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

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Historical documents available at NIOSH Docket 129
http://www.cdc.gov/niosh/docket/NIOSHdocket0129.html

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

Subsequently, the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) requested the Institute of Medicine (IOM) of the National Academies (NA) examine the issues regarding PPE for healthcare workers in the event of pandemic influenza. The IOM issued a report, Assessment of Pandemic Preparedness and the associated PPE needs for Healthcare Workers (2007) in September 2007 to provide recommendations to NPPTL. In July 2009, in response to a request from the Centers for Disease Control and Prevention and the Occupational Safety & Health Administration, an ad hoc committee of the Institute of Medicine (IOM) was formed to conduct a study and issue a letter report to the CDC director and Assistant Secretary for Occupational Safety and Health by September 1, 2009. The committee provided recommendations regarding the necessary personal protective equipment (PPE) for healthcare workers in their workplace against the novel influenza A (nH1N1) virus. Issues to be addressed to the extent feasible given available evidence and within the timeline for this letter report include: the potential for exposure to the nH1N1 virus among healthcare workers, which groups of workers are at risk, which patient care activities pose a risk of exposure and what degree of risk, and what is known and what is unknown about transmissibility, severity and virulence of the current virus and how transmissibility might change. The committee based its recommendations on the available current state of scientific and empirical evidence about nH1N1 virus, as well its expert judgment. Economic and logistical considerations regarding PPE equipment were not to be addressed in the letter report. In determining the appropriate PPE for the U.S. healthcare workforce, attention was given to the current PPE guidance documents offered by the CDC and by the World Health Organization for novel H1N1 influenza and for seasonal influenza.

This plan responds the recommendations provided by the IOM in both reports.

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

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

The IOM report, Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report, September 2009, identifies three research related recommendations:

- Resolve the unanswered questions regarding the relative contribution of various routes of influenza transmission

- Fully explore the effectiveness of personal respiratory protection technologies in a variety of clinical settings through randomized clinical trials, and
- Design and develop the next generation of personal respiratory protection technologies for healthcare workers to enhance safety, comfort, and ability to perform work-related tasks.

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

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

This plan summarizes the recommendations and the actions planned for the next five years to address the recommendations in the main document. NIOSH Docket 129 contains the full action plan and appendices [http://www.cdc.gov/niosh/docket/NIOSHdocket0129.html]. Appendix A is the most recent version of the more detailed action plan which describes the research needs in greater detail over a ten year timeline. Appendix B provides an overview of the NIOSH Cough Study described in Appendix A. Appendix C provides the response to the comments submitted to NIOSH Docket 129 on this subject.

Recommendation 1.1: Understanding influenza transmission

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

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

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

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

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

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

Summary: Clinical research to explore the effectiveness of respiratory protection in a variety of clinical settings and to measure the amount and size of airborne particles containing influenza virus in a hospital will be conducted to resolve unanswered questions regarding the contributions of various routes of influenza transmission.

a. During the 2008 influenza season, healthcare workers in a hospital emergency department wore personal aerosol samplers that collect airborne material from the environment while they worked. Stationary aerosol samplers were also placed in the waiting rooms, reception area and two exam rooms. Preliminary results indicate that influenza virus was detected in 3 of 14 personal samplers and 10 of 98 stationary samplers, and that 50% of the virus was on particles less than 4 µm in diameter (these particles are small enough to stay airborne for half an hour or more and to be drawn deep into the lungs). This work should continue and be expanded across state-based surveillance programs where possible.

b. Implement an approved but unfunded project using a human experimental influenza model to study modes of transmission: http://www07.grants.gov/search/search.do?&mode=VIEW&flag2006=false&oppId=44491

c. Augment the already-approved project by adding studies using the human experimental influenza model to evaluate efficacy of surgical masks and various levels of respiratory protection to prevent transmission of influenza.

d. Conduct a multi-center randomized controlled trial of respiratory protection vs. surgical mask in collaboration with the Veterans' Administration. The study would evaluate the real-world effectiveness of respiratory protection as compared to surgical masks in preventing transmission of influenza to healthcare workers in ambulatory care settings. This investment would allow expansion of a project currently under development at the VA to enough sites to have the power to collect informative data over a limited number of influenza seasons.

