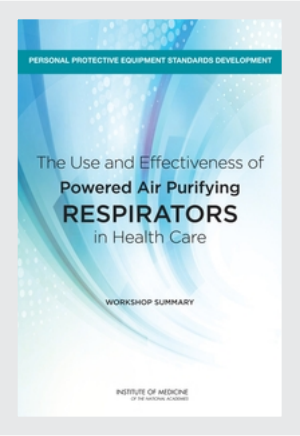

The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary

DETAILS

80 pages | 8.5 x 11 | PAPERBACK
ISBN 978-0-309-31595-1 | DOI 10.17226/18990

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The Use and Effectiveness of Powered Air Purifying RESPIRATORS in Health Care

WORKSHOP SUMMARY

Catharyn T. Liverman, Sarah B. Domnitz, and
Margaret A. McCoy, *Rapporteurs*

Board on Health Sciences Policy

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OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

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NOTICE: The workshop that is the subject of this workshop summary was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

This project was supported by Award #10002141 between the National Academy of Sciences and the United States Department of Health and Human Services Centers for Disease Control and Prevention. The views presented in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

International Standard Book Number-13: 978-0-309-31595-1
International Standard Book Number-10: 0-309-31595-6

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Suggested citation: IOM (Institute of Medicine). 2015. *The use and effectiveness of powered air purifying respirators in health care: Workshop summary.* Washington, DC: The National Academies Press.

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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This workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this workshop summary:

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Although reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the summary before its release. The review of this workshop summary was overseen by **LEWIS R. GOLDFRANK,** New York University School of Medicine; Bellevue Hospital Center and New York University Hospitals; and New York City Poison Center. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this

summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this workshop summary rests entirely with the rapporteurs and the institution.

Contents

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Introduction[1]

Protecting 18 million U.S. health care workers from infectious agents—known and unknown—involves a range of occupational safety and health measures[2] that include identifying and using appropriate protective equipment (CDC, 2014a). The 2009 H1N1 influenza pandemic and the 2014 Ebola virus outbreak in West Africa have called attention to the importance of personal protective equipment (PPE)[3] in different health care settings and have raised questions about how best to ensure appropriate and effective use of different kinds of PPE (such as respirators), not only to promote occupational safety but also to reduce disease transmission in general.

Since 2005, the National Personal Protective Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH) has sponsored the Institute of Medicine (IOM) Standing Committee on Personal Protective Equipment for Workplace Safety and Health.[4]

[1]The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants and are not necessarily endorsed or verified by the Institute of Medicine, and they should not be construed as reflecting any group consensus.

[2]Occupational safety and health programs rely on a well-established hierarchy of control measures aimed at eliminating a hazard or limiting exposures and related risks. This is done through engineering and environmental controls, administrative measures, and personal protective equipment (PPE) and work practices.

[3]PPE includes respirators, gloves, gowns, eye protection, and face shields.

[4]This committee provides a forum for discussion of scientific and technical issues relevant to the development, certification, deployment, and use of PPE, PPE standards, and related systems used to ensure workplace safety and health.

Additionally, NPPTL has sponsored multiple IOM reports on PPE, several of which focused on PPE for health care workers in the event of pandemic influenza (IOM, 2008, 2011). In mid-2014, NPPTL asked the IOM to convene a workshop, "The Use and Effectiveness of Powered Air Purifying Respirators in Health Care," to help prioritize and accelerate NIOSH activities to update certification requirements for powered air purifying respirators (PAPRs). Box 1-1 provides the statement of task for this workshop. A separate planning committee was appointed to organize the workshop, which brought together representatives from federal, state, regional, and local government agencies; health care institutions (including clinics and hospitals); professional associations; device manufacturers; and health worker unions.[5]

BOX 1-1
The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: A Workshop Statement of Task

An ad hoc committee will plan and conduct a workshop to explore the current state of practices and research related to powered air purifying respirators (PAPRs) and potential updates to PAPR performance requirements in 42 CFR Part 84. Presentations and discussions will highlight current health care practices using PAPRs and outline the research to date on the use and effectiveness of PAPRs in health care settings with a focus on the performance requirements. Research focus will include efficacy, current training, maintenance, supplies, and possible enhancements and barriers to use. Settings will include inpatient, clinic, nursing home, and community (home) settings. The workshop will also explore the strengths and weaknesses of using various approaches to health care PAPR standards (i.e., current standards, the International Organization for Standardization (ISO) respiratory protective device standards, or a consensus standard that could be incorporated by reference or introduced). Workshop participants will:

1. Present information on
    - why, where, and how PAPRs are being used in health care;
    - the measures and protections that need to be addressed to reduce exposures in health care;

[5]The planning committee attempted to include representatives of small and rural hospitals, nursing homes, and home health agencies in the workshop, but those they contacted reported that their institution is not currently using PAPRs.

- actions that need to be taken to ensure PAPRs are properly used in the health care setting, especially as part of the national pandemic preparedness;
- the real and perceived barriers to the use of PAPRs in the health care setting; and
- the benefits of PAPRs in health care settings.

2. Explore research and policy directions, including
   a. Research and/or policy activities with potential for removing or reducing the barriers (real and perceived) that may hamper the use of PAPRs in the health care setting. Include a focus on the option for a lower flow rate unit for health care workers and/or the option for a shorter life battery (e.g., 1-hour or 2-hour unit).
   b. Comments submitted on the review responses to the National Institute for Occupational Safety and Health (NIOSH) request for information (Federal Register Vol. 79, No. 50, pp. 14515-14517, CDC-2014-0005, Docket number NIOSH-272) and other pertinent information to discuss approaches to remove barriers to the use of PAPRs in health care.
   c. Strengths and weaknesses of various approaches to modifying the PAPR certification requirements, through
      - Use of current NIOSH standards and certification processes
      - Potential enhancements to the PAPR certification standard that could be incorporated in 42 CFR 84 to provide improved health care worker protection
      - Use of the ISO standards for the certification of health care PAPRs. Specific questions to be discussed regarding the ISO standards include
        - If the ISO standards can be incorporated by reference, what scientific studies are available to support the incorporation of the standards as currently drafted?
        - What scientific studies are needed to validate the draft standards to address these requirements?
        - What safeguards would be necessary to ensure the intended work rates are not exceeded?

The committee will plan and organize the workshop, select and invite speakers and discussants, and moderate the discussions. An individually authored summary of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

This workshop summary describes the presentations given and the topics discussed. Generally, all text included under a specific presentation is attributable to the individual presenter listed. The workshop discussions with the audience have also been captured throughout this summary. Some material has been rearranged to provide a better flow for readers.

Following this introductory chapter, Chapter 2 summarizes the discussion on current standards and regulations related to PAPRs—the NIOSH standards that must be met for devices to be certified for use in the United States and the standards of the International Organization for Standardization (ISO). The experience of California's Division of Occupational Safety and Health Administration (Cal/OSHA) also is included. Chapter 3 describes presentations about the experiences of health care and emergency response workers that are relevant to PAPRs as well as the perspectives of employers. The design and research needs for PAPRs intended for use by health care workers are discussed in Chapter 4. The workshop summary concludes in Chapter 5 with a synopsis of the workshop's major themes and discussions:

- *Improve PAPR design and standards by assessing risks and protective factors, identifying desired design attributes, and driving* the market to meet health care needs;
- Increase education and training; and
- Strengthen implementation and use of PAPRs in health care.

OPENING REMARKS

In his welcome and introductory remarks, James Johnson, chair of the IOM workshop planning committee and a consultant for JSJ and Associates, noted that the workshop was focused on the health care workplace and challenged the participants to focus on improving PAPRs for use by health care workers by addressing four questions:

1. How can PAPRs be better utilized?
2. What is preventing them from being utilized?
3. How do they need to be changed?
4. How might the current PAPR certification standards followed by NPPTL be revised to help improve the equipment and make it more useful to health care?

Linda Hawes Clever, chair of the IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health and a senior physician at California Pacific Medical Center, said the workshop was meant to be practical, taking into account such considerations as equipment cost and the personnel time needed for respirator fitting and training. She said she hoped the workshop would present information that, when disseminated, could change how PAPRs and other protective respiratory equipment could be used to assure the health and safety of all those who provide health care.

Maryann D'Alessandro, NPPTL, stated that NIOSH anticipated that more information from end users and manufacturers could lead to revised NIOSH certification standards, which could support the development of improved product design and capabilities to meet user needs.[6] D'Alessandro further explained that the 1995 National Technology Transfer and Advancement Act (Public Law 104-113) directs federal agencies to work with consensus standards and not to rely solely on existing federal standards in updating regulations. One of the issues the workshop is to address is whether and how to tie respirator certification standards (42 CFR Part 84) to ISO consensus standards.

[6]In addition to the IOM workshop, NPPTL sought comments on PAPR standards for health care workers through the Federal Register docket, and some of the workshop presenters noted these comments in their remarks (CDC, 2014b).

2

Defining PAPRs and Current Standards

The workshop opened with presentations that defined and described powered air purifying respirators (PAPRs) and the current regulatory landscape influencing PAPR design and use. In general, PAPRs can be described as respirators that protect the user by filtering out contaminants in the air and use a battery-operated blower to provide the user with clean air through a tight-fitting respirator, a loose-fitting hood, or a helmet. Use of tight-fitting PAPRs (see Figure 2-1) requires fit testing; use of loose-fitting PAPRs (see Figure 2-2) does not require fit testing.[1]

The Occupational Safety and Health Administration (OSHA) provides a functional definition of a PAPR as "an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering" (29 CFR 1910.134(b)). The National Institute for Occupational Safety and Health (NIOSH) definition of PAPRs describes the components in a PAPR—a facepiece, hood, or helmet; a breathing tube; a canister or cartridge with filter; and a blower (42 CFR 84.2(z)).

NIOSH CERTIFICATION STANDARDS

Roland Berry Ann
National Personal Protective Technology Laboratory

OSHA regulates workplace implementation of respiratory protection programs (29 CFR 1910.134) and requires that all respirators used in OSHA-regulated workplaces be certified by NIOSH (42 CFR Part 84).

[1]Workshop speakers in most cases did not specify the type of PAPR they were talking about, but as depicted in their slides and descriptions, loose-fitting PAPRs were the type that were primarily discussed during the workshop.

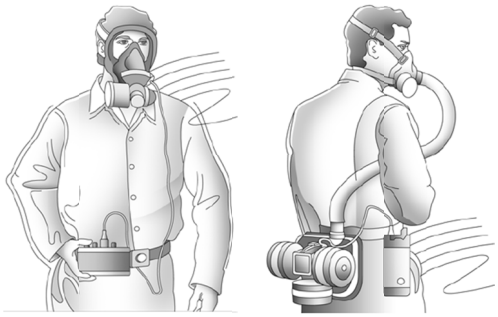

FIGURE 2-1 Examples of tight-fitting powered air purifying respirators.
SOURCE: OSHA, 2011.

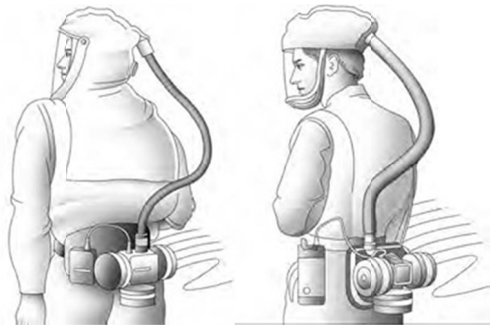

FIGURE 2-2 Examples of loose-fitting powered air purifying respirators.
SOURCE: OSHA, 2009.

Federal regulations delineate U.S. respirator performance standards (see Box 2-1). Through the National Personal Protective Technology Laboratory (NPPTL), NIOSH tests and certifies that PAPRs and other respirators meet these standards. Among other requirements, NIOSH PAPR testing includes an assessment of airflow, that measures

1. Minimum airflow rate: A tight-fitting PAPR must provide a constant airflow of 115 liters per minute; a loose-fitting PAPR must provide 170 liters per minute.

