Framework for Setting the NIOSH PPT Program Action Plan for Healthcare Worker Personal Protective Equipment: 2013-2018

Background

Following the severe acute respiratory syndrome (SARS) outbreak in 2003, increased attention was given to identifying the best ways to protect healthcare workers (HCWs) from emerging respiratory pathogens. Keeping the ~18 million HCWs providing patient care healthy is an important component of pandemic planning. Among the various non-pharmaceutical intervention strategies available to reduce pathogen transmission in occupational settings, the use of personal protective equipment (PPE) plays a critical role. PPE can be defined as equipment such as gowns, gloves, face shields, eyewear, respirators, and surgical masks worn to minimize exposure to a hazard.

In 2006, the National Institute for Occupational Safety and Health's (NIOSH) Personal Protective Technology (PPT) program began an initiative to develop and execute a comprehensive approach to HCW protection. This action plan was to include research and intervention, certification, standards development, and information dissemination program to improve the efficacy and effectiveness of PPE used by HCWs during a pandemic.

The process to develop the initial action plan[(1)] and its updates[(2-4)] has been driven by inputs from three primary sources. One source of inputs is from a series of reports[(5-8)] from the Institute of Medicine (IOM) of the National Academies, beginning in 2008. A second major source of inputs comes from the outputs and outcomes from completed and on-going research and intervention activities. The third major source is from the program's stakeholders, including its annual stakeholder meetings.[(9-13)]

The action plan and its updates provide both a near-term and a long-term strategy for NIOSH's influenza pandemic activities. The action plans have also served to assist other government agencies in their research agenda setting process. The NIOSH PPT program is preparing to again update the PPE for HCW action plan for 2013-2018. This following framework will serve four initial purposes:

(1) Identifies proposed "recommendations" and "activities" to use in an updated PPE for HCW action plan;
(2) Compares current NIOSH intramural and extramural program activities versus the proposed recommendations and activities;
(3) Proposes an overarching strategy for NIOSH PPT program management to prioritize among competing recommendations, activities, and future action steps; and
(4) Outlines the process planned for seeking stakeholder input on what "action steps" should be taken by NIOSH and the NIOSH PPT program to address the recommendations.

Identifying Proposed Recommendations and Activities

As discussed in the previous section, the first draft version[(1)] and the subsequent two revisions of the action plan were based on the 2008 IOM report[(5)], while version 4 of the action plan[(4)] incorporated the recommendations from the 2009 IOM letter report.[(6)] The most recent 2011 IOM report[(7)] identified 12

recommendations in four major areas: (1) transmission of influenza and the use of PPE in preventing transmission, (2) designing and engineering PPE to be effective and wearable, (3) use of PPE by HCWs, and (4) PPE policy, standards, and certification. Because of the thoroughness of this report[7] and our historical practice of using IOM recommendations as the framework for the action plan, we decided to use these 12 IOM recommendations as the starting framework for this proposed revision.

One advantage of using these recommendations is that they encompass the full spectrum of needed research, including basic and applied research through policy/regulatory science. Figure 1 outlines IOM's conceptual approach to moving from research into practice.[7] As noted in the report, "*this approach ensures that basic science initiatives are fully explored, while also addressing clinical needs and testing the results in real-work settings*".

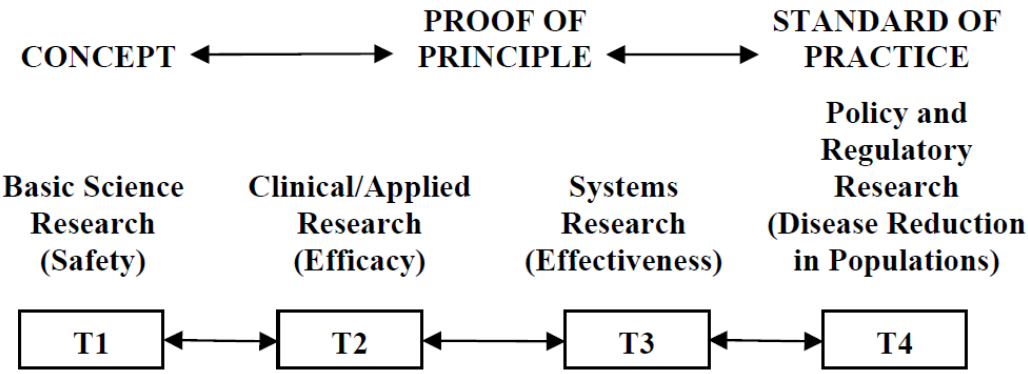

Figure 1. An integrated system moving research into practice, depicting the translation of research from basic science research (T1) through policy and regulatory research (T4). Source: IOM report[7] Page 26, Figure 1-2.

