Evaluation of Spirometry for Medical Clearance in Occupations Requiring Respirator Usage

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Abstract

Medical certification of workers for respirator use is an important activity of occupational medicine health professionals. Spirometry is a diagnostic tool to evaluate respiratory distress/insufficiency that may affect respirator use. The pulmonary function data of 337 subjects from different occupations that required medical evaluation to wear a respirator were analyzed to determine the effect of using various spirometric equations on respirator fitness outcomes. Of 337 subjects who were cleared for respiratory use by medical questionnaires for respirator compliance, 14 (4.15%) failed to pass respirator compliance by NFPA criteria and 5 (1.48%) failed to pass respirator compliance measures by ATS criteria. We compared the use of different spirometric equations to evaluate these measures, and it was determined that the Crapo equation cleared more workers for respirator use as compared to the Knudson and NHANES III equations. As some workers were able to qualify for respirator use based on questionnaire alone but failed respirator clearance after pulmonary function testing, it is recommended that spirometry is used to evaluate clearance for all workers who will use a respirator in the workplace. As well, using different spirometric equations can affect the outcome on passing or failing clearance for respirator use, and this should be considered in a respiratory medical certification program.

1. Introduction

According to the Occupational Safety & Health Administration (OSHA), approximately 2.6 million workers use respirators either occasionally or frequently to protect their health in the workplace [1]. Respiratory protection is a last line

of control measure and is widely used by industries to reduce the risk of airborne chemical exposure [2]. OSHA allows the use of respirators in the workplace when implementations of other control measures are not efficient and pragmatic. To protect workers' health and provide proper guidance regarding respirator use, OSHA requires a respirator protection program in the workplace. In 1998, OSHA revised the criteria for respiratory protection for general industry, shipyards, construction, and maritime industries under 29 CFR 1910 & 1926 [3]. According to these standards, employers are required to establish a written respiratory protection program when the use of a respirator is mandatory to protect the health of employees in the workplace. It also allows the voluntary use of respirators to prevent exposure to hazardous airborne contaminants. The goals of the respiratory protection program are to provide information on selecting respirators for specific work conditions, a medical evaluation of the workers who are using respirators, and training and maintenance for the respirators used in the workplace [4]. Medical evaluation and certification before respirator use in the workplace is a critical component of the respiratory protection program.

Using respirators in the workplace may induce various physiological and psychological effects on workers [5]. The most common physiological effects from using respirators are cardiopulmonary related [6] [7]. Other effects of using respirators are discomfort, extra weight and ergonomic concerns, psychological and social consequences, dermatological problems, and visual impairments [5] [8]. The physiological effects of respirator use are described in Table 1 [9]-[20]. The purpose of a medical evaluation for respirator certification is to determine employees' ability to wear a respirator before fit testing [21]. Spirometry outcomes provide valuable diagnostic information regarding pulmonary function that may lead to a determination of respirator fitness.

There are, however, some areas of uncertainty regarding the interpretation of spirometry outcomes. Different reference values/equations are available for interpretation of spirometry results. Several regulatory agencies and academic institutions recommended the National Health and Nutritional Survey III (NHANES III) reference equation as this equation included Caucasian, African American, and Hispanic populations to develop reference values, compared to other reference values that are based solely on Caucasian, non-smoking, healthy subjects.

Table 1. Health effects of using respirators [9]-[20].

Respiratory Effects	• Increased dead space volumes • Increases airway resistance
Cardiovascular Effects	• Increased intrathoracic pressure • Reduces cardiac output
Other Ill-Health Effects	• Heat stress • Dehydration • Vision and hearing impairment • Claustrophobia • Ergonomic health issues • Dermatological effects

As well, there are varying medical criteria that suggest a particular level of pulmonary function will allow a worker to safely use a respirator in the workplace. The American Thoracic Society recommends that employees with >FEV1 of 60% of predicted value be allowed to wear a respirator [22]; National Fire Protection Agency (NFPA-1582) suggests that any firefighter with FVC or FEV1 < 70% prevents the safe use of SCBA respirators [23] [24].

The most commonly used and recommended reference values are based on the National Health and Nutrition Examination Survey III (NHANES III) derived by Hankinson *et al.* 1999. However, spirometric reference equations derived by Crapo *et al.* (Crapo), Knudson *et al.* (Knudson) and Morris *et al.* (Morris) are also currently used in the contemporary interpretation of spirometry outcomes [24] [25] [26] [27].

