FINAL REPORT

Title: **Respirator Effects in Impaired Workers**

Principal Investigator: Philip Harber

PI Contact: UCLA Occupational-Environmental Preventive Medicine
10880 Wilshire Blvd., Suite 1800
Los Angeles, CA 90024
310-794-8144
pharber@mednet.ucla.edu

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TABLE OF CONTENTS

TERMS AND ABBREVIATIONS

H1N1	Novel influenza A. (sometimes called "swine flu")
SARS	Severe Acute Respiratory Syndrome
N95	A particular respirator type; in this document, it refers to a filtering facepiece N95
HFM	Half facemask respirator (dual cartridge type in this document)
COPD	Chronic obstructive pulmonary disease
Vt	Inspiratory Tidal Volume
Ve	Minute Ventilation
Fb	Respiratory Rate
HR	Heart Rate
Ti	Inspiratory Time
Te	Expiratory Time
Tt	Total Breath Time
Ti/Tt	Fractional Inspiratory Time
Vt/Ti	Mean Inspiratory Flow
PifVt	Peak Inspiratory Flow
PefVt	Peak Expiratory Flow of Vt
PifTTi	Time to Reach Peak Inspiratory Flow
PefTTe	Time to Reach Peak Expiratory Flow

ABSTRACT

The focus of this research project is respiratory protection. Respirators, technically known as respiratory personal protective devices, have traditionally been used in occupational settings to protect workers against inhalation hazards such as toxic materials. Persons who might use respirators were medically evaluated, and many persons with health disorders excluded from work requiring respiratory protection. More recently, however, a need for more widespread respirator use has been identified for several reasons: more industries and jobs require respiratory protection (e.g., the healthcare sector in addition to traditional mining/manufacturing sectors); respirators may be needed in many community settings (e.g., Hurricane Katrina cleanup, H1N1 influenza pandemic); and respirators may be needed if there is a bioterrorism concern. In addition, the workforce increasingly includes persons with impairments. Therefore, this research project sought to determine if persons with mild respiratory impairments could continue working while using respirators. In addition, despite extensive prior research studies, the reasons why some people tolerate respirator use poorly are not well understood. The project therefore also investigated the mechanisms of respirator effects.

The project studied normal individuals and persons with mild respiratory impairments (COPD, asthma, and rhinitis) in both a research exercise physiology laboratory setting and while they performed a variety of work tasks using respirators. Two commonly used types of respirators were studied. Several different effects were analyzed- effects on ventilation (breathing), subjective effects, respirator induced anxiety, proper mask placement on the face, and impact upon the work productivity. This research project developed new methods for making many of these measurements.

The data demonstrated that persons with mild respiratory impairments are able to safely and effectively use respirators. Improved methods of assessing effects were demonstrated, including a multidimensional subjective rating assessment and emphasis upon respiratory pattern control rather than simply measuring the total air breathed. The results showed that the two categories of respirators differed significantly in both physiologic and subjective effect. The respirator types also differed in the level of anxiety they induced. In addition, although mildly impaired subjects were able to continue doing the work with respirators, the patterns of adaptation and the types and magnitude of respirator effects differed significantly among the respiratory disease categories. Furthermore, this study directly measured work productivity while using respirators.

Significant implications of this research include the following: (1) It is not necessary to exclude persons with mild respiratory disorders from work for which a respirator must be employed. (2) Specific medical evaluation considerations are needed depending on the type of respiratory disease. (3) The criteria for certifying new respirator designs by NIOSH should be reevaluated; in particular, the current testing methods may be augmented by measurement of impacts upon respiratory pattern, several types of subjective response, and work productivity. (4) Choosing the best respirator for an individual must consider interpersonal variability; there may be a trade-off between a higher level of protection afforded by some devices versus a lower likelihood that they will be actually properly used. (5) Methods developed in this study may be applicable to future respirator research to help produce devices that are likely to be well tolerated and actually properly used by a high proportion of potential users. (6) The study provided

insights to address questions about why some users report problems, and why some respirator types may be better tolerated than others.

