Toward Better Fitting Respirators

No Fit Test Respirator Workshop and Research Roadmap

RFQ 2008-Q-10205

Lisa M Brosseau, ScD, CIH
University of Minnesota
School of Public Health
Division of Environmental Health Sciences
Minneapolis, MN 55455

Executive Summary

Respirator fit and the value of fit testing are the least understood and most controversial aspects of respirator performance. Research has shown that fit testing is necessary to assure that respirators are properly worn and provide a preliminary level of expected protection. It is not yet possible, however, to identify or predict which combination of facial features and respirator design characteristics will assure both initial and long-term fit.

This project was conducted by the University of Minnesota for the National Personal Protective Technology Program at the National Institute for Occupational Safety and Health, in response to a Request for Quotations (2008-Q-10205) seeking recommendations for research, procedures and policies leading to improvements in the fit of half-mask air purifying respirators. Two research tasks were undertaken: 1) an evaluation of barriers and incentives for recent innovations in respirator design and fit test methods and 2) conduct of a workshop to explore new ideas and research directions for better fitting respirators. This project was focused on recommendations for future NIOSH actions that might lead to improvements in respirator fit, not on the elimination of the need for fit testing.

Four successful innovations (the ambient aerosol quantitative fit test method, strap cradle or head harness, double-flanged facepiece and flat fold design for filtering facepiece respirators) and two less successful innovations (adhesive face seal and user seal checks) were selected. Literature reviews, patent searches and interviews were conducted for each innovation. Interviews sought information on incentives for development, costs of development and marketing, effect on respirator use and regulation, effect of regulations, reasons for success (or not) and effect on respirator fit.

Eleven platform and 13 poster presentations were included in the one-day workshop held on November 6, 2008 in Pittsburgh PA. Workshop participants attended three breakout sessions and offered ideas about new materials and design, new fit test methods and knowledge gaps about fit. Workshop proceedings are available at: http://cpheo.sph.umn.edu/cpheo/mcohs/courses/nofit/home.html.

There have been numerous important improvements in both respirator design and fit test methods over the past 30-40 years. In most cases, technology push or market pull (or both) played an important role in the success of the innovations we examined; regulations generally had a neutral, or, in a few cases, limiting effect on their adoption. Researchers and research publications can play an important role in the adoption of an innovation. Published comparisons of new with current products or methods can encourage adoption; lack of publications can lead to skepticism about efficacy and slower adoption. Health and safety professionals, who rely on published research, user input and personal experience, can also encourage or discourage adoption of new products or methods. There continues to be high potential for innovation in design and fit test methods for better-fitting respirators. Success depends on a combination of specialized knowledge (of materials and technology), preliminary and supporting research, significant financial support, regulatory assistance and flexibility, and ultimately, health and safety professional and user acceptance.

Recommendations are offered in the following areas of research:

Recommendation 1.1: Conduct research to clarify the role of respirator design (technologies, materials and systems) in respirator fit, particularly with respect to strap designs, methods for facepiece cooling, methods for inducing positive pressure inside the facepiece, improvements that lower breathing resistance, and technologies and materials for improving facepiece seals.

Recommendation 1.2: Conduct research to clarify the influence of facepiece design, multiple facepiece sizes and aging on the interaction between facial measurements and respirator fit.

Recommendation 1.3: Conduct research on the role of user seal checks in establishing respirator fit, particularly for filtering facepiece respirators.

Recommendation 1.4: Conduct research on new methods for checking facepiece seals. In particular, efforts should be made to identify methods that continuously track and report facepiece fit.

Recommendation 1.5: Conduct research to elucidate the effect on respirator fit of a) other types of personal protective equipment (PPE) and b) environmental conditions such as temperature, relative humidity and dust.

Recommendations are also offered to NIOSH to ensure implementation and incorporation of research findings into its programs and activities:

Recommendation 2.1: Quantitative assessments of respirator fit using a human test panel should be included in the certification requirements of all half-mask negative pressure air purifying respirators.

Recommendation 2.2: Consultative panel(s) representing key stakeholders --including respirator users and program managers, inventors, researchers, and manufacturers – should be used to ensure a forum for identifying issues, exchanging ideas, discussing research findings and defining future research directions.

Recommendation 2.3: Collaborations among government agencies should be continued to combine resources for supporting internal and external research that is responsive to common needs.

Recommendation 2.4: A formal assistance program should be developed to provide financial and other types of support to inventors and small businesses seeking to bring new ideas to market.

Recommendation 2.5: A method should be established for conducting regular reviews of certification regulations in light of new technologies for respirator design and performance.

Recommendation 2.6: More opportunities should be available, in addition to stakeholder meetings, for interactions between internal NIOSH researchers and external investigators.

Personnel

Study Team

Lisa M. Brosseau, ScD, CIH
Associate Professor
University of Minnesota
School of Public Health
Division of Environmental Health Sciences
MMC 807, 420 Delaware St SE
Minneapolis MN 55455
612-624-3143
brosseau@umn.edu

Nicole Koktavy, MPH
Research Assistant
University of Minnesota, School of Public Health
Division of Environmental Health Sciences

Advisory Board

Jeff Birkner, PhD, CIH
Moldex Metric Inc.
Culver City, CA

Bill Borwegen
Occupational Health and Safety Director
Service Employees International Union
Washington DC

Janice Comer Bradley, CSP
International Safety Equipment Association (ISEA)
Arlington VA

Mark Catlin
Service Employees International Union
Washington DC

Howard Cohen, PhD, CIH
University of New Haven
New Haven, CT

Alan Hack, MA, CIH, CSP
Los Alamos, NM (retired)

Curt Hering
Equipment Services
Toronto EMS

Nicole Vars McCullough, PhD, CIH
3M Occupational Health and Environmental Safety Division
St Paul, MN

Peter Nelson
Silent Power, Inc. and Breathe Safely
Baxter MN

Jeff Weed
Weed Respiratory Protection Solutions, LLC
White Bear Lake, MN

Table of Contents

Introduction

The goal of this project is to:

> "Describe the current state of technology available to enhance the fitting characteristics of negative pressure half-mask air purifying respirator technologies and future interdisciplinary research needs and challenges in developing and certifying air purifying respirators with improved fitting characteristics, leading towards the development of a so-called 'no fit test' respirator." [NIOSH Request for Quotations 2008-Q-10205]

The National Institute for Occupational Safety and Health (NIOSH) plans to use this report:

1. To provide input to its research agenda
2. To guide procedures and policies for respirator certification
3. To encourage government agencies and manufacturers to conduct further research

To meet these goals, two complementary tasks were proposed:

Task 1: Describe development and impact of innovations in respirator design and fit test methods, to understand better the incentives and barriers for improvements.

Task 2: Develop and offer a one-day workshop focused on current design issues and new ideas and areas where research could lead to better fitting negative pressure half-facepiece air purifying respirators.

While NIOSH should be viewed as the primary audience for this report, the findings should be useful and relevant to other government agencies, respirator manufacturers, researchers and respirator users.

It should be noted that this project does not seek to eliminate the need for fit testing, but rather to explore developments in respirator design and test methods that may lead in this direction. Respirators that fit well each time they are worn and need no fit testing could offer significant advantages to employers and employees, including lower costs (in both time and money) for fit testing and greater assurance of protection. Such respirators might also ensure better fit for un-trained or naïve wearers. On the other hand, annual fit testing offers an opportunity to conduct training about proper donning, maintenance and other factors that can play an important role in on-going respirator performance and protection.

This project does not seek to endorse any particular idea, but rather to elucidate the role that ideas and research can play in the development of respirators with good fitting characteristics. We expect the results of this project to be of use to researchers interested in developing new and better designs or methods for ensuring better fitting respirators. There is no expectation that the current regulatory requirements for respirator fit testing will be eliminated as a result of this project, however.

Fit and the value of fit testing remain the least understood and most controversial aspects of respirator performance. A 2001 NIOSH survey of respirator use in industrial settings found that only 50% of companies provide fit testing for their employees.[1] In 2007, an IOM panel suggested that the Department of Health and Human Services "should sponsor and/or conduct research on issues related to public education on and compliance with respiratory protection guidelines, including the importance of proper fit…"[2]

Research by NIOSH investigators has demonstrated that fit testing is necessary to assure that respirators are properly worn and provide at least the preliminary level of expected protection.[3-9] However, it is still not

possible to identify or predict with any certainty which combination of facial features and respirator design characteristics will assure both initial and long-term fit.

In response to its update of 42 CFR Part 84 in the early 1990s, NIOSH received many comments about testing respirator fit for certification of particulate respirators. Some suggested eliminating fit testing as part of respirator certification while others recommended that manufacturers be required to submit test data. Some thought that NIOSH should continue to certify fit, but noted that qualitative tests (e.g. using isoamyl acetate and filters modified with a carbon-impregnated layer) were not meaningful and should be replaced by a quantitative method.[10]

As NIOSH noted in the preamble to its Final Rule, "problems associated with testing the facepiece-fit in a certification program have been recognized for years. Efforts have been made to seek more meaningful test results; nevertheless, the validity of the test results remains questionable." NIOSH noted that current approaches to certifying respirator fit do not assure that the respirator will fit in the workplace. Thus, every respirator user should receive a fit test, although these will not necessarily assure long-term protection. NIOSH decided to address facepiece fit for particulate filters in separate rulemaking, relying in the interim on OSHA's regulatory requirements for fit-testing and fit-checking to assure individual protection.[10]

Since that time, NIOSH has continued to explore issues important to determining respirator fit, including methods for in-facepiece sampling, assessments of respirator performance in workplaces, accuracy and reproducibility of various fit test methods and, most recently, the relationship between facial anthropometric measurements and fit. As promised in its 1995 promulgation of 42 CFR Part 84, NIOSH has been working toward the development of an approach for certifying the fit of particulate respirators.

Following a 2004 anthropometric survey of 4000 respirator users, NIOSH asked an IOM panel to evaluate the survey and resulting proposals for a fit test for certifying respirators.[11, 12] The panel found that the new dataset was an improvement over a previous 1970s dataset, while also noting that the 2004 survey had some important weaknesses.[13]

In particular, the IOM report notes that NIOSH must give careful attention to the effectiveness of fit test panels in assuring that well-fitting respirators are available for the full range of facial sizes. Because facial size characteristics cannot be easily translated to fit, however, the IOM report also recommends that further research is needed to assess which facial features play the greatest role in fit and user protection.[13]

The panel also recommended that filtering facepiece respirators be included in the agency's plans for fit testing, while assuring that its regulations not prevent manufacturers from designing respirators in sizes that fit underrepresented categories of users.[13]

Historical Review of Respiratory Protection

Pliny (23-79 AD) described some of the first respirators made from animal bladders to protect miners from lead exposure. The forerunners to today's respirators, however, were not developed until the late 1700s, also for protection of miners. In the 1800s, the focus was on respirators for firefighting; developments in this era included early filter cartridges (1814), the development of filters with lower pressure drop following the discovery of Brownian motion for small particles (1827) and the use of charcoal for gas and vapor capture (1854). By the early 1900s miners in the United States had access to well-designed respirators imported from European countries; other workers were generally not protected. It was not until the first workers' compensation law in 1919 that other industries were expected to provide respiratory protection for their employees.[14, 15]

The United States began to pay greater attention to respirator design, particularly of gas masks, with its entry into World War I in 1917. Many of today's designs grew out of those developed by the Bureau of Mines for protection of soldiers from toxic gases and aerosols. Following World War I, the Bureau of Mines was given the responsibility for approving respiratory protective devices. Approval schedules were first developed for self-contained breathing apparatus and gas masks in 1919 followed by schedules for dust/fume/mist respirators in 1934, supplied air respirators in 1939 and chemical cartridge respirators in 1944.[14] Additional schedules and changes to existing schedules continued until the 1970s.[16]

Limitations to the Bureau of Mines approval process were several: 1) there were no procedures for removing certification from older devices, 2) many respirators were being used in non-mining environments, and 3) there was no regulation of non-certified respirators. Resin-impregnated (electrostatic) filters, developed in the 1930s, led to improvements in both filter efficiency and breathing resistance and by the 1960s a number of respirator designs were commercially available but not approved by the Bureau of Mines, including particulate respirators for highly toxic materials (e.g. radioactive aerosols, beryllium and pesticides) and chemical cartridge respirators for materials other than organic vapors.[16]

It was not easy to determine, however, whether a respirator lacked approval because there was no appropriate schedule or because the manufacturer had not submitted the device for approval. The lack of regulatory oversight for respiratory use in workplaces often led to decisions based on breathing resistance (comfort) and price rather than on degree of protection.[16]

It was not until the passage of the 1970 Occupational Safety and Health Act that a regulatory agency was given oversight of the use of respirators in most United States workplaces. The regulation (29 CFR Part 1910.134) stated that "respirators shall be provided by the employer when such equipment is necessary to protect the health of the employee" and that "approved or accepted respirators shall be used when they are available." Accepted respirators were those approved by the Bureau of Mines.

The Bureau of Mines (BOM) continued to develop additional approval schedules until 1972, when the National Institute for Occupational Safety and Health (NIOSH) and the BOM jointly assumed approval of all respirators with the passage of a new regulation – 30 CFR Part 11 -- to which was added an approval for pesticide respirators along with previous, but updated, schedules. All old devices eventually lost their approvals; manufacturers had to seek re-approval under the new regulation.[14, 15]

Since the creation of the Occupational Safety and Health Administration (OSHA) and NIOSH in the early 1970s, much greater regulatory attention has been given to respiratory protection in occupational settings. In 1995, NIOSH published a new regulation, 42 CFR Part 84, replacing 30 CFR Part 11 and giving NIOSH sole authority over certification of respiratory protective devices. Among the most significant changes in this regulation were new tests and certification categories for particulate filters. Respiratory protection was addressed by OSHA in a number of substance-specific regulations until two revisions of 29 CFR Part 1910.134 in 1998 and 2006 consolidated most requirements into a single respiratory protection standard.

New Applications for Respirators

Prior to the 1980s, respirators were used primarily in industrial and manufacturing settings, where it was generally understood and accepted that respirators must be worn in the context of a respiratory protection program, with proper selection, training, medical evaluation, fit testing, maintenance, etc. With time, respirator use has expanded into new worksites, presenting new challenges for design, fit testing and program management.

While there were respirators with facepieces consisting largely of filter material prior to the 1970s, there was no mechanism for certifying such designs until the passage of 30 CFR Part 11 in 1972. Filtering facepiece respirators developed since that time have enjoyed considerable popularity, for reasons of comfort and disposability.

The OSHA standard for protection of healthcare and other workers from exposure to tuberculosis (TB) in 1997 (since rescinded) marked an expansion of the use of respirators into new employment settings and resulted in considerable discussion about the efficacy of respirators and the need for fit testing. With the TB standard also began a discussion that continues today about the nature of infectious disease transmission. Much of the infectious disease community believes that most infectious diseases are not transmitted via the airborne route – TB being an unusual exception to this rule. This remains one of the central arguments against the need for respiratory protection for exposures to infectious disease.

