NIOSH Healthcare Personal Protective Technology Targets for 2020 to 2030

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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On May 16, 2022, NIOSH published a request for public review in the *Federal Register* [87 FR 29748] on the draft version of the NIOSH Healthcare Personal Protective Technology (PPT) Targets for 2020 to 2030 (Draft PPT Targets). We received sixteen sets of comments from manufacturers, distributors/vendors, healthcare providers, government agencies, academia, professional organizations, non-government organizations, and members of the public. NIOSH reviewed the comments and revised the document where appropriate.

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Glossary

To effectively set and describe objectives for PPT Targets in this report, the following definitions of key terminology are provided.

Barrier Face Covering (BFC): A face-worn product with the primary purpose of providing source control. A face-worn product providing a degree of particulate filtration that reduces the amount of inhaled particulate matter to meet ASTM F3502 Standard Specification for Barrier Face Coverings may be considered a BFC.

Cloth Mask: A reusable source control product made of a cloth material such as cotton that may be used in accordance with public health recommendations but does not conform to any specific performance standard.

Conformity Assessment Scheme: A series of activities performed to demonstrate that a product conforms to (or meets) pre-defined requirements.

Elastomeric Half-mask Respirator (EHMR): An EHMR may be an air-purifying respirator (APR) or an air-supplying respirator. Because APRs for particulate hazards are the most common respirators used in healthcare, EHMRs in this context refers to those that are APRs. These EHMRs are negative-pressure, reusable respirators designed to cover the wearer's nose and mouth from the bridge of the nose to below the chin with replaceable filters, cartridges, or canisters.

Face-worn Product: A device worn on the face intended to provide a barrier between the wearer's nose and mouth and the environment.

Filtering Facepiece Respirator (FFR): A negative-pressure, disposable respirator (with or without an exhalation valve) designed to cover the wearer's nose and mouth from the bridge of the nose to below the chin with an integral non-replaceable filter or where the entire facepiece is the filtering medium.

Gases: Aeriform fluids (i.e., having the nature of air) that are in a gaseous state at ordinary temperature and pressure.

Mask: Any face-worn product that does not meet the definition of a respirator but provides source control. Certain products that are considered masks may additionally provide some level of particulate filtration during inhalation.

NIOSH Approved® Respirator: Any respirator approved by NIOSH as meeting the requirements of 42 CFR Part 84.

N95® FFR: A NIOSH Approved FFR that offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR Part 84.174.

Powered Air-purifying Respirator (PAPR): A respirator with a battery-powered blower that pulls air through attached filters, cartridges, or canisters.

PPE: Equipment worn to protect from physical, chemical, and biological hazards. PPE frequently worn by HCP include not just respirators, but gowns, gloves, goggles, face shields, head covers, shoe covers, and surgical masks.

PPT*:* PPT includes PPE (e.g., respirators) worn by individuals. However, it also refers to the technical methods (e.g., respirator fit testing), processes, techniques, and materials that support the development and use of PPE.

Respirator:[1] A device that protects the wearer from inhaling dangerous substances, such as chemicals and infectious particles. In healthcare, APRs are the most recommended respirator type. APRs remove respirable hazards during inhalation using a filter media or adsorption (a chemical process that neutralizes a hazard).

Respiratory Protection: The *demonstrated and referenceable* prevention of droplets, particulates, gases, or vapors from entering a person's respiratory tract during inhalation when in a potentially hazardous atmosphere.

Source Control: Preventing the development of a hazardous atmosphere by addressing the hazard at its source.

Surgical Mask/Medical Mask: A loose-fitting, disposable device that provides a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.

Vapors: The gaseous states of substances that are liquids or solids at ordinary temperature and pressure.

Introduction

In 2006, the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) began to develop and execute a comprehensive strategic approach to protecting healthcare personnel (HCP). The resulting NIOSH Healthcare PPT Action Plan focused resources and attention on the personal protective technology (PPT) needs of HCP during a potential influenza pandemic. NIOSH subsequently undertook a research agenda to advance clinical practices, drive performance standards development, and inform regulation. NIOSH also strategically disseminated information to healthcare organizations and HCP, emphasizing the role of personal protective equipment (PPE). The most recent plan focused on PPE to reduce exposures to viral respiratory pathogens, including the influenza virus.

Reflecting on the past decade of our nation's experiences with infectious diseases and non-infectious hazards, NIOSH recognizes a need for more types of PPT. An opportunity also exists to address existing gaps by leveraging NIOSH's unique capabilities related to PPT research, PPT development, performance standards and test methods, and conformity assessment (CA).

[1] In discussing respirators, an important distinction arises in this report in relation to respirators that are NIOSH Approved (as defined earlier) and "international respirators." In the context of this report, international respirators can be defined as those where the supplier claims to meet a certification standard set by a non-U.S. entity, including but not limited to the following: Brazilian standards (ABNT NBR 13698: 2022-09-23); Korean standards (KMOEL: 2017-64—where a common example is the KF94 model); Chinese standards (GBT 32610: 2016, GB19083: 2010, and GB2626: 2006—where a common example is the KN95 model); European standards (EN 149:2001+A1:2009—where the three classes are FFP1 (80% filtration efficiency), FFP2 (94% filtration efficiency), and FFP3 (99% filtration efficiency).

To address this need, in 2022 NIOSH developed the document, "Draft NIOSH Healthcare Personal Protective Technology (PPT) Targets for 2020 to 2030." NIOSH then requested public comment of the document through a Federal Register Notice. Comments received from the public and NIOSH's ongoing PPT research informed the current report, hereafter referred to as "PPT Targets."

PPT Targets Objectives

NIOSH's PPT Targets defines six broad objectives:

1. Conduct workplace exposure assessments and hazard evaluations to inform PPT policy, standards, and CA needs.
2. Develop, evaluate, and continually innovate PPE performance requirements and test methods by integrating advanced PPT and design guidance.
3. Develop and disseminate strategies and tactics to extend PPT supplies during emergencies, disasters, or PPT shortages.
4. Develop and disseminate guidance and best practices to inform PPT implementation and enhance user adherence.
5. Provide national leadership to inform the design and execution of NIOSH's Respirator Approval Program (RAP) and other PPT CA schemes.
6. Expand U.S. capacity for PPT research and innovation.

NIOSH engages in the following process to meet these objectives, further discussed in detail in this report:

- Analyzing knowledge gaps by summarizing input from the following resources and approaches:
    - stakeholders,
    - literature review, and
    - assessment of current relevant trends and legislation, where applicable.
- Identifying priorities and detailing supporting targets that will help to close critical gaps in the protection of HCP. Achieving the stated targets depends upon the resources available.
- Partnering with the following:
    - *Other federal agencies* such as entities within the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, the Occupational Safety and Health Administration, U.S. Customs and Border Protection, the United States Patent and Trademark Office, and the Administration for Strategic Preparedness and Response—including its Strategic National Stockpile.
    - *Standards development organizations* including ASTM International, the International Organization for Standardization, and the American National Standards Institute.

