Draft Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan

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 COPPE determined that there is an urgent need to address the lack of preparedness regarding effective PPE for use in an influenza pandemic. Subsequently, the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH) asked the Institute of Medicine (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 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 maintain the patient's respiration following endotracheal intubation. 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 relevant sizes of aerosols?
- What is the infectivity of aerosols?
- Is high humidity an issue with wearing respirators?
- How does air flow exchange and ventilation affect transmission?
- and 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 weblinks 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 Healthcare Workers (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 Department of Health and Human Services (DHHS), in collaboration with U.S. and global partners through the World Health Organization, 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. 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, the Department of Defense, manufacturers, and other relevant organizations and agencies should fund research directed at the design and development of the next generation of respirators, gowns, gloves, and eye protection for healthcare workers that would enhance their safety and comfort.
  - 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.

- 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.
- IOM Recommendation #10: Strengthen pre-market testing of PPE for healthcare workers. FDA, NIOSH, and other relevant agencies and organizations should strengthen pre-market testing requirements for healthcare PPE by requiring field testing of PPE prior to approval and by reevaluating the FDA medical device classification for healthcare PPE. Testing requirements should use rigorous standards while also providing expeditious review of innovative approaches.
- IOM Recommendation #11: Strengthen post-market evaluation of PPE for healthcare workers. NIOSH, FDA, and other relevant agencies and organizations should support and strengthen adverse event reporting and post-market evaluation studies and surveillance regarding the effectiveness of PPE used by healthcare workers.
- 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.

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

- Substantial gaps in knowledge regarding the design and implementation of PPE for family members and others during an influenza pandemic
- 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.
- Limited oversight of PPE sold in the retail marketplace.

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 weblinks 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.**
- 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
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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 – April 2008)
- Revise action plan based on comments received (May 2008)
- Propose new projects as part of PPT Program strategic planning for FY09 and beyond (June 2008)
- Revise action plan based on strategic planning decisions and project outputs (August 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.

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 (Chap 2, p 68)

The Department of Health and Human Services (DHHS), in collaboration with U.S. and global partners through the World Health Organization, 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

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 Centers for Disease Control and Prevention (CDC) which includes the National Institute for Occupational Safety and Health (NIOSH) and six Coordinating Centers/Offices. The Food and Drug Administration (FDA) and the National Institutes of Health (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. 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 Department of Defense (DoD), the Department of State, and the U.S. Agency for International Development (USAID).
- 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 World Health Organization (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 Role of these environmental parameters on the effectiveness of PPE is long term research.

1.2.2.2 ** 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 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.

1.3 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 NORA 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)?

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 cm^2 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.

1.3.4.2.2 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/Health Effects Lad Division (HELD) and Division of Respiratory Disease Studies (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. Selected workers in a local hospital emergency department will wear a two-stage bioaerosol sampler during their normal work routine to determine whether airborne influenza virus is detected during the months of high influenza activity. The samplers will also be deployed in fixed locations for area sampling. Since the sampler fractionates the aerosol particles by size, the particle size information will help to determine if the virus is transported in larger droplets and/or smaller droplet nuclei. Collected samples will be evaluated for the presence of influenza virus by a PCR-based virus

detection system. Results will be analyzed by particle size to deduce by which mechanisms the aerosolized virus may be transmitted, e.g. by (i) large droplet contact, and/or (ii) small droplet nuclei in circulating air.

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 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 initiatives are described in Reference B.

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 B. 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 What percentage of patients aerosolize influenza virus during an infection?

1.4.2.1 ** Long term research.

1.4.3 How distinct is transmission in different venues including healthcare, schools, and households?

1.4.3.1 ** Long term research.

1.4.4 What is the time sequence of infectivity?

1.4.4.1 ** Long term research.

1.4.5 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)?

1.4.5.1 ** Long term research.

1.4.6 When patients receive antiviral drugs do they continue to excrete virus?

1.4.6.1 ** Long term research.

1.4.7 What is the virus concentration in saliva and nasal fluids when a person is asymptomatic, during infection, and during recovery?

1.4.7.1 ** Long term research.

1.4.8 What is the impact of masking patients on transmission risk? If effective, how long should a medical mask be worn?

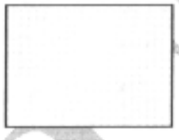
1.4.8.1 ** Long term research.

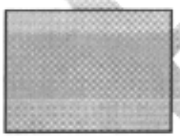
1.4.8.2 ** Funding to develop appropriate surveillance initiatives is needed.

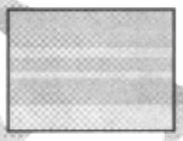
1.4.8.3 Cough project will evaluate surgical masks as described in Reference B. Also, see write-up in 1.3.3.1 for details of this project.

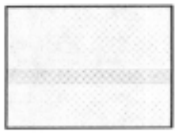
PPT Program PPE for HCW Action plan

*** For the recommendation charts below:

Objects with yellow fill represent NPPTL 

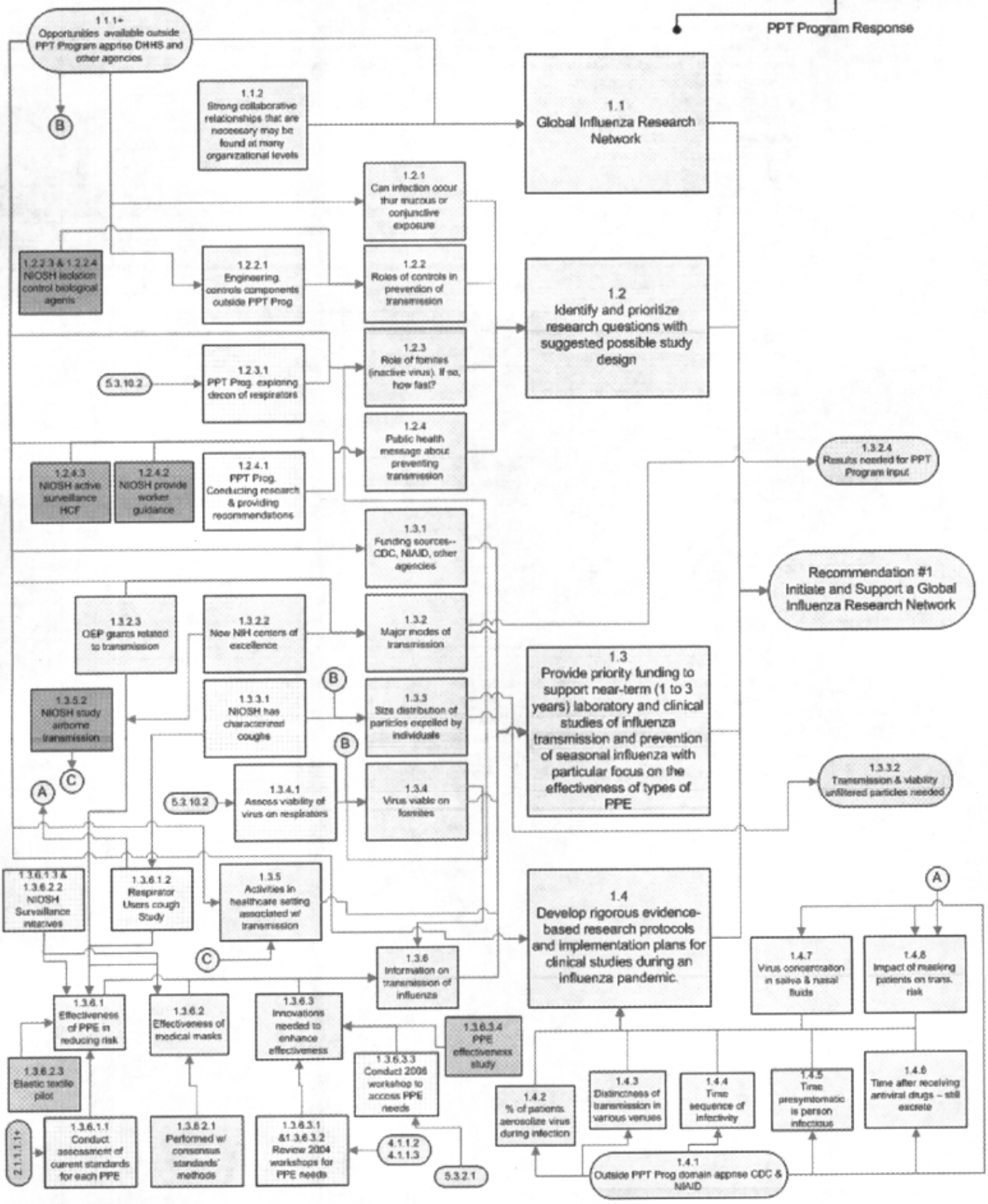
Objects with orange fill represent NIOSH 

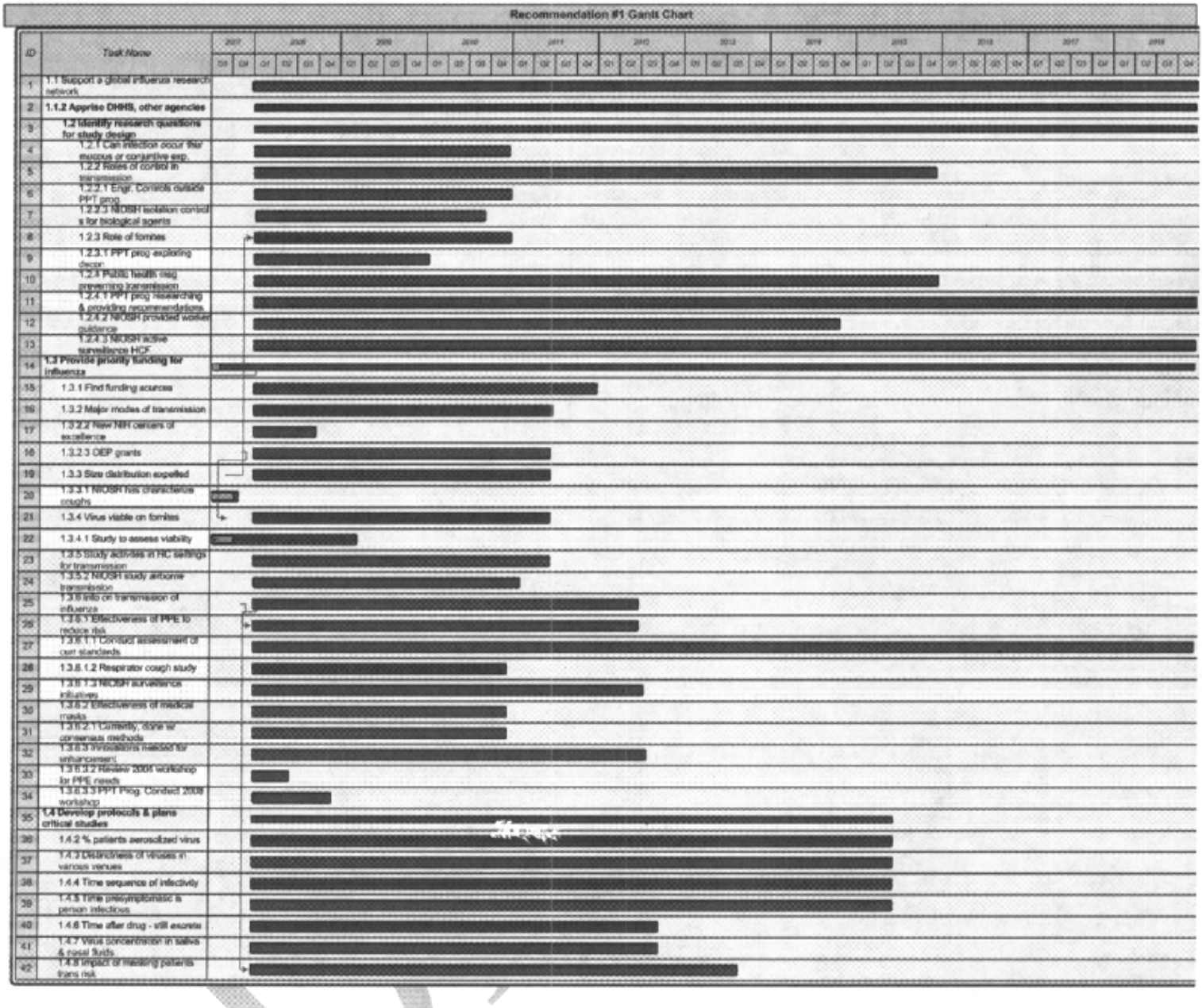
Objects with light purple fill represent CDC 

Objects with light green fill represent connectivity with other recommendations 

2/22/2008

IOM Recommendation #1




Recommendation #1 Gantt Chart
ID
Task Name
1 1.1 Support a global influenza research network
2 1.1.2 Apprise DHHS, other agencies
3 1.2 Identify research questions for study design
4 1.2.1 Can infection occur thru' mucous or conjuntive exp.
5 1.2.2 Roles of control in transmission
6 1.2.2.1 Engr. Controls outside PPT prog
7 1.2.2.3 NIOSH isolation control s for biological agents
8 1.2.3 Role of fomites
9 1.2.3.1 PPT prog exploring decon
10 1.2.3 Public health mes preventing transmission
11 1.2.4.1 PPT prog researching & providing recommendations
12 1.2.4.2 NIOSH provided worker guidance
13 1.2.4.3 NIOSH active surveillance HCF
14 1.3 Provide priority funding for influenza
15 1.3.1 Find funding acuncs
16 1.3.2 Major modes of transmission
17 1.3.2.2 New NIH centers of excellence
18 1.3.2.3 OEP grants
19 1.3.3 Size distribution expelled
20 1.3.3.1 NIOSH has characterize coughs
21 1.3.4 Virus viable on fomites
22 1.3.4.1 Study to assess viability
23 1.3.5 Study activities in HC settings for transmission
24 1.3.5.2 NIOSH study airborne transmission
25 1.3.6 Info on transmission of influenza
26 1.3.6.1 Effectiveness of PPE to reduce risk
27 1.3.6.1.1 Conduct assessment of curr standards
28 1.3.6.1.2 Respirator cough study
29 1.3.6.1.3 NIOSH surveillance initiatives
30 1.3.6.2 Effectiveness of medical masks
31 1.3.6.2.1 Currently, done w/ consensus methods
32 1.3.6.3 Innovations needed for enhancement
33 1.3.6.3.2 Review 2006 workshop for PPE needs
34 1.3.6.3.3 PPT Prog. Conduct 2008 workshop
35 1.4 Develop protocols & plans critical studies
36 1.4.2 % patients aerosolized virus
37 1.4.3 Distinctness of viruses in various venues
38 1.4.4 Time sequence of infectivity
39 1.4.5 Time presymptomatic is person infectious
40 1.4.6 Time after drug - still excrete
41 1.4.7 Virus concentration in saliva & nasal fluids
42 1.4.8 Impact of masking patients trans risk

IOM Recommendation # 2: Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE (Chap 3, p 106)

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

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 Occupational Safety and Health Administration (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, ANSI and 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. [References 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 Veterans Health Administration (VHA), 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, VHA 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 Possible project on doffing garments.