2. Maximal operation flow rate: Tests are done for 4 hours of continuous operation with the given PAPR being set for maximal operational flow, which could be up to 250 liters per minute.
3. Specific characteristics such as inhalation and exhalation resistance.

One part of NIOSH's certification testing for PAPR filters is a silica dust loading test, which is a method used to test for filter effectiveness in work conditions found in industrial settings, principally mining. Mining activities typically expose workers to dusty conditions and require workers to engage in moderate to high physical exertion rates, which means that respirators used in these settings must have high airflow rates to meet worker breathing demands. These workplace environments and

BOX 2-1
U.S. Regulatory Structure for Respirator Certification

The National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention of the Department of Health and Human Services, administers regulations for the certification of respiratory protective devices (42 CFR Part 84). For respirators used in mine rescue operations and other mine emergencies, this administrative authority is jointly held with the Department of Labor's Mine Safety and Health Administration.

42 CFR Part 84 specifies minimum mandatory requirements. Subparts A through G of this regulation provide general information and requirements applicable to all respirator types. Included are such topics as application procedures, fees, certificates of approval and disapproval, quality assurance, the classification of approved respirators, and general construction requirements. In addition, subparts H through L and N define minimum design, performance, and test requirements for various devices that provide respiratory protection for fixed periods of time against hazards specified in the certificate of approval.

Common types of respirators certified by NIOSH include self-contained breathing apparatus (subpart H), gas mask air purifying respirators (subpart I), supplied-air respirators (subpart J), air purifying particulate respirators (subpart K), chemical cartridge air purifying respirators (subpart L), powered air purifying respirators (PAPRs) (subparts G, I, L, KK), and special use respirators such as vinyl chloride respirators (subpart N). For respirators that provide combined protections (such as for gas, vapor, and particulates), portions of individual subparts apply.

conditions differ from those experienced by health care personnel, and therefore it may be necessary to reexamine the requirements and testing processes for certifying PAPRs to be used in health care settings.

NIOSH has the regulatory flexibility under existing authorities to certify PAPRs that have different performance characteristics than those currently in place. For example, NIOSH has made changes to its certification standards in response to a request to approve a breath-response PAPR. This type of PAPR does not have a constant flow rate, but rather it adjusts to the wearer's breathing rate (the greater the demand, the higher the rate of air supply). After developing an appropriate test, NIOSH defined and approved the breath-response PAPR as a new class of PAPR (42 CFR 84.60 and 42 CFR 84.63).

In the future, the performance requirements and certification standards for PAPRs used in health care settings could be altered to account for the light-to-moderate exertion requirements of health care workers. Berry Ann suggested that potential next steps for PAPRs for health care could include

- Assessing the potential for a new respirator class structure that would meet different performance requirements;
- Developing strategies for the selection and use of PAPRs with alternate flow-rate levels that could match the respiratory needs of various types of health care workers and could address comfort and tolerability concerns;
- Conducting workplace studies to determine the work exertion rates for different types of health care workers and settings as well as the "net effect of alternative PAPR flow rates on health care worker protection"; and
- Assessing the International Organization for Standardization (ISO) requirements for respiratory protective devices to see if they could be used to inform improvements in NIOSH regulations.

Additionally, workplace studies and improved regulations might enable the development of new products that better "match the capabilities to the user's needs."

REGULATORY PERSPECTIVE

Deborah Gold, Cal/OSHA

California has 1 of 22 OSHA state plans that cover both public-sector and private-sector workers. State plans must include respiratory protections for workers that are at least as effective as those required by OSHA. California's Division of Occupational Safety and Health Administration (Cal/OSHA) regulations affecting PAPR use in health care focus on multiple areas:

- Chemical exposure: These standards include permissible exposure limits for various substances, such as formaldehyde, ethylene oxide, and glutaraldehyde. They require the use of respirators to reduce exposure if exposure is not reduced by other means. These standards for respiratory protection programs address program administration, respirator selection, training, medical evaluation, fit testing, and use.
- Blood-borne pathogens: Full facepiece PAPRs and some loose-fitting PAPRs provide face and eye protection against bodily fluids as required by the standard regarding blood-borne pathogens.
- Aerosol-transmissible disease: This California standard generally requires the use of NIOSH-approved respirators for respiratory protection in providing care to patients who are suspected of or confirmed to have an airborne infectious disease.[2] The standard requires respiratory protection for novel or unknown pathogens and those for which California's public health agencies recommend airborne infection isolation. The standard also requires, with some exceptions, the use of PAPRs for high-hazard procedures (such as sputum induction, administration of aerosolized medications, bronchoscopy, and pulmonary function testing) that may involve airborne infectious diseases or aerosol transmissible pathogens.[3]

[2]Infectious diseases identified by the Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee that require airborne infection isolation include tuberculosis, severe acute respiratory syndrome (SARS), measles, and varicella.

[3]California's Occupational Safety and Health Administration Standards Board adopted this standard in 2009 after a 6-year regulatory development project that included 10 formal public advisory meetings.

Under Cal/OSHA regulations, PAPRs are specified for high-hazard procedures because they can offer assigned protection factors (APFs)[4] ranging from 25 to 1,000, which reduce the risk more than the protection factors provided by N95 respirators.[5] The improved protection is largely provided by the positive pressure in the head covering or facepiece. PAPRs with loose-fitting hoods provide additional potential advantages in that they do not need to be fit tested and they can be used by health care workers for whom an acceptable seal cannot be achieved due to facial hair or other factors. The hoods of PAPRs can provide splash protection and some degree of eye protection, and some workers have reported that the airflow can keep the shield from fogging and can reduce heat buildup. In the agency's experience, there have been fewer equipment shortages for PAPRs than for disposable N95 respirators.

The most common concern Cal/OSHA receives regarding the use of PAPRs has been their effect on the sterile field, such as during surgery, as PAPRs do not filter the discharged air. Some health care facilities have tried using surgical masks under the loose-fitting head coverings or placing the ends of the PAPR hood under the surgical gown, but neither is a tested or certified configuration. There appears to be little reliable information on infection risks from using a standard surgical ensemble, which includes a surgical cap and facemask, compared to the risks from using a PAPR, nor is there much information about how those risks can be reduced. Another concern with PAPRs is the vulnerability of the external connections, such as hoses, cords, and filters, which may become dislodged in congested emergency environments where many people may be moving quickly. Concerns have also been raised about the level of protection that is achieved and the ability of the PAPR to remain in place in different work postures, such as when workers need to bend or stoop to provide care. Challenges in disinfecting the external working parts as workers move from patient to patient were also noted. Additionally, some health care institutions may not provide training for those who use loose-fitting PAPRs because often respiratory protection training is

[4]The assigned protection factor (APF) of a respirator denotes the level of protection that the respirator is expected to provide to users who are properly fitted and trained. For example, an APF of 10 "means that a user could expect to inhale no more than one tenth of the airborne contaminant present" (OSHA, 2014).

[5]N95 particulate filtering facepiece respirators filter at least 95 percent of airborne particles and have APF of 10. In addition to certification by NIOSH, some N95 respirators have also been cleared by the Food and Drug Administration to meet additional requirements; these are called surgical N95 respirators.

conducted in the same session as a fit test, and for these types of PAPRS a fit test is not required.

Gold said that she has found that employers and employees support PAPR use when the PAPRs are part of a well-devised respiratory protection program. The deployment of PAPRs has been carried out in various ways. One hospital in California set up a program in which the hospital's central supply, on request, sends a PAPR system to the designated patient care unit. The system, which is on a rolling rack, includes multiple PAPRs and charging stations, a place to put each individual worker's head covering, disposable items, and equipment for disinfection between uses. When the PAPR is no longer needed, it is returned to central supply for reprocessing, including decontamination and disinfection. Other hospitals have equipped airborne infection isolation rooms with multiple PAPRs, batteries, charging stations, and disinfecting equipment. The equipment is maintained during maintenance rounds. Some hospitals maintain PAPRs in respiratory therapy or similar units. Successful programs are those in which all affected workers are trained on how to use the PAPRs, with the training refreshed periodically and reinforced by unit-based champions for PAPR use. However, PAPRs are often not used in cases where the onus is on the individual health care worker to request the PAPR and there are no effective procedures to mobilize the resource.

"We need NPPTL to develop criteria that satisfy infection control goals as well as employee protection in order for these respirators to be broadly accepted in health care," stated Gold. She continued by saying that improvements to PAPRs and PAPR certification for use by health care workers should consider the following issues:

- Examine and define the impact of various PAPR designs on infection prevention. Questions include
  - Can PAPR design be improved to direct and/or filter exhaust air?
  - What is the standard of filtration that a PAPR should be expected to meet for discharged air? For example, many existing surgical masks do not provide a high level of filtration.
  - What are the appropriate procedures for the disinfection of PAPR components? Which components need to be disposable?
- Aim for an APF higher than 25 for common health care PAPRs while increasing usability, and provide information on the

specific APF range as confirmed by NIOSH in the respirator certification. A higher level of respiratory protection needs to be available for aerosol-generating procedures and for exposure to more hazardous pathogens.

- Include durability criteria in PAPR certification, such as the ability of the device to maintain configuration, flow, and protection in different postures. At a minimum, PAPRs should have a label stating for which postures they have been certified for use.
- Written materials included with respirator certification should have clear, plainly written statements to facilitate employer selection and employee training on the use, advantages, and limitations of specific equipment. Distinctions between different types of respirators need to be made.

ISO RESPIRATORY PROTECTIVE DEVICE STANDARDS

Craig Colton, 3M

In 2001, the ISO Technical Committee on Personal Safety—Protective Clothing and Equipment (TC94) formed a subcommittee (SC15) to develop ISO standards for respiratory protective devices. The American National Standards Institute, through an accredited technical advisory group administered by NIOSH, represents the United States on ISO SC15, which develops standards for filtering devices (including PAPRs) dependent on the ambient atmosphere (as opposed to respirators that supply breathable gas independent of the ambient atmosphere).

In the United States, respirators are classified based on the type of device (e.g., half-facepiece, PAPR or full facepiece, PAPR). By contrast, ISO standards classify respirators based on performance criteria (see Table 2-1). When considering whether NIOSH should adopt a regulatory framework that better parallels ISO classifications, Colton suggested that manufacturers would argue for performance specifications rather than design specifications to allow them to develop a PAPR that can do what it needs to do. ISO assigns respiratory protective devices to one of six classes based on the results of a total inward leakage (TIL) test.[6] One of

[6]In the TIL test, a person wears the PAPR in a chamber into which particulates (such as sodium chloride) are introduced at a specific concentration. The particle levels inside the PAPR are compared with the particle levels in the chamber to determine the total

TABLE 2-1 Comparison of Key Differences Between Current Standards and Proposed ISO Standards

	Current NIOSH/European Union (EU) Standards	Proposed ISO Standards
Basic classification	Type	Total inward leakage (TIL) laboratory test
Work rates	Not classified: some validation (e.g., firefighting SCBA)	Four work rate classes
Particle filters	NIOSH: 9 particle filters EU: ~6 particle filters	Potential for 20 particle filters (four work rates, each with five efficiencies)
Gas and vapor	Classified by capacity	Classified by capacity and work rate
Selection and use	Varies by region or country but generally based on protection factors	Based on ISO classification, the protection level is linked to the TIL

NOTES: ISO = International Organization for Standardization; NIOSH = The National Institute for Occupational Safety and Health; SCBA = Self-contained breathing apparatus.

the areas needing further exploration is the correlation between how a device performs in the TIL test and how it performs in real work experiences. For health care settings, it will be important to know the level of airflow needed to determine an acceptable protection level for work in that setting.

One of the major ISO performance requirements for a respirator is based on the work rate that the respirator is designed to support. Proposed ISO standards include four ISO work rate classifications, with the

inward leakage of the respirator; the TIL level is then extrapolated to set the protection level.

W1 work rate classification covering approximately 90 percent of industrial workplaces. The work rate represents the level of airflow that is needed by the worker to meet the job requirements. A manufacturer can, therefore, design a PAPR to meet desired performance criteria. However, for many workplaces, including health care settings, much remains to be learned about work rate classification.

