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Respiratory Protective Devices: Rates of Medical Clearance and Causes for Work Restrictions

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Background *There are no published data on the outcomes and benefits of medical evaluations for the use of respiratory protective devices. We, therefore, conducted a retrospective database and chart review to assess the rates of medical clearance and causes for work restrictions at a Department of Energy complex.*

Methods *All workers with work restrictions or denied clearance over a one-year period were identified and their medical records abstracted.*

Results *Of the 5,569 workers who received medical evaluation, only 71 (1.3%) received limitations on respirator use documented in their medical record. Of the 65 workers with sufficient medical records for additional analysis, 9 of the 5,569 workers (0.2%) were denied medical clearance, while 56 workers (1.1%) received work restrictions. Pregnancy was the most common cause for denying medical clearance for respirator use. Lung disease, cardiovascular disease, and claustrophobia were the most common causes for work restrictions. Physical examination and spirometry added little to the detection of relevant medical conditions.*

Conclusions *We conclude that few workers fail medical clearance for respirator use or receive work restrictions. Data on adverse events from respirator use are needed to help design appropriate medical evaluations and uniform criteria for work restrictions or denial of medical clearance.* Am. J. Ind. Med. 35:390–394, 1999.

KEY WORDS: occupational medicine; respiratory protective devices; medical surveillance

INTRODUCTION

The United States Occupational Safety and Health Administration and the American National Standards Institute require that workers receive medical clearance prior to respirator use (ANSI, 1992; OSHA 29 CRF 1910.134). The outcomes and benefits of these evaluations have not been well studied. Medical evaluations currently range from self-administered questionnaires to physician interviews, physical examinations, spirometry, and exercise testing. Despite extensive work on the physiologic and psychologic effects of respirator use, there are few data on rates of medical clearance for respirator use following medical evaluations (Harber, 1984, 1988; Harber et al., 1996; Hodous, 1986; Louhevaara, 1984; Morgan, 1983; Raven et al., 1979). In addition, the physician-determined causes for work restrictions have not been well characterized in industrial settings.

OSHA has recently released its new respirator rule, which calls for a mandatory questionnaire to be provided to all workers required to wear respirators [OSHA 1910.134, January 8, 1998]. The questionnaire is used to help determine which workers may require more in-depth evaluation. Among other items, the questionnaire identifies workers

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who are current smokers, have history of cardiovascular disease, pulmonary disease, hypertension or symptoms of dyspnea, chest discomfort or wheezing as requiring additional medical evaluation. Based on the questionnaire, it is likely that large segments of the respirator-wearing population will require additional medical evaluation prior to receiving medical clearance for respirator use. Given the widespread use of respirators and the frequency of medical evaluations, we assessed the rates of medical clearance and causes for work restrictions at a large occupational health services contractor serving a United States Department of Energy (US DOE) complex.

METHODS

Following approval by the Human Subjects Committee at the University of Washington, a retrospective computerized database review was performed by the occupational medicine services contractor serving a US DOE complex. The total number of workers evaluated for respirator clearance between January 2, 1996 and December 31, 1996 was determined. All workers who received physician-imposed work restrictions for use of respirators or were denied respirator clearance were identified, and their medical records were abstracted, stripped of personal identifying information, and reviewed.

All workers at this facility routinely receive a medical survey, physician interview, review of medical history, physical examination, and spirometry for purposes of respirator qualification. Physicians performing the evaluations considered a broad range of medical conditions, environmental factors, types of respirators required, and levels of activity in making their determination of fitness for respirator use. The physicians had previously been provided with institutional guidelines for the evaluation of respirator users, describing commonly applied principles of assessment for respirator use. Physical examinations included vital signs, general appearance, and standardized examination of each organ system recorded by checklist. Abnormalities were further described with written comments. Physical examination was typically comprehensive as most individuals were enrolled in multiple occupational health surveillance programs; however, special consideration to examination of the cardiovascular system, eyes, respiratory system, skin, and musculoskeletal system was recommended as part of the respirator clearance examination. The guidelines suggested an FVC of less than 80% or an FEV_1 of less than 70% predicted as criteria requiring clinical correlation when assessing a worker for respirator use. The guidelines did not provide any specific clinical or spirometry criteria that would result in restriction for respirator use, leaving this determination to the evaluating physician. Spirometry was performed in accordance with American Thoracic Society criteria. Medical history, physical examination, and spirometry were reviewed and coded as normal or abnormal.

TABLE I. Demographic Data of 65 DOE Employees Denied or Restricted in Respirator Use During 1996

Age	
Mean (SD)	46 (8.4)
Range	22–66
Gender	
Male, n (%)	48 (74)
Female, n (%)	14 (21)
Missing	3 (5)
Race	
Caucasian, n (%)	53 (81)
African-American	5 (8)
Other	4 (6)
Missing	3 (5)
Respirator user, n (%)[a]	48 (74)
Current smoker, n (%)	14 (22)

[a]Affirmative response to ''Have you ever worn a respirator, either at work or recreationally such as SCUBA Diving?''

