Risk Assessment and Biosafety Support for SARS-CoV-2 and COVID-19 Research: Challenges in established ABSL-2 and ABSL-3 research programs

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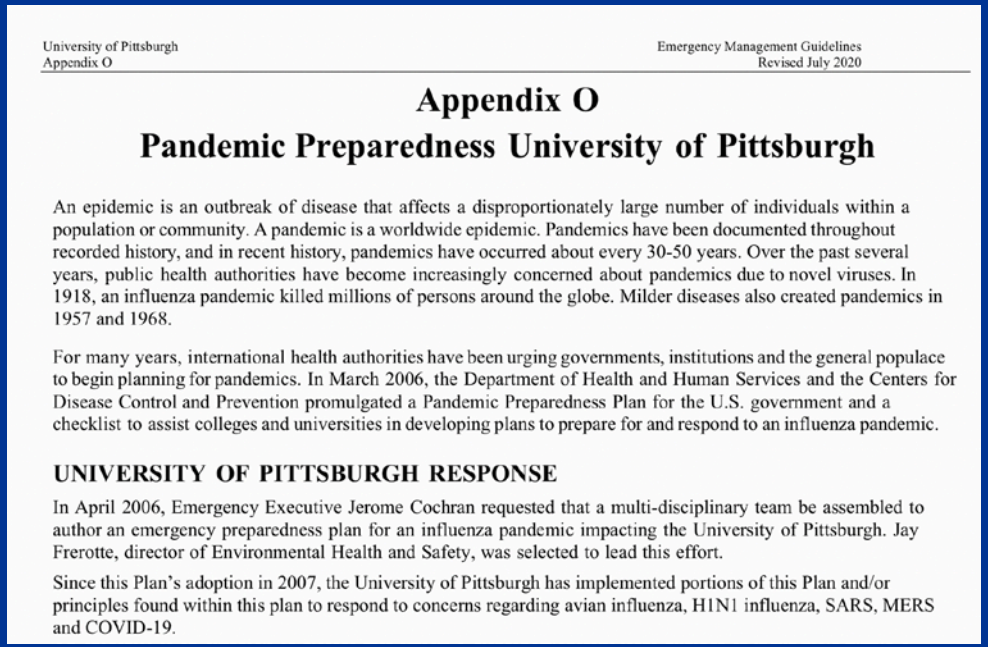
Pitt had a plan and expertise in place

Emergency Management Guidelines



Appendix O
Pandemic Preparedness University of Pittsburgh

An epidemic is an outbreak of disease that affects a disproportionately large number of individuals within a population or community. A pandemic is a worldwide epidemic. Pandemics have been documented throughout recorded history, and in recent history, pandemics have occurred about every 30-50 years. Over the past several years, public health authorities have become increasingly concerned about pandemics due to novel viruses. In 1918, an influenza pandemic killed millions of persons around the globe. Milder diseases also created pandemics in 1957 and 1968.

For many years, international health authorities have been urging governments, institutions and the general populace to begin planning for pandemics. In March 2006, the Department of Health and Human Services and the Centers for Disease Control and Prevention promulgated a Pandemic Preparedness Plan for the U.S. government and a checklist to assist colleges and universities in developing plans to prepare for and respond to an influenza pandemic.

UNIVERSITY OF PITTSBURGH RESPONSE

In April 2006, Emergency Executive Jerome Cochran requested that a multi-disciplinary team be assembled to author an emergency preparedness plan for an influenza pandemic impacting the University of Pittsburgh. Jay Frerotte, director of Environmental Health and Safety, was selected to lead this effort.

Since this Plan's adoption in 2007, the University of Pittsburgh has implemented portions of this Plan and/or principles found within this plan to respond to concerns regarding avian influenza, H1N1 influenza, SARS, MERS and COVID-19.