In addition to potential benefit for protecting workers, results of this research are likely to have significant implications for use in the general community as well.

SECTION 1:

HIGHLIGHTS & SIGNIFICANT FINDINGS:

In the past, respirator use was largely limited to carefully selected workers known to be in good health who work in a limited range of occupational settings. However, the need for respiratory protection has become much broader. Therefore, the project evaluated whether people with mild respiratory impairments could use respirators safely and effectively. The research also investigated the factors that determine whether a respirator will be well tolerated, considering both differences among respirators and among people. The research was conducted by testing normal individuals and persons with several mild respiratory diseases. Each was tested in a research physiology laboratory as well as while conducting a variety of work tasks. Significant findings of this NIOSH sponsored research project include the following:

1. *Respirator use is not limited by physiologic ventilatory limitation*: It was believed that the ability of many potential users would be limited by the physical effort to overcome the resistance of the filter or the mask dead space. This assumption was used in research, for certifying new respirators based upon their resistance, and for medical assessments. This project shows that reduction in breathing volumes is not the major effect.

2. *Respirator tolerance, rather than airflow limitation, probably determines whether respirators can and will be properly utilized*. Most actual respirator use occurs at low-moderate exertion. Therefore, subjective sensation rather than inability to move air through the mask/filter is most important except at very high exertion levels.

3. *Respiratory pattern adaptation is likely to be the most relevant physiologic effect.* Our studies show that respirator users consistently change the respiratory pattern (such as inspiratory time prolongation); this is consistent with findings in respiratory disease patients and experimentally imposed respiratory loads. This finding has implications for research and for testing persons who may need to use respirators.

4. *Subjective effects are important and multidimensional*. The studies compared two categories of respirators. Subjective effects depend upon on both the respirator type and personal characteristics. Although many prior studies assessed only one type of subjective response, this study demonstrated three distinct categories of responses.

5. Adequate protection by respirators depends upon not moving the mask on the face. This study showed that *intentional mask dislodgment is uncommon*. Our current studies using video recording showed that intentionally moving the mask is relatively uncommon, even with naive subjects who were not specifically trained.

6. *Measuring productivity is both important and feasible*. Respirators should protect *both* health and productivity. Our studies have complemented health effect assessment with measurement of productivity impact. Subjects were able to complete the tasks, and the two respirator types did not differ significantly in their productivity impact.

7. *Respirator types differ significantly in their impacts and acceptability*. The studies compared two commonly used respirators, and significant differences were seen in

subjective tolerance and in several key physiologic variables. Overall, a panel of test procedures was developed that can effectively differentiate among respirator types.

8. *Human testing is essential for evaluating and certifying designs of respirators.* This study shows that the range of human effects is large, and therefore human testing measuring multiple outcomes is advisable as an integral component.

9. *Respiratory disease, even if mild, modified the effect of respirators*. Respiratory health status (e.g., normal, asthma, rhinitis, COPD) modified the subjective and physiologic responses. Therefore, results from normal individuals or persons with one type of respiratory disease cannot simply be applied to others.

10. *Persons with mild respiratory diseases can use respirators safely and effectively*. In this research study, respiratory disease patients were able to successfully complete the study and conduct the low-moderate exertion work tasks

TRANSLATION OF FINDINGS

Significant implications of this NIOSH sponsored research project for occupational health research and for prevention of disease in workers and community members include:

Many persons with mild respiratory impairments can safely and effectively use respirators. The results support respirator use when appropriate in settings such as the healthcare sector and when there are concerns about epidemics and bioterrorism. For example, they were widely used during the Hurricane Katrina cleanup and will probably be widely used if the H1N1 influenza or other epidemic becomes quite severe.

Worker productivity should be considered in respirator research and certification. While the primary purpose of respirators is to protect the user, it is also important that the worker be able to continue productive work. Methods developed in this project may be incorporated in testing new respirator designs and perhaps in certification process.

The work also led to better understanding of the types of effect respirators have upon users. This can lead to better respirator design as well as certification testing.

