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Evaluation of Pulmonary Risks Associated with Selected Occupations

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Evaluation of Pulmonary Risks Associated with Selected Occupations

by

Stephen Casey Harbison

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
Department of Environmental and Occupational Health
College of Public Health
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Dedication

This is dedicated to my father who always encouraged me to do my best, my mother who always believed in me, and my wife who loves me unconditionally.

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List of Acronyms

American College of Chest Physicians	ACCP
Bureau of Environmental Public Health Medicine	EPHM
Centers for Disease Control and Prevention	CDC
Center for the Health Assessment of Mothers and Children of Salinas	CHAMACOS
Chronic Obstructive Pulmonary Disease	COPD
Clinical Antipsychotic Trials of Intervention Effectiveness	CATIE
Coal Workers' Pneumoconiosis	CWP
Community Programs for Clinical Research on AIDS	CPCRA
Council of State and Territorial Epidemiologist	CSTE
Enhanced Coal Workers' Health Surveillance Program	ECWHSP
Epidemiology of Diabetes Interventions and Complications	EDIC
Expiratory Reserve Volume	ERV
Forced Expiratory Flow at 25%-75% Vital Capacity	FEF ₂₅₋₇₅
Forced Expiratory Volume at 1 Second	FEV1
Forced Vital Capacity	FVC
Heart and Estrogen/Progestin Replacement Study	HERS
Inspiratory Capacity	IC
Inspiratory Reserve Volume	IRV
Institutional Review Board	IRB
Maximum Expiratory Flow	MEF
Maximum Voluntary Ventilation	MVV

National Health and Nutrition Examination Survey	NHANES
National Institute for Occupational Safety and Health	NIOSH
Nitrogen Oxide	NO
Nitrogen Dioxide	NO ₂
Occupational Safety and Health Administration	OSHA
Peak Expiratory Flow Rate	PEFR
Polychlorinated Biphenyl	PCB
Progressive Massive Fibrosis	PMF
Pulmonary Arterial Hypertension	PAH
Registry to Evaluate Early and Long-term PAH Disease Management	REVEAL
Slow Vital Capacity	SVC
Sulfur Dioxide	SO ₂
United States Environmental Protection Agency	USEPA
Vital Capacity	VC

Abstract

Occupational health surveillance programs are designed to evaluate and reduce injury, illness, and deaths related to workplace hazards. In the state of Florida, there are numerous industries where workers are potentially exposed to airborne hazards from gases, vapors and dusts. Airborne occupational exposures to irritants, vesicants, and fibrogens have the potential to cause pulmonary function impairment if exposures are not properly controlled for high-level acute exposure as well as chronic exposure. For occupations that demand workers be exposed to substances known to be associated with pulmonary function impairment, respirators may be a principal method for exposure control. OSHA requires pulmonary function testing for specific substances and it is a best practice that is utilized in a majority of occupational settings and is typically included in an organizations respiratory protection program. A literature review identified that boat manufacturing, utilities, and first responders in the State of Florida have the potential for increased pulmonary impairment amongst workers. This research demonstrated the feasibility of using pulmonary function data collected for the purposes of compliance and/or best practices for workers who use respiratory protection because they are potentially exposed to pulmonary toxicants in the workplace. This research did not identify any pulmonary function deficits in the target occupational populations and it demonstrated that in most cases, the study populations had modestly superior pulmonary function compared to a baseline population.

Chapter 1

Introduction

Occupational health surveillance programs are designed to evaluate and reduce injury, illness, and deaths related to workplace hazards. Since potential adverse health effects may not present for many years, it is imperative that surveillance tools be developed and utilized to identify potential hazards in the workplace before they cause substantial and potentially irreversible health outcomes. Proven methods and procedures used to capture critical occupational health data is the basis for an effective surveillance program. Ali (2008) states:

Workers' health surveillance entails procedures for the assessment of workers' health by means of detection and identification of any abnormalities. Such procedures may include biological monitoring, medical examinations, questionnaires, radiological examinations and reviews of workers' health records, among others.

The National Institute for Occupational Safety and Health (NIOSH) has recognized the importance for in-depth investigations and prevention aimed at particular diseases, injuries, hazards, and specific worker populations. Occupational health surveillance has been a priority at NIOSH since its inception by the Occupational Safety and Health Act in 1970. Since that time, NIOSH has been able to identify areas that need

additional research and prevention efforts for both existing and new problems alike. NIOSH (2012a) has established that data and information derived from surveillance can be used to:

- Guide immediate action for cases of public health importance
- Measure the burden of an injury or disease including changes in related factors, the identification of populations at high risk, and the identification of new or emerging health concerns
- Guide the planning, implementation, and evaluation of programs to prevent and control injuries, disease, or adverse exposures
- Evaluate public policy
- Detect changes in health practices and the effects of the changes
- Prioritize the allocation of health resources
- Describe the clinical course of disease
- Provide a basis for epidemiologic research

While NIOSH has made significant progress in helping reduce work-related diseases and injuries, occupational health surveillance in the United States is not consistent and data gaps exist. Baker et al. (1988) recognized such deficiencies and stated:

Unfortunately, in the minds of many occupational health professionals, surveillance systems are viewed as passive and ponderous systems designed to collect information of uncertain utility. To achieve a broader involvement of occupational health professionals in surveillance of occupational disorders,

systems must be developed that are intrinsically active and allow for rapid response to emerging trends of illness and injury.

This recognition by NIOSH and other public health professionals has led to the development and continued funding of state-based occupational safety and health surveillance programs. These state-based surveillance programs use existing reporting systems to collect data on occupational safety and health hazards and effects; identify new sources of data; conduct surveillance; interpret findings; and develop and/or recommend interventions (NIOSH, 2012b). Currently, NIOSH is providing financial and technical assistance for twenty-three state-based surveillance programs. These states include California, Colorado, Connecticut, Florida, Georgia, Illinois, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, New York State, North Carolina, Oregon, Texas, Washington, and Wisconsin.

Part of the strategic plan for NIOSH includes the development and expansion of mechanisms for occupational health surveillance on both the state and federal levels (NIOSH, 2012c). It is clear that there is a continued need to develop and utilize surveillance methodologies that are capable of efficiently evaluating occupational populations for health status, identifying changes in health status over time, and comparing the health status of occupational populations to baseline populations. The use of existing health data to quickly evaluate the health status of a population provides efficiency in both cost and time by limiting the need to perform prospective data collection on a population of interest.

Florida is one of the twenty-three states receiving financial and technical assistance from NIOSH for a state-based occupational safety and health surveillance program. The ultimate goal of the program is to continually improve the overall health of the workforce in the state. A preliminary description of the NIOSH state-based surveillance program for Florida is as follows (NIOSH, 2012b):

The Florida Department of Health, Division of Environmental Health, Bureau of Environmental Public Health Medicine (EPHM) will develop and implement a Fundamental State-Based Occupational Safety and Health Surveillance Program by collecting and analyzing various data sets including data from the Bureau of Labor Statistics and Surveys, Florida hospital discharge, ambulatory and emergency departments, vital statistics death file, Florida Cancer Registry, census information and other data sources in order to produce and disseminate information on the Centers for Disease Control and Prevention (CDC)/Council of State and Territorial Epidemiologists (CSTE) occupational health indicators relevant to Florida. Additionally, EPHM will work collaboratively with numerous partners including universities, local, state, and federal agencies to identify new data sources to enhance ongoing surveillance activities. EPHM plans to use these data sources to gain a better understanding of the health impact of occupational exposures and injuries in Florida. EPHM will compare Florida's experience with statistics from other states in order to develop a better overall view of Florida's experience compared to the nation. Florida also plans to convene an Occupational Health Surveillance Program Advisory Board. This group will have representatives from clinical medicine, public health,

academia, and industry in Florida and will serve to guide the program in its efforts and help to prioritize surveillance efforts, disseminate findings and participate in research and prevention activities. EPHM plans to form a collaborative partnership with the University of South Florida's OSHA Training Institute Education Center to identify occupations and industries that would benefit from more in-depth surveys and investigations designed to identify interventions that reduce workplace morbidity.

In the state of Florida, there are numerous industries where workers are potentially exposed to airborne hazards from gases, vapors, and dusts. Airborne occupational exposures to irritants, vesicants, and fibrogens have the potential to cause pulmonary function impairment if exposures are not properly controlled for high-level acute exposure as well as extended periods of time.

For occupations that demand workers be exposed to substances known to be associated with pulmonary function impairment, respirators may be a principal method for exposure control. Therefore, governmental standards have been established to ensure the protection of workers when the elimination of the airborne hazard cannot be removed and engineering controls are not possible. Occupational Safety and Health Administration (OSHA) Respirator Protection Standard 1910.134 (OSHA, 2012a) states:

In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures

(for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.

When respirators are required to be used in the workplace, it is universally recognized that a respiratory protection program be established. The safe use of a respirator requires at a minimum that the following program elements be addressed (Colton & Nelson, 2003):

- Program administration
- Written work site specific operating procedures
- Exposure assessment
- Medical evaluation of respirator wearers
- Proper selection of respiratory protective equipment
- Training
- Respirator fitting
- Cleaning, inspection, maintenance, and storage
- Program evaluation

As stated above, a medical evaluation of respirator wearers is a required element of a respiratory protection program. To comply with this requirement, employees may be required to undergo pulmonary function testing to determine if they are able to safely wear a respirator. It is important to note that the respiratory protection standard only requires a physician to establish the necessary health and physical conditions for a worker

to be able to perform their assigned job functions while wearing a respirator. It does not make it mandatory to administer a particular evaluation procedure, such as a pulmonary function test unless it is required in the provisions of specific OSHA standards.