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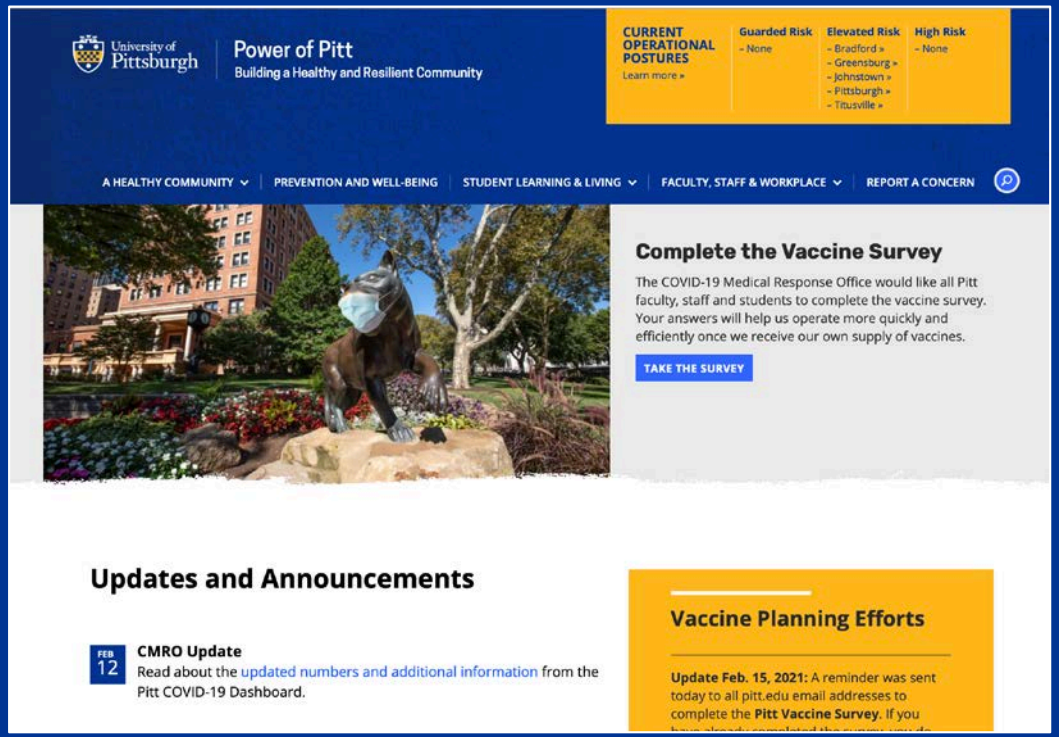
Activated Late January 2020

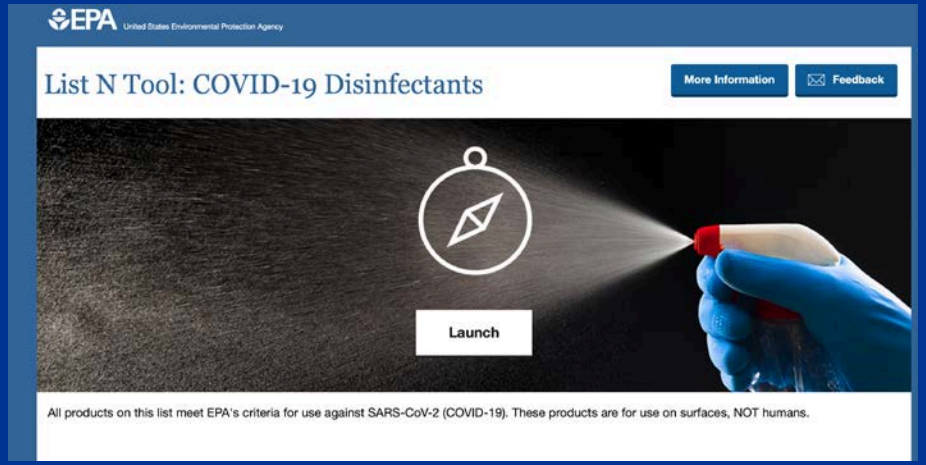
University Emergency Operations Center



- Eliminate silos
  - Unified support for recommendations with broad impact
  - Complex guidelines and recommendations in a rapidly evolving situation

University Emergency Operations Center

- New connections and resources identified to improve post-pandemic operations
  - Leveraging institutional purchasing power
    - Seek expert review before purchasing disinfectants and PPE



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Developing Response Guidelines: Room decontamination

Who was on the team?