- *Labor and industry associations* such as American Federal of Labor and Congress of Industrial Organizations, the International Safety Equipment Institute, and the American Mask Manufacturer's Association.
- *Academia* including NIOSH's Education and Research Centers and infection prevention/control entities.
- *State and local public health departments*.
- *Healthcare providers.*
- *Other relevant entities*.

Background

The well-being of HCP is one of NIOSH's priorities in its mission to protect the U.S. workforce from injury and illness through scientific research, practice interventions, and partnerships. To develop and promote ways to reduce harmful workplace exposures, NIOSH works with many partners who serve HCP. These partners include those in healthcare settings with potential for direct or indirect exposure to patients and other professionals who support the protection and well-being of HCP. These professionals span a wide range of occupations, including industrial hygienists, infection preventionists, social scientists, and engineers. Organizations such as professional societies and government agencies also play a key role in protecting HCP. The successes of these efforts are evidenced in work by the National Occupational Research Agenda (NORA). Healthcare and Social Assistance Sector Council and the 2019 NIOSH Strategic Plan [1].

While engineering and administrative solutions serve as the first line of defense in infection prevention, PPT nevertheless plays an important role in preventing transmission of infectious diseases, in particular PPE. HCP have been wearing some PPE, such as surgical masks and gloves, in healthcare settings for over 100 years. However, the emergence of new pathogens and increased medical knowledge have evolved PPE use. In addition to infectious hazards, non-infectious hazards such as chemicals and exposure to hazardous drugs continue to pose a threat to HCP.

In its efforts to protect HCP, NIOSH's overarching goal remains to reduce worker illness and injury and advance worker well-being. This goal informs or directs the design, evaluation, standards development, CA, selection, care, maintenance, and use of PPT in all healthcare settings.

The Burden of HCP Morbidity and Mortality

Currently, the healthcare industry in the United States employs almost 17 million people [2]. Bureau of Labor Statistics (BLS) data show that employment growth in healthcare will account for nearly one-third of the projected job growth for all industries from 2016 to 2026. This would add 4.0 million jobs during this period. Several factors continue to increase healthcare demands, such as the aging population, longer life expectancies, and growing rates of chronic conditions [3].

Healthcare settings include the following:

- ambulatory healthcare services
- hospitals
- nursing and residential care facilities
- dental offices
- clinics
- private home care

All of these settings provide services that may involve complex care once only considered appropriate for hospitals. Further, the BLS projects that one of the occupational groups—home healthcare aides—will grow 33.7% by 2029 [4].

In 2020, the Healthcare and Social Assistance Sector reported 5.5 injury and illness cases per 100 full-time workers. This amounts to about 806,200 total cases. This number reaches higher than for any other private industry sector, including manufacturing and construction [5]. Injuries and illnesses in healthcare accounted for 19.9% of the total for all industries. During 2019, in hospitals alone, non-fatal injury or illnesses resulting in days away from work reached 129.7 per 10,000 full-time equivalent (FTE) workers. In 2020, the rate increased to 371.7 per 10,000 FTE workers. [6]. Data on workers' compensation claims estimated the average loss per claim settled for hospital workers' injuries in 2011 was $15,860. During 2011, injuries and illnesses cost the healthcare industry $13.1 billion and more than 2 million lost workdays [7]. Nursing and residential care facilities had the highest injury or illness incidence in 2020. These facilities had 791.7 cases per 10,000 FTE workers being injured on the job [6]. Additionally, high financial and societal costs exist when replacing HCP who leave the profession because of workplace injury or illness.

The NIOSH Healthcare and Social Assistance Program prioritizes the prevention of illnesses caused by hazardous drugs and infectious agents (e.g., influenza, Ebola, etc.) through respiratory and dermal exposure. Dermal and respiratory exposure can be mitigated using PPE. Adverse health effects can be associated with exposure to antineoplastic drugs, which inhibit or prevent the growth and spread of tumors or malignant cells. These adverse health effects include acute effects such as nausea, headache, skin and eye irritation, and hair loss. Long-term effects also occur, such as DNA damage, miscarriage, leukemia, and other cancers [8-13].

From the "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings," the current list for healthcare settings includes nearly 220 drugs and continues to grow. NIOSH estimates [15] that 8 million U.S. HCP are potentially being exposed to hazardous drugs, including:

- pharmacy and nursing personnel
- physicians
- operating room personnel
- environmental services workers
- workers in research laboratories
- veterinary care workers

- shipping and receiving personnel

A recent NIOSH study found that some nurses, including those expecting children, did not wear protective gloves and gowns while handling or administering antineoplastic and other hazardous drugs [16]. Specifically, 12% of nonpregnant nurses and 9% of pregnant nurses indicated that they never wore gloves. Further, 42% of nonpregnant nurses and 38% of pregnant nurses reported never using a gown. Gloves, gowns, and goggles remain critical components, often considered the minimum required PPE, for handling and administering antineoplastic and other hazardous drugs [17].

NIOSH found that over 400 HCP reported acute illnesses or injuries related to disinfectant exposure from 2002 to 2007 in four states [18]. A 2021 systematic review using meta-analysis estimated that nurses, compared to those in other occupations, face an increased risk of new-onset asthma and bronchial hyperresponsiveness-related symptoms [19]. In this same category of risk, environmental services workers represent the most common occupation (24%), followed by nursing and medical assistants (16%), technicians (15%), and nurses (11%). HCP account for about 16% of all occupational asthma cases, with up to 24% of these cases caused by exposure to cleaning agents [20]. HCP face one of the highest rates of occupational asthma at 8.8%, compared to 7.2% among all workers [20-21].

Other respiratory hazards for HCP include surgical smoke and waste anesthetic gases. Several studies report toxic, mutagenic, and potentially infectious effects from smoke generated from lasers or electrosurgical devices during surgery [22-24]. The Occupational Safety and Health Administration (OSHA) estimates exposure of 500,000 workers to surgical smoke each year [25]. Studies show associations between anesthetic or analgesic gases and vapors that escape during dental and medical procedures and impaired cognition and manual dexterity as well as adverse reproductive outcomes [26-27]. An estimated 250,000 U.S. HCP may be exposed to these waste anesthetic gases, putting them at risk of developing adverse health effects [28].