OSHA substance specific standards such as Asbestos (1910.1001), Cadmium (1910.1027), Coke Oven Emissions (1910.1029), Cotton Dust (1910.1043), Benzene (1910.1028), and Formaldehyde (1910.1048) require pulmonary function tests as part of the medical evaluation and are to include forced vital capacity (FVC) and forced expiratory volume at one second (FEV1). Some of these substance specific standards have detailed sections that present pulmonary function testing requirements while other specific standards include pulmonary function testing as part of the medical surveillance requirements. For example, the pulmonary function standard for Cotton Dust (1910.1043) includes sections regarding the apparatus, the technique for measurement of forced vital capacity maneuver, the interpretation of the spirogram, and the qualifications of personnel administering the test. The Interpretation of Spirogram section presented in Cotton Dust (1910.1043) Appendix D (OSHA, 2012b) is as follows:

- The first step in evaluating a spirogram should be to determine whether or not the patient has performed the test properly or as described in II above. From the three satisfactory tracings, the FVC and FEV1 shall be measured and recorded. The largest observed FVC and largest observed FEV1 shall be used in the analysis regardless of the curve(s) on which they occur.
- The following guidelines are recommended by NIOSH for the evaluation and management of workers exposed to cotton dust. It is important to note that

employees who show reductions in FEV1/FVC ratio below .75 or drops in Monday FEV1 of five percent or greater on their initial screening exam, should be re-evaluated within a month of the first exam. Those who show consistent decrease in lung function, as shown on the following table, should be managed as recommended.

Figure 1 presents an example of a spirogram with volumes and measurements including FVC and FEV1.

For other OSHA substance specific standards such as Benzene (1910.1028) (OSHA, 2012c), pulmonary function testing is covered under the medical surveillance section:

- **1910.1028(i)(1)(iii)**
 - The employer shall assure that persons other than licensed physicians who administer the pulmonary function testing required by this section shall complete a training course in spirometry sponsored by an appropriate governmental, academic or professional institution.
- **1910.1028(i)(2)(i)(E)**
 - For all workers required to wear respirators for at least thirty days a year, the physical examination shall pay special attention to the cardiopulmonary system and shall include a pulmonary function test.
- **1910.1028(i)(3)(iii)**
 - For persons required to use respirators for at least thirty days a year, a pulmonary function test shall be performed every three years. A

specific evaluation of the cardiopulmonary system shall be made at the time of the pulmonary function test.

Individual medical surveillance required by the respiratory protection program and substance specific standards provide an opportunity to collect group health information that can be integrated into an occupational health surveillance database. Pastides & Mundt (2003) state the importance of such information:

Surveillance, however, cannot be accomplished at the individual level, but becomes possible only when data from groups of employees are pooled and evaluated. This group perspective is the fundamental attribute that launched epidemiology into the forefront of communicable disease research, and it continues to be a cornerstone of the profession today. Typically, the rate or prevalence of disease, or prevalence of some indicator of exposure or risk, are compared among groups of employees or with some other referent group (such as the general population).

The development of an occupational health surveillance database and the subsequent use of such health data (pulmonary function tests) provide an opportunity to quickly evaluate the health status of a population in an efficient manner by limiting the need to perform prospective data collection on a population of interest.

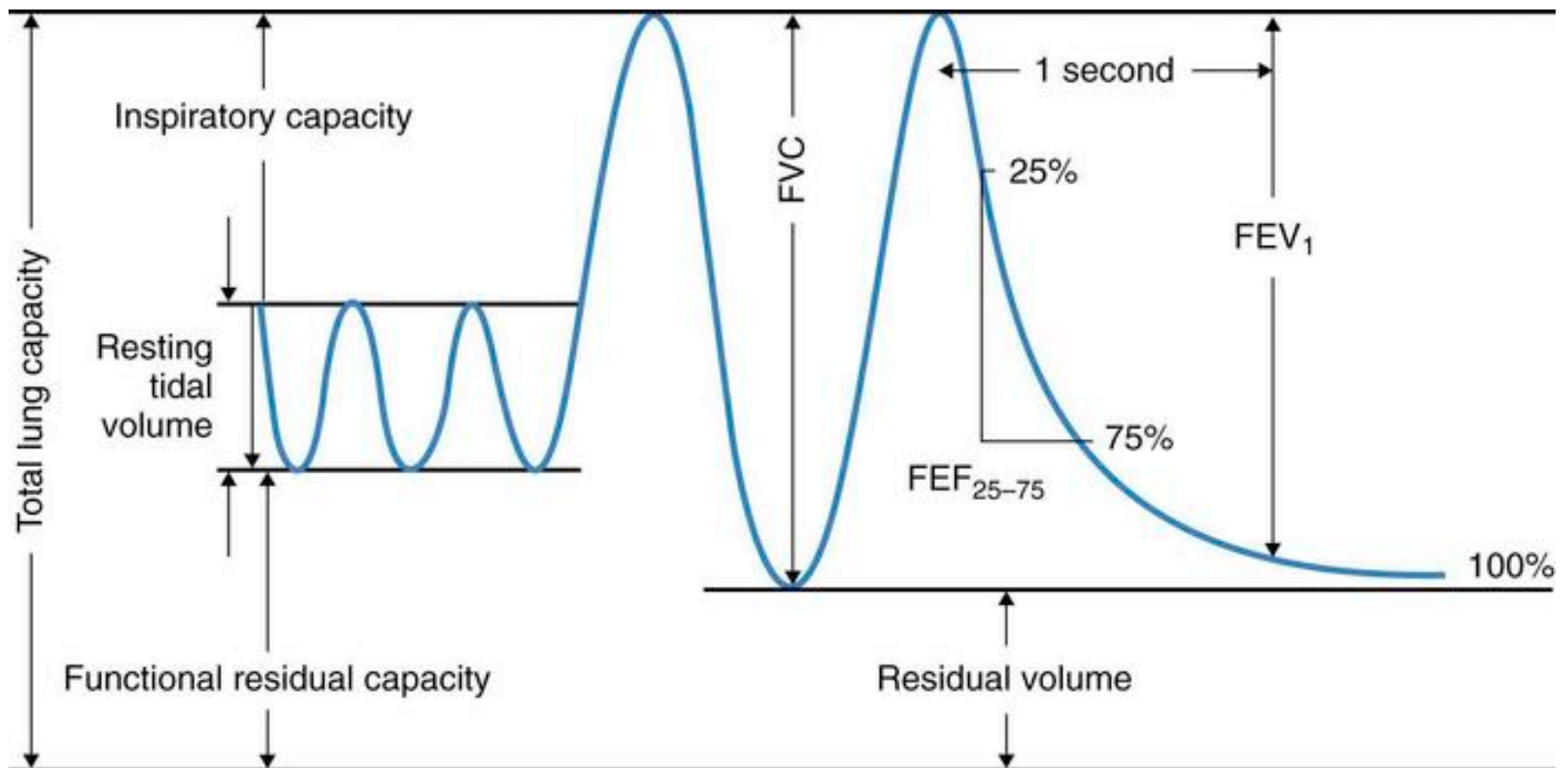


Figure 1: Spirogram with Volume and Measurements. FEF₂₅₋₇₅, forced expiratory flow at 25%-75% vital capacity; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity. (Adapted from Siberry GK, Iannone R (Eds.) The Johns Hopkins Hospital Harriet Lane Handbook, 15th ed. St. Louis: Mosby, 1999.)

While pulmonary function testing is not required for all employees who wear respirators, it is a best practice that is utilized in a majority of occupational settings and is typically included in an organizations respiratory protection program. Spirometry is the most frequently performed pulmonary function test and is the cornerstone of occupational respiratory evaluation programs (Townsend, 2011).

In the occupational health setting, spirometry plays a critical role in the primary, secondary, and tertiary prevention of workplace-related lung disease (American College of Occupational and Environmental Medicine, 2000). Spirometry data collected as a result of both standard medical practice and required testing provides a unique opportunity to perform occupational health surveillance among workers in targeted industrial occupations known to have potentially harmful exposures in the workplace. It also provides another opportunity to perform a vital function of occupational health surveillance as identified by Markowitz (2007):

Occupational health surveillance is an important means of discovering new associations between occupational agents and accompanying diseases. The potential toxicity of approximately eighty percent of the chemicals used in the workplace has not been evaluated in humans or in in vivo or in vitro test systems. Discovery of rare diseases, patterns of common diseases, or suspicious exposure-disease associations through surveillance activities in the workplace can provide vital leads for more conclusive scientific evaluation of the problem and possible verification of new occupational diseases.

Unfortunately, the vast majority of this data is used to simply validate individual capacity for respirator use and is ignored for population level analysis. Determining whether such data can be used efficiently to conduct a population level analysis is in line with the directive of EPHM to identify new data sources to enhance ongoing surveillance activities with the ultimate goal of gaining a better understanding of the health impact of occupational exposures in Florida.

The objectives of the current study are as follows:

- Identify industries in the State of Florida that have the potential for increased pulmonary impairment amongst workers
- Evaluate the feasibility of using pulmonary function data collected for purposes of compliance and/or best practices for workers who use respiratory protection because they are potentially exposed to pulmonary toxicants in the workplace

This study will attempt to test the following hypothesis:

- Pulmonary function is impaired among workers of selected industries exposed to various airborne toxicants

Chapter 2

Spirometry and Lung Function

In order to evaluate the data produced from pulmonary function testing, it is important to have a basic understanding of lung function and how it is measured. Pulmonary function tests evaluate the functionality of the lungs. Spirometry is the most basic type of pulmonary function test and provides air volume and flow rate within the lungs. Schlegelmilch and Kramme state:

Spirometers are noninvasive diagnostic instruments for screening and basic testing of pulmonary function. Offering essential diagnostic insight into the type and extent of lung function impairment, spirometry tests can be performed fast at fairly low cost. In the light of ever-increasing prevalence of airway diseases such as asthma, bronchitis, and emphysema, pulmonary function instruments have become indispensable diagnostic tools, in clinical and office settings, in industrial and preventive medicine, as well as in epidemiology.

As mentioned in Chapter 1, spirometry is the most frequently performed pulmonary function test other than an arterial blood gas study and plays an important role in diagnosing the presence and type of lung ‘abnormality’ and classifying its severity (Sood et al., 2007). The utility of spirometry as a tool to evaluate pulmonary health is further discussed by Petty (2005):

Normal spirometry predicts a high likelihood of long-time survival; abnormal spirometry indicates an adverse prognosis. Simple spirometric measures provide an important database for the primary care physician and specialist. One example is the patient who comes to the physician with cough and dyspnea thought to be associated with a certain occupation. Knowledge of prior spirometry will give a baseline for comparison.