2.3.2 Develop standards for other than respirators.

2.3.2.1 Identify approaches to address gaps.

763 2.3.2.1.1 An assessment of current standards needs to be conducted to categorize
764 existing PPE as it relates to current standards. NPPTL currently certifies
765 performance of respirators, other PPE performance is assessed by third
766 party certification authorities in accordance with consensus standards' test
767 methods. The PPT Program has limited infrastructure for PPT research,
768 development and investigative testing beyond respirator issues. The PPT
769 Program is planning to expand its capability in protective clothing
770 research, development and investigative testing through training,
771 additional personnel, and cooperative efforts with third party certification
772 authorities and laboratories.
773 2.3.2.1.2 Other PPE performance is assessed by third party certification authorities
774 in accordance with consensus standards' test methods.
775 2.3.2.1.3 Collaboration with ASTM, ISO, ANSI and ISEA.
776 2.4 Durability – Adequate wear life, Strength—(tear, tensile, burst), Abrasion resistance,
777 Corrosion resistance.
778 2.4.1 Develop standards for respiratory PPE.
779 2.4.1.1 Identify approaches to address gaps.
780 2.4.1.1.1 Existing and ongoing revisions of ANSI, ISO and other applicable
781 respiratory protection consensus standards are being assessed for
782 alignment and potential adoption by the PPT Program.
783 2.4.1.1.2 NPPTL continues to certify performance of respirators through 42 CFR
784 Part 84. [Reference S]
785 2.4.1.1.3 Collaboration with ISEA and PPT Program.
786 2.4.2 Develop standards for other than respirators. Long term research.
787 2.4.2.1 Identify approaches to address gaps.
788 2.4.2.1.1 An assessment of current standards needs to be conducted to categorize
789 existing PPE as it relates to current standards. NPPTL currently certifies
790 performance of respirators, other PPE performance is assessed by third
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793 development and investigative testing beyond respirator issues. The PPT
794 Program is planning to expand its capability in protective clothing
795 research, development and investigative testing through training,
796 additional personnel, and cooperative efforts with third party certification
797 authorities and laboratories.
798 2.4.2.1.2 Other PPE performance is assessed in accordance with consensus
799 standards' test methods
800 2.4.2.1.3 Collaboration with ASTM, ISO, ANSI and ISEA.
801 2.5 Maintenance and Reuse – Easy to decontaminate and discard disposable elements, Easy to
802 clean and replace parts in reusable PPE.
803 2.5.1 Develop standards for respiratory PPE.
804 2.5.1.1 Identify approaches to address gaps.
805 2.5.1.1.1 Existing and ongoing revisions of ANSI, ISO and other applicable
806 respiratory protection consensus standards are being assessed for
807 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.

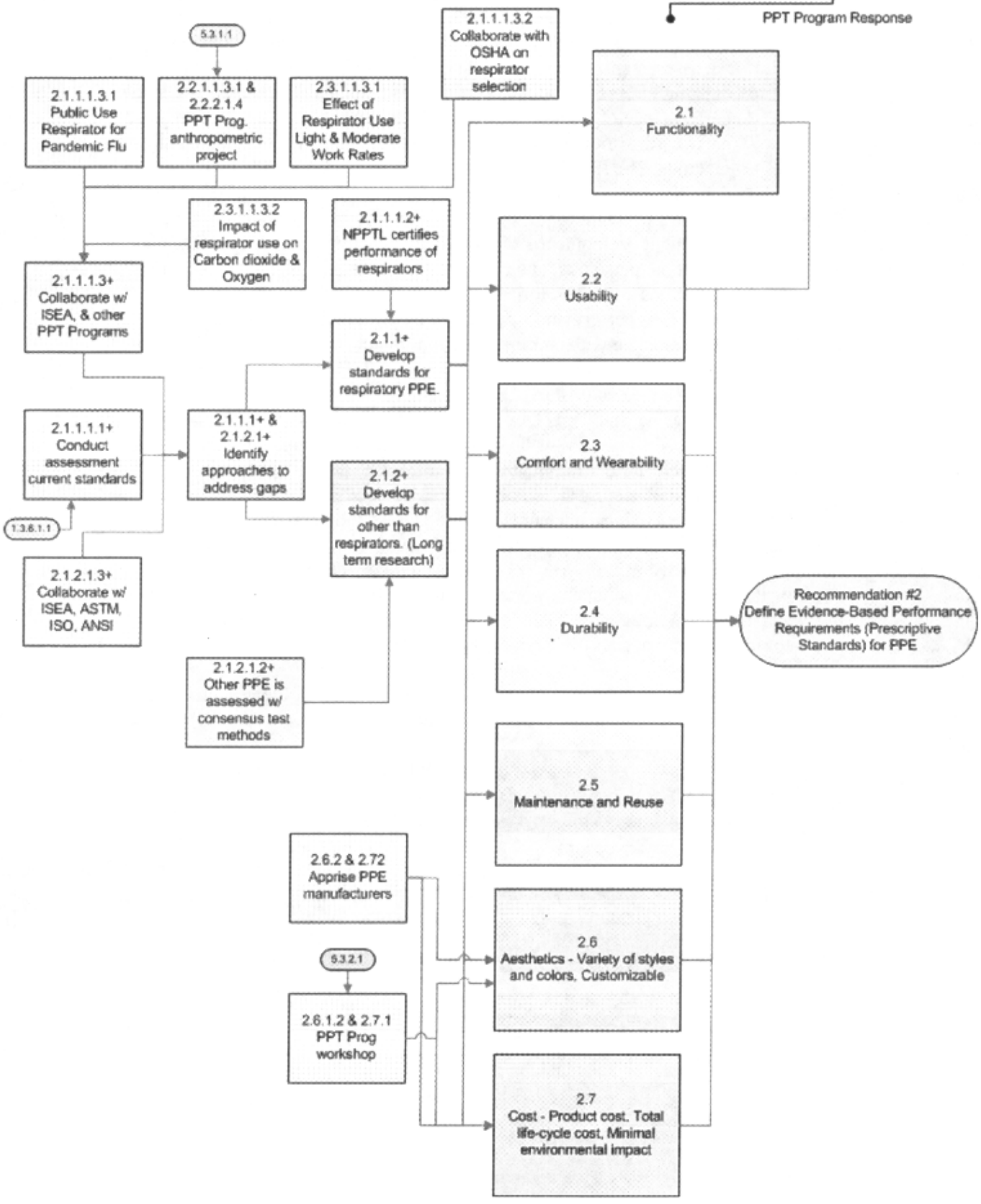
2.7 Cost - Product cost, Total life-cycle cost, Minimal environmental impact

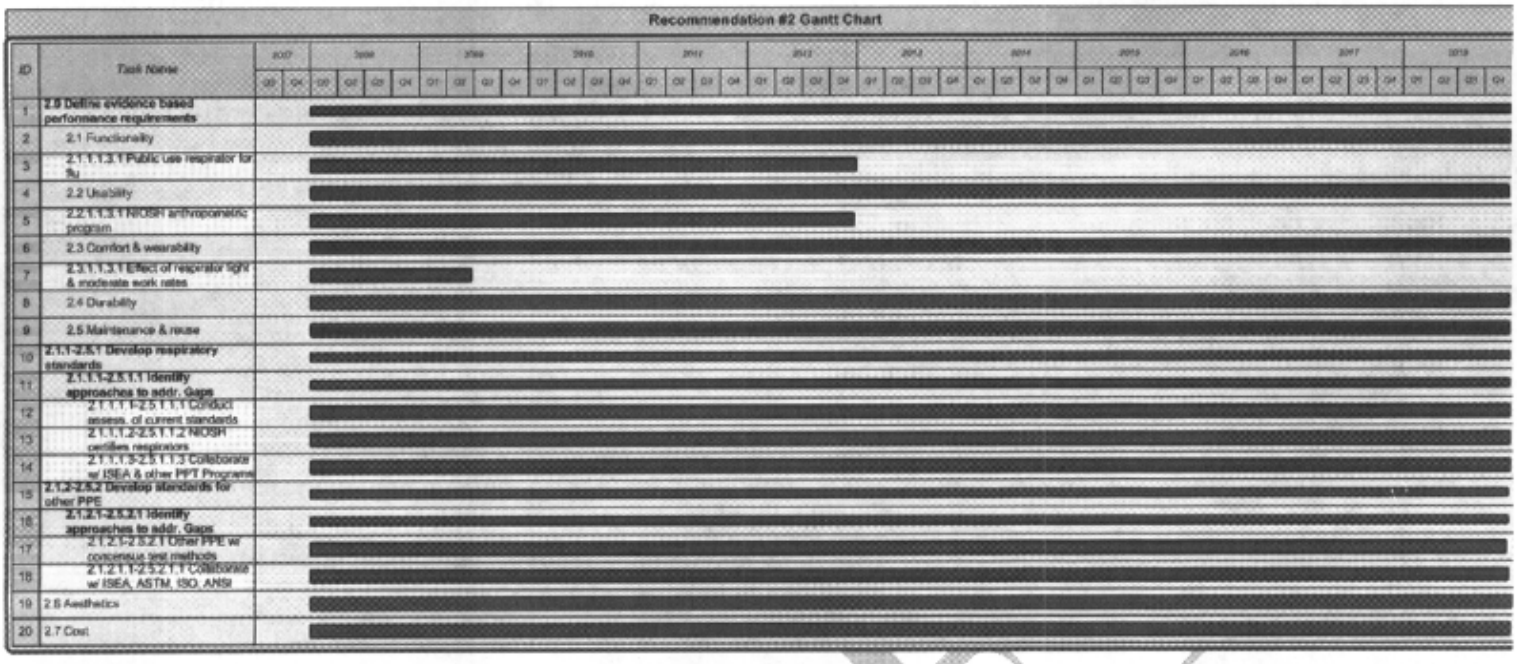
2.7.1 PPT Program will conduct a workshop in 2008 to assess the current state of technology. A commerce business daily presolicitation for a contractor to coordinate and conduct the workshop was published on Nov 8, 2007. [Reference D]

2.7.2 ** Apprise PPE manufacturers of capabilities to increase cost effectiveness of PPE.

2/5/2008

IOM Recommendation #2




Recommendation #2 Gantt Chart
ID
Task Name
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
1 2.0 Define evidence based performance requirements
2 2.1 Functionality
3 2.1.1.3.1 Public use respirator for flu
4 2.2 Usability
5 2.2.1.3.1 NIOSH anthropometric program
6 2.3 Comfort & wearability
7 2.3.1.3.1 Effect of respirator light & moderate work rates
8 2.4 Durability
9 2.5 Maintenance & reuse
10 2.1.1-2.5.1 Develop respiratory standards
11 2.1.1.1-2.5.1.1 Identify approaches to addr. Gaps
12 2.1.1.1 F-2.5.1.1.1 Conduct assess. of current standards
13 2.1.1.2-2.5.1.1.2 NIOSH certifies respirators
14 2.1.1.3-2.5.1.1.3 Collaborate w/ ISEA & other PPT Programs
15 2.1.2-2.5.2 Develop standards for other PPE
16 2.1.2.1-2.5.2.1 Identify approaches to addr. Gaps
17 2.1.2.1-2.5.2.1 Other PPE w/ concensus test methods
18 2.1.2.1.1-2.5.2.1.1 Collaborate w/ ISEA, ASTM, ISO, ANSI
19 2.6 Aesthetics
20 2.7 Cost

IOM Recommendation # 3: Adopt a Systems Approach to the Design and Development of PPE (Chap 3, p 106)

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

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 CBRN/NFPA 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.