In addition to the 12 overarching recommendations, each chapter of the IOM report[7] identified additional findings and research needs which were usually a subset of a one or more of the 12 recommendations. These findings and research needs serve as the basis for the proposed activity areas within each recommendation. While the 2011 IOM report[7] serves as the starting point, research needs identified by DHHS[14, 15] and NORA[16] have been incorporated to the extent possible. For example, IOM recommendation #10 that focused specifically on clarifying PPE guidelines for outbreaks serves as a natural location for incorporating several of the HHS improvement plan[15] recommendations related to PPE. In developing this framework document, we also reviewed the NIOSH PPT program's Government Performance and Results Act (GPRA) goals[17] and the NIOSH Board of Scientific Counselors report[18] on the program's progress toward those goals. The five GPRA goals are not targeted specifically toward HCW, but areas where a given HCW PPE research action step supports the broader PPT program GPRA goal can be identified within the actions steps to further ensure alignment of goals, recommendations, activities, and action steps within the program.

Appendix 1 contains the 12 proposed overarching recommendations and 36 proposed activities (note: there are another 10 sub-activity items below two of the activities related to recommendation #3). Appendix 2 is a cross-walk of the recommendations from the 2011 IOM report[7], the DHHS H1N1 improvement plan[15], and NORA HCSA sector goals.[16] The data in Appendix 2 show good overlap

among the three sources, suggesting that the 2011 IOM report is a valid source for identifying proposed recommendations and activities.

Comparing the Current NIOSH PPT Program and Proposed Recommendations

The 12 proposed recommendations were compared to the existing NIOSH research portfolio to identify areas of current NIOSH research and for possible gaps for developing specific action items in the next phase of the process. Short summaries of NIOSH intramural projects related to HCW PPE are available.[19-21] Internal resources (e.g., the NIOSH Project Planning and Management (NPPM) System) and an external grants database[22] were also used to identify relevant projects both within the intramural and extramural NIOSH PPT program portfolio and in related NIOSH program areas. Figure 2 summarizes the recommendations in which there is current activity within NIOSH. Given the priority of these research areas within the NIOSH PPT program since 2006 and the HCSA sector, it is not surprising that NIOSH is involved in most of the areas, either in a leadership role or in supporting the efforts of other government agencies. Even within the areas where NIOSH was considered to play a more supportive role; there may be specific NIOSH research projects that support one of the activities. The only area in which there is no current activity can be considered completed with the NIOSH contributions to a CDC transmission workshop report.[23]

