Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan to address Actions for the next 5 years

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Table of contents

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In the event of pandemic influenza, personal protective equipment, including disposable particulate respirators and surgical facemasks, will be one of several public health interventions that make up the first line defense against human-to-human transmission of the virus.

Subsequently, the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) requested the Institute of Medicine (IOM) of the National Academies (NA) examine the issues regarding PPE for healthcare workers in the event of pandemic influenza. The IOM issued a report, Assessment of Pandemic Preparedness and the associated PPE needs for Healthcare Workers (2007) in September 2007 to provided recommendations to NPPTL. This plan responds the recommendations provided by the IOM in the report.

The IOM report, Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers, September 2007, defines an urgent need to address the lack of preparedness regarding effective PPE for use in an influenza pandemic. The IOM report identifies recommendations for research and policy actions in three critical areas:

- Understanding influenza transmission.
- Commit to worker safety and appropriate use of PPE.
- Innovate and strengthen PPE design, testing and certification.

These three areas are defined and examined in detail as "Issues" below.

The IOM recommendations in these areas are extensive, requiring the involvement of numerous federal agencies, the private sector and international partners. The report recommends the Department of Health and Human Services (DHHS) lead a focused research effort to facilitate understanding of the transmission and prevention of seasonal and pandemic influenza. NIOSH and the Personal Protective Technology (PPT) Program are charged with assisting in this effort as it relates to understanding transmission among healthcare workers, and conducting research to design and promote the appropriate use of PPE.

The IOM report recommends the expansion of existing research, such as the hospital influenza transmission study currently funded by Pandemic Flu Preparedness funds, as well as the initiation of new projects to possibly be funded through the National Occupational Research Agenda (NORA) process. Key activities to be conducted by NIOSH are outlined below, in accordance with the three critical research areas outlined in the IOM report. Each recommendation identifies current activities in progress within NIOSH and subsequent activities to be conducted.

This plan summarizes the recommendations and the actions planned for the next five years to address the recommendations in the main document. Appendix A is the most recent version of the more detailed action plan which describes the research needs in greater detail over a ten year timeline. Appendix B provides an overview of the NIOSH Cough Study described in Appendix

A. Appendix C provides the response to the comments submitted to NIOSH Docket 129 on this subject.

Recommendation 1.1: Understanding influenza transmission

Desired Outcome: The mechanisms and routes of human-to-human influenza transmission are understood.

The current knowledge of key aspects of influenza transmission is rudimentary. Increased understanding is required on the extent of droplet, aerosol, and contact transmission, and the optimum ways to prevent transmission. Research initiatives are needed to address these matters and the viability/infectivity of the airborne virus. As these issues are more clearly understood, successful mitigation and prevention strategies can be developed and deployed.

ACTIVITY 1.1.1: Research to develop an understanding of influenza transmission.

ACTION STEP 1.1.1.1: Measure the size and quantity of aerosol droplets produced by people when they cough.

Summary: Measure the size and quantity of aerosol droplets produced by people when they cough – Healthy volunteer subjects and volunteer subjects with influenza will be asked to cough into a collection bag. Aerosol measurement instruments will then draw the air from the bag and measure the quantity and size of airborne droplets that are produced. (PPE HCW AP 1.3.3)

ACTION STEP 1.1.1.2: Measure the amount and size of airborne particles containing influenza virus in a hospital. (PPE HCW AP 1.3.4)

Summary: Measure the amount and size of airborne particles containing influenza virus in a hospital – During the 2008 influenza season, healthcare workers in a hospital emergency department wore personal aerosol samplers that collect airborne material from the environment while they worked. Stationary aerosol samplers were also placed in the waiting rooms, reception area and two exam rooms. Preliminary results indicate that influenza virus was detected in 3 of 14 personal samplers and 10 of 98 stationary samplers, and that 50% of the virus was on particles less than 4 μm in diameter (these particles are small enough to stay airborne for half an hour or more and to be drawn deep into the lungs). An expanded study is planned for next year.

ACTION STEP 1.1.1.3: Simulate the exposure of a healthcare worker to an infectious aerosol. (PPE HCW AP 1.3.6.1.2)

Summary: Simulate the exposure of a healthcare worker to an infectious aerosol – A simulated exam room is being created with a cough aerosol simulator (simulating a coughing patient with influenza) and a breathing mannequin (simulating a healthcare worker) to test how well healthcare workers are protected from cough-generated aerosols. The breathing mannequin can be outfitted with a mask or respirator to simulate different types of respiratory protection. As part of this work, the viability (infectivity) of a surrogate laboratory strain of influenza will be studied. Experiments are

planned to determine the viability of the virus in an aerosol and the effect of capture in the sampler on virus viability.

Recommendation 1.2: Commit to worker safety and appropriate use of PPE

Desired Outcome: A culture of safety is evident in both individuals and organizations within the healthcare community.

Appropriate PPE use and HCW safety should be a priority for all individuals within the healthcare workplace, as well as being made an integral part of the operation culture of their parent organizations. A primary way to bring about these desired results is to emphasize the correct use (and disposal) of PPE during patient care across healthcare employees and management through training and accreditation.

Another appropriate mechanism involves conducting demonstration projects on PPE compliance and use. These efforts can be used to identify best practices for improving PPE use. Publication and broad dissemination of the results of these projects can ensure the proliferation of successful PPE strategies.

Finally, additional research is needed 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.

ACTIVITY 1.2.1: Research, training, and interventions to ensure the appropriate use of PPT.

ACTION STEP 1.2.1.1: Collaborating to conduct research and disseminate research findings. (PPE HCW AP 1.1.1)

Summary: Collaboration with other federal agencies, healthcare organizations, standards development organizations and other stakeholders is a critical element for successful implementation of the IOM recommendations. The PPT Program will actively seek stakeholder participation and involvement in the actions of the program and will strive to maintain transparency in carrying out program actions. Information on best practices and other research findings will be disseminated via the NIOSH website, printed literature, conference participation, standards development meetings and annual stakeholder meetings. Key findings will also be translated into documents to be shared with healthcare workers and employers directly.

ACTION STEP 1.2.1.2: Training for healthcare professionals. (PPE HCW AP 6.4.2)

Summary: In 2008, NIOSH initiated an Occupational Medicine rotation for Internal Medicine and Family Medicine residents to enhance their skills and knowledge of PPE. The one-day rotation includes shadowing an Occupational Medicine physician, respirator fit testing practice, and audiogram performance and interpretation. Oversight of the rotation is provided by the NIOSH NPPTL Research Medical Officer. NIOSH will expand this program to further advance PPE training for healthcare workers.

ACTION STEP 1.2.1.3: Surveillance of PPE usage. (PPE HCW AP 1.3.6.1.3)

Summary: The PPT Program, in partnership with healthcare organizations, will develop and strengthen the use of surveillance data to identify priorities, trends and emerging issues associated with the use of PPE in the workplace. Information gathered will be used to establish a baseline on PPE usage, develop performance measures, sharpen the focus of NIOSH research, and aid in the development of a more effective and active dissemination program.

Recommendation 1.3: Innovate and strengthen PPE design, testing and certification

Desired Outcome: Effective PPE, with initial emphasis on filtering facepiece respirators (FFR), are designed, tested, certified, and readily available for use by the healthcare workforce, for routine and non-routine applications.

The use of PPE in any specific workplace environment places unique demands on the design and engineering of these products. This is of particular importance in the healthcare industry where these products have to be focused on interactions between the workers and their patients. In these circumstances, the concerns are not only that the workers not be infected by the patients, but also that they (the workers) also do not transmit infections to subsequent patients through the equipment they use to protect themselves.

An integrated effort is needed to fully understand the unique requirements of HCWs and to develop innovative materials, technologies, and products that can meet their needs, as well as those of their patients.

Core issues regarding the responsibilities of federal agencies and organizations have to be clarified. Further, increasing the use of testing in the pre-market phase and conducting post-marketing evaluations is vital to the development and effective use of such products.

Some of the key scientific questions to be addressed by this research program include (note: several of the research questions pertaining to Recommendation 4 of the PPT Implementation Plan (IP) are relevant here as well):

- Can PPE (in particular single-use FFRs) be decontaminated to remove infectious material and then be safety reused?
- How effective are the various strategies (e.g., stockpiling, surgical mask overlay, decontamination, etc.) for mitigating the impact of a respirator shortage during a pandemic? Are there best practices that can be shared?
- What are risks of handling PPE exposed to infectious materials? What is the likelihood of contaminated PPE serving as a fomite? What are the best methods (e.g., donning/doffing procedures) or technologies (e.g.,. antimicrobial coatings) for mitigating those risks?

ACTIVITY 1.3.1: Research to develop and test PPE.

ACTION STEP 1.3.1.1: Handling and use of contaminated PPE. (PPE HCW AP 1.3.4 and 5.3.10.2)

Summary: Although respirators serve to protect the wearer, concerns exist that viruses remaining on a respirator transform it into a fomite that may serve as a vehicle for infection of the wearer, or others. The PPT Program will conduct research to assess the viability of an influenza surrogate virus on various models of filtering facepiece respirators (including respirators with antimicrobial components). Data generated will offer important information on fomite-related issues and also allow for the quantification of subsequent decontamination effects on the respirator.

ACTION STEP 1.3.1.2: Strategies for decontamination of PPE. (PPE HCW AP 1.2.3 and 5.3.10.2)

Summary: The availability of FFRs during a pandemic influenza is a subject of major concern. Respirator manufacturers have warned that they may not be able to meet the anticipated demand. This has placed more emphasis upon the idea of decontaminating FFRs for reuse. Research will be planned and conducted to address the reusability of FFRs following various types of decontamination (e.g., heat, soap & water, chemicals, ultraviolet light, gas sterilization, microwaving). The data will be used to categorize the various decontamination agents with respect to their effects on filtration performance of the respirator.

ACTION STEP 1.3.1.3: Protective differences between various types of PPE. (PPE HCW AP 4.2.1 and 5.3.9)

Summary: Relative performance of N95 and P100 FFRs will be evaluated in laboratory protection level studies. The tests will measure total protection provided by the respirators assessing all potential leakage paths. Test subjects will wear the respirators while performing work at different work levels in order to evaluate performance at different breathing rates. Test results would be applicable to virus particles, whether aerosol or droplet transmission.

ACTION STEP 1.3.1.4: PPE systems integration requirements for healthcare workers. (PPE HCW AP 4.5.1.2 and 3.0 and PPT IP 4)

Summary: Respirators utilized in healthcare settings were not designed for that particular venue. Therefore, there are features of respirators that do not necessarily lend themselves well to the healthcare environment. The PPT Program, in conjunction with the Veterans' Health Administration (VA) and academia, initiated the Project Better Respirator Equipment and Technology for Healthcare Employees (BREATHE). Currently in its developmental stages, this endeavor will first bring together a working group to address respirator characteristics germane to healthcare workers (e.g., speech intelligibility, visibility, hearing, etc.) with the goal of identifying features that would enhance respirator performance in the healthcare setting. The second stage of this project will consist of presenting the recommendations to respirator manufacturers with the intent of developing a respirator that is designed specifically with the healthcare worker in mind.

ACTION STEP 1.3.1.5: New materials and innovative technologies. (PPE HCW AP 4.1 and PPT IP 4.2)

Summary: Application of new materials and innovative concepts in the design and development of respirators and other PPE can present an opportunity to improve performance of PPE. Innovative application of new technologies such as incorporating sensors into PPE to detect breaches and notify users of end of service life and other protection information will be explored.

ACTION STEP 1.3.1.6: Respirator fit test science and pre-use checks research. (PPE HCW AP 5.3 and 5.3.1.1 and PPT IP 4.2.1.1)

Summary: Frequency of fit testing research will be performed to assess the rate at which respirator fit changes as a function of time, and investigate the factors that affect such change. The metric for respirator fit will be the respirator penetration. Pre-use check research investigating the efficacy of user seal checks on FFRs will also be performed.

ACTION STEP 1.3.1.7: PPE usage and physiological consequences. (PPE HCW AP 4.1.2 and PPT IP 4.2)

Summary: The PPT Program will investigate carbon dioxide and oxygen levels in healthcare workers who wear respirators for prolonged periods, as would occur in a pandemic influenza. If elevated Carbon Dioxide (CO2) levels or depressed Oxygen (O2) levels are measured that would lead to symptoms, mitigation strategies will be developed.

ACTIVITY 1.3.2: Research to develop evidenced based performance standards. (PPE HCW AP 2.0)

ACTION STEP 1.3.2.1: Evidence-based performance requirements for PPE in healthcare settings. (PPE HCW AP 2.0)

Summary: The PPT Program will work to identify PPE used by healthcare workers and the existing performance standards. A quantitative performance analysis will be conducted to assess the effectiveness of each type of PPE (gowns, gloves, respirators, etc.) in reducing the risk of influenza transmission. The findings combined with surveillance data will form the basis for developing enhanced, evidence-based performance requirements.

ACTIVITY 1.3.3: Research to conduct PPE evaluations.

ACTION STEP 1.3.3.1: Pre-market and post-market PPE testing. (PPE HCW AP 10.0 and 11.0)

Summary: The PPT Program will investigate methods to implement pre- and post-market testing of PPE used in healthcare settings. This could include analysis of the requirements and use of PPE to identify methods to perform workplace and simulated workplace testing to achieve a true assessment of PPE effectiveness. The findings of this study could aid in the improvement of PPE design and use.

ACTION STEP 1.3.3.2: PPE Certification. (PPT IP 1.3.1.1)

Summary: The IOM report states: "The development and implementation of certification processes should be explored by NIOSH [PPT Program] and the Food and Drug Administration (FDA), with certification testing occurring in the NPPTL laboratory or by a process determined to be best suited for increased pre-market testing." As stated in PPT IP 1.3.1.1, a workshop similar to the PPE for HCW workshop will be organized by IOM to address options for PPT certification. The workshop is anticipated to be a Fiscal Year (FY) 2010 activity.

FY 09 PPT Program Activities and Projects Related to Recommendations

The PPT Program has identified the FY09 PPT activities that support this recommendation. This diverse portfolio of research addresses critical aspects of the research gaps identified above in action steps 1-1, 1-2, and 1-3. All of these research activities are conducted by our intramural staff in collaboration with various partners and stakeholders. Several projects work closely with the various American Society for Testing and Materials (ASTM) International, International Organization for Standardization (ISO), and National Fire Protection Association (NFPA) committees to transition PPT intramural program outputs into recognized standards and test methods. Project BREATHE cuts across several of the research gaps by seeking to develop a respirator optimized for the healthcare sector featuring better integration with other PPE, less job interference, better fit, and improved comfort. Several projects are focused on understanding critical issues related to concerns of a possible respirator shortage caused by a pandemic. For example, one project involves collaboration with the Department of Defense (DoD) Air Force research lab (AFRL), FDA and several universities with funding provided by the DoD Technical Support Working Group (TSWG) to study decontamination/reuse of FFRs. Establishing a better understanding of respirator fit and performance are the goals of several other projects. All program activities related to this plan can be located at the following link: http://www.cdc.gov/niosh/programs/ppt/projects.html. Approximately $400 Thousand (K) discretionary funds are dedicated in FY09 to support these initiatives.

Appendix A: PPE for HCW Action Plan-081908.doc Docket# 129

Summary

During an influenza pandemic, healthcare workers will be on the front lines delivering care to patients and preventing further spread of the disease. As the nation prepares for pandemic influenza, multiple avenues for protecting the health of the public are being carefully considered, ranging from rapid development of appropriate vaccines to quarantine plans should the need arise for their implementation. One vital aspect of pandemic influenza planning is the use of PPE—the respirators, gowns, gloves, face shields, eye protection, and other equipment that will be used by healthcare workers and others in their day-to-day patient care responsibilities.

However, efforts to appropriately protect healthcare workers from illness or from infecting their families and their patients are greatly hindered by the scarcity of data on the transmission of influenza and the challenges associated with training and equipping healthcare workers with effective personal protective equipment. Due to this lack of knowledge on influenza transmission, it is not possible at the present time to definitively inform healthcare workers about what PPE is critical and what level of protection this equipment will provide in a pandemic. The outbreaks of severe acute respiratory syndrome (SARS) in 2003 have underscored the importance of protecting healthcare workers from infectious agents. The surge capacity that will be required to reduce mortality from a pandemic cannot be met if healthcare workers are themselves ill or are absent due to concerns about PPE efficacy. The increased emphasis on healthcare PPE and the related challenges anticipated during an influenza pandemic necessitate prompt attention to ensure the safety and efficacy of PPE products and their use.

In 2006, the IOM Committee on Personal Protective Equipment (COPPE) determined that there is an urgent need to address the lack of preparedness regarding effective PPE for use in an influenza pandemic. Subsequently, NPPTL at NIOSH asked the IOM to examine issues regarding PPE for healthcare workers in the event of pandemic influenza. The IOM committee was charged with examining research directions, certification and the establishment of standards, and risk assessment issues specific to personal protective equipment for healthcare workers during an influenza pandemic.

The IOM provided three overarching conclusions and a series of recommendations for maximizing the opportunity to incorporate PPE into influenza pandemic research. The committee also provided recommendations regarding future research opportunities. The twelve recommendations made to address the three overarching conclusions are as follows:

Understand Influenza Transmission

- Initiate and Support a Global Influenza Research Network

Commit to Worker Safety and Appropriate Use of PPE

- Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training
- Identify and Disseminate Best Practices for Improving PPE Compliance and Use
- Increase Research and Research Translation Efforts Relevant to PPE Compliance

Innovate and Strengthen PPE Design, Testing, and Certification

- Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE
- Adopt a Systems Approach to the Design and Development of PPE
- Increase Research on the Design and Engineering of the Next Generation of PPE
- Establish Measures to Assess and Compare the Effectiveness of PPE
- Ensure Balance and Transparency of Standards-Setting Processes
- Strengthen Pre-market Testing of PPE for Healthcare Workers
- Strengthen Post-market Evaluation of PPE for Healthcare Workers
- Coordinate Efforts and Expand Resources for Research and Approval of PPE

One of the challenges for the healthcare field is to clearly understand the differences between respirators and medical masks as well as their appropriate uses. Medical masks (the term is used in this report to encompass surgical masks and procedure masks) are loose-fitting coverings of the nose and mouth designed to protect the patient from the cough or exhaled secretions of the physician, nurse, or other healthcare worker. Medical masks are not designed or certified to protect the wearer from exposure to airborne hazards. They may offer some limited, as yet largely undefined, protection as a barrier to splashes and large droplets. However, because of the loose-fitting design of medical masks and their lack of protective engineering, medical masks are not considered personal protective equipment.

A terminology issue has further confused and blurred the boundary between medical masks and respirators. The term "respirator" is commonly used in the healthcare field to refer to two different medical devices: (1) the personal protective equipment discussed in this report that is used to reduce the wearer's risk of inhaling hazardous substances and (2) the mechanical ventilator device that is used to ventilate patients in respiratory failure (such devices are more properly called "ventilators" than "respirators"). This dual (medical and occupational) use of the term respirator has prompted many healthcare workers to refer to PPE respirators as masks, thereby confounding the important distinctions between medical masks and respirators.

Protection of the healthcare worker against infectious disease can also involve gloves, eye protection, face shields, gowns, and other protection. For the most part, these products are designed to provide a barrier to microbial transfer with particular attention to protecting the wearer's mucous membranes. The extent of liquid penetration is a major issue with gowns and gloves. Comfort and wearability issues include the breathability of the fabric or material and biocompatibility or sensitivity to avoid contact dermatitis and other skin irritations. Issues related to viral survival on contaminated surfaces and objects, viral penetrance, and reusability remain to be explored as do considerations about how best to integrate the use of the various types of protective equipment to ensure that they integrate effectively (e.g., the respirator and eye protection).

More than 14 million workers in the United States (approximately 10 percent of the U.S. workforce) are employed in the healthcare field. Thus, it's important that we protect those workers on the front lines with the best available PPE and prevention methods to handle an influenza pandemic. To that end, it is imperative that a global influenza research network be established to examine the influenza transmission issues that directly affect the PPT Program. Some of the major questions that need answers are:

- What are the major modes of transmission? How much does each mode of transmission contribute individually or with other methods of transmission?
- What is the size distribution of particles expelled by infectious individuals, and how does that continuum of sizes affect transmission?
- Can infection take place through mucous membranes or conjunctiva exposure?
- What is the role of UV light, humidity, temperature, pressure differentials, air flow and exchange and ventilation in preventing transmission?
- and How effective is each type of PPE (gowns, gloves, respirators, etc.) in reducing the risk of influenza transmission? Should other than respirator PPE be certified, if so who's responsibility is it?

NIOSH/NPPTL has the overall management responsibility for the NIOSH PPT Program and is responding to the IOM report by developing an action plan for addressing the issues and recommendations within the PPT program domain described in the report. The action plan provides both a near term and long term strategy for influenza pandemic research, development, and investigative testing for the PPT Program. The action plan is structured to align with the recommendations outlined in the IOM report, ***Preparing for an Influenza Pandemic: PPE for Healthcare Workers, 2008***. Each recommendation identifies current activities in progress within the NIOSH PPT Program and subsequent activities which should be considered for both near term and long term implementation. Associated references and web links are provided for ongoing activities where available. Each text description is accompanied by a flow chart which provides a pictorial representation of the information described in the associated text. Associated Gantt Charts identifying anticipated timelines for conducting the activities in response to each recommendation follow the flow charts. The PPT Program ongoing and potential future activities are highlighted in yellow. The action plan addresses implementation of research recommendations in the workplace. The following steps are being taken to develop the action plan:

- Assess the IOM recommendations to identify actions within the PPT Program domain
- Review on-going and proposed PPT Program activities
- Assess the IOM recommendations to determine if existing data are available to make decisions on whether the recommendations should be implemented near or long term
- Apprise applicable organizations to disseminate actions outside the PPT Program domain.
- Solicit stakeholder input on action plan.
- Review on-going activities in NIOSH, academia, government, and industry related to influenza pandemic preparedness.
- Prioritize activities in response to recommendations within the PPT Program domain
- Determine if new initiatives for PPT Program should be managed through intra- or extra-mural processes
- Schedule project proposals into the PPT Program strategic planning process
- Develop final PPE for HCW Action Plan
- Implement PPE for HCW Action Plan

Being ready for an influenza pandemic—having the necessary resources to minimize morbidity and mortality—is the goal of ongoing global efforts in many areas of endeavor. Since healthcare workers are essential for providing patient care during a pandemic, the personal protective equipment that can protect these workers from becoming infected or from transmitting infection is a vital part of these efforts. Healthcare worker safety is essential for patient safety and patient care. Being prepared for an influenza pandemic places a priority on protecting the healthcare workforce.

I. Introduction

In 2005, the NIOSH NPPTL asked the IOM to form a standing committee to provide strategic guidance in addressing Personal Protective Equipment issues for workers. One issue the committee deemed of high importance is PPE for HCW in the event of pandemic influenza. NPPTL then funded a 12 month study conducted by an adhoc IOM committee. The IOM committee was charged with examining research directions, certification and the establishment of standards, and risk assessment issues specific to PPE for healthcare workers during an influenza pandemic.

The IOM completed the study and issued the report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers* to the PPT Program in September 2007. The IOM provided three overarching conclusions and a series of recommendations for maximizing the opportunity to incorporate PPE into influenza pandemic research. The committee also provided recommendations regarding future research opportunities. The three overarching conclusions are stated here:

- Understanding influenza transmission—Current knowledge is rudimentary regarding the mechanisms and routes of human-to-human influenza transmission (Chapter 2), but with dedicated resources and new technologies, more can be known about the extent of droplet, aerosol, and contact transmission and the optimum ways to prevent transmission.
- Making the commitment to worker safety and appropriate use of PPE—Healthcare workers often do not wear the protective equipment needed to ensure that they are adequately protected from exposure to hazardous agents including infectious disease. Strengthening the commitment of healthcare employers to worker safety and enhancing the culture of safety in the workplace involve both an organizational and an individual commitment to the appropriate use of PPE (Chapter 4).
- Designing, testing, and certifying effective PPE for the healthcare workforce—Using PPE in a healthcare workplace places specific demands on the design and engineering of these products that are particularly focused on interactions with patients and ensuring that healthcare workers do not become infected and do not transmit infection. An integrated effort is needed to further understand the requirements of healthcare workers and to develop innovative materials and technologies that can meet these needs (Chapter 3). Issues regarding the responsibilities of federal agencies and organizations have to be clarified. Further, increasing the use of the field testing in the pre-market phase and conducting thorough post-marketing evaluations is vital to the development of effective products (Chapter 5).

The IOM recommendations encompass a nationwide focus for the PPT program and applicable government agencies, manufacturers, and the healthcare industry. The twelve recommendations made to address the three overarching conclusions are as follows:

- Understanding influenza transmission
  - IOM Recommendation #1: Initiate and support a global influenza research network. The DHHS, in collaboration with U.S. and global partners through the World Health Organization (WHO), should lead a multination, multicity, and multicenter focused research effort to facilitate understanding of the transmission and prevention of seasonal and pandemic influenza. A global research network of excellence should be developed and implemented.
- Making the commitment to worker safety and appropriate use of PPE
  - IOM Recommendation #6: Emphasize appropriate PPE use in patient care and in healthcare management, accreditation, and training. Appropriate PPE use and healthcare worker safety should be a priority for healthcare organizations and healthcare workers, and in accreditation, regulatory policy, and training.
  - IOM Recommendation #7: Identify and disseminate best practices for improving PPE compliance and use. Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ) should support and evaluate demonstration projects on improving PPE compliance and use. This effort would identify and disseminate relevant best practices that are being used by hospitals and other healthcare facilities.
  - IOM Recommendation #8: Increase research and research translation efforts relevant to PPE compliance. NIOSH, the National Institutes of Health (NIH), AHRQ, and other relevant agencies and organizations should support research on improving the human factors and behavioral issues related to ease and effectiveness of PPE use for extended periods and in patient care-interactive work environments.
- Designing, testing, and certifying effective PPE for the healthcare workforce
  - IOM Recommendation #2: Define evidence-based performance requirements (prescriptive standards) for PPE. NIOSH, through the National Personal Protective Technology Laboratory (NPPTL), in collaboration with extramural researchers, manufacturers, and regulatory agencies, should define a set of evidence-based performance requirements or prescriptive standards for PPE to facilitate their design and development that optimally balances the cost, comfort, and degree of protection of PPE and enhances the compliance with their use in the field.
  - IOM Recommendation #3: Adopt a systems approach to the design and development of PPE. NIOSH should promote a systems approach to the design, development, testing, and certification of PPE using evidence-based performance requirements or prescriptive standards and fostering closer collaboration between the users, manufacturers, and research and regulatory agencies.
  - IOM Recommendation #4: Increase research on the design and engineering of the next generation of PPE. NIOSH, the Department of Homeland Security (DHS), the DoD, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of

562 respirators, gowns, gloves, and eye protection for healthcare workers that would
563 enhance their safety and comfort.
564 - IOM Recommendation #5: Establish measures to assess and compare the
565 effectiveness of PPE. NIOSH, through NPPTL, should develop and promote a
566 validated set of measures for comparing the effectiveness of PPE products. The
567 goal is a set of measures that would allow users to compare and select appropriate
568 PPE commensurate with the assessed risk and desired level of protection.
569 Particular attention should be paid to disseminating information to healthcare
570 workers on PPE effectiveness relevant to influenza.
571 - IOM Recommendation #9: Ensure balance and transparency of standards-setting
572 processes. Federal agencies (e.g., FDA, NIOSH, Occupational Safety and Health
573 Administration (OSHA)) should use standards developed through a consensus-
574 based transparent process that sets specific and clearly-defined limits regarding
575 conflicts of interest (financial or other) and involves broad representation of all
576 affected parties.
577 - IOM Recommendation #10: Strengthen pre-market testing of PPE for healthcare
578 workers. FDA, NIOSH, and other relevant agencies and organizations should
579 strengthen pre-market testing requirements for healthcare PPE by requiring field
580 testing of PPE prior to approval and by reevaluating the FDA medical device
581 classification for healthcare PPE. Testing requirements should use rigorous
582 standards while also providing expeditious review of innovative approaches.
583 - IOM Recommendation #11: Strengthen post-market evaluation of PPE for
584 healthcare workers. NIOSH, FDA, and other relevant agencies and organizations
585 should support and strengthen adverse event reporting and post-market evaluation
586 studies and surveillance regarding the effectiveness of PPE used by healthcare
587 workers.
588 - IOM Recommendation #12: Coordinate efforts and expand resources for research
589 and approval of PPE. Congress should expand the resources provided to NIOSH
590 to further research efforts on the next generation of PPE and to coordinate and
591 expedite the approval of effective PPE. Efforts to coordinate PPE testing,
592 certification, and approval across all relevant federal agencies should include
593 developing evidence-based performance standards for all types of PPE for
594 healthcare workers.

595 Additional issues the IOM committee identified as needing to be addressed are:

596 - Substantial gaps in knowledge regarding the design and implementation of PPE for
597 family members and others during an influenza pandemic
598 - Challenges include the benefits of minimizing or negating fit testing of respirators,
599 protecting people with a wide range of face sizes (including children), protecting people
600 with respiratory impairment.
601 - Limited oversight of PPE sold in the retail marketplace.
602
603 NIOSH/NPPTL has the overall management responsibility for the NIOSH PPT Program and is
604 responding to the IOM report by developing an action plan for addressing the issues and
605 recommendations within the PPT program domain described in the report. The action plan
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607 and investigative testing for the PPT Program. The action plan is structured to align with the

recommendations outlined in the IOM report, ***Preparing for an Influenza Pandemic: PPE for Healthcare Workers, 2007***. Each recommendation identifies current activities in progress within the NIOSH PPT Program and subsequent activities which should be considered for both near term and long term implementation. Associated references and web links are provided for ongoing activities where available. Each text description is accompanied by a flow chart which provides a pictorial representation of the information described in the associated text. Associated Gantt Charts identifying anticipated timelines for conducting the activities in response to each recommendation follow the flow charts. The PPT Program ongoing and potential future activities are highlighted in yellow. The action plan addresses implementation of research recommendations in the workplace. The following steps are being taken to develop the action plan:

- Assess the IOM recommendations to identify actions within the PPT Program domain
- Review on-going and proposed PPT Program activities
- Assess the IOM recommendations to determine if existing data are available to make decisions on whether the recommendations should be implemented near or long term
- Apprise applicable organizations to disseminate actions outside the PPT Program domain. **Activities annotated with ** in the action plan are outside the PPT Program domain; however some of these activities are within the scope of work being pursued or that could be pursued by other NIOSH divisions.**
- Solicit stakeholder input on action plan.
- Review on-going activities in NIOSH, academia, government, and industry related to influenza pandemic preparedness.
- Prioritize activities in response to recommendations within the PPT Program domain
- Determine if new initiatives for PPT Program should be managed through intra- or extra-mural processes
- Schedule project proposals into the PPT Program strategic planning process
- Develop final PPE for HCW Action Plan
- Implement PPE for HCW Action Plan

The next two sections describe: (1) the PPT Program assessment of the projects and activities which would fulfill the IOM recommendations, i.e., detailed point by point response to each IOM recommendation; and (2) PPE for HCW Action Plan, i.e., prioritized 10-year plan for a sequence of activities to address recommendations.

