1. Comment:

Name
Peter A. Langes

Organization
Berkerley Building Education Center

Email

Address
USA

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

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

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

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

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

Peter Langes

Response:

Dear Mr. Langes:

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

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

2. Comment:

Thank you for providing an opportunity to provide input regarding PPE for HCWs Action Plan - NIOSH Docket #129.

The Council of Canadian Academies (CCA) formed an expert panel on influenza & personal protective respiratory equipment last year and the expert panel report was published December 2007.

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

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

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

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

Bob Janssen, MSc, ROH
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Prevention Policy & Regulation Review Department
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CONFIDENTIALITY DISCLAIMER

Response:

Dear Mr. Janssen:

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

3. Comment:

Good Afternoon,

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

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

Lines 57-65: True indeed medical face masks do not provide the same level of protection as a N95, but the reality is that nine times out of ten our healthcare workers are choosing a surgical or procedure mask in lieu of an N95. They are relying on these products to provide the protection they need for the majority of the things they are exposed to. Although they are not deemed personal protective equipment by this group, they are looked at as such by the end user. I challenge this group to reconsider the position taken on medical face masks or work to change the regulations to ensure that an N95 is chosen every time a mask is needed.

Lines 508-516: I, again, challenge your group to expand your definition of PPT to include medical face masks. If they aren't providing the protection today that warrants their inclusion in that category then we need to create new product requirements that translate into their being included into PPT and manufacturers need to adjust accordingly.

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

Humbly Submitted,

Jennifer Jones
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Convertors Marketing
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Response:

Dear Ms. Jones:

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

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

4. Comment:

Dear NIOSH:

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

Regards,

Bill Kojola
Industrial Hygienist
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Response:
Dear Mr. Kojola:

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

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

2) Critically examine the aerosol particle exposure 3 foot vs 6 foot rule…

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

3) Prioritize the planning and carrying out of an effectiveness assessment of antimicrobial respirator technology….

This is the goal of the action plan to provide NIOSH with a strategy and road map in which to proceed. We realize that this is an important research and that it needs to be done and will eliminate 'possible' project from the action plan. This change will be reflected in recommendation 5.

4) Develop a comprehensive research plan with the overall objective of developing some measure of an "assigned protection factor" for respirators used to protect wearers against airborne infectious agents….

NIOSH is focusing on ways to develop sound scientific evidence from which to harmonize PPE standards that includes the following: protecting the health and safety of respirator users, providing an assurance to the user that the equipment will afford the degree of protection required, and considering the person who is being required to wear the protective device to accomplish their job. These concerns are being addressed in recommendations 2, 5 and 7.

5) Complete as soon as possible the total inward leakage (TIL) certification requirements for respirators…

Currently, TIL has made its way out of NIOSH and down to HHS to start the rulemaking process.

6) Assess economics and level of fit/protection of elastomeric respirators (equipped with particulate filters) versus filtering facepiece respirators for use by healthcare workers who provide care for pandemic flu patients…

We currently have a study underway to examine fit (see http://www.cdc.gov/niosh/blog/nsb042108_respiratorfit.html). The study deals mostly with N95FFR types of respirators; however, we plan on doing a small study with elastomeric as well. This is being done in recommendation 5.

7) Collaborate with other divisions in NIOSH to examine the wide range of options for controlling worker exposure to pandemic influenza and other infectious agents…

We are working with Emergency Planning and Response Office (EPRO) in providing up-to-date information on pandemic influenza research that can be accessed via the web (http://www.pandemicflu.gov/). This process has started and is defined in recommendation 1.

8) Conduct research to determine the maximum use time for filtering facepiece respirators...

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

9) Develop a health care PAPR…

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

one area. This effort will result in significant improvement in PAPR requirements and the first formal incorporation of CBRN requirements into the regulations and allow for the development of a healthcare PAPR.

10) Initiate, coordinate, and catalyze the work of other segments of NIOSH outside of NPPTL and other federal government agencies around this action plan...

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

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

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

12) We found the organization of this document hard to read and at times repetitious…

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

5. Comment:

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

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Response:

Dear Ms. Jones:

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

6. Comment:

Comments from APIC President, Janet Frain, are attached.

Lisa Tomlinson
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Response:
Dear Ms. Tomlinson:

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

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

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

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

4) You said, "If research studies to define risk levels for influenza during workplace activities in various locations are outside the scope of NIOSH research, it would be helpful to indict if such studies are being done." The PPT Program has established a work group within NIOSH to identify areas of overlap to confront potential misconceptions in terms of NIOSH capabilities, identify what non-NIOSH entities should/can do, and discuss what's possible in the future (recommendation 1). We also

plan on establishing lines of communication with other organizations to keep abreast of on going and plan research in the PPT area.