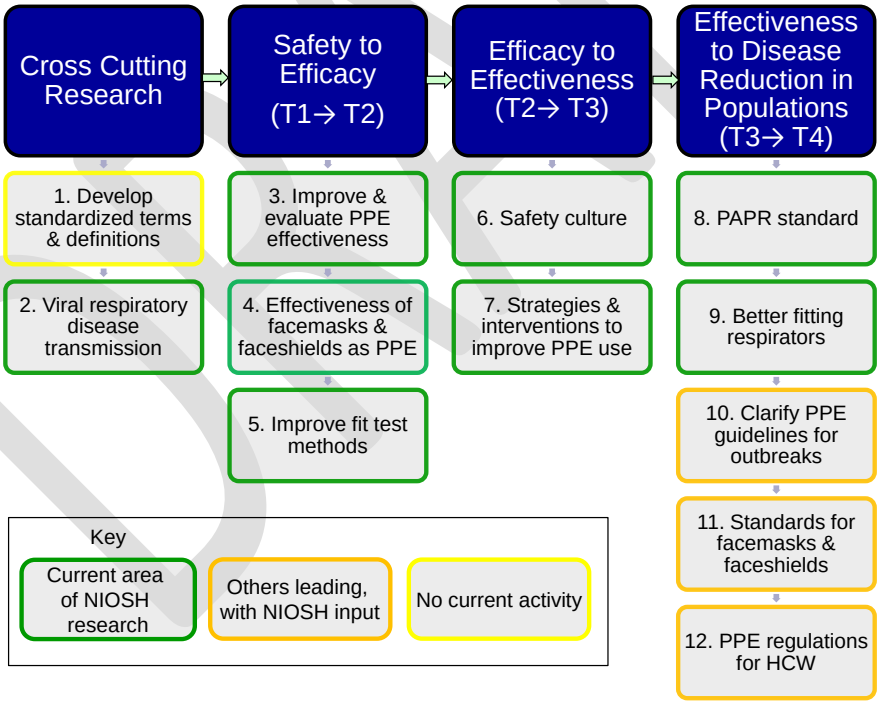

Figure 2. Mapping current NIOSH research projects to the 12 proposed recommendations

Proposed Prioritization Strategy

All of the proposed recommendations and activities (Appendix 1) are important, but it is not practical to expect that NIOSH has the resources and expertise to tackle all of them simultaneously. Furthermore,

during times of increased budget scrutiny, NIOSH and other government agencies cannot fund all of the desirable research projects, but instead need to make difficult decisions. Prioritization tools will enable NIOSH and its stakeholders to implement the action plan in the most efficient way.

For this action plan, we propose to use improving HCW PPE compliance as the overarching goal for prioritization. Observational studies of HCW compliance with proper PPE use practices and procedures indicate that adherence is often quite low. [7] Surveys of workers (i.e., self-reporting) have come to similar conclusions. Like other interventions (e.g., hand washing, use of seat belts, etc.), a limitation of PPE is its reliance upon the wearer to perform the intervention correctly (e.g., wear their PPE at all times during the entire period of exposure). The reasons for non-compliance and barriers to proper PPE use among HCWs include both organizational and individual factors. The 2011[7] and 2008[5] IOM reports identified a number of potential factors, including lack of accountability for PPE non-compliance, workload issues, time constraints, risk perception, PPE effectiveness concerns, PPE availability, PPE comfort, PPE interference with patient care, and the inability to communicate while wearing PPE. The rationale for prioritizing activities that can be used to improve HCW PPE compliance is three-fold.

- There is a strong relationship between compliance and protection.[24, 25] The effects of poor compliance have been studied by the industrial hygiene community. For example, Figure 3 illustrates the relationship between wear time (a critical component of compliance) and effective protection factor (EPF) (i.e., actual exposure reduction). This relationship, first described by the American Industrial Hygiene Association respiratory protection committee[26], is based upon time-weighted averages of a constant exposure. In this figure, the lines represent three different types of hypothetical respirators including a filtering facepiece respirator (FFR), hooded powered air purifying respirator (PAPR), and full facepiece air purifying elastomeric, providing different levels of workplace protection factors (WPF). This model suggests that compliance needs to be > 75% to see more than a 25% increase in EPF, even for a respirator (e.g., full facepiece elastomeric) with superior ability to reduce exposure. Similar theoretical examples can be given for other types of PPE.