The purpose of the current study is to evaluate the use of spirometry as a screening tool for pulmonary fitness for respirator usage in the workplace. As well, we evaluate the impact of using different spirometric equations as well as different clearance thresholds of pulmonary function test outcomes on certification of respirator fitness. This study advances the application of spirometry for respirator clearance and demonstrates the impact of criteria selection when performing occupational pulmonary function testing.

2. Methods

2.1. Subject Selection

This study selected subjects who underwent pulmonary function testing for respirator fitness certification in the boat manufacturing industry, emergency responders, and utility workers in the state of the Florida. Selection of study participants was based on the following criteria:

1) He or she is working in either of the above occupational sectors.

2) Age at or above 18 years.

3) Used a regular respirator in the workplace.

4) Repeatedly conducted spirometry for medical clearance to wear a respirator.

A record review was performed on pulmonary function tests from a population currently employed in above occupation sectors. Of these, 337 workers were identified based on the inclusion criteria. This study was approved by the University of South Florida, Institutional Review Board (IRB) # 00001348.

2.2. Statistical Analyses

Kappa Statistics (κ) were used to measure agreement between spirometric results derived from NHANES III, Crapo, and Knudson in meeting the spirometric criteria of the American Thoracic Society and National Fire Protection Association for medical certification for respirator clearance. The Kappa statistic is defined as an interobservation agreement [28]. Kappa statistics are anticipated to provide the reader a quantitative evaluation of the magnitude of agreement between

observations [29]. Kappa statistics are based on the difference between "observed" agreements to chance agreements ("Expected" agreements) [29] [30]. Kappa statistics for categorical data were interpreted by guidelines suggested by Landis *et al.* 1977 [31]. The Generalized McNemar's test was used to measure the presence of bias. A p value of <0.05 for the hypothesis (H0: $\kappa = 0$) was considered to be significant.

Interclass correlation coefficients (ICC) are used to evaluate interrater reliability for continuous data. ICC is the assessment of the correlation between two measurements made on the same worker. ICC provides an evaluation of reliability, but many forms of ICC exist, and each is appropriate under limited conditions [32] [33] [34] [35] [36]. In this study ICC was calculated for pulmonary function outcomes such as Forced Expiratory Volume in First Second (FEV1), Forced Vital Capacity (FVC) and the FEV1/FVC ratio derived from the different reference equations Knudson (1983), Crapo (1981) and NHANES III [25] [26]. The potentially confounding factors age, gender, smoking history, weight, and height are included in the statistical analysis.

All statistical analyzes were conducted using SAS 9.4 software package.

3. Results

The demographics of the study population are described in Table 2. The study

Table 2. Study population demographics.

Total Number	337	100%
Gender		
Male	296	87.83%
Female	41	12.16%
Smoking History		
Yes	120	35.61%
No	217	64.39%
Race		
Caucasian	282	83.68%
African-American	24	7.12%
Hispanic	31	9.20%
Occupations		
Boat Manufacturing	122	36.20%
First Responders	129	38.28%
Utility Workers	86	25.52%
Age		
≤54 years old	307	91.10%
≥55 years old	30	8.90%

population was primarily male (approximately 87%), mainly Caucasian (approximately 83%) and about 35% had a smoking history. The average age of the study population is 40 years, and the average height of the population is 69 inches.

3.1. National Fire Protection Association (NFPA) Criteria

This study used the NFPA spirometry criteria (FEV1 or FVC ≥ 70) for screening fitness to wear respirators in the workplace. Table 3 and Table 4 indicate the summary of subjects who met the spirometry criteria stratified by spirometric reference equations. A small number of subjects with FEV1 (14, 4.15%) and FVC (9, 2.67%) were not able to pass the spirometry screening criteria despite having passed the OSHA recommended questionnaire.

3.2. American Thoracic Society Criteria

This study also applied the criteria (FEV1 ≥ 60) recommended by the American Thoracic Society for screening purposes to wear respirators. A small percentage of the subjects who had been cleared by the OSHA approved questionnaire failed to pass the selection criteria to wear respirators. Table 5 presents the number of subjects who failed to meet standards recommended by the ATS.

Table 3. Number of workers who met the national fire protection association (FEV1) criteria to wear respirators.