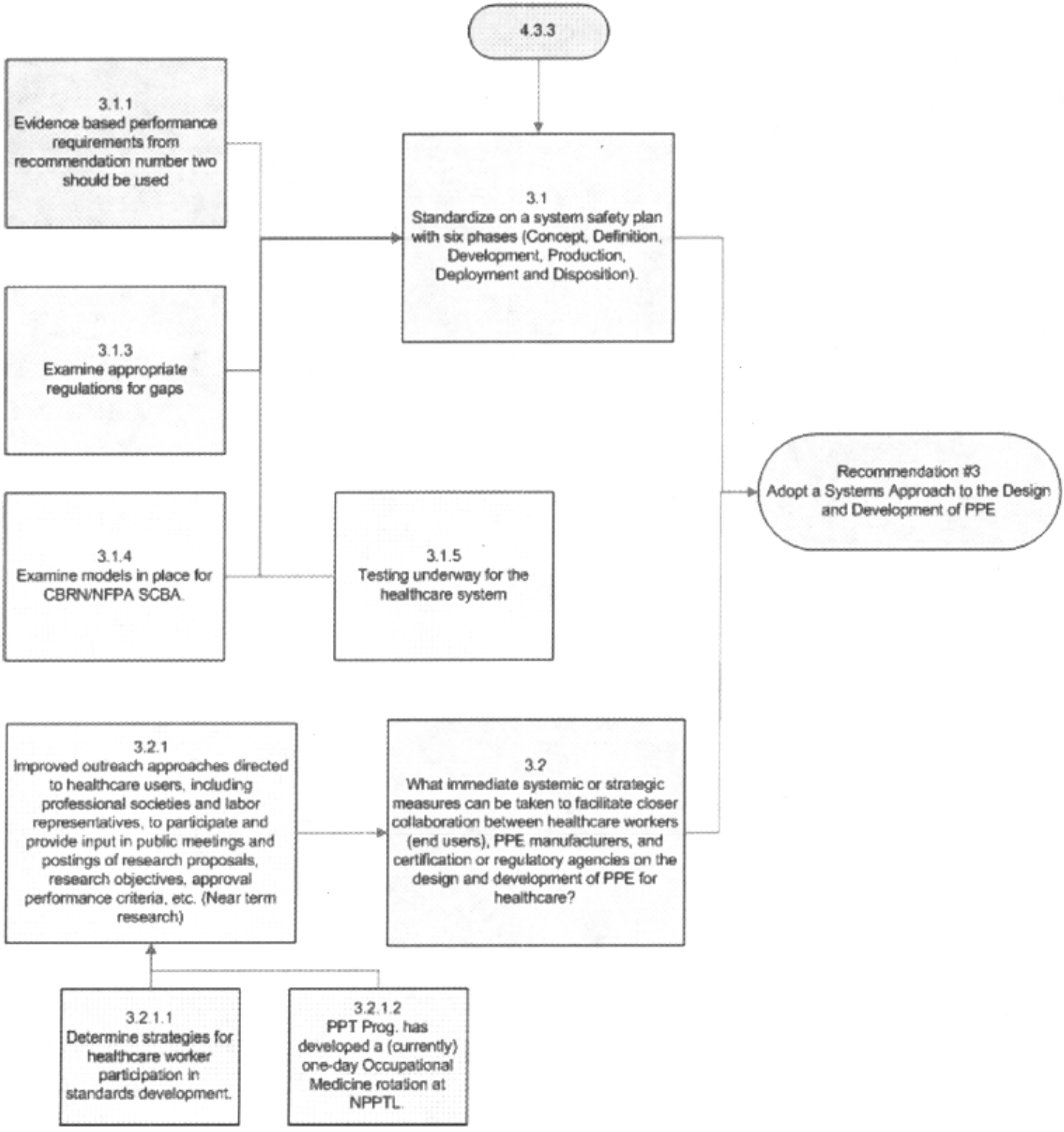
3.2.1.2 Currently, Occupational Medicine residency programs graduate < 100 physicians per year in the U.S. and many of these individuals enter academia. Many medically-related Occupational Medicine tasks (e.g., respirator fit testing, audiology testing and review, baseline pulmonary function interpretations, etc.) are overseen by Internal Medicine and Family Medicine practitioners who may have limited training in these

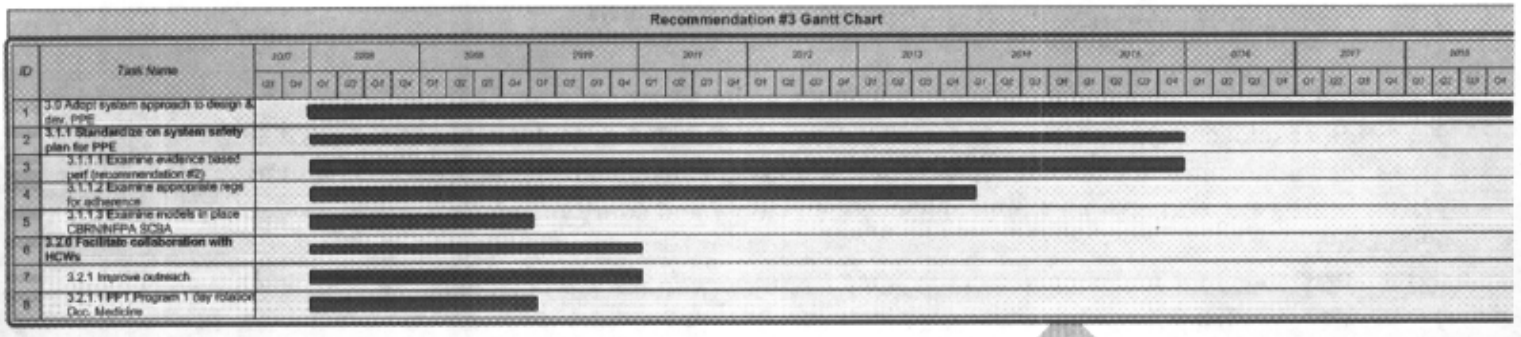
areas. During a pandemic influenza, demands on these practitioners regarding such issues as respirator fit testing may take on additional importance. The PPT Program has developed a one-day Occupational Medicine rotation at NPPTL, for Internal Medicine and Family Medicine resident physicians that offer 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.

2/5/2008

IOM Recommendation #3

PPT Program Response




Recommendation #3 Gantt Chart
ID
Task Name
1 3.0 Adopt system approach to design & dev. PPE
2 3.1.1 Standardize on system safety plan for PPE
3 3.1.1.1 Examine evidence based perf (recommendation #2)
4 3.1.1.2 Examine appropriate regs for adherence
5 3.1.1.3 Examine models in place CBRN/NFPA SCBA
6 3.2.0 Facilitate collaboration with HCWs
7 3.2.1 Improve outreach
8 3.2.1.1 PPT Program 1 day rotation Occ. Medicine

IOM Recommendation # 4: Increase Research on the Design and Engineering of the Next Generation of PPE (Chap 3, p 106-107)

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

PPT Program Plan in response to IOM Recommendation # 4

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 Filtering Facepiece Respirators (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 Possible project to study antimicrobial respirator technology.

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 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 VHA and academia initiated Project BREATHE (Better Respiratory Equipment And Technology for Healthcare Employees). 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

1003 are likely to be better tolerated during periods of prolonged use, such as
1004 influenza pandemics.
1005 4.6 Incorporating sensors into PPE to detect breaches and notify users of end of service life and
1006 other protection information. Sensors for face seal leakage is the key issue in this
1007 recommendation. If the PPE was not donned properly or no longer fitting, can this be
1008 detected and the user alerted?
1009 4.6.1 Can the protection levels of the PPE worn by healthcare workers (e.g., N95
1010 respirators) be continuously monitored during use to provide an alert to change the
1011 PPE when it is no longer effective?
1012 4.6.1.1 PPT Program will conduct workshop in 2008 to assess the current state of
1013 technology. A commerce business daily presolicitation was published on Nov
1014 8, 2007. Reference D.
1015 4.6.1.2 PPT Program – New Sensor Technology Development for ESLI: Reference H.
1016 Even though this project doesn't apply directly to pandemic flu it may be
1017 possible to use some of the lessons learned in this project and apply it to
1018 healthcare PPE (ie like working with manufacturers to develop sensor
1019 technology).
1020 4.6.2 Develop other-than-respiratory PPE with technology to alert the user when
1021 effectiveness may be compromised.
1022 4.6.2.1 Add colorimetric write-up.
1023 4.6.2.2 Add innovative indicator write-up for chemical protective clothing (CPC).
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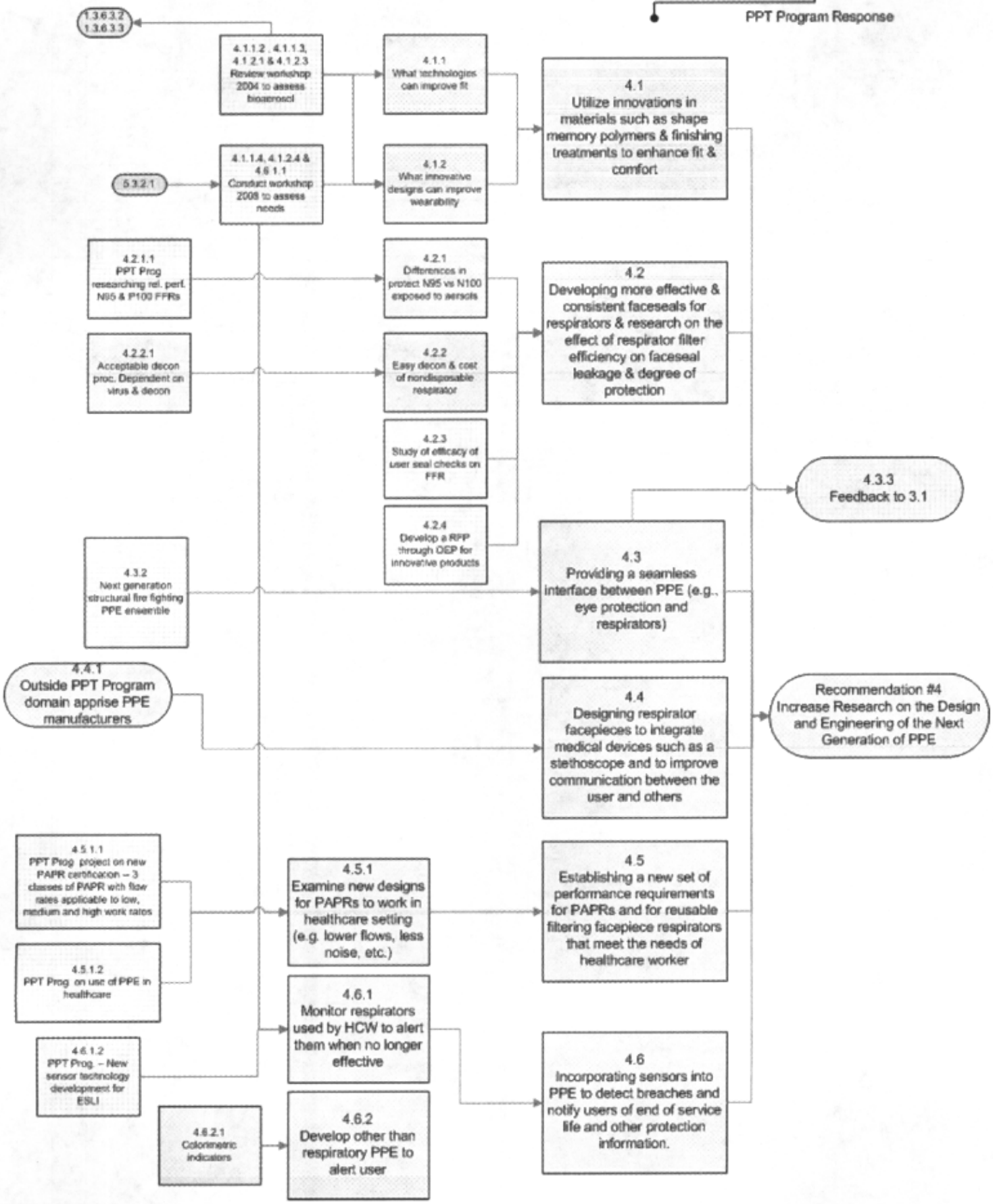
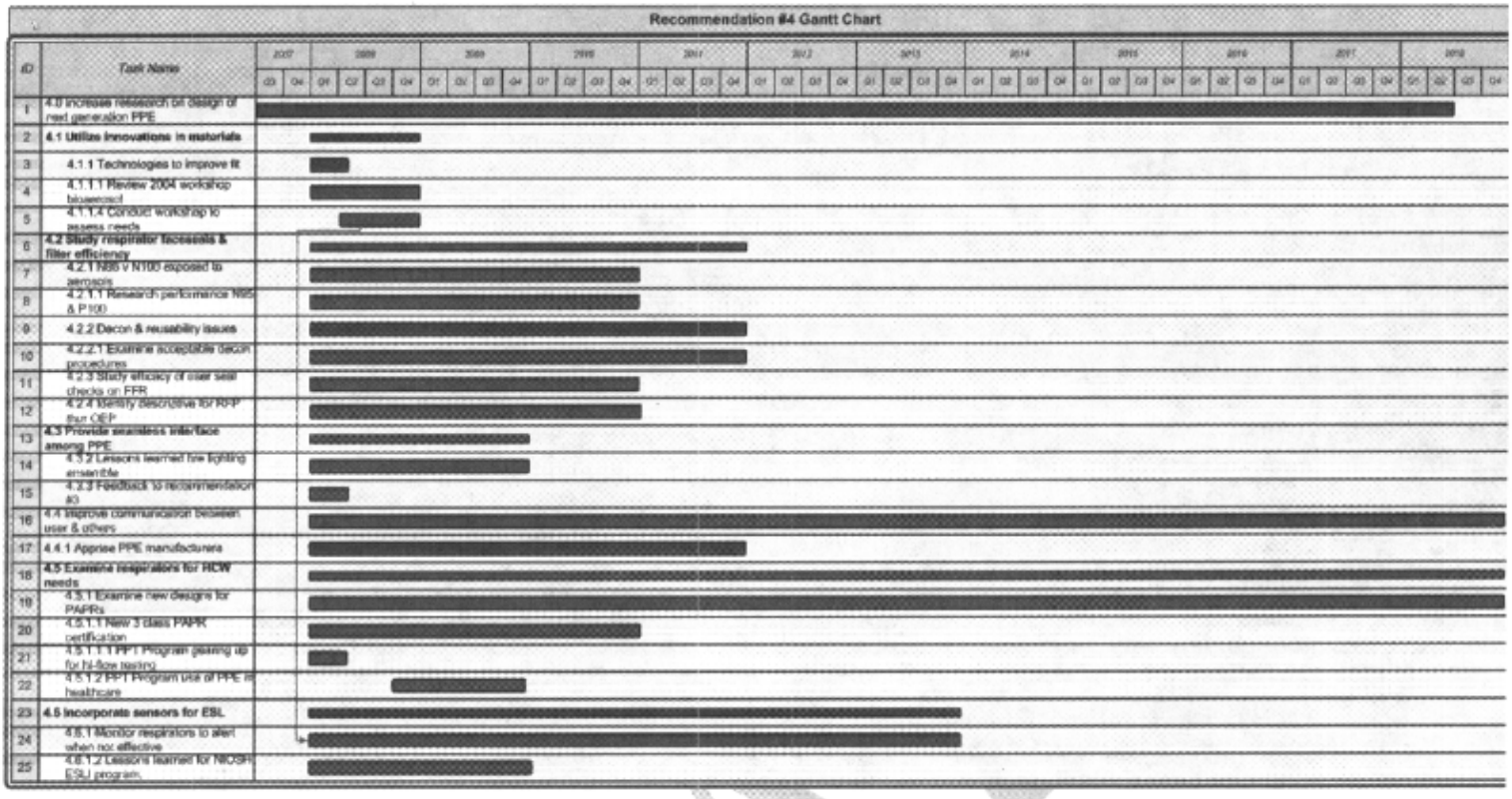
2/5/2008

