Education and training for wearers

Challenge: disinfection

- Applied Research Associates (Panama City, Florida) studied the effectiveness of manual cleaning and disinfecting procedures for five EHMRs and three PAPRs in lab setting
- Respirators were contaminated with influenza virus and soiling agents (artificial skin oil, artificial saliva) on multiple surfaces (facemask, straps, etc.)
- Contaminated respirators were treated with one of two methods:
  - Cleaned (neutral detergent only)
  - Cleaned and disinfected (neutral detergent and disinfectant)
- On average, a 4.5-log reduction was observed across all 41 surfaces tested
- Cleaning alone was found to be sufficient for removing/killing influenza (Lawrence, *et al.*)

Challenge: Disinfection

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JULY 2014, VOL. 35, NO. 7

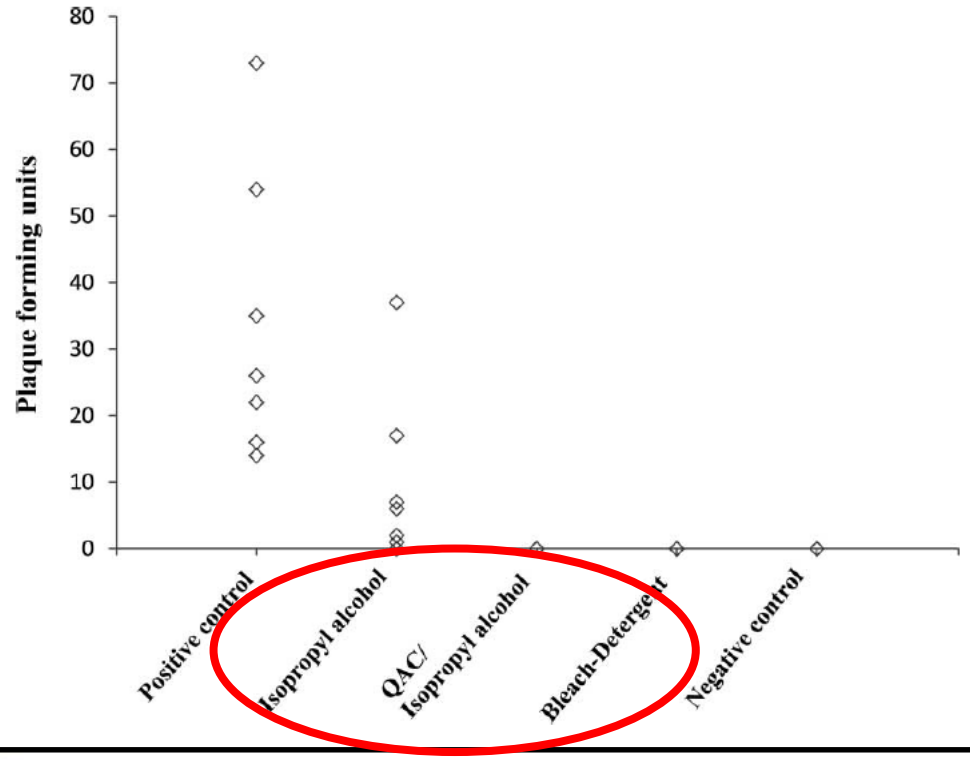
CONCISE COMMUNICATION

Effectiveness of Common Healthcare Disinfectants against H1N1 Influenza Virus on Reusable Elastomeric Respirators

Shobha S. Subhash, MS, MPH;[1] Maria Cavaiuolo;[2] Lewis J. Radonovich Jr, MD;[1,3] Aaron Eagan, RN, BSN;[1] Martin L. Lee, PhD;[4] Sheldon Campbell, MD, PhD;[2,5] Richard A. Martinello, MD[6,7]

This study evaluated the efficacy of 3 common hospital disinfectan
to inactivate influenza virus on elastomeric respirators. Quaterna
ammonium/isopropyl alcohol and bleach detergent wipes eliminat
live virus, whereas 70% isopropyl alcohol alone was ineffective.

