The National Academies of SCIENCES ENGINEERING MEDICINE

Advances in Personal Protective Equipment

The Role of Independent Expert Guidance and Scientific Input for NIOSH/NPPTL

FROM THE NATIONAL ACADEMIES
Committee on Personal Protective Equipment
for Workplace Safety and Health

CONTENTS

FOREWORD FROM THE COMMITTEE CHAIR

Over its 15 years of existence, the Standing Committee on Personal Protective Equipment for Workplace Safety and Health (COPPE) has been tasked to consider both legacy safety and health threats and novel viral infectious disease challenges to workers and the wider public's health. The committee's input and deliberations have provided scientific guidance in support of the National Institute for Occupational Safety and Health's (NIOSH's) National Personal Protective Technology Laboratory (NPPTL) mission to improve occupational health and safety by advancing the state of knowledge and application of personal protective technology (PPT) toward hazard prevention solutions.

The committee, a multidisciplinary group of engineers, hygienists, physicians and nurses, epidemiologists, and other technical experts, reflecting the multiple disciplines that make up the practice of occupational health itself, have provided a rich nexus of expertise and viewpoints serving to inform the present NIOSH/NPPTL research and service agenda and to forecast the future PPT needs of the nation's workforce.

This compilation highlights the many important scientific work products, topical syntheses, and technical reports of the committee's work that reflect the significant impact of NIOSH/NPPTL's impressive contributions in the safety and aerosol sciences, conformity assessment, public health policy, and worker education. Certainly, recent key contributions of NIOSH/NPPTL in leading personal protective equipment (PPE) efforts impacting the COVID-19 response, including the significant increase to the inventory of respirators available during the COVID-19 pandemic, the tremendous role in evaluating international respirators, research that led to the stockpiling guidance and extended use and reuse guidance, the research portfolio addressing the utility of reusable elastomeric respirators in health care, their participation in the ASTM standard on barrier face coverings for public use, and their ongoing contributions to the national stockpile for PPE are highly visible examples of why NIOSH/NPPTL is the recognized and trusted source of PPT expertise within the Centers for Disease Control and Prevention (CDC), nationally, and, indeed, beyond.

It is both a professional challenge and personal privilege to participate on this committee in service to the NIOSH/NPPTL worker health mission and in the company of such passionate, committed, and scientifically informed colleagues.

COPPE Committee Origins and Purpose

The health and safety of the nation's workforce is prerequisite to a healthy and productive nation. Whenever possible, occupational health and safety risks should be eliminated or mitigated through environmental, engineering, or administrative controls. But for millions of workers, prevention of injury and illness from occupational hazards must necessarily rely on personal technologies (PPT), including respirators, protective clothing, gloves, and eyewear. The establishment of NPPTL within NIOSH in 2001 increased the national focus on the importance of PPT. Nearly 20 years later, NIOSH celebrated 100 years of respiratory protection, which has seen a remarkable transformation since the first respirator was certified in 1920. The advancements in respiratory protection recognized and celebrated during the recent centennial exemplify the evolution of PPT more broadly and reflect the efforts of a committed group of occupational safety and health professionals.

As the nation's foremost experts in personal protection, the staff of NIOSH/NPPTL are dedicated to the agency's mission of preventing and reducing work-related illness, injury, and death by ensuring the development, certification, deployment, and use of PPT. This responsibility demands a highly qualified workforce and a wide range of scientific and technical expertise.

In 2004, the current Director of NIOSH/NPPTL (then the NPPTL Associate Director for Science), Dr. Maryann D'Alessandro, visited the National Academies seeking independent, expert guidance and scientific input on the relevance and impact of NIOSH/NPPTL's PPE program and to help expand and enhance its research and service activities. In response to this request, the (then) Institute of Medicine (IOM) established the Standing Committee on Personal Protective Equipment for Workplace Safety and Health within the Board on Health Sciences Policy. The committee was charged with convening diverse subject-matter experts and providing a forum for discussion of scientific and technical issues relevant to the development and use of PPE, standards, and related systems to ensure workplace safety and health. It further is tasked with reviewing and providing strategic direction on NIOSH/NPPTL programs and activities. The committee also stands ready to respond rapidly to provide guidance during emerging threats, such as the Ebola outbreak and, most recently, the COVID-19 pandemic.

COMMITTEE MEMBERSHIP

The unique value of COPPE to NIOSH/NPPTL stems in large part from the multidisciplinary composition of the membership that represents a mix of research and applied experience, and balances perspectives from different industries, academia, and labor organizations. The committee members bring expertise in such diverse fields as occupational safety and health; industrial hygiene; PPE research and development; material science; health care systems, practice, and policy; public safety; epidemiology; employer health systems; labor unions; public policy; hazard assessment; and risk management.

2021 Standing Committee on Personal Protective Equipment for Workplace Safety and Health Membership Roster (As of September 2020)

- Melissa McDiarmid, *Committee Chair*, University of Maryland School of Medicine
- Christina Baxter, Emergency Response TIPS, LLC
- Howard Cohen, University of New Haven (*retired*)
- Craig Colton, CCR Consulting, LLC
- Kristin Cummings, California Department of Public Health
- MaryAnn Gruden, Alleghany Hospital
- Sundaresan Jayaraman, Georgia Institute of Technology
- David Prezant, New York City Fire Department
- Mark Shirley, Sutter Health
- Simon Smith, 3M Canada (*retired*)
- Guowen Song, Iowa State University
- Geeta Sood, Johns Hopkins Bayview Medical Center
- Richard Stein, United States Bureau of Mines (*retired*)

Past Committee Membership

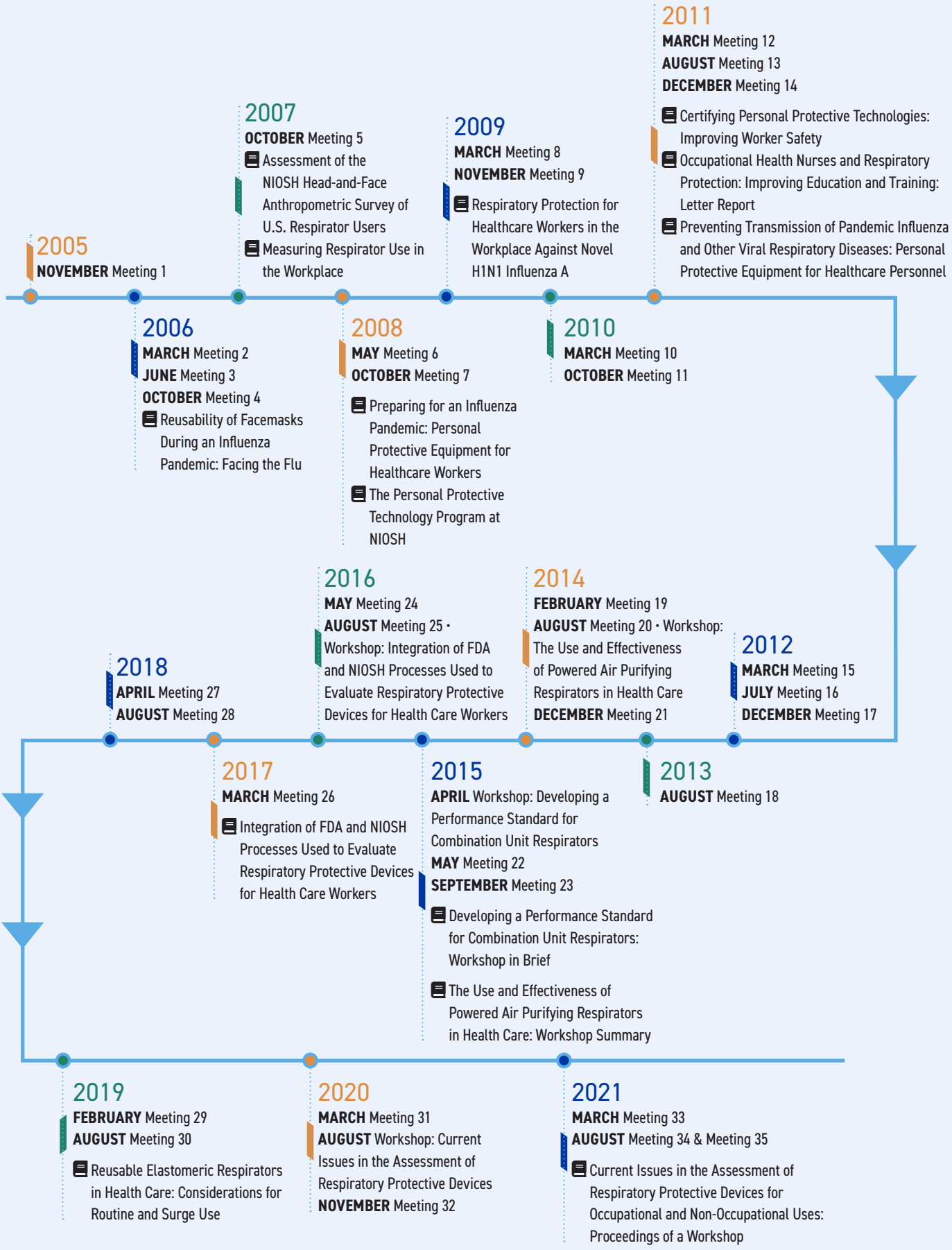
- Charles Austin, Sheet Metal Occupational Health Institute Trust
- Roger Barker, North Carolina State University
- Robert Bass, Maryland Institute for Emergency Medical Services Systems (retired)
- Linda Hawes Clever, Former Chair, California Pacific Medical Center
- Robert Cohen, Stroger Hospital of Cook County
- Barbara DeBaun, Cynosure Health
- David DeJoy, University of Georgia
- Emiel DenHartog, North Carolina State University
- Mary Ellen Flanagan, University of Washington
- Robyn Gershon, University of California, San Francisco
- Lewis Goldfrank, *Former Chair,* New York University Grossman School of Medicine
- Leslie Israel, University of California, Irvine
- James Johnson, JSJ and Associates
- William Kojola, AFL-CIO (retired)
- Susan P. McGrath, Dartmouth College
- Hernando R. Perez, Department of Homeland Security
- Jimmy L. Perkins, University of Texas Health Science Center and San Antonio
- James Platner, The Center for Construction Research and Training
- Patricia Quinlan, University of California, San Francisco
- Knut Ringen, Independent Consultant
- M.E. Bonnie Rogers, University of North Carolina Occupation Safety and Health Education Research Center
- Cecile S. Rose, National Jewish Health
- Kerri Rupe, University of Iowa
- Joseph Schwerha, University of Pittsburgh
- Anugrah Shaw, University of Maryland, Eastern Shore
- Daniel K. Shipp, International Safety Equipment Association
- Lynette Stokes, Department of Labor
- Jeffrey O. Stull, International Personal Protection, Inc.
- James Tacci, Xerox Corporation
- Gary C. Tepper, Virginia Commonwealth University
- James P. Zeigler, J.P. Zeigler, LLC

RESPONDING TO SPONSOR NEEDS

COPPE Meetings and Affiliated Activities

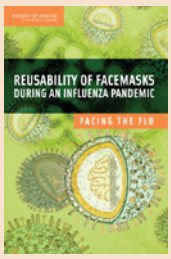
In November 2005, COPPE held its first meeting to become familiar with NIOSH/NPPTL's mission, research, and portfolio of work. Since 2005, the committee has met more than 30 times, and topics have evolved in response to NIOSH/NPPTL needs and emerging issues. Together these meetings have featured more than 130 invited speakers and participants. Recurring discussion topics that have woven throughout the COPPE meetings include standards setting, PPE certification and approval, postmarket surveillance, PPE needs for emerging infectious diseases, and stockpiling of PPE.

Over the past 15 years, COPPE has supported a variety of other National Academies activities outside of its own meetings that have provided opportunities for engaging key stakeholders from across the PPT enterprise, fostering discussion, and providing guidance and input for NIOSH/NPPTL activities. COPPE is specifically charged with offering scientific input for future PPE program efforts and proposing the formation of and liaising with ad hoc committees for workshops and/or consensus studies, which, unlike COPPE meetings, result in National Academies publications. National Academies workshops provide an opportunity to convene a broad group of experts and stakeholders to explore and report on the state of knowledge for a specific scientific or policy topic, but the resulting Proceedings product may not include recommendations. In contrast, consensus studies (and the shorter letter reports) are the primary mechanism the National Academies use to provide answers to critical questions in health and science and often result in a set of conclusions and actionable recommendations in response to the committee's charge. Since its inception, COPPE has overseen four workshops, eight consensus studies, and two letter reports, with discussions at COPPE meetings guiding the development of the statements of task for these affiliated activities and COPPE members serving on these ad hoc committees.