- Facilities management
- Animal care and IACUC
- EH&S
- Student affairs
- Custodial staff

How do we shutdown and decon rooms occupied by COVID-19 positive individuals?

- Procedures for reporting illness and symptomatic person on campus
- Link from occupational health clinic to FM = EH&S
  - Situation-specific risk assessment with stakeholders

Developing Response Guidelines: Room decontamination

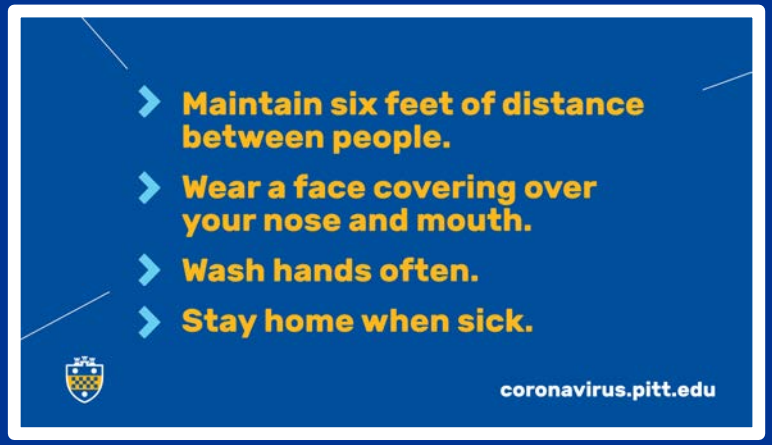
Preplanning continued:

- Campus-wide HVAC assessment
- Purchase of room decontamination equipment and training of personnel

What did we learn during first few risk assessments?

- Most often notified of symptomatic individual more than 12 hours past last time on campus
  - Enhanced disinfection of all high touch surfaces University-wide
  - In areas with high air change rates (e.g. animal facilities, labs) risk of persistent aerosols is reduced

Developing Response Guidelines: Room decontamination



For majority of animal facility scenarios:

- Confirmed increased disinfection, conformance with mitigation, high air exchange rate
- In most cases no room shutdown or full decon recommended

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Developing Response Guidelines: Room decontamination

- Just to be clear: Risk assessment for non-laboratory areas, classrooms, on-campus student housing led to different result
  - On-campus student housing, isolation, and quarantine facilities
    - Room shutdown for 72 hours (preferred) followed by room decon
  - In-person EH&S support for new decon team increased personnel confidence
    - Addressing concerns and answering questions
    - Advice for donning/doffing PPE, waste handling in actual decon scenario