Worldwide outbreaks in the 2000s of a new disease, severe acute respiratory syndrome (SARS), resulted in many healthcare worker deaths. The conditions in which SARS was contracted suggest that the airborne route may have been an important mode of transmission, particularly during aerosol-generating procedures. The Centers for Disease Control and Prevention guidelines for SARS now recommend the use of filtering facepiece respirators (N95 filters) (with a full respiratory protection program) during patient care.[17]

Recent concerns about pandemic influenza have also brought renewed attention to airborne transmission of infectious disease. Because other methods of control (e.g. vaccinations) are either unlikely or uncertain to provide protection, respirators have received considerable attention. Organizations planning for an influenza pandemic have asked for new filtering facepiece respirator designs that are easier to wear, fit test and provide protect against liquid splashes.

In 2006, an IOM panel was asked to evaluate whether filtering facepiece (N95) respirators and surgical masks could be cleaned or re-used during a pandemic. In the course of its discussions, the panel found that neither was amenable to reuse. Filtering facepiece respirators offered greater levels of protection – but the panel was careful to note that "the need for fit testing respirators is critical and must be an integral part of any program that promotes their use." The panel also found "no simple modifications to currently existing N95 filtering facepiece respirators that would obviate the need for fit-testing."[2]

The panel also suggested research "on issues related to public education and compliance with respiratory protection guidelines, including the importance of proper fit..." The panel emphasized that one of the important differences between respirators and masks was that of fit, with the latter being unfitted and unlikely to fit closely to the face. No specific suggestions were made, however, for respirator designs not requiring fit.[2]

Based on this and other input, CDC revised its recommendations for protecting healthcare workers when caring for patients suspected of pandemic influenza to include the use of a "fit-tested respirator, at least as protective as a NIOSH-approved N-95 filtering facepiece (i.e., disposable) respirator…"[18]

Responses to emergency situations resulting from terrorism and natural disasters have also focused attention on respiratory protection for response and cleanup workers. Just as with an infectious disease pandemic, it can be difficult to assure in such settings that all elements of a respiratory protection program (especially medical evaluation and fit testing) are met. Surveys of cleanup workers in New Orleans, for example, found that a majority (75%) did not know how to properly don a filtering facepiece respirator. Those with previous work experience requiring respiratory protection and fit testing were most likely to demonstrate knowledge of proper donning. Residents and workers cited respirator discomfort as the most common reason for failing to use a respirator during cleanup activities. Only 50% of workers had received fit testing.[19, 20]

Effect of Government Actions on Innovation

Innovation, as defined by the Product Development and Management Association (www.pdma.org), is the "act of creating a new product or process" where "the act includes invention as well as the work required to bring an idea or concept into final form." New products can result from "market pull" (recognition of market needs) or "technology push" (advances in technology).[21]

Product innovation can be either stimulated or discouraged by government actions (e.g. regulations or incentives). For example, when high levels of product safety and efficacy must be demonstrated prior to marketing (as is true for respirators), manufacturers face additional testing costs in addition to the price of research and development. In combination, these may prevent smaller companies from entering the market. Regulations can also lower profitability by increasing development costs (requiring more expensive materials or methods), introducing delays to marketing (via permits or certification), redirecting personnel (who must participate in regulatory-related meetings and activities) and decreasing the period of patent protection.[21, 22]

On the other hand, regulations can also reduce risk and limit unpredictable product liability suits, encourage innovation in new technologies or markets and encourage companies to conduct joint research and development efforts.[21] Companies that respond positively to government regulation can become more innovative in the long run, due to improved problem-solving skills and higher levels of creativity.[22] A review of the effect of environment, health and safety regulations on the chemical industry found that regulations of products tended to lead to product innovation, particularly when regulations were both stringent and technology-forcing in nature.[23]

The *direct* impact of regulations on the success of a particular product innovation, however, is generally very small. Rather, the effects of regulation are more likely to be indirect ones: diverting resources from commercial innovation to compliance research and development; delaying launch of new products; or increasing uncertainty when regulatory changes appear likely but have not yet occurred.[22]

The development and testing of a new respirator design can require considerable resources prior to commercialization and marketing. While certification procedures ensure that respirators meet high performance standards, their requirements may hinder or slow innovation. There may be other barriers to innovation, as well, such as litigation, competition from off-shore sources or inadequate regulatory enforcement of respirator selection and use.

Safety equipment manufacturers must spend considerable resources on user education to ensure that companies purchase equipment that meets appropriate standards and is not just low cost.[24] Safety equipment manufacturers also expend considerable resources toward the development of product standards, but are frustrated to find that many non-U.S. companies do not understand or follow U.S. requirements for product certification. OSHA used to be a major driver for product development and innovation, but has become much less so with few or no new standards.

Other factors unrelated to regulation have also had considerable effect on safety equipment manufacturers. Loss of manufacturing jobs due to automation and globalization has lowered the demand for safety equipment in the United States. OSHA enforcement of personal protection standards has been lacking, even in high risk, high growth industries such as construction and small manufacturing businesses. On the other hand, there has been growth in demand for safety equipment in global markets.[24]

Research Questions

Numerous changes have led to ever-expanding expectations for the use and performance of respirators. As more non-industrial and non-traditional groups of employees (e.g. healthcare) need respirators in their day-to-

day work, there has been considerable pressure to make these respirators easier to use and to lessen or change the expectations for medical evaluation, fit testing, training, maintenance, etc. Healthcare workers, who are used to wearing surgical masks, expect respirators to be comfortable, inexpensive and easy to wear. Casual users (hobbyists) expect respirators to be immediately wearable without the need for complicated instructions or warnings. Many small businesses rely on respirators as the primary means of employee protection, but are often unaware of the need to establish a program that includes proper selection, training and other required elements. The most important issue encountered in all of these venues is how to measure and ensure long-term respirator fit.

This request by NIOSH for a "no fit test" respirator is directly reflective of on-going and increasing user requests for more comfortable, easier to use, easier to fit personal protective devices. There is some concern, however, that the rate or nature of innovation in this field has not been responsive enough to these needs.

There are a number of important research gaps preventing the development of a "no fit test" respirator. These include lack of knowledge or data about:

1. The connection between facial characteristics (and the dynamic effects of facial movement) on long-term respirator fit.
2. Correlations between initial fit and long-term respirator performance.
3. Features of materials that could enhance facial comfort.
4. How to communicate information about proper donning.
5. Easy-to-use, inexpensive fit test or fit check methods and the efficacy of fit checks.
6. The correlation between long-term performance and respirator certification using fit test panels.

This investigation focuses on the nature and process of product innovation and development in respiratory protective equipment, with the goal of understanding how future NIOSH research and regulatory activities can encourage on-going development of more comfortable respirators that are easier to use and fit without compromising long-term protection. In particular, this project attempts to answer the following questions:

- What have been the most important innovations in respirators in the recent past – and what contributed most to their development and success?
- Are there inventions that, while innovative, have not proved to be commercial successes?
- Has the pace of innovation in respiratory protection slowed in recent years, and if so, why?
- Do current regulatory, economic or political conditions prevent new innovations in respiratory protection?
- Are there research directions or regulatory approaches that could encourage further innovation?
- What combination of regulation, research and manufacturer innovation might lead to more "user-friendly" respirators?
- Do current and potential respirator manufacturers understand the needs of current and future users?
- Are there barriers that prevent respirator manufacturers from responding quickly to users' needs?
- Have manufacturers' failed to apply or recognize technological improvements from other fields?
- Are users looking for improvements for which technology does not yet exist?

Methods

Advisory Board

An Advisory Board was formed, consisting of representatives from a broad range of stakeholders, including respirator and fit test equipment manufacturers, research laboratories, fit test companies and users (employers and employees).

There were 10 advisory board members:

1. Nicole Vars McCullough, PhD, CIH, 3M Occupational Health and Environmental Safety Division, St Paul, MN
2. Alan Hack, MA, CIH, CSP, Los Alamos, NM (retired)
3. Jeff Weed, Weed Respiratory Protection Solutions, LLC, White Bear Lake, MN
4. Peter Nelson, Silent Power, Inc. and Breathe Safely, Baxter MN
5. Janice Comer Bradley, CSP, International Safety Equipment Association (ISEA), Arlington VA
6. Howard Cohen, PhD, CIH, University of New Haven, New Haven, CT
7. Jeff Birkner, PhD, CIH, Moldex Metric Inc., Culver City, CA
8. Bill Borwegen, Occupational Health and Safety Director, Service Employees International Union, Washington DC
9. Curt Hering, Equipment Services, Toronto EMS
10. Mark Catlin, Service Employees International Union, Washington DC

The Advisory Board met four times to provide assistance with the following tasks:

1. Identify successful innovations in respiratory protection (products, technology, materials or methods) and, for each innovation, describe:
    a. Incentives for development
    b. Costs for research, development and commercialization
    c. Effect on respiratory use and regulation
2. Identify unsuccessful innovations and describe their development and reasons for failure as commercial products.
3. Help select 1-3 successful and 1-3 unsuccessful innovations for further research.
4. Identify experts and resources to provide further information about each innovation.
5. Review research findings.
6. Assist with design of a one-day workshop to be held November 6, 2008.
7. Review workshop findings and final report

Investigation of Innovations

A survey was developed by the contractor and sent to members of the Advisory Board and of the American Industrial Hygiene Association Respiratory Protection Committee as well as to NIOSH employees and other professionals identified by Advisory Board members. Survey questions were:

1. Please identify the top 5 to 10 innovations occurring in the past 40 years that led to significant improvements in respirator performance (in particular, respirator fit). For each innovation, briefly describe why this innovation was important and how it changed respirator performance (fit).

2. Please list 5 to 10 innovations that were either not successful or were not widely adopted and did not lead to significant improvements in respirator performance (in particular, fit). Also briefly describe the importance of each innovation and why it did not lead to improvements.

Innovations could be in the area of materials, design, technology, certification, regulations, fit testing, etc.

The survey was sent to the Chair of the AIHA Respiratory Protection Committee for distribution to committee members. Advisory Board members were asked to complete the survey as well as to distribute further to members of their organization. It is estimated that approximately 60 people received the survey. Three weeks following distribution, 16 completed surveys had been received. Respondents listed numerous successful and unsuccessful innovations in facepiece design, fit testing and regulations (Tables 1 and 2).

Survey responses were reviewed with the Advisory Board before a final selection of innovations to investigate further was made by the study team. Advisory Board members were asked for recommendations on resources that should be consulted for each of the innovations selected.

For each innovation selected, we conducted a literature review, patent search and multiple interviews. Where appropriate, interviewees were asked to respond to the following questions:

1. What were the incentives for developing this innovation?
2. What were the costs of research, development and commercialization of this innovation?
3. What effect did this innovation have on respirator use and regulations?
4. What effect did regulations have on the development and commercialization of this innovation?
5. What were the primary reasons for the success (or lack of success) of this innovation?
6. What effect did this innovation have on better fit of respirators? Why?
7. What patents, research publications or other materials should we consult with respect to this innovation?
8. Whom else should we consult about this innovation?

Table 1 Innovations Identified by Survey Respondents as Successful (Number of Respondents; n=16)

<table>
<tr><td>Facepiece Materials
Silicone and other similar flexible polymer facepiece materials (9)</td><td>Filter Design
Electrostatic filter media, decreased pressure drop (7)</td></tr>
<tr><td rowspan="2">Elastomeric Respirator Facepiece Designs
Head harness or cradle for straps (6)
Double or triple flanges or flaps for sealing peripheries (2)
Ratchets for harness assemblies (2)
Foam materials in facial sealing area (1)
Using “yoke” to attach headband to facepiece (1)
Improvements in attachment of cartridges to facepiece (1)
Using center section of hard plastic to reduce weight and cost and make connections easier (1)
“Rhombus” shaped cartridges offset out of field of view (1)
Easy and quick bayonet mounts for cartridges (1)
Single strap design across cross-section of facepiece (1)
Adjustable straps with numbers at adjustment points (1)
Latch on half-mask respirator (1)
Drop down feature (respirator hangs around neck when not in use) (1)
Ergonomic design of face seal (1)</td><td>Other Respirator Design Aspects
Better speech transmission (3)
Multiple size facepieces (2)
Self-monitoring devices (1)
Fit check button on valve or filter (1)
Use of anthropometric data to design facepieces (1)
Increase in respirator makes and models (1)
Elimination of quarter mask (1)</td></tr>
<tr><td>Regulatory Changes
Filter certification changes (2)
End of service life programs (1)
Modification of the NIOSH facial dimension panel (1)
OSHA revised standard (1)</td></tr>
<tr><td>Fit Testing
Quantitative fit testing (3)
PortaCount (4)
Reliable qualitative fit tests for particulate filters (4)
LANL panels (1)
Quantitative fit test adapters (1)
Negative pressure fit test method (1)</td><td>Filtering Facepiece Design
Flat fold filtering facepiece respirators (2)
Filtering facepiece respirators (3)
Molded “around the nose” area instead of metal strip (2)
Supporting filter media to prevent collapse during moisture buildup (1)
Exhalation valves for filtering facepiece respirators (1)
Closed-cell foam on nose area (1)</td></tr>
</table>

Other Centralized respirator medical evaluation, training, fit testing for unions (1)	**Cartridge Designs** Increase in cartridges for specific gases (1) Multi-contaminant cartridges (1)

Table 2 Innovations Identified by Survey Respondents as Unsuccessful (Number of Respondents; n=16)

Elastomeric Respirator Facepiece Designs Adjustable pneumatic sealing periphery (3) Replaceable face seals (2) Adhesive on sealing surface (1) Breath responsive respirators (1) Personal face-forming face seal (1) Ultra-soft face seal or gel seal (1) Multiple head harness adjustment points (1) Face seal inserts (1)
Cartridge Designs End of service life indicator for organic vapor cartridges (1) End of service life indicators (1)
Other Respirator Design Aspects Scanning faces to design respirators (2) Measuring devices with each box of masks (1) One size fits all (1)
Other Hotel/fire emergency escape respirators (1)

Workshop

A one-day workshop was held in Pittsburgh on November 6, 2008. The workshop agenda (Appendix 1) included eleven speakers representing a broad range of stakeholders: users, program managers, inventors, manufacturers, and researchers. A range of industries and uses was represented. Thirteen poster presentations addressed current and on-going research on respirator fit and design, user experiences and new approaches to respirator certification. Workshop attendees were invited to participate in one of three afternoon break-out sessions, where further ideas were sought about research needs for better fitting respirators. The topics of the break-out sessions included new materials and designs, new fit test methods and knowledge gaps about fit. Each breakout session was facilitated to encourage attendees to participate in discussion and respond to prepared questions (Table 3). Facilitators prepared a summary of their session, which was delivered to the full group at the end of the workshop.