FEV1 ≥ 70 (Total Number = 337)		
	Pass	Fail
NHANES III (1999)	323 (95.84%)	14 (4.15%)
Crapo *et al.* 1981	318 (94.36%)	19 (5.63%)
Knudson *et al.* 1983	322 (95.54%)	15 (4.45%)

Table 4. Number of workers who met the national fire protection association (FVC) criteria to wear respirators.

FVC ≥ 70 (Total Number = 337)		
	Pass	Fail
NHANES III (1999)	328 (97.32%)	9 (2.67%)
Crapo *et al.* 1981	325 (96.43%)	12 (3.5%)
Knudson *et al.* 1983	330 (97.92%)	7 (2.07%)

Table 5. Number of workers who met the American thoracic criteria to wear respirators.

FEV1 ≥ 60 (Total Number = 337)		
	Pass	Fail
NHANES III (1999)	332 (98.51%)	5 (1.48%)
Crapo *et al.* 1981	330 (97.92%)	7 (2.07%)
Knudson *et al.* 1983	331 (98.21%)	6 (1.78%)

Figure 1 outlines the comparison of different spirometric criteria used to certify "suitable to wear a respirator" in various occupations.

3.3. Agreement between NHANES III and Crapo Reference Equations

This study analyzed 337 subjects using the NHANES III and the Crapo reference equations [24] [26]. For comparing the various compliance criteria, the level of agreement between the NHANES III reference standard with the Crapo reference standard is varied from good (κ = 0.76) to very good (κ = 0.85) as shown in Table 6.

3.4. Agreement between the NHANES III and the Knudson Reference Standards

To compare the spirometry compliance criteria, the study analyzed the 337 workers using the NHANES III and the Knudson reference equations [24] [25]. For comparing the various compliance criteria, the level of agreement between the NHANES III reference standard and the Knudson reference standard is very good (κ = 0.83 to 0.96) as shown in Table 7.

3.5. Interclass Correlation Coefficient

In this study, interpretation of lung function of workers using different spirometry reference standards was utilized. An ICC was calculated for these different reference standards for the assessment of lung functions and interclass correlation coefficient are shown in Table 8.
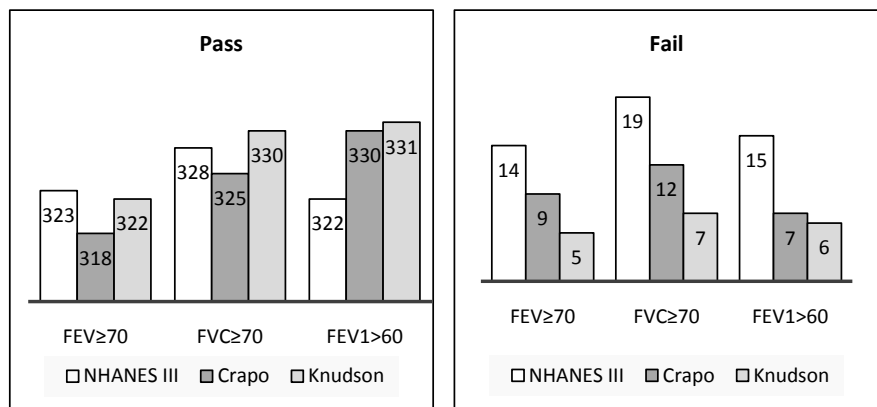

Figure 1. Comparison of different spirometric criteria to wear respirators.

Table 6. Agreement between the NHANES III and the crapo standards for the respirator screening criteria.

Compliance Criteria	Kappa Statistics*	Generalized McNemar's Test	p-Value
NFPA Criteria (FEV1 < 70)	0.8409 (0.7042 - 0.9775)	p = 0.0253	P < 0.001
NFPA Criteria (FVC < 70)	0.8526 (0.6885 - 1.00)	p = 0.0833	P < 0.001
ATS Criteria (FEV1 > 60)	0.8304 (0.5994 - 1.00)	p = 0.1533	P < 0.001

Table 7. Agreement between the NHANES III and the Knudson reference standards for the respirator screening criteria.