Another way in which ISO classifies respirators is by the respiratory interface—how much of the face or the nose and mouth area the respirator covers and the respirator's fit (tight or loose). Using ISO classifications, similar-looking devices could have different levels of protection, and devices that appear different could have similar classifications—a PAPR could be classified the same as a half-mask respirator, for example, if the TIL test performance is the same.

Filters are classified by ISO based on performance, work rate class, and whether they are usable for only a single work shift or are reusable. Whereas NIOSH has 9 particle filter categories, ISO has some 20 options. Special applications also are considered in the classification (e.g., mining operations, firefighting, CBRN [chemical, biological, radiological, and nuclear]), and there are requirements for respiratory protection device noise levels and for warning indicators for battery life and airflow. NIOSH uses a silica dust loading test for PAPR certification, but this may not be relevant to the health care setting.

DISCUSSION ON STANDARDS AND REGULATION

The discussion among the workshop participants focused on four major issues: (1) acceptable protection levels and how these levels should be determined for health care workers, (2) performance criteria and the determination of the protection factors of PAPRs, (3) the extent to which ISO standards can be incorporated into U.S. regulatory standards, and (4) the specific needs for health care PAPRs and health care workers using PAPRs.

First, health care workers face a variety of pathogens and hazards, which affect acceptable protection levels for PAPRs. Lewis Radonovich, Department of Veterans Affairs, noted that upper thresholds for acceptable exposure levels have not been set, and setting those limits would be difficult because so little is known about the necessary inoculum size for respiratory viruses to cause infection. He also suggested that discussion is needed about which exposure levels are acceptable and achievable.

Second, more information is needed to determine whether PAPR performance criteria translate to appropriate protection factors in practice. For example, does a device's acceptable amount of inward leakage (which determines the protection factor) protect workers against a highly infectious disease? Richard Metzler, NPPTL, remarked that research is needed on how the laboratory TIL test relates to the performance of a PAPR in real-life workplaces. Stating that it is important to understand the level of protection needed and the workplace performance requirements in order to assess lower flow rate products, Metzler also commented that further efforts are needed to determine if the TIL test used in Europe is "equivalent to and predictive in a manner that OSHA's assigned protection factors are." OSHA has determined APFs that apply to all respirators of a specific type or class (e.g., the APF for loose-fitting PAPRs is 25 and for full facepiece tight-fitting PAPRs is 1,000); ISO standards would base the protection factor on the results of the TIL tests for a specific product.

Third, the extent to which ISO standards can be incorporated into U.S. regulatory standards remains unclear. Bill Kojola questioned how the ISO approach would work with OSHA's respiratory protection programs and wondered if the approach would help or hinder respirator selection by employers. Would it be confusing to employers? Maryann D'Alessandro noted that NPPTL is taking a modular approach to the incorporation of the ISO standards and will start with PAPR-related standards. Metzler stated that selection and industrial hygiene issues are being carefully examined and that ISO standards could lead to different APFs within a specific class of respirator.[7] Dan Shipp, International Safety Equipment Association, noted that the ISO standards would require a much different approach to certification testing. He added that currently NIOSH certifies respirators as a complete unit (rather than by performance of their component parts) with tests and standards for the nine different classifications of respirators, but it will be challenging to move to a certification system that could have 40 different combinations of work rates, filter efficiencies, and other performance measures.

Colleen Miller, NPPTL, noted that NPPTL is building TIL testing chambers according to the ISO standards. The TIL tests will involve three different challenges: corn oil, which is also used for CBRN respirators; sodium chloride aerosol; and a sulfur hexafluoride challenge for respirators that may be tight-fitting but have some kind of a porous barri-

[7]Currently, all half-mask respirators have an APF of 10.

er that needs to be evaluated. NPPTL also is exploring other new respirator tests, including a breathing test to develop work rate classes.

Fourth, health care workers may have special needs that should be considered when designing regulations for PAPRs used in health care settings. While PAPRs are not recommended for use during surgery, Gold noted that some surgical teams would like to use PAPRs but there are concerns that the unfiltered exhaust from the respirator might contaminate the sterile field. She added that NIOSH could provide leadership in this area by examining how to assess the contamination of the sterile field and standards regarding air exhaust. Larry Green, Syntech International, commented that surgical helmet systems have filtration systems for the exhaust air but that these systems are not approved for employee respiratory protection. Gold stated that "we have to figure out how we are going to address employee protection as well as the protection of the sterile field."

Discussions of respiratory protection for health care workers should encompass the education and training of those workers. Frank Califano, North Shore–Long Island Jewish Health System, noted that the use of respirators by health care workers is complicated because the workers may not use respirators as part of their daily routine and therefore respirator use is "out of the norm," suggesting that "maintaining the equipment, maintaining the training level, [and maintaining the] proficiency level [will] be the hard part." Califano contrasted the health care workers' experience to that of firefighters, who are more familiar with, and often rely on, SCBA (self-contained breathing apparatus) devices. These issues were discussed in greater detail later in the workshop.

3

Why, Where, and How PAPRs Are Being Used in Health Care

WORKER EXPERIENCE IN USING PAPRs IN HEALTH CARE SETTINGS

Both N95 respirators and powered air purifying respirators (PAPRs) are used in health care settings. Information was presented from two respirator research studies that quantified the differences in respirator use around the country. Representatives of two hospitals and one union shared what they have learned from health care workers about PAPR use and preferences.

Translating Research Findings into Clinical Practice

Debra Novak, National Personal Protective Technology Laboratory

The National Personal Protective Technology Laboratory (NPPTL), along with partnering organizations and universities, conducted two studies to better understand the use of respirators in health care: the Prevalence of Respiratory Protection Devices in U.S. Healthcare Facilities Survey (2014) and REACH II Public Health Practice Study—Respirator Evaluation in Acute Care Hospitals (2010–2012).

Prevalence of Respiratory Protection Devices in U.S. Healthcare Facilities Survey (2014)

This survey was undertaken with the American Association of Occupational Health Nurses (AAOHN) to fill a gap in research about what types of respiratory protection devices are being used daily in clinical

practice. The 11-item, online survey was disseminated to members of AAOHN and the Association of Occupational Health Professionals in Healthcare. In all, 322 completed surveys were received from 47 states. Device use varied by geographic region. N95 respirator use was most prevalent in the Northeast, while PAPR use was most prevalent in the Midwest. Respondents in the Midwest (88.0 percent) and West (86.7 percent) were more likely than respondents in the South (67.0 percent) and Northeast (65.1 percent) to have employees who had used a PAPR at least once in the past year. If follow-up studies on PAPRs are needed, this information could be useful for determining where to conduct those studies.

REACH II Public Health Practice Study—Respirator Evaluation in Acute Care Hospitals (2010–2012)

The REACH II Study evaluated hospitals' respiratory protection programs and respirator usage in six states/five regions across the United States: California, Michigan, Minnesota/Illinois, New York, and North Carolina. Data were collected from 1,500 hospital managers, unit managers, and health care workers from 98 hospitals and included 300 demonstrations of donning and doffing protective equipment. More than 85 percent of hospital managers and unit managers who participated said their facilities had PAPRs available for use when employees needed them, with only 10 percent or fewer saying they did not know if PAPRs were available. In contrast, nearly 30 percent of the health care workers themselves—those working closest to the patient bedside—did not know whether PAPRs were available for use in their facility. Furthermore, nearly 40 percent of health care workers did not know what would happen at their facility if an employee could not be successfully fit tested for a respirator. More than 40 percent of health care workers did not know whether their program evaluations included a determination of whether respirators were being properly maintained. In each case, health care workers reported much more uncertainty about the respiratory protection program than did hospital managers or unit managers.

Although caution should be taken in generalizing the results, the REACH II Study provides several findings:

- Respiratory protection program plans exist on paper.
- Health care workers may provide different responses to questions about respiratory protection than hospital or unit managers.

- Health care workers are unclear about when to use respiratory protection, what type of protective device should be used, and how to properly don and doff the equipment.
- The focus is on fit testing rather than training. Health care workers usually receive less than 15 minutes of respiratory protection training per year.

Unit-based champions of personal protective equipment (PPE) are important resources, and respiratory protection training needs to be a hospital-based, practice-based competency within an organization. Respirator instructions should provide guidance for use and be easily understood by the end user. Practice performance specifications need to be developed through field studies, feasibility analyses, and greater understanding of how PAPRs are being used in practice, including how they are used as part of a protective ensemble.

Docket Comments

PAPR use is increasing. Novak noted that this is demonstrated not only in the study results she presented, but also in several comments on PAPRs that were in response to the published request for information through the National Institute for Occupational Safety and Health (NIOSH) docket (CDC, 2014b). Jennie Mayfield, Association for Professionals in Infection Control and Epidemiology, stated, "Based on experiences in the facilities of some of our members, we anticipate that, as PAPRs become cheaper and lighter, health care employers may consider expanding PAPR use to alleviate the burden of N95 fit testing, rather than from any appreciable benefit of employee protection." Similar comments were submitted by Dan Diekema, Society for Healthcare Epidemiology of America, and Barbara Murray, Infectious Disease Society of America, who noted, "Many facilities with low incidence of [tuberculosis]—and therefore infrequent need for respirators for routine care—have opted for PAPR-only policies as a cost-effective alternative to cumbersome annual fit testing of hundreds of employees enrolled in their respiratory programs."

PAPR Use at OSF Saint Francis Medical Center
Peoria, Illinois
Jo Garrison, OSF Saint Francis Medical Center

In 2010, OSF Saint Francis Medical Center, like other health care facilities around the United States, had an H1N1 influenza crisis. With limited supplies of N95 respirators, the health system turned to its PAPR program, which was already in place. However, "What we found out is we weren't really as prepared as we would like to have been," stated Garrison. Recognizing that this was an opportunity to improve processes, the medical center's management instituted a Six Sigma project to establish a standard process to make sure that all employees would be protected and there would be an adequate supply of respirators. Administrators had to determine which workers could have potential hazardous exposures and needed to be included in the respiratory protection program to ensure worker protection and effective patient care. OSF Saint Francis Medical Center has large departments but very few exposures, so its employees do not use respirators very often. They have approximately 2,400 employees in the respiratory protection program.

Health care workers have to complete a two-page questionnaire about their health histories. Those who are in the respiratory protection program complete a mandatory computer-based respiratory education module. The employees who are identified as candidates for N95 respirator use attend a fit testing. The employee health department tracks fit testing compliance with a goal of 80 percent compliance each year. This program is very labor intensive.

"Everybody wants to be part of the PAPR program because then they don't have to do the N95 fit test, which takes 20 minutes," said Garrison. From a manager's perspective, the advantage to using PAPRs is that employees do not have to be taken away from work and patient care in order to complete N95 respirator training. From the employee's viewpoint, the advantages to PAPRs are that they are less restricting and more user-friendly, and they accommodate facial hair. Furthermore, patients can see the worker's face more easily when the worker is wearing a PAPR than when the person is wearing an N95 respirator, so patients are not as frightened.

The biggest challenge to using PAPRs is financial. Each PAPR costs about $1,800, which comes out of departmental equipment budgets. Currently the hospital's 35 PAPRs are kept in individual departments rather than in one central location. Once a department purchases PAPRs, it is

not eager to share them with other departments. Every department leader is responsible for assuring that the department's employees are trained.

A second challenge is that PAPRs can be difficult to keep track of because the equipment is compact and can fit in a file cabinet or drawer. Sometimes a PAPR cannot be found when needed, and when the PAPR is found, sometimes it is missing certain pieces. This may be an argument in favor of having PAPRs in a central location and available to be checked out as needed.

"I do not see us ever trying to get away from the N95 or the PAPR," Garrison said. "We will continue to use both because there are different needs."

PAPR Use at California Pacific Medical Center
San Francisco, California

Karen Anderson, California Pacific Medical Center

Any discussion of PAPRs inevitably draws comparisons with N95 respirators, which are very much in use but not the topic of the current workshop. Anderson described an informal survey conducted in several California hospitals that found a mixture of respiratory protection devices being used, although the use was heavily weighted toward N95 respirators.