The contribution of medical history, physical examination, and spirometry towards physician decisions regarding work restriction or denial of medical clearance was determined by review of abstracted medical records by an occupational medicine physician (G.P.). If factors contributing to decisions about work restrictions or denial of clearance were not well defined, all reasonable factors recorded in the medical records were considered as contributing towards the physician's decision. Analysis was performed using SPSS for Windows Version 6.1. Preliminary results were shared with contractors, physicians, and workers' representatives.

RESULTS

Between January 2, 1996 and December 31, 1996, 5,569 workers at a US DOE complex were evaluated for medical evaluation for respirator clearance. Retrospective computerized database review by the occupational health services contractor and our review of abstracted medical records identified 71 workers (1.3%) as being denied respirator clearance or having work restrictions imposed by a physician regarding the use of respirators. Sufficient information was present in the abstracted records to determine the causes for work restrictions and denial of medical clearance in 65 of the 71 workers (92%); these workers were used for subsequent analysis. Demographic data on these 65 workers are presented in Table I; the causes for work restrictions and denial of medical clearance for respirator use are listed in Table II.

TABLE II. Reasons for Work Restrictions and Denial of Medical Clearance for Respirator Use Among 65 DOE Workers, 1996*

Cause for work restriction	Condition identified by history	Condition identified by examination	Abnormal spirometry
Claustrophobia	13	0	1
Lung disease			
Asthma	9	2	4
Emphysema	3	1	2[a]
Sarcoidosis	1	0	1
Cardiovascular disease			
Coronary artery disease	10	1	2
Cardiac arrhythmia or syncope	3	1	0
1st degree heart block	0	0	0
Facial skin conditions			
Pseudofolliculitis barbae	3	0	0
Contact allergy to respirator mask	1	1	0
Skin cancer	1	1	0
Previous facial surgery	1	1	0
Pregnancy	4	2	0
Hypertension	0	3	1
Musculoskeletal conditions			
Back pain	1	0	0
Neck/shoulder pain	2	1[a]	0
Gastrointestinal conditions			
Crohn's disease	1	0	0
Recurrent nausea	1	0	0
Neurological conditions			
Seizures	1	0	0
Headaches	1	0	0
Facial nerve pain	1	0	0
Diabetes mellitus on insulin	1	1	[a]
Perforated tympanic membrane	0	1	0
Recent urological surgery	1	[a]	[a]

*Individual workers may have had more than one reason for work restrictions.
[a]Incomplete data for one subject.

Nine workers (0.16%) were denied medical clearance for respirator use. The most frequent cause for denying medical clearance was pregnancy (n = 4). The remaining 5 were each denied medical clearance for the following reasons (one each): exertional chest pain, uncontrolled hypertension with blood pressure 230/110, atrial fibrillation, recent urological surgery, and refusal to complete physical examination. An additional fifty-six workers (1%) received work restrictions for respirator use. Several subjects received ECGs as part of other (non-respirator) medical surveillance programs at the DOE site. As this information was available to the physicians performing the respirator medical evaluations, it was included in the decision making process and resulted in one individual receiving a work restriction due to first degree AV block.

Medical evaluation components of history, physical examination, and spirometry were evaluated by an occupational medicine physician to determine their respective contributions towards physician decisions regarding work restrictions or denial of medical clearance. For each medical condition, the contribution of medical history, physical examination, and the presence of spirometric abnormalities is listed in Table II. Of the 65 workers who received work restrictions or denial of clearance, medical history contributed to the physician's decision in 58 workers (89%). Physical examination revealed findings leading to restrictions in 16 workers (25%), and was the sole reason for work restriction or denial of clearance for 3 workers (5%). The reasons for work restrictions based on physical examination alone included uncontrolled hypertension (n = 2) and perforated tympanic membrane (n = 1). Abnormal spirometry contributed towards decisions for work restrictions in 11 workers (17%), and was the sole cause for imposing work restrictions in 5 workers (8%). Using the entire cohort as the denominator (n = 5,569), medical history, physical examination, and spirometry contributed to physician imposed work restrictions or denial of medical clearance in 1, 0.3, and 0.2%, respectively.

Current cigarette smoking is listed in the new OSHA respirator questionnaire as a criterion for additional evaluation. Fourteen (22%) of the workers who received restrictions on respirator use were current smokers. Of these 14 workers, restrictions were imposed due to obstructive lung disease in 4, hypertension in 2, and coronary artery disease in 1, and first degree heart block in 1. The remainder of the conditions were not directly attributable to cigarette smoking (pregnancy, musculoskeletal pain, Crohn's disease, claustrophobia, syncope). The prevalence of smoking in the entire year's cohort of respirator users is unknown; however, analysis of a sub-cohort of 413 workers presenting for respirator medical evaluation over a one-month period of time found the prevalence of current smokers to be 23% (Pappas et al., 1999).