The proposed timeline to finalize the action plan is described as follows:

- Draft action plan posted to NPPTL website (February2008)
- Present plan at stakeholder meeting (March 2008)
- Open docket to solicit comments (February 2008 – May 2008)
- Revise action plan based on comments received (August 2008)
- Propose new projects as part of PPT Program strategic planning for FY09 and beyond (October 2008)
- Revise action plan based on strategic planning decisions and project outputs (November 2008).
- Implement action plan

The final HCW Action Plan will be used to prioritize and select future PPT Program initiatives including funding, staffing, and upgrading laboratory capabilities. As noted previously, activities annotated with ** are outside the PPT Program domain; however some of these activities are within the scope of work being pursued or that could be pursued by other NIOSH divisions.

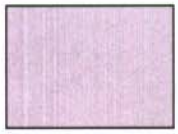
PPT Program PPE for HCW Action plan

*** For the text and recommendation charts below:

Objects with yellow fill represent NPPTL

Objects with orange fill represent NIOSH

Objects with light purple fill represent CDC



Objects with light green fill represent connectivity with other recommendations

II. Assessment of Projects and Activities that align with the IOM Recommendations and Additional Issues

IOM Recommendation # 1: Initiate and Support a Global Influenza Research Network

The DHHS, in collaboration with U.S. and global partners through the WHO, should lead a multination, multicity, and multicenter focused research effort to facilitate understanding of the transmission and prevention of seasonal and pandemic influenza. A global research network of excellence should be developed and implemented.

PPT Program Plan in response to IOM Recommendation # 1

Activity #	Activity/Comment
1.1	Global Influenza Research Network
1.1.1	** The near and long term opportunities for strong collaborative relationships are found at many organizational levels, including: • Within DHHS. DHHS is the parent agency of the CDC which includes NIOSH and six Coordinating Centers/Offices. The FDA and the NIH also are located in DHHS. Within NIH, National Institute of Allergy and Infectious Diseases (NIAID) plays the lead role in influenza research. CDC is the lead U.S. agency for public health response and disease surveillance; CDC also carries out research in influenza epidemiology and molecular virology, and conducts development activities for vaccines and diagnostic tests. Within NIOSH, NPPTL has the specialized expertise relevant to PPE and Health Effects Laboratory Division (HELD) and Division of Respiratory Disease Studies (DRDS) have considerable experience in the collection and analysis of bioaerosols. FDA regulates medical devices, vaccines, and therapies, and its Center for Biologics Evaluation and Research conducts influenza research. • Across Federal Agencies. Several agencies across the Federal government are involved in activities relevant to influenza research, including the U.S. Department of Agriculture (USDA), the Department of the Interior, the DoD, the Department of State, and the U.S. Agency for International Development (USAID). • With Academia. Collaborations with academia need to continue amongst all participants to be on the fore front of new technologies. • With Private Industry. Both established pharmaceutical corporations and new start-up companies play a vital role in the development of new products and strategies for control of influenza. Efficient development of improved vaccines, therapeutics, and diagnostics therefore requires close collaboration with the private sector. • Internationally. The WHO is responsible for coordinating global influenza surveillance and the global response to an emerging influenza pandemic. DHHS is the official point of contact between WHO and the U.S. government; CDC is a designated WHO Influenza Reference Center and thus has the most extensive relationship with the WHO influenza program.
1.2	Identify and prioritize research questions with suggested possible study designs
1.2.1	Can infection take place through mucous membranes or conjunctiva exposure?
1.2.1.1	** Near term research is needed to determine the appropriate levels of protection for all viable routes of transmission.
1.2.2	What is role of UV light, humidity, temperature, pressure differentials, air flow and

exchange, and ventilation in preventing transmission?

1.2.2.1 What is the role of these environmental parameters on the effectiveness of PPE is long term research.

1.2.2.2 ** More research is needed on the effectiveness of engineering control components to regulate these environmental parameters.

1.2.2.3 NIOSH Division of Applied Research and Technology (DART) is exploring isolation controls for biological agents. The current initiative is "Expedient Patient Isolation for Bioterrorism and Epidemic Response". This project seeks to identify and provide detailed implementation guidance on expedient patient isolation techniques that can be implemented during public health emergencies and are affordable, easily implemented, provide effective isolation, reduce potential healthcare worker exposures and do not interfere with hands-on healthcare activities.

1.2.2.4 NIOSH DART is exploring isolation controls for biological agents. Another ongoing initiative is "Expedient Airborne Isolation for Emergency Response Exercises". This research will attempt to translate knowledge learned from prior research on expedient isolation within healthcare environments to non-traditional "infectious" mass casualty environments such as that which might be established in a cafeteria, gymnasium, or other shelter.

1.2.3 Do some fomites inactivate the virus and, if so, how rapidly?

1.2.3.1 NIOSH PPT Program is exploring decontamination of respirators. Current initiatives available here: Reference A.
Concerns over the unavailability, or decreased availability, of filtering facepiece respirators in planning exercises of a pandemic influenza have raised the question of the possibility of re-use of these respirators following decontamination. Because little data exist on this very important issue, the PPT Program has undertaken a research study looking at the effects of various methods of decontamination (e.g., chemical, soap & water, UV light, gas sterilization, microwaving, heat [e.g., autoclaving]) upon the filtration performance of filtering facepiece respirators. The data have served to identify some methods of decontamination (UV light, hydrogen peroxide) that do not affect filtration performance and could potentially be useful, whereas others (bleach, ethylene oxide, microwave) degrade the respirator somewhat (but not enough to cause filtration performance to drop below NIOSH certification standards), and others (isopropyl alcohol, soap & water, and autoclaving) excessively degrade the performance or deform the respirator. This work will also allow for the development of a standardized test protocol for measuring the sterilization efficacy of a decontamination procedure for filter medial and filtering facepiece respirators.

1.2.3.2 ** Long term research is needed to determine conditions and materials that do not support long-term survivability and viability.

1.2.4 What should the public health messages be with regard to preventing transmission (e.g., open windows, use hand sanitizers)?

1.2.4.1 PPT Program continues to conduct research and provide recommendations for the prudent use of PPE based on the best available knowledge.

1.2.4.2 NIOSH/Division of Surveillance, Hazard Evaluations and Field Studies (DSHEFS) has capabilities to provide guidance and assistance to employers and workers, including healthcare workers, addressing workplace hazards associated with pandemic influenza and aerobiological contaminants as a part of HHS pandemic influenza response plan

	responsibilities.
1.2.4.3	NIOSH/DSHEFS has developed a proposal for active surveillance of healthcare facilities that would assemble information relevant to a number of issues pertinent to the spread and preventive practices of influenza. Information identified for collection includes use of respirators, infection control practices, rates of infection, and infection patterns that may distinguish different types of healthcare workers. This would also have the potential to relate influenza infection patterns to various circumstances and work practices that may contribute to infection.
1.2.4.4	** Long term research is needed to better define viable routes of infection and virulence, conditions that support transmissibility and conditions that support long-term survivability and viability.
1.2.4.4.1	HELD has recently proposed research to examine the viability of airborne influenza virus.
1.3	Provide priority funding to support near-term (1 to 3 years) laboratory and clinical studies of influenza transmission and prevention of seasonal influenza with particular focus on the effectiveness of types of PPE
1.3.1	** Possible funding sources – CDC pandemic funds, NIH/NIAID
1.3.2	** What are the major modes of transmission? How much does each mode of transmission contribute individually or with other methods of transmission?
1.3.2.1	** CDC/Office of the Director/Office of Strategy and Innovation (CDC/OD/OSI)
1.3.2.2	New NIH Centers of Excellence identified in FY07 may be appropriate to conduct studies.
1.3.2.3	Potential for Office of Extramural Programs (OEP) to provide grants for studies related to transmission.
1.3.2.4	Results of this work are needed for PPT recommendations and serve as input to PPT Program strategic planning (research, policy, etc).
1.3.3	What is the size distribution of particles expelled by infectious individuals, and how does that continuum of sizes affect transmission?
1.3.3.1	NIOSH PPT Program has a project to characterize the particle sizes, quantity and size distribution of particles produced and expelled by coughing, the dissemination of cough-generated aerosols in the environment, and the effectiveness of disposable masks and respirators at preventing the release of cough-generated particles. Based on results, NIOSH will be proceeding to assess the affect of wearing respiratory protection when coughing and when in the presence of someone coughing. This work is summarized here [Reference B]. FY07 intramural program funding was $269K. Results for this effort will also feed into Recommendation 1 (1.3.6).
1.3.3.2	** Research on the transmission and viability of unfiltered particles is needed.
1.3.4	Is the virus viable and infectious on fomites and for how long? Are fomites a means of transmission and are some more able to transmit than others (i.e., viruses on respirators or cloth versus metal or wood surfaces)? What can be done to decontaminate respirators, allowing re-use under conditions of short supply?

1.3.4.1	Assess viability of virus on respirators. Although respirators serve to protect the wearer, concerns exist that viruses remaining on a respirator transform it into a fomite that may serve as a vehicle for infection of the wearer, or others, through handling or reaerosolization. Utilizing the MS-2 viral E-coli bacteriophage as an influenza surrogate, the NIOSH PPT Program has undertaken a study addressing the viability of the MS-2 virus on various models of filtering facepiece respirators (including respirators with antimicrobial components). Samples of 2.5x2.5 cm2 pieces of respirator filter material exposed to MS2 particles are stored for various times under optimal growth conditions. Since temperature is a major determinant for MS2 survival, samples are stored at 22°, 30°, and 37°C. After incubation for 4 hrs, 1, 2, 4 and 7 days, the samples are processed and the percentage of MS-2 survival is calculated. Data generated by this study will offer important information on fomite-related issues and also allow for the quantification of subsequent decontamination effects on the respirator. This work is summarized here: Reference A.
1.3.4.2	** Research on the transmissibility and viability (infectivity) of viruses is needed to quantify the level and type of controls required to protect HCW from potential formite exposures.
1.3.4.2.1	CDC/National Center for Preparedness, Detection and Control of Infectious Diseases (CDC/NCPDCID) and NIAID will be apprised of the research needs.
1.3.4.2.2	** PPE effectiveness study will examine survival rate of the live vaccine/virus on internal and external surfaces of the PPE as described in Reference V.
1.3.4.2.3	These needs may be achievable under NIAID grants.
1.3.4.3	** Research on the viability of viruses on materials and surfaces used for PPE other than respirators and their ability to be decontaminated is needed.
1.3.4.3.1	CDC and NIAID will be apprised of the research needs.
1.3.4.3.2	These needs may be achievable under NIAID grants.
1.3.5	What activities in the healthcare setting are associated with minimal or increased transmission?
1.3.5.1	** Research studies, including surveillance and activity definitions, are needed to define risk levels of workplace activities and locations for influenza transmission in healthcare settings. These present both near and long term opportunities.
1.3.5.2	NIOSH/HELD and DRDS are working in collaboration with researchers at West Virginia University on a project to examine the potential for airborne transmission of influenza virus in a hospital emergency department. The objective of the study is to better understand the mechanisms by which influenza may be transmitted from infected patients to healthcare workers and others in a healthcare facility. During the pilot study, sampling was conducted on 8 days for 3 to 5 hours per day during influenza season. Fourteen healthcare workers were equipped with personal samplers, and 98 samplers were mounted on stands in waiting rooms, exam rooms and reception areas. Ribonucleic Acid (RNA) in the collected material was isolated, reverse-transcribed and amplified using real-time Polymerase Chain Reaction (PCR) with primers specific to Influenza A matrix protein. Influenza virus was detected in 3 of 14 personal samplers and 10 of 98 stationary samplers. Further, 50% of the virus was found on airborne particles less than 4 μm in diameter, which are small enough to stay airborne for 30 minutes or longer and to be inhaled deeply into the lungs.

1.3.6	In light of the information that is gained on influenza transmission:
1.3.6.1	How effective is each type of PPE (gowns, gloves, respirators, etc.) in reducing the risk of influenza transmission (quantitative performance analysis)?
1.3.6.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
1.3.6.1.2	A NORA funded respirator users cough study. Construction of a cough aerosol exposure simulation system will enable measurement of how well surgical masks and disposable filtering facepiece respirators protect healthcare workers from potentially infectious aerosols produced by patients during coughing, and to provide healthcare recommendations based upon the research results. A cough simulator will be built that "coughs" a simulated aerosol-laden cough through a standard head form (called the coughing head form). A second head form (called the breathing head form) will be connected to a breathing machine to simulate the inhalation and exhalation of a healthcare worker; this second head form can be outfitted with a surgical mask or respirator. The coughing and breathing head forms will be placed in a test chamber to simulate the cough of a patient and the respiration of a healthcare worker, and measure the amount of the cough aerosol that is inhaled by the breathing head form with or without a surgical mask or respirator. Five surgical masks and five respirators corresponding to those in the CDC Strategic National Stockpile, which could potentially be used to support healthcare operations in the event of a pandemic, will be tested in this project. Current initiative is described in Reference W.
1.3.6.1.3	Funding to develop appropriate surveillance initiatives is needed. The goal of surveillance within the PPT Program will be to develop and strengthen the use of surveillance data to identify priorities, trends, and emerging issues associated with the use of PPE/PPT in the workplace. Information gathered through the surveillance program will be used to provide baseline data on PPE/PPT use in workplaces, develop outcome measures for other NIOSH programs, help sharpen the focus of NPPTL's research program, as well as aid in the development of a more effective and active information dissemination program. The surveillance plan activities applicable to this action plan include: analysis and linking of existing databases, initial demonstration/pilot studies, and development of a sentinel system for healthcare. The aim of the Sentinel System for Healthcare is to develop an ongoing Demonstration and Sentinel Surveillance System for the ongoing monitoring of PPE/PPT (N-95, EUAE (Emergency Use Authorization Equipment) etc) selection, usage, fitting, periodicity and effectiveness in five major hospitals in the United States to evaluate and enhance timely interventional response to Pandemic Influenza, Bioterrorism and other Disasters (natural and man-made). A proposal for this work is under development.
1.3.6.2	How effective are medical masks?
1.3.6.2.1	** Currently, performance is assessed in accordance with consensus standards' test methods as FDA cleared medical devices.
1.3.6.2.2	Cough project will evaluate surgical masks as described in Reference W. Also, see write-up in 1.3.3.1 for details of this project.
1.3.6.2.3	** Elastic textile solution pilot for prototype masks will examine masks for potential

	protection against infectious aerosols as described in Reference U.
1.3.6.2.4	Funding to develop appropriate surveillance initiatives is needed.
1.3.6.3	What innovations regarding PPE are needed to enhance effectiveness?
1.3.6.3.1	NIOSH conducted workshops with RAND Jan 2004 to identify future PPE needs.
1.3.6.3.2	Nov 30 - Dec1 2004 PPT Program conducted workshop to assess current state of knowledge of infectivity of bioaerosol: Workshop minutes are provided in Reference C.
1.3.6.3.3	PPT Program will conduct a workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation for a contractor to coordinate and conduct the workshop was published on Nov 8, 2007. [Reference D]
1.3.6.3.4	** PPE Effectiveness Study will provide scientific evidence of the efficacy of PPE (e.g. masks, respirators, eye protection) in reducing airborne transmission of influenza as described in Reference V.
1.4	** Develop rigorous evidence-based research protocols and implementation plans for clinical studies during an influenza pandemic.
1.4.1	Apprise CDC/NCPDCID of research needs and recommendations.
1.4.2	** Long term research is needed to better define "What percentage of patients aerosolize influenza virus during an infection?"
1.4.3	** Long term research is needed to better define "How distinct is transmission in different venues including healthcare, schools, and households?"
1.4.4	** Long term research is needed to better define "What is the time sequence of infectivity?"
1.4.5	** Long term research is needed to better define "If a person excretes virus during the presymptomatic period, is the individual infectious; is virus found in the exhaled air during normal breathing or if someone has a normal cough or sneeze (i.e., allergic cause)?"
1.4.6	** Long term research is needed to better define "When patients receive antiviral drugs do they continue to excrete virus?"
1.4.7	** Long term research is needed to better define "What is the virus concentration in saliva and nasal fluids when a person is asymptomatic, during infection, and during recovery?"
1.4.8	** Long term research is needed to better define "What is the impact of masking patients on transmission risk? If effective, how long should a medical mask be worn?"
1.4.8.1	Funding to develop appropriate surveillance initiatives is needed.
1.4.8.2	Cough project will evaluate surgical masks as described in Reference B. Also, see write-up in 1.3.3.1 for details of this project.

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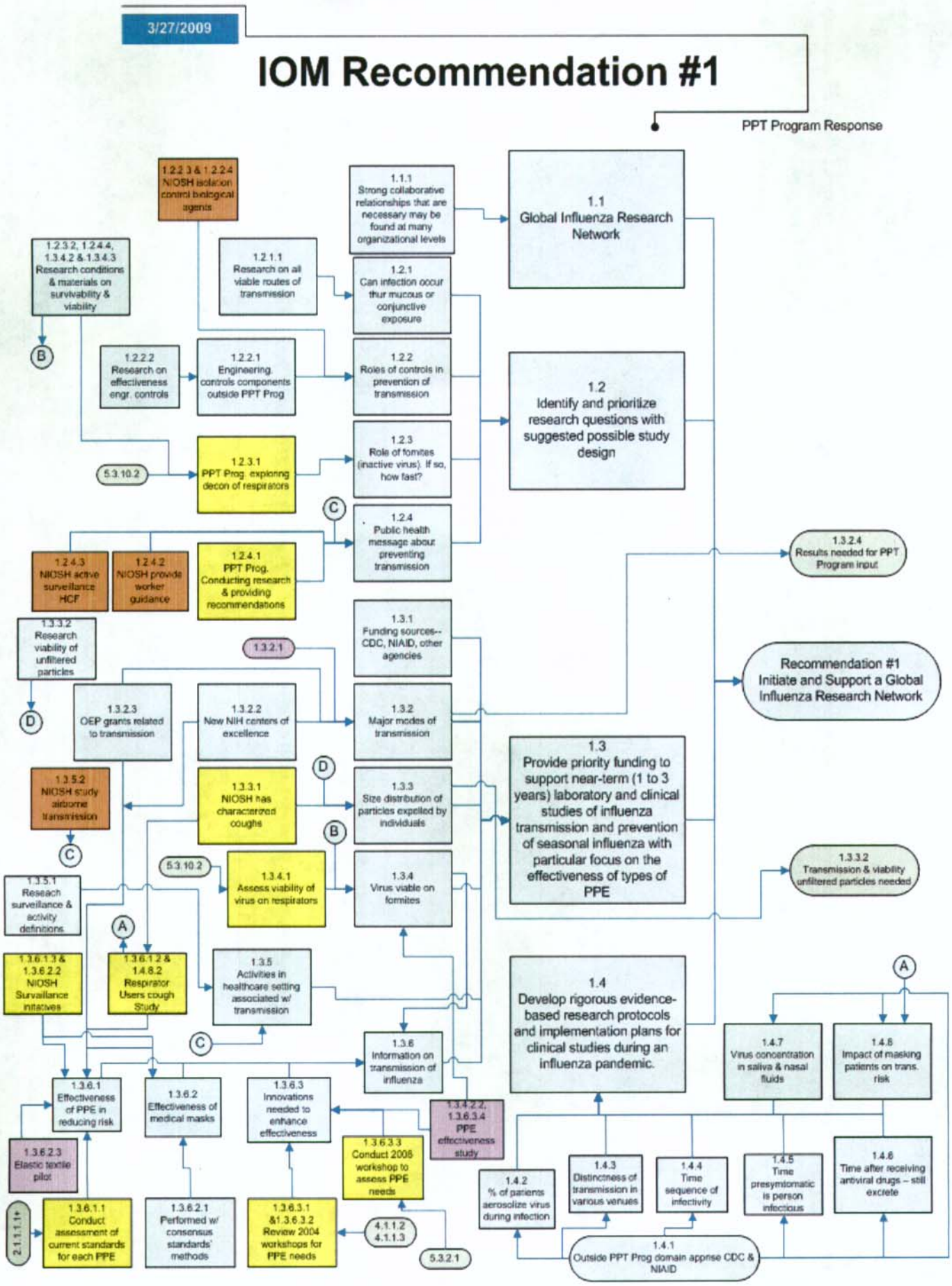
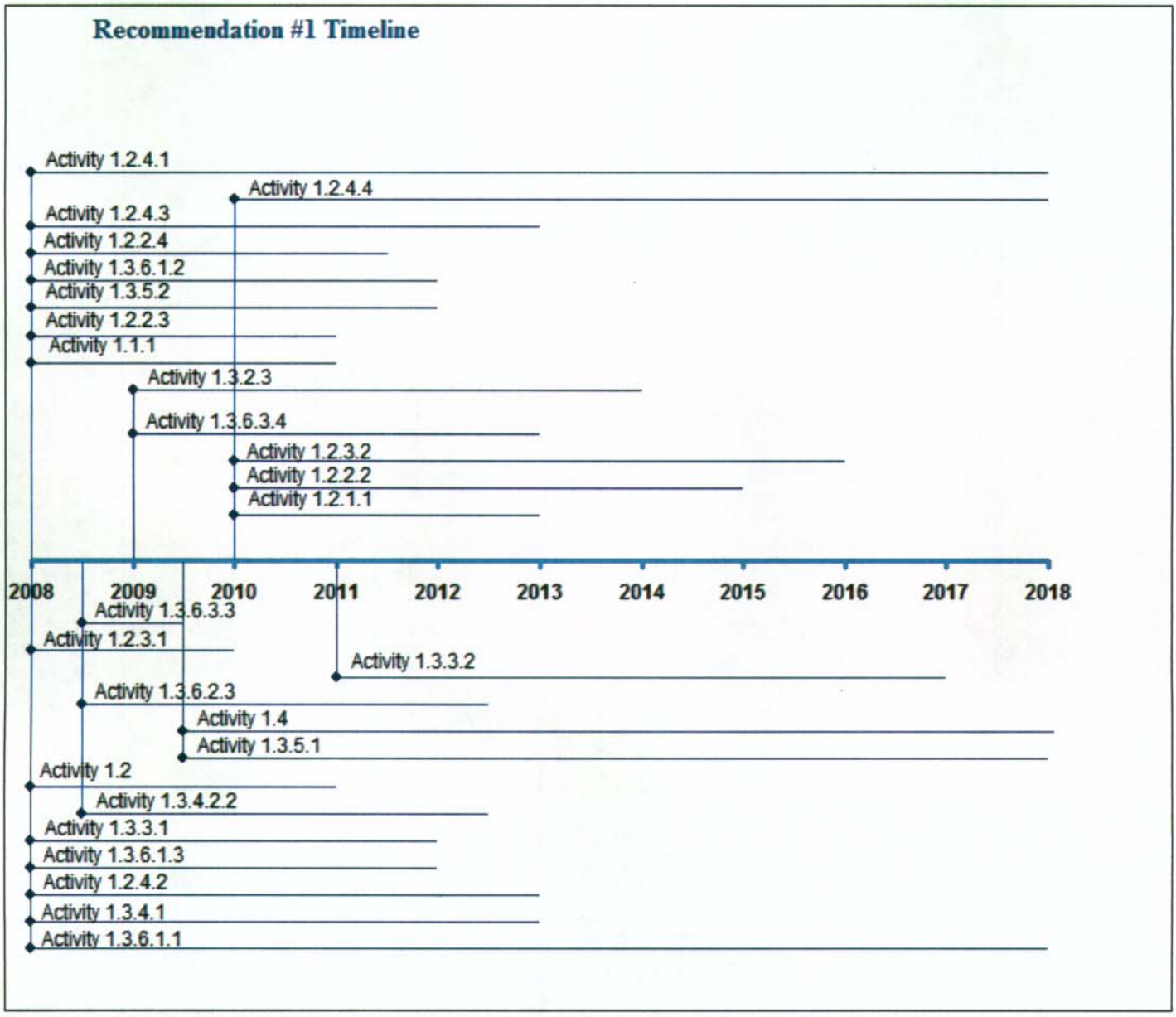

3/27/2009
IOM Recommendation #1
PPT Program Response
1.2.2.3 & 1.2.2.4 NIOSH isolation control biological agents
1.1.1 Strong collaborative relationships that are necessary may be found at many organizational levels
1.1 Global Influenza Research Network
1.2.3.2, 1.2.4.4, 1.3.4.2 & 1.3.4.3 Research conditions & materials on survivability & viability
1.2.1.1 Research on all viable routes of transmission
1.2.1 Can infection occur thur mucous or conjunctive exposure
B
1.2.2.2 Research on effectiveness engr. controls
1.2.2.1 Engineering controls components outside PPT Prog
1.2.2 Roles of controls in prevention of transmission
1.2 Identify and prioritize research questions with suggested possible study design
1.2.3 Role of fomites (inactive virus): If so, how fast?
5.3.10.2
1.2.3.1 PPT Prog. exploring decon of respirators
C
1.2.4 Public health message about preventing transmission
1.2.4.3 NIOSH active surveillance HCF
1.2.4.2 NIOSH provide worker guidance
1.2.4.1 PPT Prog. Conducting research & providing recommendations
1.3.2.4 Results needed for PPT Program input
1.3.3.2 Research viability of unfiltered particles
1.3.2.1
1.3.1 Funding sources-- CDC, NIAID, other agencies
Recommendation #1 Initiate and Support a Global Influenza Research Network
D
1.3.2.3 OEP grants related to transmission
1.3.2.2 New NIH centers of excellence
1.3.2 Major modes of transmission
1.3.5.2 NIOSH study airborne transmission
1.3.3.1 NIOSH has characterized coughs
1.3.3 Size distribution of particles expelled by individuals
1.3 Provide priority funding to support near-term (1 to 3 years) laboratory and clinical studies of influenza transmission and prevention of seasonal influenza with particular focus on the effectiveness of types of PPE
B
C
5.3.10.2
1.3.4.1 Assess viability of virus on respirators
1.3.4 Virus viable on fomites
1.3.3.2 Transmission & viability unfiltered particles needed
1.3.5.1 Reseach surveillance & activity definitions
A
1.3.6.1.3 & 1.3.6.2.2 NIOSH Survaillance initatives
1.3.6.1.2 & 1.4.8.2 Respirator Users cough Study
1.3.5 Activities in healthcare setting associated w/ transmission
1.4 Develop rigorous evidence-based research protocols and implementation plans for clinical studies during an influenza pandemic.
A
1.4.7 Virus concentration in saliva & nasal fluids
1.4.8 Impact of masking patients on trans. risk
C
1.3.6 Information on transmission of influenza
1.3.6.1 Effectiveness of PPE in reducing risk
1.3.6.2 Effectiveness of medical masks
1.3.6.3 Innovations needed to enhance effectiveness
1.3.4.2.2, 1.3.6.3.4 PPE effectiveness study
1.3.6.2.3 Elastic textile pilot
1.3.6.3.3 Conduct 2008 workshop to assess PPE needs
1.4.2 % of patients aerosolize virus during infection
1.4.3 Distinctness of transmission in various venues
1.4.4 Time sequence of infectivity
1.4.5 Time presymtomatic is person infectious
1.4.6 Time after receiving antiviral drugs – still excrete
2.1.1.1.1+
1.3.6.1.1 Conduct assessment of current standards for each PPE
1.3.6.2.1 Performed w/ consensus standards' methods
1.3.6.3.1 &1.3.6.3.2 Review 2004 workshops for PPE needs
4.1.1.2 4.1.1.3
5.3.2.1
1.4.1 Outside PPT Prog domain apprise CDC & NIAID


Recommendation #1 Timeline
Activity 1.2.4.1
Activity 1.2.4.4
Activity 1.2.4.3
Activity 1.2.2.4
Activity 1.3.6.1.2
Activity 1.3.5.2
Activity 1.2.2.3
Activity 1.1.1
Activity 1.3.2.3
Activity 1.3.6.3.4
Activity 1.2.3.2
Activity 1.2.2.2
Activity 1.2.1.1
2008
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Activity 1.3.6.3.3
Activity 1.2.3.1
Activity 1.3.3.2
Activity 1.3.6.2.3
Activity 1.4
Activity 1.3.5.1
Activity 1.2
Activity 1.3.4.2.2
Activity 1.3.3.1
Activity 1.3.6.1.3
Activity 1.2.4.2
Activity 1.3.4.1
Activity 1.3.6.1.1

IOM Recommendation # 2: Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE

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

PPT Program Plan in response to IOM Recommendation #2

Activity #	Activity/Comment
2.1	Functionality – Protect against influenza virus, Guard against contact with contaminated fluids and aerosols.
2.1.1	Develop standards for respiratory PPE.
2.1.1.1	Identify approaches to address gaps.
2.1.1.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
2.1.1.1.2	NPPTL continues to certify performance of respirators through 42 CFR Part 84. NPPTL has increased its capacity for Part 84 testing of N95 respirators from 2 particulate filter penetration test instruments to 3 test instruments and a fourth instrument available as a backup or additional capacity.
2.1.1.1.3	Collaboration with Users/Other Agencies and the PPT Program.
2.1.1.1.3.1	NPPTL has a program in place with FDA to certify penetration characteristics for respirators to be designated as "Public Use Respirator for Pandemic Flu" by the FDA. Two filtering facepieces from one manufacturer are currently certified by FDA. PPT Program has an additional program in place with FDA for manufacturers seeking to make an antimicrobial claim on their FF products. PPT Program handles the particulate testing and performance evaluation, FDA makes the antimicrobial efficiency and safety determinations.
2.1.1.1.3.2	The PPT Program continues to collaborate with OSHA for coordination and support for respirator selection and use requirements during emergency as well as routine applications.
2.1.2	Develop standards for other than respirators.
2.1.2.1	Identify approaches to address gaps.
2.1.2.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for

	PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
2.1.2.1.2	Other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods
2.1.2.1.3	Collaboration with ASTM, ISO, American National Standards Institute (ANSI) and International Safety Equipment Association (ISEA).
2.2	Usability – Maintain biomechanical efficiency and sense of touch and feel, odor-free, hypoallergenic, accommodate wide range of users (face and body profiles), compatibility across various elements of the PPE ensemble and with other equipment (e.g., stethoscope), non-startling to patients and families, facilitates communication with others (verbal, facial).
2.2.1	Develop standards for respiratory PPE.
2.2.1.1	Identify approaches to address gaps.
2.2.1.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
2.2.1.1.2	NPPTL continues to certify performance of respirators through 42 CFR Part 84.
2.2.1.1.3	Collaboration between ISEA and the PPT Program.
2.2.1.1.3.1	PPT Program anthropometric initiatives ongoing. [References Q & R]
2.2.2	Develop standards for other than respirators.
2.2.2.1	Identify approaches to address gaps.
2.2.2.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
2.2.2.1.2	Other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods.
2.2.2.1.3	Collaboration with ASTM, ISO, ANSI and ISEA.
2.2.2.1.4	DSR input for whole body anthropometrics. [Reference T]

2.3 Comfort and Wearability – Comfortable—no skin irritation or pressure points, Breathable—air, prolonged use without discomfort permeable, Moisture absorbent—wickability, Low bulk and weight, dimensional stability, easy to put on and take off (don and doff).

2.3.1 Develop standards for respiratory PPE.

2.3.1.1 Identify approaches to address gaps.

2.3.1.1.1 An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.

2.3.1.1.2 NPPTL continues to certify performance of respirators through 42 CFR Part 84.

2.3.1.1.3 Collaboration between Users/Other Agencies and the PPT Program.

2.3.1.1.3.1 The comfort of a respirator may impact the user's ability to tolerate long periods of use as would occur in the healthcare environment during a pandemic influenza. The PPT Program has served in a consultant role to the VA, which is addressing the issue of nurses' tolerability for respirators (i.e., filtering facepiece respirators, powered air-purifying respirators, half-facepiece elastomeric respirators) in a recently-completed study at the Gainesville, FL, VA hospital Intensive Care Unit. Preliminary data analysis indicates that there are two general groups of nurse users of respirators and that both have different tolerance capacities for long-term wear. This data is of potential import in situations, such as a pandemic influenza, where lengthy work shifts (e.g., >12 hours) can be anticipated.