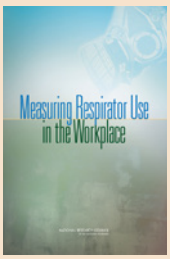

2005
NOVEMBER Meeting 1
2006
MARCH Meeting 2
JUNE Meeting 3
OCTOBER Meeting 4
Reusability of Facemasks During an Influenza Pandemic: Facing the Flu
2007
OCTOBER Meeting 5
Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users
Measuring Respirator Use in the Workplace
2008
MAY Meeting 6
OCTOBER Meeting 7
Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers
The Personal Protective Technology Program at NIOSH
2009
MARCH Meeting 8
NOVEMBER Meeting 9
Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A
2010
MARCH Meeting 10
OCTOBER Meeting 11
2011
MARCH Meeting 12
AUGUST Meeting 13
DECEMBER Meeting 14
Certifying Personal Protective Technologies: Improving Worker Safety
Occupational Health Nurses and Respiratory Protection: Improving Education and Training: Letter Report
Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel
2012
MARCH Meeting 15
JULY Meeting 16
DECEMBER Meeting 17
2013
AUGUST Meeting 18
2014
FEBRUARY Meeting 19
AUGUST Meeting 20 • Workshop: The Use and Effectiveness of Powered Air Purifying Respirators in Health Care
DECEMBER Meeting 21
2015
APRIL Workshop: Developing a Performance Standard for Combination Unit Respirators
MAY Meeting 22
SEPTEMBER Meeting 23
Developing a Performance Standard for Combination Unit Respirators: Workshop in Brief
The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary
2016
MAY Meeting 24
AUGUST Meeting 25 • Workshop: Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers
2017
MARCH Meeting 26
Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers
2018
APRIL Meeting 27
AUGUST Meeting 28
2019
FEBRUARY Meeting 29
AUGUST Meeting 30
Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use
2020
MARCH Meeting 31
AUGUST Workshop: Current Issues in the Assessment of Respiratory Protective Devices
NOVEMBER Meeting 32
2021
MARCH Meeting 33
AUGUST Meeting 34 & Meeting 35
Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses: Proceedings of a Workshop

LIST OF COPPE-AFFILIATED PUBLICATIONS

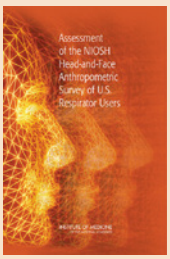
CONSENSUS STUDY REPORTS



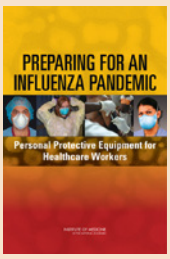
Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006)



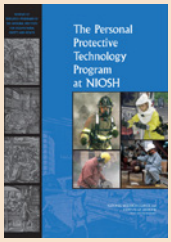
Measuring Respirator Use in the Workplace (2007)



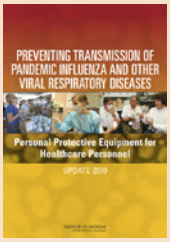
Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users (2007)



Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008)

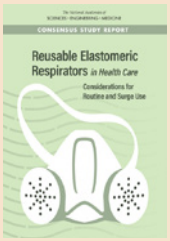


The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health (2008)



Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2011)

Certifying Personal Protective Technologies: Improving Worker Safety (2011)

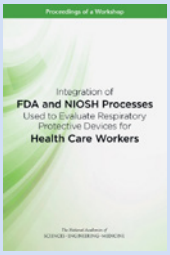


Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019)

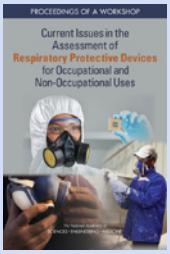
WORKSHOP PROCEEDINGS

The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary (2015)

Developing a Performance Standard for Combination Unit Respirators: Workshop in Brief (2015)



Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers: Proceedings of a Workshop (2017)



Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses: Proceedings of a Workshop (2021)

LETTER REPORTS

Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report (2009)

Occupational Health Nurses and Respiratory Protection: Improving Education and Training: Letter Report (2011)

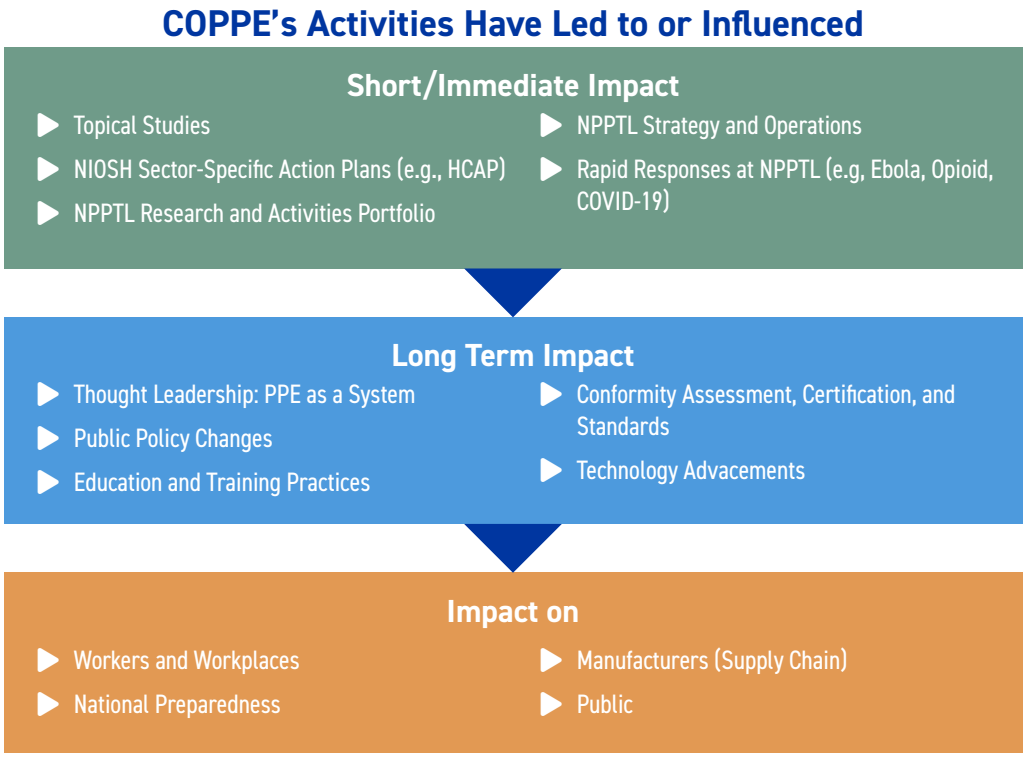
COPPE Impact Summary

ASSESSING OUR IMPACT

The work of COPPE and its affiliated studies and workshops have had broad impacts on the field of occupational safety and health by contributing to the development of new standards for PPE, expanding consideration of PPE as part of a system, informing the strategic direction of research and policy for federal agencies, influencing PPE-related education and training programs to improve worker knowledge and practice, and promoting advancements in personal protective technologies to better meet the needs of workers. Importantly, the work of COPPE has helped to shape the field of workplace safety and health by elevating critical issues, laying out the path for future work, and pushing for continual advancement.

The National Academies define three core types of impact for its work—fostering relationships and collaboration, influencing policies and programs (including legislation, programmatic planning, and educational initiatives), and inspiring new ideas that shape the field. This document shines a light on some of the most significant examples of such impacts from across COPPE's work and related publications in each of these different impact areas. These 15 years of impacts, summarized below, range from direct achievements to more intangible examples of engagement and include both short- and long-term impacts (as depicted in Figure 1) that have advanced incrementally the state of knowledge, policy, and practice across a number of key areas.

FIGURE 1 Model for understanding the breadth of COPPE's impact over time.



SOURCE: Developed by S. Jayaraman, COPPE member, 2021.

IMPACT BY THE NUMBERS

Statistics on COPPE-Affiliated National Academies Publications

14 PUBLICATIONS: 41,500+ downloads, and 245,000+ "Read Online" sessions[1]

MENTIONED IN 41 DIFFERENT NEWS OUTLETS, including *The New York Times*, *USA Today*, and *NBC News*

REPORTS REFERENCED IN 350+ ACADEMIC JOURNAL ARTICLES, including the *American Journal of Infection Control*, *Journal of Occupational and Environmental Hygiene*, and *Workplace Health and Safety*

Top Three Most Downloaded Publications

1

Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006)

- Top 1% of all National Academies of Sciences, Engineering, and Medicine publications
- 13,400+ downloads and 174,000+ "Read Online" sessions
- Downloaded in 147 countries and in all 50 states and the District of Columbia
- Cited 114 times

2

Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report (2009)

- Top 4% of all National Academies of Sciences, Engineering, and Medicine publications
- 6,600+ downloads and 3,500+ "Read Online" sessions
- Downloaded in 110 countries and in all 50 states and the District of Columbia
- Cited 37 times

3

Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019)

- Top 9% of all National Academies of Sciences, Engineering, and Medicine publications
- 6,300+ downloads and 6,300+ "Read Online" sessions
- Downloaded in 98 countries and in all 50 states and the District of Columbia
- Cited 19 times

1 "Read Online" sessions provide access to the full publication text without requiring a download.

FOSTERING RELATIONSHIPS AND COLLABORATION

A core value of the Standing Committee on Personal Protective Equipment for Workplace Safety and Health is its ability to bring the right people to the table. This function of the committee as a convener of multidisciplinary groups of participants around topics of critical importance to PPT and broader systems for occupational safety and health fosters the creation of professional relationships, collaboration across sectors and stakeholders, and opportunities for professional development. Over the past 15 years, these connections among NIOSH/NPPTL, COPPE members, and invited participants have sparked countless secondary collaborations that have each played their incremental role in advancing PPT for the nation's workforce. Most significantly, COPPE serves as a space to cultivate collaborations and interagency relationships to address challenges that result from the diffusion of roles and responsibilities related to PPT across multiple federal agencies. For example, strengthened relationships between NIOSH/NPPTL and such partners as the Food and Drug Administration (FDA) and the Strategic National Stockpile (SNS), cultivated in the context of COPPE and its related activities, have demonstrated value through interagency agreements and collaborations on PPE efforts. Additionally, COPPE's purposeful engagement with organized labor has led to greater representation of worker perspectives in NIOSH/NPPTL activities by creating bidirectional pathways for communication and opportunities for the collection of critical user input.

INFLUENCING POLICIES AND PROGRAMS AND INSPIRING NEW IDEAS THAT SHAPE THE FIELD

Themes from COPPE Work and Affiliated Activities

The work of the standing committee and its affiliated activities has spanned an impressive number of topics. From this varied body of work, several key themes emerge that define how the committee has influenced policies and programs and inspired new ideas to shape the field over the past 15 years. These themes will be used throughout this document to describe the scope of impacts and achievements of the standing committee in advancing the state of workplace safety and health.

- **Protecting health care workers:** Much of the work of COPPE and its affiliated activities has focused on understanding the risks to and needs of the health care workforce to prioritize the development and use of PPE that is safe, acceptable, and functional for this unique group of users.
- **Responding to emerging threats to the nation's workforce:** Multiple hazards have emerged over the past 15 years to threaten the health and safety of the nation's workforce. The efforts of COPPE and recommendations from affiliated activities have served to enhance preparedness and guidance for PPT, particularly for respiratory protective devices.
- **Improving conformity assessment:** Conformity assessment, from the analysis of the science behind standards to evaluations of conformity assessment in practice, has been a critical focus of COPPE since its creation.
- **Guiding personal protective equipment research:** The ongoing dialog between COPPE and NIOSH/NPPTL, supported by the recommendations of related consensus studies, has served to identify critical research needs and to inform the current and future research roadmap for PPT at NIOSH/NPPTL.
- **Creating a culture of safety through workforce education and training:** Interest in safety culture and worker education and training, in particular, developed from early COPPE discussions as part of the exploration of PPE use by health care workers. COPPE work has since focused on a need for comprehensive education and training at all levels of education as part of efforts to build a culture of safety for all workplaces but particularly in the health care sector.
- **Advancing innovation in personal protective technologies:** COPPE and its affiliated activities have provided strategic input and direction to support efforts to continuously advance respiratory protection technologies. This includes calls for improvements to safety and advancement in technological innovations to enhance function and usability for users.

Each of the following sections expands on one of the above themes and includes a description of the catalyst that spurred the interest of COPPE and NIOSH/NPPTL in advancing work in that area, an overview of standing committee and related activities' efforts and publications, key National Academies recommendations, and highlights of some of the most significant impacts that have resulted from this work.

Protecting Health Care Workers

CATALYST

The protection of the 22 million health care workers in the United States is essential to maintaining the ability to provide care to our communities, particularly during times of crisis. However, the needs of this workforce and the hazards they face are diverse and necessitate different types of PPE (gloves, gowns, surgical masks and face shields, and respiratory protection) and supportive structures than those used in industrial settings. Early COPPE discussions and consensus studies, beginning with the 2006 report *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu*, provided the external validation for NIOSH's increasing interest in the PPE needs of health care workers and the impetus for expanding their research efforts beyond the fire service and mining spheres. Of this need for a greater focus on the health care workforce, a consensus study committee wrote, "there was no better strategy to address the NIOSH/NPPTL mission than through investigating how to protect health care workers in the event of an influenza pandemic."[1]

> "Protecting the health and safety of health care workers is vital to the health of each of us. Preparing for and responding to a future influenza pandemic or to a sustained outbreak of an airborne transmissible disease requires a high-level commitment to respiratory protection for health care workers across the wide range of settings in which they work and the jobs that they perform."
>
> *Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use, 2019, p. 1*

RELEVANT REPORTS

- Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006 consensus study)
- Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)
- Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A (2009 letter report)
- Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel (2011 consensus study)
- Occupational Health Nurses and Respiratory Protection: Improving Education and Training (2011 letter report)
- The Use and Effectiveness of Powered Air Purifying Respirators in Health Care (2015 workshop proceedings)
- Integration of FDA and NIOSH Processes to Evaluate Respiratory Protective Devices for Healthcare Workers (2017 workshop proceedings)
- Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)

AFFILIATED CONSENSUS STUDY AND WORKSHOP PLANNING COMMITTEE WORK

In 2006, NIOSH/NPPTL asked the (then) IOM to review PPE requirements for health care workers and make recommendations about how to best protect this workforce from threats like pandemic influenza. A series of standalone workshops, consensus studies, and publications evolved from these ongoing COPPE discussions that, starting in 2005, focused on advancing health care–oriented PPE. This body of work has addressed challenges related to protecting the health and safety of health care workers through a variety of lenses.

These health care worker–focused reports tackle the systemic challenges that have resulted from the lack of access to or utilization of safe and acceptable PPE in the clinical setting, particularly respiratory protective devices. Collectively, these reports champion the need for innovative respiratory protective devices that meet the needs of this workforce across diverse worksites, job functions, and varied levels of risk; call for a dedicated commitment to building a culture of safety within the health care system; and outline necessary investment in research to understand hazards, such as influenza and other viral respiratory diseases, and device requirements related to decontamination, reusability, comfort, and fit. Over the past 15 years, COPPE input and the recommendations of affiliated consensus studies have resulted in diffuse impacts across research, policy, and practice and have addressed incrementally the unmet needs of health care workers.

> "Keeping health care workers healthy is an ethical commitment both in terms of addressing the occupational risks faced by health care workers and of providing for the continuity of patient care and services needed to maintain the health of individuals and communities."
>
> *Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use, 2019, p. 1.*

KEY RECOMMENDATIONS

Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training	Appropriate PPE use and health care worker safety should be a priority for health care organizations and health care workers, and in accreditation, regulatory policy, and training. *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)*
Identify and Disseminate Best Practices for Improving PPE Compliance and Use	CDC and the Agency for Healthcare Research and Quality should support and evaluate demonstration projects on improving PPE compliance and use. This effort would identify and disseminate relevant best practices that are being used by hospitals and other health care facilities. *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)*
Develop and Certify Powered Air-Purifying Respirators (PAPRs) for Healthcare Personnel	NPPTL should develop certification requirements for a low-noise, loose-fitting PAPR for health care personnel. *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel (2011 consensus study)*
Increase Research on the Design and Engineering of the Next Generation of PPE	NIOSH, the Department of Homeland Security, the Department of Defense, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of respirators, gowns, gloves, and eye protection for health care workers that would enhance their safety and comfort. *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)*

SIGNIFICANT IMPACTS

Influencing Policies and Programs and Inspiring New Ideas That Shape the Field

Health Care PPE Action Plan

NIOSH/NPPTL's Heath Care PPE Action plan[2] provides a roadmap to address preparedness and effective use of PPE in the context of an influenza pandemic and other public health emergencies. NIOSH/NPPTL's interest in a more comprehensive approach to health care worker protection in the workplace originated prior to 2006 and led to a series of National Academies consensus study reports related to health care workers and influenza. The resulting recommendations across these reports called out the urgent need to address PPE preparedness for the health care workforce as well as the need to fill critical research and technology gaps related to scientific knowledge of influenza transmission, PPE effectiveness for viral respiratory hazards, and the development of PPE designed for health care. From these recommendations, NIOSH/NPPTL developed the Health Care PPE Action Plan. Following these initial efforts, COPPE served to provide input on user needs to be addressed in the Action Plan and reviews of updates to the Action Plan at 5-year intervals.