IOM Recommendation #4

PPT Program Response




Recommendation #4 Gantt Chart
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Task Name
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1 4.0 Increase research on design of next generation PPE
2 4.1 Utilize innovations in materials
3 4.1.1 Technologies to improve fit
4 4.1.1.1 Review 2004 workshop
5 4.1.1.4 Conduct workshop to
6 4.2 Study respirator facesels & filter efficiency
7 4.2.1 N95 v N100 exposed to
8 4.2.1.1 Research performance N95 & P100
9 4.2.2 Decon & reusability issues
10 4.2.2.1 Examine acceptable decon procedures
11 4.2.3 Study efficacy of user seal checks on FFR
12 4.2.4 Identify descriptive for R-P
13 4.3 Provide seamless interface among PPE
14 4.3.2 Lessons learned fire fighting ensemble
15 4.2.3 Feedback to recommendation #3
16 4.4 Improve communication between user & others
17 4.4.1 Apprise PPE manufacturers
18 4.5 Examine respirators for HCW needs
19 4.5.1 Examine new designs for PAPRs
20 4.5.1.1 New 3 class PAPR certification
21 4.5.1.1.1 PP1 Program gearing up for hi-flow testing
22 4.5.1.2 PP1 Program use of PPE in healthcare
23 4.6 Incorporate sensors for ESL
24 4.6.1 Monitor respirators to alert when not effective
25 4.6.1.2 Lessons learned for NIOSH ESLI program

IOM Recommendation # 5: Establish Measures to Assess and Compare the Effectiveness of PPE (Chap 3, p 107)

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

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. References 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 Filtering Facepiece Respirators 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

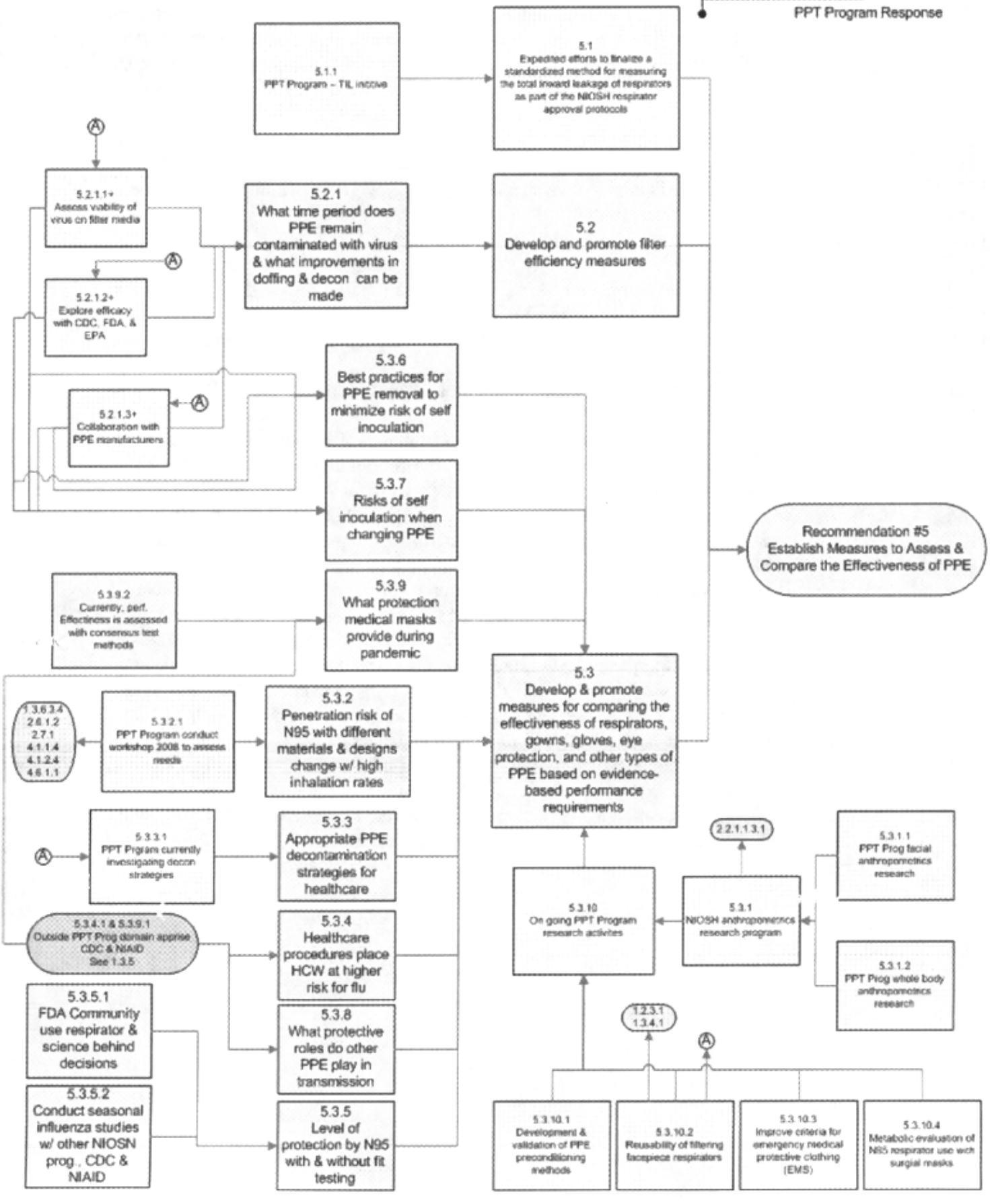
categorize the various decontamination agents with respect to their effects on filtration performance of the respirator.

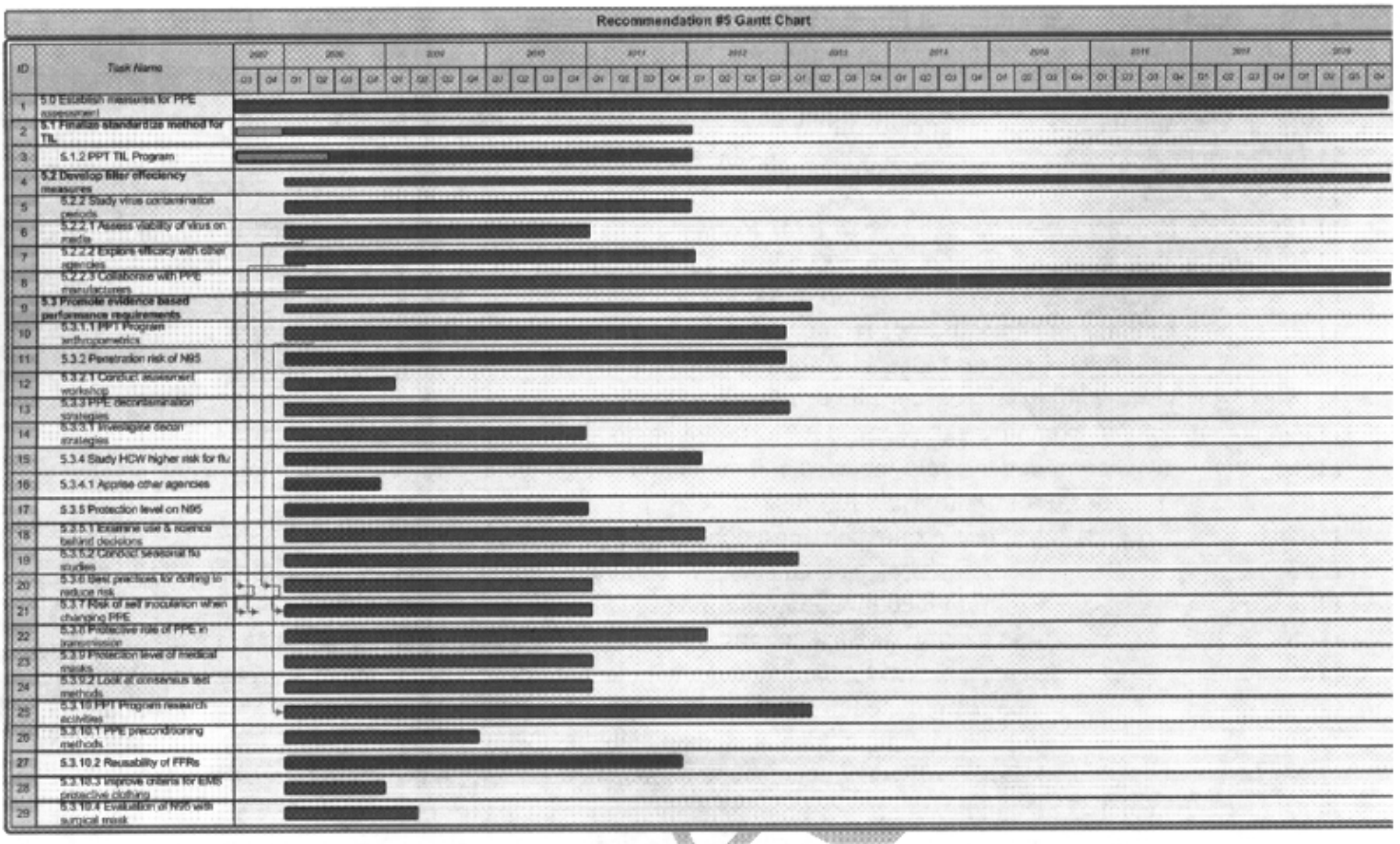
5.3.10.3 Improve criteria for emergency medical protective clothing (EMS): Reference K. The PPT Program has undertaken a project to address the issue of protective clothing for Emergency Medical Services personnel who respond to patients with infectious diseases (approximately 1/29 of EMS calls), such 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 Emergency Medical Services 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 for correlative analysis.