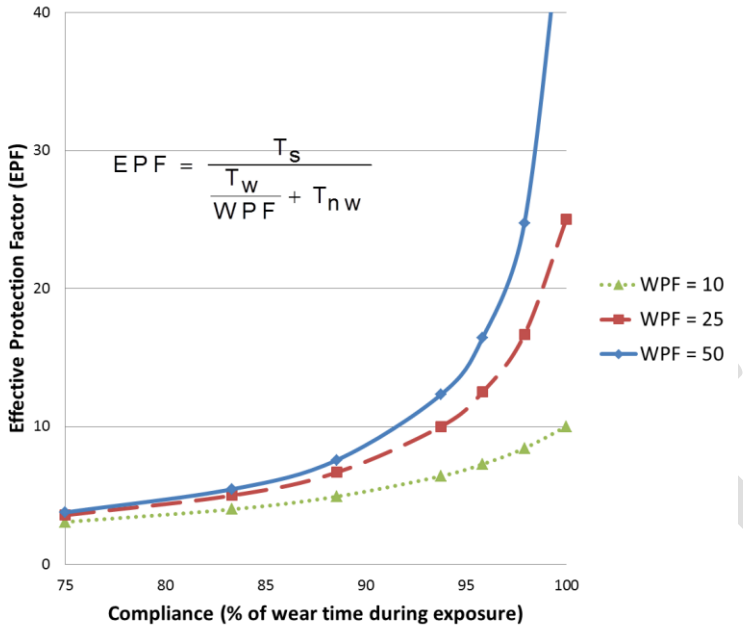

Figure 3. Model depicting the relationship between EPF and Compliance. In this example, the 3 hypothetic respiratory types are FFR (WPF = 10), hooded PAPR (WPF = 25), and full facepiece air purifying elastomeric (WPF = 50). T_e = Exposure duration, T_w = Time Worn, T_{nw} = Time Not Worn, WPF = Workplace Protection Factor. Source: adapted from multiple sources.[24-26]

- No single solution exists that will address all of the reasons for non-compliance and barriers to proper use. A multi-pronged or "bundled" strategy is needed to increase compliance during both normal and emergency situations, which could include research and interventions such as:
  - Changing the organizational safety culture;
  - Creating improved educational modalities and methods of information dissemination such as the use of social media and new technologies like mobile-phone apps);
  - Developing clear polices/recommendations based upon sound science;
  - Better understanding of the modes of human to human transmission and recommended infection control precautions for respiratory pathogens;
  - PPE clinical effectiveness studies;
  - Less burdensome fit test methods for tight fitting respirators; and
  - Better fitting / more comfortable PPE.

While no single solution is likely to be successful by itself, studies of other public health interventions demonstrate how research (e.g., new technologies and innovations) can improve compliance. For example, studies[27-29] have found that hand hygiene compliance rates improved significantly when educational campaigns were bundled with wide spread distribution of alcohol-based hand rub bottles/dispensers. In these instances, the intervention involved a new technology, alcohol-based hand rub, which eliminated a known barrier to traditional hand washing by decreasing the time needed to perform the action. Because of the multi-disciplinary nature of interventional research, focusing on compliance will encourage collaborations among

NIOSH intramural and extramural researchers and draw interest from new partners (e.g., end-users, hospitals, etc.). These synergistic interactions will enhance the current HCW PPE research program.

- Focusing on improving HCW PPE compliance is consistent with the NIOSH PPT program mission "*To prevent work-related injury, illness, and death by advancing the state of knowledge and application of PPT*". Proper use of PPE is an important *application* of PPT. Concentrating on HCWs and compliance in healthcare settings is consistent with the NIOSH focus on workers and the workplace. As noted the NORA HCSA sector goals[16], promoting a "culture of safety" and appropriate use of PPE are important.

Process for Obtaining Stakeholder Input

We plan to obtain stakeholder comments in three specific areas:

1. Our proposed use of the IOM recommendations as the basis for the 12 overarching recommendations and 36 activities in next revision of the action plan;
2. Our proposed use of improving HCW PPE compliance as the overarching goal for prioritization; and
3. Specific actions that NIOSH and the NIOSH PPT program should take to address the proposed recommendations

The Table shows the timeframe and process for updating the NIOSH PPT program HCW PPE action plan.

Timeframe	Milestone
April – June 2013	Form internal NIOSH PPT program Working Group Publish NIOSH Science Blog[30] seeking comments on research needs to improve PPE compliance in healthcare Discuss Framework document at the NIOSH PPT Program Healthcare Stakeholder Meeting[13]
July – September 2013	Publish Framework document on the NIOSH Docket Publish Federal Register Notice seeking public comment NIOSH PPT program Working Group drafts initial action plan
October – December 2014	NIOSH PPT program Working Group revises draft action plan Final action plan is published to the NIOSH docket and the NIOSH PPT program website

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Appendix 1. Proposed Recommendations and Activities