2.3.1.1.3.2 The PPT Program is undertaking a 2008 study (The Impact of Respirator Use on Carbon Dioxide and Oxygen Saturation, Project ID 921ZBFS) to determine carbon dioxide and oxygen levels in healthcare workers who wear respirators (i.e., N95FFR with and without exhalation valves, and with and without surgical mask overlay, elastomeric half-facepiece respirators) for prolonged periods as would occur in a pandemic influenza. If elevated CO2 levels or depressed O2 levels are measured that would lead to symptoms, mitigation strategies can be developed.

2.3.1.1.3.3 Project on doffing garments FY10.

2.3.2 Develop standards for other than respirators.

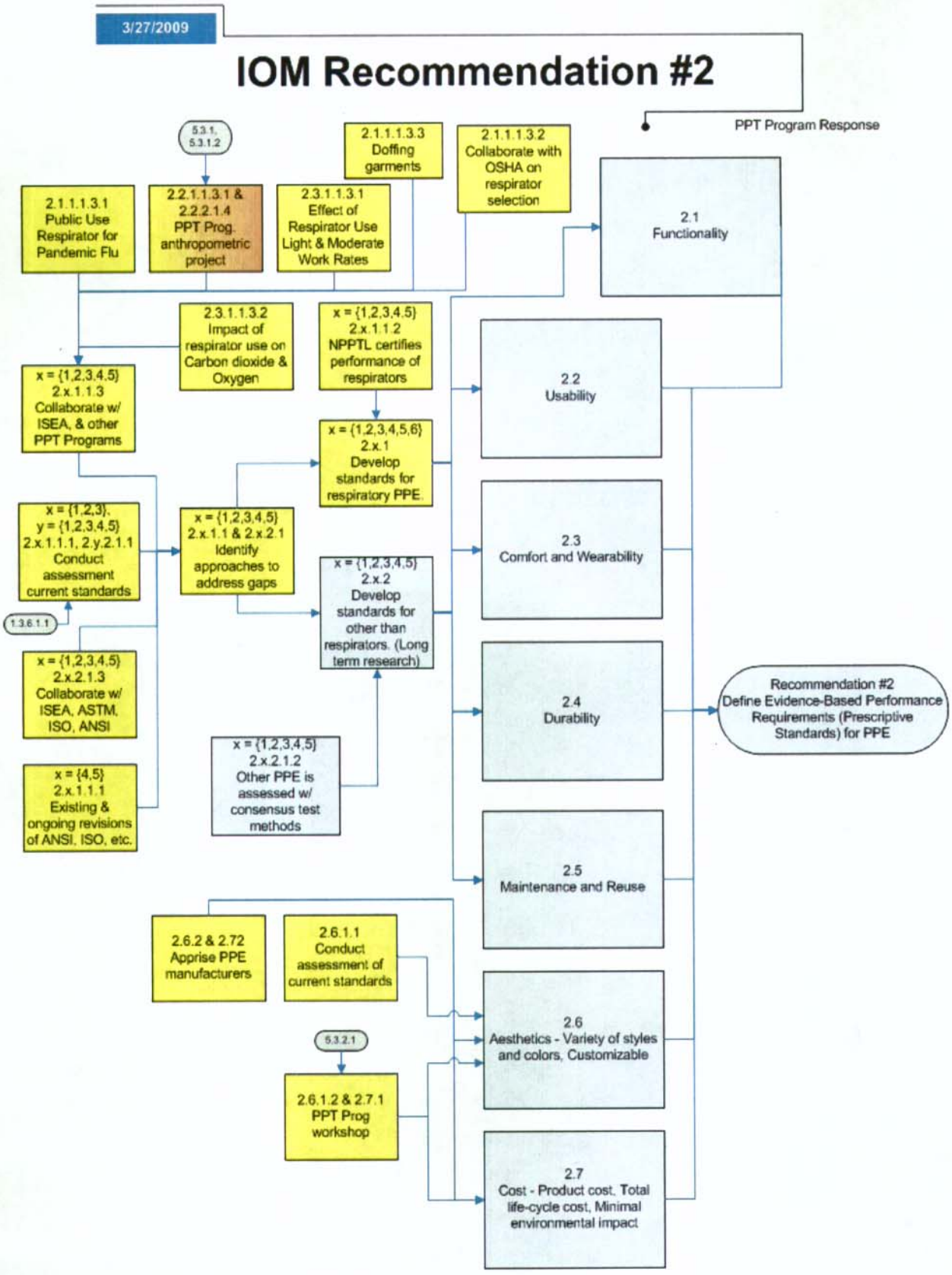
2.3.2.1 Identify approaches to address gaps.

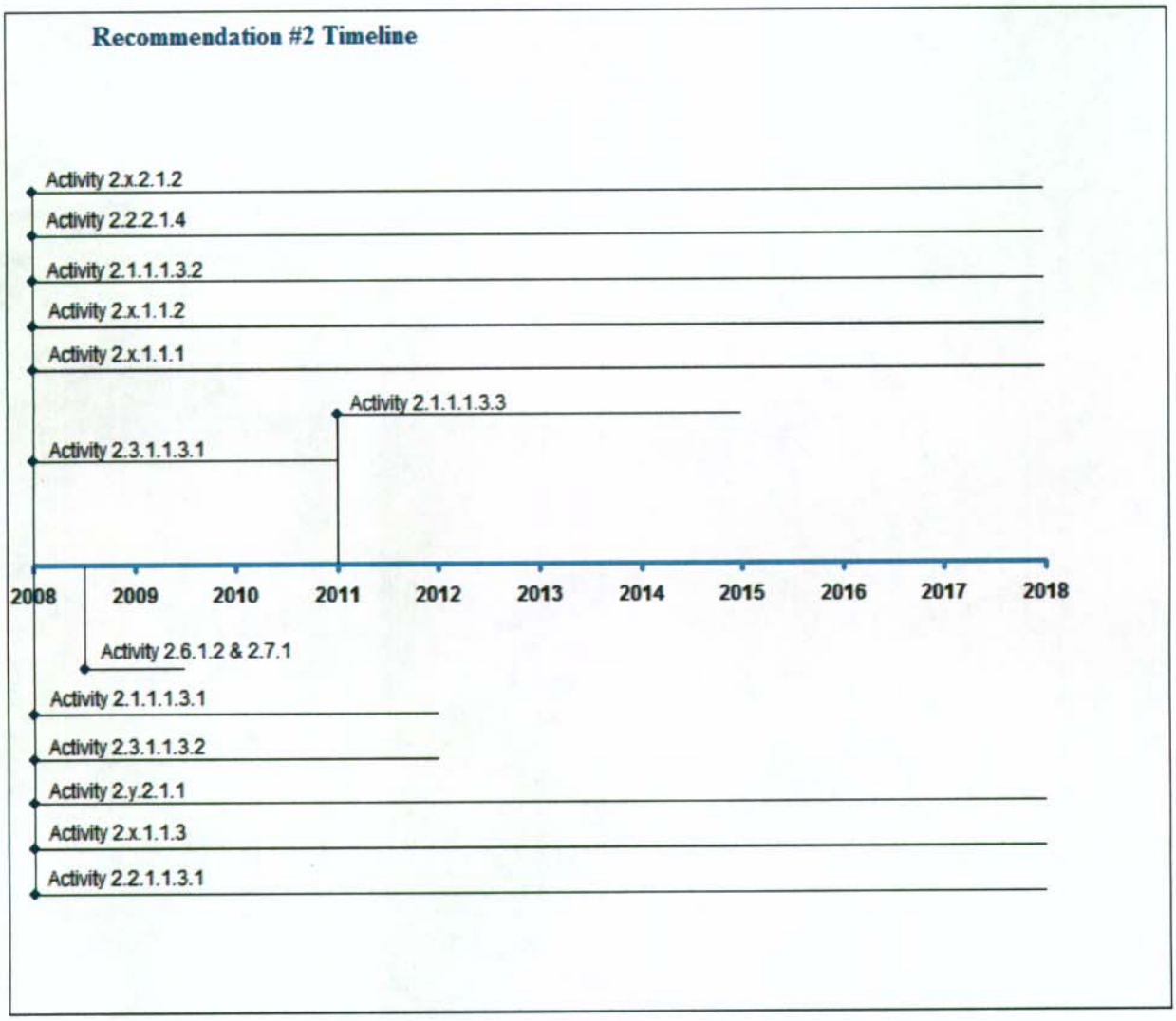
2.3.2.1.1 An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.

2.3.2.1.2	Other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods.
2.3.2.1.3	Collaboration with ASTM, ISO, ANSI and ISEA.
2.4	Durability – Adequate wear life, Strength—(tear, tensile, burst), Abrasion resistance, Corrosion resistance.
2.4.1	Develop standards for respiratory PPE.
2.4.1.1	Identify approaches to address gaps.
2.4.1.1.1	Existing and ongoing revisions of ANSI, ISO and other applicable respiratory protection consensus standards are being assessed for alignment and potential adoption by the PPT Program.
2.4.1.1.2	NPPTL continues to certify performance of respirators through 42 CFR Part 84. [Reference S]
2.4.1.1.3	Collaboration with ISEA and PPT Program.
2.4.2	Develop standards for other than respirators. Long term research.
2.4.2.1	Identify approaches to address gaps.
2.4.2.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
2.4.2.1.2	Other PPE performance is assessed in accordance with consensus standards' test methods.
2.4.2.1.3	Collaboration with ASTM, ISO, ANSI and ISEA.
2.5	Maintenance and Reuse – Easy to decontaminate and discard disposable elements, Easy to clean and replace parts in reusable PPE.
2.5.1	Develop standards for respiratory PPE.
2.5.1.1	Identify approaches to address gaps.
2.5.1.1.1	Existing and ongoing revisions of ANSI, ISO and other applicable respiratory protection consensus standards are being assessed for alignment and potential adoption by the PPT Program.
2.5.1.1.2	NPPTL continues to certify performance of respirators through 42 CFR Part 84. [Reference S]
2.5.1.1.3	Collaboration with Users/Other Agencies and the PPT Program.
2.5.2	Develop standards for other than respirators.

2.5.2.1	Identify approaches to address gaps.
2.5.2.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods. The PPT Program has limited infrastructure for PPT research, development and investigative testing beyond respirator issues. The PPT Program is planning to expand its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party certification authorities and laboratories.
2.5.2.1.2	Other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods.
2.5.2.1.3	Collaboration with ASTM, ISO, ANSI and ISEA.
2.6	Aesthetics – Variety of styles and colors, Customizable.
2.6.1	The PPT Program and Standards Development Organizations (SDO) to develop performance –based standards to allow maximum customization and design to meet customer aesthetic desires without adversely impacting performance.
2.6.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. NPPTL currently certifies performance of respirators, other PPE performance is assessed by third party certification authorities in accordance with consensus standards' test methods.
2.6.1.2	PPT Program will conduct a workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation for a contractor to coordinate and conduct the workshop was published on Nov 8, 2007. [Reference D]
2.6.2	** Apprise PPE manufacturers of the ability to use new technologies, and identified available technologies, to address users' aesthetic desires.
2.7	Cost - Product cost, Total life-cycle cost, Minimal environmental impact
2.7.1	PPT Program will conduct a workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation for a contractor to coordinate and conduct the workshop was published on Nov 8, 2007. [Reference D]
2.7.2	** Apprise PPE manufacturers of capabilities to increase cost effectiveness of PPE.

11


3/27/2009
IOM Recommendation #2
PPT Program Response
5.3.1, 5.3.1.2
2.1.1.1.3.3 Doffing garments
2.1.1.1.3.2 Collaborate with OSHA on respirator selection
2.1.1.1.3.1 Public Use Respirator for Pandemic Flu
2.2.1.1.3.1 & 2.2.2.1.4 PPT Prog. anthropometric project
2.3.1.1.3.1 Effect of Respirator Use Light & Moderate Work Rates
2.1 Functionality
2.3.1.1.3.2 Impact of respirator use on Carbon dioxide & Oxygen
x = {1,2,3,4,5} 2.x.1.1.2 NPPTL certifies performance of respirators
x = {1,2,3,4,5} 2.x.1.3 Collaborate w/ ISEA, & other PPT Programs
2.2 Usability
x = {1,2,3,4,5,6} 2.x.1 Develop standards for respiratory PPE.
x = {1,2,3}, y = {1,2,3,4,5} 2.x.1.1.1, 2.y.2.1.1 Conduct assessment current standards
x = {1,2,3,4,5} 2.x.1.1 & 2.x.2.1 Identify approaches to address gaps
2.3 Comfort and Wearability
x = {1,2,3,4,5} 2.x.2 Develop standards for other than respirators. (Long term research)
1.3.6.1.1
x = {1,2,3,4,5} 2.x.2.1.3 Collaborate w/ ISEA, ASTM, ISO, ANSI
2.4 Durability
Recommendation #2 Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE
x = {1,2,3,4,5} 2.x.2.1.2 Other PPE is assessed w/ consensus test methods
x = {4,5} 2.x.1.1.1 Existing & ongoing revisions of ANSI, ISO, etc.
2.5 Maintenance and Reuse
2.6.2 & 2.72 Apprise PPE manufacturers
2.6.1.1 Conduct assessment of current standards
2.6 Aesthetics - Variety of styles and colors, Customizable
5.3.2.1
2.6.1.2 & 2.7.1 PPT Prog workshop
2.7 Cost - Product cost, Total life-cycle cost, Minimal environmental impact


Recommendation #2 Timeline
Activity 2.x.2.1.2
Activity 2.2.2.1.4
Activity 2.1.1.1.3.2
Activity 2.x.1.1.2
Activity 2.x.1.1.1
Activity 2.1.1.1.3.3
Activity 2.3.1.1.3.1
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2018
Activity 2.6.1.2 & 2.7.1
Activity 2.1.1.1.3.1
Activity 2.3.1.1.3.2
Activity 2.y.2.1.1
Activity 2.x.1.1.3
Activity 2.2.1.1.3.1

13

IOM Recommendation # 3: Adopt a Systems Approach to the Design and Development of PPE

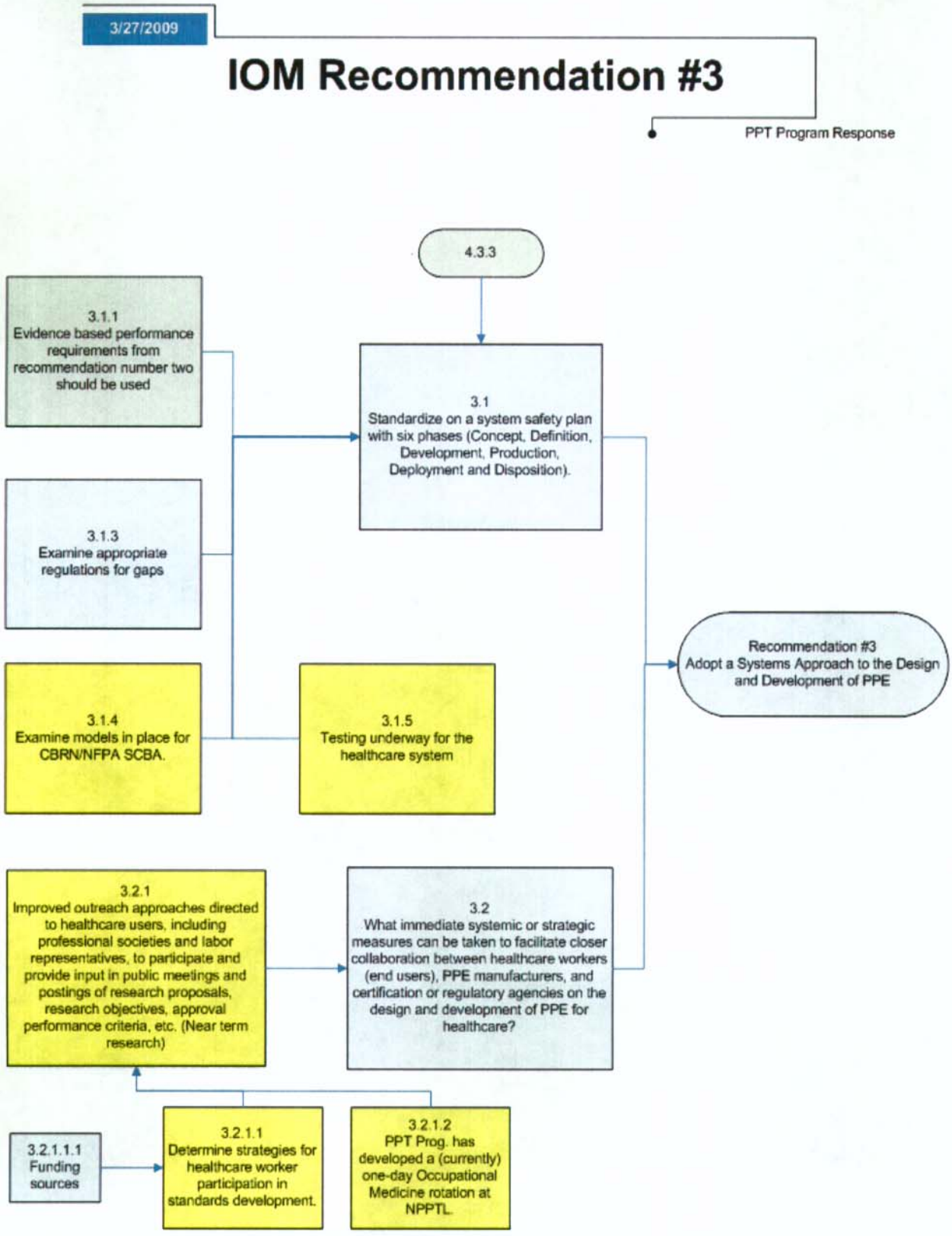
NIOSH should promote a systems approach to the design, development, testing, and certification of PPE using evidence-based performance requirements or prescriptive standards and fostering closer collaboration between the users, manufacturers, and research and regulatory agencies.

PPT Program Plan in response to IOM Recommendation # 3

Activity #	Activity/Comment
3.1	Standardize on a system safety plan with six phases (Concept, Definition, Development, Production, Deployment and Disposition). The concept phase is the initial period in which background and future technologies are developed to give a basis for the proposed system hazard analysis. The definition phase allows for verification of the initial design and engineering of the PPE. The development phase provides system input for environmental impact, PPE engineering, integration support and use studies. The production phase is where the PPE is manufactured and quality control inspection and testing is achieved. The deployment phase is where the PPE becomes available to the users and training and auditing is done. The disposition phase is where the PPE is retired and disposed of correctly.
3.1.1	Evidence based performance requirements from recommendation number two should be used as inputs into these activities.
3.1.2	Outputs from 4.3 are to be used as inputs into these activities.
3.1.3	Examine appropriate regulations for gaps where systems-approach requirements could be added to existing standards.
3.1.4	The program in place for Chemical, Biological, Radiological, and Nuclear (CBRN)/NFPA Self-Contained Breathing Apparatus (SCBA) could be considered as a model for "lessons learned".
3.1.5	Some testing required to developing a healthcare system is currently underway and will inform future options, i.e. N95 v P100, full facepiece respirator use, adhesive seal respirators, fit test evaluations [Reference E], and cough study [Reference B].
3.2	What immediate systemic or strategic measures can be taken to facilitate closer collaboration between healthcare workers (end users), PPE manufacturers, and certification or regulatory agencies on the design and development of PPE for healthcare?
3.2.1	Improved outreach approaches directed to healthcare worker PPE users, including professional societies and labor representatives, to participate and provide input in public meetings and postings of research proposals, research objectives, approval performance criteria, etc. Near term research.
3.2.1.1	Determine strategies to simulate and enhance healthcare worker participation in standards development committees, public meetings and research activities.
3.2.1.1.1	** Funding sources need identified.
3.2.1.2	Currently, Occupational Medicine residency programs graduate < 100 physicians per year in the U.S. and many of these individuals enter academia. Many medically-related Occupational Medicine tasks (e.g., respirator fit testing, audiology testing and review, baseline pulmonary function interpretations, etc.) are overseen by Internal Medicine and

Family Medicine practitioners who may have limited training in these areas. During a pandemic influenza, demands on these practitioners regarding such issues as respirator fit testing may take on additional importance. The PPT Program has developed a one-day Occupational Medicine rotation at NPPTL, for Internal Medicine and Family Medicine resident physicians that offer instruction in such areas as audiology, respirator fit testing, and shadowing of an Occupational Medicine physician in the NPPTL Occupational Medicine clinic. This outreach endeavor will serve to increase the medical practitioner's Occupational Medicine skills and also make him/her aware of NPPTL services that may be of use to the practitioner.

21


3/27/2009
IOM Recommendation #3
PPT Program Response
4.3.3
3.1.1
Evidence based performance requirements from recommendation number two should be used
3.1
Standardize on a system safety plan with six phases (Concept, Definition, Development, Production, Deployment and Disposition).
3.1.3
Examine appropriate regulations for gaps
Recommendation #3
Adopt a Systems Approach to the Design and Development of PPE
3.1.4
Examine models in place for CBRN/NFPA SCBA.
3.1.5
Testing underway for the healthcare system
3.2.1
Improved outreach approaches directed to healthcare users, including professional societies and labor representatives, to participate and provide input in public meetings and postings of research proposals, research objectives, approval performance criteria, etc. (Near term research)
3.2
What immediate systemic or strategic measures can be taken to facilitate closer collaboration between healthcare workers (end users), PPE manufacturers, and certification or regulatory agencies on the design and development of PPE for healthcare?
3.2.1.1.1
Funding sources
3.2.1.1
Determine strategies for healthcare worker participation in standards development.
3.2.1.2
PPT Prog. has developed a (currently) one-day Occupational Medicine rotation at NPPTL.

22

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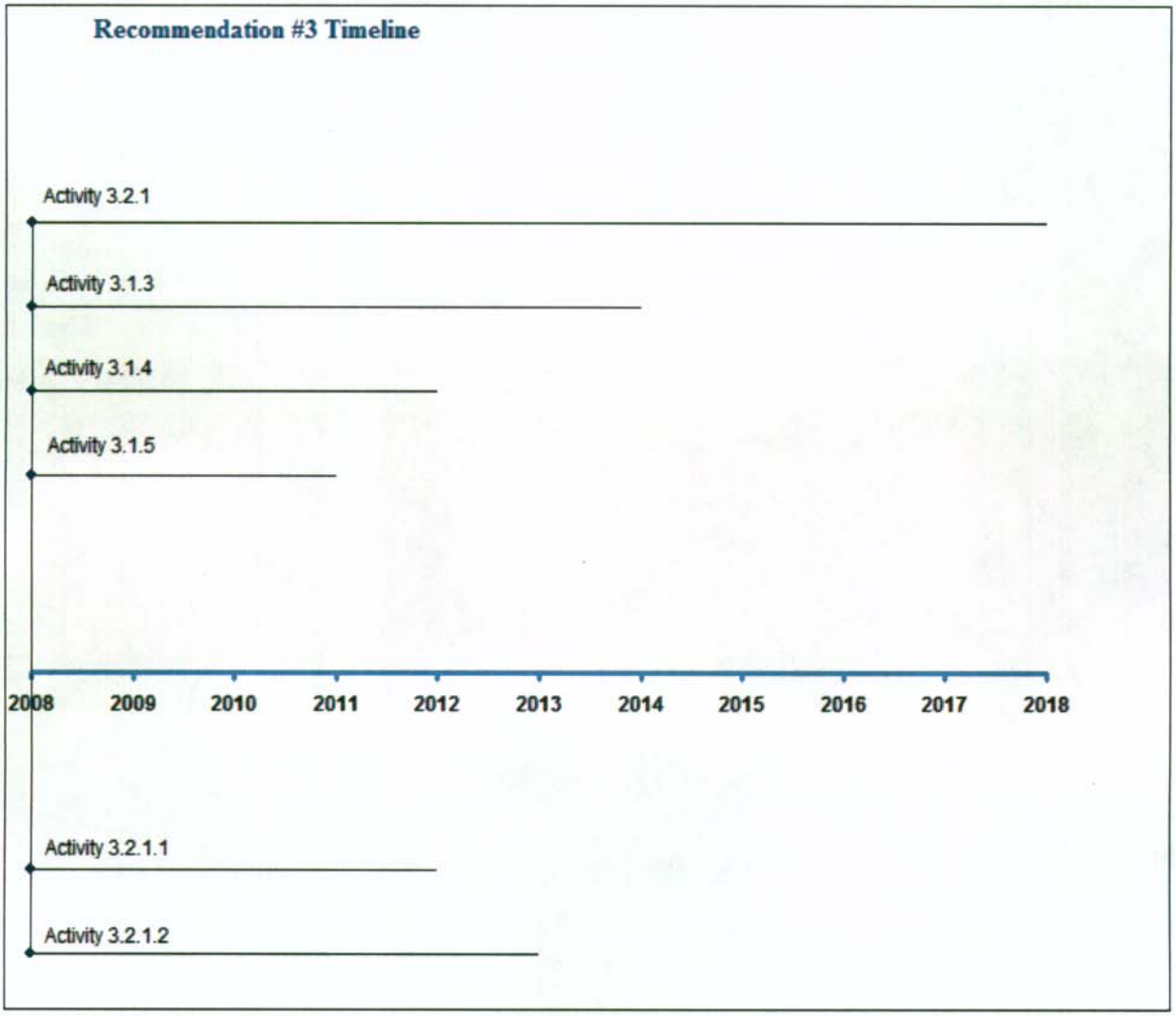
Recommendation #3 Timeline
Activity 3.2.1
Activity 3.1.3
Activity 3.1.4
Activity 3.1.5
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Activity 3.2.1.1
Activity 3.2.1.2

24

IOM Recommendation # 4: Increase Research on the Design and Engineering of the Next Generation of PPE.

NIOSH, the DHS, the DoD, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of respirators, gowns, gloves, and eye protection for healthcare workers that would enhance their safety and comfort.

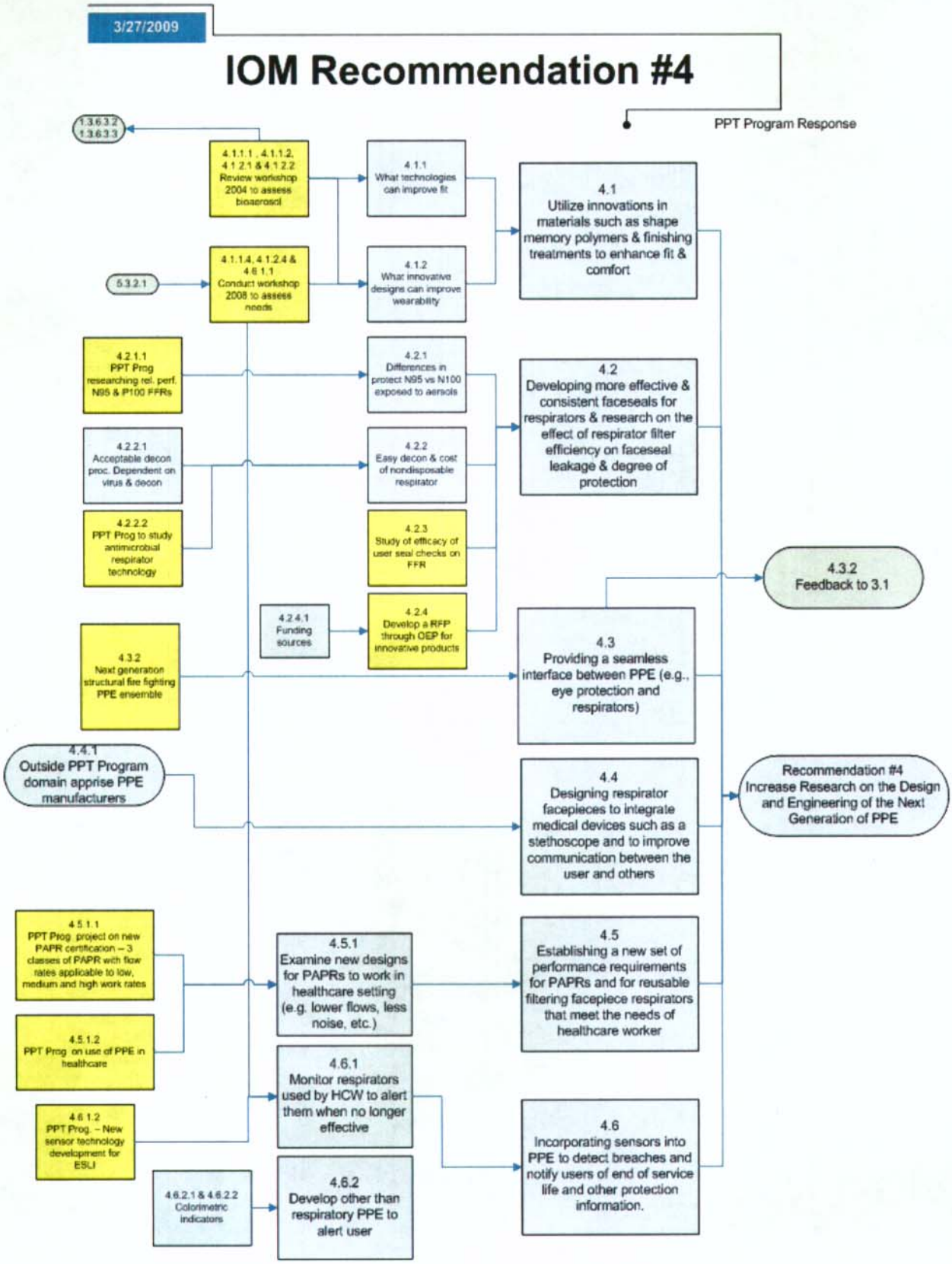
PPT Program Plan in response to IOM Recommendation # 4

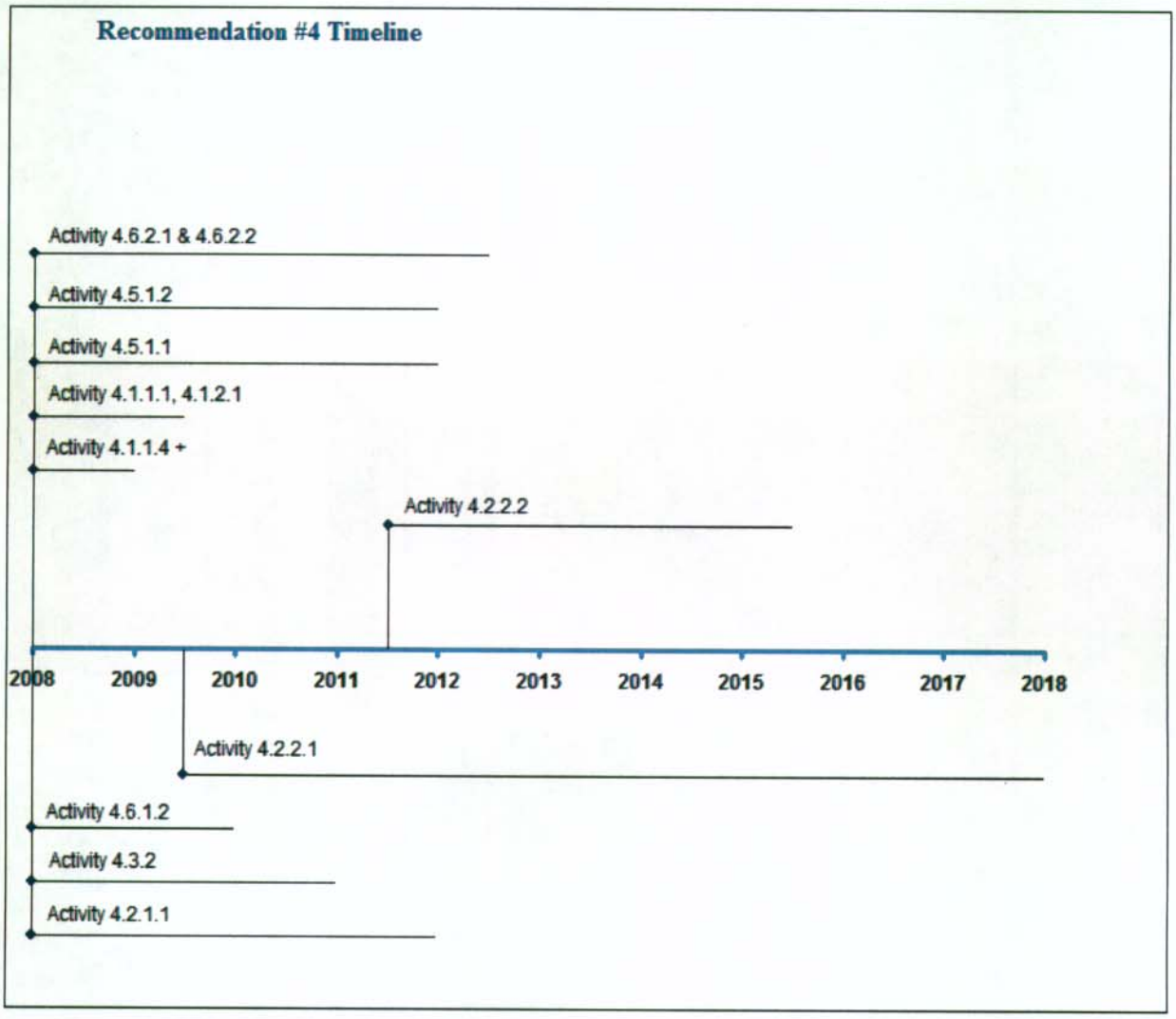
Activity #	Activity/Comment
4.1	Utilizing innovations in materials such as shape memory polymers (e.g., to obviate fit testing and enhance fit of respirators and comfort of gowns) and finishing treatments (e.g., safe antimicrobial or biocidal finishes)
4.1.1	What technologies can improve fit to circumvent the need for fit testing?
4.1.1.1	NIOSH conducted workshops with RAND Jan 2004 to identify future PPE needs.
4.1.1.2	Nov 30 - Dec1 2004 PPT Program conducted workshop to assess current state of knowledge of infectivity of bioaerosol: Reference C.
4.1.1.3	PPT Program will conduct workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation was published on Nov 8, 2007. Reference D.
4.1.2	What innovative designs can improve wearability issues regarding PPE?
4.1.2.1	NIOSH conducted workshops with RAND Jan 2004 to identify future PPE needs.
4.1.2.2	Nov 30 - Dec1 2004 PPT Program conducted workshop to assess current state of knowledge of infectivity of bioaerosol: Reference C.
4.1.2.3	PPT Program will conduct workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation was published on Nov 8, 2007. Reference D.
4.2	Developing more effective and consistent faceseals for respirators, including examination of the effect of wear and repeated donning and doffing on the quality of the faceseal of filtering facepiece respirators, and research on the effect of respirator filter efficiency on faceseal leakage and degree of protection
4.2.1	What are the differences in protection of N95 versus N100 or other respirators if exposed to human and avian influenza aerosols?
4.2.1.1	PPT Program is conducting research on relative performance of N95 and P100 FFRs in laboratory protection level studies. The draft protocol incorporates human subject testing planned using NPPTL generated aerosol (corn oil and sodium chloride) and ambient aerosol (PortaCount Plus) fit test facilities. Test results would be applicable to virus particles (whether aerosol or droplet transmission). Reference E
4.2.2	Could a nondisposable respirator be designed that could be easily decontaminated and cost-effective?
4.2.2.1	Ease of acceptable decontamination procedures are dependent on virulence of virus and effectiveness of decontamination methods.