University Emergency Operations Center

- Communications personnel embedded in EOC = consistent, coordinated messaging

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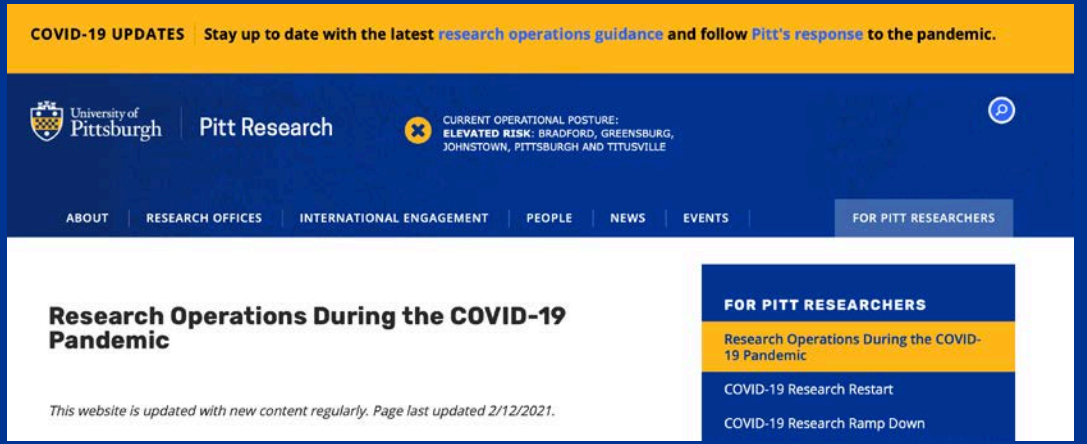
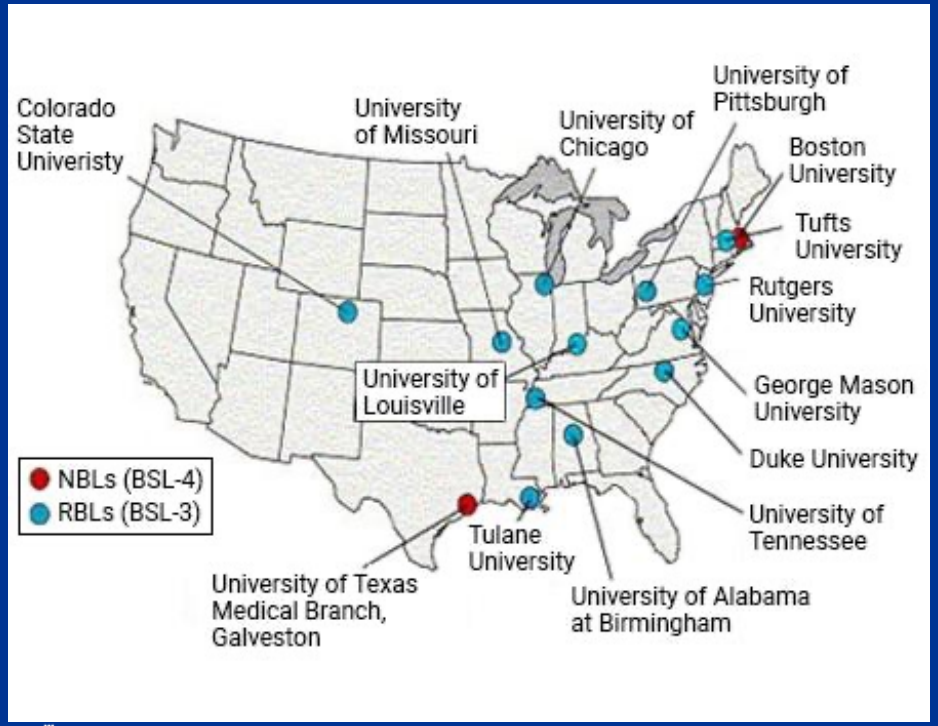
Gearing up for COVID-19 Research

SARS-CoV-2 in established BSL-3/ABSL-3 program



COVID-19 research across University

NBL/RBL Network: Responsibility to the community



- NIAID-funded Regional Biocontainment Lab (RBL)
  - Fully commissioned and operational since 2009
  - Available and prepared to assist national, state, and local public health efforts in event in emergencies

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Gearing up for SARS-CoV-2 Studies

- Each RBL has a slightly different research focus supported by specialized resources
  - Infectious disease research in small animals and non-human primates
  - RBL program elements have been leveraged across University research operations