Table 3 Questions for Breakout Sessions

New Materials and Designs for Better Fit

What material properties should be considered for the next generation of better fitting respirators? What makes a material fit better? What makes current materials fit well? What makes current materials fit poorly? What are users looking for in materials? What design properties should be considered for the next generation of respirators? What does “good fit” mean in the short and long term? What aspects of design contribute to good fit? What aspects detract? Some aspect of fit has to do with comfort. How important is comfort in assuring fit? Is a “one size fit all” respirator possible? What would make it possible to have an individually-designed respirator?
Fit Test Methods That Would Ensure Long Term Fit
Is it possible to have a respirator that doesn’t need to be fit tested? What would make this possible? What type of fit test could be relied upon to ensure that fit never needs to be measured after an initial evaluation? What aspects of a respirator make more frequent fit testing necessary? What would make it possible to never have to use a fit test – even initially?
What do we need to know about fit that would lead to better materials, designs or fit tests?
What makes a respirator fit well? What makes a respirator fit poorly? What do we know about how respirators fit different faces? What don’t we know about how respirators fit different faces? Do we need better or different measures of faces? What is it about faces that make them easy to fit? What makes faces hard to fit?

Other

We evaluated some additional approaches to better fitting respirators identified through interviews, written materials and workshop presentations.

Results

Investigation of Innovations

The following successful innovations were selected for further research:

- Ambient aerosol quantitative fit test method (TSI PortaCount™)
- Strap cradle or head harness
- Double-flanged facepiece
- Flat-fold design for filtering facepiece respirators

The following innovations were selected as either “less successful” or “not yet successful”:

- Adhesive face seal
- User seal checks

The latter were selected because information on many of the unsuccessful innovations listed by survey respondents (Table 2) was not available. Some recent research was available on the adhesive face seal, suggesting this might be an innovation that had not yet matured. "User seal checks" were selected as a fit test method to complement an innovation in respirator design. While user seal checks are thought to work with half-mask elastomeric respirators, some experts have indicated concern about their applicability to half-mask filtering facepiece respirators.

Ambient Aerosol Quantitative Fit Test Method (TSI PortaCount™)

Background

The first developers of continuous-flow condensation nuclei counters (CNC) were French investigators Bricard et al. and Sinclair and Hoopes at the U.S. Atomic Energy Commission.[25, 26] The first commercially-available single particle continuous flow CNC was developed by Agarwal and Sem in 1980 at TSI (Model 3020).[26] Willeke et al. were the first to describe the use of a TSI Model 3020 CNC and ambient aerosol as an alternative to the traditional oil aerosol-photometer respirator fit test method.[25]

These instruments were first employed to characterize environmental aerosols and were used by researchers with funding from the Department of Energy or the Environmental Protection Agency. In addition, the Soviet-Afghan war (from 1979-1989), Iranian revolution (1979) and Iran-Iraq war raised concerns about chemical and biological weapons, leading the Department of Defense to increase its aerosol research capabilities. Changes in the political climate and an economic recession in the early 1980s led to changes in environmental priorities, while concerns about chemical and biological weapons continued to increase. Many aerosol researchers migrated from environmental pollution research to defense-related investigations, as the Department of Defense continued to increase its budget in this area. Aerosol research also expanded into the semiconductor and pharmaceutical fields.

In the early 1980s, TSI adapted the Model 3020 CNC for several respirator applications. In 1982 a CNC-based instrument was developed on a contract with NIOSH for testing respirator filter performance.[27] At the same time, TSI developed a system for measuring respirator fit using a corn oil or DOP aerosol generated in a booth and sampled by a CNC similar to the booth systems employing generated aerosols and light-scattering photometers.[27] While two chambers were built for the Air Force and a third for the Army, this system was never commercialized by TSI.

The traditional booth systems were difficult to use, expensive to operate and required dedicated space and personnel. Their application was generally limited to industries where respirators were required for exposures to very toxic materials (e.g. radioactive aerosols in nuclear power plants). In 1984, the Army published a request for proposals for a portable, durable, soldier-operated instrument. TSI was one of several organizations to respond, proposing the development of a small, portable CNC using ambient aerosol as a quantitative fit test method. TSI was awarded a contract to develop and demonstrate a prototype.[28, 29]

Supported by funding (approximately $1 million) from and in collaboration with personnel from the U.S. Army Chemical Research, Development and Engineering Center, TSI developed a miniaturized continuous-flow CNC for measuring respirator fit.[30, 31] The original plans called for an instrument that would be carried by a soldier to provide continuous input on respirator fit. From 1984 to 1987 sixty prototypes were subjected to testing over a broad range of operating conditions. Results demonstrated that a miniaturized instrument could be used to fit test respirators in field settings, although the instrument was not portable enough for continuous wear by soldiers.[28, 30, 30-33]

After its contract with the Army ended in 1986 TSI decided to market the instrument as the PortaCount. While the original design was never patented, subsequent improvements have been patented. A prototype was first demonstrated at the 1986 industrial hygiene conference where it generated considerable interest. Sales of the first commercially-available PortaCount at the 1987 industrial hygiene conference greatly exceeded TSI's expectations.[28, 29]

Meanwhile, the Gulf War helped popularize the PortaCount among the armed forces; the instrument was used to fit test troops in Saudi Arabia. In 1991 the Army purchased 150 instruments made to its specifications; from 1993 to 2006 an additional 10,000 instruments were purchased. With assistance from TSI, an instrument servicing laboratory was established at the Red Stone Arsenal. TSI and Army personnel continued to work together on improvements to the instrument.[28-31]

The nuclear industry was the first civilian workplace to adopt the PortaCount. Other industries then began purchasing the instrument. Originally, there were many detractors who did not believe the ambient aerosol-CNC method was as good as the generated aerosol-photometer booth systems. Eventually, research publications and demonstrations convinced health and safety professionals of the validity of this approach.[28, 29, 34]

TSI has made on-going improvements to the PortaCount, including the development of adaptors that allowed fit testing of an individual's own respirator (1991), an AC adaptor (1993), software changes, and the N95 Companion for fit testing filtering facepiece respirators (1998).[28, 29, 35] The PortaCount continues to be one of TSI's best-selling products.

Innovation Questions

What were the incentives for developing this innovation?

- The need for an automated, easy-to-use method to replace current booth systems
- A system that eliminated the need to generate a test aerosol
- Portability for checking respirator fit in field locations immediately prior to use
- Accurate, reliable quantitative results
- Higher fit factors than were possible with qualitative tests
- Air Force and Army requirements for a method that could be used by field personnel

What were the costs of research, development and commercialization?

- Approximately $1 million to develop and test the original prototypes for the Army
- Additional money was spent by TSI to commercialize the PortaCount
- Additional funds were spent by the Army to develop final specifications prior to purchase of field instruments
- TSI and the Army have continued to spend money on testing and design improvements

What effect did this innovation have on respirator use and regulation?

- The PortaCount revolutionized quantitative fit testing, making it an acceptable and eventually expected aspect of many respirator programs.
- TSI petitioned OSHA to accept the PortaCount as a qualified fit test method. OSHA agreed that anyone using the PortaCount would receive a de minimis violation, which would result in no fine. Eventually, the ambient aerosol-CNC method was added to the 1998 OSHA respiratory regulation as an accepted method of fit testing respirators.

What effect did regulations have on the development and commercialization of this innovation?

- When the OSHA lead standard was amended to accept qualitative fit testing in place of quantitative fit tests, the sale of the booth systems declined.
- The OSHA asbestos standard required the use of quantitative fit testing for respirator use.

What were the primary reasons for the success of this innovation?
- Cost effective (approximately $6000 when first sold)
- Simple to use
- Produced quick and accurate results
- Portable
- Used ambient aerosols

What effect did this innovation have on better fit of respirators?
- Quantitative data allowed more discrimination between different respirators (models and sizes)
- Could be used with respirators with much higher fit factors (> 100) than those for which qualitative methods were considered valid

Strap cradle or head harness

Background

Strap attachment and design can play an important role in the way a respirator fits. A 1963 manual notes that: "Ideally, a respirator would be held against the face by an infinite number of adjustable supports, to direct tension where needed. Practically, a proper seal can be achieved with only a minimum number of supports." The manual suggests that "five adjustable straps on a full face mask appear to be the minimum number to ensure a seal." However, the manner in which straps were attached to early respirators often resulted in considerable pain from the protruding rivets pressing against the face.[16]

It was also noted that half mask respirators generally had one or two straps and no head harness or strap cradle. It was thought that attachment of the straps at four (rather than two) locations provided the best seal. Single straps greatly limited the size and type of face that could be fitted. It was also noted that, "to avoid a strap across the ears, the strap must pass either above or below, with further adjustment generally required because a strap will remain anchored on the back of the worker's head only at certain points." Mention is made of a paper by Tait and Byington that discusses the use of a head harness for half mask respirators, which was available on several non-U.S. masks.[16, 36]

Hyatt described tests at Los Alamos with a new respirator design by American Optical using headbands attached at two separate locations on the facepiece, rather than emanating from a single point. Fit tests with 500 subjects showed that 33% more subjects were able to obtain a "gas-tight face seal" when wearing the new design.[37]

A 1980 manual notes that "During any fitting test, the respirator head straps must be as comfortable as possible. Tightening the straps will sometimes reduce the facepiece leakage, but the wearer may be unable to tolerate the respirator for any length of time."[38]

According to interviewees, the split cradle headband has been around since the early 1900s, although it was used primarily on full facepiece respirators. The first to use a split cradle headband on a half mask respirator was North Safety Products in the 1980s.[39] There was a lot of competition with other manufacturers to design a respirator with better fit and comfort. Consumers were also looking for designs that would allow multiple donning and could be conveniently hung around the neck when not being worn. The North product eventually

had four variations to fit different work environments. The petrochemical industry, companies with spraying and pipefitting operations and industries with silica exposures were the primary users requesting these improvements.[40]

The cost to develop the new North respirator (model 7700) was approximately $1 million; however, this included the design of three face sizes. Other manufacturers developed different head strap designs. The addition of a head strap to an existing respirator design was probably not very expensive and did not generally lead to an increase in respirator cost. The North head strap design was patented.[40-42]

We were not able to locate any publications demonstrating that the head strap cradle led to better fit. Anecdotal evidence (and common sense) suggests that it will be more comfortable because it cradles the back of the head and prevents slipping.[40]

This design feature did not play a big role in the development or revision of NIOSH or OSHA regulations and vice versa. It may have led to improvements in NIOSH certification results for an individual manufacturer's respirators, but these data are not publicly available.

Innovation Questions

What were the incentives for developing this innovation?

- User expectations for more comfortable and better fitting respirators
- Hold the facepiece in place while allowing the mask to move with facial movements
- Respirators that would consistently fit well when repeatedly donned
- Competition with other respiratory manufacturers

What were the costs of research, development and commercialization?

- Probably minimal

What effect did this innovation have on respirator use and regulation?

- The head strap cradle or similar designs were eventually adopted by many manufacturers
- While no data are available, it appears that this design did ensure better comfort and fit
- There were no direct effects on regulations from this design innovation

What effect did regulations have on the development and commercialization of this innovation?

- Other than the NIOSH regulations for certifying respirators (that included fit testing) and OSHA regulations requiring fit testing, there were no other direct effects of regulations on this design improvement

What were the primary reasons for the success of this innovation?

- It must be assumed that this design improvement led to better comfort and fit

What effect did this innovation have on better fit of respirators?

- There are no published data indicating the role of this innovation on respirator fit
- A design that allows more attachment points and more consistent placement on the head, however, suggests a better-fitting respirator

Double-Flanged Facepiece

Background

A 1963 manual on respiratory protective devices describes seven designs for the periphery of gas masks in current use.[16] Based on internal research, the U.S. Navy used a pneumatic tube periphery for its full facepiece gas mask while the U.S. Army found that a flat periphery provided the best seal. Commercial full facepiece respirators generally used a flat surface; newer designs had an inner flap. Half masks generally employed internal roll or cushion designs; some used external flanged or t-style designs.

In this same manual it is noted that half mask respirators often do not seal well unless they are "adjusted firmly to the face." In fact, "the tension needed to seal all points on the periphery results in excess pressure at certain points, causing 'pain spots.'" It was noted that "In the Bureau of Mines' testing procedures half masks are fitted very tightly to most of the wearers, and the Bureau stressed that half masks must be secured firmly for proper protection of the user."[16]

Draeger, a German company, has been credited with designing the first double-flanged facepiece for full-facepiece respirators, approximately 30 to 40 years ago. This design was thought to be more comfortable and was able to pass respirator panel fit tests with just one size mask. This design was not used on half-mask respirators, however, because it added too much to weight, bulk and manufacturing expense. The company continues to offer respirators with a double-flanged facepiece, although it has expanded to three mask sizes. [43]

A double flange was thought to be both more comfortable and to fit better, because it didn't slip and because the second flange offered a backup seal in case of leakage through the first flange.[43] However, another interviewee thought that while the double flange may offer a better seal, it was not necessarily more comfortable. Instead, the additional edges may aggravate the skin.[44] While studies may have been conducted on this design, no publications were located.

Survivair was the first to offer a double flange on a half-mask respirator; the flange was only around the chin area, however. In the late 1980s Glendale developed a half-mask respirator with triple flanges, which is still sold today by Superin.[44] Revoir and Bien described improvements in the 1990s to facepiece seals through the use of a "deeper crease of the sealing area" rather than a flange.[39]

Innovation Questions

What were the incentives for developing this innovation?

- For full-facepiece respirators, fit was perhaps the most important incentive, although comfort may have been important, as well
- The incentives for adopting this design in half-mask respirators are not know, but presumably would be similar to those for full-facepiece respirators

What were the costs of research, development and commercialization?

- Not known

What effect did this innovation have on respirator use and regulation?

- There were no effects on regulations

What effect did regulations have on the development and commercialization of this innovation?

- The requirements for panel fit tests of full-facepiece respirators encouraged manufacturers to seek better fitting respirators

What were the primary reasons for the success of this innovation?

- No published research is available
- Anecdotal accounts indicate that it fit better and was more comfortable (full facepiece)

What effect did this innovation have on better fit of respirators?

- This design has been somewhat successful, because it was adopted by other manufacturers and applied to half-mask respirators. It continues to be offered on some full- and half-mask respirators. Thus, it can be assumed that users find this design to be both well-fitting and comfortable.

Flat-Fold Design for Filtering Facepiece Respirators

Background

The first modern filtering facepiece respirator was introduced by 3M in the 1970s. This was a very successful innovation with a high level of user acceptance due to low breathing resistance, light weight and portability. The first filtering facepiece respirators used a cup design with a nose-clip; in some cases the clip could be shaped to an individual's nose.