Results of such testing that is already being collected for select occupational populations can be integrated into a functional database and used to conduct medical health surveillance in a cost effective and efficient manner.

2.1 History of Spirometry

Scientific inquiry into the understanding of lung function as a process, goes far back into history and has led scientists to develop various methods and instruments to measure lung capacity. This was an important endeavor because measurement of lung volumes provides fundamental information that makes categorization and the staging of lung diseases possible. The concept of spirometry has been traced back to a doctor named Claudius Galen who lived during the time of the Roman Empire. He studied human ventilation by having a subject breathe into a bladder and discovered that over a period of time the volume of gas did not change.

The next documented experiment involving lung volumes took place around 1681 by a mathematician named Giovanni Alfonso Borelli. His experiment involved having a subject suck liquid through a cylindrical glass tube. The volume was calculated from the

bore of the tube and the height of the meniscus, which unfortunately led to a significant underestimation of true lung volumes (Garay, 2007). In the early 1700s Stephen Hales confirmed the absolute measurements of air volume recorded by James Jurin in 1718. He recorded the maximum volume of air, which could expire into a bladder using displacement of water according to the principle of Archimedes (Spriggs, 1978).

While experiments were conducted in the past, the practice of determining lung volumes began to advance in the 17th century and continued to progress with the improvement of technology and data collection methods. For example, in 1947 Tifineau introduced the concept of the timed vital capacity, which resulted in FEV1 (Petty, 2005). Since that time, spirometry has continued to evolve but still remains an easy and effective tool to measure pulmonary function. Petty (2005) states:

Spirometry is a highly useful, yet simple instrument for the measurement of expiratory air flow and volume. Spirometry is key to the diagnosis of obstructive ventilatory diseases, that is, asthma and chronic obstructive pulmonary disease (COPD), and in monitoring responses to therapy. Spirometry also identifies restrictive disease and helps monitor therapy and predicts prognosis over time.

Table 1 presents some of the main contributors and significant achievements in the history of spirometry over the past two centuries.

Table 1: History of Spirometry

Year	Contributor	Achievement
1800	Davy	Measurement of residual volume using a hydrogen gas dilution technique.
1844	Hutchinson	Designed the first spirometer. Designated the expiratory vital capacity and developed normal standards based upon approximately 2,000 assorted English persons.
1940s	Cournand & Richards	Established standard methods of assessment and published normal values of pulmonary function tests.
1947	Tiffeneau & Pinelli	Contributions to the measurement of timed vital capacity.
1949	Tiffeneau, Bousser, & Drutel	First advocated the use of the FEV1/FVC ratio.
1951	Gaensler	Analysis of the ventilation defect by timed vital capacity measurements.
1955	Leuallen & Fowler	Contributed the maximum mid-expiratory flow test.
1957	Gandevia & Hugh-Jones	Published widely accepted terminology for pulmonary physiology.
1958	Hyatt, Schilder, & Fry	The expiratory flow-volume curve was introduced.
1963	American College of Chest Physicians (ACCP)	Modification of the terminology of dynamic lung volumes.
1975	ACCP & American Thoracic Society	Published a broad exposition on pulmonary nomenclature.

(Adapted from Morris, J. F. (1976). Spirometry in the evaluation of pulmonary function (Medical Progress) Western Journal of Medicine, Volume 125, 110-118.)

2.2 Spirometry and the Respiratory System

As described previously, spirometry is considered a medical screening test that helps evaluate lung function in individuals. The lungs are part of the respiratory system which provides essential oxygen to all parts of the body as well as enabling the body to get rid of carbon dioxide. The amount and delivery of oxygen needed for human cells to function properly is a delicate balance and important for overall health. Lung morphology is determined by three major constraints: limited volume allocated to the structure, a need to protect the delicate gas exchange airways, and the large surface area needed for air-blood oxygen and carbon dioxide exchange (Miguel, 2012).

The respiratory system is made up of organs and tissues that help an individual breathe, with the main parts of this system being the airways, the lungs, and linked blood vessels, and the muscles that enable breathing (National Heart, Lung, and Blood Institute, 2012a). The airways that deliver vital oxygen-rich air to the lungs include the nose, mouth, larynx, trachea, and bronchial tree. These same airways also carry out carbon dioxide which is a waste product of cellular respiration. The oxygen that is transported through the respiratory system is ultimately transferred to the bloodstream at the alveoli located at the end of the bronchial tree. It is estimated that an adult has approximately three hundred million alveoli with a surface area for gas exchange of about seventy-five square meters, which are perfused by more than two thousand kilometers of capillaries (Miguel, 2012). Figure 2 presents a basic diagram of the respiratory system, airways, and gas exchange between the capillaries and alveoli.

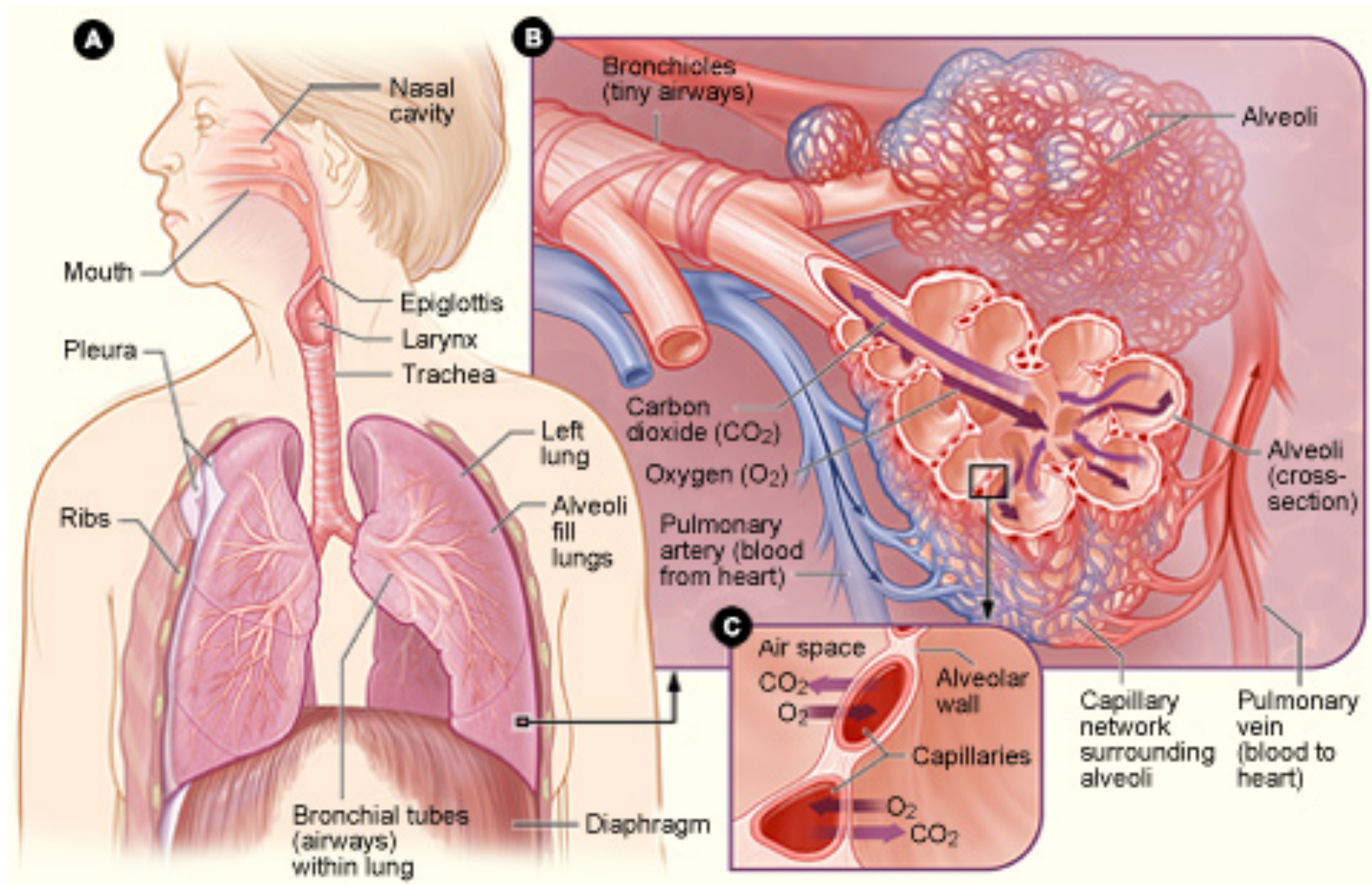


Figure 2: Diagram of the Respiratory System. (Source: National Heart Lung and Blood Institute, <http://www.nhlbi.nih.gov/health/health-topics/topics/hlw/system.html>, accessed 2012)

When an individual breathes, air is moving in and out of the lung which is referred to as ventilation. Muscles located near the lungs allow this process to happen by expanding and contracting the lungs. Muscles used in this process include the diaphragm, intercostal muscles, abdominal muscles, and muscles in the neck and collarbone area.

The movement of air into the lung is an active process called inspiration. The movement of air out of the lung is a passive process called expiration and involves elastic recoil which returns the lung to its normal size. Pulmonary compliance (stiffness) can affect elastic recoil by influencing the amount of pressure needed to increase or decrease the volume of the lung. Airflow resistance can also negatively affect lung volumes due to the difficulty of air passing through the airways. The responses of the lung to toxicants may be divided into the following general categories (Menzel & McClelln, 1980):

- Irritation of the air passages, which results in constriction of the airways. Edema often occurs and secondary infection frequently compounds the damage
- Damage to the cells lining the airways, which results in necrosis, increased permeability, and edema
- Production of fibrosis, which may become massive and cause obliteration of the respiratory capacity of the lung. Local fibrosis of the pleura also occurs, restricting the movement of the lung and producing pain through the irritation of pleural surfaces
- Constriction of the airways through allergic responses
- Oncogenesis leading to primary lung tumors

The above categories of pulmonary response to toxicants can affect pulmonary function by altering normal lung volumes. Table 2 presents a number of different lung volumes accompanied by a brief description. A spirometer can measure most lung volumes with the exceptions being total lung capacity, functional capacity, and residual volume.