Compliance Criteria	Kappa Statistics	Generalized McNemar's Test	p-value
NFPA Criteria (FEV1 < 70)	0.96 (0.89 - 1.00)	p = 0.3173	p < 0.001
NFPA Criteria (FVC < 70)	0.87 (0.69 - 1.00)	p = 0.1573	p < 0.001
ATS Criteria (FEV1 > 60)	0.90 (0.72 - 1.00)	p = 0.3173	p < 0.001

Table 8. Interclass correlation coefficients (ICC) for different reference standards (NHANES III vs. Knudson vs. Crapo reference standards).

Lung Functions	Interclass Correlation Coefficient (ICC)
FEV1	0.27783
FVC	0.87452
FEV1/FVC Ratio	0.80436

4. Discussion

This study evaluates the use of spirometry as a screening tool in addition to the OSHA recommended questionnaire for clearance to wear respirators in the workplace. A small percentage of workers (4.15%, 2.67% and 1.48%) failed the spirometry criteria to wear a respirator provided by NFPA (FEV1 and FVC) and ATS (FEV1), respectively. These subjects had passed the OSHA recommended questionnaire, indicating that the OSHA recommended questionnaire did not identify a small percentage of subjects who may not be healthy enough to wear a respirator.

Though OSHA allows the use of a questionnaire for respiratory protection program compliance, physical examination and screening tools such as spirometry help to identify workers who are at risk for cardiopulmonary stress as well as mortality, currently, there are no broadly standardized regulations available for spirometry criteria nor is there a requirement for the inclusion of screening with spirometry in a respiratory protection program. Other factors, such as a type of respirator use, work conditions and heat, and other stressors while screening for respirator use should be considered.

The American Thoracic Society/European Respiratory Society in 2005 recommended use of the NHANES III reference standards to diagnose occupational lung diseases in the United States, although it suggested that other reference standards may be utilized if there are valid reasons for the choice of these standards [27]. Alternative respiratory reference standards are used in certain mandatory conditions such as the requirement to use the Knudson 1976 standard in the cotton industry. The contemporary use of older spirometry reference standards could potentially impact the interpretation of pulmonary function tests for diagnosis and respiratory clearance.

However, the kappa statistics for the NFPA compliance criteria is very good between the NHANES III and the Crapo standards while ATS criteria have kap-

pa statistics in the range of good agreement between the NHANESIII and the Crapo standards. The agreement between these two measures is higher because they are used for screening purposes of wearing a respirator as compared to diagnostic purposes. These results suggest that using either of the reference standards does not largely affect the outcome of the spirometry screening for respirator protection use. The results of this study indicate that decreasing the spirometric criteria to wear a respirator causes more discordance between the two reference standards. Similarly, the kappa statistics for the NFPA compliance criteria and the ATS criteria is very good for the NHANES III and the Knudson standards. This agreement suggests that using the Knudson equation for respiratory compliance measures did not have substantial impact on passing the tests. Interclass correlation coefficients, as discussed above, are the relative measurement of the reliability of the research data. It is a ratio of variance derived from ANOVA [37] [38]. It is unitless and theoretically it is more similar to a R2 from regression models as compared to a Pearson coefficient (*r*) [39]. The ICC can theoretically range from 0 to 1, where 0 shows no reliability, whereas 1.0 suggests perfect reliability [38]. The ICC can extend beyond the ranges of 0 to 1.0, but it is uncommon [40].

The ICC for interpretation of FEV1 between the three reference standards is 0.27; this suggests that there may not be significant repeatability for the analysis of FEV1 outcomes. However, the ICC for FVC was 0.87, suggesting good reproducibility between these standards. For the FEV1/FVC ratio, the ICC is 0.80, suggesting that there is good reproducibility between these standards for the interpretation of lung function. It clearly indicated that assessment of pulmonary function using different reference standards may affect the outcome of occupational lung disease diagnosis.

The major limitation of this study is that investigators did not have access to medical data for the subjects to establish pulmonary diseases among those workers who produced lower pulmonary function outcomes. Future studies should consider the impact of using different reference equations on diagnostic accuracy.

5. Conclusion

The results of this study suggest that the use of spirometry as a screening tool is necessary to identify workers who may be unfit to wear a respirator, but have passed the OSHA questionnaire. While overall, there is a good agreement among various pulmonary function reference sets in establishing clearance to wear respirators, which are subtle differences, particularly for the FEV1 outcome. It is recommended that the NHANES III reference set be used when possible due the larger and more diverse reference population.

Acknowledgements

tion test records used in this study.

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