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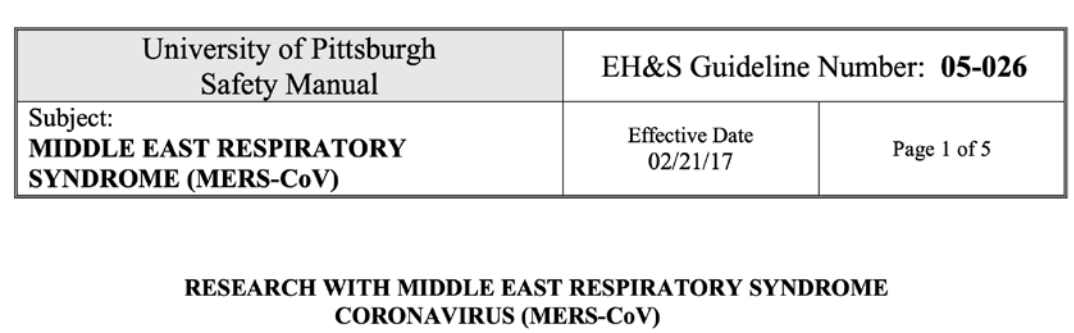
Gearing up for SARS-CoV-2 Studies

- Don’t reinvent the wheel:
  - RBL = integrated team
  - Established biosafety program
  - Robust occupational health and incident response procedures



University of Pittsburgh Safety Manual	EH&S Guideline Number: **05-026**	
Subject: **MIDDLE EAST RESPIRATORY SYNDROME (MERS-CoV)**	Effective Date 02/21/17	Page 1 of 5

RESEARCH WITH MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS (MERS-CoV)

  - Communication is crucial

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Unexpected Challenges: New Models

- New animal models: Syrian golden hamsters
  - Few personnel with experience handling hamsters
  - Preparatory training at BSL-2
  - Observations of handling techniques in uninfected hamsters at ABSL-3

Unexpected Opportunities: Communication with Community

- Emergency responders and community voiced concerns regarding safe transport and research with SARS-CoV-2 virus

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COVID-19 Research Beyond the RBL:

- While ramping down non-essential research, influx of COVID-19 related essential research
  - Vaccines and countermeasures
  - Surveillance, pathogenesis, mechanisms of disease
  - Clinical trials of new treatment modalities and vaccine candidates
  - New technology – exposure chambers

- February 2020 – June 2020
  - 219 new COVID-19-related research applications

COVID-19 Research Beyond the RBL

- How can we support training and safety practices during a posture allowing essential research only?
  - Reduced personnel availability
  - Existing personnel absorb new pandemic response duties
  - New research groups with variety of experience levels

COVID-19 Research Beyond the RBL: Unexpected Challenges

- Is research classified as essential under state and local stay-at-home orders?
  - Yes, for Pitt. Your specific situation may vary.
  - What if I get stopped on my way to/from work and asked why I'm traveling during stay-at-home order?
    - EOC and HR – authority to travel

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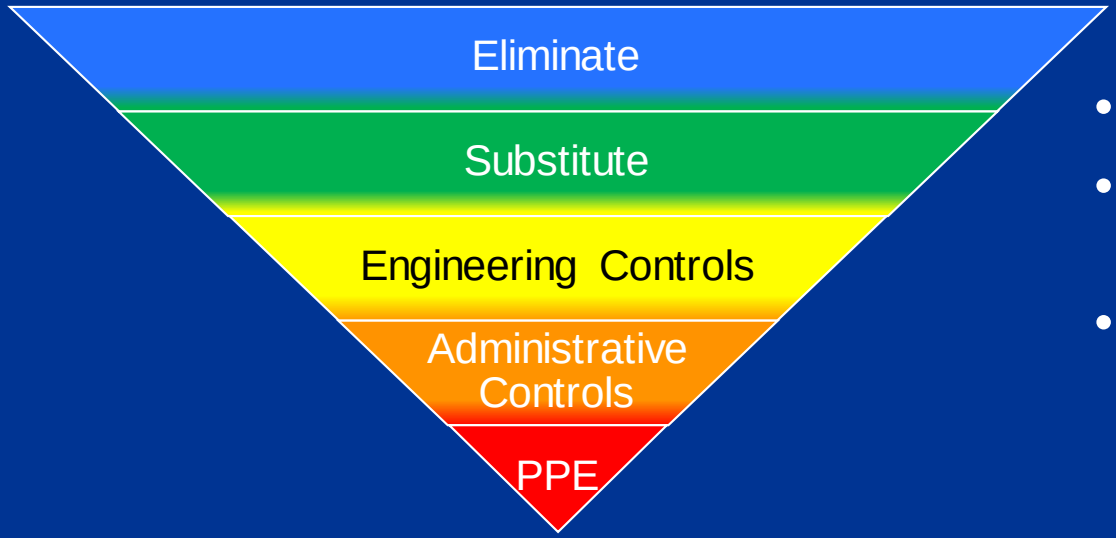
COVID-19 Research Beyond the RBL: Unexpected Challenges