4.2.2.2	Project to study antimicrobial respirator technology FY11.
4.2.3	Study of efficacy of user seal checks on filtering face-piece: Reference E. The user seal check is required with every donning of the respirator to verify that an adequate fit has been achieved. However, the value of the user seal check has not been adequately demonstrated in the literature.
4.2.4	Develop a request for proposal (RFP) to solicit development of innovative products through the NIOSH/OEP.
4.2.4.1	** Funding sources need to be identified.
4.3	Providing a seamless interface between PPE (e.g., eye protection and respirators)
4.3.1	Some of the lessons learned in the current project. Next Generation Structural Fire Fighting PPE Ensemble may be applicable to healthcare PPE, even though it doesn't apply to pandemic flu. Reference F.
4.3.2	Outputs of activities should be provided as input to recommendation number three 3.1.
4.4	Designing respirator facepieces to integrate medical devices such as a stethoscope and to improve communication between the user and others.
4.4.1	** Apprise PPE manufacturers.
4.5	Establishing a new set of performance requirements for Powered Air-Purifying Respirators (PAPRs) and for reusable filtering facepiece respirators that meet the needs of healthcare workers
4.5.1	Current PAPRs are designed to provide extremely high flow rates to protect the worker in an industrial setting. While appropriate to protect from significant dust exposures, they present serious design impediments for the healthcare worker. What are the flow rates and maximum noise levels that would be required for NIOSH to certify a PAPR that would provide adequate protection for healthcare workers? What is the risk to patients from healthcare workers wearing PAPRs (from unfiltered exhaled air), and what design modifications would be needed to eliminate such risk as well as facilitate interactions with patients?
4.5.1.1	PPT Program has developed concept for new PAPR certification provisions that would allow approval of 3 classes of PAPR with flow rates applicable to low, medium and high work rates. [Reference G] The concept also addresses incorporation of sensors into PPE to detect breaches and notify users of end of service life and other protection information.
4.5.1.2	Respirators utilized in healthcare settings were not designed for that particular venue. Therefore, there are features of respirators that do not necessarily lend themselves well to the healthcare environment. The PPT Program, in conjunction with the VA and academia initiated Project BREATHE. Currently in its developmental stages, this endeavor initially will bring together a working group consisting of healthcare workers and respirator experts from academia and government that will address respirator characteristics germane to healthcare workers (e.g., speech intelligibility, visibility, hearing, etc.) with the goal of identifying features (e.g., clear silicone components, speech diaphragms, etc.) that would enhance respirator performance in the healthcare setting. The second stage of this project would consist of bringing these recommendations to respirator manufacturers with the intent of developing a respirator

	that is designed specifically with the healthcare worker in mind. Improved respirators are likely to be better tolerated during periods of prolonged use, such as influenza pandemics.
4.6	Incorporating sensors into PPE to detect breaches and notify users of end of service life and other protection information. Sensors for face seal leakage is the key issue in this recommendation. If the PPE was not donned properly or no longer fitting, can this be detected and the user alerted?
4.6.1	Can the protection levels of the PPE worn by healthcare workers (e.g., N95 respirators) be continuously monitored during use to provide an alert to change the PPE when it is no longer effective?
4.6.1.1	PPT Program conducted a workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation was published on Nov 8, 2007. Reference D. The workshop presentations are posted http://cpheo.sph.umn.edu/mcohs/courses/nofit/ A report is being prepared for NPPTL consideration.
4.6.1.2	PPT Program – New Sensor Technology Development for End of Service Life Indicator (ESLI): Reference H. Even though this project doesn't apply directly to pandemic flu it may be possible to use some of the lessons learned in this project and apply it to healthcare PPE (i.e. like working with manufacturers to develop sensor technology).
4.6.2	Develop other-than-respiratory PPE with technology to alert the user when effectiveness may be compromised.
4.6.2.1	Use colorimetric indicators to detect and give the PPE wearer a visual indication of exposure. These chemical reaction-based indicators are used to produce reactions to individual, or classes of compounds.
4.6.2.2	Develop innovative indicator systems for integration into chemical protective clothing (CPC).

35


3/27/2009
IOM Recommendation #4
PPT Program Response
1.3.6.3.2
1.3.6.3.3
4.1.1.1 , 4.1.1.2, 4.1.2.1 & 4.1.2.2 Review workshop 2004 to assess bioaerosol
4.1.1 What technologies can improve fit
4.1 Utilize innovations in materials such as shape memory polymers & finishing treatments to enhance fit & comfort
5.3.2.1
4.1.1.4, 4.1.2.4 & 4.6.1.1 Conduct workshop 2008 to assess needs
4.1.2 What innovative designs can improve wearability
4.2.1.1 PPT Prog researching rel. perf. N95 & P100 FFRs
4.2.1 Differences in protect N95 vs N100 exposed to aerosols
4.2 Developing more effective & consistent faceseals for respirators & research on the effect of respirator filter efficiency on faceseal leakage & degree of protection
4.2.2.1 Acceptable decon proc. Dependent on virus & decon
4.2.2 Easy decon & cost of nondisposable respirator
4.2.2.2 PPT Prog to study antimicrobial respirator technology
4.2.3 Study of efficacy of user seal checks on FFR
4.3.2 Feedback to 3.1
4.2.4.1 Funding sources
4.2.4 Develop a RFP through OEP for innovative products
4.3.2 Next generation structural fire fighting PPE ensemble
4.3 Providing a seamless interface between PPE (e.g., eye protection and respirators)
4.4.1 Outside PPT Program domain apprise PPE manufacturers
4.4 Designing respirator facepieces to integrate medical devices such as a stethoscope and to improve communication between the user and others
Recommendation #4 Increase Research on the Design and Engineering of the Next Generation of PPE
4.5.1.1 PPT Prog project on new PAPR certification – 3 classes of PAPR with flow rates applicable to low, medium and high work rates
4.5.1 Examine new designs for PAPRs to work in healthcare setting (e.g. lower flows, less noise, etc.)
4.5 Establishing a new set of performance requirements for PAPRs and for reusable filtering facepiece respirators that meet the needs of healthcare worker
4.5.1.2 PPT Prog on use of PPE in healthcare
4.6.1 Monitor respirators used by HCW to alert them when no longer effective
4.6.1.2 PPT Prog. – New sensor technology development for ESLI
4.6 Incorporating sensors into PPE to detect breaches and notify users of end of service life and other protection information.
4.6.2.1 & 4.6.2.2 Colorimetric indicators
4.6.2 Develop other than respiratory PPE to alert user


Recommendation #4 Timeline
Activity 4.6.2.1 & 4.6.2.2
Activity 4.5.1.2
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Activity 4.1.1.1, 4.1.2.1
Activity 4.1.1.4 +
Activity 4.2.2.2
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Activity 4.2.2.1
Activity 4.6.1.2
Activity 4.3.2
Activity 4.2.1.1

37

IOM Recommendation # 5: Establish Measures to Assess and Compare the Effectiveness of PPE.

NIOSH, through NPPTL, should develop and promote a validated set of measures for comparing the effectiveness of PPE products. The goal is a set of measures that would allow users to compare and select appropriate PPE commensurate with the assessed risk and desired level of protection. Particular attention should be paid to disseminating information to healthcare workers on PPE effectiveness relevant to influenza.

PPT Program Plan in response to IOM Recommendation # 5

Activity #	Activity/Comment
5.1	Expedited efforts to finalize a standardized method for measuring the total inward leakage of respirators as part of the NIOSH respirator approval protocols.
5.1.1	The NPPTL Total Inward Leakage (TIL) Program will establish TIL performance requirements and laboratory test capability for testing of PPE including all classes of respirators and protective garments. The initial TIL project will address half-mask respirator requirements and testing. Other classes of respirators will be incorporated into the program following completion of the half-mask project. Respirator TIL testing is intended to quantify the ability of respirators to fit a range of facial dimensions, representative of the US workforce. Total inward leakage testing performed under laboratory conditions represents a criterion for performance that will influence PPE design. PPT Program – TIL initiative: Reference I.
5.2	Develop and promote filter efficiency measures.
5.2.1	For what period of time does PPE remain contaminated with infectious influenza viruses, and what improvements can be made in doffing and decontamination procedures given that information?
5.2.1.1	Assess the viability of influenza virus on filter media: Reference A.
5.2.1.2	Explore efficacy in collaboration with CDC, FDA and EPA: Reference A.
5.2.1.3	Collaborate with PPT manufacturers: Reference A.
5.3	Develop and promote measures for comparing the effectiveness of respirators, gowns, gloves, eye protection, and other types of PPE based on evidence-based performance requirements.
5.3.1	NIOSH has a well established anthropometrics research program in both facial and whole body anthropometrics. The current initiatives will be examined to determine how recommendations can be addressed.
5.3.1.1	The PPT Program Facial Anthropometrics Research Roadmap was created in September 2007 and posted on the web for comment. The comment period will be open until 22 February 2008. The plan can be found here. Reference R.
5.3.1.2	DSR input for whole body anthropometrics ongoing activities. Reference T.
5.3.2	How does the penetration risk of N95 respirators made of different materials and designs change with high inhalation rates?
5.3.2.1	PPT Program will conduct workshop in 2008 to assess the current state of technology.

	A commerce business daily presolicitation was published on Nov 8, 2007. Reference D.
5.3.3	What are the appropriate PPE decontamination strategies that would not compromise the integrity of the PPE while being easy and cost-effective to implement in a healthcare setting?
5.3.3.1	PPT Program is currently investigating effects of decontamination procedures on respirator performance: Reference A. PPT Program to collaborate with CDC Division of Hospital Infections re: biology of virus and best possible decontamination procedures.
5.3.4	Do specific procedures (e.g., nebulization, endotracheal intubation, bronchoscopy, cleaning of patients' rooms) place healthcare workers at higher levels of risk of influenza infection? To what extent do various types of PPE offer protection during these procedures and processes?
5.3.4.1	** (same as 1.3.5 under recommendation #1)
5.3.5	How does the level of protection afforded by N95 change with and without fit testing? What is the impact of masking influenza patients on transmission risk? If effective, how long before the respirator needs to be changed?
5.3.5.1	Describe the FDA Community use respirator and the science behind the decisions (for question 1)
5.3.5.2	Seasonal influenza studies should be conducted in collaboration with other NIOSH programs, CDC and NIAID.
5.3.6	What are the best practices for PPE removal to minimize risk of self-inoculation?
5.3.6.1	Assess the viability of influenza virus on filter media: Reference A.
5.3.6.2	Explore efficacy in collaboration with CDC, FDA and EPA: Reference A.
5.3.6.3	Collaborate with PPT manufacturers: Reference A.
5.3.7	What are the risks of self-inoculation when changing PPE (i.e., is the true acquisition risk the same when wearing a medical mask and changing to an N95 for high-risk procedures versus wearing an N95 throughout the shift?)
5.3.7.1	Assess the viability of influenza virus on filter media: Reference A.
5.3.7.2	Explore efficacy in collaboration with CDC, FDA and EPA: Reference A.
5.3.7.3	Collaborate with PPT manufacturers: Reference A.
5.3.8	What protective roles do gloves, gowns, and face shields or other eye protection play in preventing influenza transmission?
5.3.8.1	** (same as 1.3.5 under recommendation #1)
5.3.9	What protection would medical masks provide to the wearer during an influenza pandemic?
5.3.9.1	** (same as 1.3.5 under recommendation #1)

5.3.9.2 Currently, the performance effectiveness of medical masks is assessed in accordance with consensus standards' test methods.

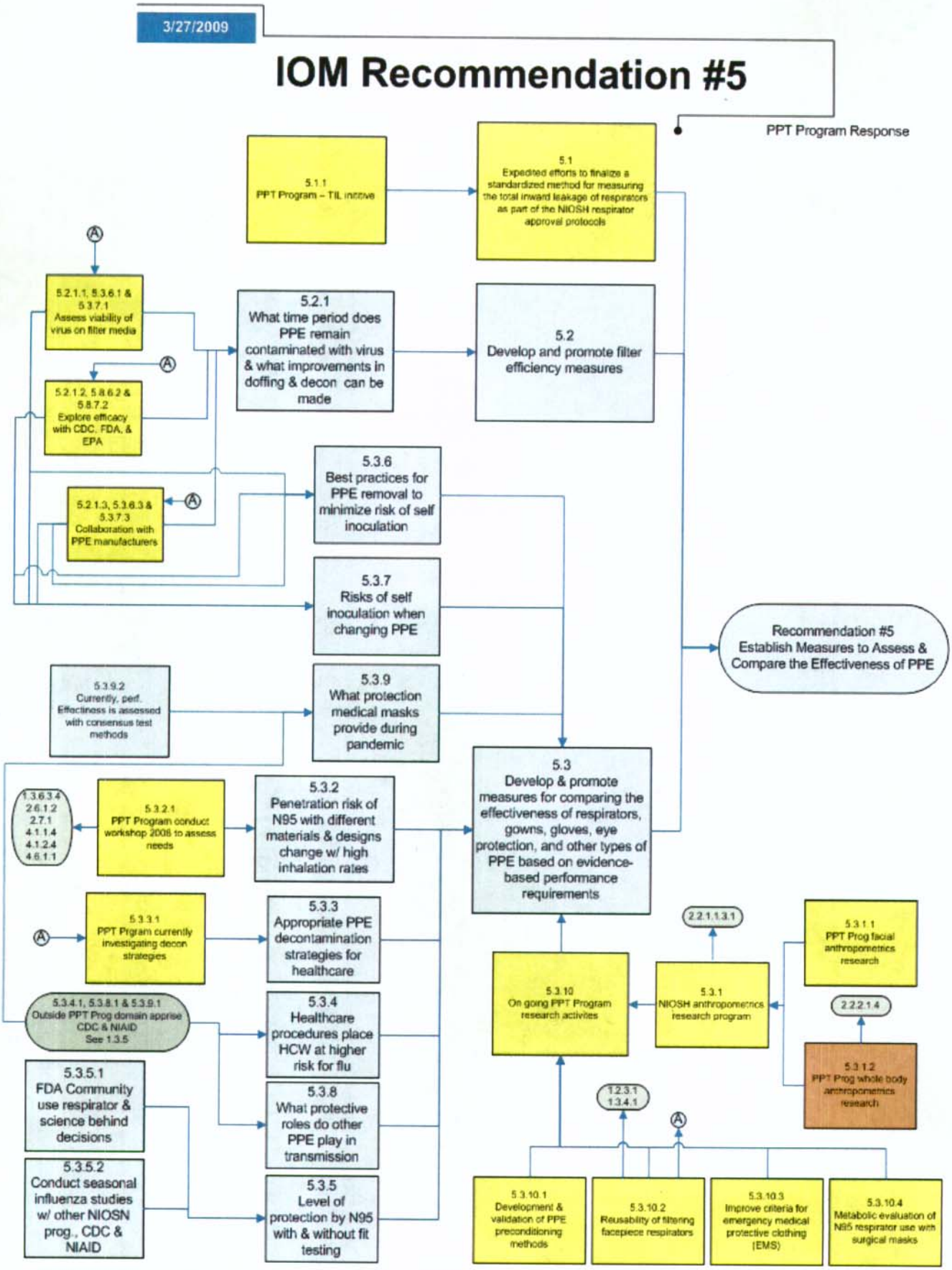
5.3.10 On going PPT Program research activities

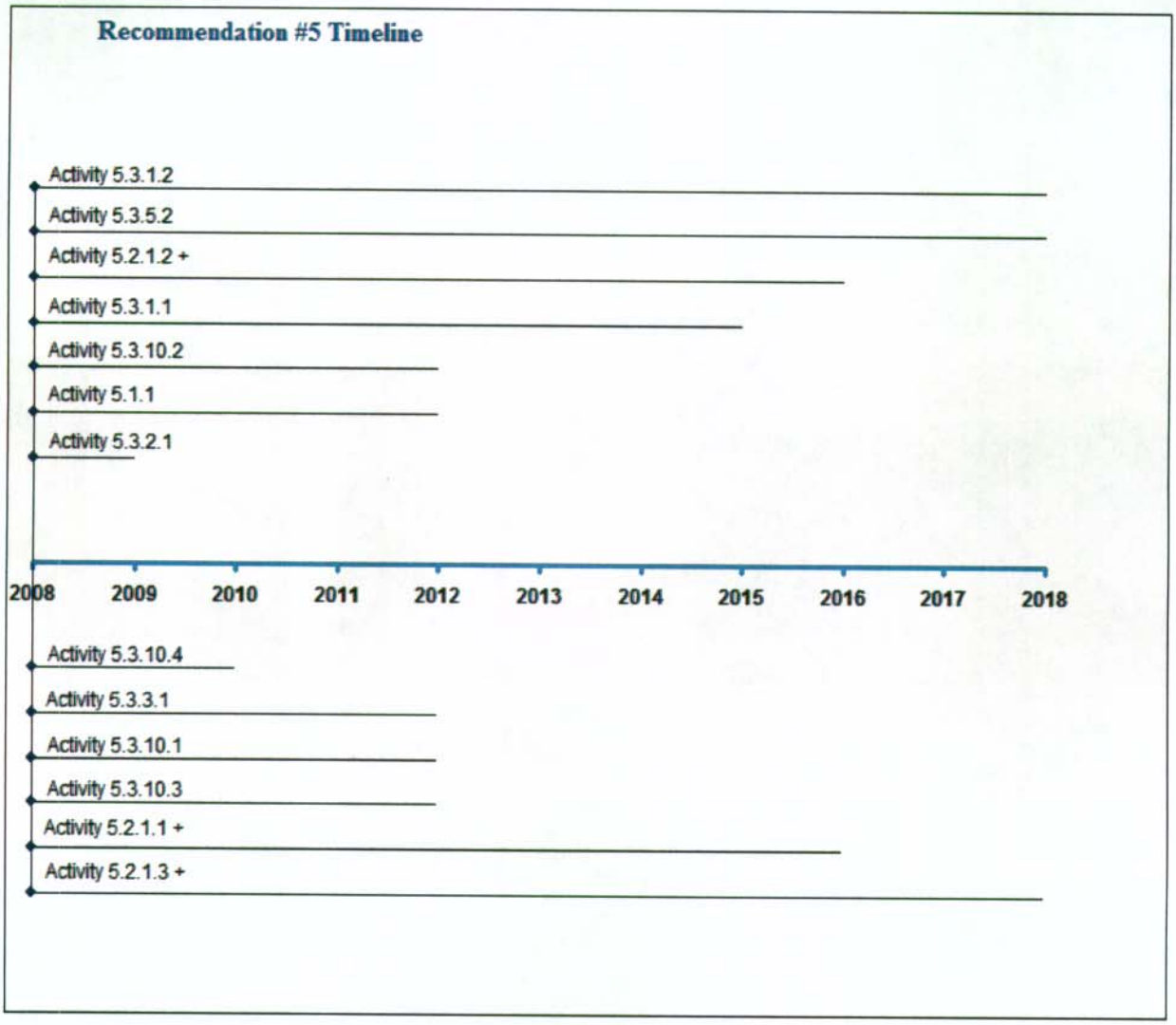
5.3.10.1 Development and validation of PPE preconditioning methods: Reference J.

5.3.10.2 Reusability of filtering facepiece respirators: Reference A.
The availability of FFR during a pandemic influenza is a subject of concern. Respirator manufacturers have warned that they may not be able to keep up with the anticipated demand. This has placed more emphasis upon the idea of decontaminating FFR for reuse. The PPT Program initiated a study in 2007 (Reusability of FFRs Exposed to Influenza Virus Simulant) to address the reusability of filtering facepiece respirators following various types of decontamination (e.g., heat, soap & water, chemicals, ultraviolet light, gas sterilization, microwaving). The data from this study have been analyzed and a manuscript prepared for journal submission. The data categorize the various decontamination agents with respect to their effects on filtration performance of the respirator.

5.3.10.3 Improve criteria for emergency medical services (EMS) protective clothing: Reference K. The PPT Program has undertaken a project to address the issue of protective clothing for EMS personnel who respond to patients with infectious diseases (approximately 1/29 of EMS calls), such as influenza, by contracting a study (Improved Criteria for Emergency Medical Protective Clothing – Project Plan Purchase Order No. 214-2006-M-15870) The objective of this project is to support the improvement of criteria for specific types of emergency medical personal protective equipment that are used by first responders. This objective specifically is defined to cover single use garments, cleaning gloves, footwear covers, and eye/face protection devices. A secondary objective of the project is to support the NFPA Technical Committee on EMS Protective Clothing and Equipment in its standards development process for modification of NFPA 1999 during its 2008 revision process. The project is intended to provide technical support for the committee to justify changes to the standard, particularly as related to changes in performance criteria.

5.3.10.4 Metabolic evaluation of N95 respirator use with surgical masks: Reference J. The IOM and the CDC have suggested that, in the face of reduced availability of filtering facepiece respirators, surgical masks placed over these respirators as a barrier might prolong their useful life. Although this recommendation has some plausibility, it has not undergone scientific scrutiny. The PPT Program initiated a study in 2006 (Metabolic Evaluation of N95 Respirator Use with Surgical Masks), utilizing an Automated Breathing and Metabolic Simulator to evaluate the concurrent use of N95FFR with surgical mask overlay. Within-respirator carbon dioxide levels, oxygen levels, and breathing resistance are being monitored to determine the effect(s) of the surgical mask on these parameters. Knowledge of these data can help predict physiological effects on wearers during prolonged periods of use, such as during a pandemic influenza. This recently-completed study (2007) by personnel from the PPT Program demonstrated that placement of a surgical mask over various models of N95FFR results in elevated breathing resistance (increases of ± 8% - 10% during inhalation and exhalation). This mannequin-based study suggests that use of a surgical mask as a barrier over a FFR will not result in breathing resistance that will have a pronounced effect upon the wearer. The data from this study will eventually be compared with that from the current study utilizing the Automated Breathing and Metabolic Simulator (ABMS) for correlative analysis.


3/27/2009
IOM Recommendation #5
PPT Program Response
5.1.1 PPT Program – TIL initiative
5.1 Expedited efforts to finalize a standardized method for measuring the total inward leakage of respirators as part of the NIOSH respirator approval protocols
5.2.1.1, 5.3.6.1 & 5.3.7.1 Assess viability of virus on filter media
5.2.1 What time period does PPE remain contaminated with virus & what improvements in doffing & decon can be made
5.2 Develop and promote filter efficiency measures
5.2.1.2, 5.8.6.2 & 5.8.7.2 Explore efficacy with CDC, FDA, & EPA
5.3.6 Best practices for PPE removal to minimize risk of self inoculation
5.2.1.3, 5.3.6.3 & 5.3.7.3 Collaboration with PPE manufacturers
5.3.7 Risks of self inoculation when changing PPE
Recommendation #5 Establish Measures to Assess & Compare the Effectiveness of PPE
5.3.9.2 Currently, perf. Effectiness is assessed with consensus test methods
5.3.9 What protection medical masks provide during pandemic
1.3.6.3.4 2.6.1.2 2.7.1 4.1.1.4 4.1.2.4 4.6.1.1
5.3.2.1 PPT Program conduct workshop 2008 to assess needs
5.3.2 Penetration risk of N95 with different materials & designs change w/ high inhalation rates
5.3 Develop & promote measures for comparing the effectiveness of respirators, gowns, gloves, eye protection, and other types of PPE based on evidence-based performance requirements
5.3.3.1 PPT Prgram currently investigating decon strategies
5.3.3 Appropriate PPE decontamination strategies for healthcare
2.2.1.1.3.1
5.3.1.1 PPT Prog facial anthropometrics research
5.3.10 On going PPT Program research activites
5.3.1 NIOSH anthropometrics research program
2.2.2.1.4
5.3.4.1, 5.3.8.1 & 5.3.9.1 Outside PPT Prog domain apprise CDC & NIAID See 1.3.5
5.3.4 Healthcare procedures place HCW at higher risk for flu
5.3.1.2 PPT Prog whole body anthroponemics research
5.3.5.1 FDA Community use respirator & science behind decisions
5.3.8 What protective roles do other PPE play in transmission
1.2.3.1 1.3.4.1
5.3.5.2 Conduct seasonal influenza studies w/ other NIOSN prog., CDC & NIAID
5.3.5 Level of protection by N95 with & without fit testing
5.3.10.1 Development & validation of PPE preconditioning methods
5.3.10.2 Reusability of filtering facepiece respirators
5.3.10.3 Improve criteria for emergency medical protective clothing (EMS)
5.3.10.4 Metabolic evaluation of N95 respirator use with surgical masks


Recommendation #5 Timeline
Activity 5.3.1.2
Activity 5.3.5.2
Activity 5.2.1.2 +
Activity 5.3.1.1
Activity 5.3.10.2
Activity 5.1.1
Activity 5.3.2.1
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Activity 5.3.10.4
Activity 5.3.3.1
Activity 5.3.10.1
Activity 5.3.10.3
Activity 5.2.1.1 +
Activity 5.2.1.3 +

49

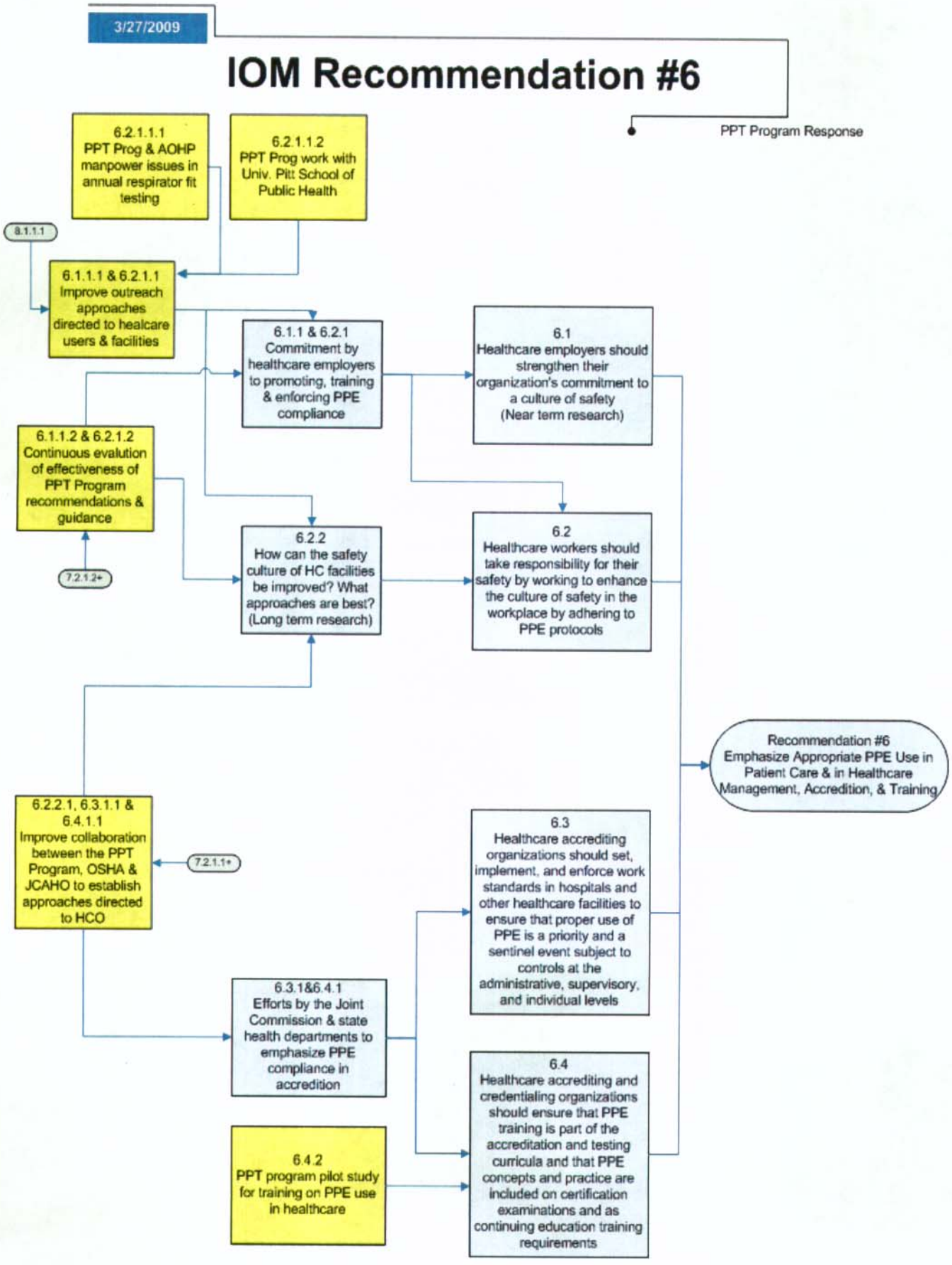
IOM Recommendation # 6: Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training.