The first flat-fold filtering facepiece respirator was developed in the 1980s by American Optical and was known as the "Dust Demon" (later re-named to Pleats and then Pleats Plus). The original design was patented (we could not locate the patent number, however); the patent was not renewed for later designs. This respirator consisted of multiple horizontal folds and was developed in response to user requests for a respirator that was easily stored and available for frequent donning.[45] Later, it was found that this design was easier to breathe through, due to higher surface area and lower pressure drop.[45, 46] This design may also fit better because it adjusts to changes in the face as it is worn.[47]

Other companies began making flat-fold filtering facepiece respirators in the 1990s, largely in response to requests from users in the healthcare industry following concerns about exposure to multiple-drug resistant tuberculosis.[48] A number of different companies now make flat fold filtering facepiece respirators, with a varying number and type of pleats. Some of these designs are patented.

When first introduced, the Dust Demon was not very successful, because its design was different from the traditional cup-shaped respirator and made wearers feel awkward. It is thought that two events contributed to greater user acceptance, especially in healthcare settings.[45, 48] In 2003, the Toronto SARS epidemic led to increased attention to respirator wear for infectious disease exposures. Since the OSHA tuberculosis standard in the 1990s (which was subsequently revoked), the healthcare industry has been searching for a respirator with a design similar to that of surgical masks that can be easily fit to most individuals. And in 2004, a publication by Lee et al found that the AO Pleats Plus respirator had the highest fit test pass rate (98%) when compared to four other respirators among wearers in a TB respirator program.[49]

The flat-fold respirator was originally found to be more expensive to manufacture than the cup-shaped model.[45] According to one interviewee, however, this type of respirator can be less expensive to make because it does not require the molding or multiple steps of a cup-shaped model.[46] Some interviewees thought there may be differences in the performance of different types of flat-fold designs, with horizontal folds fitting better than vertical folds. However, there are no data to substantiate this.[47] Zhuang et al. evaluated the performance of 18 models of N95 filtering facepiece respirators and found that respirator design (4 folding vs. 14 cup style) was not a significant factor in respirator fit.[7, 50]

Innovation Questions

What were the incentives for developing this innovation?

- Convenience was the primary incentive.
- Similarity to masks used in healthcare settings was a secondary incentive.

What were the costs of research, development and commercialization?

- One interviewee noted that it cost approximately $1 million to develop a new flat fold respirator, although other design innovations were also included.

What effect did this innovation have on respirator use and regulation?

- Initial effects on respirator use were minimal.
- Market forces and a publication led to greater acceptance.
- This particular innovation did not have any direct effect on regulations.

What effect did regulations have on the development and commercialization of this innovation?

- Respirator regulations did not have a significant effect on the design of filtering facepiece respirators, because fit test methods were not available and fit test panels were not employed by NIOSH for certifying this class of respirators.

What were the primary reasons for the success of this innovation?

- Convenience.
- Similarity to surgical masks (healthcare industry).
- Fits a broader range of face sizes.

What effect did this innovation have on better fit of respirators?

- While one publication showed higher levels of fit and acceptance for a flat fold design in comparison to four other filtering facepiece designs, another comparison did not show significant differences in fit between flat fold models and cup-shaped respirators.

Adhesive Face Seal

Background

One interviewee noted that adhesive face seals have been explored in the past. The most important issues preventing their commercialization have been comfort, concern about skin reaction to the adhesive materials and exfoliation caused by multiple removals.[51]

Data were presented at the November 2008 workshop for two different adhesive designs. The ViraMask™ (patent pending), was developed by Wein Products Inc. (Los Angeles, CA) using a hypoallergenic medical sealing material (FitSeal™). Testing a prototype with straps, Grinshpun found that subjects reported high levels of comfort when compared to a traditional cup-shaped respirator (manufacturer and model not described). Tests with a different prototype showed fit factors ranging from 20,000 to 60,000.[52, 53]. (It should be noted that Dr. Grinshpun performed this work as an independent consulting contract with Wein Products, Inc., rather than as a research contract via the University of Cincinnati.) The ViraMask™ was first developed for use by the general population, but has recently received NIOSH certification for two adhesive, strapless models with N95 and N99 filters; these certifications included quantitative measurements of facial fit with a human test panel.[54]

Also at the November 6, 2008 workshop Nelson and Weed described a comparison of fit performance using a NIOSH-certified N95 filtering facepiece respirator (3M 1860) with and without a double bead of adhesive sealing

material applied to the respirator edge.[55] Overall quantitative fit factors improved by 271% with the adhesive seal. Seventy percent of subjects reported that the respirator with an adhesive seal was more comfortable and 100% of subjects thought it was more protective. This approach to an adhesive respirator has been patented.[56]

In the Nelson and Weed approach, the adhesive would be applied during the respirator manufacturing process. However, they note that it may be possible to develop a process to apply the adhesive to an existing respirator; however, this could not be easily accomplished by an individual respirator user.

No data were presented by either investigator on the number of times an adhesive respirator could be re-donned or the effect of multiple donning on comfort. It was noted that some women complained of facial discomfort after multiple donning of the Wein respirator in NIOSH certification tests.[46] Other factors important to the long-term performance of adhesive respirators include degradation or contamination of the adhesive after multiple donning and the effect of facial hair, cosmetic products or other impediments on the adhesive seal.

In a platform presentation at the November 2008 workshop, Nelson described some additional impediments to commercialization of an adhesive sealing material. Because NIOSH regulations state that any change to a respirator will negate its certification, application of an adhesive to after-market respirators is not possible. Only one respirator manufacturer was willing to consider purchasing a license to incorporate the adhesive application into its processes. Liability was the primary concern of most manufacturers contacted.

Innovation Questions

What were the incentives for developing this innovation?

- Better fit.
- Possibly, no need to fit test, although no data were available to support this.

What were the costs of research, development and commercialization?

- Costs for developing, testing and commercializing the Wein Products respirator are estimated to be more than $2 million.

What effect did this innovation have on respirator use and regulation?

- None.

What effect did regulations have on the development and commercialization of this innovation?

- The lack of a fit test panel for half-mask respirators may be an impediment to marketing this respirator.
- The requirements governing modification of respirators has been a major impediment to marketing the Nelson and Weed respirator.

What were the primary reasons for the success of this innovation?

- It is too early to assess the successfulness of this innovation as a respirator design.

What effect did this innovation have on better fit of respirators?

- None to date.

User Seal Checks

Background

The invention of filtering facepiece respirators posed new challenges to checking fit. In many cases, it was difficult to cover the entire facepiece with the hands, especially for people with smaller hands or for respirators with exhalation valves. One company developed a fit check cup that worked fairly well, but it was difficult to ensure that a cup was always available each time the respirator was donned.[57, 58]

An early respirator manual describes a fit test method, but does not attach a name (e.g. fit check, positive pressure test) to this method:

> "A convenient means for testing the face fit is to close off the exhalation valve and exhale gently into the facepiece. The face fit is satisfactory if a slight positive pressure can be built up in the facepiece without any evidence of outward leakage of air at the periphery."[16] (p.130)

The first standard to address respiratory protection in detail, ANSI Z88.2-1969, states that "the ability to form a good facepiece-to-face seal depends on respirator design and facial features, and is usually the most important factor in obtaining proper protection with an air purifying respirator, particularly of the half-mask type." This standard required that "To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator. This may be done by following the manufacturer's facepiece-fitting instructions" or by using two simple field tests, referred to as negative and positive pressure tests.[59]

In 1970 the Occupational Safety and Health Act was the first regulation to address the use of respiratory protection in workplaces (29 CFR Part 1910.134). With respect to fit, the regulation states that "every respirator wearer shall receive fitting instructions including demonstrations and practice in how the respirator should be worn, how to adjust it, and how to determine if it fits properly….To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator. This may be done by following the manufacturer's facepiece fitting instructions." No specific fit check methods were described in the regulation.

A 1977 respirator manual states that a "respirator facepiece shall be checked for fit each time [it] is worn," using positive- or negative-pressure tests, which were considered qualitative fit tests. However, isoamyl acetate or irritant smoke tests were considered superior qualitative tests. The term "fit check" is not used in this manual.[15] It was noted that both the negative and positive pressure tests have significant limitations, because they require handling of the respirator after it has been positioned on the face, which could lead to changes in the seal. The author notes that: "It is strongly recommended that [these tests] be used only as a very gross determination of fit when the respirator is to be used in relatively toxic environments. The wearer should use [these tests] just before entering any toxic atmosphere."[15] Similar guidance and language appear in a 1978 NIOSH manual for employers.[60]

The 1980 ANSI standard for respiratory protection (ANSI Z88.2-1980) recommends that each wearer be required to check the seal of the respirator before entering a harmful atmosphere, again by following the manufacturer's instructions or using any of several field tests. A negative-pressure sealing test is described and a warning is given that "this test may be difficult or impossible to carry out on valveless respirators." A positive-pressure sealing test is also described, with a note that the required tasks "often are difficult to carry out without disturbing the fit of the respirator to the wearer." A separate warning is also included with respect to these sealing tests: "Care must be taken in carrying out [these tests]; otherwise, the results of the sealing test may be unreliable. Thorough training in carrying out these tests should be given to respirator wearers."[61]

A 1980 respirator manual notes that OSHA regulations require that workers be allowed to test the seal of their respirator. Again, the negative and positive pressure tests are described as "qualitative" fit test methods. The same warnings about the effects of handling on the seal are described.[38] In another 1980 respirator guide fit checks are referred to as "pressure checks." These methods of testing fit are described as being used the most frequently, because they are easily done by the user each time the respirator is donned. However, they are also the "least precise" and can only detect "large leaks." Figures included in this guide show wearers performing a positive pressure test on a "dual cartridge" respirator by covering the exhalation valve with one hand and a negative pressure test on a "disposable" respirator by covering the facepiece with two hands.[62]

A 1986 respirator manual for the asbestos abatement industry describes the use of "sealing tests for routine donning of respirators" but warns that some respirators require the removal of the exhalation valve cover before performing the positive pressure test, which can be difficult to accomplish without changing the fit.

> "To ensure proper protection, the wearer of a respirator equipped with a tight fitting facepiece must check the seal of the facepiece routinely prior to entry into the abatement area. This may be done by using the sealing test procedures recommended by the manufacturer or (where the manufacturer does not provide such recommendations) by using the negative and pressure sealing tests… Sealing tests should NOT be substituted for the initial, required quantitative fit tests. Adequate training of respirator users is essential for satisfactory sealing tests."[63]

In a 1987 respirator guide, NIOSH uses the term "fit test" to describe the negative and positive pressure tests.[64] The test descriptions and warnings are similar to those found in earlier NIOSH documents. The first use of the term "fit check" can be found in a 1991 manual, which states that "Prior to fit testing, a positive and/or negative pressure fit check should be conducted with all tight-fitting respirators to determine if an inadequate respirator was chosen and to train the person to conduct such a test each time the respirator is worn. The fit checks can be performed by following the respirator manufacturer's instructions or the appropriate set of instructions below." The descriptions of negative and positive pressure tests do not mention any of the drawbacks or limitations included in earlier references.[65]

The 1992 ANSI standard uses the term "fit check" and notes that "Care must be taken in conducting negative and positive pressure fit checks. Thorough training in carrying out these tests should be given to respirator wearers. Fit checks are not substitutes for qualitative or quantitative fit tests." Users should follow manufacturer's instructions or the procedures described in the standard.[66]

Myers et al. note that manufacturers of filtering facepiece respirators generally recommend covering the facepiece with both hands, exhaling and checking for air flow at the facepiece seal.[67] Prior to these investigators' 1995 study, no previous research had been published evaluating the efficacy of fit checks. In one set of experiments, a group trained in donning a respirator (no fit checks) was compared to a group trained in donning and fit check procedures. Each subject wore up to 4 half facepiece respirators (3 filtering facepiece and 1 elastomeric). For one respirator (elastomeric) the groups did not exhibit differences in quantitative measurements. Fit checks led to improvements in fit for the filtering facepiece respirators; in some cases the improvements occurred only for respirators with fit factors less than 100 while in other cases there were improvements for the full range of fit factors.[67]

In a second set of experiments, subjects donned pre-formed respirators and performed fit checks but did not adjust the respirator if the fit check failed. A measure of sensitivity was then calculated by dividing the number of failed fit tests where the user indicated a failed fit check by the total number of failed fit tests (perfect sensitivity = 100%). The sensitivity of fit checks ranged from 80-100% for the filtering facepiece respirators and

was 100% for the elastomeric respirator. Fit checks were least sensitive for the least efficient type of filtering facepiece respirator (in this case, dust/mist filters) and most sensitive for respirators with the most efficient filters (high efficiency). It should be noted that these experiments were conducted with respirator filters that are no longer manufactured or certified under the current NIOSH regulations.[67]

The authors concluded that fit checks "have value in assisting the wearer to properly don a respirator" and "can be a useful tool for more consistently maintaining the quality of respirator donning."[67]

In a 1997 guide, Revoir and Bien state that "the only satisfactory method to check the facepiece seal prior to entry into the hazardous place is to perform a negative-pressure and positive-pressure fit check." However, because most filtering facepiece respirators lack exhalation valves, manufacturers generally recommend only the negative pressure test.[39]

The term "fit check" was changed to "user seal check" in the 1998 adoption of a new OSHA respiratory protection standard (30 CFR 1910.134) because many users were confused by the differences between fit tests and fit checks. The OSHA Respiratory Protection Standard requires a user seal check each time a tight-fitting respirator is donned. The user seal check is defined as "an action conducted by the respirator user to determine if the respirator is properly seated to the face;" this definition was derived from the definition for "fit check" in the ANSI Z88.2-1992 standard. OSHA states that a user seal check must be performed using procedures listed in Appendix B-1 of the standard or those recommended by the manufacturer (which must be as effective as those listed in the appendix). OSHA did not describe any specific procedures for testing the seal of a filtering facepiece respirator, however, nor are there any procedures described for demonstrating the effectiveness of a user seal check method. Current NIOSH certification tests do not evaluate the fit of half-mask filtering facepiece respirators and thus do not assess the effectiveness of user seal checks.

A 2001 respirator manual notes that "Care must be taken in conducting user seal checks, respirator wearers should be given thorough training on how to carry out these tests and how to recognize the test end point." It is noted that "It has been shown that recommended procedures for disposable, filtering facepiece respirators that require covering the mask with both hands, exhaling, and checking for airflow…were effective at detecting and preventing poor donning practices."[68] The study by Myers et al is cited in support of this statement.[67]

Delaney et al found that user seal checks rarely identified damaged exhalation valves in full facepiece respirators, when compared to quantitative fit test measurements.[69]

Derrick et al found that user seal checks performed by healthcare employees wearing N95 and N99 filtering facepiece respirators incorrectly indicated lack of fit 21-40% of the time and incorrectly indicated a good fit 18-31% of the time, when compared to quantitative fit test results.[70] These data suggest somewhat lower levels of sensitivity (60-80%) than the Myers study, which may be the result of differences in protocol or respirators.

Limited published research suggests that fit checks may have some value in detecting respirators that do not fit well due to poor facepiece seals. However, fit checks are not perfect and may allow a respirator to pass when it shouldn't as often as 40% of the time. It appears that fit checks are not capable of detecting failure of an exhalation valve, but it is not clear under what circumstances fit checks will not detect failure of a facepiece seal.