2/5/2008

IOM Recommendation #5




Recommendation #5 Gantt Chart
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Task Name
5.0 Establish measures for PPE assessment
5.1 Finalize standardize method for TIL
5.1.2 PPT TIL Program
5.2 Develop filter efficiency measures
5.2.2 Study virus contamination periods
5.2.2.1 Assess viability of virus on media
5.2.2.2 Explore efficacy with other agencies
5.2.2.3 Collaborate with PPE manufacturers
5.3 Promote evidence based performance requirements
5.3.1.1 PPT Program anthropometrics
5.3.2 Penetration risk of N95
5.3.2.1 Conduct assessment workshop
5.3.3 PPE decontamination strategies
5.3.3.1 Investigate decon strategies
5.3.4 Study HCW higher risk for flu
5.3.4.1 Apprise other agencies
5.3.5 Protection level on N95
5.3.5.1 Examine use & science behind decisions
5.3.5.2 Conduct seasonal flu studies
5.3.6 Best practices for clothing to reduce risk
5.3.7 Risk of self inoculation when changing PPE
5.3.8 Protective role of PPE in transmission
5.3.9 Protection level of medical masks
5.3.10.2 Look at consensus test methods
5.3.10 PPT Program research activities
5.3.10.1 PPE preconditioning methods
5.3.10.2 Reusability of FFRs
5.3.10.3 Improve criteria for BMB protective clothing
5.3.10.4 Evaluation of N95 with surgical mask

IOM Recommendation # 6: Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training (Chap 4, p 140)

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

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 Healthcare Nurses 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 HealthProfessionals 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 Practitioners 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 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.

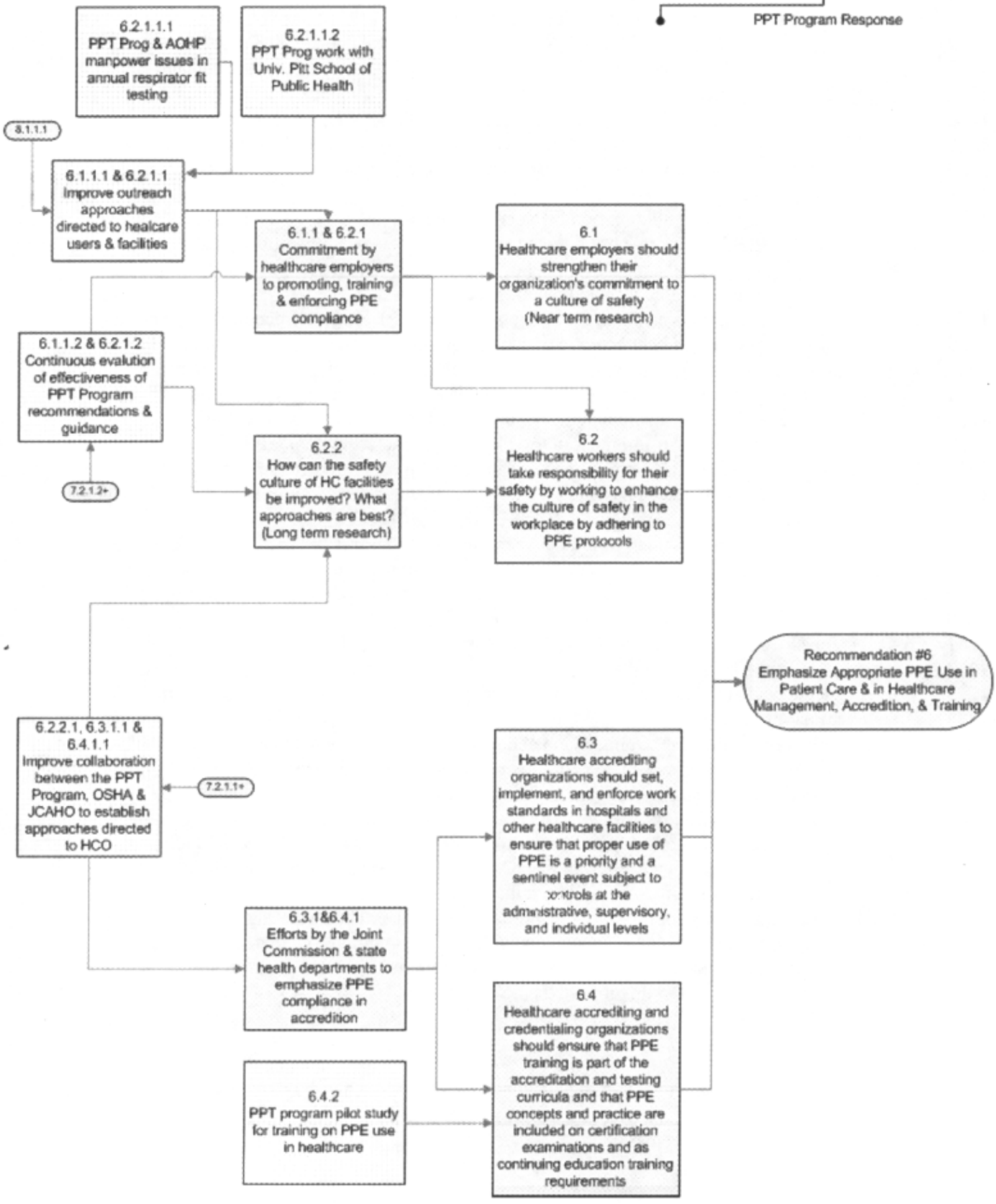
6.4.1.1 Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.

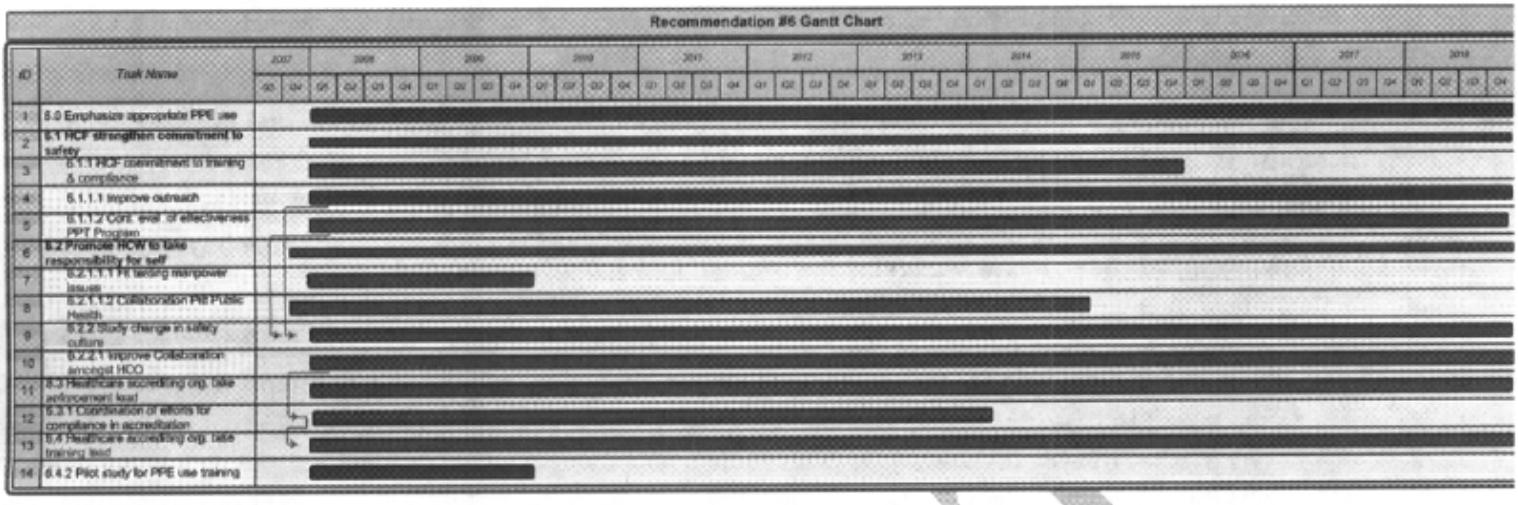
6.4.2 PPT Program pilot program for training on PPE use. The PPT Program has instituted an Occupational Medicine rotation at NPPTL for Internal Medicine and Family Medicine resident physicians to acclimate them to issues that are germane to their involvement in Occupation Medicine tasks.

2/5/2008

IOM Recommendation #6

PPT Program Response




Recommendation #6 Gantt Chart
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1 6.0 Emphasize appropriate PPE use
2 6.1 HCF strengthen commitment to safety
3 6.1.1 HCF commitment to training & compliance
4 6.1.1.1 Improve outreach
5 6.1.1.2 Cont. eval. of effectiveness PPT Program
6 6.2 Promote HCW to take responsibility for self
7 6.2.1.1.1 Fit testing manpower issues
8 6.2.1.1.2 Collaboration Fit Public Health
9 6.2.2 Study change in safety culture
10 6.2.2.1 Improve Collaboration amongst HCO
11 6.3 Healthcare accrediting org. take enforcement lead
12 6.3.1 Coordination of efforts for compliance in accreditation
13 6.4 Healthcare accrediting org. take training lead
14 6.4.2 Pilot study for PPE use training

IOM Recommendation # 7: Identify and Disseminate Best Practices for Improving PPE Compliance and Use (Chap 4, p 140-141)

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.

PPT Program Plan in response to IOM Recommendation # 7

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 Filtering Facepiece Respirators Worn Concurrently With a Loose-fitting, Powered Air-purifying Respirator: 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, Powered Air-purifying Respirator: 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, Powered Air-purifying Respirator: 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?

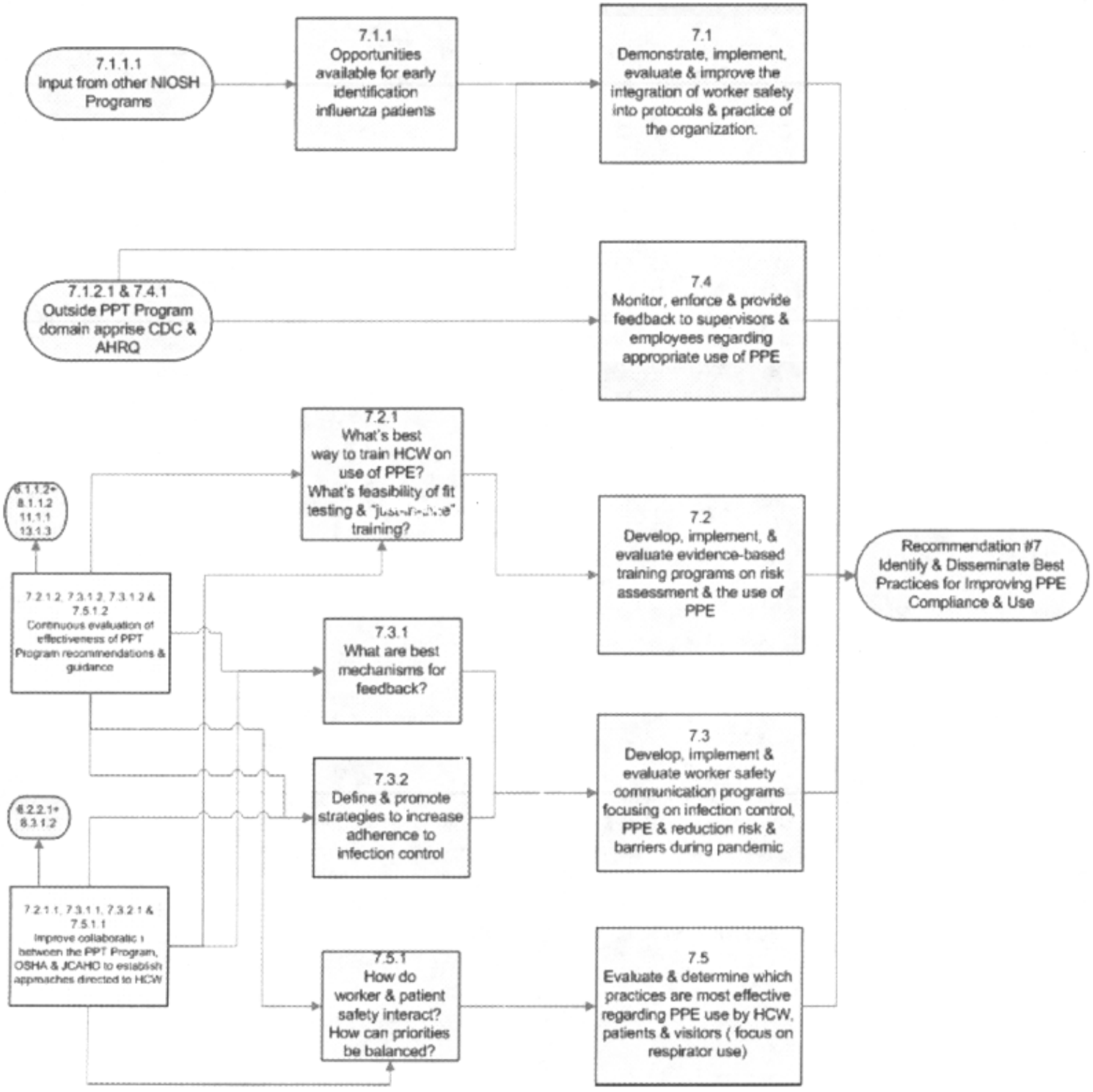
7.5.1.1 Improved collaboration between the PPT Program, OSHA, and JCAHO to establish approaches directed to healthcare users and facilities, including professional societies and labor representatives to disseminate and enforce PPT protocols, guidance and compliance issues.