Table 2: Lung Volumes

Tidal Volume
The volume of gas which is inhaled or exhaled during the course of a normal resting breath.
Residual Volume
The volume of gas that remains in the lungs after a maximal forced expiration.
Inspiratory Reserve Volume
The volume of gas that can be further inhaled after the end of a normal tidal inhalation.
Expiratory Reserve Volume
The volume of gas that can be exhaled from the resting end-expiratory level.
Capacity
The sum of one or more lung volumes.
Vital Capacity
The volume of gas inhaled when a maximal expiration is followed immediately by a maximal inspiration.
Functional Residual Capacity
The volume of gas that remains in the lungs after a normal tidal expiration.

(Adapted from Physics, Pharmacology and Physiology for Anesthetists, 2008)

Airborne contaminants in the form of gases, liquids, or solids have the potential to harm the lungs if inhaled and ultimately decrease pulmonary function. NIOSH (1977) recognizes the importance of the inhalation route in occupational settings and states:

Some of the highly reactive industrial gases and vapors of low solubility can produce an immediate irritation and inflammation of the respiratory tract and pulmonary edema. Prolonged or continued exposure to these gases and vapors may lead to chronic inflammatory or neoplastic changes or to fibrosis of the lung. Fibrosis, as well as granulomatosis and malignancy, also may be produced by certain insoluble and relatively inert fibrous and nonfibrous solid particulates found in industry. Indeed, it is now thought that one of the prerequisites for particulate-induced bronchogenic carcinoma may be the insolubility of the particulate in the fluids and tissues of the respiratory tract, which thereby allows requisite residence time in the lung for tumor induction.

The fact that the surface area of the lungs is so large, potential for occupational lung disease is a concern if airborne hazards of the workplace are not controlled through appropriate measures. Consider that many occupations require physical exertion which can increase the amount of air inhaled. For example, a person at rest inhales approximately six liters of air a minute compared to approximately seventy-five liters per minute during heavy exercise (NIOSH, 2003).

An airborne contaminant can affect pulmonary function if they pass through the respiratory system and reach the alveoli. Menzel & McClellan (1980) state the following about the toxic responses of the respiratory system:

The deposition and retention of inhaled gases and aerosols are influenced by many anatomic features of the respiratory tract, including lung volume, alveolar surface area, and structure and spatial relationships of conducting airways into alveoli. Distribution of deposited material as a function of time, in combination with the location of the over forty cell types identified in the respiratory tract, determines the cells at risk for any inhaled material.

Gases, fumes, and vapors all have the potential to affect lung function. This group includes irritant acid gases, very soluble gases, and gases and vapors of low water solubility but high fat solubility. Irritant acid gases for the most part are fast acting chemicals that affect the upper airway passages. Very soluble gases typically deposit in the upper or proximal airways and if the dose is sufficient, emphysema and fibrosis may develop. Gases and vapors of low water solubility and high fat solubility are more likely to reach the distal airways and ultimately the blood.

The deposition, retention, distribution, and ultimate health effects of particulates differs from that of gases, fumes and vapors. The aerodynamic properties of particles and fibers determine how far they can travel into the body and ultimately determine where they are deposited in the respiratory system. Particles up to one hundred microns can be inhaled though the nose, however particles larger than fifty microns typically do not remain airborne long enough to be inhaled. If they are inhaled, they become trapped in the nasal passage. Particles less than ten microns are considered to be respirable and have the potential to reach deep into the lungs. Particles one to five microns in size are more likely to deposit in the trachea and bronchi while particles 0.01 to one micron in

size are likely to reach the bronchioles, alveolar ducts, and alveoli. Figure 3 presents size ranges for various particles.

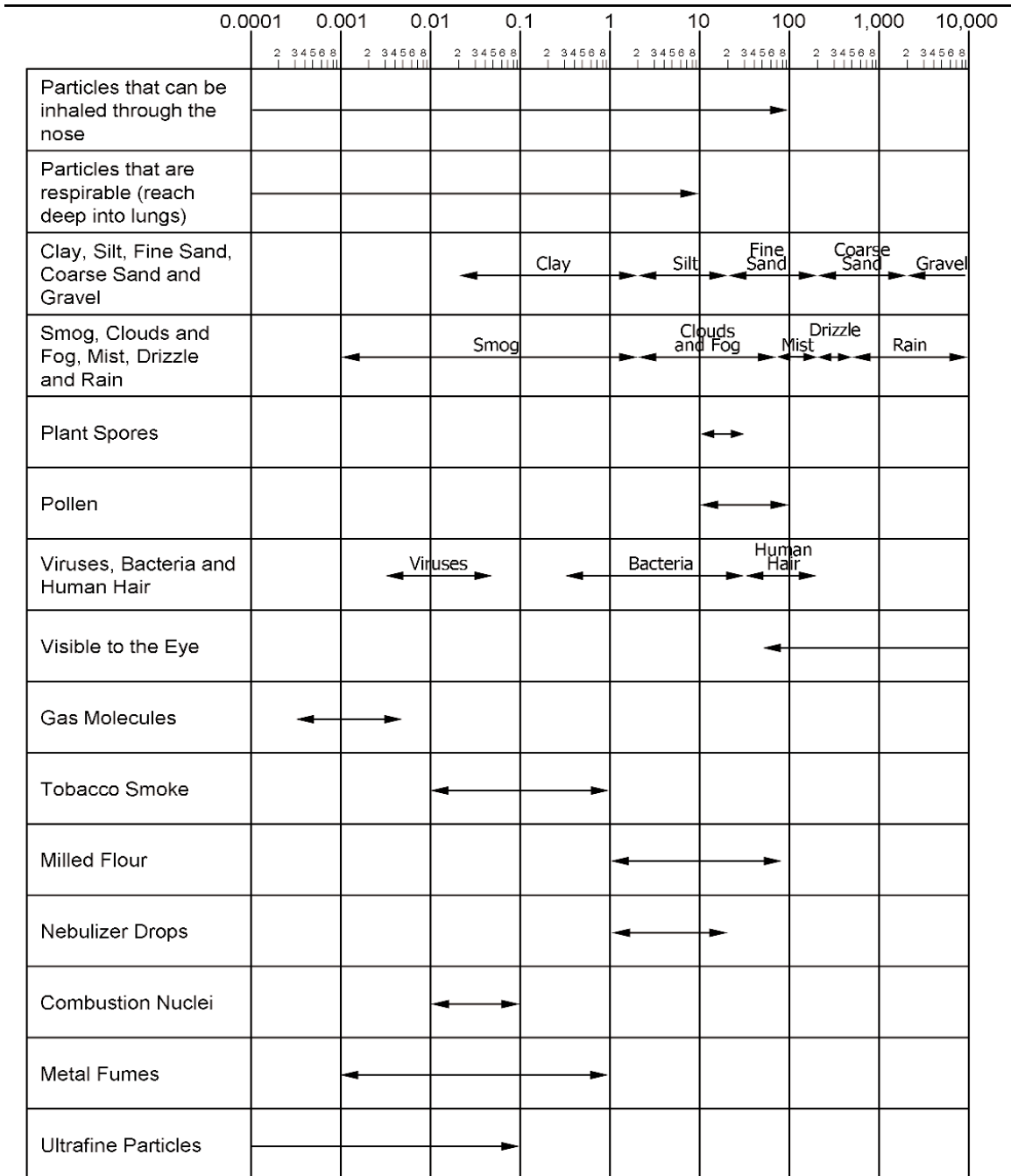


Figure 3: Particle Size Distribution Graph in Microns. (Source: National Institute of Environmental Health Sciences, www.niehs.nih.gov/health/assets/docs_a_e/ehp_student_edition_lesson_particles_size_makes_all_the_difference.pdf, accessed 2012)

2.3 Spirometry Testing and Results

Spirometry is conducted using a spirometer, which measures the quantity of air a person inhales or exhales and the rate at which the air is moved in and out of the lungs. The process of obtaining spirometric volumes is relatively easy and is explained by Garay (2007):

The subject is instructed to breathe normally with a resting tidal pattern as the volume is being recorded. Next, the subject inspires maximally, then exhales as completely as possible with a slow, continuous, smooth exhalation and returns to tidal breathing. The result is the slow vital capacity (SVC). FVC is measured with virtually the same maneuver, but the patient is instructed to exert maximal forced expiratory effort.

Spirograms are graphic representations of the information obtained from the test. Spirometers can measure volume through the amount of air exhaled or inhaled within a certain time or they can measure flow by determining how fast the air flows in or out as the volume of air inhaled or exhaled increases. Figure 4 presents a flow-volume loop and a volume-time curve.