Innovation Questions

What were the incentives for developing this innovation?

- It was recognized as early as the 1960s that respirator fit is the most important aspect of protection and that performing a check every time the respirator is donned may help identify poor seals.

- The user seal check was not really an innovation, but rather a common-sense method for checking fit that gradually gained more acceptance with its incorporation into consensus and regulatory standards.

What were the costs of research, development and commercialization?
- Not applicable.

What effect did this innovation have on respirator use and regulation?
- The work by Myers' in 1995 appears to have helped this "innovation" move from a recommended to a required practice, particularly with the adoption of a new respirator standard by OSHA in 1998.

What effect did regulations have on the development and commercialization of this innovation?
- ANSI standards, NIOSH guidance documents and OSHA standards apparently built upon each other in moving this method from a recommended to a required practice.

What were the primary reasons for the success of this innovation?
- Eventually, published research led to a requirement for user seal checks in the 1998 OSHA standard.

What effect did this innovation have on better fit of respirators?
- The user seal check does not appear to have had a significant impact on the design of better fitting respirators.

Interviewees for Each Innovation

Note: Only the current employer or organizational affiliation are listed for each interviewee. Interviews were based on both current and past experience with respirators. Interviewees were sought for their knowledge and opinions, which may not be representative of their organizations.

PortaCount
Klaus Willeke (University of Cincinnati, retired)
Jeff Weed (Weed Respiratory Protection Solutions LLC)
Pete Nelson (Breathe Safely)
Jugal Agarwal (TSI)
Richard Remiarz (TSI)
Randolph Laye (Aberdeen Proving Ground)
Paul Gardner (Aberdeen Proving Ground)

Adhesive
Stan Weinberg (Wein Products)
Sergey Grinshpun (University of Cincinnati)
Jeff Peterson (NIOSH)
Pete Nelson (Breathe Safely)

Strap Cradle
Jeff Peterson (NIOSH)
Bill Newcomb (NIOSH)
Rich Stein (Quick Protective Systems)
Rick Sustello (North Safety Products, now Honeywell)

Double-Flanged Facepiece
George Blank (Draeger Safety Inc.)
Andrew Viner (3M)
Rick Sustello (North Safety Products, now Honeywell)

Flat Fold
Jay Parker (NIOSH)
Andrew Viner (3M)
Julie Tremblay (3M)
Bill Newcomb (NIOSH)
Jeff Peterson (NIOSH)

User Seal Check
Bill Newcomb (NIOSH)
John Steelnack (OSHA)
Andy Levinson (OSHA)

Other
Lew Radonovich (VA)

Workshop

Workshop presentations for which permission to post was given are available for download on the University of Minnesota website:

http://cpheo.sph.umn.edu/cpheo/mcohs/courses/nofit/home.html

Slides summarizing participant input for each of the breakout sessions are also available at this website.

Describing the Problem

Natalie Gaydos from PPG summarized input from respirator program managers at PPG sites. Managers indicated that "good fit" means both a good face seal (secure, snug, and properly worn) and maximum comfort.[71] Some difficulties encountered when trying to obtain good fits included problems matching facial contours, size and shape; improper placement of straps; and missing teeth or dentures. Some common difficulties encountered with fit testing were: inability to taste or smell the test agent, user not clean shaven, failure to tighten straps or place nose piece, small faces and unique facial features. Some managers thought fit could change over time, especially with changes in weight, age or dental work. Some managers thought annual fit testing was necessary for older workers and to provide an opportunity to re-train; others thought it could be less frequent unless changes in weight, facial features or health status had occurred. Program managers made the following recommendations for improvements in respirator design:

- Allow for more facial hair
- Better-fitting nose pieces, chin cups, facepieces, neck straps
- Neck straps that do not tear and maintain elasticity
- Filtering facepiece respirators that are more resilient to high temperatures
- Better materials (softer, more pliable)

Speakers representing users (Mark Catlin, Bill Kojola and Jim Platner) summarized input from their constituencies (healthcare, industry and construction, respectively). Healthcare workers were in favor of single size filtering facepiece respirators that fit everyone. The experience of these users has been that they are often

not trained in how to use respirators, do not know the differences between different types of respirators, cannot perform a user seal check for filtering facepiece respirators and do not know when to discard used filtering facepiece respirators. Some have reported effects such as headache, shortness of breath and fatigue from wearing respirators.[72]

Users in industry also report not being fit tested or trained in how to use respirators – especially filtering facepieces. Recommendations were made to complete the total inward leakage certification requirements and to conduct research to improve respirator fit and assess facial changes over time. More understanding is also needed about respirator performance (both filter efficiency and fit) for exposures to biological agents.[73]

In a 2001 survey of respirator use in the construction industry, almost 80% of respondents reported wearing filtering facepiece masks and nearly 70% had been fit tested. Construction workers face particular challenges when wearing respirators, including lack of knowledge about the appropriate respirator; problems with comfort due to temperature, relative humidity and dust; visibility and communication; durability of respirator parts; storage; and frequent changes in tasks. Some recommendations for future research included: more field testing, testing or certifying the full ensemble of personal protective equipment (gloves, harnesses, hearing protection, etc.), setting minimum durability requirements and standardizing measures of comfort.[74]

Edie Alfano-Sobsey from Wake Human Services, described experiences with developing a train-the-trainer respiratory protection program for public health departments in North Carolina. In a survey of departments about implementation of a respiratory protection program, program administration, medical evaluation and fit testing were generally in place. On the other hand, training in hazards and respirator use, maintenance and program evaluation were reported much less frequently.[75]

Peter Nelson, a respirator designer, described his experience with commercializing an adhesive facepiece innovation (patented in 2006). After some initial subject testing, he contacted 25 respirator manufacturers about applying the adhesive during their manufacturing processes. Samples were provided to 6 to 8 of these. One manufacturer conducted internal tests, which showed better fit. However, there were significant legal concerns that prevented this manufacturer from further pursuing this innovation. In particular, could the introduction of a "sealed" product line make current products appear to be deficient or unsafe and would it lead to an expectation that all products should be sealed? In addition, there was concern about how the application of an adhesive might affect compliance with current regulations.[76]

Current Research

Ron Shaffer from NIOSH described recent and on-going research by NIOSH, including studies of fit test methods, anthropometrics and its relationship to fit, frequency of fit testing and user surveys about knowledge and program implementation.[77]

Karen Coyne from the Edgewood Chemical Biological Center (ECBC) described several current investigations to develop improvements in facepiece seals. The ECBC is collaborating with Battelle Memorial Institute to develop innovative seals that continuously adjust to changes in the seal due to face and head movements. A thermoplastic gel showed improvements in hardness and sealing and no effect from different storage conditions when compared to rubber. A second investigation using a hydrogel seal insert designed to be used with a half-mask for respired air collection showed improvements in fit tests compared to the same mask without the gel insert applied to the mask periphery. Finally, a synthetic microfiber adhesive -similar to that found on gecko or insect appendages – is being developed and evaluated at Carnegie Mellon University, supported by funds from ECBC through the Defense Threat Reduction Agency. [78]

Craig Colton described development and testing by 3M Company of a respirator for use in public health emergencies, which requires that some level of fit must be possible without the use of fit testing. Twenty-five

subjects with characteristics matching the NIOSH bivariate panel were fit tested with 3 respirator styles (cup, bi-fold and tri-fold) in two locations (room and fit test chamber) using a TSI PortaCount with N95 Companion. The geometric mean fit factor ranged from 95-226; geometric standard deviations ranged from 2.7 – 8.7. Fit factors were significantly higher for subjects who performed a seal check than for those who did not. There were some indications that fit factors improved as subjects donned new respirators, particularly for the cup and trifold styles. It was thought that better placement of straps may have occurred over time. There were problems with subjects not following instructions – failing to pull out the panels on the folded styles, not forming the nosepiece and wearing the respirator upside down.[79]

Lew Radonovich described research by the Veterans Administration with assessments of healthcare worker tolerance of and ability to use different respirator ensembles. It was concluded that currently-available respirators do not meet the needs of healthcare workers during pandemic or routine activities. In 2008, Project B.R.E.A.T.H.E. (Better Respirator Equipment Using Advanced Technologies for Healthcare Employees), an inter-agency collaboration, was initiated to bring a new respirator to the United States marketplace that meets the unique needs of healthcare workers. At the end of Phase I (nearing completion), the Working Group will issue consensus recommendations about the features that should be included in the next generation of respirator for healthcare workers. These features will include functionality, usability, comfort and wearability, maintenance and use, cost, aesthetics, and durability.[80]

Dr. Radonovich also described a 2008 fit-testing exercise using cup-shaped (model 1860 – small and regular size) and folding style (model 1870 – one size) filtering facepiece respirators by 3M. Of the 377 workers fit tested in a 5-day period, 25% could not achieve an adequate fit on the cup-shaped respirator and 7% could not be fitted with either model.[81]

Future Innovations Research

Sundaresan Jayaraman, a materials scientist from the Georgia Institute of Technology, discussed factors influencing the design of respirators and trade-offs necessary to balance cost, degree of protection, comfort and regulatory requirements. He described a systematic approach for developing new designs, which starts with a specific set of requirements that are translated into desired properties. These properties are eventually achieved by applying specific design parameters to current and future materials fabrication technologies (Figure 1).[82]

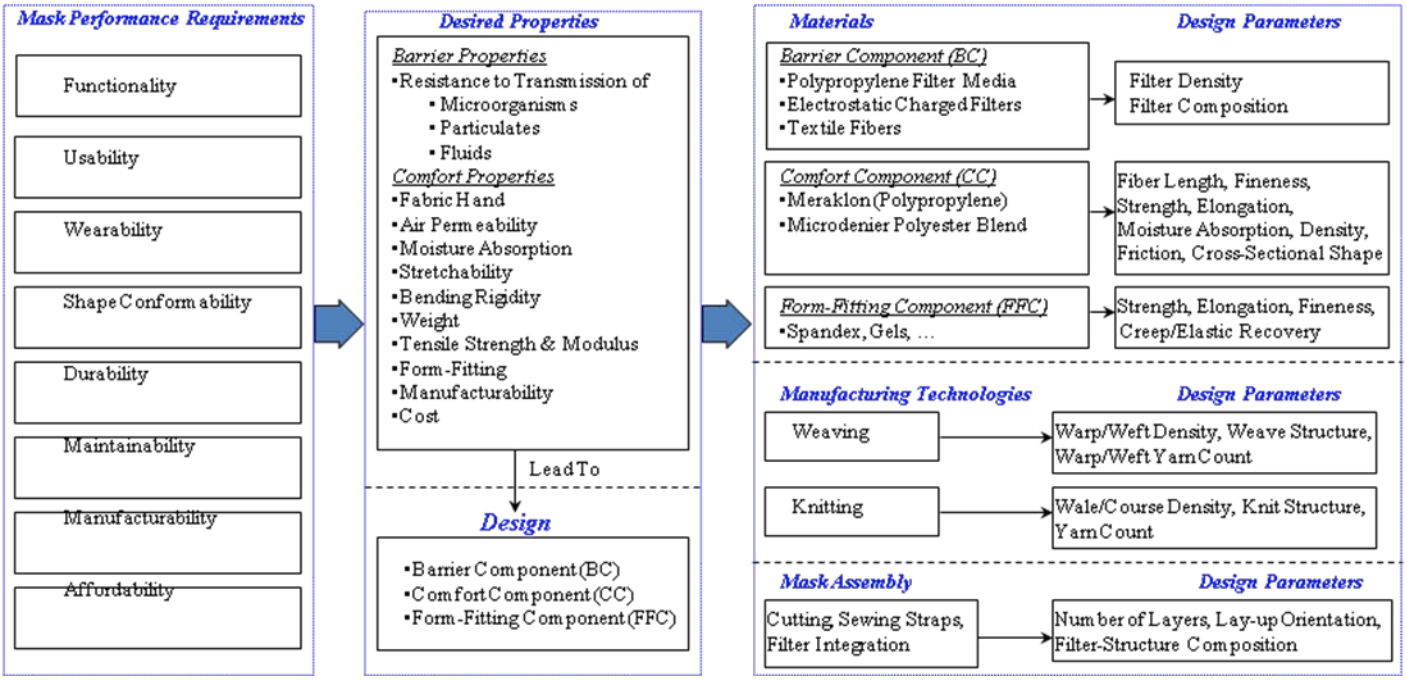

Figure 1. Framework for the design and development of a "no fit test" respirator[82]

Breakout Sessions

New Materials and Designs for Better Fit

Participants in this breakout session identified environmental factors that are important to half-mask respirator design, including temperature variations and contamination. A wide range of material properties are important to good design, including mechanical, chemical and physical properties, comfort, ability to withstand degradation, thermal conductivity, transparency, compatibility with other parts of the respirator, cost and speech transmission. Other properties included biocompatibility and whether the materials were recyclable.

Participants noted that protection and comfort are both important. Numerous characteristics of good design were identified, including low weight, able to fit many facial profiles, does not impair field of vision, uniform pressure on the face, good strap design, can be easily donned multiple time, has a limited number of parts, does not interfere with communication and is portable and easy to store. The most important point about design, however, was that each work environment is different and requires a tailored approach to design. For example, work in healthcare settings does not allow the use of respirators with exhalation valves (for patient protection reasons).

When asked whether it was possible to design a respirator that would fit all sizes, opinions were mixed. It was noted that a respirator that the best design is one that allows for user adjustments. Some participants noted that regulatory requirements were more stringent for single size respirators, which may prevent improvements in design.

This group identified a number of areas where research could lead to better fitting respirators. In particular, investigations into new materials, technologies and sensors are needed. Participants wanted more information on decontaminating respirators, whether cross contamination occurs during repeat donning, and the efficacy of biocidal coatings and whether infection rates in emergency departments are improved by the use of respirators.

It was emphasized that collaboration between NIOSH, manufacturers and users would also lead to better designs.

New Fit Test Methods

The most important ideas that emerged from this breakout session were 1) the need for a user seal check that really works and 2) that the goal should be for continuous fit checking rather than no fit test.

Knowledge Gaps about Fit

Participants in this session identified the following wearer characteristics as the biggest contributors to fit:

- Symmetry
- Chin characteristics
- Sweat
- Nose dimension
- Head dimensions (straps and harnesses)

The group noted the very wide variability in the demographics of the United States workforce, leading to wide variety in facial features. Nasal dimensions were thought to be one of more important features for fitting half-mask respirators. Participants called for more data for all groups (race/ethnicity, gender and age). In addition, they noted that aging, elasticity of the face and weight changes may all contribute to respirator fit. More research is needed to identify the reasons some people cannot pass a fit test and how respirators interface with other personal protective equipment.

Posters

Poster abstracts are included in Appendix 2.

Other

Additional information and ideas for innovations were collected from interviewees, written materials and workshop participants. Several of the more important or promising areas are described here.