Infectious diseases pose an ongoing concern among HCP. Some such as tuberculosis have been around for many decades. Others have emerged in recent years, including the 2009 H1N1 pandemic influenza, Ebola virus disease, Middle Eastern Respiratory Syndrome, and COVID-19. Recent infectious disease outbreaks disproportionally infected HCP as compared to the general public [29-32]. Even pathogens for which effective vaccines exist (e.g., the measles virus) may cause epidemics among the general population when population-level immunity wanes [33]. Multidrug-resistant organisms present a growing challenge for HCP, with 88 cases of multidrug-resistant tuberculosis and one case of extensively drug-resistant tuberculosis identified in the United States in 2015 [34].

In data across U.S. industries, healthcare occupations show one of the highest rates of musculoskeletal injuries attributable to overexertion. BLS data from 2014 show a rate of 33 per 10,000 full-time workers for overexertion injuries averaged across all industries. By comparison, BLS data show an overexertion injury rate twice that average for hospital workers (68 per 10,000), over three times that average for nursing home workers (107 per 10,000), and over five times that average for ambulance workers (174 per 10,000) [35].

The greatest risk factor for overexertion injuries in HCP remains manual patient handling. This refers to manual lifting, moving, and repositioning of patients, residents, or clients. Nursing aides, orderlies, and attendants had the highest rates of musculoskeletal disorders among all occupations in 2010.

Analysis of NIOSH PPT Targets

The following analysis details the NIOSH approach to addressing the six PPT Targets by describing the knowledge gaps and priorities and targets for each objective as listed in the Introduction.

Objective 1: Conduct workplace exposure assessments, hazard evaluations, and comparative studies to inform PPT policy, standards, and CA needs.

Knowledge Gaps

Because of the variety of hazardous chemicals and biological pathogens present in various healthcare settings, characterizing HCP occupational exposures involves intensive use of resources by qualified individuals such as industrial hygienists. Hazard evaluations also pose different sets of challenges as the exposure time and concentrations vary widely throughout job classifications and facilities.

The healthcare industry has recognized these challenges as endemic for decades. They remain a concern to this day in many healthcare settings, such as acute care, long-term care, and outpatient care facilities, including dental care. Differences in these healthcare settings influence the design, execution, and findings of hazard evaluations. However, recent assessments of several infectious diseases show higher infection rates for HCP compared to individuals from their surrounding communities [29-32], with some infections leading to HCP death [36].

Assessing the biological hazards of the workplace exposure portfolio also poses challenges. Most sampling methods, by design, evaluate biological concentrations in a room or in an area rather than specific personal exposures. This makes joining specific exposure levels to adverse health outcomes challenging [37]. Together, these issues create challenges for the development of effective PPT policies and standards, specifically considering the following:

- pathogen diversity,
- incomplete understanding of transmission pathways and the epidemiology of transmission,
- lack of knowledge about infectious dose and occupational exposure limits for many pathogens,
- lack of knowledge about community vs. occupational exposures.
- variability in worker susceptibility to infection,
- inconsistencies in workers' exposures,
- difficulties in evaluating those exposures, and
- the challenges of hazard evaluations.

These ongoing challenges demonstrate the need to identify and quantify personal exposures throughout the industry, as well as to investigate possible links between those exposures and negative health outcomes. Addressing this knowledge gap will provide the information necessary

to mitigate these exposures more effectively using engineering and administrative controls while aiding in the development of effective PPT policy and standards for those remaining exposures.

Priorities and Targets

1. Expand the evidence base to inform the necessary protection level to protect HCP in various hazard exposure scenarios for infectious and non-infectious hazards.

   Target 1: Conduct case studies or simulation studies representative of real-life situations. Include aerosol-generating procedures to inform the mean airborne and surface concentrations and duration of exposure that may be expected for infectious pathogens of concern in

   - hospitals,
   - ambulatory care (including dental) settings,
   - long-term care settings, and
   - other relevant settings where healthcare is delivered.

   Target 2: Conduct a systematic literature review to identify potential adverse health effects resulting from exposure scenarios identified in Target 1. Address remaining knowledge gaps with *in vitro* and animal models and studies of HCP who did and did not contract diseases. This will help to elicit effective PPE for specific disease burdens.

   Target 3: Conduct a systematic literature review that includes the following:

   - Published epidemiologic findings from exposure investigations.
   - Findings of well-conducted clinical trials of PPE efficacy and effectiveness.

   Use this literature review to recommend minimum level of protections necessary for various healthcare exposure scenarios. Minimum protections may include splash protection, assigned protection factor, filtration efficiency, and fit testing requirements.

   Target 4: Conduct surveys, standards reviews, and case studies to achieve the following:

   - Identify CA gaps (e.g., availability and applicability of PPE standards for various healthcare settings).
   - Estimate the impact of this assessment on HCP exposure to hazards.
   - Determine the receptivity of different areas within the healthcare industry to more robust CA requirements where appropriate.

   Target 5: Conduct case studies or simulation studies to inform non-infectious risks to HCP during the following circumstances:

   - Healthcare delivery—e.g., administering hazardous drugs such as antineoplastic drugs; patient transport or repositioning.
   - Healthcare support functions such as cleaning and disinfection, which may cause exposures to UV light, liquid cleaning agents, and gases and vapors.

2. Expand the evidence base used to inform the effectiveness of respirators and mask for providing respiratory protection or source control.

Target 1: Conduct comparative studies (field-based or simulations) using respirators well-suited for healthcare applications. Use the results to inform policies based on effectiveness, considering user adherence in various healthcare delivery settings.

Target 2: Conduct comparative studies (field-based or simulations) using masks to determine the effectiveness. Consider user adherence of these numerous product types (e.g., barrier face coverings and medical masks) in various healthcare settings.

Objective 2: Develop, evaluate, and continually innovate PPE performance requirements and test methods through the integration of advanced PPT and design guidance

Knowledge Gaps

When using PPE to protect their health and safety, HCP must have confidence in product effectiveness. CA leverages established test methods to verify that PPE conform to published performance requirements. This ensures that safety professionals who select them, and the workers who rely on them, can do so with assurance of consistent, necessary protective capabilities [38]. A CA program can instill this confidence in PPE users. Importantly, CA programs can vary. One option is first-party testing or inspection with a supplier's declaration, which is the type of CA program suited for healthcare PPE. Another is testing by a third-party laboratory (with preference for labs with accreditation). These requirements and standards provide context to establish the specific requirements used to evaluate a product's performance. However, the current healthcare PPE CA programs do not contain all the performance tests necessary to ensure that PPE will adequately protect HCP.

The outbreaks of the 2003 severe acute respiratory syndrome (SARS), the 2009 H1N1 influenza, the 2014 Ebola virus, and the 2019 COVID-19 pandemic created a heightened awareness for protecting today's HCP. As a result, NIOSH sponsored studies by the National Academies of Sciences, Engineering, and Medicine (NASEM). One was on the use and effectiveness of PAPRs [39]. A second was on the use of EHMRs in healthcare [40]. The development of test methods must be completed before HCP can routinely use these respirators.