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

Summary: Simulate the exposure of a healthcare worker to an infectious aerosol – A simulated exam room is being created with a cough aerosol simulator (simulating a

coughing patient with influenza) and a breathing mannequin (simulating a healthcare worker) to test how well healthcare workers are protected from cough-generated aerosols. The breathing mannequin can be outfitted with a mask or respirator to simulate different types of respiratory protection. As part of this work, the viability (infectivity) of a surrogate laboratory strain of influenza will be studied. Experiments are planned to determine the viability of the virus in an aerosol and the effect of capture in the sampler on virus viability.

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

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

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

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

Finally, additional research is needed to improve the understanding of how human factors and behavioral issues related to the ease and effectiveness of PPE use for extended periods of time and during diverse work environments affect PPE use and compliance.

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

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

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

a. Establish an extramural PPE Center of Excellence (COE) to research the use and usability of PPE, to include integration of various types of PPE. This initiative will include substantial workplace studies to demonstrate use and usability of various PPE in a variety of healthcare settings. This COE will

enhance knowledge regarding the barriers to PPE use (including psycho-social issues and safety culture), comfort and fit of PPE, and identify research and training gaps in the healthcare industry.

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

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

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

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

a. The current Demonstration and Sentinel Surveillance System pilot initiative will result in a consistent data gathering approach to understanding and assessing PPE availability and use in the healthcare environment. The PPE component of this system is being integrated into an existing healthcare monitoring system at Vanderbilt University.

b. An existing contract with the California Dept. of Public Health to assess policies and procedures for respirator use for influenza among healthcare workers in acute care facilities and to assess knowledge/attitudes and beliefs about respirator use among healthcare workers will be expanded to 5 additional states in the fall 2010 influenza season.

c. The National Health Interview Survey (NHIS) Occupational Health Supplement could include questions to workers which could provide information regarding PPE use across industry sectors relative to influenza preparedness. This information would provide the PPT Program knowledge regarding national PPE estimates, PPE availability and use. Previous estimates to add PPE questions to this survey were approximately $1.2 million.

d. PPT Supply Research is necessary to address availability and supply issues regarding PPE availability for the nation.

e. Initiate an extramural RFA to conduct research to establish the economic case for PPE for influenza preparedness. The economic impact of using and not using PPE will provide the data necessary to establish the need for PPE.

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

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

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

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

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

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

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

ACTIVITY 1.3.1: Research to develop and test PPE.

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

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

offer important information on fomite-related issues and also allow for the quantification of subsequent decontamination effects on the respirator.

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

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

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

Summary: Relative performance of respirators is not tested as part of the NIOSH certification program.

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

b. Initiate an extramural RFA to conduct comparative testing on various NIOSH certified particulate respirators, non-NIOSH certified particulate respirators, and surgical masks to enable users to make more informed decisions relative to the performance of available products.

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

Summary: Respirators used in healthcare settings were not originally designed for this particular venue. Therefore, there are features of respirators that do not necessarily lend themselves well to the healthcare environment. Research will be conducted to address system integration requirements for healthcare workers.

a. The PPT Program, in conjunction with the Veterans' Health Administration (VA) and academia, initiated the Project Better Respirator Equipment and Technology for Healthcare Employees (BREATHE). Currently in its developmental stages, this endeavor will first bring together a working group to address respirator characteristics germane to healthcare workers (e.g., speech intelligibility, visibility, hearing, etc.) with the goal of identifying features that would enhance respirator performance in the healthcare setting. The second stage of this project will consist of presenting the recommendations to respirator manufacturers with

the intent of developing a respirator that is designed specifically with the healthcare worker in mind.

b. Initiate an extramural RFA to address research related to HCW PPE integration into an ensemble.