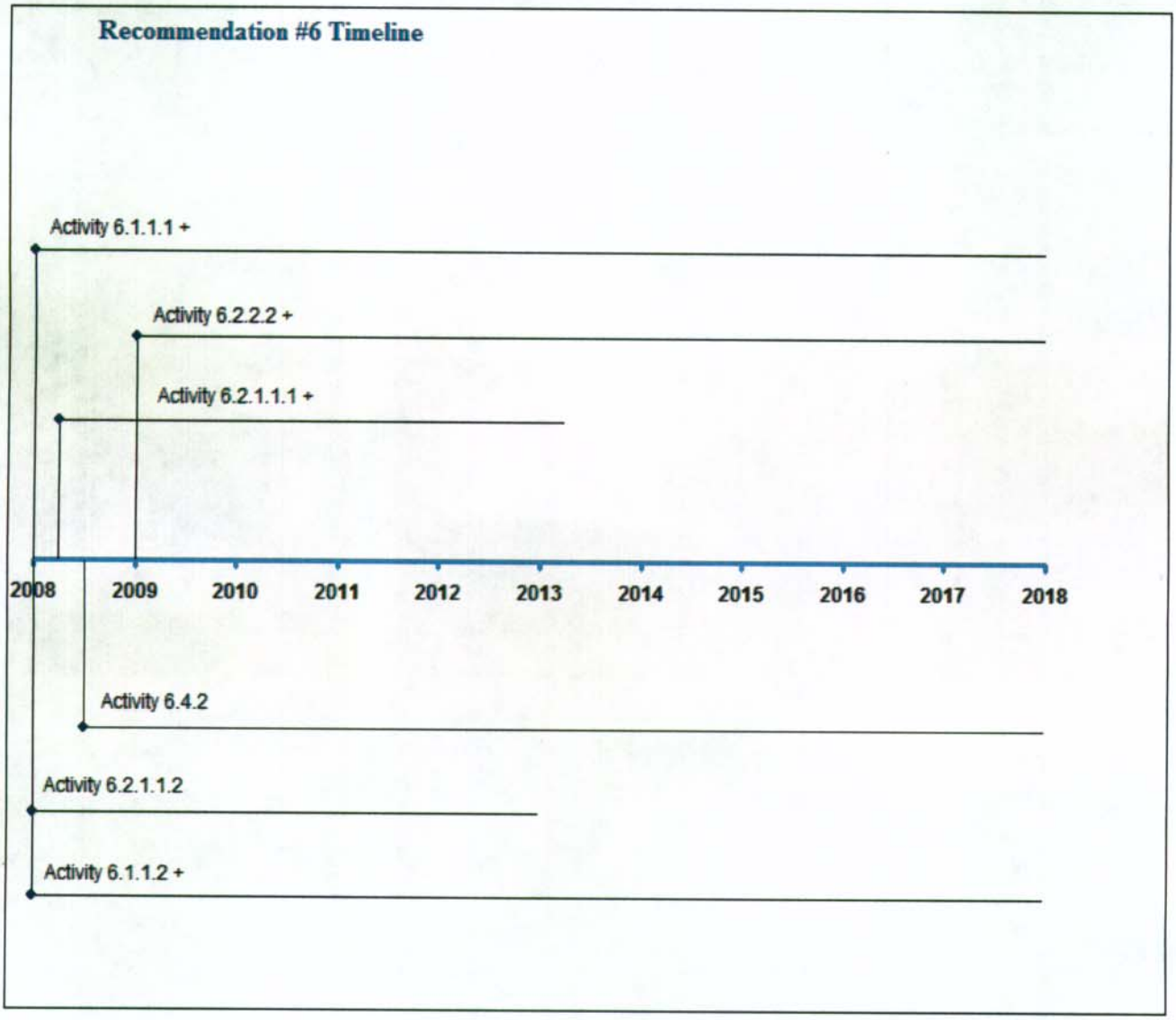
Appropriate PPE use and healthcare worker safety should be a priority for healthcare organizations and healthcare workers, and in accreditation, regulatory policy, and training.

PPT Program Plan in response to IOM Recommendation # 6

Activity #	Activity/Comment
6.1	Healthcare employers should strengthen their organization's commitment to a culture of safety by providing leadership in worker safety; instituting comprehensive, state-of-the-art training and education programs; facilitating easy access to PPE; giving feedback to supervisors and employees on PPE adherence; and enforcing disciplinary actions for noncompliance. Near term research.
6.1.1	A commitment by healthcare employers to promoting, training, and enforcing PPE compliance could increase adherence to PPE protocols and foster the expectation and norm for appropriate PPE use.
6.1.1.1	Improved outreach approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate PPT Program recommendations and guidance. NPPTL has participated in the Association of PeriOperative Registered Nurses (AORN) conference for the last two years and will be participating with an exhibit and materials in March 2008. We also participated in the EMS Update in Champion PA in 2007 and are scheduled to return in 2008. Also exhibited at the Association of Occupational Health Professionals in 2007 and plan to return in 2008.
6.1.1.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
6.2	Healthcare workers should take responsibility for their safety by working to enhance the culture of safety in the workplace and by adhering to PPE protocols.
6.2.1	A commitment by healthcare employers to promoting, training, and enforcing PPE compliance could increase adherence to PPE protocols and foster the expectation and norm for appropriate PPE use. Near term research.
6.2.1.1	Improved outreach approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate PPT Program recommendations and guidance.
6.2.1.1.1	PPT Program is currently involved in undertaking a project with members of the Association of Occupational Health Professionals in Medicine (AOHP) regarding manpower issues in annual respirator fit testing. Many AOHP members (most of whom are Registered Nurses who function within Employee Health clinics at healthcare institutions) contend that they do not have the necessary manpower to carry out OSHA-mandated annual fit testing for employees. This important issue in protecting healthcare workers takes on additional importance in the face of the increased infectious exposure that would occur during an influenza pandemic. PPT Program and AOHP members are developing a pilot program that will utilize a survey instrument (questionnaire) to determine the numbers of fit tests required per year and the available staff to carry out such testing in several local (Pittsburgh) hospitals. Data from the pilot program will be utilized to promote a larger study which will, in turn, identify manpower needs for annual fit testing in the healthcare community and how to more adequately utilize that

	manpower.
6.2.1.1.2	PPT Program has initiated contact with officials at the University of Pittsburgh's School of Public Health to look at areas of mutual interest with the eventuality of possibly engaging in research together.
6.2.1.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
6.2.2	How can the safety culture of healthcare facilities be improved? What approaches best facilitate a healthcare organizational culture that promotes safety? Long term research.
6.2.2.1	Improved collaboration between the PPT Program, OSHA, and Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.
6.2.2.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
6.3	Healthcare accrediting organizations (including the Joint Commission and state health departments) should set, implement, and enforce work standards in hospitals and other healthcare facilities to ensure that proper use of PPE is a priority and a sentinel event subject to controls at the administrative, supervisory, and individual levels.
6.3.1	Efforts by the Joint Commission and state health departments to emphasize PPE compliance in accreditation and other assessments could focus attention on PPE issues and enhance adherence to PPE protocols.
6.3.1.1	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.
6.4	Healthcare accrediting and credentialing organizations should ensure that PPE training is part of the accreditation and testing curricula of health professional schools of nursing, medicine, and allied health and that PPE concepts and practice are included on certification examinations and as continuing education training requirements.
6.4.1	Efforts by the Joint Commission and state health departments to emphasize PPE compliance in accreditation and other assessments could focus attention on PPE issues and enhance adherence to PPE protocols.
6.4.1.1	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.
6.4.2	PPT Program pilot program for training on PPE use. The PPT Program has instituted an Occupational Medicine rotation at NPPTL for Internal Medicine and Family Medicine resident physicians to acclimate them to issues that are germane to their involvement in Occupation Medicine tasks.


3/27/2009
IOM Recommendation #6
PPT Program Response
6.2.1.1.1 PPT Prog & AOHP manpower issues in annual respirator fit testing
6.2.1.1.2 PPT Prog work with Univ. Pitt School of Public Health
8.1.1.1
6.1.1.1 & 6.2.1.1 Improve outreach approaches directed to healcare users & facilities
6.1.1 & 6.2.1 Commitment by healthcare employers to promoting, training & enforcing PPE compliance
6.1 Healthcare employers should strengthen their organization's commitment to a culture of safety (Near term research)
6.1.1.2 & 6.2.1.2 Continuous evalution of effectiveness of PPT Program recommendations & guidance
7.2.1.2+
6.2.2 How can the safety culture of HC facilities be improved? What approaches are best? (Long term research)
6.2 Healthcare workers should take responsibility for their safety by working to enhance the culture of safety in the workplace by adhering to PPE protocols
Recommendation #6 Emphasize Appropriate PPE Use in Patient Care & in Healthcare Management, Accredition, & Training
6.2.2.1, 6.3.1.1 & 6.4.1.1 Improve collaboration between the PPT Program, OSHA & JCAHO to establish approaches directed to HCO
7.2.1.1+
6.3 Healthcare accrediting organizations should set, implement, and enforce work standards in hospitals and other healthcare facilities to ensure that proper use of PPE is a priority and a sentinel event subject to controls at the administrative, supervisory, and individual levels
6.3.1&6.4.1 Efforts by the Joint Commission & state health departments to emphasize PPE compliance in accredition
6.4 Healthcare accrediting and credentialing organizations should ensure that PPE training is part of the accreditation and testing curricula and that PPE concepts and practice are included on certification examinations and as continuing education training requirements
6.4.2 PPT program pilot study for training on PPE use in healthcare


Recommendation #6 Timeline
Activity 6.1.1.1 +
Activity 6.2.2.2 +
Activity 6.2.1.1.1 +
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Activity 6.4.2
Activity 6.2.1.1.2
Activity 6.1.1.2 +

58

IOM Recommendation # 7: Identify and Disseminate Best Practices for Improving PPE Compliance and Use.

CDC and the AHRQ should support and evaluate demonstration projects on improving PPE compliance and use. This effort would identify and disseminate relevant best practices that are being used by hospitals and other healthcare facilities.

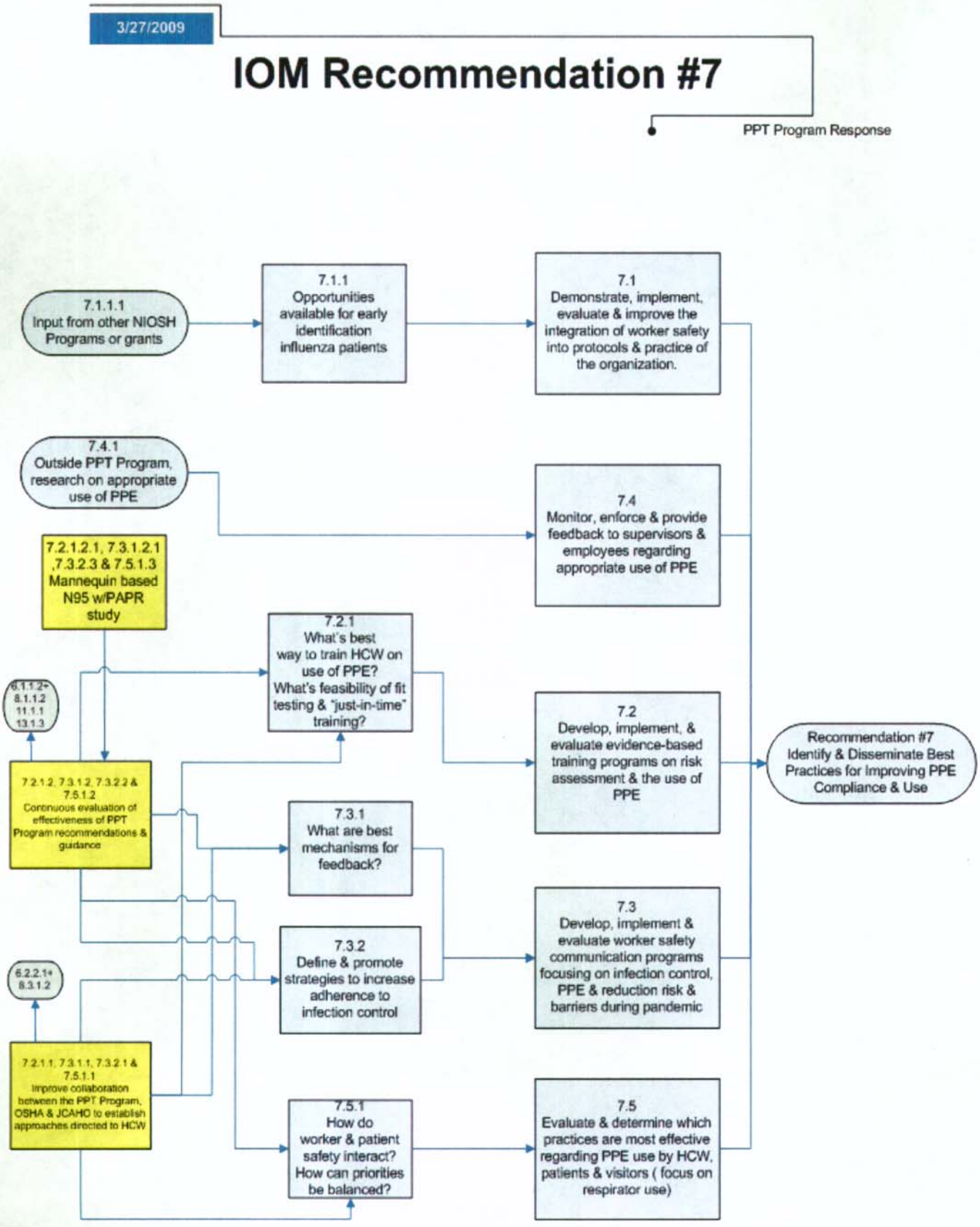
PPT Program Plan in response to IOM Recommendation # 7

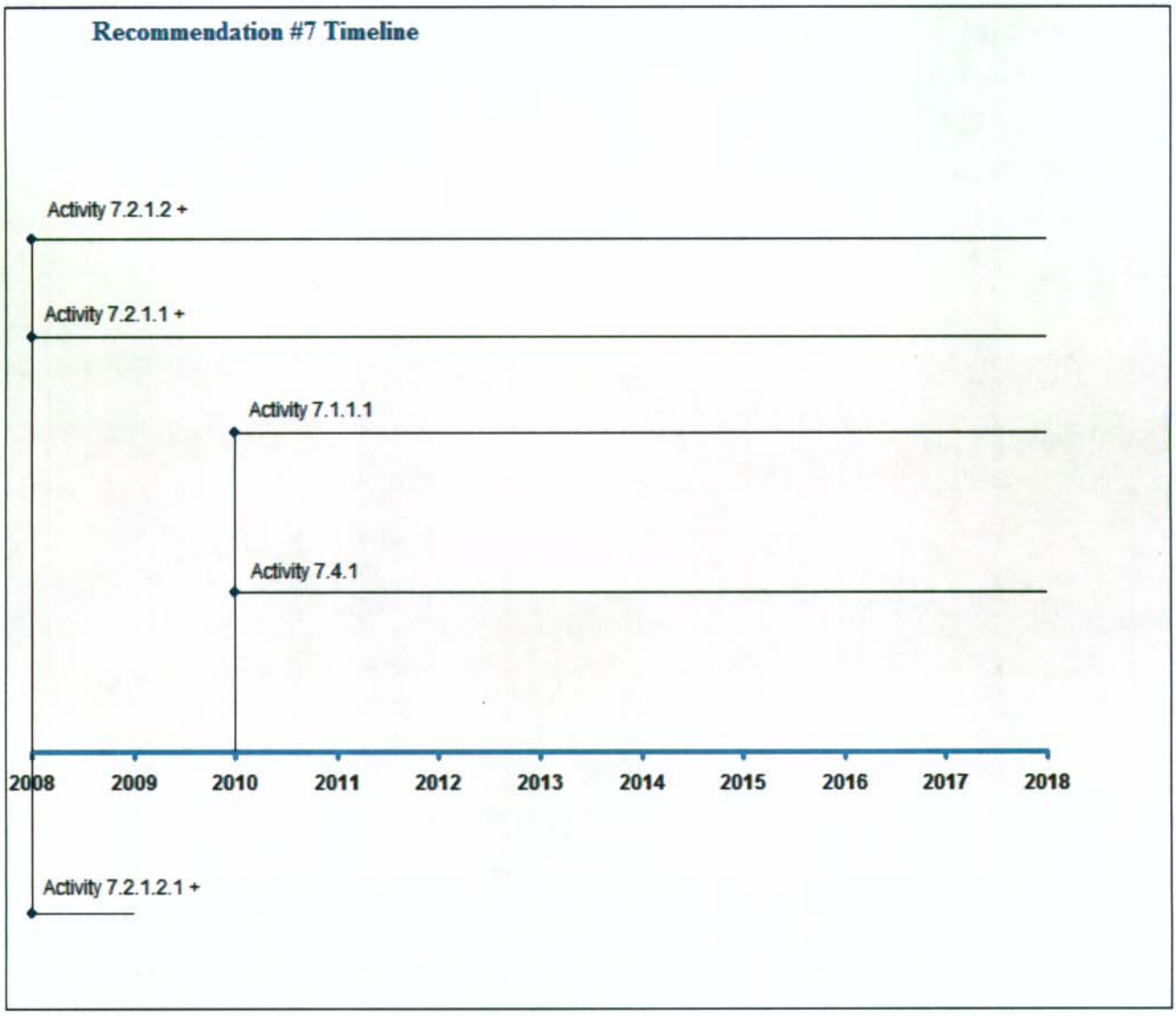
Activity #	Activity/Comment
7.1	Demonstrate, implement, evaluate, and improve the integration of worker safety into the protocols and practice of the organization.
7.1.1	** Near and long term opportunities are available for early identification influenza patients.
7.1.1.1	** These needs may be achievable under other projects or grants.
7.2	Develop, implement, and evaluate evidence-based training programs on risk assessment and the use of PPE, including addressing practical realities of wearing PPE, donning and doffing, decontamination, and waste disposal.
7.2.1	What are the best ways to train healthcare workers on appropriate use of personal protective equipment? What is the feasibility of fit testing and "just-in-time" training?
7.2.1.1	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.
7.2.1.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
7.2.1.2.1	PPT Program personnel recently completed a study (Mannequin-based Study of N95 FFRs Worn Concurrently With a Loose-fitting, PAPR: Effect on Protection Factors) that addressed the issue of wearing an N95FFR underneath a PAPR as is frequently done by healthcare workers performing potentially aerosol-generating procedures (e.g., suctioning, intubations, administering aerosolized medication treatments, etc.) on infectious patients, such as those with influenza. The study demonstrated that significant additional protection is afforded by this tandem respiratory combination that is especially significant in the event of PAPR failure. Publication of this data in a journal will serve to disseminate this information to the healthcare community.
7.3	Develop, implement, and evaluate worker safety communication programs focusing on infection control, PPE, and reduction of risk and barriers during an influenza pandemic.
7.3.1	What are the best mechanisms to communicate with and receive feedback from frontline healthcare workers in order to ensure that infection control measures are practical and feasible while still enhancing safety?
7.3.1.1	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.

7.3.1.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
7.3.1.2.1	PPT Program personnel recently completed a study (Mannequin-based Study of N95 Filtering Facepiece Respirators Worn Concurrently With a Loose-fitting, PAPR: Effect on Protection Factors) that addressed the issue of wearing an N95FFR underneath a PAPR as is frequently done by healthcare workers performing potentially aerosol-generating procedures (e.g., suctioning, intubations, administering aerosolized medication treatments, etc.) on infectious patients, such as those with influenza. The study demonstrated that significant additional protection is afforded by this tandem respiratory combination that is especially significant in the event of PAPR failure. Publication of this data in a journal will serve to disseminate this information to the healthcare community.
7.3.2	Define and promote strategies to increase adherence to infection control.
7.3.2.1	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.
7.3.2.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
7.3.2.3	PPT Program personnel recently completed a study (Mannequin-based Study of N95 Filtering Facepiece Respirators Worn Concurrently With a Loose-fitting, PAPR: Effect on Protection Factors) that addressed the issue of wearing an N95FFR underneath a PAPR as is frequently done by healthcare workers performing potentially aerosol-generating procedures (e.g., suctioning, intubations, administering aerosolized medication treatments, etc.) on infectious patients, such as those with influenza. The study demonstrated that significant additional protection is afforded by this tandem respiratory combination that is especially significant in the event of PAPR failure. Publication of this data in a journal will serve to disseminate this information to the healthcare community.
7.4	Monitor, enforce, and provide feedback to supervisors and employees regarding appropriate use of PPE.
7.4.1	** Near and long term research is needed regarding appropriate use of PPE.
7.5	Evaluate and determine which practices are most effective regarding PPE use by healthcare workers, patients, and visitors, with a focus on respirator use.
7.5.1	How do worker safety and patient safety interact? How can priorities be balanced where they conflict?
7.5.1.1	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.
7.5.1.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
7.5.1.3	PPT Program personnel recently completed a study (Mannequin-based Study of N95

FFRs Worn Concurrently With a Loose-fitting, PAPR: Effect on Protection Factors) that addressed the issue of wearing an N95FFR underneath a PAPR as is frequently done by healthcare workers performing potentially aerosol-generating procedures (e.g., suctioning, intubations, administering aerosolized medication treatments, etc.) on infectious patients, such as those with influenza. The study demonstrated that significant additional protection is afforded by this tandem respiratory combination that is especially significant in the event of PAPR failure. Publication of this data in a journal will serve to disseminate this information to the healthcare community.

68


3/27/2009
IOM Recommendation #7
PPT Program Response
7.1.1.1 Input from other NIOSH Programs or grants
7.1.1 Opportunities available for early identification influenza patients
7.1 Demonstrate, implement, evaluate & improve the integration of worker safety into protocols & practice of the organization.
7.4.1 Outside PPT Program, research on appropriate use of PPE
7.4 Monitor, enforce & provide feedback to supervisors & employees regarding appropriate use of PPE
7.2.1.2.1, 7.3.1.2.1 ,7.3.2.3 & 7.5.1.3 Mannequin based N95 w/PAPR study
7.2.1 What's best way to train HCW on use of PPE? What's feasibility of fit testing & "just-in-time" training?
6.1.1.2* 8.1.1.2 11.1.1 13.1.3
7.2 Develop, implement, & evaluate evidence-based training programs on risk assessment & the use of PPE
Recommendation #7 Identify & Disseminate Best Practices for Improving PPE Compliance & Use
7.2.1.2, 7.3.1.2, 7.3.2.2 & 7.5.1.2 Continuous evaluation of effectiveness of PPT Program recommendations & guidance
7.3.1 What are best mechanisms for feedback?
7.3 Develop, implement & evaluate worker safety communication programs focusing on infection control, PPE & reduction risk & barriers during pandemic
7.3.2 Define & promote strategies to increase adherence to infection control
6.2.2.1* 8.3.1.2
7.2.1.1, 7.3.1.1, 7.3.2.1 & 7.5.1.1 Improve collaboration between the PPT Program, OSHA & JCAHO to establish approaches directed to HCW
7.5.1 How do worker & patient safety interact? How can priorities be balanced?
7.5 Evaluate & determine which practices are most effective regarding PPE use by HCW, patients & visitors (focus on respirator use)


Recommendation #7 Timeline
Activity 7.2.1.2 +
Activity 7.2.1.1 +
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Activity 7.2.1.2.1 +

69

IOM Recommendation # 8: Increase Research and Research Translation Efforts Relevant to PPE Compliance.

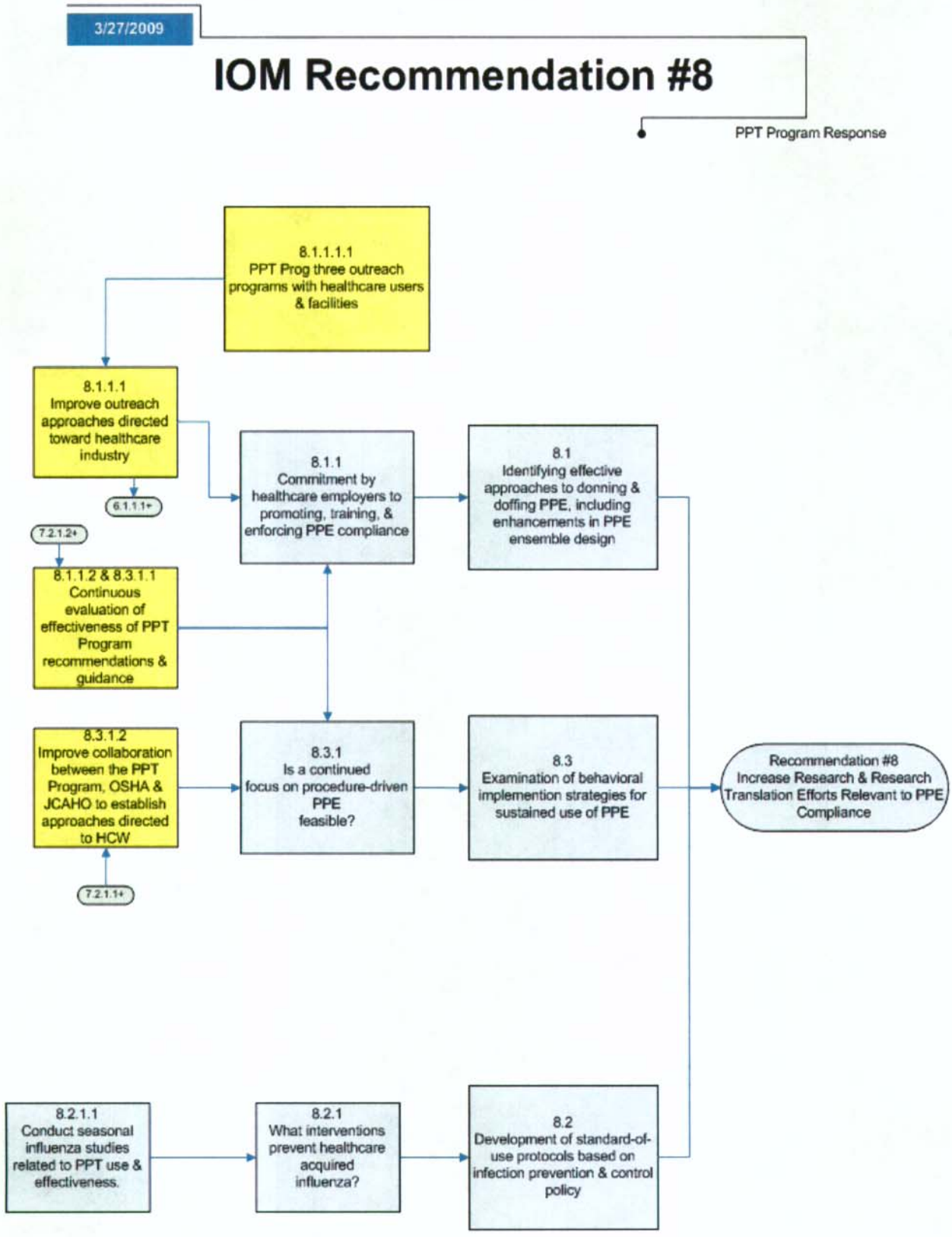
NIOSH, the NIH, AHRQ, and other relevant agencies and organizations should support research on improving the human factors and behavioral issues related to ease and effectiveness of PPE use for extended periods and in patient care-interactive work environments.