According to Anderson, the biggest disadvantage to using N95 respirators at California Pacific Medical Center is the annual fit testing needed by the approximately 3,500 employees who either have contact with patients posing an airborne infection risk or who engage in other high-hazard procedures. The four hospital campuses have a total of more than 600 stations that conduct fit testing, which occurs over a 1.5-month period each year. The fit testing and educational components combined take approximately 30 minutes per employee. The cost to the medical center for the personnel who conduct the fit testing is more than $60,000 per year. There are other institutional costs as well, such as the time each employee spends in training and not seeing patients. Because nurse-to-patient ratios must be maintained when a nurse does fit testing, each nurse has to have his or her work covered by someone else while being tested. In addition, reminding people to complete N95 respirator fit testing, and keeping track of who has completed fit testing and who has not, is quite complex from a bookkeeping perspective.

Health care workers need to have meaningful evidence to be persuaded to do something they do not want to do. Even though California's

Division of Occupational Safety and Health Administration (Cal/OSHA) regulations are law in California, some health care workers are not compliant with respiratory protection. They are not convinced of the importance of the fit testing for N95 respirators. The law requires fit testing to be done every year, whether or not there is facial change, but employees do not understand that. In addition, because nurses must be fit tested but doctors are given the option of either fit testing and wearing an N95 respirator or wearing a procedure mask, nurses complain that a double standard is being applied. "If we can convince people that this is really going to improve their health then I think they will buy into it, they will do it. But we have to have a really convincing argument."

California Pacific Medical Center uses a particular model of PAPR that employees find easier to use than other PAPR models. It is lighter in weight, the air comes through the helmet of the device so there is no tubing on the wearer's back, and the battery can fit in one's pocket. There are also indicator lights to show airflow and filter status. An added benefit of using the PAPR, as opposed to an N95 respirator, is that patients can see the health care worker's whole face. Although there had been a concern that the respirator would scare pediatric patients, medical center workers have found these patients are not frightened by PAPRs. On the other hand, there are some challenges to using PAPRs. In addition to their high cost, PAPRs can be heavy to wear and are noisy. A designated location for recharging and storing is also needed.

Respiratory therapists are in charge of the PAPRs at California Pacific Medical Center. They bring them to a care unit and take them back to storage, clean them, charge the batteries, and rotate the stock. One of the challenges related to infection prevention and occupational health is that they are not revenue-generating departments. Reducing infections and protecting employees from needle sticks and hepatitis C (and a possible liver transplant later) may save millions of dollars over time, but these efforts rarely interest a chief financial officer in advance of the event. This is an area where outcome measures could be invaluable for gathering appropriate attention.

Given the high cost per unit, PAPR availability will always be a problem in the event of a major outbreak or act of bioterrorism. Health care facilities need to have dual systems for N95 respirators and PAPRs, and they need to train health care workers to use both. Anderson suggested that the priorities for improving the use of PAPRs in health care settings are to

- Have meaningful evidence to convince hospital staff and administration that the use of respirators is necessary and not just the law;
- Make PAPRs more affordable;
- Have a system for storing and recharging PAPRs; and
- Have sufficient training so that employees are prepared in advance of an outbreak or a bioterrorism event.

An Employee Union Perspective

Mark Catlin, Service Employees International Union

Service Employees International Union (SEIU) has more than 2 million members, with more than half of them working in the health care field, including tens of thousands of physicians and nurses. A survey of about 150 SEIU members who are health care workers showed stronger support for using PAPRs than for using N95 respirators. SEIU members thought they got a higher level of protection from PAPRs. They also liked the fit of PAPRs and said that PAPRs were cooler to wear and more comfortable. PAPRs were reported to be used primarily for contact with known and suspected tuberculosis patients and during the H1N1 influenza pandemic. Occasionally they are used during surgeries.

Many of the survey respondents said they wore PAPRs rarely—only once every few months or once per year. Few people use them routinely, so remembering how to use the PAPR effectively is a challenge. However, even if a worker goes to use a PAPR and remembers how to use it properly, there can be a problem with the batteries not being charged or with parts of the PAPR missing or being worn out. Facilities often do not have a good system in place for PAPR maintenance. Although other challenges to PAPR use were reported, such as the devices being heavy and awkward to wear and the noise they produce interfering with communication, workers reported that they were able to overcome these challenges with some practice.

Catlin suggested that actions could be taken to improve the use of PAPRs by health care workers, including

- Modify respirator design to fit the hospital environment
  - Reduce noise that interferes with communication
  - Reduce weight and awkwardness for wearing
  - Modify for less strenuous but more extended use

  - Increase ease of disinfection
  - Modify exhaust airflow for use in sterile environments
- Improve training
  - Provide hands-on practice with donning, doffing, and working while wearing the equipment
  - Minimize use of slides or videos, which are not helpful in training people how to wear respirators
- Institute clear employer policies and emphasize the need for and use of respirators, including PAPRs

Often an employer does not have a clear policy about when and how to use the equipment. Sometimes, despite the existence of a corporate or hospital-wide policy that requires using respirators in certain areas, an immediate supervisor may tell a health care worker that wearing a respirator is not necessary. Later, the worker may be blamed for not wearing the respirator. There is a need for clear policies for health care workers to follow, and workers need their supervisor's support in following those policies.

Discussion on Health Care Worker Experiences Using PAPRs

During the discussion session, the workshop participants considered how PAPR use in health care should be measured and how proper respiratory protection should be extended to non-hospital health care settings. James Johnson reminded workshop participants that N95 respirators and PAPRs are respiratory protective devices that are used for different hazards. N95 respirators are used in circumstances where the hazard is low. The advantages to using them are that they are low cost and easy to wear, and many employees can be protected easily. On the other hand, PAPRs are used for a higher level of protection, but they are expensive.

Philip Harber, University of Arizona, raised the issue of what outcomes could or should be measured in studies of PAPR effectiveness and use. Anderson said a tuberculosis skin test is one outcome that could be watched for because a positive skin test might indicate that the employee did not follow proper respiratory protection protocols. Work is being done to examine outcomes, noted Lewis Radonovich. He commented that the Department of Veterans Affairs (VA) is involved in the Respiratory Protection Effectiveness Clinical Trial (ResPECT), which is comparing the effectiveness of N95 respirators to the effectiveness of

surgical masks in protecting health care workers from respiratory infections. However, this study does not include a comparison to PAPRs, and even though these types of studies are essential, they are very expensive. Radonovich added that there is a need to address the confusion among health care workers about what they should be doing to properly protect themselves and to address the fact that there are some workers who do know what they should be doing but who do not always comply with the guidelines.

Harber noted the importance of enhancing respiratory protection in ambulatory care settings where patients often go with symptoms that may signal presence of an infectious disease. Catlin concurred and observed that health care is moving away from big hospitals and becoming decentralized. He said he has found that many outlying facilities are doing little in the way of respiratory protection, noting that "it is not even on their radar screen." Edward Sinkule, NPPTL, added that private hospices and ambulance services also need to be considered. He pointed out that small business owners will have a lot of information to wade through to have a successful and effective PAPR program.

Another issue raised by Sinkule was the need for instructions on how to clean and disinfect a PAPR; these instructions are often lacking. He said, "Half the PAPRs in their user instructions just say yes, they can be cleaned and disinfected. I called to talk to the reps at the manufacturers. They had to get back to me because they did not know exactly what type of disinfectant I should be using." He added that it is also important to know how to inspect a PAPR before donning it. He stated that he was concerned that if clear instructions are not included with a PAPR, the users will probably not ask for clarification. Given the fast pace of health care, directions need to be very clear and easy to understand.

EMPLOYER EXPERIENCE IN USING PAPRs IN HEALTH CARE SETTINGS

This panel focused on the employer's perspective on PAPR use in health care settings. Speakers were asked to discuss the reasons behind their institutions' respirator choices, criteria, and use procedures and practices. Specifically, presenters were asked to discuss any challenges they had encountered in regard to PAPR storage, distribution, cleaning, and use.

PAPR Use at the University of Maryland Medical Center
Baltimore, Maryland

Jim Chang, University of Maryland Medical Center

In the center of Baltimore, the University of Maryland Medical Center (UMMC) is an academic medical center with several thousand staff members plus more than 1,000 faculty members from the various professional schools of the University of Maryland Baltimore. Challenges to respiratory protection at UMMC include tuberculosis, hazardous medications and chemicals, and novel pathogens such as H1N1 influenza, MERS-CoV (Middle East Respiratory Syndrome Coronavirus), and Ebola. When the H1N1 influenza pandemic occurred in 2009, UMMC managers found that N95 respirators were difficult to procure despite the considerable purchasing power of the 13-member health system. They were told by their primary vendor that other entities had priority for distribution. In response to this sudden shortfall of respiratory protection devices, UMMC developed a mixed protection strategy that emphasized the use of stockpiled reusable elastomeric air purifying respirators, a handful of N95 respirators, and approximately 400 PAPRs (of two different models). In addition, another 100 PAPRs were purchased. Fit testing for the elastomeric air purifying respirators involved unit-based fit testers and educators as well as centralized fit testing services. Selective deployment of PAPRs in their facilities made respiratory protection available to all staff and helped minimize the need to potentially fit test and supply tight-fitting respirators to all staff. This helped to alleviate staff concerns and allowed employees who were ineligible for fit testing to still have respiratory protection.

Learning lessons from the H1N1 influenza experience, UMMC has refined its respiratory protection strategy by identifying high-risk care units and services—for example, general medicine units, the medical intensive care unit, and services such as pulmonology, emergency medicine, and pediatrics. All new employees in these units and services are fit tested for an elastomeric air purifying respirator at the time of hire, and current employees are fit tested annually by unit-based fit testers. PAPRs are pre-deployed to high-risk units. For all other units, PAPRs are maintained and deployed by an equipment distribution group that is part of the clinical engineering function. Any care unit that asks for a PAPR gets a package of five PAPRs, head covers, and a five-pack battery charger from the central depository. UMMC also learned that the instructions

provided with PAPRs were inadequate, which prompted it to create its own guidelines for how to wear and remove PAPRs.

To advance the effective use of PAPRs in health care settings, there are three areas in greatest need of improvement, said Chang. First, manufacturers should match the equipment design with the functional needs of the different users. Bedside-care staff require different functionalities to meet their respiratory protection needs than maintenance staff. Second, respirators should be designed to be easy to use, assemble, clean, and test by a health care worker. For example, one model UMMC uses requires a battery pack clipped to a web belt, a turbo blower with breathing tube, three filter cartridges, and a hood. A simplified design, where components are housed internally, would be easier to use and less prone to user error. This is important, as some health care workers may use a PAPR only a few times per year. Last, the standardization of consumable items such as head covers should be encouraged. For example, in an emergency there are mask cartridges used for chemical, biological, radiological, and nuclear (CBRN) air purifying respirators that can be interchanged between different manufacturers' masks, although this may be in violation of certification.

PAPR Use and Research at the Department of Veterans Affairs

Lewis Radonovich, Department of Veterans Affairs

PAPRs are used in most medical centers across the VA health care system, which includes outpatient clinics and hospitals. Approximately 60 percent of VA medical centers use PAPRs routinely during clinical care; however, fewer than 5 percent rely solely on PAPRs for respiratory protection.

Acknowledging that large infectious disease outbreaks may result in a shortage of N95 respirators, VA plans to rely on elastomeric respirators as a last resort, so they are held in reserve in a national stockpile. One respirator and two sets of cartridges are available for each health care worker who sees patients, amounting to some 180,000 respirators. Elastomeric respirators are not currently used in routine clinical care.

Based on data from several studies, VA researchers have shown that employees find PAPRs more comfortable than half-face elastomeric masks or N95 respirators. However, among a variety of respirators studied, none of the tested devices were well tolerated for an entire 8-hour shift by all test participants. In one 2009 study, half of the study subjects

had removed their respiratory protective device by the end of an 8-hour work shift, regardless of the type of respirator used. VA researchers found that PAPRs were primarily disliked not because they were uncomfortable but because they might interfere with occupational activities and might be somewhat challenging to use in certain situations. In another study, when an individual was wearing a PAPR that allowed airflow to go past the ears, there was about a 15 percent decrease in the wearer's ability to repeat the words he or she heard. VA research teams also have found that the rechargeable batteries available for use with PAPRs often malfunction or are unable to be adequately recharged. Because of these concerns, the use of non-rechargeable batteries might be preferable, even though they are usually more expensive.