The Heath Care PPE Action Plan acknowledges that, in the event of pandemic influenza, PPE will serve as an essential tool to protect frontline health care workers. The Action Plan encompasses the breadth of actions to be undertaken by NIOSH/NPPTL and their collaborators to realize the mission of improved PPE preparedness. These activities include investment in research on aerosol transmission; activities to grow a culture of safety at an organizational and individual level around correct PPE use; improvements to PPE design, testing, and certification processes; evidence-based performance standards; and effective dissemination of information. The Health Care PPE Action Plan now serves as a model for action plans under development for other worker populations requiring the use of PPE, including the public safety sector.

Hospital Respiratory Protection Program Toolkit

The 2015 Hospital Respiratory Protection Program Toolkit[3] was published by NIOSH/NPPTL to fill a gap in guidance on best practices for implementing effective respiratory protection programs (RPPs) in hospitals and other health care settings. The development of this toolkit grew from a collection of National Academies publications on the prevention of influenza transmission to the health care workforce and calls for action to cultivate a culture of safety at the organizational and individual levels in the clinical environment.

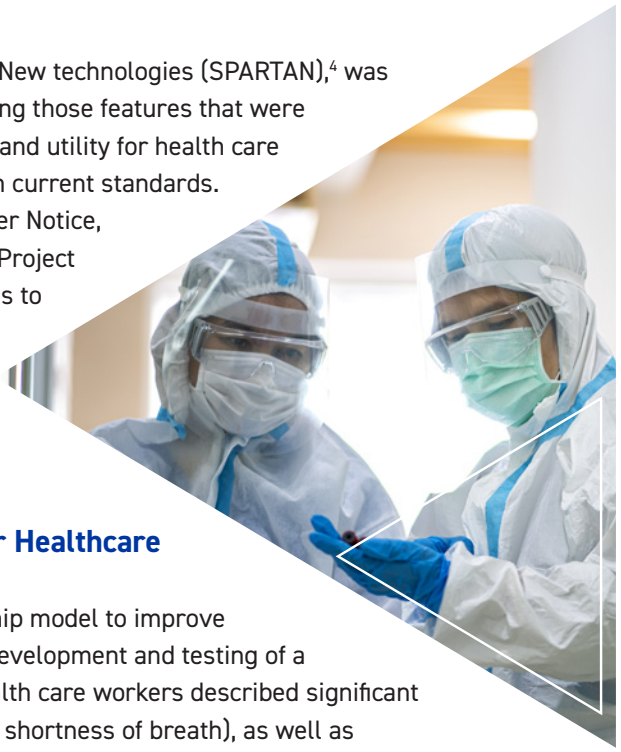
The toolkit was developed to support hospital administrators in implementing a RPP with the specific intention of preventing the transmission of aerosol transmissible diseases. This document is groundbreaking in that it brings together, in one cohesive document, research and guidance from multiple sources to lay out the need for respiratory protection, explains approaches to reduce exposure, describes types and considerations for respiratory protective devices, and describes requirements of the Occupational Safety and Health Administration (OSHA) respiratory protection standard and elements of a RPP.

Future Generation of Powered Air-Purifying Respirators for the Health Care Workforce

Launched in 2018, this project applies a public–private partnership development model to spur the creation of a future generation of PAPRs designed to meet health care worker needs. PAPRs were originally developed to protect industrial workers (primarily in mining) during an 8-hour shift. However, emerging threats like SARS in 2003, H1N1

influenza in 2009, Ebola in 2014, and COVID-19 in 2019 demonstrate the vulnerability of health care workers and the critical need for PPE designed specifically for use in the health care setting.

This effort grew from recommendations issued by COPPE-affiliated consensus study publications, including the 2008 consensus study report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers* and the 2011 consensus study report *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Workers*, as well as from discussions captured in the 2015 workshop summary *The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary.* This workshop, which was convened to prioritize NIOSH activities related to these devices, and the prior consensus study reports underscored the reality that PAPRs, as they are currently designed, are not necessarily suitable for use in the health care work environment. These reports offered a set of attributes that could be integrated into future PAPR designs including suitability for use in sterile fields; enhanced visibility and communication; greater ease of donning, doffing, and cleaning; variable flows based on work rates; smaller and less bulky designs; and sensors and alarms that monitor flow and power.



The resulting project, Superior Powered Air-purifying Respirators Tests and New technologies (SPARTAN),[4] was launched to realize this goal of bringing health care PAPRs to the market using those features that were defined by National Academies publications to enhance function, tolerability, and utility for health care workers, while maintaining a level of protection equivalent to or greater than current standards. The second phase of this project, as described by a July 2019 Federal Register Notice, will apply the government–private partnership development model used by Project B.R.E.A.T.H.E. (discussed below) to engage industry partners in collaborations to drive the technological development and approval of these novel devices using the new PAPR100 performance requirements (see Conformity Assessment section below).[5] In parallel, NPPTL continued its efforts to develop an updated standard to provide incremental updates to 42 CFR 84 including improvements to PAPR requirements.

Better Respiratory Equipment Using Advanced Technologies for Healthcare Employees Project (Project B.R.E.A.T.H.E.)

This interagency effort[6] applied an innovative government–private partnership model to improve respiratory protective equipment used by health care workers through the development and testing of a new respirator designed specifically for use in health care. During SARS, health care workers described significant respirator-associated discomforts (e.g., headaches, facial heat and pressure, shortness of breath), as well as interference with occupational duties while wearing a respirator, among other problems associated with respirator use. Such issues were viewed as significant limiting factors in work performance and concerns were raised about respirator use during future epidemics.

This project grew from recommendations from COPPE discussions and National Academies publications, particularly the 2008 consensus study report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*, which called for advancements in design, testing, and certification for health care worker PPE. Additionally, the report recommended the development of evidence-based performance measures to guide PPE design to meet the requirements of these workers. The Department of Veterans Affairs, in partnership with NIOSH/NPPTL, created the Project B.R.E.A.T.H.E. Working Group, ultimately a collaboration of 9 federal agencies, which developed a set of 28 consensus recommendations for respirators for use by health care workers and categories of desirable respirator characteristics to improve function, usability, and acceptability. This project is unique in that it was centered on the philosophy that PPE safety and effectiveness are directly associated with user comfort and tolerability, which is foundational to the future generation of PPE. This working group called for the development of a Biological N95, or B95, which provides protection against biological particulates.

Responding to Emerging Threats to America's Workerforce

CATALYST

Since the SARS outbreak, which greatly affected health care workers, there has been a growing awareness of the vulnerability of frontline responders delivering care to the population and preventing the spread of further disease. These hazards facing the nation's workforce are constantly evolving as more information is learned about existing threats and novel hazards emerge. The critical importance of occupational safety and health and the role of PPE, in particular, becomes more visible during these emergency situations. Over the course of COPPE's work, a number of emerging hazards have threatened the health and safety of the nation's workforce, including novel influenza strains (H5N1; H1N1), Ebola, and, most recently, COVID-19. Each of these threats has challenged the use of PPE in unique ways and highlighted opportunities for immediate action and future investment. COPPE and its affiliated activities have provided support to NIOSH/NPPTL during these periods of immense challenge by providing rapid feedback, but also in the inter-epidemic periods by maintaining a constant focus on sustaining progress. It is these situations that demonstrate the ability of the committee to rapidly respond to NIOSH/NPPTL's needs and the role of the National Academies study process in providing expert consensus recommendations to drive policy and advancements in the long term.

> "In the event of a pandemic, healthcare institutions and healthcare workers would face decisions about what types of PPE would offer effective prevention; many healthcare workers would not have received recent training on the appropriate use of PPE; and questions about the effectiveness of PPE in preventing influenza transmission would raise concerns. As a result, the surge capacity to treat ill patients could be severely impaired."

Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010, 2011, p. 15

RELEVANT REPORTS

Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006 consensus study)

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)

Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A (2009 letter report)

Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel (2011 consensus study)

Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)

Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses: Proceedings of a Workshop (2021 workshop proceedings)

AFFILIATED CONSENSUS STUDY AND WORKSHOP PLANNING COMMITTEE WORK

COPPE and multiple affiliated consensus committees were asked by NIOSH/NPPTL to address unanswered research questions related to novel or evolving respiratory health threats to the workforce and concerns related to preparedness, beginning in 2006 with an evaluation of the reusability of disposable filtering facepiece respirators (FFRs). In its totality, this body of work has provided ongoing assessments to NIOSH/NPPTL on the progress of PPE research and has emphasized the need for both immediate actions, such as the call for use of effective respiratory protective devices for health care workers during the H1N1 pandemic, and longer-term investments in key areas of research and practice to improve the nation's ability to prepare for and respond to the next threat. Identified gap areas include the need for research on transmission of influenza and other aerosol transmissible diseases, improved understanding of PPE effectiveness, incorporation of best practices for respiratory protection use in the context of an epidemic, and efforts to secure a sufficient supply of respiratory protective devices, among others.

KEY RECOMMENDATIONS

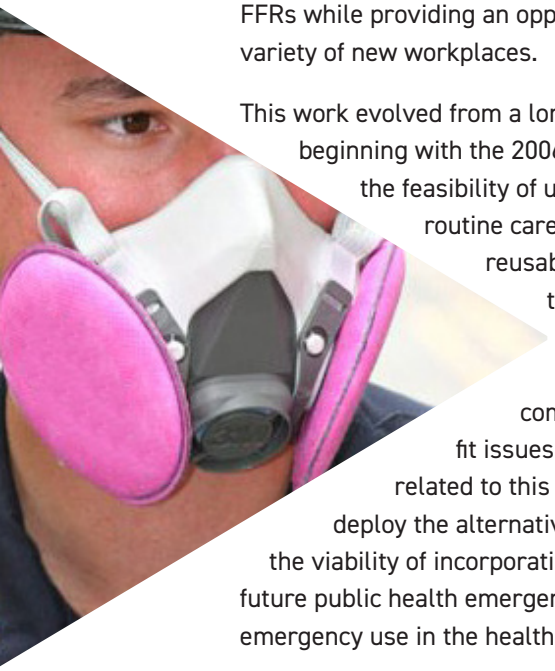
Harmonize Standards and Clarify Guidelines and Responsibilities	The Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health and the National Center for Immunization and Respiratory Diseases, Occupational Safety and Health Administration, the U.S. Food and Drug Administration, staff of the Strategic National Stockpile, and state-level regulatory and stockpile entities—in conjunction with manufacturers, standards-setting organizations, health care facilities, health care professional associations, and other relevant stakeholders—should support the harmonization of guidance and operating procedures for the use of elastomeric respirators in the health care setting. *Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)*
Clarify PPE Guidelines for Outbreaks of Novel Viral Respiratory Infections	NIOSH, other divisions of CDC, OSHA, and other public health agencies should develop a coordinated process to make, announce, and revise consistent guidelines regarding the use of PPE to be worn by healthcare personnel during a verified sustained national/international outbreak of a novel viral respiratory infection. The agencies should tailor their guidance in a timely and coordinated manner as the virulence, contagiousness, and affected populations are further characterized. *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel (2011 consensus study)*
Develop and Implement a Comprehensive Research Strategy to Understand Viral Respiratory Disease Transmission	The National Institutes of Health, in collaboration with other research agencies and organizations, should develop and fund a comprehensive research strategy to improve the understanding of viral respiratory disease transmission, including, but not limited to, examining the characteristics of influenza transmission, animal models, human challenge studies, and intervention trials. This strategy should include 1) an expedited mechanism for funding these types of studies and 2) clinical research centers of excellence for studying influenza and other respiratory virus transmission. *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel (2011 consensus study)*
Use Fit-Tested N95 Respirators	Healthcare workers (including those in non-hospital settings) who are in close contact with individuals with nH1N1 influenza or influenza-like illnesses should use fit-tested N95 respirators or respirators that are demonstrably more effective as one measure in the continuum of safety and infection control efforts to reduce the risk of infection. *Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A (2009 letter report)*

SIGNIFICANT IMPACTS

Influencing Policies and Programs and Inspiring New Ideas That Shape the Field

National Elastomeric Half-Mask Respirator Strategy for Use in Health Care Settings

Following mass shortages of FFRs during the COVID-19 crisis, in mid-2020 NIOSH/NPPTL, in partnership with the SNS, initiated an opportunity to distribute elastomeric half-mask respirators from the SNS for use by health care organizations and public safety departments. This program has a clear dual benefit of easing demand for single-use FFRs while providing an opportunity to evaluate the implementation and use practices of these reusable devices in a variety of new workplaces.



This work evolved from a long-term interest of NIOSH/NPPTL on the reusability of respiratory protective devices, beginning with the 2006 consensus study report on reusability of FFRs and culminating in a 2019 report on the feasibility of using elastomeric half-mask respirators (EHMRs) in health care settings during both routine care and in the context of a major health emergency. The 2019 report indicated that while reusable EHMRs were suitable for use in the clinical setting, there is a need to evaluate how these devices are used, identify best practices for implementation, and gather real-world data about usability and acceptability of these devices in the context of a public health emergency. Following this publication, NIOSH/NPPTL immediately initiated a comprehensive three-phase contract to three universities to evaluate just-in-time EHMR fit issues, decontamination of EHMRs, and EHMR use in a clinical setting. As the first article[7] related to this research was published, the emerging COVID-19 pandemic created an urgent need to deploy the alternative respirator options for health care workers, as well as the opportunity to evaluate the viability of incorporating reusable elastomeric respirators into the national stockpiling strategy in advance of future public health emergencies and to improve practices for integrating these reusable products into routine and emergency use in the health care and public safety sectors.

NIOSH/NPPTL issued a federal register notice in September 2020[8] announcing their plan to collaborate with the SNS to provide up to 1.5 million EHMRs to interested organizations. As of mid-2021, more than 99 first responder organizations—fire departments, emergency medical services (EMS) units, and law enforcement agencies—and health care organizations responded with interest and many have entered into Memoranda of Understanding (MOUs) with NIOSH/NPPTL to carry out this work. These frontline partners will apply the CDC elastomeric respirators guidance[9] and Hospital Implementation Guides to the rollout and use of these devices (see section on Workforce Education and Training). As part of this real-world demonstration project, NIOSH/NPPTL will then conduct surveys about user and institutional experiences with these devices, including acceptability and feasibility of implementation, to further inform updates to best practice guidelines and the Hospital Implementation Guides.