1. Develop Standardized Terms and Definitions
    1.1. Through a consensus process involving the industrial hygiene, infectious diseases, and healthcare communities, develop standardized terms, definitions, and appropriate classifications to describe transmission routes and aerodynamic diameter of particles associated with viral respiratory disease transmission.
2. Develop and Implement a Comprehensive Research Strategy to Understand Viral Respiratory Disease Transmission
    2.1. Animal studies (ferrets and guinea pigs) should be done to determine which interventions (e.g., increased air exchange, antimicrobial treated surfaces, and UV treatment of air) are likely to be the most effective.
    2.2. Environmental studies (in multiple locations, e.g., schools, public transportation, healthcare facilities) should be done to assess the effect of UV light and humidity on influenza transmission and whether the identified influenza RNA in aerosol samplers are viable and reflect the extent to which individuals are exposed to aerosols of influenza within these environments.
    2.3. Statistical and mathematical models should be developed and evaluated for their utility in prediction and inferences regarding the relative contributions of different transmission modes in varying environmental/community contexts.
    2.4. Clinical studies should be conducted to examine all possible modes of transmission, including environmental levels (air sampling and surface swabs) of contamination, serological studies of exposure to influenza virus in family members or roommates, and the size distribution of patients' respiratory particles to which healthcare personnel are exposed and some measure of the intensity of the exposure to patients that might include distance from, time in contact with, and specific procedures performed on the infected patients.
3. Continue and Expand Research on PPE for Healthcare Personnel
    3.1. Conduct studies to improve and evaluate the effectiveness of respirators for healthcare personnel in preventing the transmission of influenza or other viral respiratory diseases.
        3.1.1. Assess impact of various strategies for reuse / extended use of respirators during a respiratory disease outbreak, including conducting studies to assess promising respirator decontamination methods, their impact on protection, and their effectiveness using either influenza virus or a suitable surrogate.
        3.1.2. Develop and assess the efficacy and effectiveness of protocols (e.g., respirator donning and doffing) and new technologies (e.g., antiviral-coated respirators) to minimize self-inoculation from handling contaminated PPE.
        3.1.3. Conduct research to examine the features of N95s, PAPRs, and elastomeric respirators that impact comfort and tolerability among healthcare personnel and identify alterations in respirator design and construction that show promise in improving problem features that adversely impact comfort and tolerability.
        3.1.4. Assess respirator total inward leakage (TIL) of very small particles (< 100 nm).
        3.1.5. Conduct workplace protection studies to assess protection during typical tasks over time, determine how using typical instruments impact protection, and to identify/mitigate possible integration issues.
        3.1.6. Conduct human factors (field of view, visual acuity, communication) and operational performance studies on respirators to assess the ability of healthcare personnel to perform medical procedures in typical healthcare-specific PPE ensembles and to identify/mitigate possible issues.

3.1.7. Develop technologies and test methods to support new air-purifying respirators that specifically address the needs of healthcare personnel, including new materials to improve fit, comfort, and tolerability.

3.1.8. Develop technologies and test methods to support a new low-noise, lightweight PAPR and a face shield for healthcare personnel that are reusable and easy to clean.

3.2. Conduct studies to improve and evaluate the effectiveness of non-facial PPE (e.g., gloves, gowns) in preventing the transmission of influenza or other viral respiratory diseases.

3.2.1. Conduct research to identify factors (duration of use, material properties) affecting the comfort and usability of non-facial PPE, and identify/implement changes having the potential to positively influence comfort, tolerability, or integration with other healthcare specific PPE ensemble components.

3.2.2. Conduct studies to quantify the role of non-facial PPE on droplet spray and direct-contact (fomite) transmission.

4. Examine the Effectiveness of Face Masks and Face Shields as PPE

4.1. Conduct studies to investigate the effectiveness of goggles, face masks, and face shields in preventing aerosol transmission of viral respiratory diseases.

4.2. Perform manned and unmanned studies to investigate the effectiveness of goggles, face masks, and face shields in preventing droplet-spray and direct-contact transmission of viral respiratory diseases.

5. Improve Fit-Test Methods and Evaluate User Seal Checks

5.1. Perform research leading to the development and adoption of novel, simpler fit-test methods.

5.2. Conduct research to improve and evaluate the effectiveness of performing user seal checks on filtering facepiece respirators.

6. Explore Healthcare Safety Culture and Work Organization

6.1. Conduct research to better understand the role of safety culture and other behavioral and organizational factors on PPE compliance in healthcare settings.

6.2. Conduct human factors and ergonomics research relevant to the design and organization of healthcare work tasks to improve worker safety by reducing hazardous exposures and effectively using PPE (e.g., reduce unnecessary PPE donning and doffing).