Infect Control Hosp Epidemiol 2014;35(7):894-8



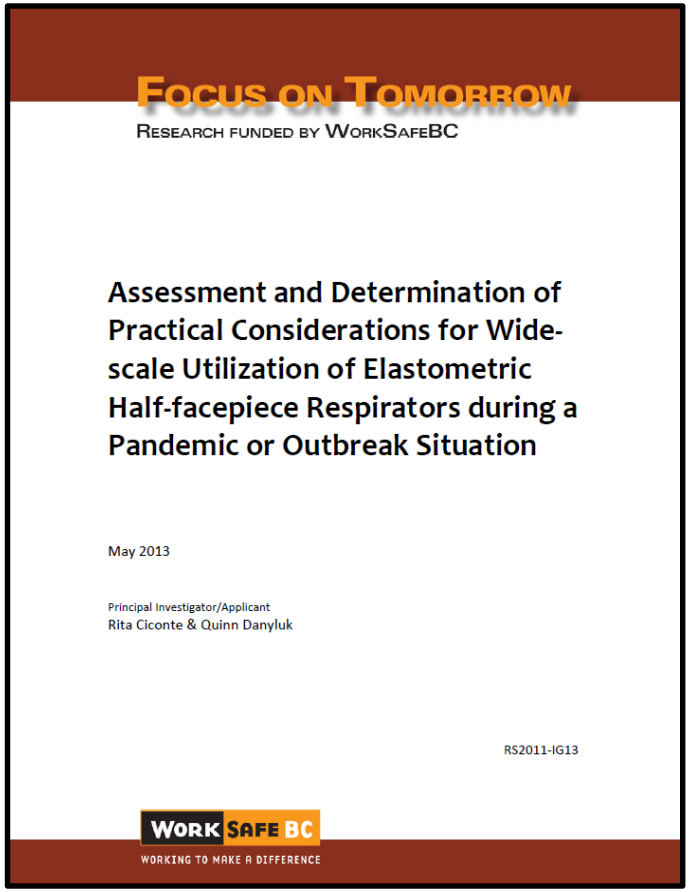
- Best method to disinfect is unclear

Contemporary Practices: Disinfection and Cleaning

- Cleaning and Disinfection Frequency
  - "Follow manufacturer recommendations"
  - Some manufacturers recommend wiping with disinfectant impregnated swab (e.g., alcohol) after each patient exposure; others lump disinfection and cleaning in fashion not directly translatable to clinical healthcare setting
  - Complete cleaning after each shift (immersion in cleaning solution)
  - Frequency of filter change
    - Industrial norm is when filters become clogged (breathing becomes difficult). Some industrial customers change filters daily.
    - In health care, may not need to change unless visibly soiled because typical particulate load is low
  - Methods
    - Industrial washers are available
    - On-site or with off-site contractor
    - Not all materials used in facepieces can withstand autoclave process

British Columbia Study, 2013

- Speech intelligibility was 7% lower with EHMRs compared to N95s
- Challenges with identifying storage space
- Challenges with cleaning at end of work shifts
- Disinfection using central processing proved challenging and took longer than expected



FOCUS ON TOMORROW

RESEARCH FUNDED BY WORKSAFEBC

Assessment and Determination of Practical Considerations for Wide-scale Utilization of Elastometric Half-facepiece Respirators during a Pandemic or Outbreak Situation

May 2013

Principal Investigator/Applicant
Rita Ciconte & Quinn Danyluk

RS2011-IG13

WORK SAFE BC
WORKING TO MAKE A DIFFERENCE

Key Questions being Posed by NIOSH

(1) In what U.S. workplaces have elastomerics been used successfully?

(2) Are elastomerics viable for wider or more routine use in U.S. healthcare, and if yes, in what settings?

(3) To what extent does the respirator's appearance affect acceptance in in U.S. healthcare?

(4) What is the feasibility of U.S. healthcare institutions converting from N95 to elastomeric use if N95 shortages occur (“just-in-time” conversion)?

Photo Courtesy of Scott Safety

Photo Courtesy of North

Conclusions Reached by the NAM Consensus Study (2018)

- ***Conclusion 1: Efficacy of Reusable Elastomeric Respirators.*** *"…*research studies in controlled laboratory settings have demonstrated the efficacy of reusable elastomeric respirators."
- ***Conclusion 2: Routine Use of Elastomeric Respirators.*** "…reusable elastomeric respirators could be a viable option for respiratory protection programs for routine use in health care when logistic and implementation challenges are addressed…".
- ***Conclusion 3: Surge Use of Elastomeric Respirators.*** *"…*reusable elastomeric respirators could be a viable option for use as needed in surge situations…when logistic and implementation challenges are addressed…".
- ***Conclusion 4: Health Care Needs Regarding Respirator Protection.*** "…addressing the respiratory health needs of health care workers…will require the design of innovative reusable respirators and the implementation of robust respiratory protection programs…".
- ***Conclusion 5: Implementation Gaps.*** *"…*urgent action is needed to resolve gaps in knowledge and leadership on reusable respiratory protection in order to protect the health and safety of health care workers, particularly in an influenza pandemic or an epidemic of an airborne transmissible disease…".

Nascent NIOSH/CDC Elastomeric Projects

- Demonstration project to understand just-in-time use in U.S. Healthcare
  - Timeline: Ongoing
- Head-to-head comparison of disinfection methods in clinical setting
  - ~ Timeline: October 2019 – December 2020
- Demonstration projects to understand feasibility for routine use in selected clinical settings
  - ~ Timeline: October 2020 – December 2021

Key Points about Respiratory Protection

- N95s, EHMRs, and PAPRs do not provide absolute respiratory protection; they all are designed to reduce exposure, but not eliminate exposure
- Respirators must be correctly worn to be effective
- OSHA requires initial (pre-employment) and annual fit-testing with N95s and EHMRs
- Correct donning, wearing, and doffing procedures are important to achieve suitable protection and avoid self-contamination
- U.S. workforce, including health care, has limited experience with EHMRs for protection against infectious aerosols
- EHMRs may be a practical option for use in selected healthcare settings, although further study and discussion are necessary

Disclaimer

The findings and conclusions in this presentation are the authors' own and do not necessarily represent the views of the National Institute for Occupational Safety and Health, the the Centers for Disease Control and Prevention, or other affiliates. Mention of product names does not imply endorsement.

Additional Reference Slides

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Additional Resources

Additional Resources

- https://www.cdc.gov/niosh/docs/2015-117/default.html
- https://www.cdc.gov/niosh/docs/wp-solutions/2016-109/default.html
- https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/
- https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html