In healthcare settings, a need exists for the fit of respirators to be improved as well as fit testing methods [41]. Fit testing represents a major barrier to the effective implementation of respirators. Employers identify the cost and logistics associated with fit testing as a primary challenge. Recruiting human subjects for laboratory testing that comes with a potential risk of infectious disease transmission, such as during a pandemic, stands as a significant challenge. NIOSH could eliminate this potential risk by using humanlike robotic technologies. If NIOSH could rely upon these technologies for testing associated with its approval and research efforts, it could notably increase the rate of output. Finally, innovation in fit testing would benefit HCPs and their employers. Ideally, employers could use even more rapid fit testing methods in medium- and large-sized facilities (e.g., acute care facilities). They could also use table-top methods in small community healthcare settings (e.g., pharmacies and nursing homes).

Workplaces also increasingly employ direct-reading sensors to detect and monitor face seal leakage in real time, reducing the burden of fit testing. Sensors may also be useful in improving the overall effectiveness of other types of healthcare PPE. Development of new test methods and protocols would support feasibility assessments related to the use of these technologies.

Source control is a practice to block respiratory secretions to prevent disease transmission to others. It remains an infection control strategy, with the additional potential benefit of ultimately reducing overall exposures of HCP to infectious diseases. However, until 2020, no standard existed to test these products against to demonstrate performance. Some entities claimed that products with the primary purpose of providing source control may also provide some level of personal respiratory protection. As a result, ASTM International (formerly the American Society for Testing and Materials) developed and published a voluntary consensus ASTM F3502-21 Standard Specification for Barrier Face Coverings. ASTM accomplished this in a short timeline of only a few months. NIOSH served as a member of the technical committee overseeing this standard. As a member, NIOSH became one of many parties with an interest in ensuring that revisions to this standard incorporated new, sound scientific evidence. Developing guidance for appropriate use of the resulting products in acute health delivery settings as well as for other health delivery settings such as long-term care facilities.

Some situations require HCP to wear multiple types of PPE simultaneously. For example, treatment of Ebola patients required HCP to wear up to seven different types of PPE from head to toe. An ensemble might include boot coverings, coveralls, respirator, gloves, and eye protection. Additional research in test methods, selection guidance, and the interoperability of individual components of ensembles for healthcare remains important. Additional issues include

- heat stress [42],
- component interfaces (e.g., glove-gown or respirator and eye protection) [43], and
- the need to integrate more efficient measurement technologies [44].

Finally, as noted earlier, manual lifting and handling patients continues to be a major source of injuries for HCP. Exosuits represent a rapidly advancing form of PPT that may reduce musculoskeletal disorder or injury risk to HCP [45]. Advancing exosuit technologies and understanding the safety and efficacy of these devices can prevent injuries in healthcare settings where other controls may not be feasible. Examples include acute care, rehabilitation, and long-term care facilities.

Priorities and Targets

1. Conduct research on NIOSH Approved respirators not traditionally used in healthcare to inform policy solutions that NIOSH may incorporate into its RAP.

   Target 1: Assess the adequacy of existing test methods to validate their utility in relation to PAPRs, EHMRs, and the mostly commonly utilized filtering facepiece respirators (FFRs) for use in healthcare settings. If existing methods are found to be inadequate, identify and develop additional performance requirements and test methods for these types of respirators.

2. Demonstrate the utility of innovative respirator design components that manufacturers can use to enhance PPE protections or user adherence and comfort.

   Target 1: Develop a Sensor Integration Roadmap and initiate identified activities.

   Target 2: Demonstrate the feasibility of using sensor technologies to provide real-time, field-based respirator fit and/or filter penetration data.

   Target 3: Explore innovative head suspension and facepiece designs that may provide improved

- fit characteristics
- communication
- comfort
- increased ease of donning/doffing (without HCP contamination)
- other desirable performance enhancements

3. Advance the use of innovative technologies to optimize respirator fit assessments.

   Target 1: Evaluate an advanced humanlike articulated headform as a means for replacing the human subject when realistic respirator seal characteristics are a necessary component of a laboratory assessment.

   Target 2: Facilitate the development and evaluation of a digital, smart-device-deployed application that scans user faces. The facial dimensions determined from the facial scans will be compared to the NIOSH Bivariate Panel and NIOSH Principal Component Analysis Panel to assign the individual to a facial sizing category. Based on the assigned category, existing NIOSH fit testing data will return to the application user a list of NIOSH Approved respirators expected to provide the best fit.

   Target 3: Within field-based test methods, evaluate the utility of sensors for FFRs to provide real-time data that inform

   - user seal checks,
   - respirator fit during use,
   - outward leakage during use, and
   - how fit testing requirements may evolve as this technology penetrates the market.

   Target 4: Evaluate the causes limiting access to fit testing in various settings where healthcare is delivered and develop solutions to improve access.

   Target 5: Develop rapid fit testing methods for use by better-resourced healthcare facilities. Develop table-top methods for use in resource-constrained healthcare settings such as those in small communities.

4. Provide evidence-based guidance for PPE intended to provide source control and some level of respiratory protection for infectious diseases spread through respiratory secretions.

   Target 1: Develop and evaluate a test method to assess sneeze and cough hazards and integrate this method into PPE performance standards. Collaborate on this with voluntary consensus standard setting organizations and academia where feasible.

   Target 2: Evaluate face-worn products (e.g., respirators, surgical masks, and cloth masks) to determine the level of source control users can expect. Use this information to inform test method development, including voluntary consensus standards.

   Target 3: Provide research, technical support, and guidance to establish and continually improve ASTM F3502-21 Standard Specification for Barrier Face Coverings. This voluntary consensus standard describes how to assess outward filtration efficiency, user comfort, and

fit. Manufacturers and others may also be interested in applying this standard to a variety of face-worn products.

Target 4: Conduct proof-of-concept studies towards the goal of designing next-generation masks to (1) enhance user adherence thereby more effectively reducing person-to-person transmission and (2) inform test method development.

5. Provide evidence-based guidance to improve performance requirements, test methods, and design guidance for the use of two or more PPT components at once. This includes
    - respirators;
    - eye and face protection such as glasses, goggles, face shields, etc.;
    - gowns, gloves, head covers, aprons;
    - footwear covers; and
    - personal safety equipment such as vests; etc.

    Target 1: Develop requirements and test methods (including voluntary consensus standards) to assess the following:
    - performance at the interface of ensemble components,
    - comfort,
    - safety (e.g., ensuring ensemble weight does not pose a risk),
    - donning and doffing ease, and
    - potential for contaminant transfer.

    Use these requirements and test methods to inform design guidance for PPT interface regions.

    Target 2: Improve the efficiency of existing laboratory-based test methods for the penetration of blood, bodily fluids, and bloodborne pathogens.