- Modified EH&S programs
  - Risk-based use of in person visits to assess laboratory set up and work practices
    - Self-inspection and targeted review for experienced PIs
    - In person inspection, SOP review and training prioritized for less experienced groups
  - Minimize on-site visits – self-inspection checklist:
    - Project description
    - Lab specific plan for key COVID-19-specific biosafety recommendations
    - Training attestation

Risk Assessments – A Disclaimer

- Risk assessments are complex and should be viewed with an eye toward continual reevaluation and improvement
  - Highlight selected high-impact considerations in Pitt's ongoing risk management
- Concrete examples can be helpful to serve as framework to think about questions at your entity
  - In no way meant to substitute for full discussion and assessment with your entities' stakeholders

Risk Assessments – The basics still apply



- Start with what we already know
- As new information emerges, do a reassessment
- Think outside the box

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PPE Risk Assessment in Animal Spaces

- Be aware of the decision-making process and assumptions made during pre-pandemic risk assessments.
  - PPE set by regulation or guidelines
    - OSHA, CDC, NRC, Professional/Industry standards
  - Infectious agent/allergen
  - Species
  - Housing type
  - Facility design
  - Project-specific hazards

PPE Risk Assessment in Animal Spaces

COVID-19 brought both additional human hazards and additional animal health status (biosecurity) concerns to animal colony management:

- Zoonotic disease and potential for caretaker to animal transmission in sensitive species.
  - Ferrets, cats, bats
- Continuity planning relies upon data
  - PPE supplies on hand and burn rate
  - Predicted supplies going forward

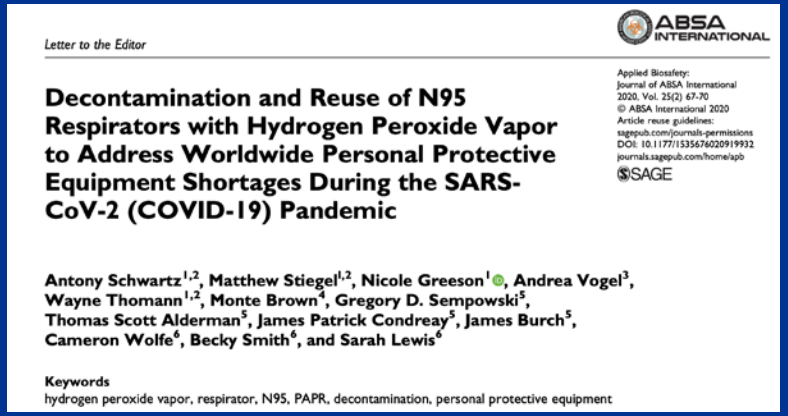
Strategies for optimizing PPE during shortages

- Evaluate the types of PPE you choose for normal operations and consider
  - Prioritizing/redirecting
  - Disposable vs. Reusable

Strategies for optimizing N95 respirators

Limited reuse of N95 respirators

- Reuse of N95 (re-donning)
- Decontamination
  - VHP
  - Cycling masks
  - Other methods
- Expired but intact