PAPRs are much more expensive than their counterparts. In one study, the cost for a PAPR was $768.20, compared with an N95 respirator, which cost approximately $1.50, and an elastomeric respirator, which cost about $20. Assessments conducted for stockpiling respirators for an influenza pandemic showed that VA would need approximately 18,343 PAPRs (at a total cost of more than $14 million) to care for a population of 1 million people, making PAPRs 20 to 30 times more expensive to stockpile than any other type of respirator.

Project BREATHE

Representatives from nine federal departments and agencies participated in Project BREATHE (Better Respiratory Equipment Using Advanced Technologies for Healthcare Employees) to make recommendations for future development of respirators for health care workers (Radonovich et al., 2009). The project identified 28 desirable characteristics for health care worker respirators, which fell into four broad categories:

1. Safety and effectiveness;
2. Support for, and no interference with, occupational activities;
3. Comfort and tolerability; and
4. Compliance with health care system policies and practices.

The major challenge with respirators lies not in designing an effective one, but in persuading people to wear it and to wear it correctly. Respiratory training is not taken as seriously as blood-borne pathogen training, but both promote a safe health care workplace.

PAPR Use at Johns Hopkins Health System
Baltimore, Maryland

Trish Perl, Johns Hopkins University School of Medicine

Johns Hopkins Health System has six hospitals plus clinics and outpatient settings serving much of the city of Baltimore, as well as a children's hospital in Florida. In 2003, the Johns Hopkins system established a two-tiered respiratory protection program using both N95 respirators and PAPRs. Staff members working in high-risk areas are trained on how to use PAPRs and also are fit tested for N95 respirators. The Department of Health, Safety, and Environment performs the fit testing and maintains the PAPRs. Staff members are trained to use respirators and must pass a medical screening examination before they are allowed to treat patients posing a risk of airborne infection, perform aerosol-generating procedures on high-risk patients, or administer certain hazardous aerosolized drugs. PAPRs are present in all care units that have potential high-risk patients. If a PAPR is not available, staff can request one from the central stores. However, the delay between request and delivery may create a period during which a patient is not seen or a health care worker is not protected. The Johns Hopkins system has approximately 1,000 PAPRs in its stockpile, 600 of which are in the care units and available for use at any given time. Department of Health, Safety, and Environment staff members check and perform maintenance on PAPRs twice per month for those that are in use and once every 6 months for devices in storage.

Health care workers at Johns Hopkins are expected to know how to don and doff a respirator without contaminating themselves, so that they do not put themselves or their patients at risk. Furthermore, the workers need to know when the PAPR headpiece can be reused and when it has to be discarded due to exposure to certain infections. Instruction on how to clean the respirator is important, as is training employees to make sure that the PAPR is returned to its charger so it will be ready for the next user. As noted by other speakers, the package instructions provided for PAPRs are quite complicated and difficult to understand.

In 2011, Johns Hopkins conducted a simulation of a pediatric resuscitation during the H1N1 influenza pandemic. During the simulation, 19 percent of the involved staff members did not wear any kind of respirator, 6 percent used PAPRs, and 75 percent used N95 respirators. Making the PAPRs easier to use and making sure the workers know how to use them will increase their use (Watson et al., 2011). Some of the reluctance to use PAPRs may be the result of the institution's relatively complicated

policy on trouble shooting problems and on the maintenance of the devices. If a problem is noticed, a member of the Department of Health, Safety, and Environment has to evaluate the device before the PAPR is used again.

Barriers to the use of PAPRs also include the time required to don the PAPR, which lengthens response times in emergencies. The devices are cumbersome and impede the health care worker's ability to care for patients, and to take a patient's vital signs in particular; also, the devices can be intimidating to patients. Often the PAPRs cannot be found when they are needed or parts are missing. The decontamination process is arduous and requires a fair amount of time both to train the workers and for workers to complete the process.

The cost of PAPRs is a definite drawback to their use: a PAPR costs around $900; the battery costs $130; and a charger for 10 PAPRs can cost from $1,700 to $2,000. This is in addition to the cost of the Department of Health, Safety, and Environment staff needed to deploy and maintain the PAPRs.

Perl stated that health care workers do see advantages in using PAPRs, as the equipment makes them feel safe; does not require them to breathe through a facepiece, which can be taxing for workers who are older or have underlying respiratory problems; and can be more convenient, because the PAPRs used in their facilities do not require fit testing and are reusable. She identified the top opportunities for overcoming barriers to the effective use of PAPRs in health care settings: decreasing noise, simplifying the cleaning and storage requirements, and improving battery life. Two research avenues suggested for improving NIOSH certification of PAPRs are (1) clarifying the cleaning requirements and (2) verifying that the improved filtration efficacy translates into enhanced health care worker safety.

PAPR Use at the Mayo Clinic
Rochester, Minnesota

Jeffrey Nesbitt, Mayo Clinic

The Mayo Clinic health care respiratory program uses a blend of tight-fitting respirators (two models, seven sizes) and one type of PAPR. On average, the program fit tests 1,370 health care workers per year. It has 200 to 300 PAPRs in a rotating stock that is always available, and the PAPRs are cleaned, maintained, and distributed through the linen and

central services units at the hospitals. Some offsite locations may have their own PAPRs, which are on a monthly rotation schedule with the stock at the hospitals. Mayo Clinic also has a separate supply of respirators in a stockpile to be used in case of an epidemic. Mayo Clinic tracks its workers' fit testing, training, and medical clearance through a centralized electronic system that requires unit managers to update the workers' status monthly.

The Mayo Clinic does not use PAPRs in surgical sterile fields, and clearer guidance is needed on how and if this could be done, stated Nesbitt. Another barrier to PAPR use is the question of cleaning and decontaminating PAPRs when they are being used by staff members who are treating multiple patients and moving between multiple rooms. The communication barrier is also of concern. Comfort and functionality are also limited by various PAPR design issues, such as the device's weight and bulk; critical switches being located on the back of the unit, making them susceptible to being turned off inadvertently; and occasional faults in the monitors for airflow and pressure. The opportunities to improve NIOSH certification for PAPRs include clarifying the issues regarding the use of PAPRs in a sterile field, providing guidance on the appropriate use and decontamination of PAPRs for novel infectious diseases, and advancing the evidence that respiratory worker safety translates to safer and healthier workers and patients.

Discussion on Health Care Employer Experiences with PAPRs

The group discussion began with a focus on respiratory protection training. Perl noted that respiratory protection training may not be as effective as it could be because it is one of many mandatory trainings. Moreover, training may be provided through slide shows or Web-based educational modules, rather than by hands-on application. Chang agreed and said the University of Maryland has similar types of training. However, because training had been highlighted as a potential weakness in UMMC's program evaluation, the medical center plans to add respirator training to its "nursing marathons," which include more hands-on and practical training. Nesbitt stated that the Mayo Clinic provides training every year through quizzes, as well as part of incident follow-up and investigation. He added that it looks at compliance rates annually. Bonnie Rogers, University of North Carolina at Chapel Hill, commented on the very low rates at which workers retain information from their respiratory

protection trainings and the quite brief amount of time that is spent on providing information on respiratory protection to health care students while they are in school.

Linda Clever added to this discussion by asking the speakers to compare their institutions' respiratory protection training with blood-borne pathogen training. Radonovich said that he thought both of these topics were covered during employee orientation at VA, as well as through annual training processes with, in his opinion, more effort put into on-the-job blood-borne pathogen training. He noted that respiratory protection may not be covered as much during trainings because it is not used as often in practice. Chang agreed but noted that this trend might improve with face-to-face respiratory protection training and hands-on practice. Nesbitt said fit tested groups probably receive better respiratory protection training, because during that training the workers are tested and observed donning and doffing the respirator. He stated that because the PAPRs used in the Mayo Clinic facilities do not need to be fit tested, the PAPR training is usually a show-and-tell format with little or no hands-on practice. An opportunity for hands-on training, noted Chang, is when an airborne isolation patient enters the University of Maryland's tracking system. When this occurs, either a safety or an infection control staff member will visit the unit that is caring for the patient to make sure the equipment is in working order and to offer just-in-time hands-on training.

The discussion also covered the need for standardized, interchangeable consumable parts as well as specific barriers and opportunities for the design of PAPRs. Frank Califano said, "Every time we buy a new PAPR, we are buying a new filter, a new battery, a new charging system." Because of the cost of replacing these items, he said there is a real need for generic, off-the-shelf batteries and chargers that could help reduce health care costs. Nesbitt reiterated that the bulk and weight of the respirators is always mentioned when he asks his workers for feedback. He also wondered if the bib length might pose a problem if PAPRs are eventually approved for use in sterile environments and if the reusable head covers, which some manufacturers offer, might have potential infection control issues, such as the spread of head lice. Chang suggested that the one-size-fits-all solution should be examined. While it offers versatility, he said he believes it does so by compromising the design. When the provider and end user are given choices in filter and breathing tube options, the likelihood of failure increases, he said. Chang also described an incident where a PAPR breathing tube was compromised because the reinforcement piece, made of plastic, had been crushed.

In response to questions about respirator performance requirements and user instruction booklets, D'Alessandro said NIOSH is moving away from prescriptive requirements and moving toward performance requirements (i.e., how a unit would have to perform to meet the needs of health care workers). She added, "It would be up to the health care workers to tell the manufacturers that 'this is the type of thing that we need.' And then we would be able to certify it. There is nothing prohibiting these types of certifications. It is just that the users are not demanding these types of products." She also explained that unlike user instructions, which are reviewed as part of the certification process, NIOSH does not review training or maintenance manuals for the respirators until an issue or event is being investigated. D'Alessandro noted that NPPTL needs to explore how to incorporate the feedback and desires of an end user into the NIOSH certification process. Although it has been suggested that different prototypes should be distributed and evaluated in the field, D'Alessandro explained that it is difficult to get institutional review board approval to test prototypes for health care purposes. She noted that user feedback data are needed and that NPPTL should devise a way to standardize that type of research in the future.

PAPRs AND EMERGENCY PLANNING

The respirator needs of "first receivers"[1] can be different from those of first responders. Five speakers at the workshop addressed the use of PAPRs and other respirators in the context of emergency response.

Use of PAPRs in Hazardous Materials Response

David Ladd
Massachusetts Department of Fire Services

The hazardous materials response teams of the Massachusetts Department of Fire Services use an array of respiratory protection, from a full face air purifying respirator (APR) to a 4-hour chemical re-breather (the latter is used in the maritime environment). However, it is estimated

[1]"First receivers" are hospital employees who are the first to care for individuals presenting at their facility who may have been exposed to hazardous substances or infectious diseases. They are distinguished from first responders such as firefighters, law enforcement, and ambulance service personnel, who typically respond to an incident site.

that some 90 percent of the time, hazardous materials technicians use a self-contained breathing apparatus, or SCBA. These technicians choose the SCBA because, as firefighters, they are familiar with the equipment and confident in the high level of respiratory protection that SCBAs provide. These two factors—familiarity and confidence—seem to be missing from respiratory protection in the health care field.

Since 1999, Massachusetts has deployed mass decontamination units to fire stations protecting every acute care hospital in the state—now some 92 in all. The firefighters who would respond to a mass contamination event are trained to use SCBAs and are comfortable doing so.

The health care field "has failed to develop a respiratory protection strategy." A layered approach should be considered with multiple types of respirators. In addition to N95 respirators and PAPRs, devices that provide higher levels of protection need to be considered, including full face APRs. This is especially important when dealing with a highly contagious or highly lethal disease. In these cases, it may be necessary to use a full ensemble that covers a person from head to toe. The biggest risk to health care would be to lose the confidence of health care workers.

"Three factors have to be met in order to provide protection: proper equipment, properly worn, by a properly trained individual." Training is critical, and teaching health care professionals how to properly use PPE should be a core element of their education. A final necessity is a sustained market that builds respirators to meet the needs of health care workers.