OUTCOMES/ RELEVANCE/ IMPACT

This NIOSH sponsored research project may have both short-term and long-term benefits to worker health and more generally to public-health. Most persons, even if they have mild respiratory disorders, may use respirators for limited times. This will encourage respiratory protection against inhaled toxins or biologic agents while maintaining worker productivity. Measuring subjective responses is feasible and should improve medical assessment of potential users.

Intermediate-term benefits include implications for designing and certifying new respirators. Respirator manufacturers and respirator certifiers (e.g., NIOSH) may wish to consider incorporating several additional areas, including multi-domain subjective responses, respiratory pattern adaptation, anxiety, and impact upon worker productivity.

In the long-term, worker and community public-health may be improved by increased understanding of how respirators, work characteristics, personal characteristics, and disease status interact as determinants of respirator tolerance and use.

SECTION 2: SCIENTIFIC REPORT

BACKGROUND

In the past, respiratory protection was required predominately for individuals in worksite settings with exposure to toxic materials (e.g., lead, asbestos). Persons with impairment generally were not required to work in settings requiring respiratory protection. Much prior research and standard setting has focused upon the effects of respirators on generally healthy individuals. There is currently a significant need to extend this research to individuals with impairments. This project considered the most common respiratory impairments: asthma, rhinitis, and chronic obstructive pulmonary disease

Recent events increase the likelihood that much greater utilization of respiratory personal protection will be necessary for several reasons: (1) The threat of bio-terrorism in community settings; (2) Possibility of nuclear or chemical threats; (3) The public perception that such risks are present and may be partially ameliorated by use of respirators (4) Risk of naturally occurring epidemics of respiratory transmitted infections (e.g.,H1N1, SARS) for which respiratory protection is utilized on a widespread basis.

Several policy decisions depend upon understanding the proper role of respirators: A fundamental strategic choice is whether to rely only upon "shelter in place" (limiting workers to "safe" areas within structures with HEPA filters and scrubbers in ventilation systems) or to use "personal protection" (respirators) to avoid such restriction. In addition, clear policies are necessary for delineating those persons who should not be permitted to work with respirators. Design considerations are also important because there is a need for a cheap, easy to tolerate, yet effective device.

Many studies have addressed the impact of use of personal protective equipment, particularly respirators, upon maximal exertion ability. However, such studies do not provide information directly applicable to the more moderate or sedentary work levels that are commonly practiced.

While the primary purpose of respirators is to protect the health of the individual user, they are also de facto important for allowing necessary work to continue. Therefore, the impact upon work productivity also warranted investigation.

SPECIFIC AIMS

As described in the initial application, the three primary aims were:

1. Determine the effects of respirator type loads upon mildly impaired individuals studied in a controlled laboratory setting.
2. Determine the nature and frequency of adverse performance effects of respirator use during activities similar to "real-life" work.
3. Identify personal factors, such as impairment category or anxiety, which predict subjective and objective effects.

Specific hypotheses that were specified a priori included:

1. Respirator type loads induce definable physiologic effects upon respiratory timing, peak pressure, and subjective tolerance even at low to moderate levels of exertion.
2. The effect of respirator loading depends upon health conditions.
3. In addition to physiologic impact, respiratory protective devices have significant subjective responses in several distinct domains.
4. Respirators affect work performance even at limited exertion levels.
5. Personal characteristics, such as trait anxiety, influences tolerance.
6. Incomplete compliance with proper utilization practice is common and is affected both by clinical condition and specific work task.
7. In comparison to full face mask respirators, N95 types are better tolerated but are dislodged more frequently.
8. Utilization of respiratory protection during simulated work tasks is intermittent.

METHODOLOGY

The project included both exercise laboratory and work simulation components. Much information derived from the work simulation studies, emphasized in this section. A series of eight simulated work tasks were selected to include both sedentary and moderate level exertion, some tasks involving arm motion above head level (to evaluate inadvertent mask dislodgment), and a range of concentration requirements (e.g., simulated driving vs. loading store shelves). Two types of respirators were compared—an elastomeric dual cartridge half face mask (HFM) and a filtering facepiece N95 without valves. They were selected because they are commonly used and are likely to be recommended if widespread respirator protection is necessary.