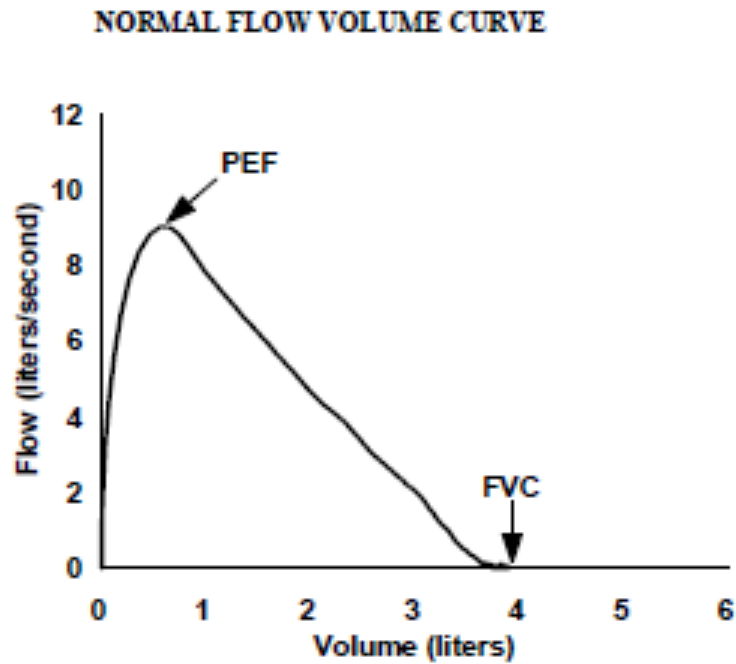
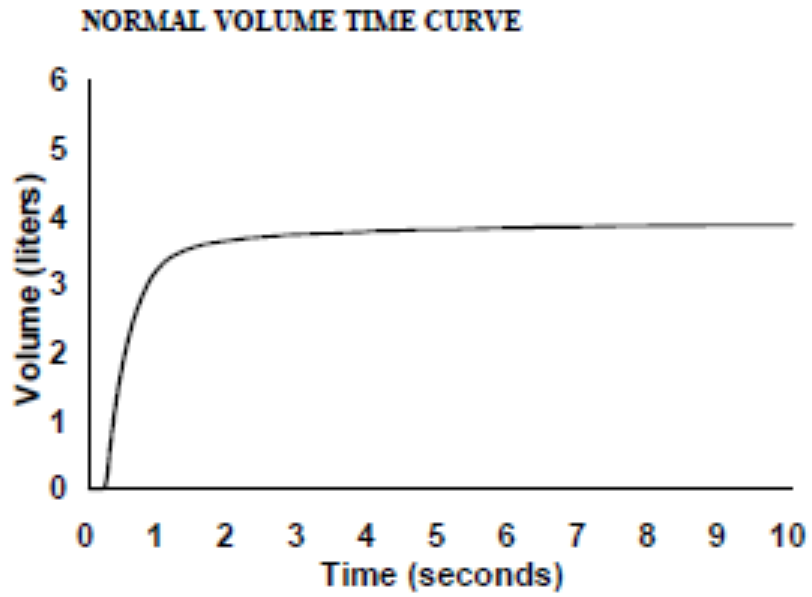


Figure 4: Normal Volume Time Curve and Flow Volume Curve. (Source: NIOSH Spirometry Training Guide, 2003)

Spirometry results indicate the presence of lung abnormalities which include obstructive patterns, restrictive patterns, or a combination of both. In obstructive diseases, less air flows in and out of the airways because of one or more of the following: airways and air sacs lose their elastic quality; walls between many of the air sacs are destroyed; walls of the airways become thick and inflamed; airways make more mucus than usual, which can clog them (National Heart Lung and Blood Institute, 2012b). Restrictive disease is a condition marked most obviously by a reduction in total lung capacity caused by a pulmonary deficit, such as pulmonary fibrosis (abnormally stiff, non-compliant lungs) (John Hopkins University School of Medicine, 2012). Table 3 presents an overview of occupational obstructive and restrictive lung diseases.

Table 3: Overview of Occupational Lung Disease

Pulmonary Diseases that Show Obstructive Patterns	Pulmonary Diseases that Show Restrictive Patterns
Occupational Asthma	Pneumoconioses
Reactive Airways Dysfunction Syndrome	Hypersensitivity Pneumonitis
Emphysema	Granulomatous Disease
Chronic Bronchitis	Other Health Conditions

(Adapted from NIOSH Spirometry Training Guide, 2003)

Chapter 3

Health Surveillance

The purpose of surveillance is to target work-related diseases and injuries so that prevention can occur (Millar, 1986). This chapter presents a number of studies that use surveillance data to determine the health status of various groups of individuals. In addition, this chapter will look specifically at pulmonary function data and its utility in comparative analysis.

3.1 Disease Surveillance

3.1.1 National Health and Nutrition Examination Survey

National Health and Nutrition Examination Survey III (NHANES III) data has been successfully used as a baseline population for health surveillance. NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the United States (Center for Disease Control and Prevention, 2012). The South Carolina Department of Health and Environmental Control (1999) recognized that NHANES III data provides the most recent and most accurate estimate of the prevalence of overweight and obesity in the United States and that when these data are applied to the adult population in South Carolina, it provides useful estimates of the number of overweight and obese individuals in the State. This is just one example of how NHANES III data can be used to determine if a population level abnormality exists with a specific

group of individuals. The following studies provide further examples of the use of the NHANES data set in comparative analyses.

McEvoy et al. (2005) conducted a study to determine the prevalence of metabolic syndrome (a risk factor for cardiovascular disease) in United States patients with schizophrenia. They used baseline data from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Schizophrenic Trial. Comparative analyses were performed using a randomly selected sample from NHANES III matched 1:1 on basis of age, gender, and race/ethnicity. In a logistic regression model with age, race, and ethnicity as covariates, CATIE males and females were more likely to have metabolic syndrome than the NHANES matched samples. The conclusion of the study indicated that metabolic syndrome is highly prevalent in United States schizophrenic patients and is a source of cardiovascular risk. They suggest that clinical attention be given to monitoring for metabolic syndrome and minimizing metabolic risks associated with antipsychotic treatment.

Lamberti et al. (2006) conducted a study to compare the prevalence of the metabolic syndrome among outpatients with schizophrenia and schizoaffective disorder receiving clozapine with a matched group from NHANES III. Ninety-three outpatients were compared to a group of 2,701 individuals matched for age, body mass index, and race/ethnicity. Logistic regression analyses were performed to determine if study variables were associated with the presence or absence of metabolic syndrome. The results of the study found that the prevalence of the metabolic syndrome was significantly higher among clozapine patients than among the NHANES III comparison group. This

research identified that regular monitoring may be especially critical for schizophrenic patients taking clozapine due to the high prevalence of metabolic abnormalities reported in this study and others.

Herrington et al. (1998) conducted a comparative analysis to determine the efficacy of postmenopausal estrogen/progestin therapy for secondary prevention of coronary heart disease. To conduct the analysis, they compared the baseline cardiovascular risk factor data from the Heart and Estrogen/Progestin Replacement Study (HERS) cohort with similar data from women presumed to have coronary heart disease from NHANES III. Age, race, and cardiovascular disease risk factors were compared in the 2,763 postmenopausal women younger than eighty years old, with a uterus, and with documented cardiovascular disease in HERS to 145 similarly aged women with clinical or electrocardiographic evidence of coronary heart disease from NHANES III. The results indicated that the HERS cohort had fewer cardiovascular risk factors than women with myocardial infarction or angina in NHANES III. It was determined that due to the number of women with diabetes and hypertriglyceridemia in the NHANES III group, these results emphasized the importance of testing strategies for secondary prevention of coronary heart disease in this high risk subgroup.

Dickerson et al. (2006) conducted a study to examine the distribution and correlates of body mass index among individuals with serious mental illness. A comparison of body mass index was made between 169 out-patients receiving community-based psychiatric care and 2,404 matched individuals from the NHANES III data set. The distribution of body mass index in individuals with serious mental illness

differed significantly from the NHANES III comparison group. The results showed that fifty percent of women and forty-one percent of men in the psychiatric sample were obese compared with twenty-seven percent and twenty percent in the NHANES III group. In addition, the higher body mass index linked to individuals with serious mental illness was associated with current hypertension, diabetes, a wish to weigh less, and reduced health-related functioning.

Goff et al. (2005) conducted a study to compare ten-year cardiac risk estimates in schizophrenia patients from the CATIE study to matched controls. Ten-year risk for coronary heart disease was calculated for 689 out-patients with a diagnosis of schizophrenia who participated in the CATIE study. They were compared to 687 NHANES III subjects matched for age, race, and gender. Ten-year coronary heart disease was significantly higher in male and female schizophrenia patients compared to the NHANES III control population. The results of this research were consistent with other studies which find that schizophrenia patients in the CATIE study at baseline have a significantly higher risk for coronary heart disease compared to matched controls. This holds true even after controlling for body mass index. The authors conclude that based upon the findings of the study that cardiac risk factors should be evaluated and monitored by clinicians and behavioral or pharmacological interventions should be implemented as indicated.

Streeten et al. (2004) conducted a study to compare hip fracture incidence and bone mineral density in Older Order Amish to the general population. To assess the bone health of the Older Order Amish population, bone mineral density data was selected from

among participants of the Amish Family Osteoporosis Study and compared to a United States non-Amish white population obtained from NHANES III. Statistical significance between the groups was assessed by estimating the variance of the pooled difference in bone mineral density across age groups. Results indicated that the Older Order Amish had a higher mean bone mineral density that was significant in women but not in men compared to the NHANES III population. The authors concluded that based upon the findings of the study that additional research of lifestyle and/or genetic differences between Amish and the general population may provide insights into etiologic factors influencing hip fracture risk.

Castorina et al. (2010) conducted a study to compare current-use pesticide and other toxicant urinary metabolite levels among pregnant women in the Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS) cohort to the general population. They measured thirty-four metabolites of current-use pesticides and other precursor compounds in urine samples collected twice a day from 538 women living in the Salinas Valley of California. Metabolite concentrations from the CHAMACOS cohort were compared with United States national reference data for 342 pregnant women sampled by NHANES to determine the impact of the women's regional environment. The results of the study found that the 95th percentile values of six of the most commonly detected compounds were significantly higher among the CHAMACOS women compared to the NHANES group after controlling for age, race, socioeconomic status, and smoking. The authors conclude that findings indicate that the CHAMACOS cohort has an additional burden of precursor pesticide exposure compared to the general population, which is possibly due to living and/or working in an agricultural area.

Xu et al. (2009) conducted a study to compare the prevalence of chronic kidney disease among native Chinese and American ethnicities. In 2006, a stratified multistage clustered screening for chronic kidney disease was conducted in Beijing and resulted in 13,626 participants. The data collected from the screening was compared to NHANES data which included 9,006 American whites, 3,447 African Americans, and 4,626 Hispanics. The results indicated that when compared to NHANES data, Chinese had a lower prevalence of adjusted albuminuria as well as the lowest risk of albuminuria when diagnosed with diabetes. Chronic renal insufficiency among Chinese when diagnosed with diabetes or hypertension was found to be lower when compared to African Americans but not significantly different than whites or Hispanics. The authors concluded that the prevalence of chronic kidney disease was significantly different between native Chinese and American ethnicities.