The National Preparedness Perspective

Robert Huebner
Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority is an advanced development organization for public health medical emergency preparedness within the Office of the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services. The agency is interested in ways to improve respiratory protection devices.

When considering PAPRs for the nation's preparedness for a pandemic, consideration is given to three questions: What is affordable? What is available? And what is acceptable? There are a suite of protective devices to choose from: surgical masks to reduce the spread of infec-

tion, and disposable N95 respirators and the more durable elastomeric respirators as well as PAPRs for worker protection.

All respiratory protection devices have advantages and disadvantages. As other workshop presenters have underscored, the major advantage of PAPRs is that many types do not require fit testing. It is estimated that close to 10 percent of workers cannot be fitted for an elastomeric or N95 respirator due to facial hair or other reasons. Another advantage to using PAPRs is their reusability. The major disadvantages are maintenance and cost. Disposable N95 respirators, while costing much less for an individual respirator, are not so economical if workers need to use respirators day after day for weeks during a pandemic.

In prior work in a select agent laboratory, lab staff worked while wearing PAPRs day in and day out and became quite familiar with them. Challenges to using PAPRs that were identified in the laboratory work included a relatively short battery life, difficulties in hearing due to the noise of the blower, and to a lesser extent, difficulties in seeing due to the hood. The dedicated laboratory staff who were wearing PAPRs did weekly equipment checks, had a battery cycling schedule, and determined the cleaning procedures. They also used a two-man rule so that when the equipment was donned and doffed there was always someone else there to ensure that it was done correctly.

Emergency Services at North Shore–Long Island Jewish Health System New York City Metropolitan Area

Frank Califano, North Shore–Long Island Jewish Health System

North Shore–LIJ Health System has 18 hospitals in the New York City metropolitan area. It is one of the largest employers in the state of New York. Each hospital in the system has 20 to 30 PAPRs, primarily in its cache for emergency response and infectious disease management.

Long Island Jewish (LIJ) Medical Center, a part of the North Shore–LIJ Health System, was involved very early on in the 2009 H1N1 influenza pandemic in the United States. One of the biggest challenges was educating staff on how to don and doff their PPE. The health system posted door-sized instructions in every care unit to explain the proper procedures for entering and exiting a unit.

The hospital system stocks more than 500,000 N95 respirators and 250,000 pairs of goggles. However, PAPRs "are the best personal protec-

tive equipment available to hospital workers in the event of trying to protect them from some type of airborne contaminant." The health system has found that the best strategy is a tiered approach in which strike teams of specific people in designated areas are trained to use the PAPRs and act as a team in response to an outbreak or other emergency. Because of their cost, PAPRs are not a feasible option for protecting all of the system's workers in the case of an emergency. At approximately $1,000 per PAPR, the cost is a major factor in decisions on changing or updating respiratory protective equipment. "Our initial response until we figure out what it is going to be is N95s. That is why we stock over half a million of them."

One of the key characteristics that is taken into account when planning for respiratory protection is the protection factor of the devices. Efforts should focus on the development of PAPRs and PAPR certification processes that provide for increased protection capabilities. An improved PAPR would be one that works with the flip of a switch and signals the user that it is ready for use. It would be useful if filters were interchangeable among devices. In addition, although a good, high-efficiency filter is needed for health care, there is no need for chemical-resistant filters. Other desirable features include hoods that provide better visual clarity, a flow meter and an alarm to notify the user of changes in flow rates, a low-battery indicator, and improved ability to decontaminate the PAPRs. Furthermore, in times of emergency, it is important to have clear and transparent directives on what PPE is needed.

Association for Professionals in Infection Control and Epidemiology

Annemarie Flood
Association for Professionals in Infection Control and Epidemiology

The Association for Professionals in Infection Control and Epidemiology (APIC) has more than 15,000 members, most of whom collect, analyze, and interpret health care–associated infection data and work to reduce such infections. During the H1N1 influenza pandemic, APIC disseminated a position paper on extending the use of or reusing respiratory protection in health care settings during disasters.

In California, the California Aerosol Transmissible Disease Standard covers not only PPE but also requires immunization for all aerosol-transmissible infections such as measles, mumps, rubella, chicken pox, diphtheria, and pertussis. PAPRs are required for high-hazard activities

such as sputum induction, bronchoscopy, aerosolized administration of medications such as pentamidine or other nebulizer-type treatments, pulmonary function tests, autopsies, and certain surgeries.

As noted by other speakers, the advantages of PAPRs include comfort, eye protection, and not having to do a fit test for certain models. Disadvantages include hearing and communication challenges, patient fear, and decontamination, as well as higher storage and battery costs. Respiratory protective equipment has both administrative costs and capital costs. Training is needed for all types of respirators. Although loose-fitting PAPRs do not have the same fit testing costs that N95 respirators have, they do have higher capital costs.

One challenge for health care is that it is difficult to show cause and effect. Health consequences of particular behaviors are not always immediate and may present days or weeks later. For example, it can be difficult to determine whether increased infection rates are due to health care workers not washing their hands adequately as they go from patient to patient or due to workers not wearing N95 respirators. Facilitating the use of PAPRs by health care workers requires equipment that is easy to use and has clear directions for its use. Ideally, PAPR design and NIOSH certification of PAPRs would consider the specific needs of health care workers.

Preparedness and Response in the Chicago Department of Public Health

Christopher Shields
Chicago Department of Public Health

The Chicago Department of Public Health oversees clinical and nonclinical emergency responders. It is prepared in an emergency to help in providing triage and care to people outside the clinical setting in order to keep hospitals from being overwhelmed. The Joint Commission requires each accredited hospital to have an alternative treatment protocol and a plan to move clinical operations into the field in order to increase surge capacity.

In response to the Joint Commission's mandate and also to serve as a storage site for 35 city hospitals, the Chicago Department of Public Health maintains a warehouse inventory of pharmaceuticals, countermeasures, and PPE in a temperature- and humidity-regulated environment. The PAPRs that are stored are seen as an important part of the PPE inventory because anyone can wear them, fit tested or not. Chicago uses

PAPRs to expand its PPE options for its traditional first-response workforce. The city maintains PAPRs at an average cost of $1,200 each, which includes an extra battery and extra filters. When deployed, the PAPRs are sent out with two batteries, a charge station, and two filters, all of which is projected to allow for 16 hours of running time. The battery maintenance program tests the batteries on a cyclical schedule to ensure all PAPRs are fully charged when they are sent into the field.

The Chicago Department of Public Health tracks its PPE and pharmaceuticals from point of purchase to point of receipt in the field, all the while controlling the temperature and humidity of the secure environment in which they are stored. Given the extraordinary maintenance measures taken, the city received manufacturer approval to extend the expiration date of its inventory. This level of control and monitoring is believed to be unique outside a military environment.

Improvements needed for PAPRs include increases in filter efficiencies and increasing the battery capacity. The Chicago program emphasizes life-cycle testing. Respiratory protective device certification should specify operational and performance qualifications so that the equipment can be retested after sale or during field deployment to determine whether it meets manufacturing specifications.

Discussion on PAPR Use in Emergency Response

The discussion began with participants voicing an overarching concern about performance requirements for PPE for health care workers. Bill Kojola raised the issue of the uncertainties about what is an infectious dose for each of various pathogens. Richard Metzler agreed and went on to highlight the need to determine a permissible exposure level and relate that to the assigned protection factor (APF) of the respiratory protective device. He also noted that particle filtration is the same regardless of whether a particle is biological or inorganic. Roland Berry Ann pointed out that although exact infectious doses may not be known, it is possible to use the APFs to assess the relative efficacy of respirators.

James Zeigler, J.P. Zeigler, LLC, and Linda Clever discussed issues related to the hierarchy of controls and the other non-PPE measures (including engineering controls) that should be in place prior to determining the type of PPE needed in a given situation. Hernando Perez, Drexel

University, brought up the subject of control banding,[2] which can provide some general assessments regarding ranges of exposures and the protective controls that are needed, and Maryann D'Alessandro stated that NIOSH is writing a document about control banding in health care environments. David DeJoy, University of Georgia, noted two things to consider when determining what is an acceptable level of risk: (1) the ability to objectively measure risk and (2) the social and political assessments of how much risk is acceptable.

An additional topic of discussion was the training and maintenance manuals for PAPRs. D'Alessandro noted that NPPTL reviews user instructions as part of the respirator certification process but does not require training or maintenance manuals and does not review those materials when they are available. Melissa McDiarmid, University of Maryland, suggested that similar to the way the Food and Drug Administration requires that certain information be included in medication package inserts, respirator package inserts could be required to include training and maintenance instructions. Zeigler suggested adding instructions on the donning and doffing of respirators. Ensuring that the end users have access to the information provided with the respirators was an issue raised by Mark Catlin. He noted that the package inserts are often not seen by the employees themselves.

A question was raised about the nation's Strategic National Stockpile, and D'Alessandro noted that PAPRs are not currently a part of that stockpile effort.

[2]The Centers for Disease Control and Prevention defines control banding as "a technique used to guide the assessment and management of workplace risks. It is a generic technique that determines a control measure (for example, dilution ventilation, engineering controls, containment, etc.) based on a range or 'band' of hazards (such as skin/eye irritant, very toxic, carcinogenic, etc.) and exposures (small, medium, large exposure)" (CDC, 2014c).

4

Research and Design Perspectives

Research on respiratory requirements and powered air purifying respirator (PAPR) design is being conducted to improve the use of PAPRs and other respirators by health care workers. Four workshop speakers discussed the physiological needs of health care workers and how to improve PAPR mechanical function for the health care setting.

RESPIRATORY DEMANDS OF THE HEALTH CARE WORKFORCE

Philip Harber, University of Arizona

Focusing on the personal protective equipment (PPE) needs of health care workers involves examining the types of work they are performing and the real-world situations that they must deal with while in protective gear. Much of the research discussed in this presentation applies to all types of respirators and is not specific to PAPRs. Harber's presentation focused on four key points:

1. Human respiratory physiology is complex, and therefore, a single flow rate criterion is not the solution.
2. Assessments of real-life utilization may be more important than the protection factor.
3. Design features for PAPRs or other types of PPE can affect utilization and need to be measured and assessed in laboratory settings.
4. Health care workers are diverse and have differing respiratory demands depending on their physiology and the types of work they are doing, in addition to other factors.

Respirator design must account for the respiratory burden to the user as well as the impact of the action of breathing on a respirator's protection—that is, on the respirator's effectiveness. To assess PAPR burden on the user, laboratory methods should be as noninvasive as possible in order to avoid interfering with normal breathing or with the operation of the PAPR. Measures of chest and abdominal movement can provide fairly accurate and direct measurements.

Breathing does not occur at a constant rate; inhalation and exhalation rates are not constant and can vary considerably. Thus, pressure and flow rates can vary widely depending on the level of physical exertion and other factors. Respirators should provide protection at the peak inspiratory flow rate. The pressure gradient is another key factor in physiological studies of the impact and effectiveness of respiratory protection.

The pathway to respiratory protection involves numerous steps including but not limited to identifying the agent, identifying persons at risk, choosing the proper respirator, training users, motivating users, making the respirator available, ensuring proper respirator function (e.g., battery is available and working), checking that the respirator is properly used, ensuring an adequate facial seal and filter effectiveness, and confirming proper equipment maintenance. Although some of the answers may not be available and quantifiable (e.g., filtration effectiveness), it is possible to "set up reasonable ranges and then look at which factors have the bigger influence on the overall utility."

Just as the engineering design is tested in the certification process, it is possible to conduct more testing on implementation issues, including donning and doffing times and effectiveness, training measures, and subjective and comfort issues. A decision support system could be effective.