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

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

a. Develop an extramural PPT Center of Excellence to address research related to new materials and innovative technologies to address comfort (e.g., nano-fiber filter media with reduced airflow resistance, thermoelectric coolers, small fans, thermal compression devices, etc) and fit of PPE as well as technologies to improve the ability to communicate while wearing PPE. New materials and innovative technologies that will obviate the need for initial and annual respirator fit testing (e.g., shape memory polymers, visual indicators of fit, adhesives, encapsulated gels, etc.) will also be part of this initiative.

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

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

a. Intramural research to assess innovative fit test methods (e.g., infrared camera and ultrasound technologies) can be expanded within the PPT Program. Additional funding will be used to conduct pilot human subject testing of these innovative technologies

b. Initiate an extramural RFA to conduct research to improve upon current fit test methods to make them less onerous and costly to the employer. The development of simpler and more efficient fit test methods amenable to "just-in-time" fit testing would reduce burden upon employers and increase surge capacity for hospitals in emergency situations.

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

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

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

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

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

a. *Continue development of the NIOSH Protective Clothing Laboratory and develop an action plan for addressing priority research for healthcare workers.*
b. *Increase intramural initiatives to provide the research to fill gaps and reduce the limitations of current test methods and protocols in support of the overall Project BREATHE initiative. Clinical and laboratory-based test methods - validated against clinical outcomes - are needed in the areas of safety/effectiveness (including fomite reduction), integration with occupational activities (including usability, communication, equipment compatibility, etc.), comfort and tolerability.*
c. *Initiate an extramural RFA to conduct research to develop and correlate PPE test methods for communications (e.g., hearing/speech intelligibility), comfort, tolerability, usability, wearability, safety (e.g., fomite reduction) etc against clinical outcomes.*
d. *Collaborate with the VA and the private sector to expedite research leading to prototype designs that meet the 28 features identified by Project BREATHE working group. This research will lead toward the development of a respirator for healthcare workers with improved communications, tolerability, comfort and fit.*

ACTIVITY 1.3.3: Research to conduct PPE evaluations.

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

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

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

Summary: The IOM report states: "The development and implementation of certification processes should be explored by NIOSH [PPT Program] and the Food

and Drug Administration (FDA), with certification testing occurring in the NPPTL laboratory or by a process determined to be best suited for increased pre-market testing." As stated in PPT IP 1.3.1.1, a workshop similar to the PPE for HCW workshop will be organized by IOM to address options for PPT certification. The contract was awarded in August 2009, and work has begun to establish a committee to explore certification of non-respiratory PPE. The IOM currently is planning to conduct several case studies regarding certification of equipment prior to conducting the workshop and preparing the report. A spring 2010 workshop is in the planning stages.

FY 10 PPT Program Activities and Projects Related to Recommendations

The PPT Program has identified the FY10 PPT activities that support this recommendation. This diverse portfolio of research addresses critical aspects of the research gaps identified above in action steps 1-1, 1-2, and 1-3. All of these research activities are conducted by our intramural staff in collaboration with various partners and stakeholders. Several projects work closely with the various American Society for Testing and Materials (ASTM) International, International Organization for Standardization (ISO), and National Fire Protection Association (NFPA) committees to transition PPT intramural program outputs into recognized standards and test methods. Project BREATHE cuts across several of the research gaps by seeking to develop a respirator optimized for the healthcare sector featuring better integration with other PPE, less job interference, better fit, and improved comfort. Several projects are focused on understanding critical issues related to concerns of a possible respirator shortage caused by a pandemic. For example, one project involves collaboration with the Department of Defense (DoD) Air Force research lab (AFRL), FDA and several universities with funding provided by the DoD Technical Support Working Group (TSWG) to study decontamination/reuse of FFRs. Establishing a better understanding of respirator fit and performance are the goals of several other projects. All program activities related to this plan can be located at the following link: http://www.cdc.gov/niosh/programs/ppt/projects.html. Approximately $2 million discretionary funds currently are dedicated in FY10 to support these initiatives.