Since not using a respirator is frequently not a workplace or community option, emphasis was upon comparing respirator types to select the optimal respirator for each individual and to delineate design factors that favor one or another type. For example, the work of most health care and prison workers places them in situations occasionally requiring respiratory protection. However, a smaller protocol was also conducted which included both respirator types as well as a no-load condition.

For the in-laboratory studies, a cardiopulmonary exercise laboratory was adapted for respirator studies. This involved reprogramming of the commercially available exercise laboratory software, which does not provide accurate data in the presence of external dead space or resistive loading. In addition, respiratory inductive plethysmography was used for respiratory parameters (both ventilation and respiratory control timing) to allow collecting data during actual work performance. Routine physiologic methods, which typically involve attaching a sensing device to the mouth or nose, themselves produce significant artifact and would interfere with work performance. In addition, the project developed a multi-domain subjective rating scale to allow study participants to quickly describe their responses on multiple questions; this used a combination of text and cartoon figures and was implemented in a touchscreen system.

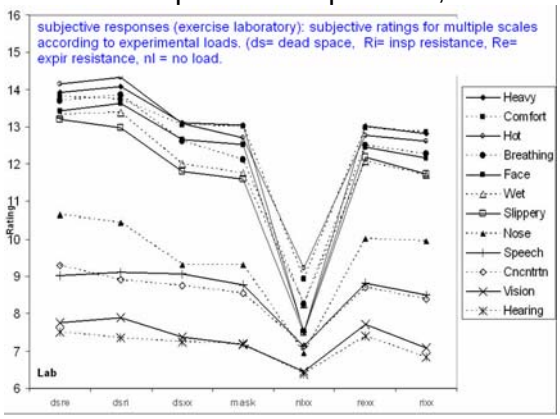
Physiologic Variables Evaluated During Simulated Work

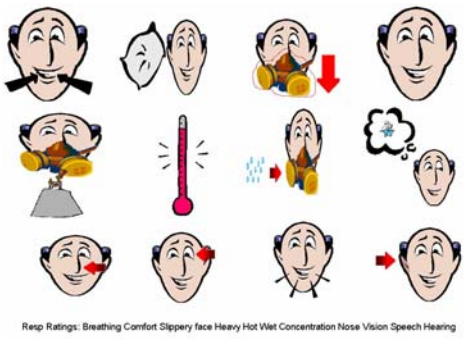
Vt	Inspiratory Tidal Volume	Tt	Total Breath Time
Ve	Minute Ventilation	Ti/Tt	Fractional Inspiratory Time
Fb	Respiratory Rate	Vt/Ti	Mean Inspiratory Flow
HR	Heart Rate	PifVt	Peak Inspiratory Flow

Ti	Inspiratory Time	PefVt	Peak Expiratory Flow of Vt
Te	Expiratory Time	PifTTi	Time to Reach Peak Inspiratory Flow
		PefTTe	Time to Reach Peak Expiratory Flow

RESULTS/DISCUSSION

Subjective Responses: Multiple domain response data were acquired throughout the study. A Borg type scale was employed with a touch screen input system to facilitate rapid input. In addition to text question format, cartoon figures helped prompt the users (see figure). As shown in the data figure, there appear to be three distinct categories of subjective effects. There were significant differences between the two respirator types; with the exception of temperature, the N95 produce less adverse effect.





Physiologic Characterization: A series of physiologic measurements were made during exercise laboratory and work simulation activities, including traditional ventilatory measures and respiratory pattern measures. During work simulation, the measurements were made unobtrusively (no mouth connection) with a respiratory inductive plethysmograph. Major variables are listed in the table below. Statistical results are summarized in the next table, which shows adjusted mean values by task and by respirator type. It also shows hypothesis tests for respirator type, task, and their interaction from the mixed model regression. Respiratory timing rather than ventilation showed the most consistent effects. Respiratory timing provides the user a method to adjust peak pressures and ventilatory work rates while maintaining overall ventilation. In addition it is sensitive to an individuals overall respiratory drive.