EVALUATING PHYSIOLOGICAL REQUIREMENTS WHEN USING PAPRs

Edward Sinkule
National Personal Protective Technology Laboratory

The National Personal Protective Technology Laboratory (NPPTL) is conducting research to characterize the physiological and subjective responses to PAPR use. This research examines work rates that are similar to those found in health care settings. It is ongoing work, so final results are not yet available. The three parts of the ongoing study are (1) to conduct physiological measurements of participants using a treadmill to

elicit specific work rates similar to those experienced by health care workers; (2) to survey the participants about their experience wearing the PAPR, especially with regard to noise level, comfort, and ease of communication; and (3) to use an automated breathing and metabolic simulator to assess the impact of varying work rates, breathing rates, and humidity levels.

NPPTL is testing several models of PAPRs—one with a tight-fitting hood and three with loose-fitting hoods. One of the areas of study has focused on understanding how carbon dioxide and oxygen levels change when PAPRs are worn at three different work rates.

Varying intensities of physical activity in health care work (and thus varying demands on airflow within the PAPR) could be examined for four work situations: (1) desk work, such as entering patient notes into a computer; (2) operating room procedures; (3) moving patients; and (4) emergency calls by paramedics or physical therapists performing patient care. The use of MET (metabolic equivalent of task) to classify PAPRs by energy expenditure could be helpful in respirator selection. The Compendium of Physical Activities uses METs and other measures to categorize the level of physical activity involved in work, and this approach could be considered as a way to overcome the subjectivity of terms for work such as "heavy" or "light," which people perceive differently (Ainsworth et al., 2000).

PAPR Batteries and Performance

Richard Metzler
National Personal Protective Technology Laboratory

Batteries powering a respiratory protective device are what make a respirator a PAPR, and they can greatly improve worker ease of use and comfort. Batteries are specifically matched with PAPR components (blowers, hoods, helmets, filtering components, and chargers). The National Institute for Occupational Safety and Health (NIOSH) certifies the complete PAPR respirator assembly, including the battery. Currently there are no requirements for the batteries or their chargers to be interchangeable or interoperable. PAPRs generally use one of three types of rechargeable batteries—nickel cadmium, nickel metal hydride, or lithium ion—or a non-rechargeable disposable battery that could be alkaline, lithium sulfur dioxide, or lithium manganese oxide. PAPRs are tested for the robustness of their batteries with the silica dust test, which draws a silica

dust cloud through the PAPR for 4 hours. Battery management is an important part of the respiratory protection program for PAPRs. Whether in use or not, batteries are constantly discharging and do not maintain their charge indefinitely in storage. Lithium ion batteries have become a preferred battery choice because they have a small discharge rate in storage (approximately 5 to 10 percent per month) compared to nickel cadmium batteries and nickel metal hydride batteries (approximately 30 percent per month).

Batteries that have not been used for several months may require reconditioning—that is, discharging and recharging to restore capacity before use. Battery instructions need to be made more easily available, as they are not always provided with the blower assembly or with the charger instructions.

Because of their battery power, PAPRs have the capacity to offer a number of product features that would be helpful to users, including battery check lights, indicators of airflow rates or duration of use, and monitors for the end-of-service life on the canisters and cartridges.

Battery power could also allow for product features to be added that would increase the utility and performance of PAPRs in the health care setting, such as electronic microphones for easier communication. Furthermore, different types of PAPRs with different assigned protection factors could be considered if the demand was evident. "Once you define those technical specifications in the engineering world, we'll link it to standards, and manufacturers will produce to those standards." The health care community has the market share to drive the PAPR market in a way similar to how the firefighter community drove the requirements for self-contained breathing apparatuses and helped to set National Fire Protection Association standards. Efforts are under way, including Project BREATHE (discussed earlier by Lewis Radonovich), NIOSH evaluation initiatives, and field studies to identify the respiratory protection needs of health care workers and the tasks and capabilities that should be specified for future respirators that more closely meet the needs of the health care workforce.

IMPACT OF CERTIFICATION STANDARDS ON RESEARCH AND DESIGN

Larry Green, Syntech International

PAPRs could be designed to better meet the needs of different work environments, including health care. Regulations should be written so

that the tests are appropriate for the design features needed for a particular work environment. The obvious test that is currently required but that does not apply to the health care work environment is the silica dust test, which, as noted by other speakers, is designed for a mining or other dusty work environment. For health care, "combining LRPL [Laboratory Respirator Protection Level] testing with active airflow and battery-level warnings should be allowed in place of silica dust testing." Consideration should also be given to loose-fitting PAPRs being tested as part of a PPE system that integrates with a surgical gown or other body covering.

Some of the lessons that can be learned from surgical helmet systems, which look similar to PAPRs but are not certified as respiratory protection, include

- Increase visibility by designing for a wide and clear visibility field with optically clear lenses;
- Improve communication by decreasing noise from the blower;
- Reduce weight of the PAPR to improve comfort;
- Reduce carbon dioxide levels to the fullest extent possible;
- Ensure that the battery meter and airflow alarm are easily visible;
- Avoid hyperthermia by ensuring a cooling airflow and minimize breathing resistance; and
- Integrate the hoods or cowls into protective clothing systems, particularly with consideration of how the donning and doffing of the PPE is done, to maintain sterile PPE on initial contact with a patient and lack of contact with contaminated equipment when removing the PPE.

Green concluded by suggesting, "the key to new advances are appropriate regulations which dictate sound design and applicable standards based on the widest range of needs, not a narrow set of tests applicable to a narrow set of needs."

5

Priorities and Opportunities for Improving PAPRs for Use in Health Care

The workshop concluded with several discussion sessions, including an audience discussion and an opportunity to hear from speakers who were asked to provide a summary of the workshop and to identify priorities for next steps.[1] While the perspectives varied and included those of health care workers and managers, respirator manufacturers, staff from professional associations and unions, federal agency staff, and emergency management administrators, the suggestions for improvement in powered air purifying respirator (PAPR) design and use greatly overlapped. What follows is a summary of the views expressed, categorized into three main themes:

1. Improve PAPR design and standards: assess the risks and protective factors, identify design attributes, and drive the market to meet health care needs;
2. Increase education and training; and
3. Strengthen implementation and use of PAPRs in health care.

IMPROVE PAPR DESIGN AND STANDARDS: ASSESSING THE RISKS AND INCORPORATING HEALTH CARE NEEDS

As noted throughout this summary, numerous workshop participants said that respirator standards relevant to PAPRs could be revised and

[1]This section summarizes the discussion session after the Panel 5 presentations, the Audience Discussion session, and the issues raised by Panel 6 speakers who were asked to summarize the workshop.

expanded to allow for PAPRs that better meet the needs of health care workers. Current PAPR certification standards, developed primarily for industrial applications, are not always appropriate for the health care work environment.

Assessing the Risks and Protection Factors

James Johnson and other respiratory researchers emphasized that it is clear from aerosol physics research that for the purposes of assessing respirator filter performance, all particles are the same, regardless of whether they are biological particles, radioactive particles, or toxic material particles.

The challenges for ensuring health care worker safety lie in quantifying the infectious dose and in determining the level of protection that needs to be achieved with respiratory protection. Much remains to be learned about acceptable risk and the inoculum amount necessary for specific infectious diseases. Lewis Radonovich noted that one of the goals in respiratory protection for health care workers is to know more about the exposures. He said that information is needed that can provide a characterization of risk for health care workers that is similar to the characterization of risk used in the industrial hygiene approach to chemical exposures. However, "if we cannot define the risk, we should base our decisions on the precautionary principle," Radonovich noted.

In an earlier discussion Deborah Gold had emphasized that PAPR design for health care workers should aim for an assigned protection factor (APF) of better than 25 and include a specific APF range, as confirmed by the National Institute for Occupational Safety and Health (NIOSH) in the respirator certification process. She said that PAPRs should be labeled for the various worker postures for which they are certified to maintain airflow and protection.

Identifying Design Attributes

Because the way in which health care workers use personal protective devices such as PAPRs can differ significantly from how workers in industrial settings use the same equipment (e.g., numerous interactions with a variety of patients, exposures that are difficult to quantify, intermittent or infrequent use of personal protective equipment [PPE], and

reduced workload and subsequent airflow demands), there are design features that could be improved to meet the specific needs of health care workers. Any such changes would need to be incorporated into PAPR certification regulations and processes.

Maintaining the Sterile Field

In his summary remarks, Craig Colton reemphasized the need to explore the design parameters of PAPRs that would allow for surgeons and others to maintain a sterile environment. Currently, PAPRs use an externally venting air exhaust system. Various approaches to filtering the exhaust air could be explored and then tested in the certification process.

Visibility and Communication

Health care work inevitably involves interaction with others. As Karen Anderson pointed out, PAPRs need to be patient friendly. In addition to the need for facial visibility, health care workers need to communicate with patients, including listening to them or to their vital signs. The noise of a PAPR fan can interfere with this aspect of their work. Reductions in the requirements for high-flow systems could significantly reduce the noise levels, noted Larry Green.

In a comment on the NIOSH docket, Jennie Mayfield noted, "We have concerns that the use of PAPRs impedes health care workers' ability to observe and communicate with the patient and other members of the health care team, which affects patient safety."

Ease of Donning, Doffing, and Cleaning

A number of participants commented on the need to better measure and train for donning and doffing. Philip Harber suggested that laboratory- and health care facility–based tests could be used to assess and improve a number of the design attributes, including donning and doffing procedures.

Multiple Flow Rates

A multiple flow rate PAPR was suggested by several speakers, including Johnson. Having a switch or sensing device that changes the airflow rate depending on the work rate—low, such as when taking vital signs, and high, such as when helping to move a patient—could provide

increased comfort and workability features for health care workers. Jim Chang noted that it might be hard to determine the appropriate flow rate for sporadic users of PAPRs, but automatic adjustments could be helpful.

Other Design Enhancements

Other enhancements suggested by workshop participants included

- Reduced size and bulkiness;
- Improvements in battery charge/drain times and filter efficiencies for longer-term use in field situations in the event of a pandemic;
- Interchangeable batteries and filters between models, which would simplify and extend their use;
- Better equipment-related feedback for wearers, such as flow pressure and power monitoring; and
- Improved training materials that are also a part of the requirements for the certification process.

Cost

Many workshop participants noted that cost is a key barrier to the use of PAPRs by health care organizations. Some of the costs may be due to the requirements to meet the specifications of the silica dust test performed for NIOSH certification, said Green. Cost savings may be achievable, according to Green and other speakers, by revising the specifications to meet health care needs.

Performance-Based Standards

Testing is an integral part of the NIOSH certification process for PAPRs. A number of participants expressed the opinion that testing standards should be based on the activities in which the user is engaged. Colton stated, "As a manufacturer, we would argue for performance orientation versus specification to allow us to make it do what it needs to do rather than be restricted to minimum flow rates and a battery that has to last this specified mandatory time to get through the tests. Get away from the specifications and go to performance."

Driving the Market to Meet the Needs of Health Care Workers

Changing the design and standards for PAPRs to meet the needs of health care workers will require concerted efforts. Several presenters, including Edward Sinkule, pointed out that health care workers do not currently have an organization that is focused on providing the momentum for change in respiratory protection for the health care work environment. The changes leading to improved firefighter protection resulted in large part from the unifying and energizing force that the National Fire Protection Association and the International Association of Fire Fighters brought to the world of fire protection. Roland Berry Ann and Radonovich noted that Project BREATHE (discussed in Chapter 3) assembled a collaboration of federal agencies and other organizations to put together a list of performance attributes for N95 respirators for health care workers. A similar effort could be done for PAPRs for health care workers.

During the workshop, a number of representatives from various respirator manufacturing and health care PPE companies expressed their willingness to listen to what is needed for respiratory protection, including PAPRs, and to develop products based on those specialized needs, using health care performance requirements to drive specifications.

Determining the extent of the health care market is challenging, said James Zeigler. He noted that a large number of nonsurgical N95 respirators are being used in the health care industry, which adds to the market share but may not be included in market assessments. He also said that the health care industry is viewed as a valuable and growing market space. As Richard Metzler stated, "The health care community across the United States is huge. You would really be able to demand almost anything you want if you got together and identified what those specifications were and laid them out for the manufacturers. You specify it, and they will come."

INCREASE EDUCATION AND TRAINING

A number of workshop participants, including Trish Perl, noted that while the one-size-fits-all design of loose-fitting PAPRs is appealing to providers because it negates the need for costly and time-consuming fit testing, the design does not negate the need for education and training.