Appendix A: PPE for HCW Action Plan-081908.doc Docket# 129 *(Refer to Mar 09)*

Refer to "Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan to address Actions for the next 5 years", dated March 27, 2009. (Appendix A has not been revised)

Appendix B: Respirator & Surgical Mask Efficacy from Cough Aerosols *(Refer to Mar 09)*

Refer to "Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan to address Actions for the next 5 years", dated March 27, 2009. (Appendix B has not been revised)

Appendix C: Response to NIOSH Docket 129 Comments *(Refer to Mar 09)*

Refer to "Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan to address Actions for the next 5 years", dated March 27, 2009. (Appendix C has not been revised)

Appendix D: List of Acronyms *(Refer to Mar 09)*

Refer to "Personal Protective Equipment (PPE) for Healthcare Workers (HCW) Action Plan to address Actions for the next 5 years", dated March 27, 2009. (Appendix D has not been revised)

Appendix E: Recently Funded Activities

Influenza Research Agenda: Synopsis of 5 "Fast-Track" Projects for the Federal Interagency Committee on Indoor Air Quality (CIAQ)

I. Virologic evaluation of the modes of influenza virus transmission among humans

Understanding the risk of influenza transmission among persons is critical for the development of evidence-based infection control guidance for healthcare, household and other settings for seasonal and pandemic influenza. However, the modes and relative contribution of different modes of influenza transmission during symptomatic viral shedding are unknown. This lack of information greatly handicaps the development of evidence-based seasonal and pandemic influenza prevention recommendations.

CDC will seek proposals for conducting studies in humans to assess the relative contribution of different modes of influenza transmission among humans. Such modes include contact transmission, large droplet transmission and droplet nuclei transmission. Study designs may include: (1) a human influenza virus challenge study where some volunteers are infected with a wild-type influenza virus strain via intra-nasal inoculation and then non-ill persons are exposed to ill persons or (2) exposure of humans to a person naturally infected with influenza virus. Proposals for conducting human challenge studies must have prior experience in conducting such studies and access to good manufacturing quality (GMQ) influenza virus that is acceptable for use in humans.

All of the following objectives must be addressed:
(1) Methods to recruit influenza infected persons for the ill group and to identify persons for the exposure group who are antibody negative to influenza viruses and 18-49 years of age, not pregnant and have no underlying health conditions.
(2) Assess the risk of influenza transmission from ill persons with laboratory confirmed influenza infection to antibody negative (exposed) persons in the same room and within 6 feet of the ill person. Those exposed should be divided into at least 3 different groups to assist in understanding the modes and relative contribution of different modes of influenza transmission: a) Control group of exposed persons able to touch their face and without any personal protective equipment (PPE). b) Exposed persons who are not able to touch their face, but who have no mask, respiratory or other PPE to block respiratory droplets or droplet nuclei, and c) Exposed persons with either a mask or N95 respirator or equivalent. If a respirator is used, fit testing should be conducted in advance to ascertain fit.
(3) Assess quantity of virus shed from infected persons on the day of exposure and assess the amount of viable virus detected in the air and on non-porous surfaces in the room. This project would provide information on the relative contributions of different modes of influenza transmission in a controlled setting and help to provide rationale for guidance to emphasize prevention efforts directed toward prevention of direct or indirect contact, large droplets, and/or airborne/droplet nuclei.

II. Persistence of influenza virus in aerosols

Influenza is thought to be transmitted among humans via infectious secretions transferred by touch and by large ballistic drops produced during coughing and sneezing. Influenza may also spread through the inhalation of small aerosol particles generated during coughing and breathing, but considerable controversy exists about the contribution of this route. Several studies have concluded that airborne transmission of influenza is a key pathway. However, other investigators maintain that airborne particles are not a significant means of infection.