Additionally, the NPPTL respirator approval program also has been open to evaluating innovative respirator designs and during the COVID-19 response has evaluated and approved multiple EHMRs without exhalation valves.

CDC Guidance on Respiratory Protection for Health Care Workers

COPPE discussions early in the 2009 H1N1 pandemic drove the initiation and later the dissemination of a National Academies letter report to the CDC Director and the Assistant Secretary for Occupational Safety and Health at OSHA. At the time, the recommendations provided in the report were used by the CDC as interim guidance on infection control measures for health care workers during the ongoing H1N1 pandemic.[10] These recommendations, for the first time, called for use of fit-tested N95 FFRs by all health care workers in close contact with patients with influenza-like illnesses and the implementation of clear and consistent respiratory protection guidelines that can be implemented across all health care settings.

Reuse and Extended Use of Filtering Facepiece Respirators

Questions related to the reusability of FFRs were an early area of focus for COPPE due to concerns that the nation lacked an adequate supply of respiratory protective devices to respond to the demands of an influenza pandemic. These concerns led to a 2006 consensus study report on whether disposable FFRs could be reused safely and effectively. This report, and others after it, urged NIOSH/NPPTL to address persisting research gaps related to the efficacy of reprocessing methods and their effects on respirator integrity, the risks associated with handling a respirator used for a viral exposure, and the characteristics of influenza transmission. In response to these recommendations, NIOSH/NPPTL conducted or supported a number of studies on these topics, with resulting publications that include the following:

- Bergman, M.S., D.J. Viscusi, A. Zhuang, A.J. Palmiero, J.B. Powell, and R.E. Shaffer. 2012. Impact of multiple consecutive donnings on filtering facepiece respirator fit. *American Journal of Infection Control* (40)4:375-380.
- Fisher, E.M., and R.E. Shaffer. 2014. Considerations for recommending extended use and limited reuse of filtering facepiece respirators in health care settings. *Journal of Occupational and Environmental Hygiene* (11)8:D115-D128.
- Fisher, E.M., S Rengasamy, D. Viscusi, E. Vo, and R. Shaffer. 2009. Development of a test system to apply virus-containing particles to filtering facepiece respirators for the evaluation of decontamination procedures. *Applied and Environmental Microbiology* (75)6:1500-1507.
- Noti, J.D., W.G. Lindsley, F.M. Blachere, G. Cao, M.L. Kashon, R.E. Thewlis, C.M. McMillen, W.P. King, J.V. Szalajda, and D.H. Beezhold. 2012. Detection of infectious influenza virus in cough aerosols generated in a simulated patient examination room. *Clinical Infectious Diseases* (54)11:1569-1577.

These NIOSH/NPPTL-driven studies and multiple others have proven to be invaluable during the COVID-19 pandemic as extreme shortages of FFRs have again raised questions over the safety and effectiveness of the reuse of these devices. This research base was used to develop and disseminate timely CDC guidance[11] in 2020 on the implementation of respirator reuse and extended reuse during severe N95 respirator shortages.

GETTING THE WORD OUT

Past consensus study committee and COPPE members continue to publish in support of key messages from past reports and to reach new audiences. Some recent examples relevant to the theme of Responding to Emerging Threats to America's Workforce include the following:

Friese, C.R., and L.H. Clever. 2020. *Protecting Health Care Workers from Transmissible Airborne Diseases: Challenges and Opportunities. NAM Perspectives.* Commentary, National Academy of Medicine, Washington, DC.

Friese, C.R., T.G. Veenema, J.S. Johnson, S. Jayaraman, J.C. Chang, and L.H. Clever. 2020. Respiratory protection considerations for healthcare workers during the COVID-19 pandemic. *Health Security 18(3):237-240.*

Park, S., and S. Jayaraman. 2020. From containment to harm reduction from SARS-CoV-2: A fabric mask for enhanced effectiveness, comfort, and compliance. *The Journal of the Textile Institute 112(7):1144-1158.*

Stockpiling and Respirator Shelf Life

Ongoing discussions within COPPE about stockpiling and shelf life of respiratory protective devices, beginning in 2008, provided a foundation for ongoing collaboration between NIOSH/NPPTL and the SNS.

In 2015 a robust research study was initiated which evaluated stockpiled respirators and gowns in facilities throughout the country, and led NPPTL to publish a series of 11 PPE Conformity Assessment Evaluation Reports on the performance of respirators samples following long-term storage.[12] These NIOSH/NPPTL assessments evaluated 3,971 FFRs (11 models of N95s and one P95 manufactured between 2003 and 2013) from 10 stockpiling facilities that had exceeded their manufacturer-designated shelf life and found that 98% of devices tested maintained their filtration efficiency and inhalation and exhalation resistance per NIOSH standards.[13] The resulting reports have served as the basis for the SNS release of millions of stockpiled respirators beyond their manufacturers' designated shelf life early in the COVID-19 response when respirators were in short supply.

In addition to these assessments, NPPTL's efforts expanded in 2020 during the COVID-19 pandemic in response to shortages in respiratory protective devices, specifically FFRs, and led to abbreviated evaluations by NIOSH/NPPTL of the performance of filtering facepiece respirators that had exceeded their manufacturer-designated shelf life to determine whether these devices were fit for use or other purposes, like training. These abbreviated assessments were posted on the NPPTL website to inform decision making regarding the utility of these respirators.[14]

Lastly, in addition to expanding the availability of potentially lifesaving supplies to the nation's workforce, these studies represent a critical step in understanding how storage conditions and shelf life impact performance, as well as providing valuable data for future modifications to the national stockpiling strategy and the collection of useful information for manufacturers to improve the quality and design of their products.

Improving Conformity Assessment

CATALYST

Tens of millions of workers across the nation rely on PPE to perform their work safely and avoid unnecessary injury, illness, and even death. Therefore, it is essential to ensure that these devices provide the expected level of protection through the conformity assessment process. While the pace of technological development of PPE can be slowed by the necessity of developing and implementing performance standards and conformity assessment processes, this process offers a valuable safeguard against the introduction of new and untested products or technologies that may ultimately increase risk to the user. Conformity assessment has been a major theme of the committee's work since its formation in 2005. These early meetings addressed harmonization of standards and strategies to avoid duplication within the United States and abroad and the importance of user input in the conformity assessment process. Over the years these discussions have served as the basis for consensus studies and workshops related to issues of conformity assessment and to support NIOSH/NPPTL in implementing recommendations from these reports.

"When you purchase a product, you expect it to work. Construction workers on high-rise buildings need to be confident that their safety harnesses will arrest a fall. Firefighters need to know that their gloves and other protective equipment can withstand high temperatures. Healthcare workers administering highly toxic chemotherapy agents need to know that their gloves will withstand penetration. For personal protective technologies (PPT)—where the major purpose of the product is to protect the wearer against a hazard—a deficit in product effectiveness can mean injury, illness, or death."

Certifying Personal ProtectiveTechnologies: Improving Worker Safety, 2011, p. 1

RELEVANT REPORTS

The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health (2008 consensus study)

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)

Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users (2007 consensus study)

Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)

The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary (2015 workshop proceedings)

Developing a Performance Standard for Combination Unit Respirators: Workshop in Brief (2015 workshop proceedings)

Integration of FDA and NIOSH Processes to Evaluate RPDs for Healthcare Workers (2017 Workshop Proceedings)

Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses: Proceedings of a Workshop (2021 workshop proceedings

AFFILIATED CONSENSUS STUDY AND WORKSHOP PLANNING COMMITTEE WORK

Multiple COPPE-affiliated reports, which developed from standing committee discussions, have either directly focused on or made recommendations relevant to improvements to the conformity assessment process for personal protective technologies in the United States.

"The degree of potential risk to the user from the failure of a PPT product during use in a specific task should determine the rigor of the conformity assessment process, particularly decisions regarding whether the process calls for first-, second-, or third-party declaration of conformity. The potential risk is a function of the probability of product failure and the impact on user health and safety due to the failure, assuming proper use of the product."

Certifying Personal Protective Technologies: Improving Worker Safety, 2011, p. 6

The 2008 review of the NIOSH Personal Protective Technology Program, which served as the catalyst for the *Certifying Personal Protective Technology* consensus study report in 2011, highlighted persistent "gaps and inconsistencies in the certification and other conformity assessment processes for non-respirator personal protective technology." The subsequent 2011 report similarly noted that the conformity assessment landscape was highly fragmented and required the involvement of multiple organizations and federal agencies, which allows for differences in the rigor of product testing, variations in how independent third parties are involved, and inconsistencies in requirements for manufacturing. Most importantly, these reports led to consensus around the need for NIOSH/NPPTL to develop a comprehensive, risk-based approach to personal protective technology conformity assessment for the nation and to further their engagement in consensus standards development.

COPPE-affiliated workshops focused on specific types of respiratory protection, including PAPRs, N95 FFRs, and combination unit respirators, have also touched on conformity assessment issues and have supported or spurred the development of new standards and interagency agreements to streamline certifications. In addition to these activities, COPPE itself has regularly served as a forum to hear from both the end user and from manufacturers as a mechanism for gathering input to inform updates to standards on PPE design and function in a manner that meets the specific needs of these parties.

Additionally, growing interest and pressure on NIOSH/NPPTL to address emerging concerns regarding respiratory health for underserved user groups, such as workers working outside of RPPs, as well as use of respiratory protection by the general public, led to a 2020 workshop, *Current Issues in the Assessment of Respiratory Protective Devices: Nontraditional Workers and Public Use*. This workshop examined the needs related to respiratory protection for these underserved groups and the current conformity assessment landscape for respiratory protective devices approved by NIOSH, as well as the emerging market for commercial facemasks. An ongoing consensus study on this same topic was sponsored by NIOSH and others and will be published in early 2022.

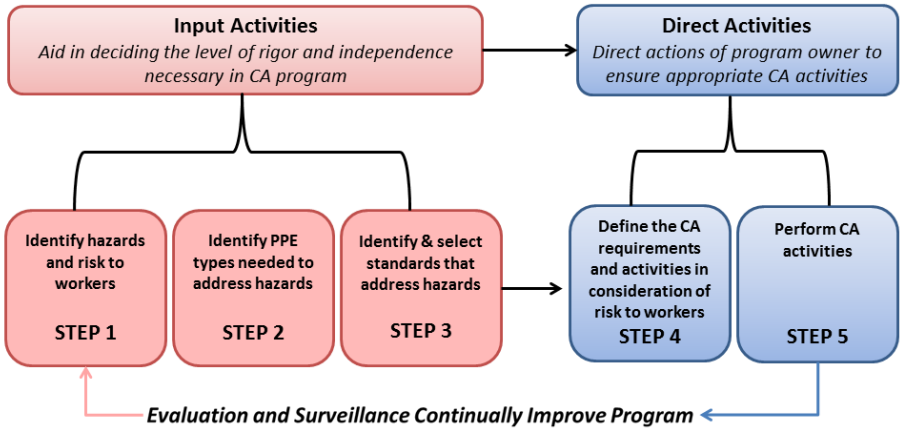


Figure 2. PPE CA Framework

KEY RECOMMENDATIONS

Implement and Sustain a Comprehensive National Personal Protective Technology Program

NIOSH should work to ensure the implementation of the 2001 Congressional mandate for a comprehensive state-of-the-art federal program focused on personal protective technology. A comprehensive program would build on the current NIOSH PPT Program and would bring unified responsibility and oversight to all PPT-related activity at NIOSH.

The Personal Protective Technology Program at NIOSH (2008 consensus study)

Develop and Implement Risk-Based Conformity Assessment Processes for Non-Respirator PPT

The National Institute for Occupational Safety and Health (NIOSH) should work with other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop, implement, and support conformity assessment processes for non-respirator PPT. These conformity assessment processes should be commensurate with the level of risk of injury, illness, or death that could result from failure of the PPT to protect the user from workplace hazards. NIOSH's National Personal Protective Technology Laboratory (NPPTL) should serve in a leadership role and convene other relevant government agencies, certifying and accrediting organizations, manufacturers, and end users to develop and implement a comprehensive, tiered risk-based framework for the classification and conformity assessment of PPT products for specific applications. This framework should be based on the degree of risk to the safety and health of the user and other factors affecting the feasibility of implementing the proposed conformity assessment processes.

Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)

Enhance Research, Standards Development, and Communication

NIOSH NPPTL should continue and expand its role in PPT conformity assessment. Specifically, NPPTL should

- Continue its involvement in standards-setting processes and committees and facilitate end-user participation in voluntary consensus performance-based standards;
- Expand research efforts on non-respirator PPT (based on risk assessment and opportunities) to include further efforts to establish standards and to develop test methods;
- Develop and maintain an online resource (available through a website and other sources) that provides access to listings of all non-respirator PPT products that meet third-party conformity assessment requirements;
- Expand its role and become the primary clearinghouse for reliable information on non-respirator PPT;
- Fund research and support standards development necessary to test and certify protective ensembles, develop criteria for standardized interfaces, and flag non-conforming ensemble components; and
- Expand its efforts in influenza pandemic-related research and conformity assessment for infection control ensembles.

Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)

Coordinate Efforts and Expand Resources for Research and Approval of PPE

Congress should expand the resources provided to NIOSH to further research efforts on the next generation of PPE and to coordinate and expedite the approval of effective PPE. Efforts to coordinate PPE testing, certification, and approval across all relevant federal agencies should include developing evidence-based performance standards for all types of PPE for healthcare workers.

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)

SIGNIFICANT IMPACTS

Influencing Policies and Programs and Inspiring New Ideas That Shape the Field

National Framework for Personal Protective Technology Conformity Assessment

The National Framework for PPT Conformity Assessment[15] provides the industry with a comprehensive, risk-based approach to conformity assessment that serves as a reference for standards development organizations and provides confidence to users.

The concept for this framework evolved from two COPPE-affiliated consensus study reports. The first, a 2008 review of the NIOSH PPT Program, recommended the development of a comprehensive National PPT program to provide coordinated oversight of all PPT to improve protections for workers through collaborations with other government agencies and industry stakeholders. The related 2011 consensus study report *Certifying Personal Protective Technologies: Improving Worker Safety* expanded on this concept, recommending that NIOSH/NPPTL develop a comprehensive risk-based conformity assessment program for all nonrespiratory PPE and serve in a leadership role as the convener and implementer of relevant agencies, certifying organizations, manufacturers, and end users.

NIOSH/NPPTL acted quickly in responding to these recommendations and in 2011 formed the Personal Protective Equipment Conformity Assessment Working Group, comprised of representatives from more than 30 public and private organizations—many of which were contacts established through the activities of the 2011 consensus study committee—to frame and then draft the final framework document. This document serves as a foundation to structure the conformity assessment process for PPT based on the risk associated with the failure of a product—high, medium, or low risk—while allowing for the integration of activities that can be tailored to the needs of end users, PPE manufacturers, and regulatory bodies.