Input from Employees

There are very few published studies of employee beliefs and attitudes about respiratory protection. A survey of 169 union spray painters found that low intentions to wear respiratory protection were significantly correlated with beliefs that respirators are uncomfortable, get in the way, cause difficulty breathing and make the wearer feel closed in. Social influence (feeling foolish) was a strong predictor of intended use; attitudes of employers, peers and union representatives also played a role in painters' intentions to wear respirators. Painters with low intentions were more likely to disagree that they would experience adverse health outcomes. It is important to note that availability was an important factor in painters' intentions and use of respirators: 49% of respondents received respirators supplied by an employer; 39% owned their own respirator. Workers with low intentions were much less likely to have an employer-provided respirator.[83]

A written survey of 255 hazardous waste workers found that concerns about exposures, fit-testing and training had the most positive influence on respirator use. Problems with communication, comfort, vision, environmental factors and fatigue were the most frequently-mentioned negative influences on respirator use. Nearly 18% of respondents were concerned about maintaining a tight seal during the entire work period, due to temperature (sweat), mask dislocation, interference from other equipment (hard hats) and awkward working positions. The most frequent adverse health outcomes related to respirator wear included headaches and problems with vision and breathing. Skin rashes and claustrophobia were reported by 10% of respondents.

Respondents who wore respirators frequently (greater than once a month) were more likely to report adverse health outcomes.[84]

There has also been little published research on the tolerability of respirators. A recent study by Radonovich et al. measured the length of time various types of masks (including a surgical mask, combination surgical mask/respirators, filtering facepiece respirators, elastomeric half facepiece respirators and powered air purifying respirators (PAPR)) were worn during an 8 hr work shift by 27 volunteer health care workers (additional protective equipment included gowns, gloves and goggles).[81] Average tolerance time was 7.6 hr (25%; 75% quartile = 1.8; 8.0) for the PAPR; 7.7 hr (4.1; 8.0) for a cup style filtering facepiece respirator with exhalation valve and 7.7 hr (4.9; 8.0) for a surgical mask. Adding a surgical mask over the filtering facepiece respirator with exhalation valve significantly lowered the average tolerance time for this respirator by 45% (4.3 hr; 1.9-8.0))(p-value = 0.3). Wearing a similar style of respirator without an exhalation valve lowered the tolerance time for the respirator by 25% to 5.8 hr (4.1; 8.0). A flat fold (duckbill) respirator without an exhalation valve had a slightly higher tolerance time of 6.6 hr (2.9; 8.0) than the cup shaped model without an exhalation valve. The tolerance time was slightly less when a surgical mask was added to a cup style filtering facepiece without an exhalation valve (4.1 hr; 1.7-7.2).

Fifty-nine percent of the subjects discontinued use of the respirator or mask before the 8 hour shift ended (ranging from 48% of PAPR users to 70% of cup style filtering facepiece respirator (no valve) + surgical mask wearers). Those wearing elastomeric (33%) and powered air purifying respirators (11%) had problems with vocal communications. None of the PAPR wearers complained of heat, facial pressure, burning eyes or itching, but 15% reported interference with job duties. Heat was the most common complaint (22-37%) for those wearing negative pressure respirators or surgical masks. Twenty-six percent of those wearing a cup style filtering facepiece respirator without an exhalation valve complained of burning eyes.[81]

Respirator Brand

Brand has been found to be an important confounder in some studies of anthropometric features, further supporting our findings that respirator design may plan an important role in respirator fit. [50, 85, 86] While there was no difference in fit factors between flat fold and cup style respirators in a study of 18 models of filtering facepiece respirators (N95 filters), the geometric mean fit factor was lowest in cup style respirators with only one size and improved significantly for models with multiple sizes.[50] A study of fit with Asian subjects using the medium size of three different brands of elastomeric half-facepiece respirators found that a U.S. mask performed well with both men and women while two South Korean masks had significantly higher fit factors for men than women.[85] A study of respirator fit using three models of half-facepiece elastomeric respirators found that one brand performed significantly better than the others. In addition to size, our research suggests that other design features, such as face style, straps, head cradles and perimeter characteristics (e.g. flanges) may also be important. Other than a comparison between flat fold and cup style in one of these studies, however, no concerted efforts have made to explain the influence of respirator design or brand on respirator fit.[86]

Facepiece Seal Technologies

A recent survey of facial seal technologies performed by Battelle for the United States Army Edgewood Chemical Biological Center identified a variety of “responsive” materials that might be appropriate for new respirator designs.[87] In particular, the survey evaluated materials that change in response to changes in temperature, pressure or voltage, including shape memory polymers, temperature activated gels, pressure sensitive materials (foams, gels, and air bladders), electroactive polymers and shape memory alloys. Three types of seal designs were evaluated:

1) passive materials or systems that responds to pressure by contracting or expanding to conform to the face (e.g. encapsulated gels, air bladders, foams)

2) custom fit materials that could be “molded” to the face (e.g. temperature activated polymers and gels)
3) active systems that employ a sensor, control system and responsive material (e.g. electroactive polymers, temperature activated gels and polymers, and shape memory alloys.

A variety of criteria were used to select the most promising technologies for use in negative pressure full facepiece respirators, including improvements in fit, degree of user involvement during donning, effects of temperature and relative humidity, commercial availability, durability, cost, power requirements, maintenance requirements, ability to integrate into current designs and unique features. The first four factors were given the greatest weight when scoring technologies.

In general, passive seal systems were scored most highly, because they were relatively mature technologies not requiring power or a leak sensor. Among the passive seal materials, encapsulated gels received the highest scores due to durability, heat dissipation and comfort. Some important factors require more research, however. Previous experience with gel and air bladder seals indicates that membrane design is an important issue: thinner membranes ensure better sealing but are more likely to be damaged. Lack of elasticity can also lead to creases, which will create leakage pathways. The gel material may leak if the membrane is punctured and may not be responsive at all environmental conditions.

Active seal systems generally received the lowest scores, because they were complex and methods for detecting leaks were uncertain. However, investigators recommended pursuing active leak detection systems for validating fit during initial donning.

“Wet” adhesive materials were also evaluated, but were not considered viable because of concerns about durability and contamination during non-use. On the other hand, dry adhesives (e.g. bio-inspired adhesives based on gecko lizard feet), which are in development at several universities, were thought to have promise.

The report also evaluated facial cooling technologies (for enhancement of fit), including thermoelectric cooler, small fans or blowers and vapor compression. Fans and blowers would also increase protection by creating positive pressure inside the facepiece.

Thermoelectric devices have advantages of durability, low maintenance and constant cooling rate. On the other hand, they require large amounts of power and are inefficient; the investigators concluded that these devices would not be applicable to respirators for soldiers. However, such systems may have application in other work settings, where only moderate cooling is needed. For example, a thermoelectric system weighing 255 g has been developed for a motorcycle helmet. The report explores several approaches for incorporating thermoelectric devices into the respirator facepiece.

Vapor compression systems have similar advantages and disadvantages of thermoelectric devices. Small (100 mm^2 x 2.5 mm thick) vapor compression patches have received attention for use in cooling suits and could easily be incorporated into the respirator facepiece material.

The report explored a variety of currently-available small fans and blowers that could be incorporated into a respirator facepiece. A Japanese half-mask respirator currently employs such a small fan that operates on 4 AA batteries lasting 12 hr. This appears to be a very promising approach to improvements in respirator fit and comfort, although one interviewee noted that current NIOSH certification regulations for powered air purifying respirators would not allow the commercialization of such a product in the United States.[44]

Discussion

The results of this project suggest that in the past 30 to 40 years there have been numerous important improvements in the design of negative pressure half facepiece respirators and in tests used to evaluate fit. Just a few of these were explored in detail, in an effort to understand how innovations occur and to suggest some approaches that will ensure innovation continues in the future. In most cases, technology push or market pull (or both) played an important role in making these improvements a success; regulations generally had a neutral or, in a few cases, limiting effect on their adoption.

The TSI PortaCount is a good example of an innovation where technology push (condensation nuclei counters) and market pull (Air Force and Army needs) combined to yield an instrument that has, in many ways, revolutionized our approach to and expectations for fit tests. It is important to note, however, that this innovation would probably not have occurred without the funds and field testing provided by the Army research center. A larger, bulkier, less user friendly and more expensive instrument might have resulted, which would have had a much smaller impact.

Filtering facepiece respirators have also had a significant impact on our expectations for respirators. This design -- in its many variations – was also the result of a combination of technology push (melt blown electrostatic filters and better molding methods) and market pull (asbestos abatement workers, among others). Conversely, the flat fold design was not an immediate commercial success until new market forces (healthcare workers' expectations for respirators that look more like surgical masks) and a research study combined to make this a more successful type of filtering facepiece respirator.

Researchers and research publications can play a very important role in the adoption of an innovation. For example, publications prior to development of the PortaCount supported this innovation and published research following its development supported its efficacy in comparison to current fit test methods. The publication by Myers et al. appears to have lent enough support to the user seal check for its inclusion in the revised 1998 OSHA respiratory protection standard.[67] Current skepticism about this innovation, however, indicates that one publication may not ensure full agreement from the professional community.

Health and safety professionals also play an important role in determining the success of an innovation in respirator design or fit testing. This group relies on published research, user input and their own personal experience before fully adopting an innovation.

While regulatory agencies with a mission of approving products must, by definition, place greater emphasis on product performance than on manufacturer profits, they must also take care not to stifle new ideas or prevent competition. Given the lengthy process for developing or amending regulations, agencies must be careful to develop performance-based standards that leave enough room for innovation while also ensuring product performance. It is difficult to ensure the on-going utility of any standard, however, as new approaches, technology or product uses will eventually occur that were never envisioned when the standards were first developed.

There are some things an agency can do to maintain regulatory flexibility and encourage innovation while not straying from its mission of certifying product performance. First, by employing non-prescriptive performance-based standard, an agency allows for flexibility when new ideas, methods and uses are presented for approval. Second, good communication with and input from all stakeholders and on-going identification of new stakeholders can ensure recognition of new needs and suggest new areas needing research or oversight. Third, a healthy mix of internal and external research – with regular interactions– can lead to new ideas and perspectives.

Our results also suggest that there continues to be high potential for innovation in designs and fit test methods for better-fitting respirators, despite many areas where knowledge is still lacking. Workshop presentations, interviews and published materials suggest that innovation in respirator design continues – in universities, government agencies and companies. This study suggests, however, that, as with all innovations, success depends on a combination of specialized knowledge (of materials and technology), preliminary and supporting research, significant financial support, regulatory assistance and flexibility, and ultimately, health and safety professional and user acceptance.

With respect to the innovations explored, there are still a number of areas where further research would be useful in the quest for a "no fit test" respirator. This is true for innovations related to respirator design – the flat fold style for filtering facepiece respirators and the double flanged edge and strap cradle for elastomeric respirators – as well as for fit test methods – in particular, the user seal check.

Our exploration of the adhesive respirator reveals some interesting barriers to innovation, namely the issues of licensing an addition to a respirator that may cause a change that invalidates certification and manufacturers' concerns about marketing an improvement that jeopardizes current products. And the very successful PortaCount illustrates the key role a large stakeholder can play in the research, development and commercialization of an innovation.

Results from workshop presentations and breakout sessions suggest that there are a number of important areas in design and fit testing that could benefit from further research, including better designs for a broader range of environmental conditions, a better understanding of the role of comfort, considering the trade-off between multiple sizes and a one-size-fits-all approach, and exploring approaches that provide continuous fit checks. Research is also needed on the influence of facial characteristics, facial responses and demographic differences.

The following questions represent a number of key areas where more information is needed in the area of respirator fit:

1. What do positive and negative pressure seal checks offer to users of half facepiece negative pressure respirators?
2. Which filtering facepiece designs offer protection for the broadest range of respirator wearers?
3. Are there better face seal technologies and how can they be incorporated into current designs?
4. Which facial characteristics are the most important to good fit?
5. Are there designs that lend themselves to better fit without fit testing, don't require frequent fit testing, fit many people with only one size and for which donning is fool-proof?
6. Are there materials or designs that work in a broad range of environmental conditions (temperature, relative humidity, dust, etc.)?
7. Are there designs that can be frequently donned and re-donned without losing fit?
8. Which strap designs lead to the most effective fit?
9. What is the trade-off between protection and comfort?
10. Are there methods for continuously checking fit – while the respirator is being worn?
11. What effect does aging have on fit over time?
12. What kinds of interactions with other types of personal protective equipment might jeopardize respirator fit?

At this point in time, it is not known whether the future holds a true "no fit test" respirator. Insisting that fit testing must always be required, however, could be an unnecessary barrier to innovations in half-mask negative pressure respirator designs. The best research takes place in an environment where all prior assumptions are

open to question, even if current policies and practices prevent the adoption of new approaches. Even the most open-ended and performance-based policies and procedures are generally reflective of current knowledge and technology. Thus, regulatory agencies must create an environment where new ideas are encouraged and regulations are responsive to innovations.

In addition, research that may lead in new directions should be encouraged, even if there is a high risk that it will fail to yield anything useful. Basic research that seeks to explain the underlying fundamentals of respirator fit is as important as applied research that seeks to test specific methods or designs.

It should be noted that this project may have some limitations. The number of respondents to the innovation survey was small (16) and it was not possible to identify the total number of people receiving the survey. Some important innovations may have been missed, although advisory board review did not indicate this was the case. It is possible that interviewees may have been reluctant to share information that might limit marketplace success. It is not likely, however, that this had a significant effect on this project, given the general nature of the information being sought.

Conclusions and Recommendations

The results of this project suggest that there remain a number of unanswered questions about respirator fit. Recommendations for improvements are offered in the areas of research, respirator certification and stakeholder input.

1. Recommendations for Research

Research in the areas of respirator design, anthropometrics and user seal checks, in particular, may lead to improvements in the fit of half facepiece negative pressure respirators. Recommendations 1.1 through 1.5 are focused on those specific areas where research is needed for improvements in fit. These five recommendations are listed in order from highest to lowest priority, which was determined by considering both the potential impact on respirator fit and the current availability of appropriate technologies, materials or methods.

Recommendation 1.1: Conduct research to clarify the role of respirator design (technologies, materials and systems) in respirator fit. In particular, investigations involving the following respirator features could lead to more comfortable, better fitting and more protective respirators:

- Strap designs (e.g. attachment points, head cradle)
- Methods for cooling the facepiece to limit slip due to sweat (e.g. thermoelectric coolers, small fans, thermal compression devices)
- Methods for increasing protection by inducing positive pressure inside the facepiece (e.g. small fans)
- Improvements that lower breathing resistance for filtering facepiece respirators (increasing filter area, adding an exhalation valve, understanding differences between folded and cup styles)
- Technologies and materials for improving facepiece seals (e.g. encapsulated gels, shape memory polymers, wet and dry adhesives)

This recommendation is of highest priority because significant improvements in respirator fit are likely to result and technologies or materials are currently available for such improvements.