    Target 3: Provide research, technical support, and guidance to inform (1) test methods and (2) a framework for integrating and ensuring ongoing protections of multi-component PPE ensembles (e.g., respirators in combination with eye and face protection).

    Target 4: Provide research, technical support, and guidance to inform (1) test methods and (2) voluntary consensus standards for issues such as comfort and wearability, disinfection, and speech intelligibility. Integrate the developed standards or test methods within NIOSH guidance.

6. Inform the test methods used to assess individual components of the HCP ensemble.

    Target 1: Provide a leadership role including research, technical support, and guidance to advance the ANSI/ISEA Z87.1 eye and face protection standard for biological hazards. Boost awareness of the Z87.62-2021 American National Standard for Occupational and Educational Eye and Face Protection Devices for Preventing Exposures Caused by Sprays or Spurts of Blood or Body Fluids in the Medical Industry.

Target 2: Ensure that test methods are adequate to assess PPE components against novel/emerging infectious and non-infectious hazards during use. Tests should not interfere with the ability of HCP to perform their job effectively and safely, including tasks requiring high levels of physicality.

Target 3: Provide a leadership role including research, technical support, and guidance to advance ASTM F3407 Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators for FFRs to also include all other air-purifying respirators (i.e., elastomeric with cartridges and canisters).

Target 4: Provide a leadership role including research, technical support, and guidance to ensure that non-respiratory PPE properly fit the diverse HCP population and accommodate religious and cultural practices. Factors to consider include the following:

- a variety of body shapes and sizes
- a variety of facial shapes, sizes, and features
- pregnant workers
- workers using assistive technology or devices

7. Support the exploration, development, and integration of innovative technologies to advance HCP ensembles and identify the need for new performance requirements or test methods.

   Target 1: Demonstrate the efficacy of various eyewear coatings to reduce fogging when HCP wear eye protection in combination with face-worn products (e.g., respirators, surgical masks, and cloth masks).

   Target 2: Advance the development of mechanized clothing HCP could wear to reduce lower-back loading during patient body manipulations or location transfers.

Objective 3: Develop and disseminate strategies and tactics to extend PPT supplies during emergencies, disasters, or PPT shortages

Knowledge Gaps

HCP use N95 FFRs more than any other respirator type. Modeling previously suggested that the demand for respirators used by HCP during an influenza pandemic would far exceed domestic supplies [46]. Some U.S. locales—despite stockpiling programs at local, regional, and national levels—experienced shortages of respirators during the H1N1 influenza pandemic in 2009-2010 and the outbreak of SARS in 2003-2004. PPE orders increased up to 200 times in October 2014 after the first U.S. Ebola fatality and issuance of updated CDC PPE guidance [47].

In 2020, during the COVID-19 pandemic, the U.S. respirator supply chain had limited surge production capacity for respirators and other PPE types, such as gowns [48]. Further, international manufacturers often serve as primary suppliers of PPE for the U.S. market. Obtaining needed PPE in 2020, especially respirators, proved to be difficult due to limited exports of raw materials and the need to import NIOSH Approved respirators produced outside of the U.S.

In response to the shortages, NIOSH assisted CDC's pandemic response in developing measures to optimize PPE supplies along the continuum of care using crisis and contingency strategies [49]. These measures included the following:

- Reuse, extended use, and decontamination of FFRs.
- Using respirators (including N95 FFRs and other types) beyond the manufacturer-designated shelf life for healthcare delivery.
- Using respirators claiming to meet international standards with requirements similar to NIOSH's filtration efficiency and inhalation and exhalation breathing resistance requirements.

In occupational settings where employers can identify respiratory hazards in advance of exposure, OSHA requires that employers establish a respiratory protection program (RPP). As a robust program, an RPP requires significant time and attention from the employer. It includes proper respirator selection, donning and doffing of respirators, fitting respirators, and identifying potential risks to those with pre-existing cardiopulmonary disease. However, HCP who are not typically exposed to respiratory hazards—and therefore not covered under an RPP—may be unexpectedly exposed to a respiratory hazard. For example, HCP delivering care in a patient's home may be exposed during a wildfire, or hospital services staff during an infectious disease outbreak/pandemic. Unfortunately, these workers urgently require respiratory protection, and the employer must sometimes establish an RPP as workers are continually exposed to a respiratory hazard. Thus, NIOSH can help fill these urgent gaps by coordinating with other federal entities to develop and implement strategies for HCP not covered by an RPP. These actions would reduce transmission rates of infectious diseases and thereby reduce the risk level to HCP.

Priorities and Targets

1. Expand national capacity to provide PPT during demand surges by developing guidance, new technologies, and approaches to supply management with consideration for global demand.

   Target 1: Empower stockpile managers to verify manufacturer performance claims of PPE initially and continually within their facilities by establishing (1) the standards and (2) a testing and evaluation framework.

   Target 2: Facilitate coordinated PPT inventory data sharing between software platforms by developing a voluntary consensus standard for PPT nomenclature and data format.

   Target 3: Using Target 2 above, develop guidance and an interoperable platform to allow stockpiles that implement Target 1 above to share test results with the product manufacturer. This would further enable product purchasing and rotation coordination between stockpile and health systems. It would also enable potential policy initiatives.

   Target 4: Develop and enhance best practice guidelines on EHMRs for HCP, including strategies for fit testing, staff training, decontamination, and other logistics.

   Target 5: Sponsor studies to evaluate use and distribution of EHMRs and PAPRs and their accessories. Educate users about the results to address future respirator shortages.

Target 6: Support initiatives and collaboration with PPE manufacturers to establish a national strategy to rapidly produce and supply PPE conforming to appropriate standards. These initiatives should include readily accessible technical support.

2. Improve the protections provided to HCP when contingency and crisis PPT strategies are implemented.

   Target 1: Conduct post-market evaluations of respirators certified to international standards that are not NIOSH Approved.

   Target 2: Develop and evaluate the following for efficacy and impact on user safety (e.g., not contaminating the HCP while doffing):

   - novel facepiece designs,
   - new laboratory-based test methods for single- and multi-use PPE decontamination, and
   - cleaning techniques and treatments (e.g., cycles and doses).

   Target 3: Develop practical field-based test methods which correlate with the more robust laboratory test methods for filter penetration. These methods will empower employers to increase confidence in FFRs deployed to the workforce that are of unverified quality (e.g., shipments with unknown origin and after decontamination).

   Target 4: Evaluate the effectiveness of past extended use and reuse practices with consideration of PPE performance using standardized test methodology. Assess the impact these practices have on user performance, acceptance, and adherence.

   Target 5: Test novel materials and construction of PPE to optimize performance and HCP use, acceptance, and adherence using accepted standards and testing methodology.