PPE-Info Database

The PPE-Info database[16] serves as a national compendium of information about PPE regulations, standards, and products. The concept for this tool originated in recommendations from the 2011 report *Certifying Personal Protective Technologies: Improving Worker Safety* for a unified information source that allows organizations, manufacturers, suppliers, purchasers, and occupational users to search and find PPE products that meet standards for specific occupations and exposures of concern. PPE-Info[17] was launched as a public website in 2012. During the 2014 Ebola epidemic, the platform was updated to include a PPE selection tool for possible Ebola exposure. This success demonstrated the value of expanding to other occupational hazards and a longer-term vision for the database. In 2018, efforts were undertaken by NIOSH/NPPTL to expand PPE-Info to include products that provide protection against occupational exposure to fentanyl and its analogues, primarily focused on first responders at risk of fentanyl exposure while responding to emergencies or conducting operations. This included a *Federal Register* notice announcing opportunities for manufacturers to participate by including their products in the database as protection against fentanyl exposure.[18] Additionally, in August 2021, PPE-Info was expanded to include a listing of barrier face coverings complying with the ASTM F3502-21 standard to meet the needs of the general public and workers using source control devices.

NIOSH-FDA Memorandum of Understanding 225-18-006

A 2018 interagency memorandum of understanding between FDA and NIOSH/NPPTL[19] provided a mechanism for coordinating the regulation of surgical N95 respirators and N95 FFRs for use in health care settings. This agreement simplified the previously burdensome approval and clearance process for N95 respirators by laying out a coordinated process to harmonize the regulatory activities of each agency as they relate to these respirators. These efforts provide greater clarity around what regulatory requirements need to be satisfied as part of the approval process and to reduce burdens on manufacturers.

These burdensome processes resulted from overlapping regulatory responsibilities of FDA and NIOSH/NPPTL for the evaluation of respirators for health care workers. All respirators used in workplaces are approved by NIOSH/NPPTL and must meet the standard listed in 42 CFR Part 84. However, a subcategory of N95 FFRs, surgical N95 respirators, prior to the 2018 MOU also received clearance via an FDA process. This overlap in oversight with regard to this subcategory of N95 respirators resulted in burdensome efforts for manufacturers and general confusion within the marketplace on what products require the approval of which agency. Discussions between FDA and NIOSH/NPPTL and separate discussions within COPPE led to a 2017 National Academies workshop on the integration of FDA-NIOSH/NPPTL processes used to evaluate respiratory protective devices for health care workers, specifically N95 FFRs. This workshop brought multiple different stakeholders—federal agencies, policy makers, manufacturers, distributors, health care professionals, and researchers—to the table to provide input on potential steps to integrate agency processes and the strengths and weaknesses of different test methods for N95 respirators. The workshop brought about the necessary visibility on the issue to achieve broad stakeholder support for harmonization and an agreement by NIOSH/NPPTL and FDA on the technical components of the MOU. The MOU streamlined the burdensome processes by permitting these products to be approved by NIOSH rather than having to complete separate processes for NIOSH and FDA to achieve the surgical N95 approval. Now, FDA review is needed only when products achieve particular thresholds, as described in the MOU.

Voluntary Consensus Standards Development

NIOSH/NPPTL has taken an increasingly active role in the development of voluntary consensus standards to more rapidly and effectively meet the needs of users outside of the rule-making process in accordance with the National Technology Transfer and Advancement Act.[20] The consensus standard process provides an opportunity to react more quickly to changing industry needs, as described in Office of Management and Budget Circular A-119.[21] The 2011 National Academies consensus study report *Certifying Personal Protective Technologies: Improving Worker Safety* strongly recommended that, while NIOSH/NPPTL is already involved with voluntary consensus standards development for PPT, these activities should be encouraged to promote greater involvement of the end user in the standards-setting process. This early engagement of diverse stakeholders as part of a consensus standard development process is important given the complexity of the needs of end users. Since the publication of this report, NIOSH/NPPTL has participated with varying degrees of involvement in the development of multiple consensus standards for PPE. Select examples include the following:

- *ASTM F3050 (2017) – Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment.*[22] This standard defines conformity assessment, as described by the National Framework for PPE Conformity Assessment and recommended by the 2011 National Academies report on certifying PPT, as a means to manage risk to the user from nonconforming PPE.

- *NFPA 1987* (Proposed) – *Standard Combination Unit Respirator Systems for Tactical and Technical Operations.*[23] This proposed standard was informed by discussions from the 2014 COPPE-affiliated National Academies workshop on the development of a performance standard for combination unit respirators, which supported the long-term efforts of NIOSH/NPPTL to address regulatory limitations for these devices. This consensus standard will address NIOSH/NPPTL regulatory restrictions on the certification of respirators with more than one assigned protection factor and classification by the respirator type with the least amount of protection.

- *ASTM F3407 (2020) – Standard Test Method for Respirator Fit Capability.*[24] Early support for this standard grew from recommendations in the 2006 report *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users* related to enhancing the fit of respirators for a diverse population of users. However, efforts to go through the rule-making process met with challenges and discussions with COPPE and staff

from the National Institute for Standards and Technology provided an alternative route through a consensus standards process.

- *ASTM F3502 (2021) – Standard Specification of Barrier Face Coverings.*[25] This standard provides assurance that face coverings worn as a means of source control meet established requirements, as well as offering the wearer a known degree of particulate filtration. Although not directly called for by National Academies report recommendations or by the work of COPPE, this standard represents an example of NIOSH/NPPTL taking the lead in the voluntary consensus standards process to meet a clear need in the marketplace.

- *ASTM F3352 (2019) – Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities.*[26] This standard specification establishes minimum requirements for the performance and labeling of isolation gowns intended for use by health care workers to provide protection for standard and transmission-based precautions. The intended use of this specification is to ensure the performance properties of isolation gowns for the protection of the wearer. Efforts to develop such a standard grew from committee recommendations related to defining evidence-based performance requirements. NIOSH/NPPTL led the development of this standard and the listed minimum requirements are based on NIOSH/NPPTL research findings.

- *ASTM F2407 (2020) – Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities.*[27] This specification establishes the minimum requirements for the performance, documentation, and labeling of surgical gowns used in health care facilities. As with the development of ASTM F3352, NIOSH/NPPTL led the development process and NIOSH/NPPTL research findings were used to define the minimum requirements listed in the standard.

PAPR100 Class of Respirators

In April 2020, the Department of Health and Human Services announced the development of an interim final rule, culminating nearly two decades of work by NIOSH/NPPTL, which creates a new class of PAPRs that better meets the needs of workers in the health care and the public safety sectors.[28] The creation of this PAPR100 class of respirators was supported by work from prior National Academies consensus study reports and a 2014 public workshop on PAPRs, which provided a forum for discussion for key stakeholders about priorities for updating performance requirements for PAPRs used by the health care workforce. These workshop discussions indicated that current PAPR performance requirements do not meet the needs of health care workers and described attributes that should be incorporated into future PAPR designs to enhance their utility. The improved PAPR concept was also reviewed at a 2019 meeting of COPPE. While PAPRs are already widely used in these occupational contexts during work with chemical hazards, bloodborne pathogens, and aerosol transmissible diseases, the bulkiness and weight of these devices, which were designed for use in the industrial environment, limits their wider adoption. The PAPR100 rule replaces silica dust testing with aerosol testing, thus allowing manufacturers to reduce the size of the PAPR battery and create devices smaller and lighter in design.

In addition to clearing a path to market for these improved devices, NIOSH/NPPTL predicts that the creation of a PAPR100 class of respirators could address

pressure points across the health care system including reducing strain on supplies of disposable N95 FFRs during pandemics, decreasing the need for fit-testing requirements, and expanding the number of potential users who can don and wear the device with ease.

Improvements to the Respirator Approval Program

NIOSH/NPPTL is responsible for respirator certification in the United States[29] and carries out this certification via the Respirator Approval Program. Through this program, NIOSH/NPPTL carries out respirator quality assurance and engineering review, testing, and postmarket activities with the goal of ensuring that high-quality respirators are available to the worker population to prevent exposure to dangerous respiratory hazards. Over the years COPPE and its related activities, such as the 2008 consensus study report *The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health*, have provided input on the components of this approval process. Suggested changes have included increasing efficiencies within the program in relation to the revision of regulations and fees, provision of postmarket notifications, recall procedures by manufacturers, methodologies for product and site auditing, and the dissemination of testing results. This input, in addition to that of independent reviewers and manufacturers, and analysis by NIOSH/NPPTL staff, informed a set of priority actions to be undertaken to improve the Respirator Approval Program. Some early successes include efforts to improve communication of routine and nonroutine information to Respirator Approval Program applicants. These updated communication mechanisms include Assessment Notices—letters announcing new approval requirements, policies, and public meetings (six published since 2018), Conformity Assessment Letters to Manufacturers,[30] and other guidance information for users and others. In addition to these improved communication mechanisms, adjustments to improve efficiencies have been made to the Standard Applications Form, the Certified Equipment List, and to the Respirator Approval Program website.

Assessments of Third-Party Laboratories

In 2020, NPPTL issued a contract to three third-party laboratories in an effort to assess the utility of using third-party laboratories to support both preapproval and postmarket activities. This effort is aligned with a recommendation from the 2011 consensus study report *Certifying Personal Protective Technologies: Improving Worker Safety* to NIOSH/NPPTL to expand its role in PPT conformity assessment. Exploration of the utility of third-party laboratories in the respirator process is one step toward this potential expansion.

Guiding Personal Protective Technology Research

CATALYST

Ensuring worker safety and health requires continuous research, evaluation, and action as worker needs, technology, and hazards are constantly evolving. Since its founding, the objective nature and expertise of COPPE and its affiliated activities has allowed for regular assessments of the research landscape to understand where incremental progress has been made and to lay out valuable research and policy directions for the future.

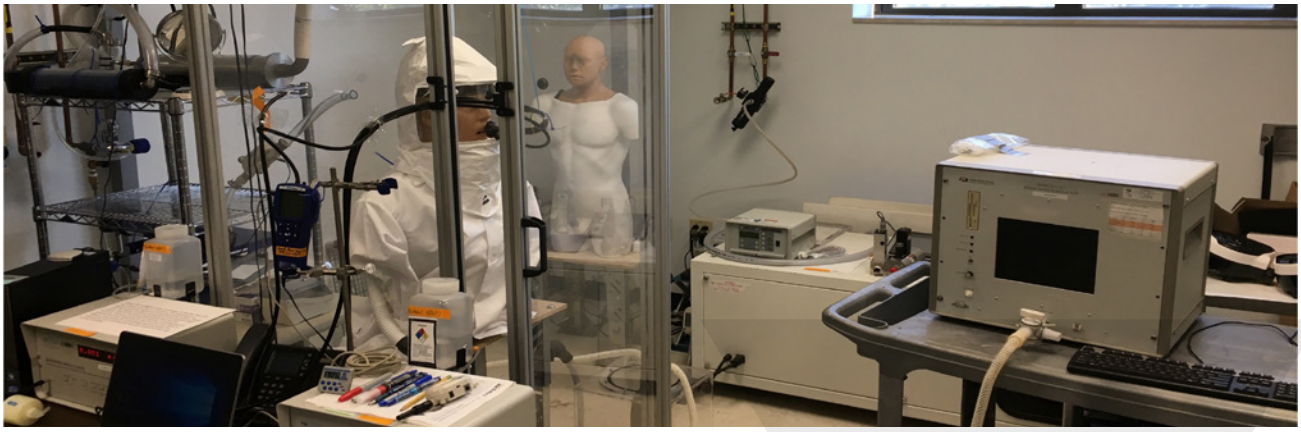
> "Having effective respiratory protection can be, and often is, a matter of life and death. Yet the scientific bases for developing and fitting effective respiratory protection remain more art than science."
>
> *Assessment of NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users, 2007, p. xi*

AFFILIATED CONSENSUS STUDY AND WORKSHOP PLANNING COMMITTEE WORK

Nearly all COPPE-affiliated National Academies reports identify research gaps to be addressed; however, the scope of these research- and policy-related conclusions and recommendations varies by report. Some pinpoint targeted research questions or policy changes while others have outlined broader research needs requiring the creation of a new body of literature or modifications to NIOSH/NPPTL's portfolio of work on personal protective technologies.

RELEVANT REPORTS

- Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006 consensus study)
- Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users (2007 consensus study)
- Measuring Respirator Use in the Workplace (2007 consensus study)
- Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)
- The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health (2008 consensus study)
- Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report (2009 letter report)
- Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2011 consensus study)
- Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)
- Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)



For example, some of the earliest COPPE-affiliated reports, such as the 2007 consensus study report *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users*, the 2007 consensus study report *Measuring Respirator Use in the Workplace*, and the 2008 consensus study report *The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health,* provided critical reviews of programs to inform the long-term direction of NIOSH/NPPTL research. Other reports identified targeted research gaps, such as the series of health care worker reports that called for further research on the mechanisms of influenza transmission and the effectiveness of FFRs against aerosol transmissible diseases.

Other identified research gaps called out in National Academies reports include the need for investigation into the role of human factors and behavioral characteristics in how PPE is used in the field; research on device engineering considerations, such as fit and filtration efficiency; efforts to design and develop next generation PPE; and real-world assessments of implementation and practice. Together these research-oriented recommendations describe the pursuit of science-based understanding of PPE for the nation's workforce.

"One of the greatest challenges to PPT effectiveness is ensuring that the worker is wearing the equipment and is wearing it correctly. Understanding that comfort is fundamentally a safety issue is a necessary prerequisite to improvement of the materials, design, and engineering of PPT in such a way that critically important human factors are taken into account."