DISCUSSION

Our retrospective review of 5,569 medical evaluations performed for respirator clearance found rates of work restriction or denial of medical clearance to be very low in this population of employees facing radiation, physical, and chemical hazards at a large US DOE complex. These evaluations included all of the respirator clearance examinations performed by the occupational medicine contractor in 1996 for all classes of workers, including environmental and laboratory technicians, facility operators, engineers, scientists, and laborers. Only 1.3% of workers were found to have conditions that restricted their use of respiratory protective

devices. The most common single cause for work restriction was claustrophobia (0.2% of workers). Lung disease, heart disease, and facial skin conditions were also frequently reported as causes for work restrictions.

Medical history was the factor that most commonly influenced physicians' decisions to impose work restrictions or deny clearance. Physical examination and spirometry had limited incremental benefit above medical history for suggesting conditions resulting which resulted in work restrictions. Only 8 workers (0.1%) received restrictions on the use of respiratory protective devices based on physical examination or spirometry findings, independent of medical history. This finding suggests that a carefully constructed questionnaire may be a useful instrument for identifying workers who may be at increased risk for adverse events related to respirator use. The recently released OSHA respirator questionnaire may prove effective in this regard; however, validation of this questionnaire is needed.

Medical evaluations for respirator clearance are designed to protect the health of workers. However, there are limited data on the type and frequency of adverse events related to respirator use in the workplace. We have recently shown that many workers with chronic medical conditions are cleared for respirator use and our current questionnaire has good sensitivity to identify workers who cannot be cleared for respirator use without restrictions (Pappas et al., 1999). Many workers who are cleared have impairments or health conditions similar to those who fail respirator clearance or receive work restrictions. Without data on adverse events related to respirator use, it is difficult to assess the value of medical clearance examinations, appropriate examination content, or criteria for work restrictions. Nonetheless, the very low rates of work restrictions or denial of respirator clearance suggest that adverse events associated with respirator use are uncommon. Understanding of the spectrum of adverse events caused by respirator use and risk factors for those events is necessary to design medical evaluations that protect worker health and safety without wasting time and resources.

Four workers were excluded from respirator use due to pregnancy. It is the practice of the physicians at the US DOE facility studied to exclude pregnant workers from respirator use to protect the mother and developing child from potentially harmful environments. The exclusion is not based on concern for adverse effects of the respirator itself. The new OSHA 1910.134 regulation does not ask about pregnancy in its mandatory questionnaire. At present, there are no good data on respirator use in pregnancy. In the absence of data, it seems prudent to base decisions on respirator use in pregnancy on: 1) the risks of the environment to the mother and the developing child, remembering that protective equipment may fail, 2) and the capability of the mother to tolerate the protective equipment required.

There are several limitations to this study. Chart review may not have identified important components of the medical evaluation, such as assessment of workplace risks or severity of impairments. In addition, physicians may not have provided chart documentation of all the information used in their decision-making processes. Physician decisions may reflect an assessment of overall fitness for duty as opposed to simply medical clearance for respirator use, despite the stated purpose of the evaluation. Second, some of the data were collected while a questionnaire on medical clearance was being tested during a one-month period. This may have biased physician results; however, it is likely that the bias would have resulted in favor of worker health and safety and resulted in additional work restrictions. Third, identification of workers was dependent on a computerized database search in which only workers with physician-designated work restrictions for respirator use were recognized. There may be workers who have conditions resulting in restrictions on respirator use who were not identified by physicians as having restrictions for respirator use. For this reason, the rates and proportions provide only estimates, and may underestimate the true rates. Finally, these results reflect the outcomes from a single workforce and medical clearance protocol, and may not be generalizable to all other cohorts. However, the site tested represents a large and diverse group of workers and the medical evaluation protocol is one that is commonly applied.

We conclude that few workers fail medical clearance for respirator use or receive work restrictions. The paucity of restrictions, lack of consistency in application of criteria, and limited incremental benefit from physical examination and spirometry lend support to the recently revised OSHA Respiratory Protection Standard offering the use of questionnaires as a means of identifying workers who may benefit from additional medical evaluation. However, the clinical effectiveness and cost-effectiveness of the new OSHA questionnaire have yet to be determined. Given the broad spectrum of the mandatory questions of the new OSHA questionnaire, it is likely that many of the workers who are identified by the questionnaire as requiring additional evaluation will not receive restrictions on respirator use. In our cohort of respirator users, 23% of workers (approximately 1300) would have been sent for additional evaluation on the basis of current cigarette smoking alone; the number of workers subsequently receiving restrictions for smoking related conditions was only 8.

Questionnaire-based respirator clearance evaluations must be linked to post-placement evaluation of workers who have difficulties with respirator use. However, we believe emergency response personnel, workers with high exertional demands, and workers requiring the use of self-contained breathing apparatus may represent groups who require more

detailed evaluation than can be provided by a questionnaire alone. The high rate of medical clearance and very low rate of restrictions argues for research and reappraisal of in-depth medical evaluations for respirator clearance. Research on adverse events related to respirator use is needed to establish protocols for respirator clearance that protect worker health and safety, while utilizing valuable resources in an efficient and effective manner.

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