Recommendation 1.2: Conduct research to clarify the influence of facepiece design, multiple facepiece sizes and aging on the interaction between facial measurements and respirator fit. Such investigations may lead to a better understanding about which anthropometric features are most closely associated with well-fitting respirators. Some percent of this research should be devoted to "high risk" research, i.e. research that may not lead to immediate practical applications but rather seeks to illuminate fundamental properties or principles or explore unique or untested technologies or methods.

This recommendation is of high priority because results will lead to improved knowledge about facial features important to respirator fit, which will lead to improvements in respirator design. The technology or materials needed to illuminate the role of facial features are probably available.

Recommendation 1.3: Conduct research on the role of user seal checks in establishing respirator fit, particularly for filtering facepiece respirators.

Research in this area is of high priority because it is feasible, would improve user understanding about fit and may lead to improvements in respirator design. The technology or materials needed to illuminate the role of user seal checks are probably available.

Recommendation 1.4: Conduct research on new methods for checking facepiece seals. In particular, efforts should be made to identify methods that continuously track and report facepiece fit.

Research in this area is of moderate priority. Although the results could have considerable impact on respirator design, technologies and materials are exploratory at this time.

Recommendation 1.5: Conduct research to elucidate the effect on respirator fit of a) other types of personal protective equipment (PPE) and b) environmental conditions such as temperature, relative humidity and dust.

Research in these areas is of low to moderate priority because it could lead to improvements in respirators (and other PPE) but would be largely exploratory in nature at this time.

---

2. Recommendations for Implementing Research Findings

The following recommendations are offered specifically to the NIOSH Personal Protective Technology Laboratory to ensure implementation and incorporation of research findings into its programs and activities.

Recommendation 2.1: Quantitative assessments of respirator fit using a human test panel should be included in the certification requirements of all half-mask negative pressure air purifying respirators. This recommendation should be accomplished through rulemaking to allow involvement of all stakeholders.

Recommendation 2.2: Consultative panel(s) representing key stakeholders --including respirator users and program managers, inventors, researchers, and manufacturers – should be used to ensure a forum for identifying issues, exchanging ideas, discussing research findings and defining future research directions.

Recommendation 2.3: Collaborations among government agencies should be continued to combine resources for supporting internal and external research that is responsive to common needs.

Recommendation 2.4: A formal assistance program should be developed to provide financial and other types of support to inventors and small businesses seeking to bring new ideas to market. It is envisioned that such assistance would extend beyond that offered by the Small Business Innovative Research program and would include advice about commercialization and certification.

Recommendation 2.5: A method should be established for conducting regular reviews of certification regulations in light of new technologies for respirator design and performance. This should include opportunities for respirator manufacturers to identify areas where current regulations may prevent new innovations from being pursued or adopted.

Recommendation 2.6: More opportunities should be available, in addition to stakeholder meetings, for interactions between internal NIOSH researchers and external investigators. Such interactions would ensure that research conducted by each of these groups is informed by up-to-date information and has practical application.

Acknowledgements

Thanks are extended to Ron Shaffer, Nicole Koktavy, Chris Western, Ruth Rasmussen, Judi Coyne, Ziqing Zhuang, the Advisory Board members, AIHA respiratory protection committee members, workshop speakers, poster presenters and facilitators, and interviewees for all their assistance with this project.

Literature Cited

1. Doney BC, Groce DW, Campbell DL, et al. A survey of private sector respirator use in the united states: An overview of findings. *J Occup Environ Hyg*. 2005;2:267-276.

2. Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic. *Reusability of Facemasks during an Influenza Pandemic: Facing the Flu.* National Academies Press; 2006.

3. Duling MG, Lawrence RB, Slaven JE, Coffey CC. Simulated workplace protection factors for half-facepiece respiratory protective devices. *J Occup Environ Hyg*. 2007;4:420-431.

4. Lawrence RB, Duling MG, Calvert CA, Coffey CC. Comparison of performance of three different types of respiratory protection devices. *J Occup Environ Hyg*. 2006;3:465-474.

5. Coffey CC, Lawrence RB, Zhuang Z, Duling MG, Campbell DL. Errors associated with three methods of assessing respirator fit. *J Occup Environ Hyg*. 2006;3:44-52.

6. Campbell DL, Coffey CC, Jensen PA, Zhuang Z. Reducing respirator fit test errors: A multi-donning approach. *J Occup Environ Hyg*. 2005;2:391-399.

7. Coffey CC, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA. Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J Occup Environ Hyg*. 2004;1:262-271.

8. Coffey CC, Lawrence RB, Zhuang Z, Campbell DL, Jensen PA, Myers WR. Comparison of five methods for fit-testing N95 filtering-facepiece respirators. *Appl Occup Environ Hyg*. 2002;17:723-730.

9. Campbell DL, Coffey CC, Lenhart SW. Respiratory protection as a function of respirator fitting characteristics and fit-test accuracy. *AIHAJ*. 2001;62:36-44.

10. Department of Health and Human Services. Respiratory protective devices; final rules and notice. 1995;42 CFR Part 84.

11. Zhuang Z, Bradtmiller B. Head-and-face anthropometric survey of U.S. respirator users. *J Occup Environ Hyg*. 2005;2:567-576.

12. Zhuang Z, Bradtmiller B, Shaffer RE. New respirator fit test panels representing the current U.S. civilian work force. *J Occup Environ Hyg*. 2007;4:647-659.

13. Committee for the Assessment of NIOSH and Anthropometric Survey of U.S. Respirator Users. *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users.* The National Academies Press; 2007.

14. Held BJ. *History of Respiratory Protective Devices in the U.S. Pre World War I.* Livermore, CA: University of California, Lawrence Livermore Laboratory.

15. Pritchard JA. A guide to respiratory protection. Los Alamos, NM: Los Alamos Scientific Laboratory; 1977;LA-6671-M.

16. Adley FE, Berry CM, Gilliland EW, et al. Respiratory protective devices manual. American Industrial Hygiene Association and American Conference of Governmental Industrial Hygienists; 1963.

17. CDC. Public health guidance for community-level preparedness and response to severe acute respiratory syndrome (SARS) version 2; supplement I: Infection control in healthcare, home, and community settings; III. infection control in healthcare facilities. 2004.

18. CDC. Interim recommendations for infection control in health-care facilities caring for patients with known or suspected avian influenza. U.S. Department of Health and Human Services; 2004.

19. Cummings KJ, Van Sickle D, Rao CY, Riggs MA, Brown CM, Moolenaar RL. Knowledge, attitudes, and practices related to mold exposure among residents and remediation workers in posthurricane new orleans. *Arch Environ Occup Health*. 2006;61:101-108.

20. Cummings KJ, Cox-Ganser J, Riggs MA, Edwards N, Kreiss K. Respirator donning in post-hurricane new orleans. *Emerg Infect Dis*. 2007;13:700-707.

21. Ashford NA, Heaton GR, Priest WC. Environmental, health, and safety regulation and technological innovation. In: Hill CT, Utterback JM, eds. *Technological Innovation for a Dynamic Economy.* Pergamon Press; 1979:161-221.

22. Rothwell R. Industrial innovation and government environmental regulation: Some lessons from the past. *Technovation*. 1992;12:447-458.

23. Ashford NA, Ayers C, Stone RF. Using regulation to change the market for innovation. *Harvard Environmental Law Review*. 1985;9:419-466.

24. Mintner SG. Safety equipment manufacturers focus on product performance. *Occupational Hazards.* 2005:34-36.

25. Willeke K, Ayer H, Blanchard J. New methods for quantitative respirator fit testing with aerosols. *AIHAJ*. 1981;42:121-125.

26. McMurray P. The history of condensation nucleus counters. *Aerosol Science and Technology*. 2000;33:297-322.

27. Remiarz RJ, Agarwal JK, Nelson PA, Moyer E. A new, automated method for testing particulate respirators. *ISRP*. 1984;2:275-287.

28. Remiarz R. Interview about PortaCount. Minneapolis MN:2008.

29. Agarwal J. Interview about PortaCount. Minneapolis MN:2008.

30. Laye R. Interview about PortaCount. Minneapolis MN:2008.

31. Gardner P. Interview about PortaCount. Minneapolis MN: 2008.

32. Nelson P. Interview about PortaCount and adhesive respirator. Minneapolis MN: 2008.

33. Weed J. Interview about PortaCount. Minneapolis MN: 2008.

34. Ernstberger HG, Gall RB, Turok CW. Experiments supporting the use of ambient aerosols for quantitative respirator fit testing. *Am Ind Hyg Assoc J*. 1988;49:613-619.

35. Rose JC, Oestenstad RK, Rose VE. A comparison of respirator fit factors determined by portable condensation nuclei counter and forward light-scattering photometric methods. *Appl Occup Environ Hyg*. 1990;5:792-797.

36. Tait GW, Byington TH. Respirator problems in atomic energy practice. *AIHA*. 1958;19:123-125.

37. HYATT EC. Current problems and new developments in respiratory protection. *Am Ind Hyg Assoc J*. 1963;24:295-304.

38. Birkner LR. *Respiratory Protection A Manual and Guideline.* 1st ed. Akron, OH: American Industrial Hygiene Association; 1980.

39. Revoir WH, Bien CT. *Respiratory Protection Handbook.* Boca Raton, Florida: CRC Press, Lewis Publishers; 1997.

40. Stein R. Interview about strap cradle. Minneapolis MN: 2008.

41. Montesi EN, Barrington RI, inventors; Siebe North I and Charleston SC, assignees. Yoke for a respirator. patent Des. 288,730. March 10, 1987, 1987.

42. Montesi EN, Barrington RI, inventors; Siebe North I and Charleston SC, assignees. Yoke for the harness of a respirator. patent 4,603,692. August 5, 1986, 1986.

43. Blank G. Interview about double-flanged facepiece. Minneapolis MN: 2008.

44. Sustello R. Interview about strap cradle and double-flanged facepiece. Minneapolis MN: 2008.

45. Tremblay J. Interview about flat fold. Minneapolis MN: 2008.

46. Parker J. Interview about flat fold. Minneapolis MN: 2008.

47. Newcomb B. Interview about strap cradle, flat fold, and user seal check. Minneapolis MN:2008.

48. Shorer B. Interview about flat fold. Minneapolis MN: 2008.

49. Lee K, Slavcev A, Nicas M. Respiratory protection against mycobacterium tuberculosis:Quantitative fit test outcomes for five type N95 filtering-facepiece respirators. *JOEH*. 2004;1:22-28.

50. Zhuang Z, Coffey CC, Ann RB. The effect of subject characteristics and respirator features on respirator fit. *J Occup Environ Hyg*. 2005;2:641-649.

51. Viner A. Interview about double-flanged facepiece, flat fold, and adhesive respirator. Minneapolis MN: 2008.

52. Grinshpun S. Interview about adhesive respirator. Minneapolis MN: 2008.

53. Grinshpun S. Adhesive facepiece respirator: Concept development and validation. Minneapolis MN: 2008.

54. Ahlers H. Approval of filtering facepiece respirators with novel head suspension systems. Pittsburgh, PA: National Institute for Occupational Safety and Health; 2009.

55. Nelson P, Weed J. Evaluation of an adhesive seal to improve the fit of N95 filtering facepiece respirators. Minneapolis MN: 2008.

56. Matich RD, inventor; Matich RD, assignee. Face mask with seal and neutralizer. patent US 7,017,577 B2. March 28, 2006, 2006.

57. Steelnack J. Interview about user seal check. Minneapolis MN: 2008.

58. Levinson A. Interview about user seal check. Minneapolis MN: 2008.

59. ANSI. ANSI Z88.2-1969 practices for respiratory protection. . 1969.

60. Bloom TF, Ruch W, Pettigrew G, Berry D. Respiratory protection...an employer's manual. Cincinnati, OH: U.S. Department of Health, Education, and Welfare; 1978;DHEW (NIOSH) Publication No. 78-193A.

61. ANSI. ANSI Z88.2-1980 Practices for respiratory protection. 1980.

62. Rajhans GS, Blackwell DSL. *Practical Guide to Respirator Usage in Industry.* Stoneham, MA: Butterworth Publishers; 1985.

63. Noonan GP, Linn HI, Reed LD. A guide to respiratory protection for the asbestos abatement industry. U.S. Environmental Protection Agency; 1986;EPA-560-OPTS-86-001.

64. Bollinger NJ, Schutz RH. NIOSH guide to industrial respiratory protection. Cincinnati, OH: National Institute for Occupational Safety and Health; 1987;DHHS (NIOSH) Publication Nol 87-116.

65. Colton CE, Birkner LR, Brosseau LM, eds. *Respiratory Protection: A Manual and Guideline.* 2nd ed. Akron, OH: American Industrial Hygiene Association; 1991.

66. ANSI. Z88.2-1992 American National Standard for respiratory protection. 1992.

67. Myers WR, Jaraiedi M, Hendricks L. Effectiveness of fit check methods on half mask respirators. *AOEH*. 1995;10:934-942.

68. Colton CE, Brosseau LM, eds. *Respiratory Protection A Manual and Guideline.* 3rd ed. Fairfax, VA: American Industrial Hygiene Association; 2001.

69. Delaney L, McKay R, Freeman A. Determination of known exhalation valve damage using a negative pressure user seal check method on full facepiece respirators. *AOEH*. 2003;18:237-243.

70. Derrick JL, Li PT, Tang SP, Gomersall CD. Protecting staff against airborne viral particles: In vivo efficiency of laser masks. *J Hosp Infect*. 2006;64:278-281.

71. Gaydos N. The experience of a respiratory protection program manager. 2008.

72. Catlin M. Describing the problems: Experience from users. 2008.

73. Kojola B. Respirator fit: Experiences and perspectives of the AFL-CIO. 2008.

74. Platner J. User experiences with respiratory protection. 2008.

75. Alfano-Sobsey E. Respiratory protection preparedness at north carolina's health deparments. 2008.

76. Nelson P. Experiences of small business respirator innovation. 2008.

77. Shaffer R. Overview of NIOSH reserach for improving and understanding respirator fit: Past, present, and future. 2008.

78. Coyne K. Investigation of novel respirator seal concepts. 2008.

79. Colton C. Respirator fit from a manufacturer's point of view. 2008.

80. Radonovich LJ. Respirator projects: Veterans health administration (VHA). 2008.

81. Radonovich LJ, Cheng J, Shenal BV. Respirator tolerance in health care workers. *JAMA*. 2009;301:36-38.

82. Jayaraman S. No fit-test respirator: Thoughts on future research in the materials and structures areas. 2008.

83. White MC, Baker EL, Larson MB, Wolford R. The role of personal beliefs and social influences as determinants of respirator use among construction painters. *Scand J Work Environ Health*. 1988;14:239-245.

84. Salazar MK, Connon C, Takaro TK, Beaudet N, Barnhart S. An evaluation of factors affecting hazardous waste workers' use of respiratory protective equipment. *AIHAJ*. 2001;62:236-245.