   Target 6: Develop clear, specific, evidence-based implementation guidance using accepted standards. This guidance should include when it is safe to implement extended use, reuse (without contamination of HCP while doffing), and decontamination of PPE during PPE shortages.

3. Coordinate with other federal partners to advance respiratory protection for HCP who are not part of an RPP when sudden respiratory hazards are present.

   Target 1: Jointly sponsor a NASEM consensus study with other federal partners to provide recommendations for how the U.S. can best identify the need for, and support the use of, respirators by HCP who are not part of an RPP. HCP include those performing ancillary functions such as environmental services, security, and food service support activities.

   Target 2: Provide national leadership to integrate NASEM's recommendations into the U.S. strategy for respiratory protection of these populations.

   Target 3: Determine the assigned protection factor that users can expect when fit testing is not feasible or delayed. Determine the protection factor with and without the use of a standardized sizing guide that matches adults to a respirator size.

   Target 4: Determine what level of protection users can expect for various FFR filtration efficiencies (i.e., 95%, 99% and 99.97%) when fit testing is not feasible or is delayed and users only perform a seal check.

Objective 4: Develop and disseminate guidance and best practices to inform PPT implementation and enhance user adherence

Knowledge Gaps

Numerous studies show that HCP have limited understanding of the purpose, selection, maintenance, and proper use of PPE [50-55]. As with other safety measures dependent on behavior, such as washing hands or wearing seat belts, PPE are most effective when properly used. For example, HCP should wear respirators or surgical gowns in the presence of hazards and don and doff them correctly to prevent exposure and provide protection.

Individual behaviors and organizational practices contribute to an effective safety culture in healthcare settings. However, on occasion, these cultural practices may run counter to HCP self-protection [50]. Several factors contribute to the practicality of HCP adherence to follow guidelines, recommendations, policies, and regulations:

- time constraints,
- incomplete knowledge of guidelines and recommendations,
- concerns about interference with patient care or occupational duties,
- perceived discomfort,
- perceived risk of exposure or consequences of exposure, and
- lack of emphasis on self-protection [50].

As with other complex organizational problems, no single solution or remedy suffices. However, organizations that achieve incremental improvements in workplace safety can offer enhanced protection for HCP.

Numerous opportunities exist for the development and validation of methods, tools, and interventions to increase HCP knowledge about PPE use. These opportunities can better position health systems to protect their workers in prudent and cost-saving ways. Healthcare organizations and HCP with a more comprehensive understanding of current health and safety management practices can better support a systems-based approach. This enables them to identify the most prevalent individual and organizational factors that contribute to low adoption and execution of desired safety practices around PPE use.

NIOSH seeks to reduce the occupational risks HCP face by conducting and supporting a systems-based approach for PPT. Such an approach considers the inter-relationship between PPE development and the use of that PPE, including guidance and user adherence. This inter-relationship includes the supporting methods, processes, techniques, tools, and materials used to design PPE. Targeted risk management interventions can thereby be developed to improve the effective use of PPE in healthcare settings.

Providing HCP and their employers with PPT guidance and information that is up to date and easily accessible fosters the most effective targeted health and safety practices. One consideration when developing guidance is addressing the needs of all workers and work circumstances. This may include the following:

- traditional (e.g., N95 FFR) and non-traditional (e.g., EHMR) healthcare PPE;

- various healthcare settings (e.g., long-term care facilities); and
- various employment arrangements (e.g., traveling nurses or contracted physicians) [56].

Additionally, the U.S. healthcare industry continues to embrace non-standard work arrangements (e.g., contract workers). Meeting the challenge of training and fitting new employees due to turnover can ensure HCP safety and effective use of PPE. This is particularly true for PPE such as respirators, where safe and effective use depends on individual factors such as fit and health status. Finally, as additional types of PPE products (e.g., PAPRs, EHMRs, FFRs, and barrier face coverings) enter healthcare settings, identifying best practices for PPE implementation, use, and effectiveness can further protect HCP.

Priorities and Targets

1. Provide mechanisms that improve accessibility to critical PPT guidance.

   Target 1: Conduct formative work (pilots or exploratory research) to identify and assess information sources that organizations and HCP use to obtain PPE best practices guidance. Information sources might include vendors, manufacturers, government agencies, and professional societies. Establish relationships with the entities that manage the content for these sources.

   Target 2: Continue to leverage NIOSH PPT communication channels (e.g., Respiratory Protection Week, PPE CASE Notes, MMWR, and social media) and use Target 1 relationships to disseminate best practices. Conduct a systematic evaluation of these channels to assess and improve their impact on users, PPE vendors, and those making PPE selections (e.g., industrial hygienists).

   Target 3: Facilitate discussions with continuing education (e.g., through the NIOSH Education and Research Centers), recertification, and licensure bodies to update training and academic program curriculums to integrate PPE best practices. Ideally, this would be added into required, formal education curriculum or modules. NIOSH can leverage the relationships that other parts of the CDC have with healthcare providers and state, local, tribal, and territorial governments.

   Target 4: Expand NIOSH's web-based tool, PPE-Info, to provide selection logic support and direct links to manufacturer products that claim to meet relevant standards. Add plain language descriptions of standards such as ASTM F3502-21 Standard Specification for Barrier Face Coverings.

2. Develop, improve, or inform implementation standards and guidance for PPT best practices.

   Target 1: Conduct workforce or workplace studies to evaluate current on-the-job training techniques and processes. Develop interventions to enhance the effectiveness of this training for all medicine and allied health services. Training interventions should be (1) applicable to various levels of nursing support including non-traditional employment arrangements (e.g., traveling nurses or contracted physicians); and (2) accessible, desirable, and useful to new HCPs and those for whom English is their second language.

   Target 2: Conduct a review of PPT best practices (e.g., reminder and initial notification techniques) for routine and crisis operations. Identify strategies and opportunities where the

two may align, reducing the need to implement a change in practice during future crises. This analysis can also be used to inform Priority 1, Target 3 above.

Target 3: Establish consensus on PPE best practices. Document the knowledge, attitudes, and behavioral practices of HCP around PPE perceptions, adoption, and sustained use. Use this to inform interventions in long-term care, at-home care, and dentistry settings.

Target 4: Update NIOSH's Respiratory Protection Toolkit to include reusable respirators, crisis strategies, and non-traditional employment arrangements (e.g., traveling nurses or contracted physicians).

Target 5: Collaborate with other federal agencies, PPE manufacturers, and other knowledgeable groups to unify (and potentially centralize) best practices for selection, use, cleaning and disinfecting, and storage practices. Create communication products to decrease confusion, increase trust, and boost confidence in guidance.

Target 6: Provide research, technical support, and guidance to inform voluntary consensus standards focused on the PPE end-user to improve awareness, acceptance, and adherence. Incorporate standards into NIOSH guidance.