6.3. Conduct studies to explore the links between patient safety and healthcare worker safety and health that are relevant to the use of PPE, identifying and evaluating strategies to mitigate organizational barriers that limit the proper use of PPE by healthcare personnel.

7. Identify and Disseminate Effective Leadership and Training Strategies and Other Interventions to Improve PPE Compliance

7.1. Support intervention effectiveness research to assess strategies, including innovative participatory approaches to training, for healthcare and supervisory staff at all levels to improve PPE compliance and other related outcomes across the range of healthcare settings.

7.2. Conduct observational studies of PPE usage by healthcare personnel in different types of work settings.

7.3. Develop, implement, and evaluate comprehensive leadership and training strategies and interventions that go beyond simple knowledge-based training.

7.4. Design training interventions specifically for supervisory and managerial personnel in different types of healthcare settings.

7.5. Examine long-term practice change and safety culture implementation related to educational interventions.

7.6. Develop strategies to improve use and understanding of PPE by home and community healthcare personnel

7.7. Develop assessment tools and metrics that take a broader approach to PPE and acknowledge the interaction of worker, task, and environmental factors
7.8. Conduct a lessons-learned summit on PPE use by healthcare personnel during the 2009 H1N1 experience.
8. Develop and Certify PAPRs for Healthcare Personnel
8.1. Conduct studies to evaluate and develop certification requirements for a low noise, loose-fitting PAPR for healthcare personnel.
9. Move Forward on Better Fitting Respirators
9.1. Continue rulemaking for TIL regulations that require respirators to meet fit criteria.
9.2. To improve consumer and purchaser information on fit capabilities, establish a website to disseminate fit-test results for specific respirator models on an anthropometric (NIOSH) test panel, where such data exist.
10. Clarify PPE Guidelines for Outbreaks of Novel Viral Respiratory Infections
10.1. Conduct and evaluate case studies on the implementation of 2009 H1N1 PPE related policies, including whether stockpiling of respirators should be continued and, if so, develop requirements, taking into account the national need, domestic manufacturing surge capacity and sourcing of raw materials, and a system for allocation and distribution.
10.2. Conduct studies that compare theoretical models of estimating quantities of PPE for emergency preparedness with recent experience to inform future public health planning.
10.3. Develop and deploy systems to monitor safety, effectiveness, and shortages of PPE.
10.4. Conduct research into cost effectiveness issues relevant to PPE, including issues of disposable vs. reusable equipment.
10.5. Perform prospective research efforts to examine the impact of public health guidance on PPE compliance by state, local, and health system policy; clinical practice; and costs.
10.6. Encourage respirator manufacturers to achieve both NIOSH certification and FDA clearance to ensure an ample supply of respirators during a respiratory disease outbreak.
10.7. Develop and/or revise relevant respirator reuse /extended use guidelines and policies.
10.8. 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.
11. Standards and Certification for Face Masks and Face Shields
11.1. Support the development of voluntary consensus standards and independent third-party testing and certification processes for face shields and face masks as PPE, with specific tests for assessing prevention of transmission of viral respiratory diseases.
12. Establish PPE Regulations for Healthcare Personnel
12.1. Promote and support the development of voluntary consensus standards for non-respiratory PPE (e.g., gowns, gloves, face shields, face masks) in the event of influenza and other viral respiratory diseases.
12.2. Support the development of aerosol-transmissible diseases standards that would include prevention of the transmission of influenza and other viral respiratory diseases.