The Personal Protective Technology Program at NIOSH, 2008, p. 16

KEY RECOMMENDATIONS

Develop Ongoing Surveys of PPE Use in the United States	NPPTL should develop for implementation an ongoing survey of employer and employees whose overarching goal is to obtain needed information on the use of respirators and other PPE in the United States. *Measuring Respirator Use in the Workplace (2007 consensus study)*
Establish PPT Research Centers of Excellence and Increase Extramural PPT Research	The PPT Program should establish and sustain extramural PPT centers of excellence and work to increase other extramural research opportunities. The PPT Program should ▶ Develop and support research centers of excellence that work closely with the NIOSH intramural research program to improve PPT, increase field research, and explore and implement research to practice interventions; and ▶ Work with the NIOSH Office of Extramural Programs to increase other research opportunities and enhance collaboration and awareness of relevant PPT research efforts among intramural and extramural researchers. *The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health (2008 consensus study)*
Increase Research on the Design and Engineering of the Next Generation of PPE	NIOSH, the Department of Homeland Security, the Department of Defense, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of respirators, gowns, gloves, and eye protection for healthcare workers that would enhance their safety and comfort. *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)*
Develop and Implement a Comprehensive Research Strategy to Understand Viral Respiratory Disease Transmission	The National Institutes of Health, in collaboration with other research agencies and organizations, should develop and fund a comprehensive research strategy to improve the understanding of viral respiratory disease transmission, including, but not limited to, examining the characteristics of influenza transmission, animal models, human challenge studies, and intervention trials. This strategy should include 1) an expedited mechanism for funding these types of studies and 2) clinical research centers of excellence for studying influenza and other respiratory virus transmission. *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2011 consensus study)*

SIGNIFICANT IMPACTS

Influencing Policies and Programs and Inspiring New Ideas That Shape the Field

Informing the NIOSH/NPPTL Research Roadmap – Respirator Use Surveillance

Guidance and support in the form of COPPE meeting discussions and consensus study report recommendations have long served as the foundation for NIOSH/NPPTL research and activities in multiple areas. One of the first National Academies reports related to the work of COPPE was the 2007 consensus study report *Measuring Respirator Use in the Workplace*, which continues to have an impact on the direction of research at NIOSH/NPPTL.

The concept for this report grew from discussions between NIOSH/NPPTL and the (then) IOM on opportunities to partner to catalyze action around the 2001 NIOSH and Bureau of Labor Statistics (BLS) survey of respirator use and practices in the United States, which provided valuable information about the complex landscape of use of such devices in occupational settings. The 2007 report reviewed this joint NIOSH-BLS effort and determined that this surveillance of respirator use, using information provided directly by employers and employees in the context of the work setting, addressed an important function and recommended that these surveillance efforts continue as sources of evaluation and input for the respirator approval program. Twenty years later, this National Academies review is now informing the approach for a follow-on NIOSH-BLS survey. This upcoming survey will provide an important update on current respirator use in the nation, which has likely changed dramatically over the past two decades, and will help to identify priorities for the NIOSH/NPPTL research agenda and guide policy into the future.

Informing the NIOSH/NPPTL Research Roadmap – Centers of Excellence

Another early COPPE-affiliated report, a 2008 review by the National Academies of the PPT Program at NIOSH, provided recommendations about the relevance and impact of the research program on occupational safety and health and on the future direction of the program. This committee found that the PPT Program had made significant contributions to worker safety and health, despite limited resources that prevented the program from expanding its work across all PPT and occupations. In its recommendations, the committee urged the establishment of PPT Research Centers of Excellence that would complement the work of the NIOSH/NPPTL intramural research program by increasing field and implementation research. This approach, a proven model for interdisciplinary collaboration, would bring to the table both greater breadth and depth of expertise, particularly in the transition of research from the laboratory to the workplace while reducing duplicative research efforts. The committee proposed that these centers could be topic or sector specific and include university research centers, nonprofit organizations, federal agencies, and state health and labor departments, among others.

Since 2008, NIOSH/NPPTL has sought to implement this recommendation, but the realization of this recommendation has been stymied by lack of funding. However, driven by rapid changes in PPE use during the COVID-19 pandemic, the need for the Centers of Excellence model is more critical than ever and has prompted NIOSH/NPPTL to push forward with plans to design and execute this mission with the hope that institutional readiness will indicate to funders the need for swift action and save time in implementation. These early efforts will allow for public input, identification of key partners and site candidates, and the justification for funding. The proposed structure revolves around defined PPT topic areas, distilled from interviews and literature reviews, with a structure for core components and a plan for administration.

Informing the NIOSH/NPPTL Research Roadmap – Significant Research Areas

National Academies consensus study report recommendations and input from COPPE on critical research needs range across the PPE life cycle, from laboratory-based, material science research to best practices for respirator decontamination and disposal in the field. Examples of intramural and extramural research supported by NIOSH/NPPTL and related to study recommendations and COPPE discussions are highlighted below.

REUSABLE RESPIRATORY PROTECTION DEVICES: Multiple COPPE discussions and NIOSH/NPPTL stakeholder meetings included discussion of the urgent need for information about the feasibility of using reusable respirators and the need to develop standardized procedures for elastomeric respirator use that could be implemented rapidly in scenarios of extreme respirator shortages. These concepts were echoed in consensus study report recommendations, including in the 2006 consensus study report *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu*, the 2008 consensus study report *Preparing for an Influenza Pandemic: PPE for Healthcare Workers*, and the 2019 consensus study report *Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use.* Following from these discussion and recommendations, several impactful research studies have been published that have served as a foundation for guidance development during the COVID-19 pandemic and reduced reliance on single-use N95 FFRs. This foundational work includes the following:

- FDA-funded research on methods for the decontamination and reuse of respiratory protection devices, including UV decontamination of N95 FFRs and reprocessing of elastomeric respirators and PAPRs. This work, conducted by Applied Research Associates and published in 2019,[31] provided data to support CDC guidance on reuse of elastomeric respirators and PAPRs during the COVID-19 pandemic.[32]
- Earlier FDA-funded research carried out by Applied Research Associates on reprocessing methods for elastomeric respirators and PAPRs exposed to influenza resulted in a 2017 publication by Lawrence et al.,[33] which provided data to support CDC guidance on use of elastomeric respirators and PAPRs during the COVID-19 pandemic.
- A 2015 feasibility study by Bessesen et al.[34] on the disinfection of reusable elastomeric respirators, which was supported by the Department of Veterans Affairs (VA), assessed methods for reprocessing three stockpiled models of elastomeric respirators for use by VA staff. This research provided data to support the CDC guidance on elastomeric respirators published during the COVID-19 pandemic.
- A 2013 report led by Ciconte and Danyluk[35] and supported by WorkSafeBC assessed the feasibility of using reusable elastomeric respirators in health care departments with high levels of N95 respirator use during public health emergencies.

INFLUENZA AND AEROSOL DISEASE TRANSMISSION: Following the 2009 Letter Report *Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza* and similar recommendations from earlier reports, CDC's Extramural Research Program Office for infectious diseases called for proposals for research on modes of influenza transmission that would assist in the development of guidelines for infection prevention and control. Some of the research conducted in response to these recommendations included an open funding opportunity (RFA-IP-11-001), which was created in 2011 and resulted in the publication of several studies related to modes of influenza transmission. Examples of this research include the following:

- Lindsley, W.G., W.P. King, R.E. Thewlis, J.S. Reynolds, K. Panday, G. Cao, and J.V. Szalajda. 2012. Dispersion and exposure to a cough-generated aerosol in a simulated medical examination room. *Journal of Occupational and Environmental Hygiene* 9(12):681-690.
- Lindsley, W.G., J.D. Noti, F.M. Blachere, J.V. Szalajda, and D.H. Beezhold. 2014. Efficacy of face shields against cough aerosol droplets from a cough simulator. *Journal of Occupational and Environmental Hygiene* 11(8)509-518.

- Noti, J.D., W.G. Lindsley, F.M. Blachere, G. Cao, M.L. Kashon, R.E. Thewlis, C.M. McMillen, W.P. King, J.V. Szalajda, and D.H. Beezhold. 2012. Detection of infectious influenza virus in cough aerosols generated in a simulated patient examination room. *Clinical Infectious Diseases* 54(11):1569-1577.
- Noti, J.D., F.M. Blachere, C.M. McMillen, W.G. Lindsley, M.L. Kashon, D.R. Slaughter, and D.H. Beezhold. 2013. High humidity leads to loss of infectious influenza virus from simulated coughs. *PLoS One* 8(2):e57485

COMFORT AND TOLERABILITY OF RESPIRATORY PROTECTIVE DEVICES: Several National Academies publications call for research related to the use of respiratory protective devices by health care workers and other workers using respiratory protection outside of an industrial setting, including the 2008 consensus study report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*. This includes research on physiological and subjective responses of users, including workers with underlying health conditions, during respirator use to assess whether these devices are suitable and safe for their intended use. Examples of this research include the following:

- Coca, A., T. Dileo, J.H. Kim, R. Roberge, and R. Shaffer. 2015. Physiological and subjective evaluation of PPE using a sweating thermal manikin. *Extreme Physiology and Medicine* 4:A27.
- Kim, J.-H., T. Wu, J. B. Powell, and R. J. Roberge. 2016. Physiologic and fit factor profiles of N95 and P100 filtering facepiece respirators for use in hot, humid environments. *American Journal of Infection Control* 44(2):194-198.
- Roberge, R.J., J.-H. Kim, and S. Benson. 2012. N95 filtering facepiece respirator deadspace temperature and humidity. *Journal of Occupational and Environmental Hygiene* 9(3):166-171.
- Roberge, R.J., J.-H. Kim, and J.B. Powell. 2014. N95 respirator use during advanced pregnancy. *American Journal of Infection Control* 42(10):1097-1100.
- Williams, W.J., A. Coca, J.-H. Kim, and R. Roberge. 2014. Repeatability of physiological responses during two repeated protective clothing performance tests under identical test conditions. *International Journal of Industrial Ergonomics* 44(5):793-799.

USER COMPLIANCE AND PRACTICE: Multiple reports have pointed to the dearth of data on user compliance and practice across different user populations and job functions in the health care setting. These data are critical to understanding the gaps to be addressed during implementation to ensure compliance and for identifying the guidance and tools these user populations need to support effective use in the context of a RPP. Following the recommendations on approaches for assessing respirator use in the 2007 consensus study report *Measuring Respirator Use in the Workplace,* NIOSH/NPPTL has supported a number of studies in this area. A selection of these studies includes the following:

- Beckman, S., B. Materna, S. Goldmacher, J. Zipprich, M. D'Alessandro, D. Novak, and R. Harrison. 2013. Evaluation of respiratory protection programs and practices in California hospitals during the 2009-2010 H1N1 influenza pandemic. *American Journal of Infection Control* 41(11):1024-1031.
- Brosseau, L.M., L.M. Conroy, M. Sietsema, K. Cline, and K. Durski. 2014. Evaluation of Minnesota and Illinois hospital respiratory protection programs and health care worker respirator use. *Journal of Occupational and Environmental Hygiene* 12(1):1-15.
- Burgel, B.J., D.A. Novak, H.E. Carpenter, M. Gruden, A.M. Lachat, and D. Taormina. 2014. Occupational Health Nurses' Achievement of Competence and Comfort in Respiratory Protection and Preferred Learning Methods: Results of a nationwide survey. *Workplace Safety and Health* (62)2:56-68.
- Hines, L., E. Rees, and N. Pavelchak. 2014. Respiratory protection policies and practice among the health care workforce exposed to influenza in New York State: Evaluating emergency preparedness for the next pandemic. *American Journal of Infection Control* 42(3):240-245.
- Peterson, K., B.M.E. Roger, L.M. Brosseau, J. Payne, J. Cooney, L. Joe, and D. Novak. 2016. Differences in hospital managers', unit managers', and health care workers' perceptions of the safety climate for respiratory protection. *Workplace Health and Safety* 64(7):326-336.

These studies have been used by NIOSH/NPPTL to identify gap areas to be addressed via the development of educational materials and trainings, including the Hospital Respiratory Protection Toolkit (see section on Protecting Health Care Workers) and training modules for occupational health nurses (see section on Creating a Culture of Safety through Workplace Education and Training).

INTERFACE AND INTEROPERABILITY RESEARCH: The 2011 consensus study report *Certifying Personal Protective Technology: Improving Worker Safety* emphasized the need for further research on PPT interfaces and related issues. This includes research to quantify leakage at the glove–gown interface in simulated clinical settings and the development of methods for testing leakage, which could be used to develop a standard test to evaluate the performance of improved glove and gown designs. NIOSH/NPPTL has conducted and funded a body of research in this area. Some examples include the following:

- Kahveci, Z., F.S. Kilinc-Balci, and P.L. Yorio. 2019. Critical investigation of glove–gown interface barrier performance in simulated surgical settings. *Journal of Occupational and Environmental Hygiene* 16(7):1-9.
- Kahveci, Z., F.S. Kilinc-Balci, and P.L. Yorio. 2021. A simulation study to assess fluid leakage through the glove-gown interface in isolation settings. *American Journal of Infection Control.* In press.
- Kilinc-Balci, F.S., Z. Kahveci, and P.L. Yorio. 2018. Novel test method for the evaluation of fluid leakage at the glove-gown interface and investigation of test parameters. *Journal of the American College of Surgeons* 227(6):573-586.

Creating a Culture of Safety Through Workforce Education and Training

CATALYST

Ensuring worker protection requires more than the provision of efficacious PPE; it requires all of the components of the broader system, including worker education and training, to function simultaneously to support safety in practice. Interest in safety culture and worker education and training, in particular, grew from early COPPE discussions on PPE use by health care workers. These discussions and a resulting series of consensus and letter reports demonstrated the need for a greater focus on comprehensive education and training for PPE users to ensure compliance with correct use practices and the deliberate actions by leadership at all organizational levels to champion these efforts.

> "A stronger understanding of the current respiratory protection roles and responsibilities of OHNs in their workplaces is needed to improve respiratory protection curricula and the teaching methods used in education and training."
>
> *Occupational Health Nurses and Respiratory Protection: Improving Education and Training: Letter Report, 2011, p. 17*

AFFILIATED CONSENSUS STUDY AND WORKSHOP PLANNING COMMITTEE WORK

COPPE-affiliated reports have emphasized the critical role that safety culture plays in creating an environment that supports compliance with PPE use practices and have called for support for dedicated training for health care workers. These reports note the importance of occupational health nurses (OHNs), who serve as educators, role models, and advocates, to achieve the necessary competencies in respiratory protection to ensure workplace

RELEVANT REPORTS

- Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)
- Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report (2009 letter report)
- Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2011 consensus study)
- Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)
- Occupational Health Nurses and Respiratory Protection: Improving Education and Training: Letter Report (2011 letter report)
- Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)

safety, as described in the 2008 consensus study report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers* and the 2011 letter report *Occupational Health Nurses and Respiratory Protection: Improving Education and Training*. This 2011 letter report directly addressed the needs of the OHN workforce by evaluating and identifying essential content on respiratory protection in occupational health nursing program curricula and best practices for teaching that content. This report concluded that essential content areas include both technical and behavioral components. The technical component encompasses the critical tasks of hazard assessment; selection, use, care, and maintenance of respirators; medical evaluation and monitoring; and fit testing. The behavioral component considers the need for merging technical components with strategies for effective behavioral change, and the role of leadership, and practices for building a culture of safety. Ultimately, these reports describe the need for respiratory protection training and education that includes not only *when* and *how* respiratory protection should be worn but also addresses *why* to more effectively convey the value of respiratory protection use in a health care setting and the importance of the integration of comprehensive respiratory protection education at all levels of nursing education.