The purpose of this study will be to develop methodologies to assess the viability of airborne influenza virus in public locations such as healthcare facilities. Previous results support the possibility that influenza can be transmitted by the airborne route. In the proposed studies volunteers with ILI will cough into a medical spirometer modified to include a bioaerosol sampler and/or the NIOSH two-stage cyclone bioaerosol sampler. The size-segregated samples will then be tested for infectious virus by the standard viral plaque assay to determine the number of viable viruses, and will also be analyzed for influenza A&B and specifically for H1N1 influenza using qPCR. Virus viability will be determined as the number of PFU/qPCR viral particle number.

A subsequent study will be performed in the urgent care clinic. Patient volunteers with ILI will be administered rapid-flu test. If the patient is confirmed to have influenza, aerosol samplers will then be placed in the treatment room before the patient enters, and will collect airborne particles while the patient is present. Samplers will be located near the patient examination table and approximately six feet from the patient and facing the examination table. Immediately after the patient leaves the room the collected samples will be processed for viable virus. A second part of the project will consist of a survey of medical procedures using real-time instrumentation to characterize the size and number of particles produced during potential aerosol generating procedures. Procedures identified as aerosol-generating will be examined in more detail using the NIOSH two-stage bioaerosol sampler. Aerosols will be collected during procedures on patients with ILI or confirmed influenza or other respiratory illnesses.

The data collected in this project will help to gain a better understanding on how much viable influenza virus can be found in the air in healthcare setting and provide evidence based information for making decisions about the level of PPE precautions that HCWs should be using.

III. Effectiveness Comparison of N95 respirators and surgical masks against influenza and influenza-like illness in healthcare workers

Despite widespread use of respiratory protective equipment in the U.S. healthcare workplace, there is very little evidence that respirators protect healthcare workers from airborne infectious diseases. Scientific investigation of this issue has been quite complicated, primarily because using respirators has become the standard of care for protection against airborne diseases, even without the evidence to support their use. The key question remains: How well do respirators protect healthcare workers (HCWs) against airborne infectious diseases? The answer to this important question has critical medical, public health, political and economic implications.

A prospective, non-blinded, cluster randomized, cross-over study will be conducted to assess and compare the effectiveness of respiratory protective equipment among HCWs in the outpatient setting. Subjects will undergo weekly nasopharyngeal swabs for PCR and viral culture. Positive cultures will be tested using the IBIS PCR method to identify known or novel influenza strains and other viral sub-types. The null hypothesis to be evaluated by this study is that the incidence of influenza and other respiratory infections will not be different among healthcare workers who wear respirators or surgical masks for the duration of their work shifts or follow CDC respiratory protection guidance for influenza.

This trial is very much needed effectiveness research that will have the statistical power to allow a comparison between N95 respirators and surgical/medical masks for worker protection against illness caused by influenza and other respiratory infections. If N95 respirators are shown to be superior, it would support current guidance. If there is no difference, it would support the use of less expensive surgical/medical masks (which do not require fit testing) for routine patient contact. The primary outcome to be measured is incidence of influenza; the secondary will be incidence of all respiratory infectious diseases.

IV. Airborne Influenza UV Inactivation and Proximity Detection Study

There is a current lack of understanding of the effectiveness of hand hygiene, cough etiquette and other non-pharmaceutical interventions (NPI). The purpose of this study is to describe the impact of UV irradiation on influenza virus inactivation and its relationship to human aerosolization patterns of pandemic H1N1 virus (H1N1v) and seasonal influenza infection in participants seen at an urban emergency department and in an intensive care setting. Specific objectives are to determine the particle size distribution and the quantity of viable airborne H1N1v and seasonal influenza viruses dispersed by symptomatic participants, to establish a spatial model of airborne H1N1v and seasonal influenza virus dispersal in clinical settings (1 meter vs. 3 meters vs. 6 meters), obtain information regarding the potential association of illness severity and risk factors to the degree of airborne virus dispersal (e.g., characteristics of "superspreaders"), and the effect of UV irradiation on viral aerosols like those generated by symptomatic individuals.