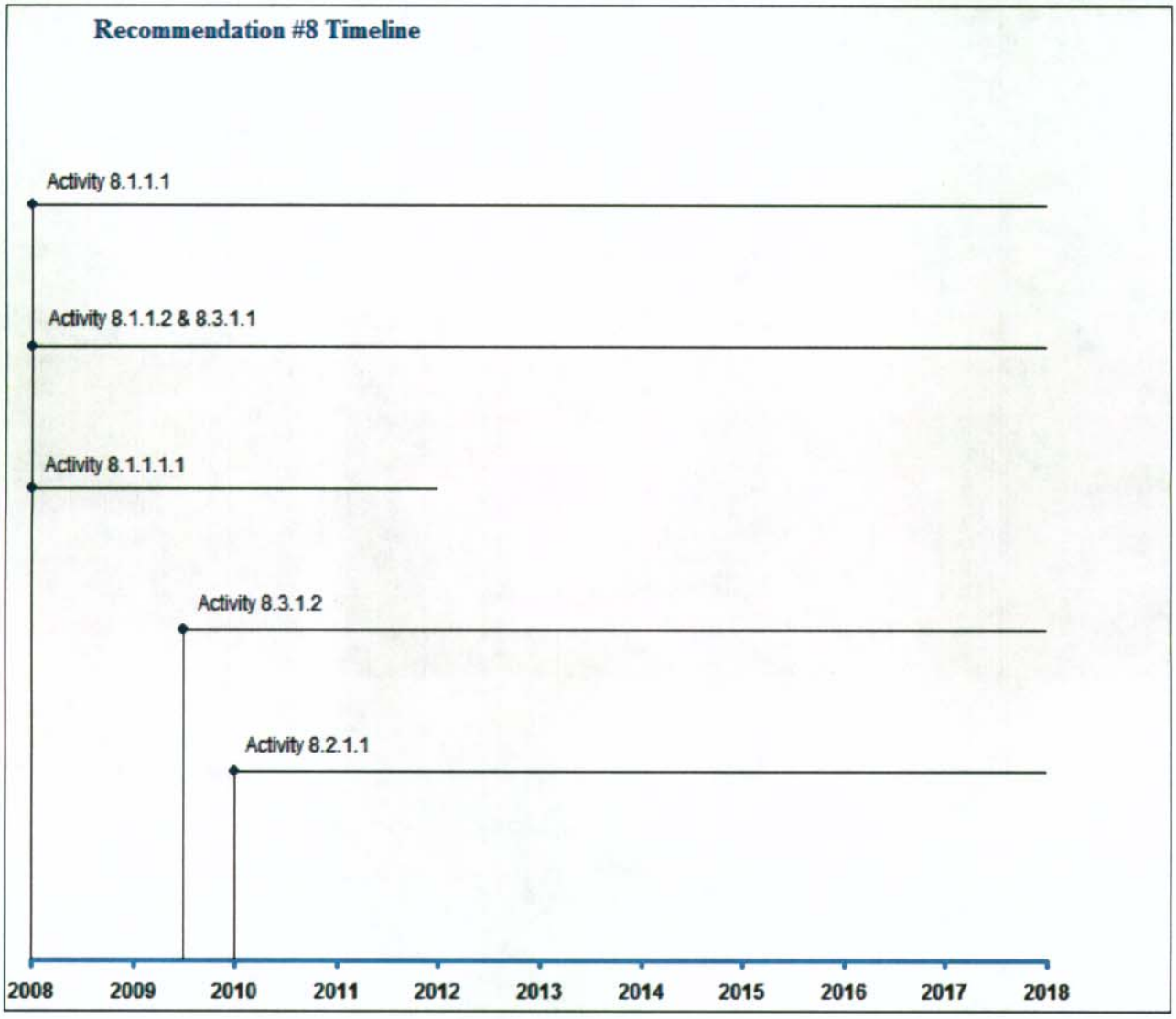
PPT Program Plan in response to IOM Recommendation # 8

Activity #	Activity/Comment
8.1	Identifying effective approaches to donning and doffing PPE, including enhancements in PPE ensemble design.
8.1.1	A commitment by healthcare employers to promoting, training, and enforcing PPE compliance could increase adherence to PPE protocols and foster the expectation and norm for appropriate PPE use.
8.1.1.1	Improved outreach approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate PPT Program recommendations and guidance.
8.1.1.1.1	The PPT Program is directing its outreach approaches in several ways. An Occupational Medicine one-day rotation for Internal Medicine and Family Medicine residents of the West-Penn/Allegheny Health System is scheduled to commence Jan, 2008. It is hoped that this outreach program will enhance the practitioners' skills, some of which could be of significant importance in the face of an influenza pandemic (e.g., respirator fit testing). The PPT Program is also reaching out to medical professional societies (e.g., AOHP in Medicine) to engage them in collaborative research efforts (e.g., manpower needs for annual fit testing) that can impact aspects of a pandemic influenza. The PPT Program is also engaging healthcare systems and institutions, including the VHA and the University of Pittsburgh School of Public Health (Department of Occupational and Environmental Health) in collaborative research efforts regarding PPE. Also, NPPTL has participated in the AORN conference for the last two years and will be participating with an exhibit and materials in March 2008. We also participated in the EMS Update in Champion PA in 2007 and are scheduled to return in 2008. Also exhibited at the Association of Occupational Health Professionals in 2007 and plan to return in 2008.
8.1.1.2	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.
8.2	Development of standard-of-use protocols based on infection prevention and control policy with clear, simple-to-use algorithms.
8.2.1	What interventions prevent healthcare-acquired influenza?
8.2.1.1	Seasonal influenza studies related to PPT use and effectiveness should be conducted in collaboration with other NIOSH programs, CDC and NIAID.
8.3	Examination of behavioral implementation strategies for sustained use of PPE, including a focus on patient and community education as well as healthcare provider education.
8.3.1	Is a continued focus on procedure-driven PPE feasible?

8.3.1.1	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others..
8.3.1.2	Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.

79


3/27/2009
IOM Recommendation #8
PPT Program Response
8.1.1.1.1
PPT Prog three outreach programs with healthcare users & facilities
8.1.1.1
Improve outreach approaches directed toward healthcare industry
6.1.1.1+
7.2.1.2+
8.1.1.2 & 8.3.1.1
Continuous evaluation of effectiveness of PPT Program recommendations & guidance
8.3.1.2
Improve collaboration between the PPT Program, OSHA & JCAHO to establish approaches directed to HCW
7.2.1.1+
8.1.1
Commitment by healthcare employers to promoting, training, & enforcing PPE compliance
8.3.1
Is a continued focus on procedure-driven PPE feasible?
8.1
Identifying effective approaches to donning & doffing PPE, including enhancements in PPE ensemble design
8.3
Examination of behavioral implemention strategies for sustained use of PPE
Recommendation #8
Increase Research & Research Translation Efforts Relevant to PPE Compliance
8.2.1.1
Conduct seasonal influenza studies related to PPT use & effectiveness.
8.2.1
What interventions prevent healthcare acquired influenza?
8.2
Development of standard-of-use protocols based on infection prevention & control policy


Recommendation #8 Timeline
Activity 8.1.1.1
Activity 8.1.1.2 & 8.3.1.1
Activity 8.1.1.1.1
Activity 8.3.1.2
Activity 8.2.1.1
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IOM Recommendation # 9: Ensure Balance and Transparency of Standards-Setting Processes.

Federal agencies (e.g., FDA, NIOSH, OSHA) should use standards developed through a consensus-based transparent process that sets specific and clearly-defined limits regarding conflicts of interest (financial or other) and involves broad representation of all affected parties.

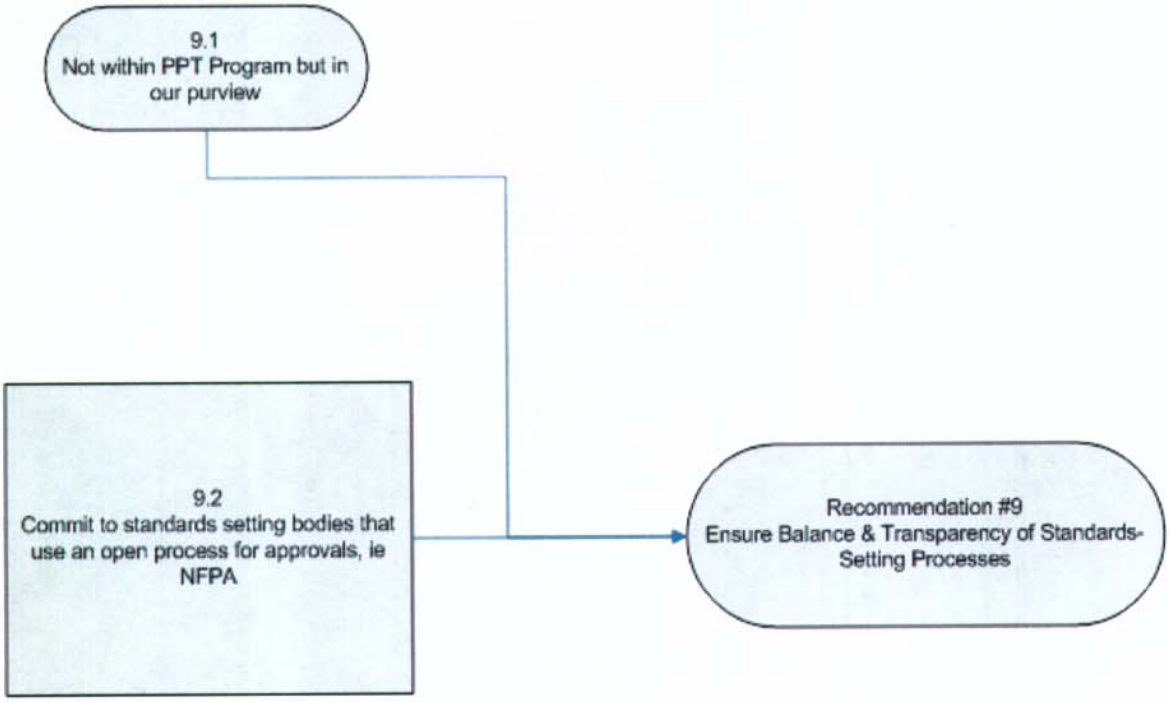
PPT Program Plan in response to IOM Recommendation # 9

Activity #	Activity/Comment
9.1	Not in PPT Program domain, but in our purview.
9.2	Commit to standards setting bodies that use an open process for approvals, i.e. NFPA.

3/27/2009

IOM Recommendation #9

PPT Program Response



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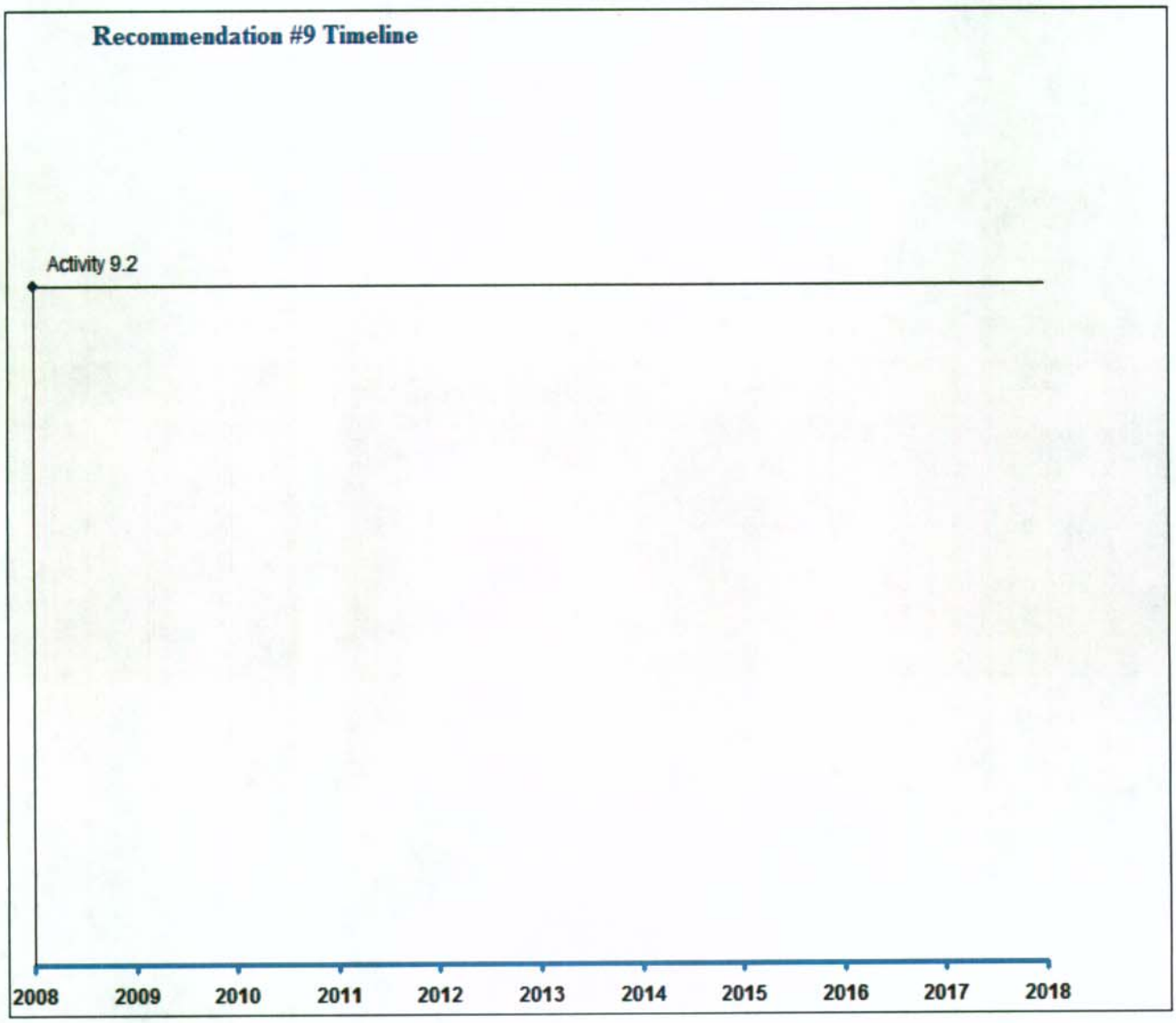
Recommendation #9 Timeline
Activity 9.2
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93
94 IOM Recommendation # 10: Strengthen Pre-market Testing of PPE for Healthcare Workers.
95
96 FDA, NIOSH, and other relevant agencies and organizations should strengthen pre-market
97 testing requirements for healthcare PPE by requiring field testing of PPE prior to approval and
98 by reevaluating the FDA medical device classification for healthcare PPE. Testing requirements
99 should use rigorous standards while also providing expeditious review of innovative approaches.
100
101 ***PPT Program Plan in response to IOM Recommendation # 10***

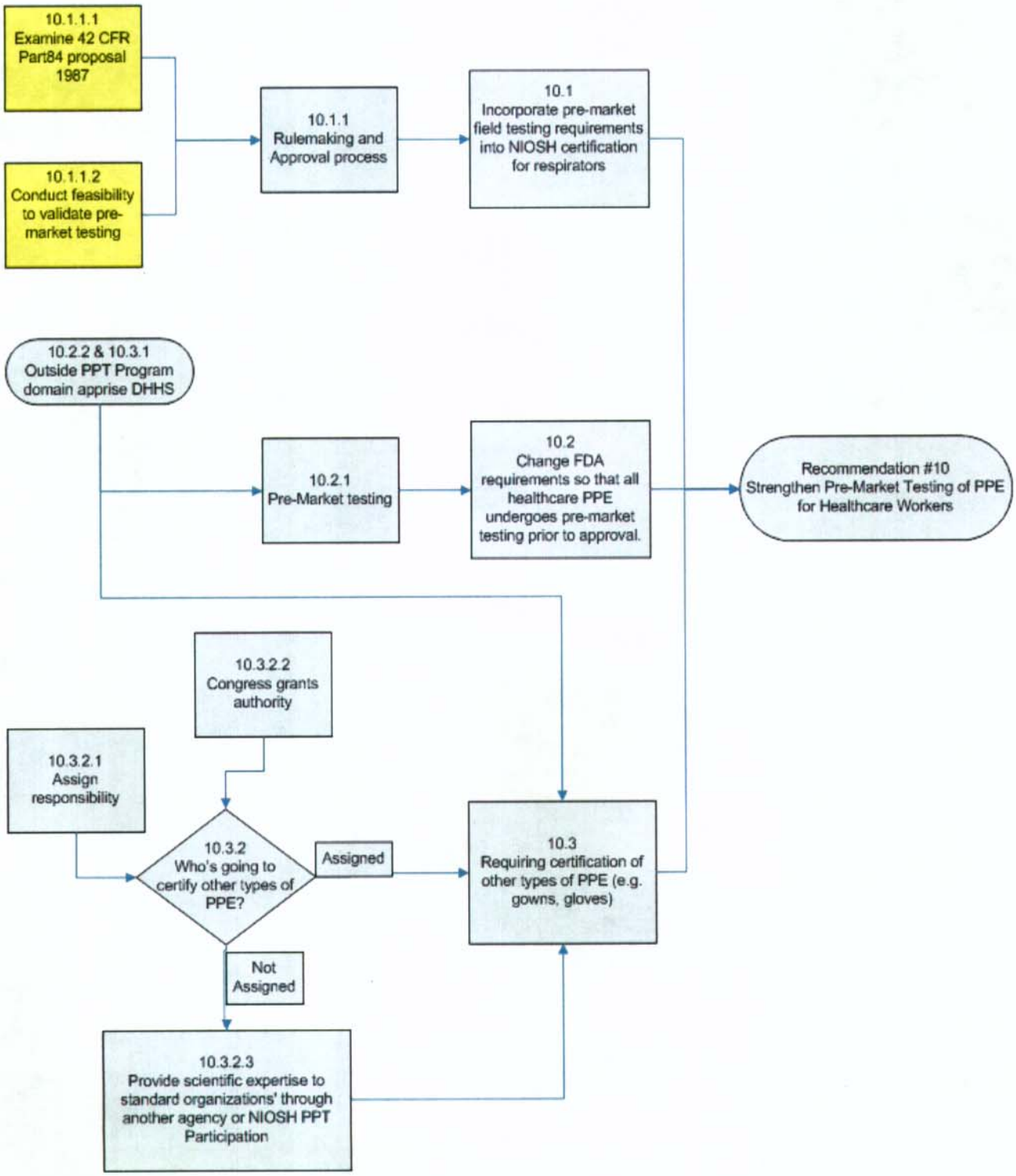
Activity #	Activity/Comment
10.1	Incorporating pre-market field testing requirements into NIOSH certification for respirators.
10.1.1	Can be done through rulemaking and/or approval processes.
10.1.1.1	Describe the Part 84 proposal in 1987 and why it was rejected and potential logistical issues.
10.1.1.2	Feasibility study should be conducted in collaboration with others to validate the need for PPE premarket testing (facilities, market share, ,etc.).
10.2	Change FDA requirements so that all healthcare PPE undergoes pre-market testing prior to approval.
10.2.1	** Pre-market testing—Immediate attention needs to be devoted in the next 6 to 12 months to determining appropriate field testing parameters and methodologies for enhancing pre-market testing of healthcare PPE to focus the testing on efficacy against transmission of infectious disease and on enhancing wearability and other critical factors for use.
10.3	** Requiring certification of other types of PPE (e.g., gowns, gloves).
10.3.1	NIOSH only has the authority to approve respirators.
10.3.2	** NIOSH does not have the authority to approve other types of PPE. However, when PPE such as gowns and gloves are considered to be medical devices, FDA has the authority to approve them.
10.3.2.1	** Have authority granted or assigned for other PPEs not already under FDA authority as medical devices.
10.3.2.2	Alternative approach -- Provide scientific expertise to standard organizations' through another agency or NIOSH PPT participation.
10.3.2.2.1	The PPT Program has several personnel who serve on various committees of Standards Organization (e.g., American National Standards Institute, International Standards Organization, etc.) to provide their valuable input. Additionally, PPE research work carried out by the PPT Program (i.e., Homeland Emergency Response Operational and Equipment Systems - HEROES project) resulted in the development of a new ASTM standard (ASTM F2668-07 Standard Practice for Determining the Physiological Responses of the Wearer to Protective Clothing Ensembles).

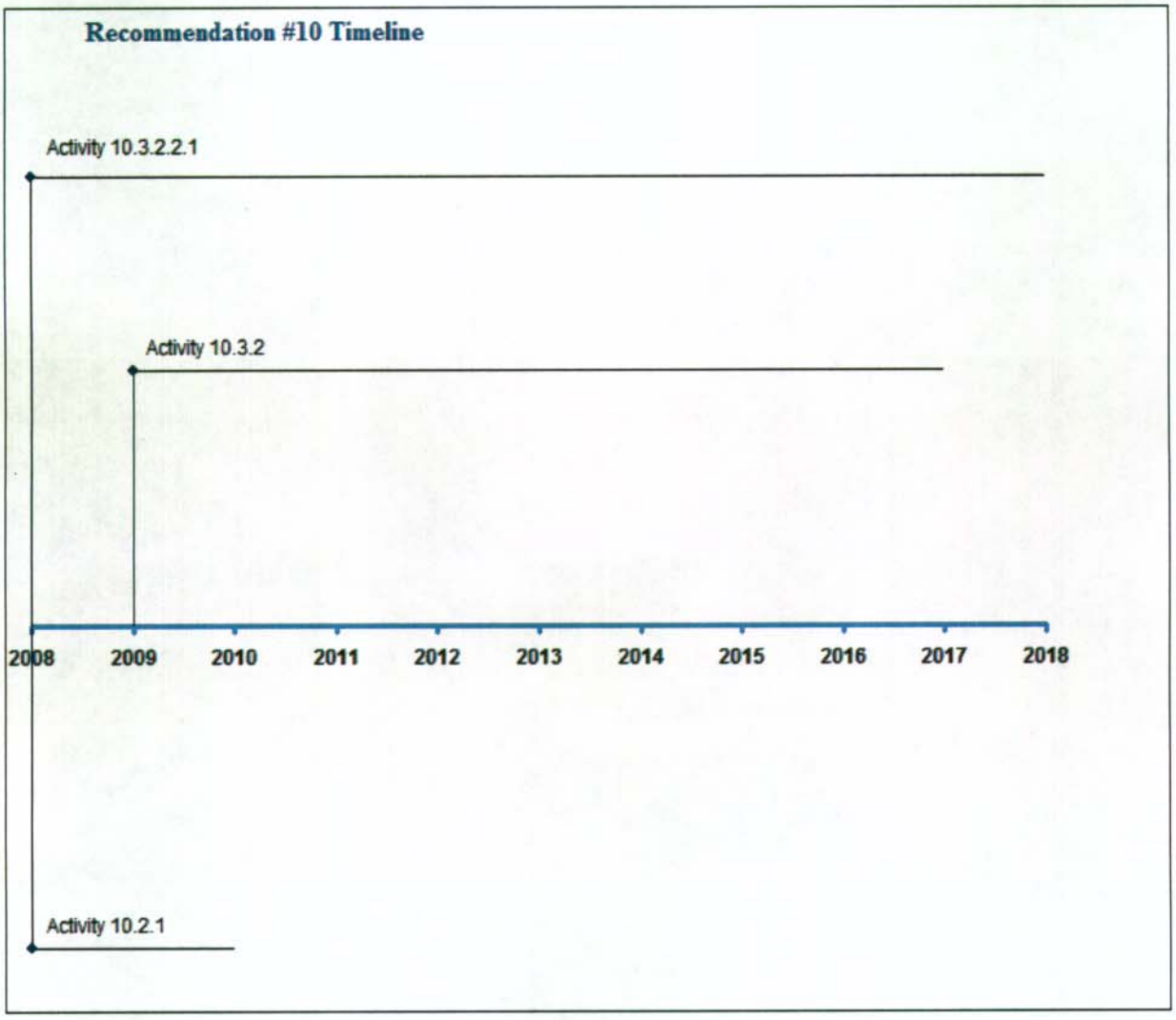
102

3/27/2009

IOM Recommendation #10

PPT Program Response




Recommendation #10 Timeline
Activity 10.3.2.2.1
Activity 10.3.2
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Activity 10.2.1

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104 IOM Recommendation # 11: Strengthen Post-market Evaluation of PPE for Healthcare Workers.
105
106 NIOSH, FDA, and other relevant agencies and organizations should support and strengthen
107 adverse event reporting and post-market evaluation studies and surveillance regarding the
108 effectiveness of PPE used by healthcare workers.
109
110 ***PPT Program Plan in response to IOM Recommendation # 11***

Activity #	Activity/Comment
11.1	Workplace effectiveness studies
11.1.1	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, other elements of CDC, and others.
11.2	Head-to-head comparison studies of the performance characteristics of PPE (including fit, filtration, and user acceptability) to allow the employer and wearer to compare and evaluate products.
11.2.1	Workplace effectiveness studies related to PPT use should be conducted in collaboration with other NIOSH programs, other elements of CDC and NIAID.
11.3	Adverse events reporting of problems with PPE use.
11.3.1	** Except for respirators apprise DHHS
11.3.2	Collaborate and share Certified Product Investigation Process (CPIP) model, used for the respirator certification program, with others: Reference L. The CPIP and QA models are being improved to be ISO 17025 and ISO 9001 compliant. These efforts will improve portability.
11.4	Worker health and medical surveillance where possible (e.g., infectivity rates).
11.4.1	** Funding is needed for evaluation and surveillance projects. Conducted by NIOSH programs, other elements of CDC, state health departments, and others.
11.5	Continue current respirator PPE report auditing program.
11.5.1	Collaborate and share Quality Assurance (QA) module for respirators with other PPE post market evaluations: Reference M. The CPIP and QA models are being improved to be ISO 17025 and ISO 9001 compliant. These efforts will improve portability.

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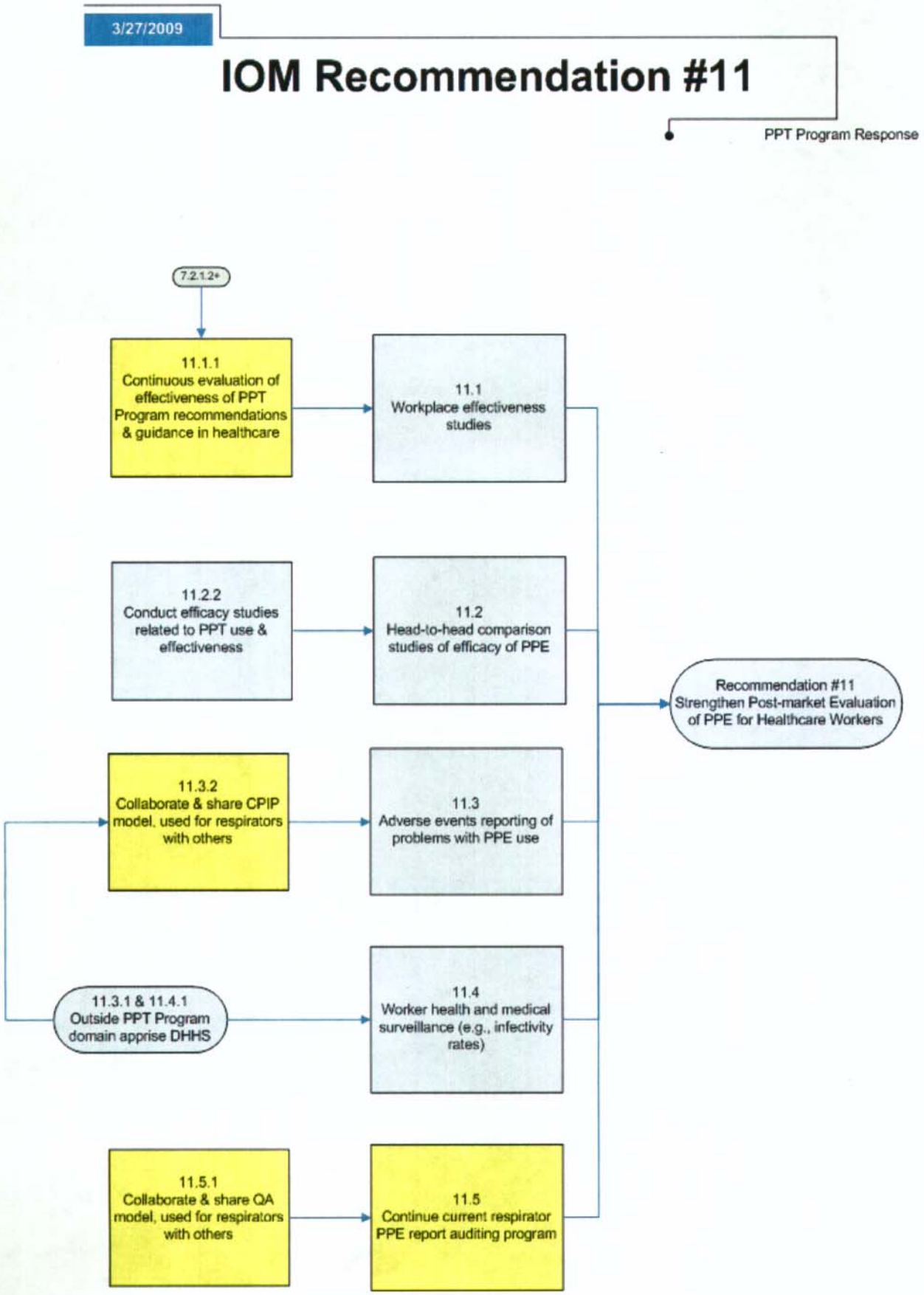
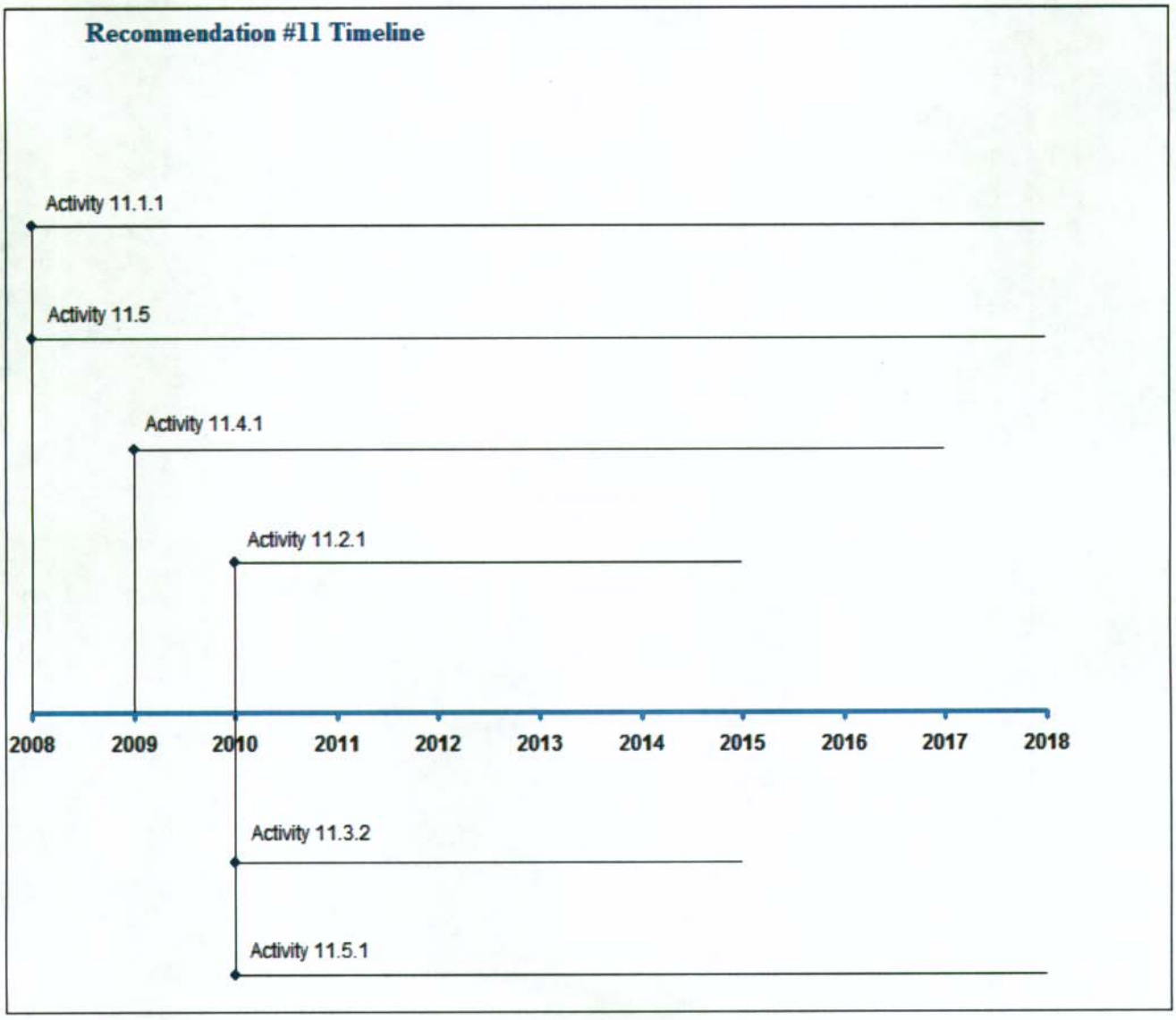

3/27/2009
IOM Recommendation #11
PPT Program Response
7.2.1.2+
11.1.1
Continuous evaluation of effectiveness of PPT Program recommendations & guidance in healthcare
11.1
Workplace effectiveness studies
11.2.2
Conduct efficacy studies related to PPT use & effectiveness
11.2
Head-to-head comparison studies of efficacy of PPE
Recommendation #11
Strengthen Post-market Evaluation of PPE for Healthcare Workers
11.3.2
Collaborate & share CPIP model, used for respirators with others
11.3
Adverse events reporting of problems with PPE use
11.3.1 & 11.4.1
Outside PPT Program domain apprise DHHS
11.4
Worker health and medical surveillance (e.g., infectivity rates)
11.5.1
Collaborate & share QA model, used for respirators with others
11.5
Continue current respirator PPE report auditing program