"For employers, and society more broadly, reciprocity includes the responsibility to actively support healthcare workers by providing up-to-date training, equipment, communication measures, and other tools needed to effectively educate, protect, and communicate with workers as they perform their duties to ensure the lowest possible level of risk."

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers, 2008, p. 23

KEY RECOMMENDATIONS

Ensure Robust Respiratory Protection Programs and Training

The leadership of health care facilities, professional associations, professional schools (including continuing education programs), and accrediting and credentialing organizations (working in collaboration with the National Institute for Occupational Safety and Health and other parts of the Centers for Disease Control and Prevention [CDC], the Occupational Safety and Health Administration [OSHA], the Joint Commission, health care workers, and other relevant stakeholders) should ensure that ongoing education and training for robust respiratory protection programs, including on the use of elastomeric respirators for health care workers, are a high priority for health care workers, managers, and leaders; that compliance is actively monitored; and that respiratory protection is championed and financially well supported across the range of health care institutions and settings.

Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)

Identify and Disseminate Effective Leadership and Training Strategies and Other Interventions to Improve PPE Use

NIOSH and other relevant agencies and professional organizations should support intervention effectiveness research to assess strategies, including innovative participatory approaches to training, for health care and supervisory staff at all levels to improve PPE usage and other related outcomes across the range of health care settings.

Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2011 consensus study)

Expand Respiratory Protection Education Across All Levels of Nursing Education and Training

Nursing education programs across all levels, including licensed practical or vocational, diploma, associate, baccalaureate, and graduate levels, should

- Introduce the basic concepts of respiratory risk and protection early in the education and training programs and throughout the curriculum;
- Reinforce this knowledge when the students begin their clinical education and are fit tested for respirators;
- Require that their graduates have a working knowledge of key elements of respiratory protection at the appropriate level for their scope of practice; and
- Look to core curricula offered by occupational health nursing graduate and continuing education programs, including the NIOSH Education and Research Centers, for guidance on required knowledge and skills to educate nurses at appropriate levels for their scope of practice.

Occupational Health Nurses and Respiratory Protection: Improving Education and Training: Letter Report (2011 letter report)

Ensure Essential Respiratory Protection Content in Occupational Health Nursing Graduate Curricula, and Adapt and Apply It to Continuing Education Programs and to the Education and Training of All Nurses

Occupational health nursing educators—in collaboration with staff from other disciplines (e.g., industrial hygiene, occupational medicine, and engineering), NIOSH, the American Association of Occupational Health Nurses (AAOHN), and other expert sources—should ensure that essential respiratory protection content is included in graduate occupational health nursing programs and integrated into continuing education courses for OHNs.

Occupational Health Nurses and Respiratory Protection: Improving Education and Training: Letter Report (2011 letter report)

SIGNIFICANT IMPACTS

Influencing Policies and Programs and Inspiring New Ideas That Shape the Field

Respiratory Protection Program Training Program Modules

A partnership of health care professional associations developed an online tool on RPPs with resources to train and educate occupational health nurses on OSHA's Respiratory Protection Standard and the role of the Respiratory Protection Program Administrator. These efforts were spurred by recommendations from the 2011 consensus study report *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel* and the 2011 letter report *Occupational Health Nurses and Respiratory Protection: Improving Education and Training*. The 2011 consensus study report recommended that comprehensive education and training on respiratory protection for the occupational health nursing workforce be expanded across all levels of nursing education and incorporate essential core content into these programs and curricula.

Following the release of these reports, NIOSH/NPPTL distributed the publications to nursing stakeholders with the request to partner in addressing the recommendations, specifically on the development of educational materials for the nursing workforce. NIOSH/NPPTL and AAOHN collaborated to create a Respiratory Protection Advisory Group to address the report's recommendations. These initial efforts led to a collaboration between AAOHN, the Association of Occupational Health Professionals in Health Care (AOHP), the American Nurses Association, and others to develop 10 educational modules that continue to serve as a free online resource designed to train occupational health nurses who work as RPP administrators to meet the requirements of OSHA's Respiratory Protection Standard.[36] As of 2016, this 90-minute training had been completed by more than 700 participants and of these participants 32.6% currently lead their organization's RPP, 15.3% will lead a RPP in the near future, and 52% did not lead a program but indicated that the training was relevant to their work. The majority of participants in this training "strongly agreed" the course materials were applicable to their work and that the course enhanced their professional expertise.[37] These modules have since been required as mandatory professional education in some health systems, including a large health care system in southwestern Pennsylvania.

To complement this 10-module, continuing education program, AAOHN developed three "Case Studies in Respiratory Protection":

- Respiratory Protection in Healthcare: An Interactive Case Study for the Occupational Health Professional
- Respiratory Use in Emergency and IDLH Conditions: An Interactive Case Study for the Occupational Health Professional
- Elastomeric Respirator Use in Autobody Repair and Painting: An Interactive Case Study for the Occupational Health Professional

Additionally, AAOHN created a training program, "Respiratory Protection for Healthcare Workers and Respiratory Training for Ancillary Healthcare Workers," to provide health care organizations with content to train their workers who are required to wear respiratory protection as part of their job requirements.

Implementation Guides to Support Use of Elastomeric Half Mask Respirators in Health Care

In September 2020, NIOSH/NPPTL published a request for information regarding the deployment and use of elastomeric half-mask respirators in health care settings and EMS organizations during the COVID-19 crisis. The request sought to collect user experiences with elastomeric half-mask respirators, including information on acceptability and feasibility of implementation, to further inform updates to CDC practice guidelines and the Hospital Implementation Guides produced by NIOSH/NPPTL-funded researchers at the University of Maryland and Allegheny Health Network. Ultimately, these findings will inform improvements to the implementation of elastomeric half-mask respirator use during the next emerging public health threat, including worker training to enhance adherence and improve workplace safety.

The need for implementation research and the development of best practices to address gaps for elastomeric respirator use were called out in a 2019 consensus study report *Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use.* This report concluded that reusable elastomeric respirators could be a viable option for RPPs in both routine and surge use in health care when logistical and implementation challenges, including issues with health care worker education and training, are addressed. To develop solutions to address these gaps and assess strategies for implementing elastomeric respirator use in a health care setting, NIOSH/NPPTL provided funding to the University of Maryland and Allegheny Health Network for the creation of two implementation guides, which were published in September 2020. These implementation guides,[38] along with additional data on the feasibility of elastomeric respirator and PAPR use in a health care setting, supported the formulation of CDC guidance on the use of reusable respirators to address N95 FFR shortages and to protect the future supply of these devices during the COVID-19 pandemic and future public health emergencies.

Hospital Respiratory Protection Program Toolkit

As discussed above in the section on Protecting Health Care Workers, the 2015 Hospital Respiratory Protection Program Toolkit[39] was developed and published by NIOSH/NPPTL to support hospital administrators in implementing a RPP with the specific intention of preventing the transmission of aerosol transmissible diseases. The development of this toolkit grew from a collection of National Academies publications on the prevention of influenza transmission to the health care workforce and calls for action to cultivate a culture of safety at the organizational and individual levels in the clinical environment. It brings together, in one cohesive document, research and guidance from multiple sources to lay out the need for respiratory protection, explains approaches to reduce exposure, and describes types and considerations for respiratory protective devices, requirements of the OSHA respiratory protection standard, and elements of a RPP. The toolkit will be updated with lessons learned from the COVID-19 pandemic.

Other Interventions to Improve PPE Knowledge and Use

COPPE and its related activities have encouraged NIOSH/NPPTL, as the nation's trusted source of information about PPE, to expand their outreach efforts to address user knowledge gaps related to PPE use. NIOSH/NPPTL have responded to this call using a variety of different methods, including the development of multiple webpages, the publication of 15 fact sheets[40] on respiratory protection and other topics, and the creation of 21 infographics[41] to promote proper protection practices. Additionally, the NIOSH Science Blog is published several times annually as a method for disseminating updated respiratory protection information and providing valuable resources to respirator users and employers. Most recently, these resources have been critical to providing updated respiratory protection resources for the COVID-19 response. For example, NPPTL and its NIOSH and CDC partners developed a series of webpages with strategies for optimizing supplies of PPE,[42] including pages focused on N95 respirators, isolation gowns, facemasks, eye protection, gloves, elastomeric respirators, and powered air purifying respirators. Additionally, NIOSH/NPPTL has significantly expanded its capacity to respond directly to user inquiries about respiratory protection and other PPE concerns; prior to the onset of the COVID-19 pandemic, it responded to approximately 500 PPE inquiries annually, but since the emergence of SARS-CoV-2, that number has increased to more than 6,800 inquiries, including requests from international organizations for assistance.

EXAMPLES OF OTHER USES OF REPORTS FOR TRAINING OR EDUCATION OF THE WORKFORCE

- In July 2020, the Washington State Nurses Association used the highlights of the 2019 Reusable Elastomeric Respirators report as required reading for a continuing education course on elastomeric respirator and PAPR use during the COVID-19 pandemic.
- The New York State Nurses Association cited the Reusable Elastomeric Respirators report's recommendations in a guide advocating for the incorporation of reusable elastomeric respirators and PAPRs into clinical settings to reduce reliance on N95 filtering facepiece respirators.
- The AOHP developed a document as part of their OSHA Alliance, titled *Beyond Getting Started Series – Respiratory Protection in Healthcare Settings Web Reference Guide*. This document includes mentions of COPPE-affiliated reports, a reference to the AAOHN competencies, and a link to 10 training modules.
- The *Journal of the Association of Occupational Professionals in Healthcare* published the Occupational Health Nurses Respiratory Protection Competencies, which were developed following the 2011 Letter Report *Occupational Health Nurses and Respiratory Protection: Improving Education and Training*, in its Summer 2014 issue.
- AOHP Poster Presentations related to these Respiratory Protection Competencies included:

  NATIONAL LEVEL:

  - September 8, 2018: "Respiratory Protection in Health Care: Where Do I Go for Answers," AOHP National Conference, Occupational Health A-Z, Glendale, AZ.
  - September 10-13, 2014: "Respiratory Protection in Healthcare Settings: Building Competence for the Occupational Health Nurse," AOHP 2014 National Conference, Get Jazzed with AOHP in New Orleans, LA.
  - September 11-14, 2013: "Respiratory Protection Competencies for Occupational Health Nurses," Poster presentation at the AOHP 2013 National Conference, Discover Your Magic, Orlando, FL.
  - October 3-6, 2012: "Occupational Health Nurses and Respiratory Protection Competency," Poster presentation at the AOHP 2012 National Conference, Entertain Your Professional Needs, Las Vegas, NV.

  STATE/LOCAL LEVEL:

  - November 14, 2017: "Building Your Respiratory Protection Program: Resources for the Occupational Health Professional in Healthcare," AOHP Pennsylvania Southwest Chapter Meeting.
  - May 1, 2015: "Respiratory Protection in Healthcare Settings: Building Competence for the Occupational Health Nurse," AOHP Pennsylvania State Conference, Lancaster, PA.

Advancing Innovation in Personal Protective Technologies

CATALYST

For more than 100 years the U.S. federal government has worked to improve respiratory protective devices, which have evolved from those used exclusively in mining and public safety settings to devices used by millions of American workers today. This expansion in users and hazards of concern has necessitated changes in the design and function of respiratory protective devices, including lowering breathing resistance and improving ergonomics to make these products more wearable by the average worker, although considerable work remains to improve acceptability and usability. Since its founding in 2005, COPPE and its affiliated activities have pushed for innovations to improve the function and usability of respiratory protective devices for such populations as health care workers, firefighters, and other public safety personnel.

"The successful focus on improving PPT for emergency responders now needs to be expanded to other occupations, including agricultural workers, construction workers, healthcare workers, and industrial workers, where the public health impact is likely to be far more substantial. Work on protective ensembles also holds great promise, and innovative approaches need to be developed to provide seamless interfaces among different types and components of PPT."

The Personal Protective Technology Program at NIOSH, 2008, p. 9

RELEVANT NATIONAL ACADEMIES PUBLICATIONS

Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006 consensus study)

The Personal Protective Technology Program at NIOSH: Reviews of Research Programs of the National Institute for Occupational Safety and Health (2008 consensus study)

Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users (2007 consensus study)

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)

Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2011 consensus study)

Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)

The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary (2015 workshop proceedings)

Developing a Performance Standard for Combination Unit Respirators: Workshop in Brief (2015 workshop proceedings)

Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)

Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses: Proceedings of a Workshop (2021 workshop proceedings)

AFFILIATED CONSENSUS STUDY AND WORKSHOP PLANNING COMMITTEE WORK

Multiple National Academies publications have called for advancements in technologies to improve wearability and functionality of personal protective technologies, specifically the development and testing of such devices for health care workers and other nonindustrial professions that may require respiratory protection. The 2019 consensus study report *Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use* concluded that there is an urgent need for incentives to spur innovation to advance current respiratory protective technologies to increase user compliance and, by extension, enhance workplace safety. For example, devices with greater durability to allow for multiple disinfections and decreased risk of fomite transmission are needed to meet gaps in currently available PPE, according to the 2006 consensus study report *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu.* Several reports note that while there are multiple avenues to developing future generations of personal protective equipment, cross-sector collaborations and partnerships, particularly those that integrate user perspectives throughout the entirety of the design and engineering process, are most effective and efficient.

"Innovations in healthcare PPE are starting to be seen in the marketplace, but much more needs to be done to move the design of PPE from an industrial perspective toward the realities of the healthcare workplace."

Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Health Care Personnel: Update 2010, 2011, p. 71

KEY RECOMMENDATIONS

Expand Research to Improve Respiratory Protection

The National Institute for Occupational Safety and Health and the National Center for Immunization and Respiratory Diseases of the Centers for Disease Control and Prevention, and the Biomedical Advanced Research and Development Authority—working in collaboration with manufacturers, researchers, infection prevention and occupational safety and health professional organizations, and other relevant agencies and organizations—should expand their support for and conduct of research on respiratory protection and reusable elastomeric respirators in the following areas for the ongoing improvement of respiratory protection for health care workers. This research should involve the collaborative efforts of a nationwide network of health care facilities that can address the research gaps, expand and refine the results for underserved health care settings, and share lessons learned and best practices.

Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use (2019 consensus study)

Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE

NIOSH, through the NPPTL, in collaboration with extramural researchers, manufacturers, and regulatory agencies, should define a set of evidence-based performance requirements or prescriptive standards for PPE to facilitate their design and development that optimally balances the cost, comfort, and degree of protection of PPE and enhances the compliance with their use in the field.

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)

Adopt a Systems Approach to the Design and Development of PPE

NIOSH should promote a systems approach to the design, development, testing, and certification of PPE using evidence-based performance requirements or prescriptive standards and fostering closer collaboration between users, manufacturers, and research and regulatory agencies.