Health Professional Education

Very little attention is being paid to teaching about respiratory protection in nursing and medical schools, said Bonnie Rogers. She said that end users need to be engaged in respiratory protection and worker safety training early on in their education and pointed out that one particularly neglected but important segment of provider education is certified nursing assistant (CNA) education. CNAs provide much of patient care both in hospitals and outside hospitals in nursing homes and the home health care environment. In responding to inquiries about respiratory protection training, administrators in community colleges in North Carolina have indicated that there is no time for this training in the CNA curriculum. Practitioners will do what they are taught, Rogers noted. Kerri Rupe, University of Iowa, concurred and noted the lack of emphasis on worker safety and respiratory protection in nursing education. She stated that "nurses want to protect themselves, and they certainly want to protect their families."

Training

Throughout the workshop, speakers mentioned the need for training health care workers on the use of PAPRs. Mark Catlin noted the importance of ensuring that training is done in advance of use, with hands-on practice in donning, doffing, and working while wearing a PAPR. Anderson pointed out that just as there is extensive education on the use of N95 respirators during fit testing, there needs to be a similar emphasis on PAPR training. She noted that health care workers who frequently use PAPRs, such as respiratory therapists, would have the expertise to train others. Also important to remember, as pointed out by Rupe, is that health care workers may not use a PAPR every day or even every week or month. The use is intermittent and more likely to occur in a surge situation. This means that there may be large gaps of time—6 months to 1 year—between when workers are trained to use a PAPR and when they actually use it.

Currently, NPPTL reviews the user instructions for respirators as part of the certification process but does not review training and maintenance manuals. Maryann D'Alessandro noted that this could be something to consider going forward and asked the workshop participants if the review of instructions and training on donning, doffing, and use of

PAPRs should be part of the NIOSH certification process. Several participants thought PAPR use could be improved by requiring manufacturers to provide training materials to purchasers. Gold noted that the written materials included with respirator certification should include clear, plainly written statements to help employers select the most appropriate devices for their needs and to train employees on the use, advantages, and limitations of specific equipment.

Green pointed to the requirements that the Food and Drug Administration (FDA) has for obtaining 510(k) approval for isolation gowns, which include instructions and training videos on how to don and doff the gowns. NIOSH could have similar requirements for training materials for PAPR certification. Melissa McDiarmid noted that the inclusion of user training information could be a recognized standard of practice for manufacturers, similar to the information required by FDA on package inserts for pharmaceuticals.

STRENGTHEN IMPLEMENTATION AND USE

Compliance with regulations for use of PAPRs and other respiratory PPE in health care can be quite different than in other industries, noted Catlin. In other industries, such as asbestos abatement, he noted, the industry determined what was needed and then "workers wore what they were provided to wear and told to wear and trained to wear" for their protection. In health care the exposures may be unknown and difficult to quantify, and the work culture is more independent. Chang noted that health care is often outcomes based, and respiratory protection is not an issue until a patient has an infectious disease.

Metzler pointed out that health care institutions are fighting the status quo and the beliefs by health care workers that surgical masks are "almost good enough" and thus an N95 respirator may not be needed. Anderson provided the perspective of a nurse manager in infection control and prevention and suggested that many health care workers believe that the fact that they have been using a surgical mask for 30 years without a problem is evidence that they do not need additional respiratory protection.

Ensuring that PPE is a priority and that its use is a core competency was a theme echoed by many participants. Rogers pointed to the value of having an individual or individuals designated as the "practice champions" on health care units; these individuals provide guidance and answer

questions regarding PPE. Frank Califano noted that accountability by an organization such as the Joint Commission would be key to driving change in the worker safety culture in health care. Furthermore, research is needed that can bolster the quantitative evidence of the effectiveness of PAPRs and of specific donning and doffing protocols. Workers and administrators need to be convinced that PAPRs can protect health care workers, their families, and their patients.

In concluding the discussion, Linda Clever noted that there are many more voices that need to be a part of the discussion, including health care workers and administrators who work in home health care, in clinics, in small or rural hospitals, and in nursing homes.

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A

Agenda

The Use and Effectiveness of
Powered Air Purifying Respirators (PAPRs) in Health Care

Keck Center of the National Academies
500 Fifth Street, NW, Room 208
Washington, DC 20001

August 7 and 8, 2014

THURSDAY, AUGUST 7—Room 208

8:30 – 8:40 a.m. **Welcome and Introductions**
Jim Johnson, Chair, IOM Workshop Planning Committee
Linda Hawes Clever, Chair, IOM Standing Committee on Personal Protective Equipment for Workplace Safety and Health (COPPE)

8:40 – 8:45 a.m. **Impetus for a Workshop on PAPR Certification Standards**
Maryann D'Alessandro, Director, National Personal Protective Technology Laboratory (NPPTL)

8:45 – 10:05 a.m. **Panel 1: Understanding Current PAPR Regulations and Standards—Certification of PAPRs for Use in Health Care Settings**
Facilitator: *Linda Clever, Chair, Standing Committee on Personal Protective Equipment for Workplace Safety and Health and Planning Committee Member*

8:45 – 8:50 Panel Introductions
8:50 – 9:35 Presentations

- NPPTL Certification Standards
  Roland Berry Ann, NPPTL
- ISO Standards
  Craig Colton, 3M Personal Safety, 3M
- Regulatory Perspective
  Deborah Gold, Cal/OSHA (via WebEx)

9:35 – 10:05 Discussion

Issues for Presentations and Discussion:

- What are the strengths and weaknesses of various approaches to modifying the PAPR certification requirements, including
  - Use of current NIOSH standards and certification processes
  - Changes to the PAPR certification standard that could be incorporated in 42 CFR 84 to provide improved health care worker protection
  - Use of the ISO standards for the certification of health care PAPRs
- If the ISO standards are incorporated by reference:

- What scientific studies are available to support the incorporation of the standards as currently drafted?
- What scientific studies are needed to validate the draft standards to address these requirements?
- What safeguards would be necessary to ensure the intended work rates are not exceeded?

10:05 – 10:20 a.m. **Break**

10:20 a.m. – 12:00 p.m. **Panel 2: Employee and Worker Experience in Using PAPRs in Health Care Settings**
Facilitator: *Bill Kojola, COPPE Committee Member*

10:20 – 10:25 Panel Introductions
10:25 – 11:25 Presentations

- *Debbie Novak*, *NPPTL* (via WebEx)
- *Jo Garrison, OSF Saint Francis Medical Center*
- *Karen Anderson, CA Pacific Medical*
- *Mark Catlin, Service Employees International Union*

11:25 – 12:00 Discussion

Issues for Presentations and Discussion:

- Why, where, and how are PAPRs being used in health care settings?
- What actions need to be taken to ensure PAPRs are properly used in the health care setting?
- What has the experience been in using PAPRs—benefits, challenges, barriers?
- What changes in PAPR design and function are needed?
- How can certification standards be used to encourage these changes?

12:00 – 12:45 p.m. **Lunch**

12:45 – 2:20 p.m. **Panel 3: Employer Experience with PAPRs in Health Care Settings**
Facilitator: *Barbara DeBaun, COPPE and Planning Committee Member*

12:45 – 12:50 Panel Introductions
12:50 – 1:50 Presentations

- *Jim Chang, University of Maryland*
- *Lewis Radonovich, Department of Veterans Affairs*
- *Trish Perl, Johns Hopkins University* (via WebEx)
- *Jeffrey C. Nesbitt, Mayo Clinic*

1:50 – 2:20 Discussion

Issues for Presentations and Discussion:

- Why are PAPRs selected over other respirators and what factors affect selection of specific PAPRs for purchase? What criteria are used for purchases of PAPRs?
- What efforts are needed to improve maintenance or life of PAPRs and how does this affect supplies?
- What steps are necessary to ensure that workers comply with instructions on use, including training and efforts to increase compliance?
- What changes in PAPR design and function are needed?

2:20 – 2:35 p.m. **Break**

2:35 – 4:25 p.m. **Panel 4: Use of PAPRs in Emergency Preparedness Planning and Response**
Facilitator: *Melissa McDiarmid, Planning Committee Member*

2:35 – 2:40 Panel Introductions
2:40 – 3:55 Presentations

- *David Ladd*, *Massachusetts Hazardous Materials Team*
- *Robert Huebner, The Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response*
- *Francis Califano*, *North Shore–LIJ Health System*
- *Annemarie Flood*, *Association for Professionals in Infection Control and Epidemiology*
- *Christopher Shields, Chicago Department of Public Health*

3:55 – 4:25 Discussion

Issues for Presentations and Discussion:

- How do PAPRs currently fit in to pandemic preparedness planning? What are the possibilities for future preparedness plans? What are the economic and logistical considerations? What are other issues that are considered in decisions about PAPRs?
- What actions need to be taken to ensure PAPRs are properly used in the health care setting, especially as part of the national pandemic preparedness?
- What changes in PAPR design and function are needed? How can certification standards be used to facilitate these changes?

4:25 – 4:45 p.m. **Public Comment**

4:45 p.m. **Adjourn**

FRIDAY, AUGUST 8—Room 208

8:30 – 8:40 a.m. **Welcome and Review of Workshop Plans**
Jim Johnson, Chair, IOM Workshop Planning Committee

8:40 – 10:15 a.m. **Panel 5: Research and Design Perspectives—Improving PAPRs for Use in Health Care Settings**
Facilitator: *Dan Shipp, COPPE and Planning Committee Member*

8:40 – 8:45 Panel Introductions
8:45 – 9:45 Presentations

- Understanding the Respiratory Demands of the Health Care Workforce
  Philip Harber, University of Arizona
- The Importance of Appropriate Battery Life in PAPR Usage, Maintenance, and Lifespan
  Rich Metzler, NPPTL
- Research and Design and the Impact of Certification Standards
  Larry Green, Syntech International
- Evaluating the Physiological Performance of PAPRs
  Edward J. Sinkule, *NPPTL*

9:45 – 10:15 Discussion

Issues for Presentations and Discussion:

- What research has been done on determining optimal flow rates for health care workers? On the need for shorter life batteries? Where are the research gaps and needs for future research?
- What work is being done to improve the interactions with patients by health care workers wearing PAPRs (e.g., noise,

visibility, communications issues, and others)?
- What work is being done to improve the design of PAPRs to improve ease and comfort of use by health care workers?

10:15 – 11:15 a.m. **Audience Discussion—How Can NPPTL's PAPR Standards Evolve to Meet the Needs of the Health Care Workforce?**
Facilitator: *Jim Johnson, Chair, IOM Workshop Planning Committee*

11:15 – 11:55 a.m. **Panel 6: Summary and Priorities—Updating Certification Standards to Drive Better Health, Use, and Innovation of PAPRs**
Facilitator: *Jim Johnson, Chair, IOM Workshop Planning Committee*

- *Bonnie Rogers, University of North Carolina at Chapel Hill*
- *Craig Colton, 3M Personal Safety*
- *Lewis Radonovich, Department of Veterans Affairs*
- *Karen Anderson, CA Pacific Medical*
- *Linda Clever, University of California, San Francisco*

Issues for Presentations and Discussion:
- What major issues have been identified?
- What are the priorities for improving the use of PAPRs in health care settings?
- What are the strengths and weaknesses of various approaches to modifying the PAPR certification requirements and standards?

11:55 a.m. – 12:00 p.m. **Closing Remarks**
Jim Johnson, Chair, IOM Workshop Planning Committee

B

Registered Attendees

Craig Allen, Intermountain Healthcare

Karen Anderson, California Pacific Medical Center

Kirk Bantz, Saint Alphonsus Regional Medical Center, Boise

Roland Berry Ann, National Personal Protective Technology Laboratory

Bill Borwegan, Service Employees International Union

Yvonne Boudreau, National Institute for Occupational Safety and Health

Lynn Brinkmeier

Jana Brott, Legacy Health

Jennifer Bunce, Springfield Hospital Center

Francis Califano, North Shore–LIJ Health System

Mark Catlin, Service Employees International Union

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