3. Provide research, technical support, and input to inform voluntary consensus standards and NIOSH guidance documents on the use of respirators and source control devices not traditionally used in U.S. healthcare settings.

   Target 1: Enable the use of EHMRs in healthcare settings for routine or crisis care. Create implementation guidance and inform best practices for integration within RPPs.

   Target 2: Enable the use of PAPRs in healthcare settings for routine or crisis care. Create implementation guidance and inform best practices for integration within RPPs to support routine or crisis use of this respirator type.

   Target 3: Conduct effectiveness studies for face-worn products at hospital facilities where source control is needed. The results of the studies will be used to inform use guidance and ASTM F3502-21 Specification Standard for Barrier Face Coverings. These studies should include wearing masks when using PAPR models without any other method of source control.

Objective 5: Provide national leadership to inform the design and execution of NIOSH's RAP and other PPT CA schemes

Knowledge Gaps

A comprehensive and tailor-made CA program is the most effective way to manage risks associated with potentially non-conforming PPE and instill user confidence in the PPE. CA uses established test methods to verify that PPE conform to published performance requirements. This then allows the safety professionals who select PPE, and the workers who rely on them, to know that needed protective capabilities are consistently present [38]. As stated by NASEM: "for the consumer or worker, CA provides confidence in the claims made about the product by the manufacturer and may assist the consumer with purchasing decisions in determining the fitness of a product for its intended use" [57].

No single regulatory body, official guidance, or mandating authority is charged with assessing conformity of all types of PPT. Historically, NIOSH has served as a national leader in PPE CA by overseeing the agency's RAP (codified at 42 CFR Part 84) and supporting or conducting research to inform worker safety regulations, PPE performance standards, and infection prevention guidance. In 2017, NIOSH published its National Framework for Personal Protective Equipment Conformity Assessment – Infrastructure [38], which guides CA program owners to optimize CA practices using a risk-based approach.

In 2017, NIOSH's RAP convened an Action Planning Team to assess the RAP and identify specific action items that would optimize its performance. NIOSH presented these action items to the International Safety Equipment Association—the largest industry association for respirator manufacturers. NIOSH then further revised the action items before finalizing its RAP Action Plan in 2018 and presenting it at a meeting with respirator manufacturers.

In 2020 and 2021, due to COVID-19, NIOSH's RAP experienced an unprecedented number of applications that outpaced human capital resources. NIOSH received a high number of applications from those inexperienced with the process who required much more support than applicants already familiar with the process. The additional support needed by the new applicants, in combination with the unprecedented number of applications received, posed a substantial (and unsustainable) resource challenge to NIOSH. Additionally, global travel limitations impacted the RAP's ability to perform manufacturing site audits or initial manufacturing site qualifications.

To address these challenges, NIOSH implemented a variety of policy and human capital solutions to achieve the following:

- accelerate application turnaround times for high-priority respirator types,
- evaluate manufacturing sites virtually, and
- provide information to fill knowledge gaps for new applicants.

NIOSH plans to assess the root causes (policy and standards gaps or resource limitations of the challenges experienced) for transitioning back to conventional operations. NIOSH also plans to review the near-term solutions implemented to address these challenges to determine the potential value if they were continued in the current (or an adapted) form.

CA challenges also exist for non-respiratory PPE. For example, the language in current standards continues to preclude third parties such as stockpiles from performing post-market quality assurance evaluations on critical PPE items such as surgical and isolation gowns [58]. This poses a particular concern as the U.S. Strategic National Stockpile, state, and private stockpiles depleted their inventory in early 2020 and subsequently needed to purchase millions of gowns with no ability to verify the initial or ongoing quality of these products. Additionally, challenges related to product labeling and packaging for surgical and isolation gowns and masks continue to be noted by stakeholders—e.g., group purchasing organizations and stockpiles. Challenges include labeling materials that are insufficiently durable to environmental conditions during shipment or that are not accessible to those managing and distributing large shipments and pallets. Further, individual product labels are sometimes misleading—e.g., claiming conformity for the material when the fully assembled and constructed product do not conform.

Finally, questions remain about the quality and performance of gloves and other PPE types (e.g., gowns) used when handling hazardous drugs (e.g., antineoplastic or chemotherapy drugs) or drugs with the potential for dermal absorption such as fentanyl and its analogs. Several studies indicate that antineoplastic drugs may permeate gloves, including nitrile gloves [59-61]. Further, researchers know little about the protective ability of gloves against continually changing formulations of drugs as well as their precursors and analogs. NIOSH's review of available products found five glove models where the manufacturer claimed protection against one drug (i.e., fentanyl), but test methods to assess product performance and validate these claims are lacking [62]. Characterizing the performance of gowns and other PPE used to prevent exposure to hazardous drugs with the potential for dermal absorption can be used to inform the CA.

Priorities and Targets

1. Optimize NIOSH RAP operations to reduce the time needed for the Respirator Certification Program review process and the burden on the applicants by integrating modern and innovative technologies and artificial intelligence approaches.

   Target 1: Develop and implement an "information enterprise system" using artificial intelligence with input from stakeholders. The system will enhance records management, internal operations processes, tracking of manufacturer approvals and applications, user access to respirator approval information, and communication between NIOSH and applicants.

   Target 2: Integrate the use of remote, digital technologies to enhance reviews and assessments of proposed or active manufacturing sites.

2. Advance the state of respiratory protection in the United States by providing research, technical support, and guidance to voluntary consensus standards bodies or by implementing policy solutions within NIOSH's RAP.

   Target 1: Continue coordination efforts with the Food and Drug Administration (including the use of voluntary consensus standards) to expand the respiratory protection available to HCP and to streamline approvals/decisions for respirators used in healthcare.

   Target 2: Continue to update requirements and test methods (federal and voluntary consensus) for PAPRs to establish evidence-based standards that enable the safe and effective use of these respirators in healthcare settings (e.g., where there is a need for a sterile field and communication).

   Target 3: Reference ASTM F3407 Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators in the regulatory framework of NIOSH's RAP.

   Target 4: Assess the outcome of Objective 1 from these NIOSH Healthcare PPT Targets to determine the need for additions or revisions to U.S.-based CA frameworks.

3. Identify the need for additional standards solutions to enhance respirator protections in the United States.

   Target 1: Conduct surveillance to assess exposure hazards and PPE usage characteristics for HCP working in facility types (e.g., outpatient settings) and healthcare occupational groups (e.g., home healthcare support in remote work locations) where limited PPE usage research has been conducted.

Target 2: Evaluate the impact of current regulations on respirator innovation.

Target 3: Develop a roadmap to address any issues identified from Targets 1 and 2 above.