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers (2008 consensus study)

Enhance Research, Standards Development, and Communication

NIOSH NPPTL should continue and expand its role in PPT conformity assessment. Specifically, NPPTL should

- Continue its involvement in standards-setting processes and committees and facilitate end-user participation in voluntary consensus performance-based standards;
- Expand research efforts on non-respirator PPT (based on risk assessment and opportunities) to include further efforts to establish standards and to develop test methods;
- Develop and maintain an online resource (available through a website and other sources) that provides access to listings of all non-respirator PPT products that meet third-party conformity assessment requirements;
- Expand its role and become the primary clearinghouse for reliable information on non-respirator PPT;
- Fund research and support standards development necessary to test and certify protective ensembles, develop criteria for standardized interfaces, and flag non-conforming ensemble components; and
- Expand its efforts in influenza pandemic-related research and conformity assessment for infection control ensembles.

Certifying Personal Protective Technologies: Improving Worker Safety (2011 consensus study)

SIGNIFICANT IMPACTS

Influencing Policies and Programs and Inspiring New Ideas That Shape the Field

Next-Generation "Hybrid" Respirators

Shortages in respiratory protective equipment, most recently and severely during the COVID-19 pandemic, have underscored the need for access to a sufficient supply of respiratory protective devices to effectively protect the health care workforce and others during public health emergencies. Multiple National Academies publications have advocated for the need for respiratory protective devices that are designed for use by health care workers and devices with the ability to be reused safely.

The Biomedical Advanced Research and Development Authority (BARDA) and Applied Research Associates have partnered to develop a device that can withstand up to 100 reuses and, by extension, address issues with shortages during public health emergencies. As part of its collaboration with BARDA, Applied Research Associates will design and develop this novel respirator prototype—a hybrid of an N95 respirator and an elastomeric half-mask respirator—which can be safely autoclaved. Once developed, the device will be submitted to NIOSH/NPPTL for approval and to FDA for clearance. Should this hybrid design be successfully brought to market, such a device could be easily integrated into health care settings in which N95 FFRs are currently used and would enhance the protection of the nation's supply of respiratory protection during a wide-scale public health emergency.

Better Respiratory Equipment Using Advanced Technologies for Health Care Employees Project (Project B.R.E.A.T.H.E.)

As described previously, this interagency effort[43] sought to improve the design and function of respiratory protective equipment used by health care workers via a public–private partnership model. Respirator usability issues experienced by health care workers during the SARS epidemic (e.g., discomforts that included headaches, facial heat and pressure, shortness of breath, as well as interference with occupational duties) were seen as significant barriers to work performance and raised concerns about respirator use during future epidemics.

A core philosophy of Project B.R.E.A.T.H.E. was that the safety and effectiveness of a respiratory protective device is directly associated with user comfort and tolerability. The project grew from recommendations from National Academies publications, particularly the 2008 consensus study report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*, which called for advancements in design, testing, and certification for health care worker PPE. Additionally, the report recommended the development of evidence-based performance measures to guide PPE design to meet the requirements of these workers. The VA, in partnership with NIOSH/NPPTL, created the Project B.R.E.A.T.H.E. Working Group, which ultimately became a collaboration of 9 federal agencies, and led to the development of a set of 28 consensus recommendations for respirators for use by health care workers and categories of desirable respirator characteristics to improve function, usability, and acceptability. This Working Group called for the development of a Biological N95, or B95, which provides protection against biological particulates. This partnership model is being replicated for an ongoing project designed to spur innovation in PAPRs for health care workers.

Future Generation of Powered Air-Purifying Respirators for the Health Care Workforce

As described previously, this project, launched in 2018, seeks to use the public–private partnership development model to create a future generation of PAPRs designed to meet health care worker needs. This effort grew from recommendations issued by COPPE-affiliated consensus study reports, including the 2008 consensus study report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers* and the 2011 consensus study report *Respiratory Diseases: Personal Protective Equipment for Healthcare Workers*, as well as from discussions captured in the 2015 workshop summary *The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary.* This PAPR workshop and the prior reports underscored the reality that PAPRs, which were originally developed to protect industrial workers (primarily in mining) for a typical 8-hour workshift, are not necessarily suitable for use in the health care work environment. From the National Academies publications, a set of attributes was identified that could be integrated into future PAPR designs, including suitability

for use in sterile fields; enhanced visibility and communication; greater ease of donning, doffing, and cleaning; variable flows based on work rates; smaller and less bulky equipment; and sensors and alarms that monitor flow and power.

The resulting project, Superior Powered Air-purifying Respirators Tests and New technologies (SPARTAN), was launched to realize the goal of bringing these PAPRs to the market[44] using those features that were defined by National Academies publications as most important to enhance function, tolerability, and utility for health care workers, while maintaining a level of protection equivalent or greater than current standards. The second phase of this project, as described by a July 2019 *Federal Register Notice,* will apply the government–private partnership development model used by Project B.R.E.A.T.H.E. to engage industry partners in collaborations to drive the technological development and approval of these novel devices.[45]

Performance Requirements and Test Methods for Head Covers, Footwear Covers, Aprons, and Glove/Protective Clothing Interface Regions

Each PPE element and interfaces between PPE elements are critical for the overall protection of the worker. The majority of PPE research is focused on respiratory protection; studies on other PPE elements, particularly gowns, aprons, head covers, footwear covers, and interface regions, are much more limited. In particular, there is a lack of knowledge about the performance and requirements for such PPE as head covers, footwear covers, and aprons. Due to this knowledge gap, CDC and the World Health Organization were unable to provide any guidance on the minimum performance requirements for head covers, footwear covers, or aprons in their recommendations during the 2014-2015 Ebola epidemic. Moreover, although the glove–gown interface is considered one of the weakest points of the protective ensemble system, there is no standard to quantify the fluid leakage in the glove and protective clothing interface for health care PPE.

Two 2011 consensus study reports identified a need for research on PPE interfaces. The report *Certifying Personal Protective Equipment: Improving Worker Safety* called out the need for investigation into protective ensembles and PPE interfaces to ensure the safety of workers using multiple types of PPE, while the report *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel* called for research on the PPE interface for health care workers in particular.

In response to the findings of these reports and the clear need that emerged during the Ebola epidemic, NIOSH/NPPTL initiated a series of research activities on the effect of movement, exposure type and duration, and other factors on fluid leakage at the glove–protective clothing interface. This research included the development of a novel test method using a robotic arm, which simulates health care personnel's arm movements during fluid exposure (see section on Interface and Interoperability Research). This method was found to be effective in quantifying the leakage at the glove–protective clothing interface, indicating the potential for use in evaluating the performance of new product designs for reducing such interface leakage in health care settings.

Development of Performance and Design Criteria for Isolation Gowns and Surgical Gowns

Gowns are the second-most-used pieces of PPE in the health care setting following gloves. Many different types of isolation gowns with varying levels of protection are currently available on the marketplace. The need for and selection of isolation gowns is based on the nature of the patient interaction. End users may have limited information on or may be unaware of the levels of barrier protection provided by different gown types. For example, users may feel protected if there is no visible liquid on their gowns even through research indicated that penetration of microorganisms can occur without visible liquid being present.

Although multiple organizations had published guidelines for the use of PPE, including standards for isolation gowns in health care settings and for liquid barrier performance for both surgical and isolation gowns, no standard existed for isolation gowns that included both minimum physical performance and design criteria. As a result, there was limited information available on the levels of protection provided by isolation gowns during isolation conditions. The need for research on gowns for health care workers was urged in the 2001 report *Certifying Personal Protective Technologies: Improving Worker Safety and in COPPE discussions.* To address this need for research and lack of a

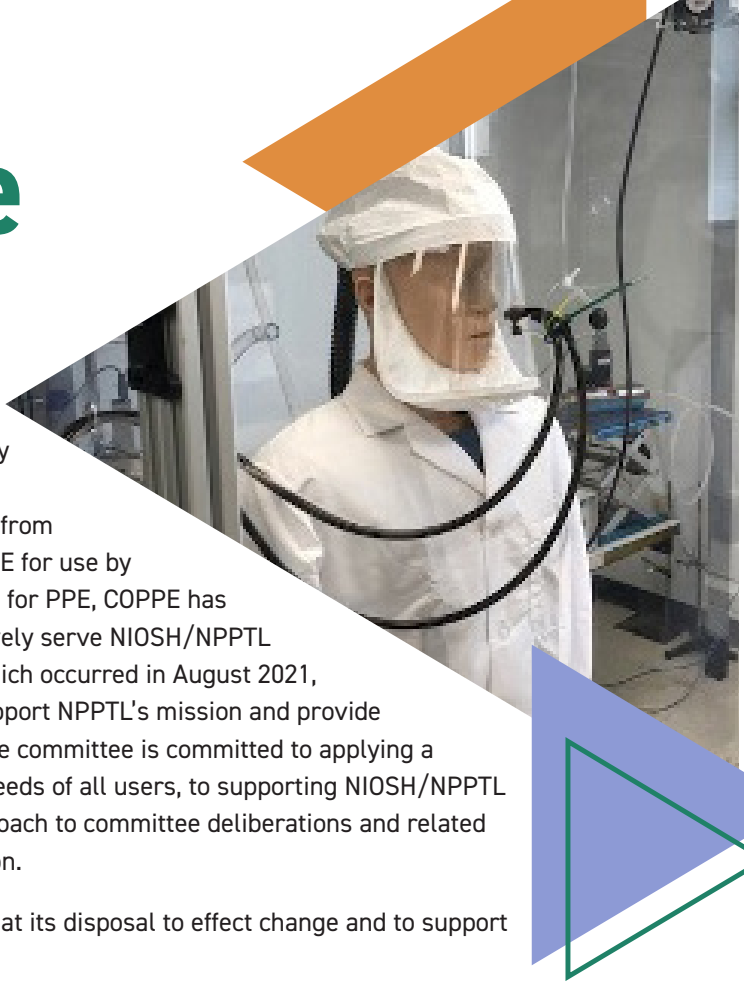
standard, NIOSH/NPPTL conducted research on the physical and barrier performance of reusable and disposable isolation gowns on the market[46] [47] [48] and used these findings to develop minimum physical performance criteria. This body of research led to multiple advancements in standards, policies, and guidance. Examples include the following:

- **DEVELOPMENT OF CONSENSUS STANDARDS:** Performance criteria developed via NIOSH/NPPTL research on gowns was used to develop a new ASTM standard for isolation gowns (see section on Voluntary Consensus Standards above). In addition, these proposed criteria were added to another ASTM standard on surgical gowns used in health care settings.[49]
- **WHO GUIDANCE:** Research findings were also used to inform the development of a 2018 World Health Organization document on product characteristics for health care worker PPE for Ebola and hemorrhagic fever outbreaks.[50]
- **FDA GUIDANCE:** FDA used these research findings to develop a 2015 guidance document on premarket notification requirements[51] that clarified the characteristics of isolation gowns considered to be Class II and subject to FDA premarket review. FDA now clarifies that 510k clearance process is required for Level 3 and 4 isolation gowns.
- **CDC EBOLA PPE GUIDELINES:** NIOSH/NPPTL research findings were used as scientific input in the development of CDC's 2015 Ebola PPE Guidance for Confirmed Ebola Patients.[52]
- **PPE CASE REPORTS:** NIOSH/NPPTL also published two PPE CASE reports[53] [54] in the area of performance of stockpiles of surgical gowns and isolation gowns, which identified the need for more research in the area of gowns and relevant standard test methods to determine the gown performance.

Advanced Headforms for the Evaluation of Respiratory Protective Devices

The 2006 consensus study report *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu* emphasized committee concerns that a future influenza pandemic could result in severe depletion of the national supply of FFRs, a fear later realized in 2020 during the COVID-19 pandemic. The recommendations of this report highlighted the significant need for research on the effectiveness of FFRs for infectious respiratory hazards in health care settings; however, to understand the protective capabilities of FFRs, innovative technology was needed to develop a nonhuman test system to assess the role of fit on inward leakage during challenges using viable pathogens. NIOSH, through a partnership with the Air Force Research Laboratory and with funding by BARDA, initiated development of advanced robotic headforms to expand opportunities for advancing research on inward leakage without the use of human subjects. Advanced headforms are fabricated with a silicone elastomer skin to simulate human facial tissues and designed to meet the facial dimensions of the NIOSH Principal Component Analysis panel. Ultimately, this technology will continue to be improved to test respirator designs against viable airborne particles and contribute to future updates and improvements to respirator certification and consensus standards.

Looking to the Future



The safety and health needs of America's workforce are continuously evolving, necessitating new research, policies, and actions by all stakeholders. The year 2020 saw unprecedented threats to workers from every sector and underscored the critical importance of effective PPE for use by diverse populations of users. In response to the changing landscape for PPE, COPPE has looked inward to assess how the committee model can most effectively serve NIOSH/NPPTL in carrying out its mission. These strategic planning discussions, which occurred in August 2021, distilled four core intentions at the heart of COPPE's objective to support NPPTL's mission and provide a framework for carrying out its work into the future. Specifically, the committee is committed to applying a systems perspective to understand PPT needs, to considering the needs of all users, to supporting NIOSH/NPPTL as a national leader for PPT, and to applying a forward-looking approach to committee deliberations and related activities to proactively identify future needs and areas for innovation.

In looking toward the future, COPPE has evaluated the mechanisms at its disposal to effect change and to support NPPTL in advancing PPT. These mechanisms for action include

1. Increasing efforts to translate and disseminate evidence-based information about PPT within committee member spheres of influence and beyond;
2. Ensuring that the expertise and perspectives of COPPE and its affiliated activities are diverse and representative of the multitude of stakeholders within the PPT space;
3. Informing future National Academies activities to ensure that these are scoped appropriately to address major areas of need within the world of PPT, as well as aiding in the dissemination of recommendations and findings from these activities within professional networks and spheres of influence;
4. Providing a neutral intellectual and professional space for catalyzing new ideas and partnerships to generate action; and
5. Supporting NIOSH/NPPTL by informing their current research activities and providing input on their future research and policy roadmap.

The Standing Committee on Personal Protective Equipment for Workplace Safety and Health is privileged to be in service of NIOSH/NPPTL as a source for trusted guidance to advance the state of PPE for America's workforce. With the work of the past 15 years serving as a foundation for action, COPPE is ready to support NIOSH/NPPTL in meeting the challenges of the future.

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ABOUT THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

The **National Academy of Sciences** was established in 1863 by an Act of Congress, signed by President Lincoln, as a private, nongovernmental institution to advise the nation on issues related to science and technology. Members are elected by their peers for outstanding contributions to research. Dr. Marcia McNutt is president.

The **National Academy of Engineering** was established in 1964 under the charter of the National Academy of Sciences to bring the practices of engineering to advising the nation. Members are elected by their peers for extraordinary contributions to engineering. Dr. John L. Anderson is president.

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ENDNOTES

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