Appendix 2. Cross-walk of Recommendations

2011 IOM recommendation	HHS recommendations	NORA HCSA Goals*
Cross-Cutting Research		
1. Develop Standardized Terms and Definitions		
2. Develop and Implement a Comprehensive Research Strategy to Understand Viral Respiratory Disease Transmission	5.4.4. Conduct research to better understand influenza transmission, to clarify when surgical masks are sufficient, and when the use of N95 respirators or other devices may be more appropriate	IG 5.1: Understanding mechanisms and routes – Investigators across a broad range of disciplines will conduct research to understand mechanisms and determinants of routes by which infectious diseases are transmitted in the healthcare and social assistance setting.
Safety to Efficacy: Basic Research (T1) to Clinical/Applied Research (T2)		
3. Continue and Expand Research on PPE for Healthcare Personnel	5.4.4. Conduct research to better understand influenza transmission, to clarify when surgical masks are sufficient, and when the use of N95 respirators or other devices may be more appropriate 5.4.5 Innovate and strengthen RPD design, use, testing, and certification for both occupational and community settings for a wide population, including the pediatric population 5.4.6 Develop and/or revise relevant RPD use/reuse guidance and policies	IG 5.10 Research and adopting best practices for PPE – With a range of partners in the public and private sectors, encourage an integrated effort to fully understand the unique requirements of healthcare and social assistance workers, and to develop innovative materials, technologies, and products that can meet their needs, as well as those of their patients. AOG 5.9.4: Conduct research to improve the understanding of how human factors and behavioral issues related to the ease and effectiveness of PPE use for extended periods of time and during diverse work environments affect PPE use and compliance.
4. Examine the Effectiveness of Face Masks and Face Shields as PPE		AOG 5.10.3: Conduct research to document the protective differences between various types of PPE using methods that simulate real-life usage and assess all potential leakage paths.
5. Improve Fit-Test Methods and Evaluate User Seal Checks		AOG 5.10.6: Conduct research on the frequency of fit testing to assess the rate at which respirator fit changes as a function of time, to investigate the factors that affect such change, and to guide recommendations for frequency and type of fit testing. AOG 5.10.7: Conduct pre-use check research, investigating the efficacy of user seal checks on filtering facepiece respirators.
Efficacy to Effectiveness: Clinical/Applied Research (T2) to Systems Research (T3)		
6. Explore Healthcare Safety Culture and Work Organization		IG 5.9: Research and adopting best practices for PPE – Healthcare and social assistance facilities will establish and promote a culture of safety where employer and employee commitment to worker safety in general, and the

		appropriate use of PPE in particular, are strengthened.
7. Identify and Disseminate Effective Leadership and Training Strategies and Other Interventions to Improve PPE Use		AOG 5.9.1: Develop and disseminate training programs which emphasize the correct use (and disposal) of PPE during patient care across HCSA settings. AOG 5.9.2: Conduct demonstration projects on PPE compliance and use. AOG 5.9.3: Publish and disseminate broadly the results of these projects to ensure the proliferation of successful PPE strategies.
Effectiveness to Disease Reduction in Populations: Systems Research (T3) to Policy/Regulatory Research (T4)		
8. Develop and Certify Powered Air-Purifying Respirators (PAPRs) for Healthcare Personnel		
9. Move Forward on Better Fitting Respirators		AOG 5.10.5: Conduct research to explore innovative application of new technologies, such as use of new materials to achieve better "out of the box" fit and reduce need for fit testing; or incorporating sensors into PPE to detect breaches and notify users of end-of-service life and other protection information.
10. Clarify PPE Guidelines for Outbreaks of Novel Viral Respiratory Infections	5.4.1 Determine whether the stockpiling of respirators in the SNS should be continued and if so, develop requirements for stockpiling, taking into account national need, including domestic manufacturing surge capabilities and sourcing of raw materials, and a system for allocation and distribution 5.4.2 Encourage RPD manufacturers to pursue both NIOSH certification and FDA clearance to ensure an ample supply of FDA-cleared N95 respirators are available for use in healthcare settings during a pandemic: 5.4.3 Develop systems to monitor safety, effectiveness, and shortages of RPDs after deployment	AOG 5.9.5: Develop surveillance of PPE usage to identify priorities, trends and emerging issues associated with the use of PPE in the workplace and use the information to establish a baseline on PPE usage, develop benchmarks and performance measures, sharpen the focus of research efforts and aid in the development of a more effective and active dissemination program.
11. Standards and Certification for Face Masks and Face Shields		
12. Establish PPE Regulations for Healthcare Personnel	5.4.2 Encourage RPD manufacturers to pursue both NIOSH certification and FDA clearance to ensure an ample supply of FDA-cleared N95 respirators are available for use in healthcare settings during a pandemic:	

297 * notes: IG = Intermediate goal. AOG = Activity/Output Goal. For brevity, only the highest level goal is
298 identified. There are several more specific sub-level Activity/Output goals associated with each
299 Intermediate Goal.
300

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