Recommendation #11 Timeline
Activity 11.1.1
Activity 11.5
Activity 11.4.1
Activity 11.2.1
2008
2009
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2016
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Activity 11.3.2
Activity 11.5.1

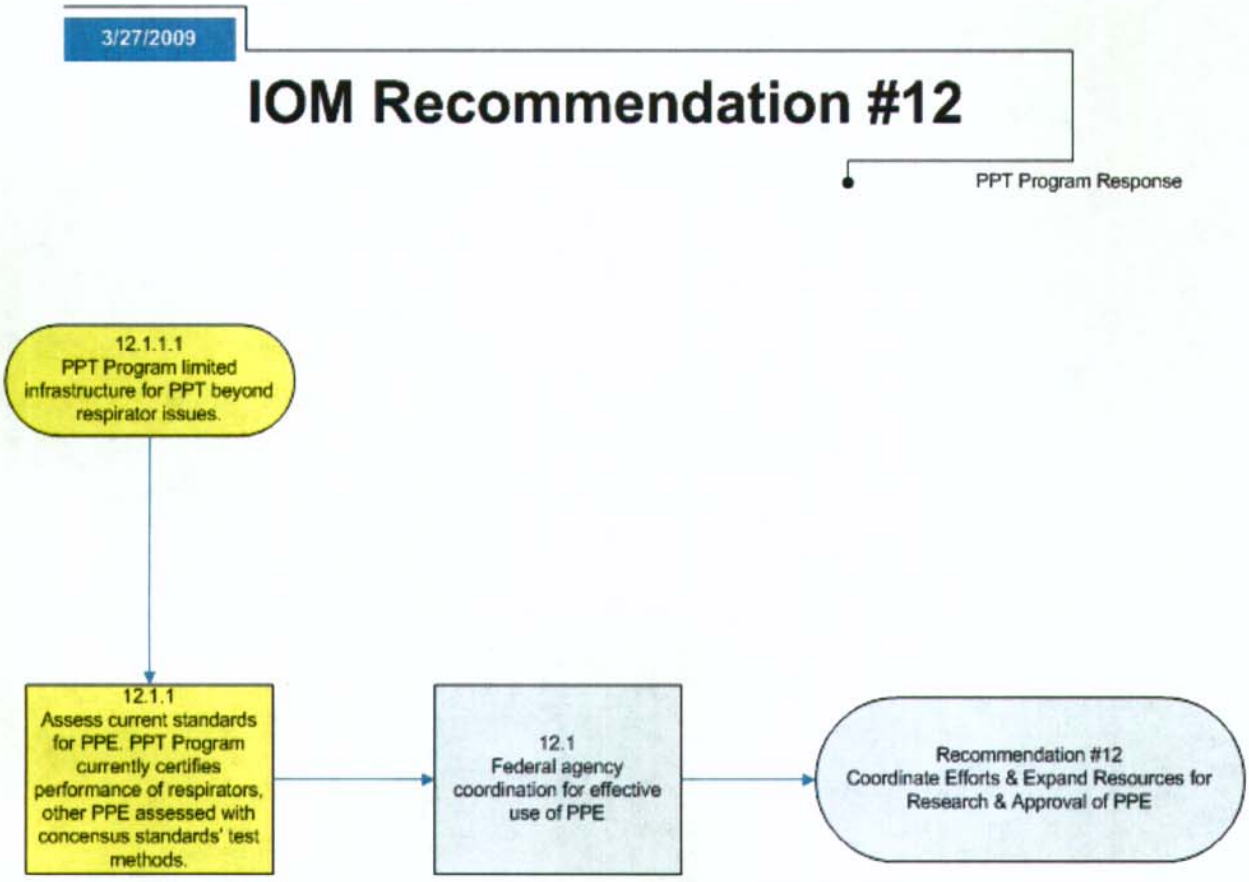
113

IOM Recommendation # 12: Coordinate Efforts and Expand Resources for Research and Approval of PPE

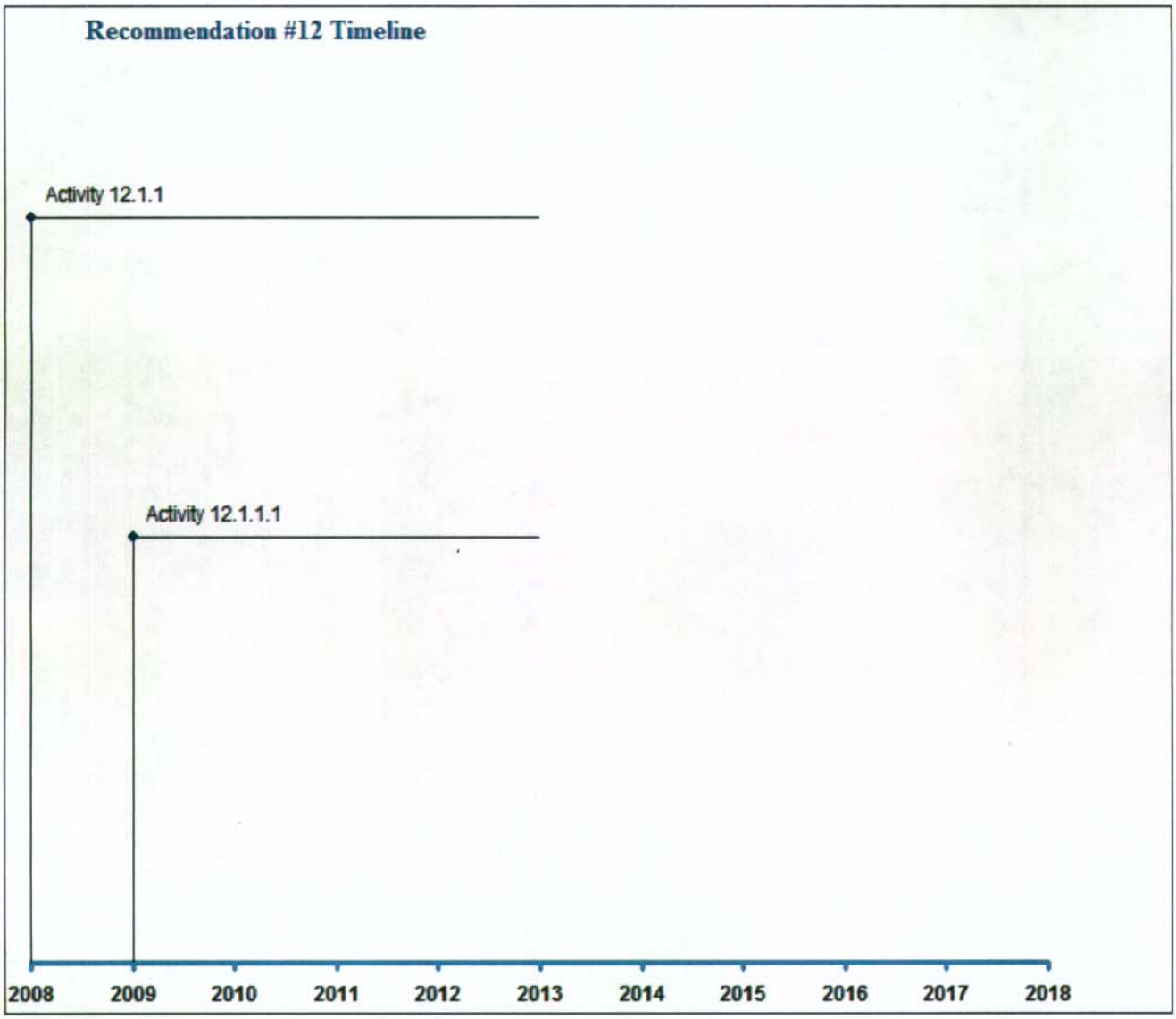
Congress should expand the resources provided to NIOSH to further research efforts on the next generation of PPE and to coordinate and expedite the approval of effective PPE. Efforts to coordinate PPE testing, certification, and approval across all relevant federal agencies should include developing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

PPT Program Plan in response to IOM Recommendation # 12

Activity #	Activity/Comment
12.1	Federal agency coordination—while each of the federal agencies has a distinct and vital role in ensuring the use of effective PPE, there is a strong need for a coordinated effort to ensure harmonization of requirements and to focus on coordinating the entire process from product design to use in the workplace. Many federal agencies in multiple departments (including the DoD, DHHS, DHS, and Labor) and the Consumer Product Safety Commission and the Environmental Protection Agency work to ensure worker safety and to approve, develop, and implement PPE.
12.1.1	An assessment of current standards needs to be conducted to categorize existing PPE as it relates to current standards. PPT Program currently certifies performance of respirators, other PPE performance is assessed in accordance with consensus standards' test methods.
12.1.1.1	PPT Program has limited infrastructure and funding for PPT research, development and investigative testing beyond respirator issues. Extensive research would be needed to develop "evidence-based performance standards for all types of PPE for healthcare workers." This would require support for both intramural and extramural research.
12.1.1.2	As resources allow, NPPTL is planning on expanding its capability in protective clothing research, development and investigative testing through training, additional personnel, and cooperative efforts with third party laboratories.


3/27/2009
IOM Recommendation #12
PPT Program Response
12.1.1.1
PPT Program limited infrastructure for PPT beyond respirator issues.
12.1.1
Assess current standards for PPE. PPT Program currently certifies performance of respirators, other PPE assessed with concensus standards' test methods.
12.1
Federal agency coordination for effective use of PPE
Recommendation #12
Coordinate Efforts & Expand Resources for Research & Approval of PPE

126


Recommendation #12 Timeline
Activity 12.1.1
Activity 12.1.1.1
2008
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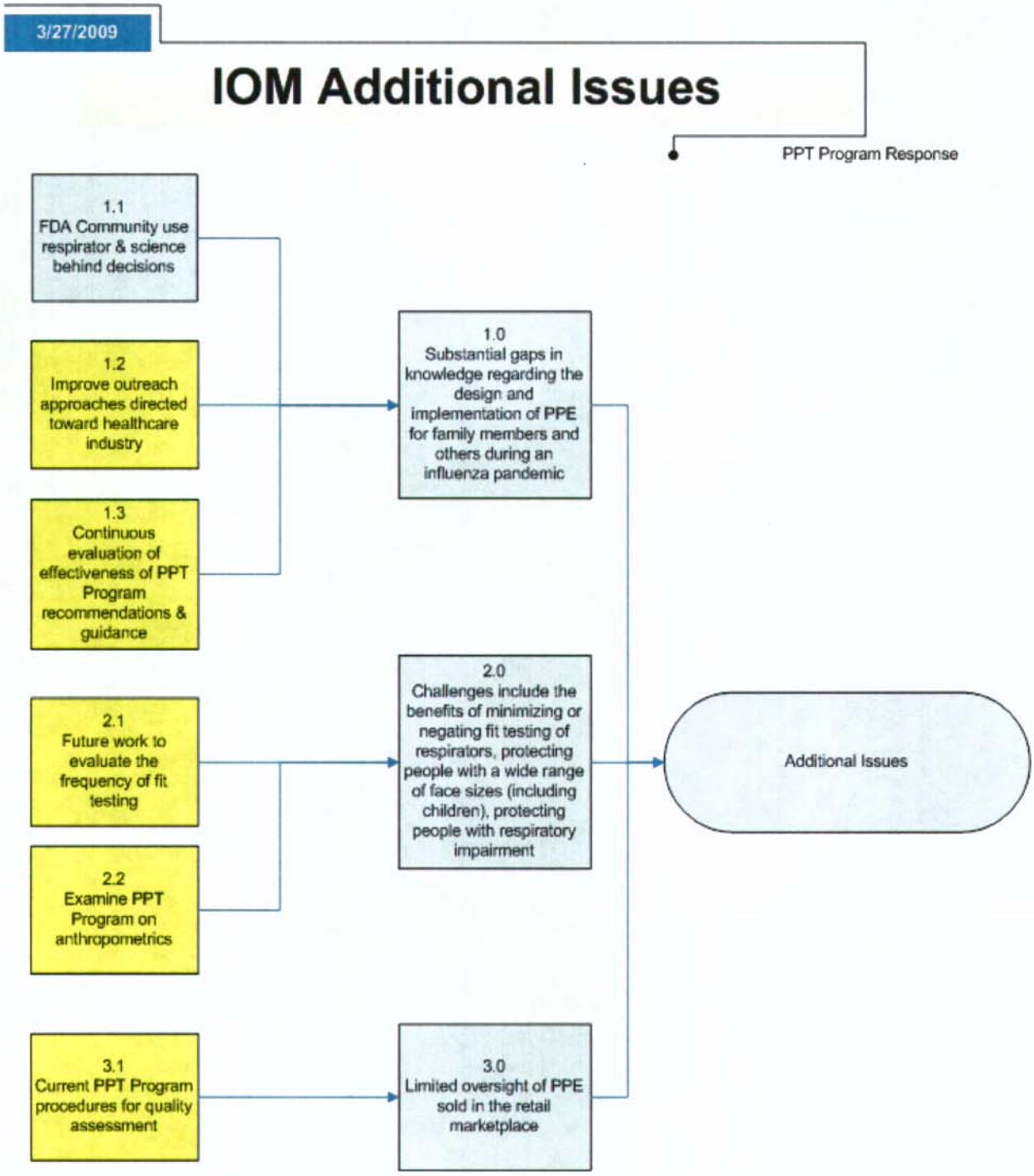
127

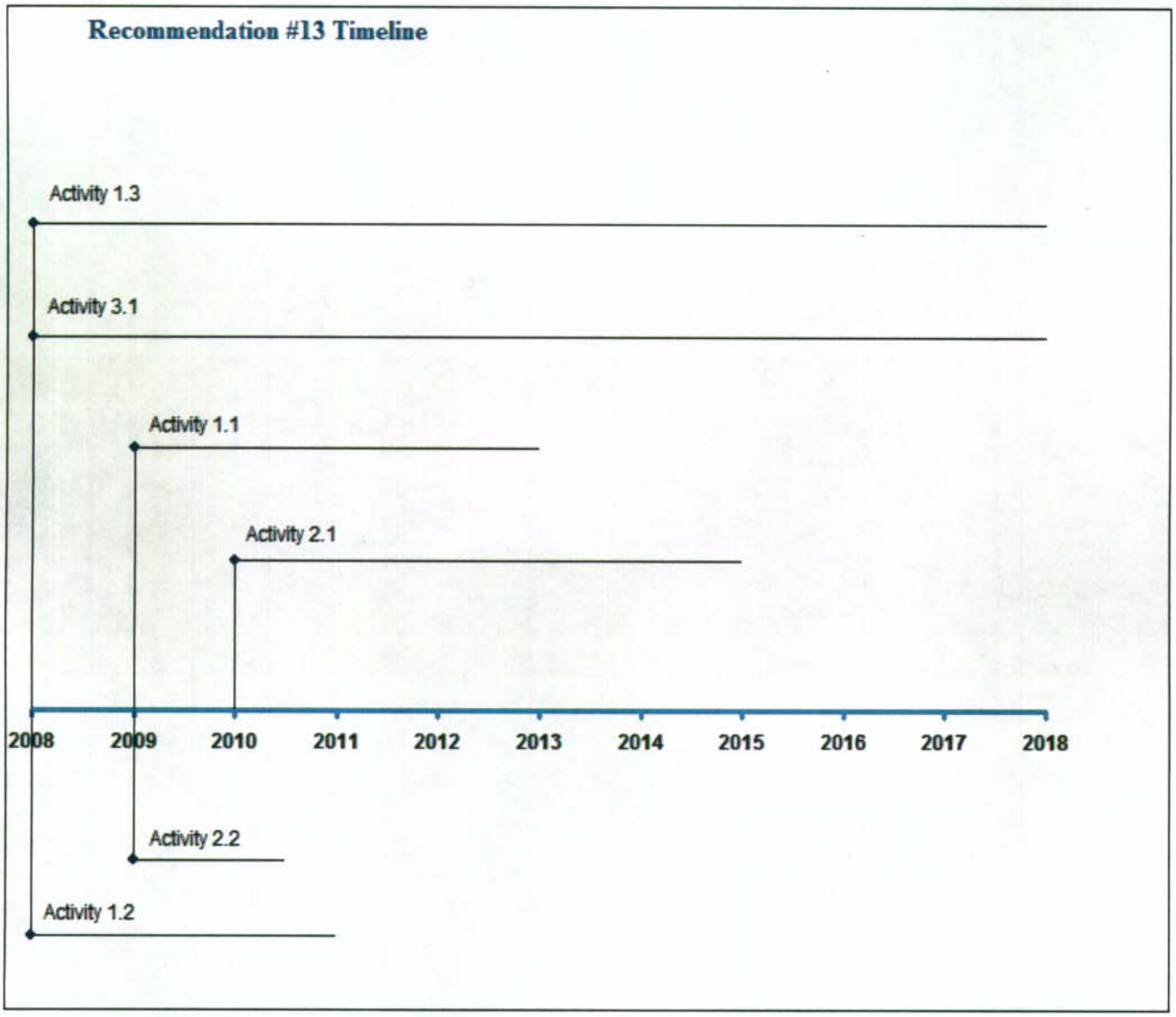
128
129 IOM Recommendation # 13: Additional issues.
130
131
132 ***PPT Program Plan in response to IOM Recommendation # 13***

Activity #	Activity/Comment
13.1	Substantial gaps in knowledge regarding the design and implementation of PPE for family members and others during an influenza pandemic.
13.1.1	Describe the FDA Community use respirator and the science behind the decisions: Reference N.
13.1.2	Improved outreach approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate PPT Program recommendations and guidance.
13.1.3	Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others. Reference O.
13.2	Challenges include the benefits of minimizing or negating fit testing of respirators, protecting people with a wide range of face sizes (including children), protecting people with respiratory impairment.
13.2.1	Describe future work to evaluate the frequency of fit testing: Reference P.
13.2.2	Examine PPT Program on anthropometrics: Reference Q.
13.3	Limited oversight of PPE sold in the retail marketplace.
13.3.1	Describe the current PPT Program procedures for quality assessment: Reference M.

133


3/27/2009
IOM Additional Issues
PPT Program Response
1.1 FDA Community use respirator & science behind decisions
1.2 Improve outreach approaches directed toward healthcare industry
1.3 Continuous evaluation of effectiveness of PPT Program recommendations & guidance
2.1 Future work to evaluate the frequency of fit testing
2.2 Examine PPT Program on anthropometrics
3.1 Current PPT Program procedures for quality assessment
1.0 Substantial gaps in knowledge regarding the design and implementation of PPE for family members and others during an influenza pandemic
2.0 Challenges include the benefits of minimizing or negating fit testing of respirators, protecting people with a wide range of face sizes (including children), protecting people with respiratory impairment
3.0 Limited oversight of PPE sold in the retail marketplace
Additional Issues

134


Recommendation #13 Timeline
Activity 1.3
Activity 3.1
Activity 1.1
Activity 2.1
2008
2009
2010
2011
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2013
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2015
2016
2017
2018
Activity 2.2
Activity 1.2

135

List of References

A. Quad chart - Reusability of Filtering Facepiece Respirators
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6PT_FY07_QC.htm

B. Quad Chart – Aerosol Generation by Cough
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/0026_FY07_QC.htm

C. Workshop on Respiratory Protection for Airborne Infectious Agents (30 Nov – 1 Dec 04)
http://www.cdc.gov/niosh/npptl/resources/pressrel/announcements/113004wkshp/questions.html

D. Commerce Business Daily – No Fit Test Respirator Workshop Nov 8, 2007
http://www.cbd-net.com/index.php/search/show/18235875

E. Quad Chart – Penetration of Nanoparticles through NIOSH-approved Respirator Filters
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z1NT_FY07_QC.htm

F. Quad Chart – Next Generation Structural Fire Fighting PPE Ensemble Project HEROES
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z4FY_FY07_QC.htm

G. Quad Chart – Industrial PAPR Module
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6JC_FY07_QC.htm

H. Quad Chart – New Sensor Technology Development and Integration for End of Service Life Indicators
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/000M_FY07_QC.htm

I. Quad Chart – Total Inward Leakage (TIL)
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/00AY_FY07_QC.htm

J. Quad Chart – Metabolic Evaluation of N95 Respirator Use with Surgical Masks
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6PV_FY07_QC.htm

K. Quad Chart – Improved Criteria for Emergency Medical Protective Clothing
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z1NR_FY07_QC.htm

L. Quad Chart – Certified Product Investigation Process (CPIP)
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/PP19_FY07_QC.htm

M. Quad Chart – Quality Assurance Module
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z4FT_FY07_QC.htm

N. U.S. FDA Respirators for Public Health Emergencies
http://www.fda.gov/consumer/updates/respirators061107.html

O. IOM Review of NIOSH Personal Protective Technology Program (PPT)
http://www.iom.edu/CMS/3740/45683.aspx

P. Quad Chart – Frequency of Fit Testing
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z1NU_FY07_QC.htm

Q. Quad Chart – Development of Computer-Aided Face-Fit Evaluation Methods
http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/PP09_FY07_QC.htm

R. NPPTL Facial Anthropometrics Research Roadmap Docket # NIOSH-111
http://www.cdc.gov/niosh/review/public/111/

S. Certified Equipment List
http://www.cdc.gov/niosh/npptl/topics/respirators/cel/

T. Whole Body Anthropometrics Research
www.cdc.gov/niosh/nas/traumainj/pdfs/TIAppendix5NAS03-07.pdf

U. Elastic Textile Solution Pilot for Prototype Masks
http://www.fbo.gov/spg/HHS/CDCP/PGOA/Reference%2DNumber%2D000HCVKD%2D2008%2D49450/SynopsisP.html

V. Personal Protective Equipment (PPE) Effectiveness Study
http://www.fbo.gov/spg/HHS/CDCP/PGOA/Reference%2DNumber%2D000HCVKD%2D2008%2D49453/SynopsisP.html

W. Respirator & Surgical Mask Efficacy from Cough Aerosols Project
See Appendix B.

Appendix B: Respirator & Surgical Mask Efficacy from Cough Aerosols

This project will be conducted in three parts: Part 1: Measure filtration performance of surgical masks and N95 respirators used in study In Part 1 of our project, all masks and respirators will be tested to determine the filtration performance of their filter media. Respirators provide protection by filtering air as it is inhaled by the wearer. The filtration performance is a measure of how well the filter media of a mask or respirator blocks the passage of particles through it. The filtration performance looks only at the filter efficiency of the mask material itself without considering any effects due to leakage through gaps in the seal between the mask and the face. For these experiments, the filtration performance will provide a common basis by which to compare the filtration abilities of the masks and respirator material, and also will provide insight as to whether particle penetration is occurring because particles are passing through the mask or respirator or are going around the mask through leaks in the face seal. Part 2: Conduct simulation experiments to evaluate exposure risk in close proximity to coughing patient The purpose of these experiments is to evaluate the potential for exposure to infectious aerosols while in close proximity to a coughing patient. These experiments are designed to simulate a "worst case" scenario by confining the cough-generated aerosol to a small space. This will allow examination of the protection offered by masks and respirators under the most challenging circumstances. These experiments will be conducted with the cough box, where the coughing head form is in one end of the box and the breathing head form in the other such that the head forms are facing each other with their mouths 2 m apart. For Part 2, an initial pilot study will be conducted using no mask, a surgical mask and an N95 respirator. After the experimental procedures have been developed and tested, a full study will be conducted using no mask, 5 types of surgical masks and 5 types of N95 respirators. Masks and respirators will be worn by the breathing head form but not by the coughing head form in order to simulate a healthcare worker exposed to an unmasked infectious patient. We will simulate a human infectious cough-generated aerosol by using a salt aerosol containing a live influenza vaccine (called FluMist) as a surrogate for the wild-type influenza virus. The amount of FluMist in collected aerosols will be measured using a quantitative PCR (qPCR) detection technique. For some experiments, fluorescein dye will be added to the aerosol fluid rather than the FluMist vaccine, and the amount of fluorescein collected will be measured using a spectrofluorometer. We anticipate that detection of the fluorescein will require collection of much larger quantities of aerosol compared to the qPCR detection of the FluMist vaccine, which will limit its use to tests with relatively high aerosol concentrations. However, the detection of fluorescein is much quicker and simpler than the qPCR technique, which makes it useful for early trials. Since the fluorescein detection and qPCR are both based on fluorescence, it may not be possible to use the two techniques at the same time. For this proposal, we will assume that sequential trials will be conducted under the same conditions for comparison. If possible, however, we will combine the two techniques. In either case, we will be able to compare the results from the fluorescein dye, the FluMist vaccine, and an optical aerosol particle counter. Part 3: Simulate exposure risk for healthcare workers in an examination room containing a coughing patient with an infectious respiratory illness The purpose of these experiments is to simulate the potential exposure of healthcare workers to an infectious aerosol generated by a coughing patient in an examination room. These experiments will be conducted using the exam room with the head forms. For the exam room, we anticipate that it will be very difficult to lower the ambient aerosol concentrations.

Appendix C: Response to NIOSH Docket 129 Comments Prepared 7-29-08.doc

1. Comment:

Name: Peter A. Langes
Organization: Berkeley Building Education Center
Email: peterlanges@yahoo.com

Address
537 Hastings Drive
Benicia, CA 94510
USA

Comments
The concern for health care workers PPE is only as good as the attitude of the technician.There is willful negligence to consider for rating the effectiveness. The SARS out break was a good example of poor worker attidue,PPE was diregarded and the results were fatal.

There exist other occupations where workers have direct contact with the public 24/7 with the same hazards in a open field environments. There is no sick leave in most construction and plumbing jobs. workers should at least know of "universal precautions"

The problem with infectious disease is the incubation period where one is exposed and the time before symptoms may or may not appear. Therefore, pandemics and epidemics and the severity can be reduced by PPE training.

It is recomended that all workers that have daily contact with the public doing route work and home services be required to have some form of PPE certtificate of training for their occupations. Since there is issue of health care costs and there is no govt health care.

The motto "prevention better than cure" by ASSE PPE is common sense in action.

Peter Langes

Response:

Dear Mr. Langes:

Thank you for your insightful comments. NIOSH is committed to reducing risk as much as possible in all occupations. As you reference, there are barriers to using PPE and the Healthcare Worker Action Plan addresses this through training and best practices in recommendations 4, 6 and 7. Additionally, state of the art equipment design can help reduce the burden on the user and will be explored in a PPT workshop being planned for November 2008.

Determining the minimum level of respiratory protection for protection against infectious aerosols is an imprecise science, based on the estimated exposure hazard level and the infectious

dose for the general worker population. Recommendations are established based on typically expected exposure and infectivity parameters. Factors such as the airborne concentration, aerodynamic size, and pathogen viability in exposure scenarios are considered in assessing the hazard level. These will be addressed in recommendation 1 with collaboration with other organizations. The ability of the normal human immune system to resist infection and illness from a pathogen is one of the factors considered in estimating the infectious dose. It would be impractical to determine the effectiveness of each individual's immunity system to resist infection by a given pathogen, or to develop recommended minimum levels of respiratory protection based on individual variations in exposure scenarios and immunity system status.

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Take a pledge to help raise awareness about young worker safety. Visit www.raiseyourhand.com

2. Comment:

Thank you for providing an opportunity to provide input regarding PPE for HCWs Action Plan - NIOSH Docket #129. The Council of Canadian Academies (CCA) formed an expert panel on influenza & personal protective respiratory equipment last year and the expert panel report was published December 2007.

As one of the panelists, I am taking this opportunity in forwarding to you for consideration the 2007 CCA report - Influenza Transmission and the Role of Personal Protective Respiratory Equipment: an Assessment of the Evidence.

What may be interest to you is that the report tackles the question of transmission of the influenza virus from a different scientific perspective, one of particle physics, respiratory tract deposition, respirator versus medical mask performance; as well, the CCA report challenges some traditional infectious control concepts such as the 3 foot rule, airborne versus droplet transmission in recognition of problems associated with medical/infection control terminology such as 'droplet nuclei', 'droplet' versus industrial hygiene terms including ballistic- / inhalable- / nasopharyngeal- / tracheobronchial- / and alveolar-sized particles. The OH&S concept of the hierarchy of controls is emphasized in consideration for the development and implemention of an effective exposure control plan.

Of interest also is that both Drs Don Low & Lisa Brosseau - contributors to the IOM report (Preparing for an Influenza Pandemic...) - were also on CCA expert panel.

<<(2007-12-19)_Influenza_PPRE_Final_Report.pdf>> <<(2007-12-19)_Report_in_Focus_-_Influenza.pdf>>

Respectfully submitted,

Response:

Dear Mr. Janssen:

Thank you for providing us with a copy of the Council of Canadian Academies 2007 CCA report - Influenza Transmission and the Role of Personal Protective Respiratory Equipment: an Assessment of the Evidence. We will certainly examine the report for the transmission of the influenza virus and the challenges of some traditional infectious control concepts as you suggested. These suggestions most aptly apply to recommendations 1 and 2.

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3. Comment:

Good Afternoon,

Thank you for the opportunity to review and provide comments on your action plan for Health Care workers. As a manufacturer of health care products, especially those geared towards protecting health care workers, your path forward in this space is extremely important to our organization. Our health care workers are trained to be selfless to the point where oftentimes they put their own health and safety at risk. It is up to us, NPPTL as a part of NIOSH and Cardinal Health as a manufacturer, to ensure that we are creating and regulating products that will provide the health care worker the highest level of protection possible. I am very excited about the focus your group is given to this industry and look forward to the future developments that will continue to unfold as a result of your focus on this industry.

To aid in your review of my comments, I will provide them based on the section of your report.

Lines 57-65: True indeed medical face masks do not provide the same level of protection as a N95, but the reality is that nine times out of ten our healthcare workers are choosing a surgical or procedure mask in lieu of an N95. They are relying on these products to provide the protection they need for the majority of the things they are exposed to. Although they are not deemed personal protective equipment by this group, they are looked at as such by the end user. I challenge this group to reconsider the position taken on medical face masks or work to change the regulations to ensure that an N95 is chosen every time a mask is needed.
Lines 508-516: I, again, challenge your group to expand your definition of PPT to include medical face masks. If they aren't providing the protection today that warrants their inclusion in that category then we need to create new product requirements that translate into their being included into PPT and manufacturers need to adjust accordingly.

Lines 555-559: The standard test methods used to clear medical face masks still warrant an assessment by your group. Especially, to audit whether or not they speak to actual in use performance.

Humbly Submitted,

Response:

Dear Ms. Jones:

Thank you for your comments and interest in the action plan. NIOSH is committed to reducing risk as much as possible in all occupations. As you said HCW are selfless to the point where oftentimes they put their own health and safety at risk and the Healthcare Worker Action Plan addresses this through training and best practices. These issues are addressed in recommendations 6 and 7. Additionally, state of the art equipment design can help reduce the burden on the user and will be explored in a PPT workshop being planned for November 2008.