Brar et al. (2007) conducted a study to compare diabetes mellitus prevalence and its predictors in antiretroviral-naïve HIV-infected patients compared to the general population. A cross-sectional analysis of 2,565 participants enrolled in three Terry Bein Community Programs for Clinical Research on AIDS (CPCRA) clinical trials were compared to 6,585 adults from the NHANES cohort for the years 2001 through 2002. The results indicated that the prevalence of diabetes mellitus was significantly lower among CPCRA subjects compared to NHANES subjects. However, after adjusting for age, race/ethnicity, and body mass index, there was no significant difference in the prevalence of diabetes mellitus between CPCRA subjects and NHANES subjects.

Burger et al. (2011) conducted a study to investigate the correlation between body mass index and pulmonary artery systolic pressure in patients enrolled in the Registry to Evaluate Early and Long-term Pulmonary Arterial Hypertension (PAH) Disease Management (REVEAL) to NHANES subjects. The two groups were matched for age and gender with ultimate goal of determining whether obesity is linked with PAH. The results indicated that there was no significant difference in mean body mass index for patients with PAH compared to the NHANES control group. However, results did find that there were higher percentages of obese and underweight patients in REVEAL. The authors concluded that further research is needed to determine the reason for increased obesity in idiopathic PAH.

Dickerson et al. (2004) conducted a study to compare sexual reproductive behaviors among persons with mental illness to the general population. The study sample consisted of 191 men and women with schizophrenia or a mood disorder recruited from two outpatient psychiatric centers. The comparison group was selected from the NHANES III data set and for age and race. The responses from the two groups were compared using regression analysis for each outcome variable by gender. The findings of this study suggest gender differences in sexual behaviors among people with mental illness. Women with mental illness reported having more partners than the NHANES III comparison group. In addition, women with mental illness had fewer live births and were less likely to get pregnant compared to the NHANES III comparison group. The authors conclude that as a result of the findings, there is a need to prevent sexually transmitted diseases and victimization of women with mental illness and that physicians need to pay special attention to the sexual and reproductive health of this group.

Sarma et al. (2009) conducted a study to determine the urinary incontinence among women with type 1 diabetes to a population based sample of women with normal glucose. A group of 550 women enrolled in the Epidemiology of Diabetes Interventions and Complications (EDIC) study were compared to 383 women with complete incontinence information from the NHANES 2001 to 2002 sample. Women from the EDIC study that had type 1 diabetes had a two-fold greater prevalence of weekly or greater urge incontinence compared to the NHANES III comparison group. Based on the findings of this study, the authors concluded that physicians treating women with type 1 diabetes should look for incontinence because it is often unrecognized and therefore untreated in women with diabetes.

Abalkhail and Shawky (2002) conducted a study to compare the body mass index, triceps skin fold thickness and mid-arm muscle circumference in Saudi adolescents to a recognized reference population. Data was collected from 2,737 Saudi adolescents selected from forty-two boys' and forty-two girls' schools in Jeddah and compared with corresponding values from NHANES I. The results of the study showed that the 85th percentile and 95th percentile for body mass index and triceps skin fold thickness were higher for Saudi adolescents compared to the NHANES I comparison group. In addition, Saudi adolescents had lower mid-arm muscle circumference at the 90th percentile and 95th percentile compared to the NHANES I reference population curves. The authors concluded that Saudi adolescents show increased weight and obesity along with increased body fat and decreased body muscle compared to the NHANES I comparison group. They suggest that public health interventions are needed to improve quality of food,

encourage physical activity, and change the perception of appropriate body stature in Saudi Arabia.

Huang et al. (2004) conducted a study to compare 1-hydroxypyrene exposure in the United States population with that in occupational exposure studies. Data was analyzed for fourteen monohydroxy polycyclic aromatic hydrocarbons from urine samples collected as part of NHANES. Reference range values were calculated for these metabolites in the United States population. As part of the analysis, it was determined that 1-hydroxypyrene was detected in more than ninety-nine percent of the samples with an overall geometric mean concentration of 79.8 nanograms per liters in the United States population. This data was used to compare the reference range of urinary 1-hydroxypyrene levels in the United States population with levels reported from various occupations by other researchers. Comparative analysis indicated that at some occupations, such as coke oven plants and carbon electrode plants, workers' urinary 1-hydroxypyrene concentration levels could be a few hundred times higher than the general United States population. The authors of this study concluded that additional research is needed that directly correlates urinary 1-hydroxypyrene with health effects such as cancer risk to gain a better understanding of occupational polycyclic aromatic hydrocarbon exposure and determination of biological limit values.

Comparative research provides an opportunity to investigate health data across different populations. This type of research is important so that evaluations can be made between different groups to identify populations at high risk and identify new or

emerging health concerns. The studies referenced in this section show the utility and strength of using NHANES data in comparative research and analysis.

3.1.2 Occupational Respiratory Disease Surveillance

In terms of occupational respiratory disease surveillance, NIOSH and the Mine Safety and Health Administration have implemented the Enhanced Coal Workers' Health Surveillance Program (ECWHSP). According to NIOSH (2012d):

Coal mining-related respiratory diseases can affect the gas exchanging tissues of the lungs. These lung tissues remove carbon dioxide and take up oxygen. The diseases can also affect the lung passages that carry air back and forth during breathing. The passages are called airways. Depending on what is in the coal mine dust that is inhaled and the part of the lung that is affected, coal miners may develop several different types of respiratory diseases.

This program was developed due to the observed onset of advanced pneumoconiosis in younger coal miners along with regional clustering of rapidly progressive cases. Pneumoconiosis is a disease of the lung and refers to the scarring of the tissue between the air sacs. The two primary pneumoconioses related to coal mining are coal workers' pneumoconiosis (CWP) and silicosis:

- CWP, commonly called Black Lung, is type of pneumoconiosis caused by inhaling respirable coal mine dust. Chest x-rays can show shadows in the lungs called opacities. In severe cases, there are more opacities in a given area of the

lung. The most severe type of CWP is called progressive massive fibrosis (PMF). In PMF, the opacities come together and become large (NIOSH, 2012d).

- Silicosis is a type of pneumoconiosis caused by inhaling respirable crystalline silica. Quartz is a type of crystalline silica that causes silicosis in coal miners because it is a major component of rocks. Silicosis causes x-ray changes similar to CWP; and it is especially seen in coal miners who are exposed to rock dust, such as roof bolters in underground mines and drillers in surface mines (NIOSH 2012d).

Surveillance of coal miners includes surveys, health questionnaires, work histories, spirometry testing, radiographic examinations, and other pertinent health information. This data is collected by specially trained personnel using a mobile examination unit. Figure 5 presents a poster promoting the participation in the Coal Workers' Health Surveillance Program.

BLACK LUNG

DON'T BECOME A VICTIM

What can YOU do?
Participate in the CWHSP!
Coal Workers' Health Surveillance Program

The X-ray Program
 Why should I participate?
 • X-ray **FREE** of charge to the miner
 • Miner receives confidential report of the x-ray result
 • If definite evidence of CWP is found, the miner has the right to work where the dust concentration is not more than 1.0mg/m³ of air, with no loss of regular pay
 • X-ray may help support a State or Federal claim for Black Lung Benefits
 • Supports research for preventing disease and disability
 What is involved?
 • Completing one form
 • Having one x-ray taken at a local facility
 Who is eligible?
 • Every underground coal miner

Other CWHSP Components
National Coal Workers' Autopsy Study
 • No cost to the family
 • Family receives a report of the autopsy findings
 • Findings may support a survivor's claim for Black Lung Benefits
 • Supports research for prevention of lung disease among coal miners
B Reader Certification Program
 • B Readers are doctors who are certified by NIOSH to classify chest x-rays for evidence of lung damage caused by dust

The Law
 The Federal Coal Mine Health and Safety Act of 1969 (as amended by the Federal Mine Safety and Health Act of 1977) was created:
 • To study the causes and consequences of coal-related respiratory disease
 • To provide early detection and prevention of coal workers' pneumoconiosis (CWP)
 • To protect the health and safety of underground coal miners
 • To require all coal mine operators and contractors to display their NIOSH-approved plan in a visible location on the bulletin board at the mine

Coal workers' pneumoconiosis (CWP), commonly called "Black Lung," can often be detected using chest x-rays. X-rays may show definite evidence of disease before the miner notices symptoms. Early detection is important, since prompt and adequate control of dust exposure can prevent or slow the progression of a disabling disease.

"The first priority and concern of all in the coal or other mining industry must be the health and safety of its most precious resource - the miner."
 Federal Coal Mine Health and Safety Act of 1969 - amended 1977

CDC
 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
 CENTERS FOR DISEASE CONTROL AND PREVENTION
 1600 CLIFTON BLVD, NE
 ATLANTA, GA 30333

NIOSH
 NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
 1015 NINTOSH BLVD
 MORGANTOWN, WV 26604
 For information: Call toll free 1-800-485-4042
 or visit <http://www.cdc.gov/niosh/blung.html>
 Email: CWHSP@cdc.gov
 Photos by Earl Dotter
 2003 (NIOSH) Publication No. 2003-123

Figure 5: Black Lung Poster. (Source: DHHS (NIOSH) Publication Number 2003-123 (2003))

In addition to the to the ECWHSP, NIOSH has a separate project called ‘Dust Control Technology for Black Lung Hot Spots’ which collects coal mineralogy, mining conditions, respirable dust and silica exposure concentrations, mining and dust control strategies, and other pertinent data in regions with disease clusters. The results of these NIOSH activities are intended to facilitate preventive actions, through the derivation of representative current estimates of the burden, distribution, and determinants of occupational lung disease in relation to coal mining in the United States (NIOSH, 2012e).

3.1.3 Pulmonary Function Surveillance Data

NIOSH (2003) recommends that employment settings where workers use respirators or are potentially exposed to airborne toxicants should have a respiratory surveillance program which should include the use of spirometry. Such programs generate pulmonary function data that can be used to conduct a population level analysis. The potential outcome of such research includes the prevention, early detection, and treatment of occupational diseases. This leads to a healthier workforce, which in turn can lessen the unnecessary burdens associated with worker’s compensation claims, litigation fees, insurance premiums, and medical bills.