In addition, despite the much larger mask dead space volume, the HFM did not have greater ventilation, suggesting that due to air streaming within the mask, its dynamic dead space was not actually greater than the N95.

The table below summarizes effects upon key physiologic variables, which were defined in the methods section above.

Respirator and Task Effects During Simulated Work

Dependent	RespEffect Diff(HFM-N95)	Task Effect (adjusted means)								p Value		
Variable		bolt	carr	case	driv	lego	mags	magw	stor	Resp	Task	Interaction
Vt	0.02	0.77	1.02	1.21	0.72	0.80	0.76	0.91	1.12	ns	<.0001	Ns
Ve	0.14	18.18	29.22	30.32	15.76	19.08	17.51	25.22	31.28	ns	<.0001	Ns
Fb	0	26	33	31	23	26	25	31	33	ns	<.0001	Ns

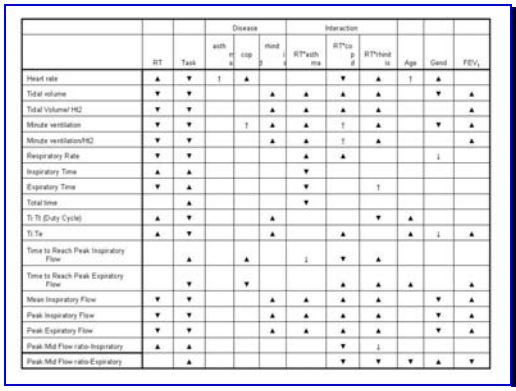
HR	0	80	94	88	80	80	82	88	96	ns	<.0001	Ns
Ti	0.04	1.17	1.01	1.10	1.22	1.17	1.21	1.06	1.02	<.0001	<.0001	Ns
Te	-0.05	1.57	1.18	1.31	1.71	1.53	1.56	1.28	1.16	0.0018	<.0001	Ns
Tt	-0.01	2.74	2.19	2.42	2.93	2.69	2.78	2.34	2.18	ns	<.0001	Ns
Ti/Tt	0.01	0.44	0.47	0.46	0.43	0.44	0.44	0.46	0.47	<.0001	<.0001	Ns
Vt_Ti	-0.02	0.69	1.06	1.12	0.61	0.72	0.66	0.91	1.14	ns	<.0001	Ns
PifVt	-0.03	1.19	1.83	2.08	1.00	1.26	1.15	1.58	1.99	ns	<.0001	Ns
PefVt	0.03	1.05	1.69	1.90	0.83	1.12	1.03	1.44	1.88	ns	<.0001	Ns
PifTTi	-0.20	51.13	50.17	50.77	49.03	50.63	50.76	50.26	50.11	ns	<.0001	Ns
PefTTe	0.40	45.44	48.52	47.20	43.10	46.53	45.21	47.66	48.47	ns	<.0001	Ns

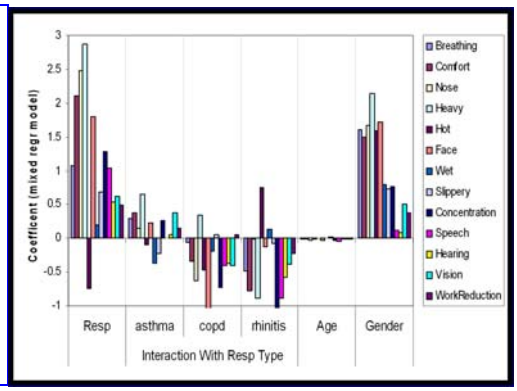
Effect of Personal Characteristics (e.g., Respiratory Health) on Subjective and Physiologic Responses:

To assess whether the type of mild respiratory disease affects respirator use, the study compared the respiratory physiologic and subjective effects of a dual cartridge half face mask respirator (HFM) to those of an N95 device. Subjects with mild COPD (n = 14), asthma (n=42), chronic rhinitis (n=17), and normal respiratory status (n=24) were studied. Mixed model regression analyses determined the effects of respirator type (comparing HFM to N95), disease status, and the interaction of respirator type and disease status.