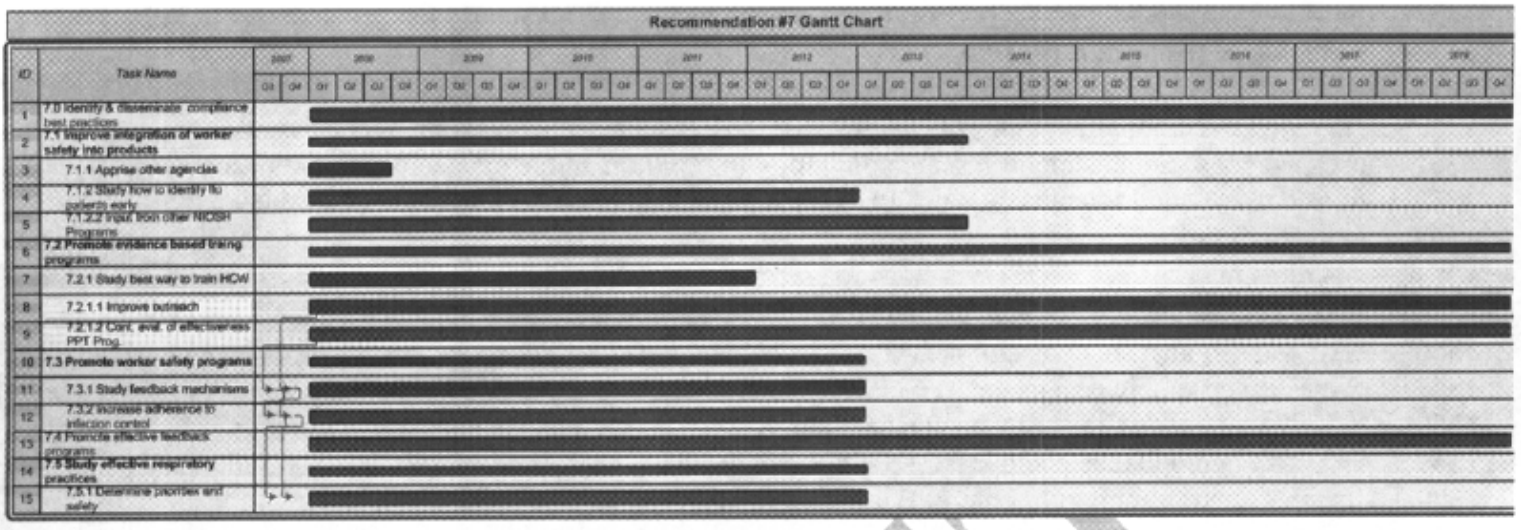
7.5.1.2 Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.

2/5/2008

IOM Recommendation #7

PPT Program Response




Recommendation #7 Gantt Chart
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1 7.0 Identify & disseminate compliance best practices
2 7.1 Improve integration of worker safety into products
3 7.1.1 Apprise other agencies
4 7.1.2 Study how to identify fit-tester(s) early
5 7.1.2.2 Input from other NIOSH Programs
6 7.2 Promote evidence based training programs
7 7.2.1 Study best way to train HCW
8 7.2.1.1 Improve outreach
9 7.2.1.2 Cont. eval. of effectiveness PPT Prog.
10 7.3 Promote worker safety programs
11 7.3.1 Study feedback mechanisms
12 7.3.2 Increase adherence to infection control
13 7.4 Promote effective feedback programs
14 7.5 Study effective respiratory practices
15 7.5.1 Determine priorities and safety

IOM Recommendation # 8: Increase Research and Research Translation Efforts Relevant to PPE Compliance (Chap 4, p 141)

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.

PPT Program Plan in response to IOM Recommendation # 8

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., Association of Occupational Healthcare Professionals 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 Association of PeriOperative Healthcare Nurses 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.

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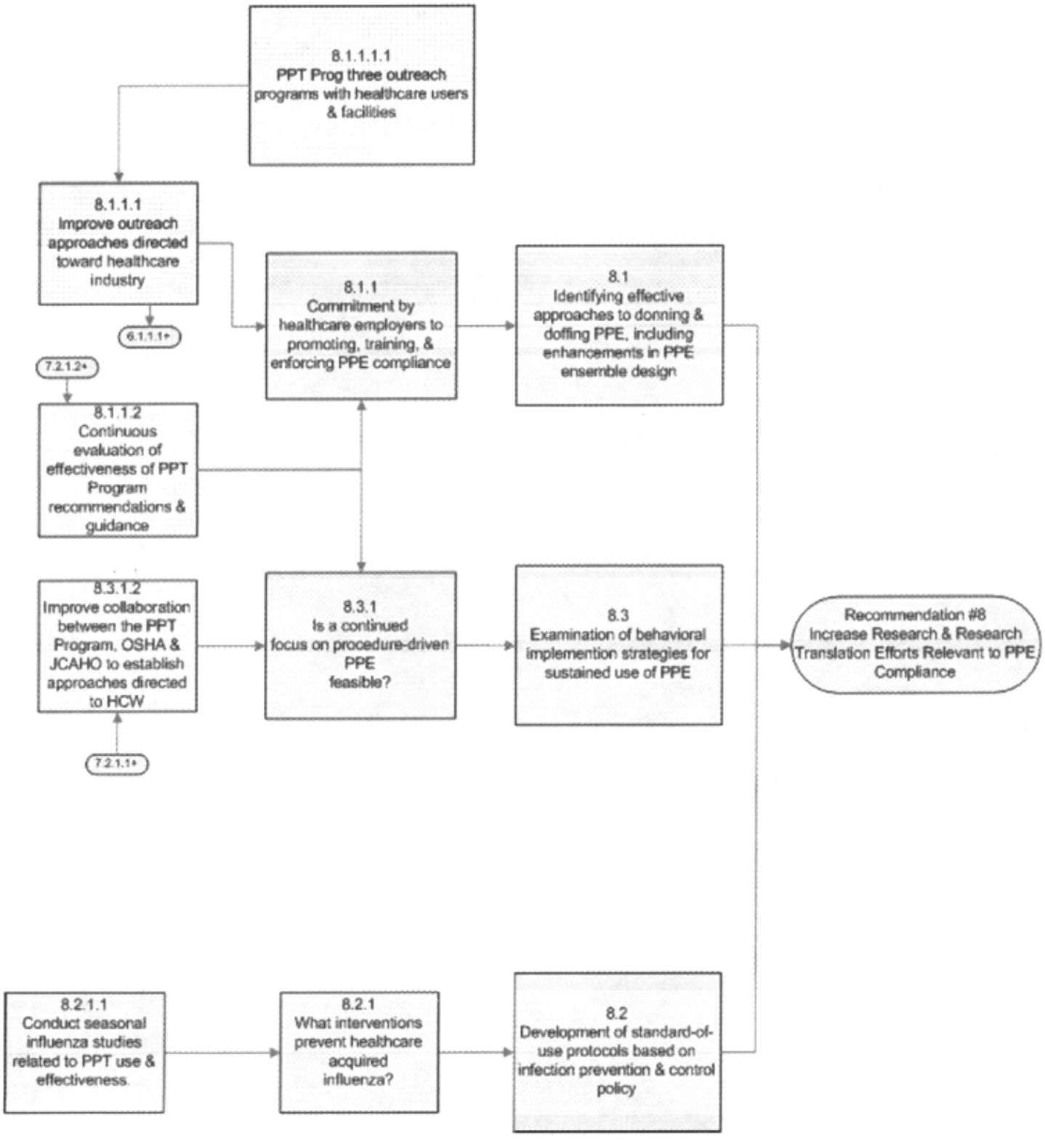
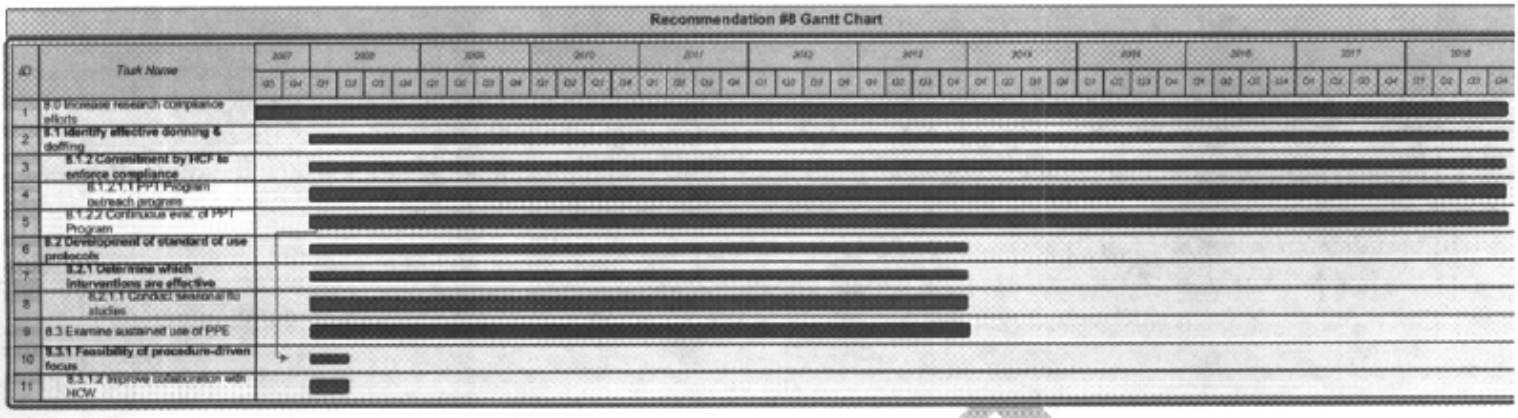
IOM Recommendation #8

PPT Program Response




Recommendation #8 Gantt Chart
ID
Task Name
8.0 Increase research compliance efforts
8.1 Identify effective donning & doffing
8.1.2 Commitment by HCF to enforce compliance
8.1.2.1 PPT Program outreach program
8.1.2.2 Continuous eval. of PPT Program
8.2 Development of standard of use protocols
8.2.1 Determine which interventions are effective
8.2.1.1 Conduct seasonal flu studies
8.3 Examine sustained use of PPE
8.3.1 Feasibility of procedure-driven focus
8.3.1.2 Improve collaboration with HCW

1417 IOM Recommendation # 9: Ensure Balance and Transparency of Standards-Setting Processes
1418 (Chap 5, p 165)
1419
1420 Federal agencies (e.g., FDA, NIOSH, OSHA) should use standards developed through a
1421 consensus-based transparent process that sets specific and clearly-defined limits regarding
1422 conflicts of interest (financial or other) and involves broad representation of all affected parties.
1423
1424 ***PPT Program Plan in response to IOM Recommendation # 9***
1425 9.1 Not in PPT Program domain, but in our purview
1426 9.2 Commit to standards setting bodies that use an open process for approvals, ie NFPA

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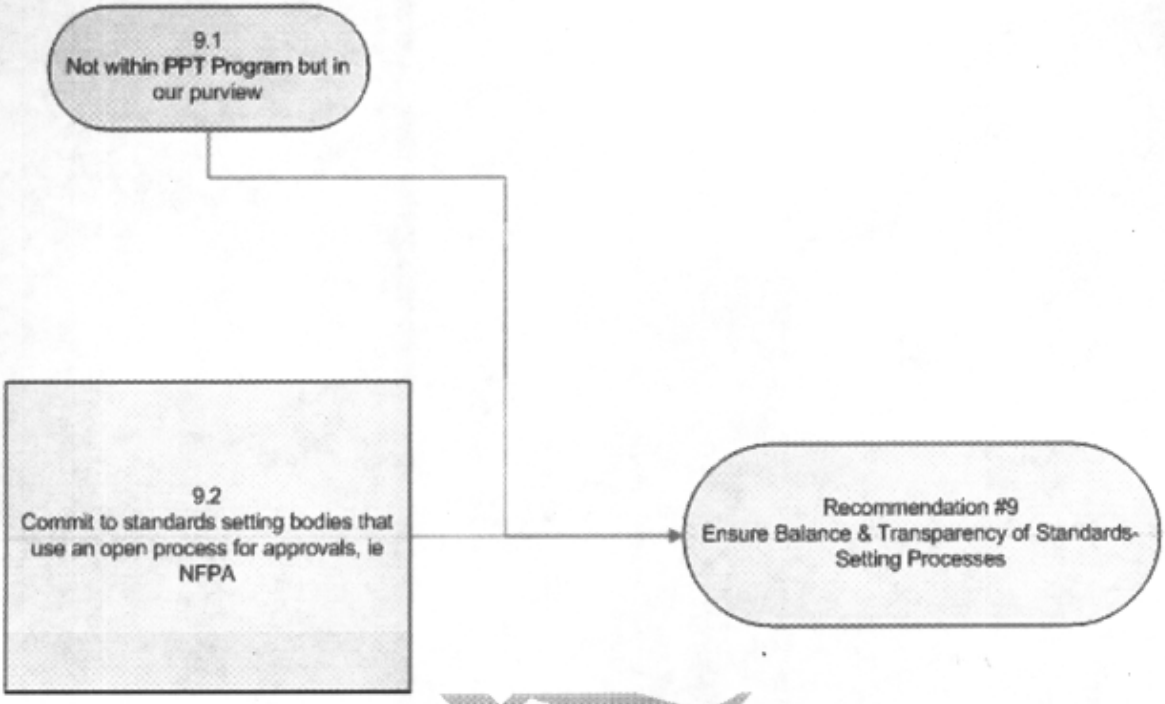
IOM Recommendation #9

PPT Program Response



Recommendation #9 Gantt Chart

ID	Task Name	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
1	9.0 Ensure balance & transparency in standards												
2	**9.1 PPT Program oversight**												
3	9.2 Commit to open process												

IOM Recommendation # 10: Strengthen Pre-market Testing of PPE for Healthcare Workers (Chap 5, p 166)

FDA, NIOSH, and other relevant agencies and organizations should strengthen pre-market testing requirements for healthcare PPE by requiring field testing of PPE prior to approval and by reevaluating the FDA medical device classification for healthcare PPE. Testing requirements should use rigorous standards while also providing expeditious review of innovative approaches.