Another concern you raised is with medical face masks and that NIOSH doesn't consider them PPE and the fact that most HCWs use them in lieu of an N95. We plan to work with the FDA who currently oversees medical masks and focus on ways to develop sound scientific evidence from which to harmonize standards. Recommendations 2, 9 and 12 address these concerns. Our research shows HCW don't use N95's because of barriers such as comfort and physiological burden. These are being explored in some of our research activities. In one research project, physiological burden is being explored by investigating the effects on inhaled carbon dioxide, inhaled oxygen, and inhalation/exhalation pressures from the Automatic Breathing Machine Simulator with the treatment of N95 particulate filtering respirators, with and without surgical masks and under light, medium and heavy work rates (see http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6PV_FY07_QC.htm). An article entitled "Effect on breathing resistance of a surgical mask worn over an N95 filtering facepiece respirator" is currently in press at The Journal of the International Society for Respiratory Protection. Finally, NIOSH recently partnered with the Veterans Health Administration to initiate Project BREATHE (Better Respiratory Equipment using Advanced Technologies for Healthcare Employees). This project seeks to determine the ideal characteristics that would be required for healthcare worker specific respirator.

Bill Kojola
Industrial Hygienist
AFL-CIO
202-637-5003
202-508-6978 (Fax)
bkojola@aflcio.org

4. Comment:

Dear NIOSH:

Attached are the comments we're submitting on the "Draft Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan", Docket No. 129.

Regards,

Response:

Dear Mr. Kojola:

Thank you for your very valuable comments and interest in our action plan. You bring up some important concerns that we need to address:

1) Your comment about adding sneezing and talking to the "cough" simulation research has been brought to the attention of the project officer and if possible will be added to the study.

2) Critically examine the aerosol particle exposure 3 foot vs 6 foot rule. Mr. Janssen (comment 2) provided us with a copy of the Council of Canadian Academies 2007 CCA report - Influenza Transmission and the Role of Personal Protective Respiratory Equipment: an Assessment of the Evidence. We will certainly examine the report for the transmission of the influenza virus and the challenges of some traditional infectious control concepts as you suggested and incorporate them into recommendations 1 and 5.

3) Prioritize the planning and carrying out of an effectiveness assessment of antimicrobial respirator technology. This is the goal of the action plan to provide NIOSH with a strategy and road map in which to proceed. We realize that this is an important research and that it needs to be done and will eliminate 'possible' project from the action plan. This change will be reflected in recommendation 5.

4) Develop a comprehensive research plan with the overall objective of developing some measure of an "assigned protection factor" for respirators used to protect wearers against airborne infectious agents. NIOSH is focusing on ways to develop sound scientific evidence from which to harmonize PPE standards that includes the following: protecting the health and safety of respirator users, providing an assurance to the user that the equipment will afford the degree of protection required, and considering the person who is being required to wear the

protective device to accomplish their job. These concerns are being addressed in recommendations 2, 5 and 7.

5) Complete as soon as possible the total inward leakage (TIL) certification requirements for respirators. Currently, TIL has made its way out of NIOSH and down to HHS to start the rulemaking process.

6) Assess economics and level of fit/protection of elastomeric respirators (equipped with particulate filters) versus filtering facepiece respirators for use by healthcare workers who provide care for pandemic flu patients. We currently have a study underway to examine fit (see http://www.cdc.gov/niosh/blog/nsb042108_respiratorfit.html). The study deals mostly with N95FFR types of respirators; however, we plan on doing a small study with elastomeric as well. This is being done in recommendation 5.

7) Collaborate with other divisions in NIOSH to examine the wide range of options for controlling worker exposure to pandemic influenza and other infectious agents. We are working with Emergency Planning and Response Office (EPRO) in providing up-to-date information on pandemic influenza research that can be accessed via the web (http://www.pandemicflu.gov/). This process has started and is defined in recommendation 1.

8) Conduct research to determine the maximum use time for filtering facepiece respirators. At this time, NIOSH has no ongoing or planned research on maximum use times of FFRs. NIOSH realizes that this is an important research topic and recommendation 5 in the action plan allows for its inclusion.

9) Develop a health care PAPR. While NIOSH is not in the business of developing equipment, the PPT Program has a project (http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6JC_FY07_QC.htm) on new PAPR certification provisions that would allow approval of 3 classes of PAPR with flow rates applicable to low, medium and high work rates. Incorporating sensors into PPE to detect breaches and notify users of end of service life and other protection information. This is part of the response for recommendation 4. This project will prepare a new PAPR subpart for 42 CFR 84 that incorporates all PAPR requirements (including CBRN) into one area. This effort will result in significant improvement in PAPR requirements and the first formal incorporation of CBRN requirements into the regulations and allow for the development of a healthcare PAPR.

10) Initiate, coordinate, and catalyze the work of other segments of NIOSH outside of NPPTL and other federal government agencies around this action plan. The PPT Program has established a work group within NIOSH to identify areas of overlap to confront potential misconceptions in terms of NIOSH capabilities, identify what non-NIOSH entities should/can do, and discuss what's possible in the future (see recommendation 1). After we identify our capabilities, we will proceed to bring in other organizations and establish lines of communication to keep abreast of on going and plan research in the PPT area.

11) Develop mechanisms for involvement of health care workers and their unions in the aspects of this research plan where it will obviously be of significant benefit to outcomes. As we

move forward with this action plan, we will continue our outreach efforts to involve and solicit information from the healthcare community through public meetings, focus group forums and conferences. These are being carried out in recommendations 6, 7 and 8.

12) We found the organization of this document hard to read and at times repetitious. The document was repetitious to show the overlap and interconnectivity of the recommendations and that you just can't look at a recommendation by itself. We will look at ways to better organize and present the information in the revised plan.

Valerie Jones, RN, BS, CIC
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St. Joseph's Medical Center
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val.jones@sjmcmn.org

5. Comment:

Please be very sure that there is evidence-based rationale for the use of PPE during a pan flu outbreak. Please carefully consider the full impact of the fit test requirement for respirators to be sure that there is scientific evidence that fit testing does, indeed, help prevent disease transmission.

Response:

Dear Ms. Jones:

Thank you for comments and interest in the HCW action plan. It is always important for PPE users to use PPE appropriate for the hazards to which they are exposed in accordance with published guidance, recommendations, and regulations. Under the Action Plan, NIOSH plans on establishing measures to assess and compare the effectiveness of PPE (recommendation 5), as well as, focusing on ways to develop sound scientific evidence from which to harmonize PPE standards (recommendation 2).

Lisa Tomlinson
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6. Comment:

Comments from APIC President, Janet Frain, are attached.

Response:

Dear Ms. Tomlinson:

Thank you for your thoughtful comments and your offer to work with NIOSH on this action plan. You bring up some important points that we should consider:

1) You said, "We greatly appreciate NIOSH's efforts to be comprehensive, but also believe the need to respond to a possible epidemic in the near-term necessitates interim recommendations." NIOSH agrees that interim best practices should be made available basic on knowledge know now and then updated as this action plan is carried out (recommendation 7). The action plan has both short and long range goals and it was never intended that recommendations wouldn't be disseminated as they became known.

2) You said, "We believe that the exclusion of 'medical masks' in this plan does not address the realities of how influenza virus is transmitted and the potential shortage of certified particulate respirators (PR)." The action plan only states that medical masks are not considered PPE. Medical masks can still part of a 'source control' effort for some people during a pandemic; however since medical masks don't provide to a very good face seal, healthcare workers should opt for N95FFR at a minimum. NIOSH has on going research into N95FFR decontamination and the effects of using a medical mask over a N95FFR (see recommendation 5).

3) You said, "Additionally, we believe research designed to access the viability of virus on respirators using a proxy should indicate whether or not the virus has survival properties after surface impaction." This is a very good observation and NIOSH will clarify the study results to indict what is being measured.

4) You said, "If research studies to define risk levels for influenza during workplace activities in various locations are outside the scope of NIOSH research, it would be helpful to indict if such studies are being done." The PPT Program has established a work group within NIOSH to identify areas of overlap to confront potential misconceptions in terms of NIOSH capabilities, identify what non-NIOSH entities should/can do, and discuss what's possible in the

future (recommendation 1). We also plan on establishing lines of communication with other organizations to keep abreast of on going and plan research in the PPT area.

5) You said, "We believe NIOSH should engage with industry on the issue of certification of 'out of the box' PRs." The NIOSH National Personal Protective Technology Laboratory and the University of Minnesota, School of Public Health, are hosting a "No Fit Test" Respirator Workshop to be held November 6, 2008 in Pittsburgh, PA to address some of the issues you raise (recommendation 1 and 5). The workshop will focus on the nature and process of product innovation and development in negative pressure half-face piece respirators, to gauge the current "state-of-the-art," and to stimulate new designs and approaches for improved respirator fit. The results of the workshop will lead to a better understanding of how future NIOSH research can encourage ongoing development of better fitting respirators without compromising long-term protection.

6) You said, "In addition, we applaud NIOSH research into the 'sterilization efficacy of a decontamination procedure for filter media and filtering facepiece respirators' as a needed area of research." We appreciate for vote of confidence for our work in this area.

7) You said, "While we appreciate the importance of NIOSH efforts to identify risks related to respirator use, we also believe that a greater focus on important measures to prevent the transmission of influenza and other infectious diseases is imperative." The IOM report, which this action plan is based, identifies recommendations for research and policy actions in three critical areas: 1) Understanding influenza transmission, 2) Commit to worker safety and appropriate use of PPE, and 3) Innovate and strengthen PPE design, testing and certification.

These recommendations, while written to address issues related to pandemic influenza preparedness identify initiatives necessary to determine the efficacy of PPE in preventing the transmission of a variety of infectious diseases. The IOM recommendations in these critical areas are extensive, requiring the involvement of numerous federal agencies, the private sector and international partners (recommendation 1). The report recommends the Department of Health and Human Services (HHS) lead a focused research effort to facilitate understanding of the transmission and prevention of seasonal and pandemic influenza. The National Institute for Occupational Safety and Health (NIOSH) is charged with assisting in this effort as it relates to understanding transmission among healthcare workers, and conducting research to design and promote the appropriate use of PPE (recommendation 1, 5, 6 and 7).

8) You said, "The NIOSH proposal for 'active surveillance of healthcare facilities that would assemble information relevant to a number of issues pertinent to the spread and preventive practices of influenza', which would include collecting information on 'use of respirators, infection control practices, rates of infection, and infection patterns that may distinguish different types of healthcare workers', would be very time-consuming and costly." True, surveillance is a costly and time consuming business; but in order to effectively manage and direct the PPT Program NIOSH needs a better PPE surveillance program to identify priorities, trends and emerging issues associated with the use of PPE in the workplace. Information gathered will be used to establish a baseline on PPE usage, develop performance measures, sharpen the focus of

NIOSH research, and aid in the development of a more effective and active dissemination program (recommendations 1 and 7).

9) You said, "Additionally, recommendations relative to personal protective equipment should underscore for HCWs the importance of understanding the 'chain of infection' and portals of entry into the body." Chain of infection is a very import topic and NIOSH in no way wants to disseminate information that is in conflict with well established infection prevention training in the healthcare setting. It is our goal to establish clear hierarchal recommendations (discussed in 6 and 7) relative to PPE to be worn for specific tasks.

Kirk Bantz, RHSO

7. Comment:

Thank you for this effort; this article addresses many key points centered on HCW PPE in case of pandemic events.

In my experience some exposure often happens before PPE is deployed when there is an outbreak. This happens because the HCW is the first receiver of the first stricken by illness. Depending on the organism (and your research findings) their training may have been eclipsed by newer information. It is my hope that, rather than preemptive training of hundreds of thousands of HCW's with less than current information, the scope of this effort could include just-in-time training recommendations for HCW's PPE. Current and up-to-date training is key to appropriate use of PPE. If this were to be included as an integral part of the design process, the resulting use of PPE may be much more effective in protecting the HCW. Incorporation of the required training into the PPE design process (as with the other performance based criteria) would enhance HCW protection and help to set a standard for training in case of pandemic events.

Respectfully,

Response:

Dear Mr. Bantz:

Thank you for your comments and interest in the HCW action plan. It is always important for PPE users to use PPE appropriate for the hazards to which they are exposed in accordance with published guidance, recommendations, and regulations. Under the Action Plan, NIOSH plans on establishing measures to assess and compare the effectiveness of PPE (recommendation 5), as well as, focusing on ways to develop sound scientific evidence from which to harmonize PPE standards (recommendation 2). NIOSH is committed to reducing risk as much as possible in all occupations. The Healthcare Worker Action Plan addresses this through up-to-date training and best practices (recommendations 7 and 8).

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moynai@trinity-health.org

IRMS http://content.trinity-health.org/irms/

8. Comment:

Good morning,

The article addresses some key points and I am glad you are looking into HCW PPE in case of pandemic events. The article does not seem to recognize the reality that for HCW's exposure often happens before PPE deploys and their periodic training becomes obsolete with newer information. Rather than prophylactic training hundreds of thousands of HCW's who may seldom, if ever, use PPE in a pandemic event, the scope of this effort could better include just-in-time training recommendations for HCW's PPE.

Training is the key component to appropriate use of PPE and we must include it as an integral part of the design process to be most effective. In this way the training (and associated compliance) is appropriate for the PPE. I believe incorporation of necessary training into the PPE design process, in addition to the other performance based criteria, will enhance compliance while setting a standard that HCW can easily comply with while conserving training resources.

Response:

Dear Mr. Moyna:

Thank you for your comments. NIOSH agrees that training is a key component to appropriate use of PPE and we must include it as an integral part of the design process to be most effective (recommendation 2).

Janice Comer Bradley, CSP
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International Safety Equipment Association-ISEA
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9. Comment:

Attached please find ISEA comments to the NIOSH Docket Number NIOSH-129.

Response:

Dear Ms. Comer Bradley:

Thank you for your informative comments and interest in this action plan. You bring up some important points that we should clarify:

1) General comment 1 – Prioritization within the Action Plan

Prioritize activities in response to recommendations within the PPT Program domain is one of the main action items we identified to achieve this action plan. Thank you for your suggestions as to the key recommendations to assure resources are available.

As for recommendation #3, NIOSH doesn't plan to reinvent the wheel and will certainly look into what is already being done in industry and incorporate it into this plan.

2) General comment 2 – Scope and Ambition of the Action Plan

Yes, this is a very ambitious action plan and can't be implemented in full without more money and personnel. The NIOSH PPT Program has leveraged its budget quite successfully for respirators and plans on continuing and improving service in this area.

3) General comment 3 – Different Certification Programs for Different Market Sectors

This report was written in response to the Institute of Medicine (IOM) examining issues regarding PPE for healthcare workers in the event of pandemic influenza. If and when this plan is implemented NIOSH will continue to serve all sectors that use PPE.

4) Request clarification on item on Page 3, line 96. Does it refer to wearer comfort in high humidity environments, or the efficacy of the filtration system in these environments? This was a general question that showed up in several recommendations. It deals mostly with comfort and fit of the respirator in humid environments, as well as, the efficacy of the filter media.

5) These issues Section 2.2 (Page 18, line 682) are addressed by currently available respirators. The respirator program manager or person doing the selection must take these issues into account when selecting appropriate PPE. Recommendation #2 deals with defining a set of evidence-based performance requirements or prescriptive standards for PPE to facilitate their design and

development that optimally balances the cost, comfort, and degree of protection of PPE and enhances the compliance with their use in the field. The line that you referred to only was describing what was meant by 'Usability'.

6) The clause in Section 2.2.2.1.1 (Page 18, line 705), along with several others throughout the document, suggest an expansion of the scope of NIOSH activities … Yes, that is correct. The NIOSH PPT Program is looking to expand and is seeking your comments as to how to proceed.

7) Respirators (Page 19, line 751) are design to last for long work days (12- 16 hours) typical in some heavy manufacturing industries… While that is true, the study on page 19 is looking at N95FFR that would be used in an emergency such as a pandemic and available from the strategic stockpile. Data is still needed for these types of respirators.

8) Heavy manufacturing usage requires more durability (Page 20, line 774) than health care usage… See response to item #5 above.

9) PPE manufacturers fully understand product costs and are continually searching to reduce costs … NIOSH agrees but see response to item #5 above.

10) Page 24, line 892 this is a valuable program for resident physicians, and we recommend it be expand to include comprehensive training in the nature, selection, use and maintenance of respiratory devices in addition to proper fit testing… Thank you for you support of this program. NIOSH is examining ways to improve and expand this program (recommendation 2).

11) Page 28, line 925 this activity regarding identifying technologies to improve fit should be a lower priority in the Plan… Yes, the best policy now is to assure adequate respiratory protection is in place and that the program is complete and effective. But in order to move forward and plan for the future, NIOSH needs to be looking at new technologies now to start the internal processes as stated in recommendations 1 and 4.

12) We request clarification of (Page 28, line 953) the intent and scope of this question, as there are currently non-disposable respirators (ie eleatomeric respirators) available that can be decontaminated… This mainly deals with decontamination of N95FFRs. Again, this is specific to if a pandemic were to occur and one may have to use a respirator more than what was originally intended.

13) The user seal check (Page 29, line 958) is important, as it requires the user to evaluate fit in a subjective way every time he dons the respirator… Thank you for your comment and we have made a note about the user seal check cannot be a substituted for formal fit testing.

14) We are concerned that this statement (Page 29, line 971) implies that medical devices would be considered accessories to the respirator in the respirator certification process… At this time, NIOSH doesn't plan on approving medical devices. This was meant more to stimulate research on better ways to improve communications between HCW and patients, etc. Thus, we are looking at new designs and engineering efforts in recommendation 4.

15) We disagree with the broad statement (Page 29, line 989). There are devices currently on the market that have been designed with healthcare sector specifically in mind… This dealt with the PAPR specifically and how there is a need to have a low flow class. We will clarify this in the next write up.

16) Request clarification on colorimetric and innovative indicator as we don't know the meaning of these two items. The descriptions of these two items were unintentionally left out and will be added in the next revision. Thank you for catching this. Colorimetric and innovative indicator refers to chemical reaction-based indicators that are used to produce reactions to individual, or classes of compounds. The reactions, such as visible color changes or other easily noted indications, are used to detect and give the PPE wearer a visual indication of exposure.

17) NIOSH should evaluate breathing resistance of N100 respirator against that of the N95 respirator covered with a surgical mask… Thanks for the suggestion. One of the reasons we are looking at the N95s is because they are in the strategic stockpile, but your comment about N100 not creating physiological effects for users based on your experience is valuable (recommendations 4 and 5).

18) We disagree with this proposal (Page 53, line 1448) regarding incorporation of pre-market field testing in NIOSH certification for respirators. This was just a suggestion and at this time NIOSH has no plans to do pre-testing of respirators. Thanks for you comment.

19) We object to this proposal (Page 53, line1461 certification for other PPE) for PPE currently addressed by consensus standards… There is a strong push to look into certifying other types of PPE. It is an issue that we need to address more fully as discussed in recommendation 2.

20) ISEA supports Workplace effectiveness studies which determine the effectiveness of respiratory protection for protection against micro-organisms… Thanks for your comment and we agree that reliable methods need to be developed for measuring concentrations and viability of micro-organisms inside and outside the respirator.

874 Mr. Borwegen
875
876 10. Comment:

Please docket

SEIU
Stronger Together

May 27, 2008

NIOSH Docket No. 129
NIOSH Mailstop C-34
Robert A. Taft Laboratory
4676 Columbia Parkway
Cincinnati, OH 45226

Re: Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan, Docket No. 129

Dear Sir or Madam:

The Service Employees International Union (SEIU) appreciates the opportunity to provide comments to NIOSH on its draft document, Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan. We're very pleased that NIOSH is preparing this research action plan in response to the Institute of Medicine's (IOM) report, *Preparing for An Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*. The IOM's findings and recommendations for additional research on understanding influenza transmission, the need improve the use of PPE and create a culture of safety in the healthcare industry, and strengthening PPE design and testing are critically important for advancing the protections that healthcare workers will need from PPE when the pandemic occurs.

Our nation's ability to respond effectively in providing care for patients with pandemic flu rests squarely on our ability to protect the health and safety of health care workers responsible for giving that care. While PPE will play a substantial part in the effort to protect health care workers, the full hierarchy of controls will need to be implemented, first, engineering approaches (such as isolation rooms and UV lights) and secondly, applying administrative measures (such as minimizing the number of workers in an infected patients room). PPE will represent the last, and least effective, element of the exposure control hierarchy. Given the IOM's concern about the general lack of a safety culture in this industry, we believe NIOSH should clearly place this PPE research action plan within a larger plan to examine the current status of prevention efforts in this industry and provide recommendations for the entire hierarchy of controls. NIOSH has done excellent work on such reports on various industries in the past and these have been very useful in improving health and safety conditions.

ANDREW L. STERN
International President

ANNA BURGER
International Secretary-Treasurer

MARY KAY HENRY
Executive Vice President

GERRY HUDSON
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877

Response:

Dear Mr. Borwegen:

Thank you for your informative comments and interest in this action plan. Our response to your suggestions follows:

1) Your comment about adding sneezing and talking to the "cough" simulation research has been brought to the attention of the project officer and if possible will be added to the study.

2) Critically examine the aerosol particle exposure 3 foot vs 6 foot rule. Mr. Janssen (comment 2) provided us with a copy of the Council of Canadian Academies 2007 CCA report - Influenza Transmission and the Role of Personal Protective Respiratory Equipment: an Assessment of the Evidence. We will certainly examine the report for the transmission of the influenza virus and the challenges of some traditional infectious control concepts as you suggested and incorporate them into recommendations 1 and 5.

3) Prioritize the planning and carrying out of an effectiveness assessment of antimicrobial respirator technology. This is the goal of the action plan to provide NIOSH with a strategy and road map in which to proceed. We realize that this is an important research and that it needs to be done and will eliminate 'possible' project from the action plan. This change will be reflected in recommendation 5.

4) Develop a comprehensive research plan with the overall objective of developing some measure of an "assigned protection factor" for respirators used to protect wearers against airborne infectious agents. NIOSH is focusing on ways to develop sound scientific evidence from which to harmonize PPE standards that includes the following: protecting the health and safety of respirator users, providing an assurance to the user that the equipment will afford the degree of protection required, and considering the person who is being required to wear the protective device to accomplish their job. These concerns are being addressed in recommendations 2, 5 and 7.

5) Complete as soon as possible the total inward leakage (TIL) certification requirements for respirators. Currently, TIL has made its way out of NIOSH and down to HHS to start the rulemaking process.

6) Assess economics and level of fit/protection of elastomeric respirators (equipped with particulate filters) versus filtering facepiece respirators for use by healthcare workers who provide care for pandemic flu patients. We currently have a study underway to examine fit (see http://www.cdc.gov/niosh/blog/nsb042108_respiratorfit.html). The study deals mostly with N95FFR types of respirators; however, we plan on doing a small study with elastomeric as well. This is being done in recommendation 5.

7) Collaborate with other divisions in NIOSH to examine the wide range of options for controlling worker exposure to pandemic influenza and other infectious agents. We are working with Emergency Planning and Response Office (EPRO) in providing up-to-date information on

pandemic influenza research that can be accessed via the web (http://www.pandemicflu.gov/). This process has started and is defined in recommendation 1.

8) Conduct research to determine the maximum use time for filtering facepiece respirators. At this time, NIOSH has no ongoing or planned research on maximum use times FFR's. NIOSH realizes that this is an important research topic and recommendation 5 in the action plan allows for its inclusion.

9) Develop a health care PAPR. While NIOSH is not in the business of developing equipment, the PPT Program has a project (http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6JC_FY07_QC.htm) on new PAPR certification provisions that would allow approval of 3 classes of PAPR with flow rates applicable to low, medium and high work rates. Incorporating sensors into PPE to detect breaches and notify users of end of service life and other protection information. This is part of the response for recommendation 4. This project will prepare a new PAPR subpart for 42 CFR 84 that incorporates all PAPR requirements (including CBRN) into one area. This effort will result in significant improvement in PAPR requirements and the first formal incorporation of CBRN requirements into the regulations and allow for the development of a healthcare PAPR.

10) Initiate, coordinate, and catalyze the work of other segments of NIOSH outside of NPPTL and other federal government agencies around this action plan. The PPT Program has established a work group within NIOSH to identify areas of overlap to confront potential misconceptions in terms of NIOSH capabilities, identify what non-NIOSH entities should/can do, and discuss what's possible in the future (see recommendation 1). After we identify our capabilities, we will proceed to bring in other organizations and establish lines of communication to keep abreast of on going and plan research in the PPT area.

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12) We found the organization of this document hard to read and at times repetitious. The document was repetitious to show the overlap and interconnectivity of the recommendations and that you just can't look at a recommendation by itself. We will look at ways to better organize and present the information in the revised plan.

Nancy J. Olins, MA
Policy and Strategic Initiatives Manager
Society for Healthcare Epidemiology of America (SHEA)
1300 Wilson Blvd., Suite 300
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nolins@shea-online.org

11. Comment:

Attached please find The Society for Healthcare Epidemiology of America (SHEA) comments on Personal Protective Equipment (PPE) for Healthcare Workers Action Plan Docket #129. Thank you for the opportunity to comment.

Response:

Dear Ms. Olins:

Thank you for your informative comments and interest in this action plan. Our response to your suggestions follows:

1) You are concerned that the report assumes that NIOSH certified respirators should remain the minimal standard for respiratory protection during and influenza pandemic…
Determining the minimum level of respiratory protection for protection against infectious aerosols is an imprecise science, based on the estimated exposure hazard level and the infectious dose for the general worker population. Recommendations are established based on typically expected exposure and infectivity parameters. Factors such as the airborne concentration, aerodynamic size, and pathogen viability in exposure scenarios are considered in assessing the hazard level. The ability of the normal human immune system to resist infection and illness from a pathogen is one of the factors considered in estimating the infectious dose. These type of topics are covered in recommendation 1. Our research shows HCW don't use N95's because of barriers such as comfort and physiological burden. These are being explored in some of our research activities (recommendation 5). In one research project, physiological burden is being explored by investigating the effects on inhaled carbon dioxide, inhaled oxygen, and inhalation/exhalation pressures from the Automatic Breathing Machine Simulator with the treatment of N95 particulate filtering respirators, with and without surgical masks and under light, medium and heavy work rates (see http://www.cdc.gov/niosh/nas/ppt/QUADCharts07/Z6PV_FY07_QC.htm). An article entitled "Effect on breathing resistance of a surgical mask worn over an N95 filtering facepiece respirator" is currently in press at The Journal of the International Society for Respiratory Protection. Finally, NIOSH recently partnered with the Veterans Health Administration to initiate Project BREATHE (Better Respiratory Equipment using Advanced Technologies for Healthcare Employees). This project seeks to determine the ideal characteristics that would be required for healthcare worker specific respirator. Also, NIOSH is researching the sterilization efficacy of a decontamination procedure for filter media and filtering facepiece respirators (recommendation 2).

2) You acknowledge the joint responsibilities of NIOSH and the FDA in certifying the manufacture and use of both masks and respirators. You note that the FDA has previously approved N95 type respirators for public use during an influenza pandemic without regard to the need for prior fit-testing. You want NIOSH to review the successful practice in Europe of certifying respirators for both filtration capability and facial fit without the need for fit-testing… We plan to work with the FDA who currently oversees medical masks and focus on ways to develop sound scientific evidence from which to harmonize standards. Recommendations 2, 9 and 12 address these concerns. The NIOSH National Personal Protective Technology Laboratory and the University of Minnesota, School of Public Health, are hosting a "No Fit Test" Respirator Workshop to be held November 6, 2008 in Pittsburgh, PA to address some of the issues you raise. The workshop will focus on the nature and process of product innovation and development in negative pressure half-face piece respirators, to gauge the current "state-of-the-art," and to stimulate new designs and approaches for improved respirator fit. The results of the workshop will lead to a better understanding of how future NIOSH research can encourage ongoing development of better fitting respirators without compromising long-term protection (recommendations 4 and 5).

3) You are pleased that NIOSH/NPPTL did not limit their response to the IOM report to respiratory protection. You agree that a comprehensive review of PPE in healthcare settings is overdue including PPE utilized during both routine and emergency circumstances… It is always important for PPE users to use PPE appropriate for the hazards to which they are exposed in accordance with published guidance, recommendations, and regulations. Under the Action Plan, NIOSH plans on establishing measures to assess and compare the effectiveness of PPE (recommendation 5), as well as, focusing on ways to develop sound scientific evidence from which to harmonize PPE standards (recommendation 2). Also, NIOSH is building a surveillance program to identify priorities, trends and emerging issues associated with the use of PPE in the workplace. Information gathered will be used to establish a baseline on PPE usage, develop performance measures, sharpen the focus of NIOSH research, and aid in the development of a more effective and active dissemination program (recommendation 1). As you reference, there are barriers (like unpredictable contacts between patients and HCW, the need for unimpeded communications and financial stress on the healthcare industry) to using PPE and the Healthcare Worker Action Plan addresses this through training and best practices (recommendations 7 and 8).

Appendix D: List of Acronyms

A	
ABMS	Automated Breathing and Metabolic Simulator
AFRL	Air Force Research Lab (Wright-Patterson AFB)
AHRQ	Agency for Healthcare Research and Quality
ANSI	American National Standards Institute
AOHP	Association of Occupational Health Professionals
AORN	Association of periOperative Registered Nurses
ASTM	American Society for Testing and Materials International
B	
BREATHE	Better Respirator Equipment and Technology for Healthcare Employees
BSC	Board of Scientific Counselors
C	
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CO_2	Carbon Dioxide
COPPE	Committee on Personal Protective Equipment
CPC	Chemical Protective Clothing
CPIP	Certified Product Investigation Process
D	
DART	Division of Applied Research and Technology
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DoD	Department of Defense
DRDS	Division of Respiratory Disease Studies (NIOSH)
DSHEFS	Division of Surveillance, Hazard Evaluations and Field Studies (NIOSH)
E	
EMS	emergency medical services
EPA	Environmental Protection Agency
ESLI	End of Service Life Indicator
EUAE	Emergency Use Authorization Equipment
F	
FDA	U.S. Food and Drug Administration
FFR	filtering facepiece respirator
FY	fiscal year
G	
H	
HCW	Healthcare Worker
HELD	Health Effects Laboratory Division/NIOSH
HEROES	Homeland Emergency Response Operational and Equipment Systems
HHS	Health and Human Services
I	
IOM	Institute of Medicine
IP	Implementation Plan
ISEA	International Safety Equipment Association

ISO	International Organization for Standardization
J	
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
K	
K	Thousand
L	
M	
N	
NA	the National Academies
NCPDCID	National Center for Preparedness Detection and Control of Infectious Diseases
NFPA	National Fire Protection Association
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institute of Health
NIOSH	National Institute for Occupational Safety and Health
NORA	National Occupational Research Agenda
NPPTL	National Personal Protective Technology Laboratory
O	
O2	Oxygen
OD	Office of the Director
OEP	Office of Extramural Programs
OSHA	Occupational Safety and Health Administration (DOL)
OSI	Office of Strategy and Innovation
P	
PAPR	powered air-purifying respirator
PCR	Polymerase Chain Reaction
PPE	personal protective equipment
PPT	personal protective technology
Q	
QA	Quality Assurance
R	
RFP	Request for Proposals
RNA	Ribonucleic Acid
S	
SARS	Severe Acute Respiratory Syndrome
SCBA	self-contained breathing apparatus
SDO	Standards Development Organizations
T	
TIL	total inward leakage
TSWG	Technical Support Working Group
U	
USAID	U.S. Agency for International Development
USDA	U.S. Department of Agriculture
V	

VA	U.S. Department of Veterans Affairs / Veterans Health Administration

W

WHO	World Health Organization

Y

Z