85. Han DH, Choi KL. Facial dimensions and predictors of fit for half-mask respirators in Koreans. *AIHA J (Fairfax, Va)*. 2003;64:815-822.

86. Oestenstad RK, Elliott LJ, Beasley TM. The effect of gender and respirator brand on the association of respirator fit with facial dimensions. *J Occup Environ Hyg*. 2007;4:923-930.

87. Richardson AW, Hofacre KC, Gardner PD. Technology survey for enhancement of chemical, biological, radiological, and nuclear respiratory protection. Columbus, OH: Battelle Memorial Institute; 2008;ECBC-CR-094.

Appendix 1 - Workshop Agenda

NO FIT TEST RESPIRATOR WORKSHOP

Overview & Description of Workshop Goals

Welcome - Les Boord, NIOSH

NIOSH Workshop Goals - Ron Shaffer, NIOSH

Innovations in Respirator Design and Fit Test Methods - Lisa Brosseau, University of Minnesota

Describing the Problem

The Experience of a Respiratory Protection Program Manager - Natalie Gaydos, PPG

User Experiences with Respiratory Protection - Bill Borwegen, SEIU**,** Bill Kojola, AFL-CIO**,** Jim Platner, CPWR

Respiratory Protection Preparedness at North Carolina's Health Departments - Edie Alfano-Sobsey, Wake Human Services

Experiences of Small Business Respirator Innovation - Peter Nelson, Breathe Safely

Current Progress Toward Better Fitting Respirators

NIOSH Research - Ron Shaffer, NIOSH

Military Research - Karen Coyne, Aberdeen Proving Ground

Respirator Fit From a Manufacturer's Point of View - Craig Colton, 3M

Perspective of a Large Respirator User - Lew Radonovich, Veterans Administration

What is Coming in the Future?

Ideas about Future Research in the Materials and Structures Areas - Sundaresen Jayaraman, Georgia Institute of Technology

Concurrent Breakout Sessions

I. New Materials and Designs

Facilitator: Sundaresan Jayaraman, Georgia Institute of Technology

II. New Fit Test Methods

Facilitator – Jim Platner, CPWR

III. Knowledge Gaps About Fit

Facilitator – Kent Oestenstad, UAB

Reports from Breakout Sessions

Summary and Next Steps

Appendix 2 - Poster Abstracts

A Computational Method for Evaluating Fit
K.M. Butler, N National Institute of Standards and Technology, Gaithersburg MD

A method is being developed for characterizing the relationship between respirator fit and the physical dimensions of faces and respirators, using real material properties for facial skin and the respirator seal. Given 3D digital geometries, the respirator is computationally pushed onto the face, distorting its shape as necessary, until the head is "wearing" the respirator. As the respirator is pushed into place, the software determines the areas of contact and contours of stress. Contours of low stress indicate areas where leaks would be most likely, and contours of high stress indicate areas where the respirator would need to be tightened to get a good seal, potentially representing areas of tactile discomfort.

Respiratory Protection Training and Fit Testing for Healthcare Facilities: A Labor-Management Model Program from New York City
Steve Schrag, Hazardous Materials Training Coordinator, 1199 SEIU/League Training and Upgrading Fund, New York NY; Mark Catlin, Industrial Hygienist, SEIU Education and Support Fund, Washington DC

This poster describes a labor-management partnership for delivering respiratory protection training and fit-testing to front-line healthcare workers. Specially trained peer trainers fit-tested and trained 1500 front-line employees over an 18-month period. The partnership continues with an in-house experienced team to continue with new hires and annual refresher training and fit testing for staff. The program was initially developed as a partnership between Brooklyn's Long Island College Hospital (LICH) and the two Training Funds. The 1199 SEIU/League Training and Upgrading Fund is working to expand the program through New York City and to add quantitative fit testing using the PortaCount.

Respirator Donning in Post-Hurricane New Orleans: Implications for Protecting the Public from Airborne Hazards
KJ Cummings, MD, MPH[1], J Cox-Ganser, PhD[1], MA Riggs, PhD[2], N Edwards, MS[1], K Kreiss, MD[1], [1]National Institute for Occupational Safety and Health (NIOSH), Morgantown, WV, United States, [2]NIOSH, Cincinnati, OH, United States

Following flooding caused by Hurricanes Katrina and Rita, public health officials recommended that the New Orleans public use N-95 respirators when remediating moldy water-damaged buildings. Anecdotal reports suggested some New Orleans residents were not properly donning N-95 respirators, compromising protection. In March 2006, we conducted a population-based survey of 600 residential sites in New Orleans, selected using geographic information system software. We interviewed adults about post-hurricane experiences, observed participants don an N-95 respirator, and documented donning issues that could contribute to a poor respirator fit. Using multivariable logistic regression, we investigated factors associated with proper donning.

We interviewed 553 participants (92% response rate) and observed 538 (97%) don an N-95 respirator. A total of 129 (24%) participants demonstrated proper donning. The most common donning issues were nose clip not tightened (71%) and straps misplaced (52%); 22% donned the respirator upside-down. In multivariable analyses,

six factors were associated with proper donning: ever having used a mask or respirator (odds ratio [OR] 5.28; 95% confidence interval [CI], 1.79-22.64); ever having had a respirator fit test (OR 4.40; 95% CI, 2.52-7.81); being male (OR 2.44; 95% CI, 1.50-4.03), white race (OR 2.09; 95% CI, 1.32-3.33); having a certified respirator at the time of the interview (OR 1.99, 95% CI 1.20-3.28); and having participated in mold clean-up activities (OR 1.82; 95% CI,1.00-3.41). A minority of participants demonstrated proper N-95 respirator donning. Thus, most would not derive full protection. In planning for future events in which public use of N-95 respirators may occur, from floods to pandemic influenza, health agencies should consider interventions to improve respirator donning.

Adhesive Facepiece Respirator: Concept Development and Validation

Sergey A. Grinshpun, Center for Health-Related Aerosol Studies, University of Cincinnati, Cincinnati, Ohio, USA

The face-seal leakage may significantly decrease the protection level of a filtering facepiece particulate respirator. The National Academies call for "developing more effective and consistent face seals for respirators" (*Preparing for an Influenza Pandemic*, IOM, 2008). To address this demand, a flat strapless respirator was developed with a circumferential medical-grade adhesive and a high efficiency low resistance composite filtration material. The new respiratory protection technology was evaluated and found capable to significantly minimize the total inward leakage. Several models were prototyped and have been (or are being) certified for N95, N99, N100, and P100 ratings. Based on the tests performed in several laboratories across the US, the filter penetration was found to be as low as 0.005% for 0.3 µm particles DOP or NaCl with breathing resistance of 9 to 14 mm H_20 at 85 L/min. The fit factors as high as 20,000 – 60,000 were achieved. The new technology is designed to protect the workers and the general population.

Evaluation of an Adhesive Seal to Improve the Fit of N95 Filtering Facepiece Respirators

Peter Nelson, Breathe Safely, LLC; Jeff Weed, WeedRPS, LLC

Workers were each quantitatively fit tested twice with the same model and size N95 filtering facepiece respirator. One test used the standard NIOSH-approved respirator and the other used an identical respirator modified with an adhesive material pre-applied to the sealing surface. After testing, subjects were asked their opinion regarding the affect of the adhesive on comfort and confidence. Quantitative results showed that the adhesive improved overall fit factors by an average of 270%. Qualitative results showed that 70% of subjects felt that the respirator with adhesive was more comfortable, and 100% indicated that the respirator with adhesive felt more protective.

P100 versus N95 Protection for Halfmask Respirators

Jeffrey Peterson, Pat Wiltanger and Jeremy Brannen, Test & Performance Evaluation Team Leader, NPPTL, NIOSH

Title 42, Code of Federal Regulations, Part 84 (42 CFR 84) states that respirators shall be designed and constructed to fit persons with various facial shapes and sizes and *Title 29, Code of Federal Regulations, Part 1910.134* (29 CFR 1910.134) mandates that all employers covered under the jurisdiction of the Occupational Safety and Health Administration shall perform fit testing prior to issuing NIOSH approved respirators. Many questions from the user community have been raised as to whether a P100 filter or filtering facepiece actually provides more protection than an N95 filter or filtering facepiece.

The National Personal Protective Technology Laboratory is conducting a comparison study of filtering facepieces and elastomeric facepieces with N95 and P100 protections to determine the relative protection achieved by each type of respirator on the same panel of users. The test panel chosen to use for this study consisted of 10

individuals who were representative of the Los Alamos National Laboratory Panel for half mask respirators. Data are currently being reviewed and will be shared with stakeholders upon completion of the analysis.

Total Inward Leakage (TIL) Program
William E. Newcomb and Jon Szalajdaz, NPPTL, NIOSH

The NPPTL Total Inward Leakage (TIL) program will establish TIL performance requirements and laboratory test capability for testing of personal protective equipment (PPE), including all classes of respirators and protective garments. The NPPTL TIL program will be organized into multiple projects. The initial TIL project will address half-mask respirator requirements and testing. Other classes of respirators will be incorporated into the program following completion of the half-mask project. TIL testing is intended to quantify the ability of respirators to fit individuals and is not intended to replace individual fit testing as mandated by OSHA or to predict the workplace protection offered by respirators during actual use. While total inward leakage testing performed under laboratory conditions does not necessarily reflect expected actual field level PPE performance, it does represent a criterion for performance that influences PPE design.

Laboratory Respirator Protection Level (LRPL) Fit Testing
Heinz Ahlers, Jeff Peterson, Terry Thornton and Pat Wiltanger, NPPTL, NIOSH

The National Personal Protective Technology Laboratory of the National Institute for Occupational Safety and Health employs a Laboratory Respirator Protection Level (LRPL) test as part of the certification process for Chemical, Biological, Radiological and Nuclear (CBRN) rated respirators. The LRPL is an advanced form of evaluating the fitting characteristics of respirators for CBRN approval. The design of the generated corn oil atmosphere testing facility for LRPL and the experience bringing this facility into use will be discussed. The characteristics of the chamber environment including particle size distribution, airborne concentration, and air flow will be addressed and an overview of our approval testing results, chamber capabilities and correlation with selected other fit test methods will be provided.

Development of Computer-Aided Face-Fit Evaluation Methods
Ziqing Zhuang, Dennis Viscusi, and Ronald Shaffer, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA

The goal of this project is to develop computer-aided face-fit evaluation methods. A database containing anthropometric measurements for 3,997 respirator users was created in 2003 from a nationwide survey. Two new respirator fit test panels representative of the current U.S. work force were developed. A correlation was found between respirator fit and the new NIOSH bivariate fit test panel cells. The current research includes: 1) development of test head forms representative of U.S. work force; 2) characterization of shape features and variations from 3-D scan data; 3) investigation of the association between respirator fit and 3-D shape parameters.

Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering-Facepiece Respirator Fit
Ziqing Zhuang, Ronald Shaffer and Dennis Viscusi, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA

To address questions surrounding the periodicity of respirator fit testing, this first-of-its-kind study will assess respirator fit and facial dimension changes as a function of time for a representative sample of 200 subjects wearing filtering-facepiece respirators. For each participant, 13 traditional face measurements, height, weight,

and a scanned image using a Cyberware Model 3030 head scanner will be collected at the onset of the study and every six months thereafter for three years. Knowledge gained from this research will be used to formulate hypotheses for additional studies to further explore questions surrounding the periodicity of respirator fit testing.

Appendix 3 – Results of Breakout Sessions

Breakout Session 1 – New Materials and Designs for Better Fit

1. What material properties should be considered for the next generation of better fitting respirators?

- Environment in which the device is used
  - Temperature Variation
  - Degree of Contamination
  - Material Environment Interaction
- Material Properties
  - Mechanical
  - Chemical
  - Physical
  - Degradation
  - Comfort
  - Thermal Conductivity
  - Transparency
  - Compatibility with other parts of device
  - Cost
  - Sound
  - Biocompatibility
  - Sustainable/Recyclable
- Material Environment Interaction

2. What design properties should be considered for the next generation of respirators?

- Safety and Comfort Go Together
- Uniform Pressure Distribution on Face
- Position of Respirators
  - Maximize Area of Contact
- Role of Straps
- Weight of Materials
- Number of Seals/Seal Design
- Easy to Clean and Decontaminate
- End of Life Indicator
- Shelf Life/Aging Properties
- Different Face Profiles
- Novelty of Interaction
- Does not impair field of vision
- Key Point: Work Environment-Specific Requirements
  - Health Care Workers No Exhalation Valves, Visually Appealing
  - Construction Workers UV Exposure
  - Industrial: New Risks-Complex Paints, Temperature Distribution
- Novelty of Users

- Donning Indicator
- Storage/Portability
- Communication
- Multiple Donning
- Minimize Number of Parts

3. Is "one size fits all" respirator possible?
   - Varied Opinions
   - Key Point:
     - Adjustable Size : By User
   - Mouth Bit Respirator
   - Inflatable Seal
   - Regulatory Issues Vs. Technology

4. Research Topics
   - Investigation of New Materials and Technology
   - New Design
   - Concept of Making Mold and then Using Liquid Silicone
     - CAD/CAE/Rapid Prototyping
   - Infection Rates in ER: Determine need for and Degree of Protection
   - Reusable Respirator
   - Decontamination
   - Cross Contamination by Repeat Use of Mask
   - Selective Biocide Coating on Respirator
   - Sensors
   - NIOSH/Manufacturer/User Collaboration
   - Investment in Use vs. Cost in Non-Use

Breakout Session 2: New Fit Test Methods

- A user seal check that really works.
- A goal of 'continuous fit check' rather than 'no-fit-test'.

1. What would make it possible to never have to use a fit test, even initially?
Would have to be one that required zero training and zero adjustment.

2. Is it possible to develop a fit test method that is always available to the user (e.g. part of the respirator)?
No. Even if you had a perfect detector, people would have to be trained to respond to it.

3. Research Priorities:
   - What can we do to identify a user seal check that really works?
   - What constitutes an effect train-the-trainer for fit testers?

Breakout Session 3: Knowledge Gaps about Fit

1. What wearer characteristics contribute to good and poor fit of a respirator?

- Symmetry
- chin characteristics
- Sweat
- Nose dimension
- Head dimensions for head straps and harnesses

2. What is the role of facial features? What remains to be discovered?
   - Demographics for workforce subgroups (industry, health care workers, construction, etc)
   - Large amount of variation
   - Nasal dimensions
   - Lip width?
   - Need data for all groups (race, ethnicity, gender, age)

3. What is the role of other characteristics (race, gender, age, and ethnicity)?
   - Accommodation for women
   - Elasticity of face/skin, weight, how these correlate to fit
   - The effect of aging on respirator fit?

4. Are there other knowledge gaps that should be considered or explored?
   - Research on association of facial dimensions and fit of full face piece respirators
   - Identify leak sites and association with facial & respirator dimensions
   - What happens to the outliers who can't get a fit?
     - Who are these people?
     - Why can't they be accommodated?
   - 3D description of the face
   - Interface with other PPE