The results will be used to guide policymakers in the assessment of the airborne exposure risk to H1N1v. By collecting data on participants in an ED and ICU setting, we will be able to assess the true exposure to H1N1v and seasonal influenza virus in a real world setting. It is estimated that approximately 50 patients with H1N1v will have to ultimately be enrolled to reliably estimate the airborne dispersal patterns of influenza and to obtain information regarding potential associations of the scale of viral aerosols with severity of illness and underlying risk factors. Using those dispersal data, infectious aerosol recovery will be measured in the presence of UV irradiation to determine its effect on airborne virus survival. At the time of enrollment, demographics, medical history, including prior influenza and pneumococcal vaccination, and treatments prescribed, including antivirals, will be recorded. A nasopharyngeal swab will be obtained. The swab will be placed in viral transport medium and sent to our research laboratory for cell culture and reverse transcriptase-polymerase-chain-reaction (RT-PCR) testing for diagnosis of influenza A. The airborne dispersal pattern of H1N1v and seasonal influenza will be assessed by three six-stage Andersen air-samplers placed at 1 meter, 3 meters, and 6 meters distance from the participant. The stages of the Andersen sampler represent roughly the sections of the human respiratory tract (stage 1: >7μm, stage 2: 4.7-7.0μm, stage 3: 3.3-4.7μm, stage 4: 2.1-3.3μm, stage 5: 1.1-2.1μm, stage 6: 0.65-1.1μm). Therefore, detection of virus in particular stages allows a direct evaluation of the natural dispersal patterns. Hanks balanced salt solution will be used as adhesion medium for viral particle carriers. This has been shown to not interfere with virus recovery (based on investigator's preliminary data). Subsequent quantitative cell culture and RT-PCR will be used to determine the amount and proportional viability of airborne virus collected in the different particle sizes. In the ED the participant will be asked to remove any source control equipment such as face masks during the 20 minute sampling sessions.

V. Evaluation of the impact of work or school exclusion criteria on the spread of influenza and influenza-like-illness

Social distancing measures are a key pandemic planning strategy to reduce the transmission of influenza, particularly in the absence of adequate amounts of effective vaccine. One measure recommended during the 2009 H1N1 influenza pandemic as well as during seasonal influenza is for persons with ILI (fever plus cough or sore throat) to stay home from work or school until fever has been gone for at least 24 hours. However, there is little current information regarding the benefits of such a strategy, particularly given that approximately 40% of persons with influenza will not have a fever. The effectiveness of different durations of exclusion from work or school among ill persons in preventing influenza transmission and other causes of ILI has not been evaluated. Because respiratory illnesses are very common (approximately 6 per year in children and 1-3 per year in adults), exclusion policies can impose substantial economic and social restrictions on ill persons.

The purpose of this research is to determine the effectiveness of different exclusion criteria in preventing influenza-like-illness (ILI) and laboratory-confirmed influenza in either healthcare or non-health care work settings or school settings. The objectives of the studies are to assess the effectiveness of illness exclusion criteria to prevent illnesses in work and/or school settings.

CDC will seek proposals to assess the effectiveness of exclusion criteria for ILI that are randomized studies with groups assigned to different exclusion criteria versus standard practices and include active prospective surveillance for laboratory confirmed influenza and testing for other respiratory viruses as well. In addition to differences in exclusion criteria (e.g. no exclusion criteria vs. exclusion for a set number of days for any acute respiratory illness vs. exclusion only during fever of febrile illness, etc.), inclusion of other non-pharmaceutical interventions may be included.