Pulmonary function testing is particularly well suited for occupational surveillance with the availability of the NHANES III Raw Spirometry data set. NHANES III was conducted from 1988 to 1994, and is comprised of a random sample of the United States population living in households. In terms of spirometry data, NHANES III improved upon data collection and data quality. Hankinson et al. (1999) describe such improvements:

One significant aspect of NHANES III was the use of equipment and procedures that met the 1987 American Thoracic Society's spirometry recommendations, and featured automated quality assessment during test performance. To maintain the highest level of technician performance, a quality control center continuously reviewed the data and provided quality control reports and follow-up training as appropriate. In 1994, as NHANES III was completing data collection, the American Thoracic Society revised its 1987 spirometry recommendations, which included changes in both the extrapolated volume and the reproducibility criteria. In addition the NHANES III spirometry protocol called for each participant to perform a minimum of five maneuvers, which differed from the three acceptable maneuvers recommended by the American Thoracic Society. To make findings from NHANES III useful to future investigations utilizing the 1994 American Thoracic Society's recommendations, the raw data were also reanalyzed to follow the 1994 American Thoracic Society's recommendations, and the impact of using a minimum of five versus three maneuvers was investigated.

This data allows for population level analysis of worker spirometry data to be compared to a standard population, adjusted for age, height, tobacco smoking, and other factors that impact pulmonary function not related to the occupational environment.

Spirometric interpretation utilizes reference equations as threshold criteria for the diagnosis of lung disease. Many studies have published lung function values, so there has been considerable debate in the past regarding the applicability of the various

reference equations used for analysis. Pellegrino et al. (2005) determined that in the United States, ethnically appropriate NHANES III reference equations are recommended for those aged eight to eighty years. Furthermore, Collen et al. (2008) has conducted research on discordance in spirometric interpretations using three commonly used reference equations versus NHANES III and found that:

Although our study was not designed to identify the optimal reference equation for this population, we believe the NHANES III equations are the best available to date. The NHANES III equations are based on a sample size that was ten-fold greater than those in any of the prior studies and included a heterogeneous population that was enrolled from 1988 to 1994. These equations are less subject to cohort effect in comparison to those derived by the Crapo, Morris, and Knudson studies, which enrolled patients in earlier decades.

The NHANES III Raw Spirometry data contains over 15,000 individual spirograms matched to standard NHANES demographic and survey data. Once compiled, mandatory pulmonary function data from exposed workers can be reliably analyzed for comparison to NHANES III data to determine if a population level abnormality exists within a specific occupation.

The objective of this research is to compile raw data from occupational health monitoring reports into a coherent database to determine the utility and feasibility of this data as an instrument for evaluating potential health effects associated with working in various occupational sectors. The results of this research can be used to develop and implement safe work practices that reduce chemical exposure for workers in the State of

Florida. The hypothesis that was tested was: Pulmonary function is impaired among workers of selected industries exposed to various toxicants. Three principle occupational sectors represented in the data source include boat manufacturers, electric utility workers, and first responders. Previous findings indicate that these occupational sectors have unique exposures that put them at risk for specific pulmonary diseases.

Chapter 4

Literature Review

Various occupational sectors including the public sector, general industry, construction, and maritime have unique exposures, which if uncontrolled, may lead to adverse health effects. While regulations exist to protect workers from these exposures, it is necessary to monitor certain health outcomes to ensure these exposure controls are effective for each individual. Analysis of this health outcome data on the population level may provide insight into health effects that occur in occupational sectors despite the presence of protective regulatory measures. This research focuses on boat manufacturers, electric utility workers, and first responders. Previous findings indicate that these occupational sectors have an increased risk for pulmonary function impairment to occur among workers because of potential exposure to airborne hazards.

It should be noted that uncertainty is inherent in pulmonary function measurements. However, the objective of this research is to collect available pulmonary function data and use this information to evaluate potential health effects associated with working in various occupational sectors. The articles presented as part of the literature review were included to provide some justification to investigate and identify occupational sectors that may be susceptible to pulmonary function impairment with the ultimate goal of minimizing exposure of workers through hazard control.

4.1 Boat Manufacturing

Manufacturing is an important part of Florida's growing economy. In 2011, Florida was the home to nearly eighteen thousand manufacturing facilities that employed close to 312,000 people with a total payroll of more than sixteen million dollars (eFlorida, 2012). The National Marine Manufacturers Association (NMMA) reported that in 2008, there were 242 active boat builders in Florida (NMMA, 2012). The United States Environmental Protection Agency (USEPA) (2008) states:

Several types of boats are manufactured in the United States, including sailboats, powerboats, yachts, personal watercraft, and small miscellaneous boats such as kayaks and canoes. These boats are manufactured from a variety of materials, including, but not limited to, fiber glass (also known as fiber reinforced plastic or FRP), aluminum, rotationally molded (rotomolded) polyethylene, and wood. Fiberglass is the most common material used in boat manufacturing.

During the manufacturing of fiberglass boats, there are a number of sources of volatile organic compound emissions. The USEPA (2008) reports:

Styrene and methyl methacrylate are the primary volatile organic compounds emitted from fiberglass boat manufacturing materials. The resins contain styrene and the gel coats contain both compounds. Styrene and methyl methacrylate are monomers. A monomer is a volatile organic compound that partially combines itself, or other similar compounds, by a cross-linking reaction

to become a part of the cured resin. A fraction of each monomer evaporates during resin and gel coat application and curing.

In the boat manufacturing industry, styrene is widely used in the production of fiberglass based hulls. In 1995, Florida had thirty-nine boat manufacturing facilities that reported styrene emissions to the Toxic Release Inventory database (USEPA, 2001). Styrene is used as an intermediate for chemical synthesis resins and in the manufacture of polymeric plastics (Baselt, 2002). Styrene is a respiratory irritant, and acute exposures of three hundred to seven hundred parts per million result in nasal and pulmonary irritation and inflammation (Carpenter, 1944; Stewart, 1968; NIOSH, 1983). Obstructive pulmonary disorders have been observed in chronically exposed workers, though exposures controlled at the OSHA permissible exposure limit of one hundred parts per million are thought to prevent chronic pulmonary impairment (Chmielewski & Renke, 1975). However, not all respiratory system studies are conclusive. For example, Stewart et al. (1968) studied the effects of styrene on pulmonary function and found that FEV1 was significantly decreased in only twenty percent of a group of workers exposed to styrene.

While some studies are inconclusive regarding long term styrene inhalation and occupational asthma due to additional chemicals in the environment to which the workers may have been exposed, styrene has been reported as a cause of occupational asthma in a few case reports. Oner et al. (2004) conducted a study to investigate the risk for occupational asthma in relation to exposure to styrene in a large number of workers. He used pulmonary function testing as a measure to associate styrene exposure and

occupational asthma. The findings of the study were not conclusive about the causative role of styrene in occupational asthma but concluded that further research in this area should be conducted.

Current research by Sati et al. (2011) evaluated pulmonary function in workers exposed to styrene in a plastic factory and found a statistically significant reduction (p-value less than 0.05) in most of the lung volumes, capacities (FVC, FEV1, Vital Capacity (VC), Expiratory Reserve Volume (ERV), Inspiratory Reserve Volume (IRV), and Inspiratory Capacity (IC)) and flow rates (Peak Expiratory Flow Rate (PEFR), Maximum Expiratory Flow (MEF) (75%), and Maximum Voluntary Ventilation (MVV)) in the study group (workers) as compared to controls.

In the boat manufacturing industry, methyl methacrylate is also used in the production of fiberglass based hulls. Methyl methacrylate has an odor threshold of less than 0.4 parts per million and is immediately dangerous to life and health at a concentration of one thousand parts per million (Ungers, 2007). A number of studies have shown occupational asthma associated with exposures to methacrylates or more specifically methyl methacrylate in an occupational setting. Occupational asthma is a disease characterized by variable airflow limitation and/or airway hyper responsiveness due to causes and conditions attributable to a particular occupational environment and not to stimuli encountered outside the workplace (Bernstein, 1993).

Piirila et al. (1998) conducted a study of occupational respiratory hypersensitivity caused by preparations containing acrylates in dental personnel. The objective of the study was to report the cases of acrylates induced respiratory hypersensitivity in dental

personnel over a six year period. The results of the study found that twelve cases of respiratory hypersensitivity caused by acrylates were diagnosed in dental personnel in Finland from 1992 to 1997. Nine cases of occupational asthma were verified according to challenge tests with dental acrylate compounds (acrylates, methacrylates, and epoxy acrylates). Peak expiratory flow follow-up showed an occupational effect in the eight examined patients with diagnosed asthma.

In 2002, Piirila et al. published a follow-up study regarding occupational respiratory hypersensitivity in dental personnel. The objective of the study was to evaluate the causes of respiratory hypersensitivity in dental personnel based upon statistics provided by the Finnish Register of Occupational Diseases (1975-1998) and the patient material of the Finnish Institute of Occupational Health (1990-1998). Results of the study found that a total of sixty-four cases of occupational respiratory diseases were diagnosed in dental personnel during 1975 to 1998. Twenty-eight of the reported cases were of occupational asthma with eighteen of those caused by methacrylates. The study showed an increasing frequency of respiratory hypersensitivity among dental personnel with methacrylates being an important cause of the condition.

Marez et al. (1993) investigated bronchial symptoms and respiratory function in workers exposed to methyl methacrylate. The study showed that spirometric values at the start of the work shift were similar in the control group and study group, but a mild airways obstruction appeared during the work shift. The maximum expiratory flow when 50 percent of the forced vital capacity remained to be exhaled (MEF_{50}) and the ratio of MEF_{50} to maximal expiratory flow decreased significantly during the work shift among

exposed workers compared to the controls. It should be noted that the differences remained the same after adjusting for smoking habits. The results of this study support the hypothesis that methyl methacrylate can cause pulmonary function disorders and airway obstruction among exposed workers.