Both category of disease and respirator type had significant effects upon several physiologic measures. The effects of the respirator type differed among the disease categories as shown by statistically significant interaction terms. Respiratory timing parameters were more affected than ventilatory volumes. In general, persons with asthma showed greater respirator-disease interactions than COPD, rhinitis, or normal subjects. This indicates that the effects of respirator type differ according to the category of respiratory disease. Persons with asthma may warrant particular concern if respirators are used.

The subjective responses for multiple domains were evaluated in 104 volunteers during simulated work using an HFM and a filtering facepiece (N95) respirator. Mixed model regression analyses determined the effects of respirator type, disease, gender, and age. HFM produced more adverse subjective response than the N95 for most scales. There were significant interactions, such that disease status modified the effect of respirator type. In general, women reported greater adverse ratings than did men, but the difference between respirator types was lower than in men. This suggests respirator designs should be evaluated using panels including persons with mild respiratory disease. The optimal respirator for a worker may depend upon health status.





Productivity Impact: The impact of respirator use upon work productivity was measured. For each of the tasks, two scales were employed- speed of performance and accuracy of performance. The scales measured different attributes, with correlation coefficients ranging from 0.06 - 0.79 within individuals. There were no statistically significant differences between respirator types in either task performance metric. The work showed that productivity impact can be measured effectively and should be considered as part of respirator design testing.

Anxiety: The State and Trait Anxiety Inventory (STAI) was administered to a group of subjects. Trait anxiety, a characteristic of the individual, was generally similar to normative reference values, suggesting that the subject population was not unusually anxious. Unlike trait anxiety, State Anxiety varies with conditions. In one protocol, State Anxiety was measured before donning the respirator and at the midpoint of task performance. The difference between these values represents the impact of the respirator use upon the individual. For the 14 subjects completing this particular protocol, with block randomized order of respirator type, there were statistically significant differences: The HFM respirator increased anxiety in comparison to the minimal effect of the N95 ($p < 0.05$). Further, the difference (HFM effect – N95 effect) within individuals was statistically significant. This suggests that the larger, more complex mask of the HFM respirator type may induce anxiety, which could potentially discourage use despite the greater protection factor provided.

Mask Movement (Video Analysis): Subjects were video recorded while performing the tasks using the respirator. Using a sampling frame, segments of each task performance were coded for a series of actions that might be related to mask dislodgment (e.g., mask movement, strap movement, touching respirator). In this study, subjects received only limited training about respirator use, but they were told not to move the mask. Results were analyzed according to task and respirator type. Very few mask dislodgments occurred with either respirator type; as shown in the figure, mask actions such as inadvertently moving it slightly ("adjustment") or more serious movements tended to occur in tasks when hand use was not constrained by the task itself (for example, while sorting bolts, both hands were busy). The data suggest that even with naive subjects, intentional mask movement is rare, but touching the mask is likely to occur during prolonged use. (Therefore, a measured protection factor immediately after donning the respirator may not accurately reflect the degree of protection during actual use; inadvertent mask movement may account for much of the difference between measured and workplace protection factors).

CONCLUSIONS

Relationship to Specific Aims and Hypotheses:

The research project successfully addressed its three specific aims. The work characterized the effects of two types of commonly used respirators. In addition, the project utilized respirator surrogate loads in the physiology laboratory, permitting testing the effect of each particular type of load independently. The study also showed work performance could be effectively measured. The interaction of personal factors (e.g., respiratory health status) with respirator type was also described. After preliminary testing and review of which respirators are likely to be used on a widespread basis, half-mask dual cartridge respirators were substituted for the full face mask respirators, which appeared unlikely to be widely used.

Several hypotheses had been specified a priori. As discussed in detail above, the respirator loads' impacts were shown. There is significant interaction between the respirator type and health status as determinants of pattern of adaptation. The significant multi-domain subjective response was described. Trait Anxiety, as a personal characteristic, was hypothesized to determine successful use of respirators; the study did not confirm this hypothesis. It did show that State Anxiety, which represents the current state, was affected differently by type of respirator used. In contrast to the a priori hypothesis that voluntary dislodging of the mask would depend upon the respirator mask type, the study found that the N95 and half mask types were comparable on these outcomes. As hypothesized, however, the N95 types were better tolerated subjectively. Finally, at least over the several hour duration of the studies, subjects were able to use the devices continuously rather than intermittently.