4. Implement changes to practices, procedures, and informational products used by the NIOSH RAP to optimize performance.

   Target 1: Enhance existing post-market respirator testing and evaluation to include evaluating respirators at the point-of-use (e.g., evaluate the effect of storage conditions), leveraging the PPT nomenclature and data format standard and resulting software platforms mentioned previously (refer to Objective 3, Priority 1, Targets 2 and 3).

   Target 2: Leverage the PPT nomenclature and data format into a voluntary consensus standard to provide greater connectivity between the NIOSH RAP's Certified Equipment List and third-party vendor platforms for PPT inventory management.

   Target 3: Develop NIOSH-accredited third-party facility knowledge, skills, and abilities for NIOSH respirator testing and quality assurance capabilities. The goal is to enhance NIOSH agility during surge events and improve efficiencies and support technology innovators during routine demands, to provide trusted testing support, and to develop a strategy for leveraging and maintaining trust with these laboratories (per federal guidance as described by the National Institute of Standards and Technology).

   Target 4: Establish a sustainable approach to routinely review and update the NIOSH Standard Testing Procedures with consideration for the latest technological advancements.

   Target 5: Develop and formalize crisis strategy practices, procedures, and informational products that the NIOSH RAP will implement in an emergency.

5. Inform the design of CA schemes where no scheme owner exists.

   Target 1: Provide leadership through research, technical support, and guidance to optimize the CA schemes for HCP PPE ensembles and components (e.g., surgical and isolation gowns, gloves, eye protection).

   Target 2: Provide leadership through research, technical support, and guidance to establish or refine CA schemes for face-worn products making source control claims.

   Target 3: Assess the effectiveness of existing product and package labeling requirements for PPE used by HCP. Then document the ability of PPE selectors, purchasers, distributors, and users to accurately discern the appropriate use conditions for a given product.

Objective 6: Expand U.S. capacity for PPT research and innovation

Knowledge Gaps

In 2008, NASEM recommended that NIOSH establish and sustain extramural PPT Centers of Excellence. These PPT Centers could be developed to "work closely with the NIOSH intramural research program to improve PPT, increase field research, and explore and implement research to practice interventions." Realization of this recommendation would establish a strong extramural community and provide the opportunity to extend scientific inquiry into the behavioral sciences and other types of expertise not yet well developed within NIOSH's Personal Protective Technology Program.

Several recent efforts also recognize the need for greater PPT research and innovation capacity where recommendations align with NIOSH's unique capabilities, as detailed below.

- December 2020: The Federal Emergency Management Agency announced a Plan of Action to establish a national strategy for the manufacture, allocation, and distribution of medical devices to respond to COVID-19 as part of a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.
- January 2021: President Biden signed Executive Order 14001, resulting in the July 2021 National Strategy for a Resilient Public Health Supply Chain, which recommends launching "a new public health supplies innovation center and product standardization task force." Also, the National Strategy for the COVID-19 Response and Pandemic Preparedness was published. Goal 4 of the strategy directs for the immediate expansion of "emergency relief and exercise of the Defense Production Act," with subsequent text discussing both PPE as a critical supply and specific needs to address shortages.
- September 2021: The White House released American Pandemic Preparedness: Transforming our Capabilities. The first goal under Building Core Capabilities was to have effective, comfortable, and affordable PPE, and a sub-goal focused on PPE innovation.

Meeting the objectives outlined in these strategy documents requires not only greater national capacity for PPT research and innovation, but also equitable PPE protections for HCP.

Addressing gaps in PPE use, availability, accessibility, acceptability, and knowledge that exist for only a subset of PPE users with shared characteristics may reduce inequities related to PPE. These worker populations may include, but are not limited to, workers who are of an atypical size; who are members of a gender, racial, ethnic, or linguistic minority group; who conduct non-traditional HCP activities; or who are members of sub-disciplines that are not the primary focus of the current PPT activities within their larger field (e.g., housekeeping staff employed in healthcare settings) [63]. Examples of challenges faced by some members of these populations include difficulty finding a single-use FFR that fits their facial dimensions, PPE limitations when religious practices require growing facial hair or wearing a head wrap, language difficulties and cultural differences when reading guidance documents, and limited scientific studies or training modules that address hazard scenarios experienced by a small sub-population of workers.

Priorities and Targets

1. Expand private sector engagement in PPT research and technology development.

   Target 1: Provide research grants to establish PPT Centers of Excellence within academic institutions having accredited programs in areas such as occupational and environmental health to support a pipeline of PPT researchers by establishing laboratory capabilities, administering academic training, and fostering outreach and continuing education specific to PPT.

   Target 2: Establish a NIOSH Program that leverages both Broad Agency Announcement and Request for Proposal contract types to engage technology developers, engineering firms, suppliers, and manufacturers to advance the development and production of next-generation PPT for HCP.

Target 3: Using Target 2 above, leverage contracts and PPT Centers of Excellence to drive innovative PPT design. These designs may include novel lightweight, protective materials; construction; use of sensors; and usability issues (e.g., grip and tactile sensitivity).

Target 4: Guide PPT Centers of Excellence to develop the national capacity for the following:

1. Research and development of new technologies and approaches to PPT, including sensor technology to increase efficacy.
2. Human factors or ergonomics approaches to evaluating the factors that influence the adoption and usage of PPE such as performance, comfort, fit, and usability.
3. Sociotechnical systems analyses of the influences of factors such as health and safety management systems, safety culture, and regulatory requirements.
4. Innovative approaches to the design, manufacture, and maintenance of PPE that enhance factors such as the effectiveness and acceptance of PPE in varied user populations, availability, and the ability to rapidly customize and produce PPT during crises.

Target 5: Leverage the research conducted by the newly established PPT Centers of Excellence to establish evidence-based PPT guidance.

2. Address gaps in PPE use, availability, accessibility, acceptability, and knowledge to meet the goal of providing equitable PPE protections for HCPs, provide research, technical support, and guidance to voluntary consensus standards organizations and others.

   Target 1: Establish relationships with the research community and voluntary consensus standard development organizations that address PPE equity challenges and challenges for workers whose jobs place them at higher levels of risk.

   Target 2: Conduct literature reviews and engage with members of the PPE community to identify PPE equity challenges related to availability, accessibility, knowledge, and persistent issues for high-risk workers.

   Target 3: Integrate test procedures and tasks into existing and newly developed research projects to address the unique needs of both PPE users experiencing inequitable PPE protections and workers whose jobs place them at high risk.

   Target 4: Leverage ASTM F3407 Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators to identify populations of workers who may not have adequate options for respiratory protection and recommend possible strategies to close this gap.

   Target 5: Publish a national strategy to provide equitable PPE protections for HCP by (1) identifying and prioritizing goals into near-, mid-, and long-term efforts; and (2) providing a roadmap and timelines for how members of the PPE community can work in coordination to systematically address all gaps and challenges.

ATTRIBUTION

N95 and NIOSH Approved are certification marks of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

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