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

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

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

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

8) You said, "The NIOSH proposal for 'active surveillance of healthcare facilities that would assemble information relevant to a number of issues pertinent to the spread and preventive practices of influenza', which would include collecting information on 'use of respirators, infection control practices, rates of infection, and infection patterns that may distinguish different types of healthcare workers', would be very time-consuming and costly." True, surveillance is a costly and time consuming business; but in order to effectively manage and direct the PPT Program NIOSH needs a better PPE surveillance

program to identify priorities, trends and emerging issues associated with the use of PPE in the workplace. Information gathered will be used to establish a baseline on PPE usage, develop performance measures, sharpen the focus of NIOSH research, and aid in the development of a more effective and active dissemination program (recommendations 1 and 7).

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

7. Comment:

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

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

Respectfully,

Kirk Bantz, RHSO

Response:

Dear Mr. Bantz:

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

8. Comment:

Good morning,

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

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

Irwin Moyna, Director
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Response:

Dear Mr. Moyna:

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

9. Comment:

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

Janice Comer Bradley, CSP
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Response:
Dear Ms. Comer Bradley:

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

1) General comment 1 – Prioritization within the Action Plan

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

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

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

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

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

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

4) Request clarification on item on Page 3, line 96. Does it refer to wearer comfort in high humidity environments, or the efficacy of the filtration system in these environments?

This was a general question that showed up in several recommendations. It deals mostly with comfort and fit of the respirator in humid environments, as well as, the efficacy of the filter media.

5) These issues Section 2.2 (Page 18, line 682) are addressed by currently available respirators. The respirator program manager or person doing the selection must take these issues into account when selecting appropriate PPE. Recommendation #2 deals with

defining a set of evidence-based performance requirements or prescriptive standards for PPE to facilitate their design and development that optimally balances the cost, comfort, and degree of protection of PPE and enhances the compliance with their use in the field. The line that you referred to only was describing what was meant by 'Usability'.

6) The clause in Section 2.2.2.1.1 (Page 18, line 705), along with several others throughout the document, suggest an expansion of the scope of NIOSH activities …

Yes, that is correct. The NIOSH PPT Program is looking to expand and is seeking your comments as to how to proceed.

7) Respirators (Page 19, line 751) are design to last for long work days (12- 16 hours) typical in some heavy manufacturing industries…

While that is true, the study on page 19 is looking at N95FFR that would be used in an emergency such as a pandemic and available from the strategic stockpile. Data is still needed for these types of respirators.

8) Heavy manufacturing usage requires more durability (Page 20, line 774) than health care usage…

See response to item #5 above.

9) PPE manufacturers fully understand product costs and are continually searching to reduce costs …

NIOSH agrees but see response to item #5 above.

10) Page 24, line 892 this is a valuable program for resident physicians, and we recommend it be expand to include comprehensive training in the nature, selection, use and maintenance of respiratory devices in addition to proper fit testing…

Thank you for you support of this program. NIOSH is examining ways to improve and expand this program (recommendation 2).

11) Page 28, line 925 this activity regarding identifying technologies to improve fit should be a lower priority in the Plan…

Yes, the best policy now is to assure adequate respiratory protection is in place and that the program is complete and effective. But in order to move forward and plan for the future, NIOSH needs to be looking at new technologies now to start the internal processes as stated in recommendations 1 and 4.

12) We request clarification of (Page 28, line 953) the intent and scope of this question, as there are currently non-disposable respirators (ie eleatomeric respirators) available that can be decontaminated…

This mainly deals with decontamination of N95FFRs. Again, this is specific to if a pandemic were to occur and one may have to use a respirator more than what was originally intended.

13) The user seal check (Page 29, line 958) is important, as it requires the user to evaluate fit in a subjective way every time he dons the respirator…

Thank you for your comment and we have made a note about the user seal check cannot be a substituted for formal fit testing.

14) We are concerned that this statement (Page 29, line 971) implies that medical devices would be considered accessories to the respirator in the respirator certification process…

At this time, NIOSH doesn't plan on approving medical devices. This was meant more to stimulate research on better ways to improve communications between HCW and patients, etc. Thus, we are looking at new designs and engineering efforts in recommendation 4.

15) We disagree with the broad statement (Page 29, line 989). There are devices currently on the market that have been designed with healthcare sector specifically in mind…

This dealt with the PAPR specifically and how there is a need to have a low flow class. We will clarify this in the next write up.

16) Request clarification on colorimetric and innovative indicator as we don't know the meaning of these two items.