Letter to the Editor

ABSA INTERNATIONAL

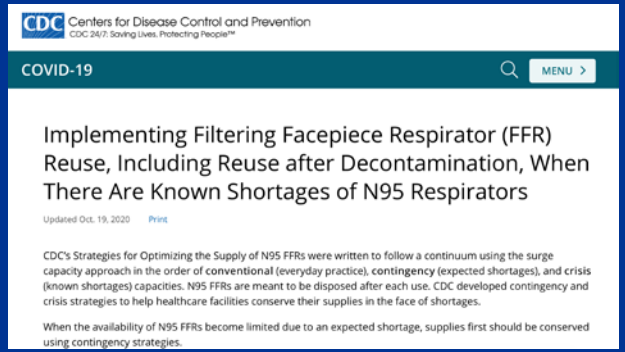
Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor to Address Worldwide Personal Protective Equipment Shortages During the SARS-CoV-2 (COVID-19) Pandemic

Applied Biosafety:
Journal of ABSA International
2020, Vol. 25(2) 67-70

DOI: 10.1177/1535676020919932
journals.sagepub.com/home/apb
SAGE

Antony Schwartz[1,2], Matthew Stiegel[1,2], Nicole Greeson[1], Andrea Vogel[3], Wayne Thomann[1,2], Monte Brown[4], Gregory D. Sempowski[5], Thomas Scott Alderman[5], James Patrick Condreay[5], James Burch[5], Cameron Wolfe[6], Becky Smith[6], and Sarah Lewis[6]

Keywords
hydrogen peroxide vapor, respirator, N95, PAPR, decontamination, personal protective equipment



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

COVID-19 MENU

Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators

Updated Oct. 19, 2020 Print

CDC's Strategies for Optimizing the Supply of N95 FFRs were written to follow a continuum using the surge capacity approach in the order of **conventional** (everyday practice), **contingency** (expected shortages), and **crisis** (known shortages) capacities. N95 FFRs are meant to be disposed after each use. CDC developed contingency and crisis strategies to help healthcare facilities conserve their supplies in the face of shortages.

When the availability of N95 FFRs become limited due to an expected shortage, supplies first should be conserved using contingency strategies.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

PPE Supply Logistics

Availability of N95 in marketplace

- Price control and Rationing
  - Prices of N95s soared 500 to 600%
  - Prioritizing supplies
  - Approving KN95 and overseas vendors
- Inconsistent quality and counterfeit N95s

Resources: NBL/RBL Network

- COVID-19 has highlighted the benefits of investments in emerging infectious disease and vaccine development research
- NBLs and RBLs are a national resource
  - Research and collaboration for entities that need high and maximum containment expertise
  - Valuable lessons learned

Resources needed

- RBLs all constructed and commissioned on similar timelines

- Operational funding for critical infrastructure maintenance/replacement is needed to preserve this critical research and response capability

Resources needed

- Funding and support to train the next generations of public health professionals and local emergency responders
  - Biosafety and biosecurity training programs for high and maximum containment research strengthen culture of research safety and public health preparedness
  - Universities can, and should, be a community resource
    - Even with a well-established and high-functioning county health department, resources quickly became overwhelmed

Resources needed

- Maintain investments in surveillance, data collection, and lines of communication
- Link local public health and emergency responders to national preparedness and response resources
  - Some institutions had preparedness stockpiles, but these were rapidly depleted
  - Include suppliers and manufacturers of critical response resources in the training and exercise framework

Thank You!
And thanks to everyone at Pitt who continues to contribute to our health and safety programs.

Jay Frerotte
Assistant Vice Chancellor and Director, EH&S

Dr. Joseph Newsome
Associate Director DLAR and Associate Professor of Pathology

Dr. Paul Duprex
CVR Director and Jonas Salk Chair of Vaccine Research

References and additional resources

- Solid Waste Association of North America (https://swana.org/initiatives/guidance-on-coronavirus-(covid-19))
- International Sanitary Supply Association (https://www.issa.com/cleaning-and-disinfecting-for-the-coronavirus-sars-cov-2)
- American Dental Association (ADA.org)
- CDC/NIOSH Reuse and Decontamination of N95s Guidelines (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html)
- FDA EUA Expired N95s (https://www.fda.gov/media/135763/download)
- FDA PPE EUA list (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas)

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