PPT Program Plan in response to IOM Recommendation # 10

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 ** Only have authority to approve respirators.
- 10.3.2 Neither have responsibility or authority to approve other types of PPE
  - 10.3.2.1 Have authority granted or assigned for other PPEs
  - 10.3.2.2 Congress grants approval for other types of PPEs
  - 10.3.2.3 Next best thing -- Provide scientific expertise to standard organizations' through another agency or NIOSH PPT participation.
    - 10.3.2.3.1 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 American Society for Testing and Materials (ASTM) standard (ASTM F2668-07 Standard Practice for Determining the Physiological Responses of the Wearer to Protective Clothing Ensembles).

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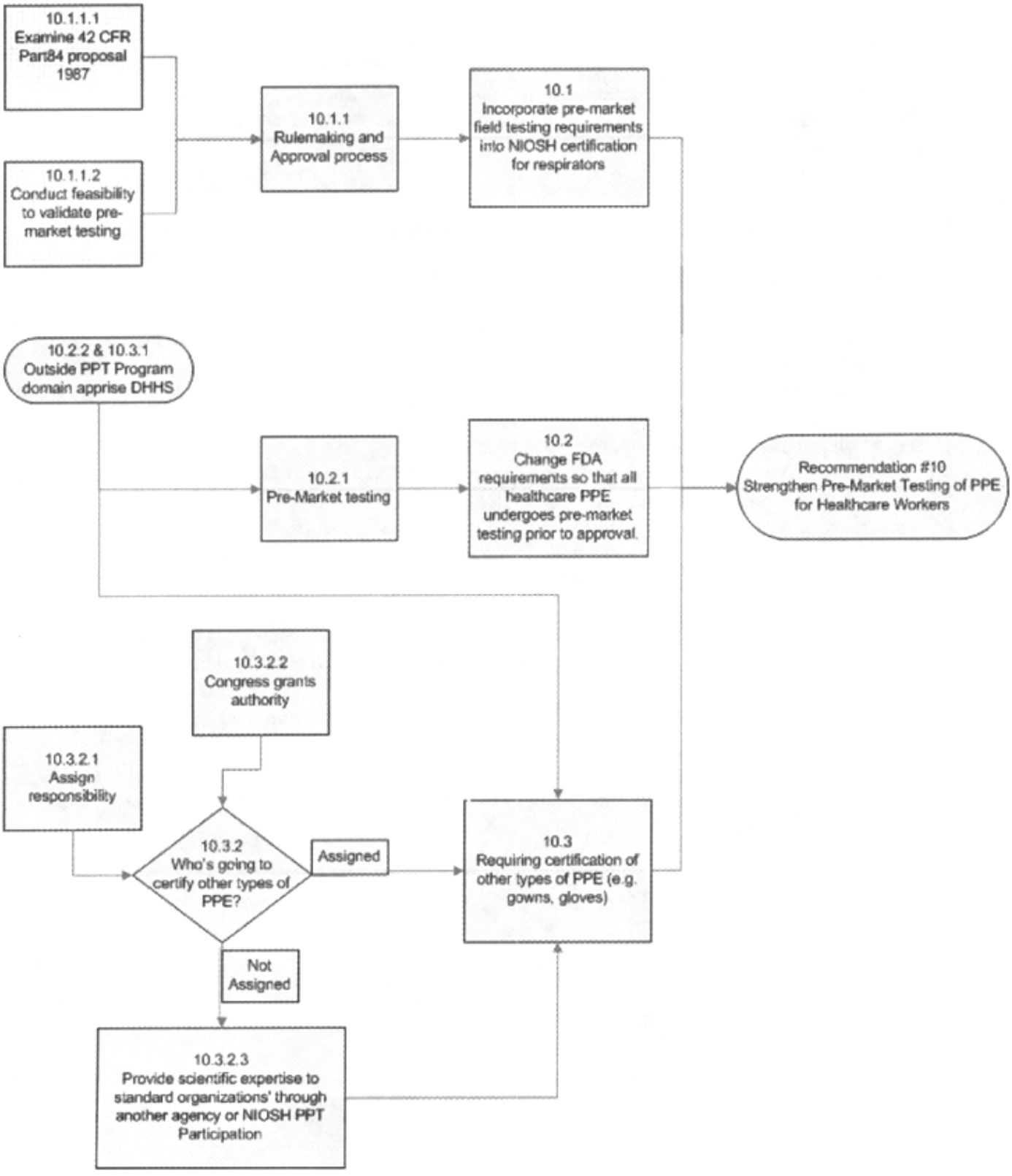
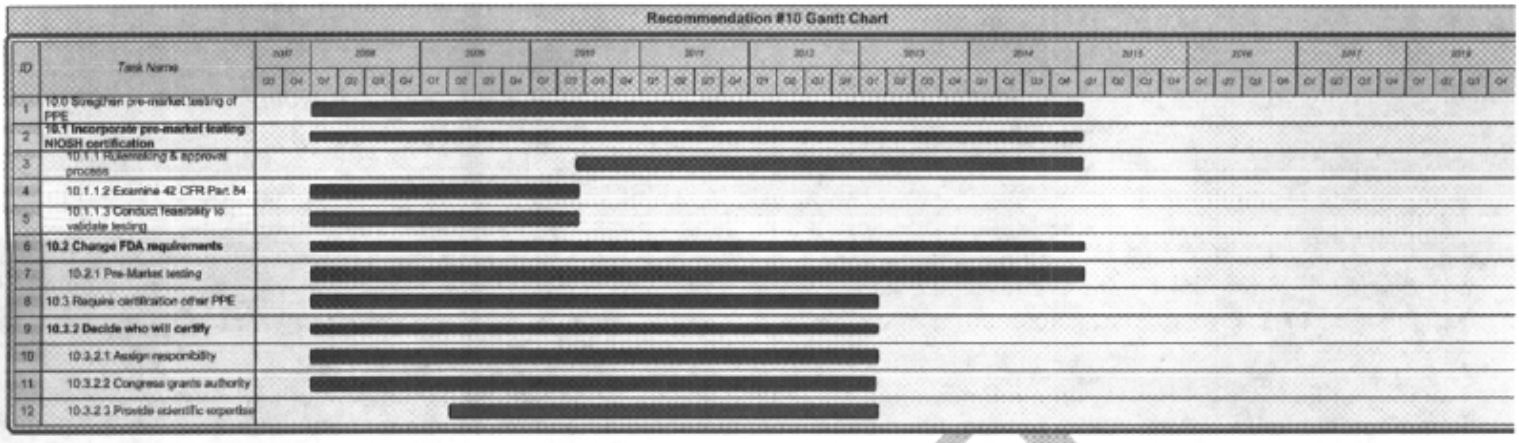
IOM Recommendation #10

PPT Program Response




Recommendation #10 Gantt Chart
ID
Task Name
10.0 Strengthen pre-market testing of PPE
10.1 Incorporate pre-market testing NIOSH certification
10.1.1 Rulemaking & approval process
10.1.1.2 Examine 42 CFR Part 84
10.1.1.3 Conduct feasibility to validate testing
10.2 Change FDA requirements
10.2.1 Pre-Market testing
10.3 Require certification other PPE
10.3.2 Decide who will certify
10.3.2.1 Assign responibility
10.3.2.2 Congress grants authority
10.3.2.3 Provide scientific expertise

IOM Recommendation # 11: Strengthen Post-market Evaluation of PPE for Healthcare Workers (Chap 5, p 166)

NIOSH, FDA, and other relevant agencies and organizations should support and strengthen adverse event reporting and post-market evaluation studies and surveillance regarding the effectiveness of PPE used by healthcare workers.

PPT Program Plan in response to IOM Recommendation # 11

11.1 Workplace effectiveness studies
- 11.1.1 Continuous evaluation of effectiveness of PPT Program recommendations and guidance in healthcare in collaboration with NIOSH, CDC, and others.

11.2 Head-to-head comparison studies of the efficacy of PPE to allow the employer and wearer to compare and evaluate products
- 11.2.1 Efficacy studies related to PPT use and effectiveness should be conducted in collaboration with other NIOSH programs, 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 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 ** Near and long term opportunities exist for evaluation and surveillance projects.

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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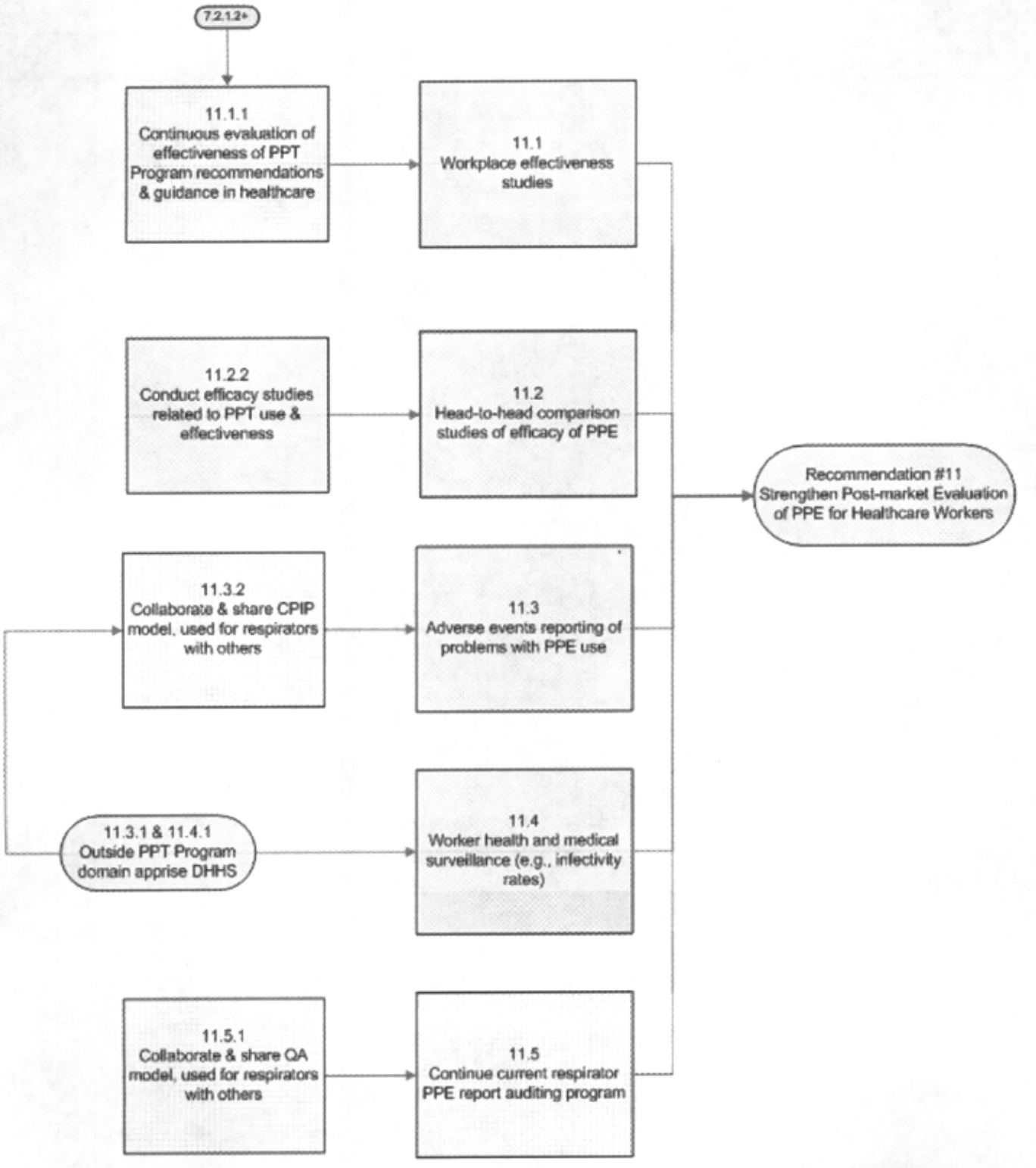
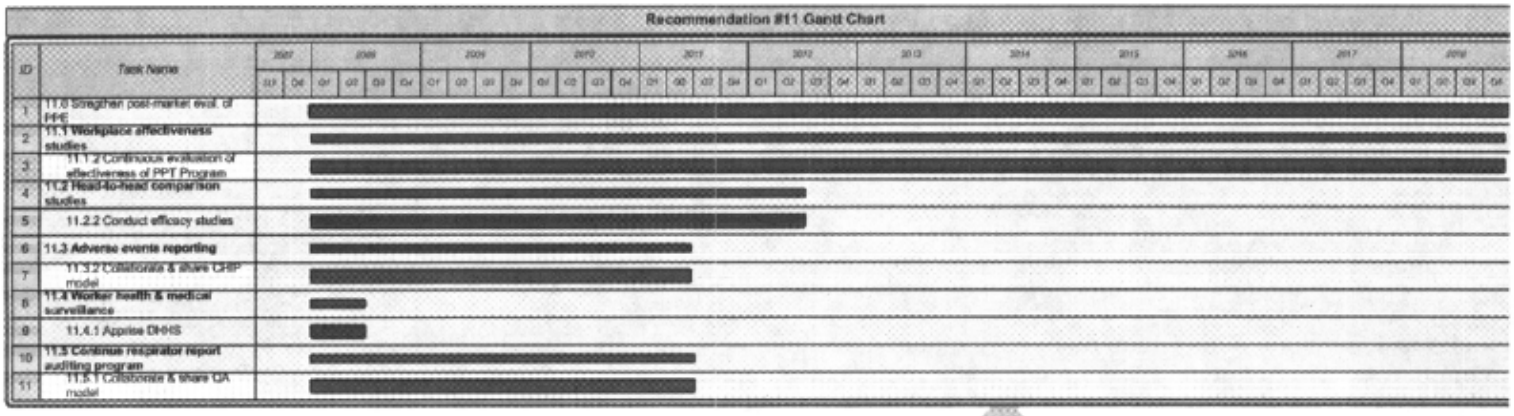
IOM Recommendation #11

PPT Program Response




Recommendation #11 Gantt Chart
ID
Task Name
11.0 Strengthen post-market eval. of PPE
11.1 Workplace effectiveness studies
11.1.2 Continuous evaluation of effectiveness of PPT Program
11.2 Head-to-head comparison studies
11.2.2 Conduct efficacy studies
11.3 Adverse events reporting
11.3.2 Collaborate & share CHIP model
11.4 Worker health & medical surveillance
11.4.1 Apprise DHHS
11.5 Continue respirator report auditing program
11.5.1 Collaborate & share OA model

IOM Recommendation # 12: Coordinate Efforts and Expand Resources for Research and Approval of PPE (Chap 5, p 166-167)

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

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 Departments of Defense, Health and Human Services, Homeland Security, 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 for PPT research, development and investigative testing beyond respirator issues. 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.