Overall conclusions:

The study led to the following general conclusions:

Respirator use is not limited by physiologic ventilatory limitation at the low-moderate exertion levels typical of most work. Instead, respirator tolerance, rather than physiologic limitation to ventilation (airflow), probably determines whether respirators can and will be properly utilized. Several components of respirator tolerance were investigated in this study: (a) Subjective effect in three distinct domains. These may be broadly classified as "comfort", "activity functional impact", and "indirectly/minimally affected". (b) Respiratory pattern adaptation: This set of parameters is not routinely measured in clinical settings, but it is likely to represent the most consistent effect of respirator use and is likely to be sensitive to differences in patterns among individuals. (c) Ventilatory mechanics (e.g., airway pressures, ventilation). (d) Mask dislodgment. (e) Anxiety. (f) Impact on work productivity.

The study also showed that individuals with mild respiratory impairments (mild-moderate COPD, asthma without current acute attack, chronic rhinitis) are able to tolerate both types of respirator use during simulated work activity. However, the nature of respiratory adaptation and the extent of subjective response differed according to respirator type.

These results therefore suggest that most individuals with mild respiratory disease can work using respirators. Medical evaluation, however, should consider the type of respiratory condition present. Furthermore, although in general the N95 filtering facepiece respirators were better tolerated than the dual cartridge half-mask devices, there may be significant inter-individual variability. The study also has potential implications for testing and certification of new respirator designs. Human panel testing, rather than reliance upon inanimate breathing machines, is probably advisable. Also, since the patterns of physiologic effects and subjective responses differed according to respiratory disease status, testing of new models should be conducted with a test panel representative of the range of potential users. Finally, impact on both anxiety and work productivity can be measured in standardized fashion; these aspects should be incorporated in assessing respirator designs.

There are, however, significant areas requiring additional research. The study was limited to relatively brief duration of respirator use, and longer-term use should be investigated in both laboratory and work simulation settings. Furthermore, the work considered only two types of respirators. While they were typical for their classes,

additional study with a filtering facepiece with exhalation valve and a dual cartridge half-mask respirator with lower resistance cartridges would be worthwhile. In addition, the controlled experimental designs should be complemented by field studies under actual use conditions. Finally, there is a need to examine how to most effectively convert a naïve user to one who tolerates the device well and has both motivation and knowledge to properly use it when necessary.

PUBLICATIONS

Research Publications

Harber P, Santiago S, Wu S, et al. Subjective Response to Respirator Type: Impact of Disease Status and Gender. (Accepted). 2009.

Harber P, Santiago S, Bansal S, Liu Y, Yun D, Wu S. Respirator Physiologic Impact in Persons with Mild Respiratory Disease. J Occup Environ Med. 2009 (in press).

Harber P, Bansal S, Santiago S, et al. Multidomain Subjective Response to Respirator Use During Simulated Work. J Occup Environ Med. 2009;51:38-45.

Bansal S, Harber P, Yun D, et al. Respirator physiological effects under simulated work conditions. J Occup Environ Hyg. 2009;6:221-227.

(Additional research publications are under review, in revision, or in process)

Presentations and Published Abstracts:

Harber P. Respirator Tolerance (research presentation). *National Personal Protective Technology Conference (CDC/NIOSH)*. Pittsburgh; 2009 (http://www.cdc.gov/niosh/npptl/resources/certpgmspt/meetings/032009/pdfs/presentations/13_PHarber.pdf)).

Harber P, Bansal S, Santiago S. Factors Affecting Respirator Tolerance. *Personal Protective Technology Program Stakeholders Meeting*. Pittsburgh, PA: NIOSH/ NPPTL; 2009.(http://www.cdc.gov/niosh/npptl/resources/certpgmspt/meetings/032009/pdfs/posters/inhalation.pdf)

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