The descriptions of these two items were unintentionally left out and will be added in the next revision. Thank you for catching this. Colorimetric and innovative indicator refers to chemical reaction-based indicators that are used to produce reactions to individual, or classes of compounds. The reactions, such as visible color changes or other easily noted indications, are used to detect and give the PPE wearer a visual indication of exposure.

17) NIOSH should evaluate breathing resistance of N100 respirator against that of the N95 respirator covered with a surgical mask…

Thanks for the suggestion. One of the reasons we are looking at the N95s is because they are in the strategic stockpile, but your comment about N100 not creating physiological effects for users based on your experience is valuable (recommendations 4 and 5).

18) We disagree with this proposal (Page 53, line 1448) regarding incorporation of pre-market field testing in NIOSH certification for respirators.

This was just a suggestion and at this time NIOSH has no plans to do pre-testing of respirators. Thanks for you comment.

19) We object to this proposal (Page 53, line1461 certification for other PPE) for PPE currently addressed by consensus standards…

There is a strong push to look into certifying other types of PPE. It is an issue that we need to address more fully as discussed in recommendation 2.

20) ISEA supports Workplace effectiveness studies which determine the effectiveness of respiratory protection for protection against micro-organisms…

Thanks for your comment and we agree that reliable methods need to be developed for measuring concentrations and viability of micro-organisms inside and outside the respirator.

10. Comment:

Docket 129

SEIU
Stronger Together

May 27, 2008

NIOSH Docket No. 129
NIOSH Mailstop: C-34
Robert A. Taft Laboratory
1676 Columbia Parkway
Cincinnati, OH 45226

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

Dear Sir or Madam:

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

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

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Response:
Dear Mr. Borwegen:

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

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

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

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

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

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

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

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

(http://www.pandemicflu.gov/). This process has started and is defined in recommendation 1.

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

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

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

11) Develop mechanisms for involvement of health care workers and their unions in the aspects of this research plan where it will obviously be of significant benefit to outcomes. As we move forward with this action plan, we will continue our outreach efforts to involve and solicit information from the healthcare community through public meetings, focus group forums and conferences. These are being carried out in recommendations 6, 7 and 8.

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

11. Comment:

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

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Response:

Dear Ms. Olins:

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

1) You are concerned that the report assumes that NIOSH certified respirators should remain the minimal standard for respiratory protection during and influenza pandemic…

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

ideal characteristics that would be required for healthcare worker specific respirator. Also, NIOSH is researching the sterilization efficacy of a decontamination procedure for filter media and filtering facepiece respirators (recommendation 2).

2) You acknowledge the joint responsibilities of NIOSH and the FDA in certifying the manufacture and use of both masks and respirators. You note that the FDA has previously approved N95 type respirators for public use during an influenza pandemic without regard to the need for prior fit-testing. You want NIOSH to review the successful practice in Europe of certifying respirators for both filtration capability and facial fit without the need for fit-testing…

We plan to work with the FDA who currently oversees medical masks and focus on ways to develop sound scientific evidence from which to harmonize standards. Recommendations 2, 9 and 12 address these concerns. The NIOSH National Personal Protective Technology Laboratory and the University of Minnesota, School of Public Health, are hosting a "No Fit Test" Respirator Workshop to be held November 6, 2008 in Pittsburgh, PA to address some of the issues you raise. The workshop will focus on the nature and process of product innovation and development in negative pressure half-face piece respirators, to gauge the current "state-of-the-art," and to stimulate new designs and approaches for improved respirator fit. The results of the workshop will lead to a better understanding of how future NIOSH research can encourage ongoing development of better fitting respirators without compromising long-term protection (recommendations 4 and 5).

3) You are pleased that NIOSH/NPPTL did not limit their response to the IOM report to respiratory protection. You agree that a comprehensive review of PPE in healthcare settings is overdue including PPE utilized during both routine and emergency circumstances…

It is always important for PPE users to use PPE appropriate for the hazards to which they are exposed in accordance with published guidance, recommendations, and regulations. Under the Action Plan, NIOSH plans on establishing measures to assess and compare the effectiveness of PPE (recommendation 5), as well as, focusing on ways to develop sound scientific evidence from which to harmonize PPE standards (recommendation 2). Also, NIOSH is building a surveillance program to identify priorities, trends and emerging issues associated with the use of PPE in the workplace. Information gathered will be used to establish a baseline on PPE usage, develop performance measures, sharpen the focus of NIOSH research, and aid in the development of a more effective and active dissemination program (recommendation 1). As you reference, there are barriers (like unpredictable contacts between patients and HCW, the need for unimpeded communications and financial stress on the healthcare industry) to using PPE and the Healthcare Worker Action Plan addresses this through training and best practices (recommendations 7 and 8).