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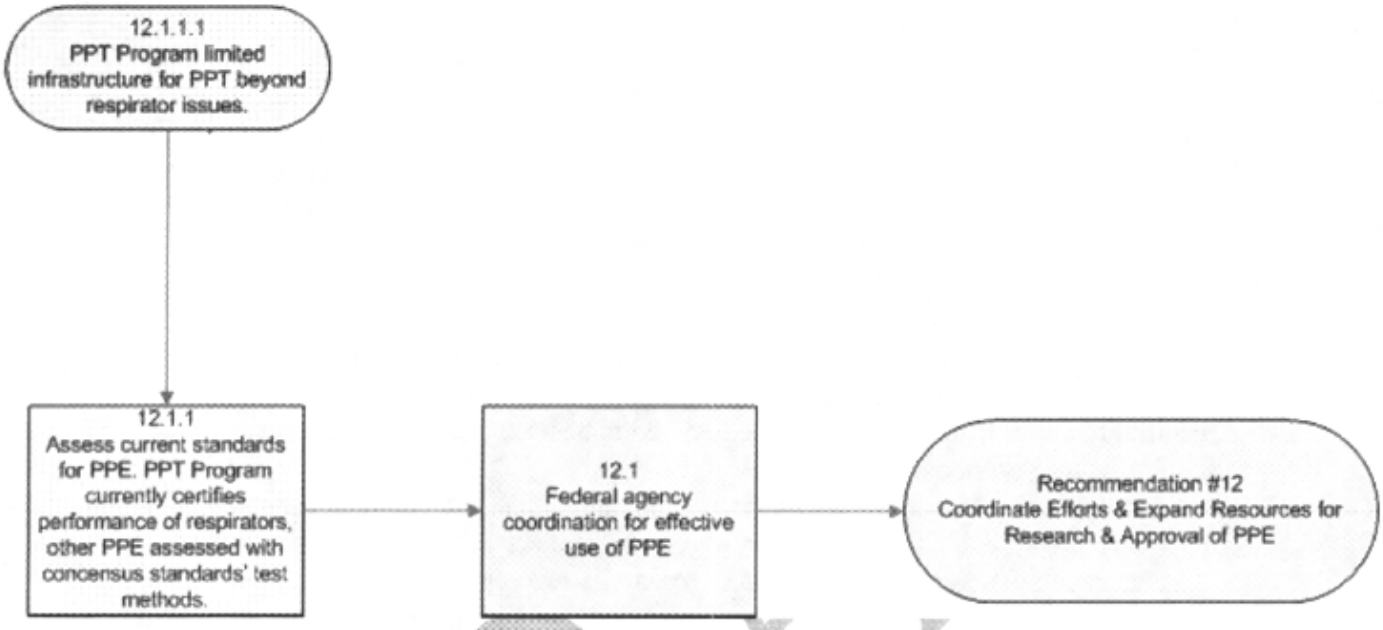
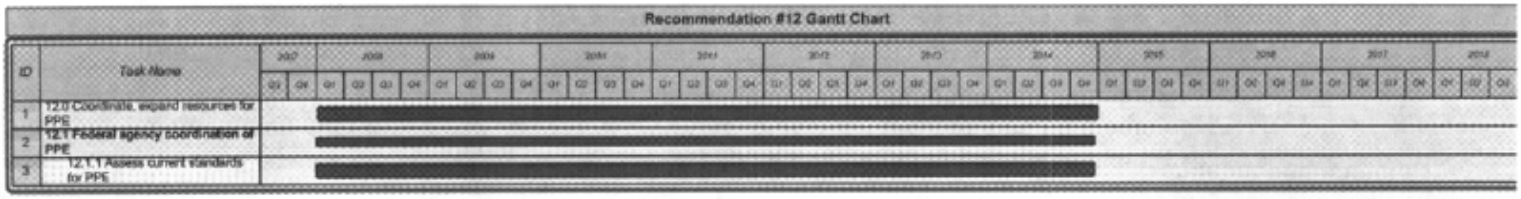
IOM Recommendation #12

PPT Program Response




Recommendation #12 Gantt Chart
ID
Task Name
1 12.0 Coordinate, expand resources for PPE
2 12.1 Federal agency coordination of PPE
3 12.1.1 Assess current standards for PPE

PPT Program Plan in response to IOM Additional Issues # 13

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.

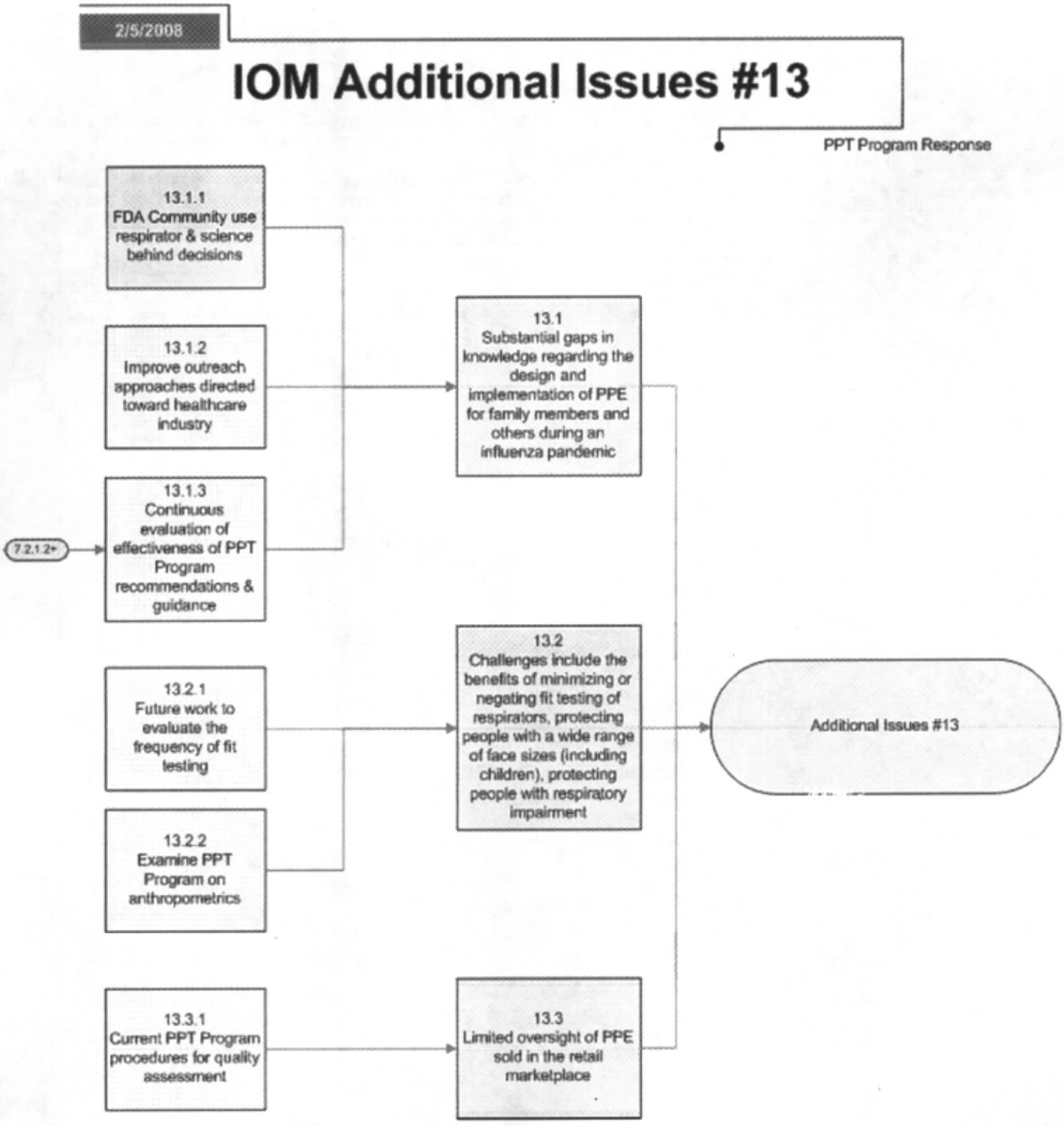
13.2 Challenges include the benefits of minimizing or negating fit testing of respirators, protecting people with a wide range of face sizes (including children), protecting people with respiratory impairment.

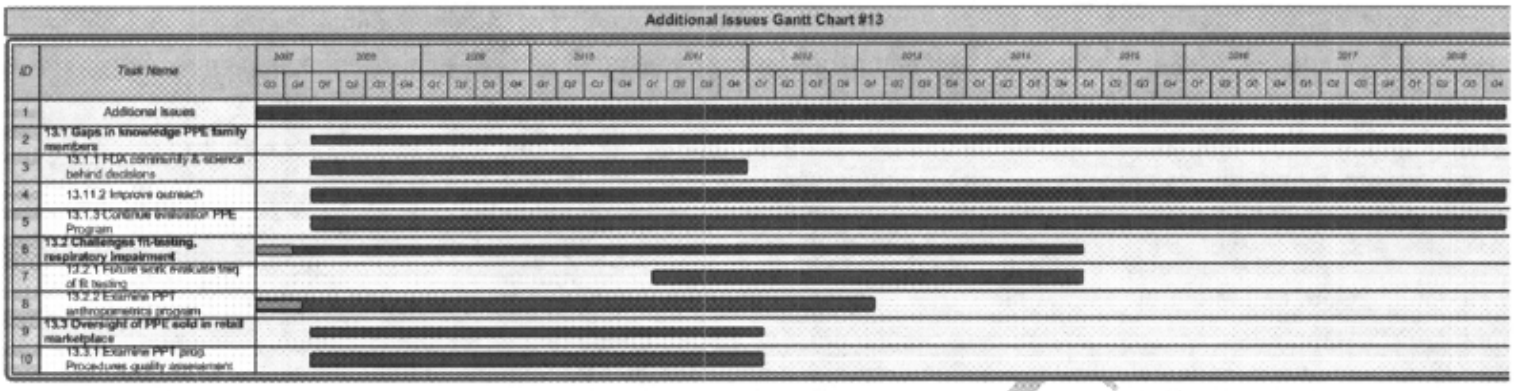
13.2.1 Describe future work to evaluate the frequency of fit testing: Reference P.

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.


2/5/2008
IOM Additional Issues #13
PPT Program Response
13.1.1 FDA Community use respirator & science behind decisions
13.1.2 Improve outreach approaches directed toward healthcare industry
13.1.3 Continuous evaluation of effectiveness of PPT Program recommendations & guidance
7.2.1.2+
13.1 Substantial gaps in knowledge regarding the design and implementation of PPE for family members and others during an influenza pandemic
13.2.1 Future work to evaluate the frequency of fit testing
13.2.2 Examine PPT Program on anthropometrics
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
13.3.1 Current PPT Program procedures for quality assessment
13.3 Limited oversight of PPE sold in the retail marketplace
Additional Issues #13


Additional Issues Gantt Chart #13
ID
Task Name
1 Additional Issues
2 13.1 Gaps in knowledge PPE family members
3 13.1.1 FDA community & science behind decisions
4 13.11.2 Improve outreach
5 13.1.3 Continue evaluation PPE Program
6 13.2 Challenges fit-testing, respiratory impairment
7 13.2.1 Future work evaluate freq of fit testing
8 13.2.2 Examine PPT anthropometrics program
9 13.3 Oversight of PPE sold in retail marketplace
10 13.3.1 Examine PPT prog Procedures quality assessment

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