Pickering et al. (1986) evaluated occupational asthma due to methyl methacrylate in an orthopaedic theatre sister. A fifty-six year old theatre sister who presented with asthma had worked in an orthopaedic operating theatre for eleven years in which the mixing process used to make dental implants created a brief period of a high concentration of methyl methacrylate in the air. Her asthmatic symptoms consistently resolved when she was absent from work for a period of time. Testing was conducted and results found that a late asthmatic reaction occurred in the patient after challenge with methyl methacrylate which resulted in a maximal fall in FEV1 of twenty-five percent. The authors concluded that brief but repeated exposure to high peak concentrations of methyl methacrylate which is a known pulmonary sensitizer is undesirable and that the use of a fume cupboard for the initial mixing process is strongly recommended.

Lozewicz et al. (1985) evaluated occupational asthma due to methyl methacrylate and cyanoacrylates in seven patients. One of two patients exposed to methyl methacrylate had an asthmatic reaction. The patient was a dental assistant that produced paste by mixing polymethyl methacrylate powder with monomethyl methacrylate liquid for the production of dental prosthetic trays. Inhalation testing included modeling his exposure at work to methyl methacrylate for twenty minutes, which provoked a fall in PEF of twenty-four percent. The test was repeated two weeks later and produced similar

immediate asthmatic reaction, which also resolved over a two-hour period. The author's conclusion included substitution of less volatile, longer chain alkyl cyanoacrylate homologues as well as the use of appropriate ventilation when using acrylates.

Jerdrychowski et al. (1982) assessed the biological effect of styrene and methyl methacrylate on the respiratory system in an industrial population. Four hundred and fifty four males from the exposed group and 683 workers from the control were evaluated by standardized interviews on chest symptoms and lung function testing. The frequency of lung obstruction appeared to be more than twice as high among the exposed group compared to the control group. The exposed group showed much poorer lung function as well when compared to the control group. The overall results of the study showed that the harmful effect of styrene and methyl methacrylate on lung function was strong despite the rather low prevalence of chronic chest symptoms. The results of the study further support the need for epidemiological evidence aimed at explaining a cause-effect relationship between low-level concentrations of styrene and methyl methacrylate in the industrial environment and potential harmful effects.

Due to the potential for occupational exposure to styrene and methyl methacrylate during the boat manufacturing process, the potential for pulmonary function impairment among workers exist. Spirometry data provides an opportunity to perform occupational health surveillance and further determine the potential association between styrene exposure and pulmonary function impairment as well as develop safe work practices in this industry with the ultimate goal of reducing chemical exposure.

4.2 Utilities

In Florida, fossil fuel power generation is used to provide electricity to sustain commercial, agricultural, and residential needs. Operations involved in these power plants include coal handling, boiler-turbine operation, and routine maintenance. Utility workers that perform these operations have the potential to be exposed to chemicals in the workplace that can affect pulmonary function. For example, coal handling includes coal receiving, storage, and recovery for fueling the turbine generator units and leads to certain tasks which are associated with high coal dust air levels and require respiratory protection (Jackson, 1998).

During boiler maintenance, cleaning, and repair, utility workers can be exposed to fossil fuel ash particles. Hauser et al. (2001) conducted a two-year longitudinal study of lung function among 118 boilermakers and found that working at gas, oil, and coal-fired plants is associated with an annual loss in FEV1.

Bridbord et al. (1979) identified a number of irritants, vesicants, and fibrogens within coal-fired power plants which included sulfur dioxide (SO₂), SO₂ reaction products, nitrogen oxide (NO), nitrogen dioxide (NO₂), fly ash, aldehydes, coal dust, and asbestos. Potential sources of these chemicals included boiler leaks, flue gas leaks, stack emissions, all stages of coal handling, and insulation material. Over sixty-five percent of SO₂ released to the air, or more than thirteen million tons per year, comes from electric utilities, especially those that burn coal (Scientific Committee on Occupational Exposure Limits, 2008). NIOSH (1978) has identified SO₂ as a respiratory irritant and indicates that studies have shown increased pulmonary resistance at various concentrations.

Asbestos is another airborne risk that electric utility workers encounter during routine maintenance. Vathesatogkit et al. (2004) conducted a study related to asbestos exposure by using subjects recruited from Consolidated Edison, which is an electric utility located in New York City. In regard to pulmonary function, the study concluded that in individuals with a history of asbestos exposure, the presence of asbestos bodies in BAL cells is associated with a higher prevalence of parenchymal abnormalities, respiratory symptoms, and a reduction in pulmonary function.

Utility workers also have the potential to be exposed to polychlorinated biphenyl (PCB) when working with transformers and capacitors. Warshaw et al. (1979) found a decrease in vital capacity in PCB-exposed workers in a capacitor manufacturing facility. This finding indicates the potential for compromise in pulmonary function after PCB exposure.

Due to the potential for occupational exposure of electrical utility workers during fossil fuel power generation and routine maintenance to a variety of chemicals that may decrease pulmonary function, spirometry data provides an opportunity to perform occupational health surveillance and evaluate safe work practices in this industry with the ultimate goal of reducing chemical exposure.

4.3 First Responders

First responders are exposed to a variety of fumes, gases, and particulates during the course of their job. They often disregard the risk of chemical exposure in order to attend to injured victims and/or contain the release. Consider the first responders that

were on the scene after the collapse of the World Trade Center. They encountered high levels of airborne pollutants and have since reported respiratory symptoms and developed pulmonary function abnormalities. Banauch et al. (2006) found that World Trade Center–exposed workers experienced a substantial reduction in adjusted average FEV1 during the year after 09/11/2001 and that this exposure-related FEV1 decrement equaled twelve years of aging-related FEV1 decline.

First responders include fire fighters, police, and emergency medical personnel. All of these occupations are physically demanding and challenging, with potential for exposing workers to toxic agents in a dynamic and uncontrolled environment. For example, toxic chemicals emitted as a result of incomplete combustion and pyrolysis include hydrochloric acids, carbon monoxide, vinyl chloride, hydrogen sulfide, etc. (Becker, 1985). These chemicals have the potential to cause pulmonary function impairment if exposures are not properly controlled. Burgess et al. (2001) state:

Occupational smoke exposure may result in acute adverse health effects, particularly during periods when respiratory protection is not worn. These changes include transient reductions in spirometric measurements and increased airway reactivity. Chronic respiratory effects may also occur, although the increased use of respiratory protection appears to have had a beneficial effect.

Musk et al. (1979) found that following smoke exposure, the average decrease in FEV1 was 0.05 liters among firefighters and that this decline in FEV1 was related to the severity of smoke exposure as estimated by the firefighter and to the measured particulate concentration of the smoke to which he was exposed. In addition, the effect of

pulmonary function impairment following exposure to house fires has shown a decrease in FEV1 with a small subgroup of firefighters who develop more substantial and potentially clinically important decreases in pulmonary function after smoke exposure (Large, 1990).

Chattopadhyay et al. (2004) conducted a study on the effect of respiratory function of firefighters as a result of a chemical warehouse fire and found restrictive, obstructive and combined restrictive and obstructive types of pulmonary dysfunction as a result of exposure. Research conducted by Sparrow et al. (1982) also found that firefighters had a greater loss of pulmonary function (FVC and FEV1) than non-firefighters, which confirm earlier reports of a chronic effect of firefighting on pulmonary function and suggest an association of this occupation with increased respiratory symptoms and disease.

Burgess et al. (2001) evaluated adverse respiratory effects following overhaul in firefighters. A total of fifty-one firefighters were monitored for exposure to products of combustion to determine any changes in spirometric measurements and lung permeability. Approximately half of the firefighters in the study wore no respiratory protection during overhaul while the other half wore cartridge respirators. The results of the study revealed acute changes in spirometric measurements and lung permeability following firefighter overhaul even in those participants wearing full-face cartridge respirators. Changes in FEV1 were associated with levels of specific products of combustion, demonstrating a dose-response relationship. Based on the results of the

study, the authors recommend that a self-contained breathing apparatus continue to be used during overhaul.

First responders are potentially exposed to a variety of chemicals in uncontrolled situations that could affect pulmonary function. Spirometry data provides an opportunity to perform occupational health surveillance to evaluate pulmonary function impairment as well develop safe work practices in this industry with the ultimate goal of reducing chemical exposure.

Chapter 5

Methods

5.1 Study Population

A record review was conducted on pulmonary function tests from the workers of boat manufacturing companies, electric utility companies, and first responders in the state of Florida. Inclusion criteria included any worker over the age of eighteen whose respirator use required pulmonary function testing. Records included data for principal confounding factors regarding pulmonary function outcomes including smoking history, age, gender, and height.

A standard population for comparison consisted of the NHANES III Raw Spirometry cohort, which consists of pulmonary function tests for 16,606 individuals sampled in the United States. The Raw Spirometry file was merged by respondent identification number with the NHANES III Household Adult Data file to obtain demographic and behavioral confounder data. The NHANES III control population was further restricted by age to reflect the age range of the study population and unacceptable tests were removed from analysis by technician quality code. Record reviews were approved under the University of South Florida Institutional Review Board (IRB) # 00001348. A copy of the IRB approval letter is presented in Appendix I.

5.2 Pulmonary Function

All study population pulmonary function testing was conducted using the Koko spirometry system. The best attempt of a minimum of three spirometry trials was used for analysis in both the study population and the control population. The pulmonary function test outcomes used for analysis included FEV1 and FVC. All spirograms were reviewed by a licensed physician and spirograms not meeting American Thoracic Society acceptability and reproducibility criteria presented in Table 4 were removed from analysis.

Table 4: American Thoracic Society Acceptability and Reproducibility Criteria

ACCEPTABILITY CRITERIA
Good start-of-test: <ul style="list-style-type: none">• Extrapolated volume is less than 5% of FVC or 0.15 L, whichever is greater;• No hesitation or false start;• A rapid start to rise time;• No cough, especially during the first second on the maneuver;• No early termination of exhalation;• A minimum exhalation time of 6 seconds is recommended, unless there is an obvious plateau of reasonable duration or the subject cannot or should not continue to exhale further;• No maneuver should be eliminated solely because of early termination.
REPRODUCIBILITY CRITERIA
After three acceptable spirograms have been obtained, apply the following tests: <ul style="list-style-type: none">• Are the two largest FVCs within 0.2L of each other?• Are the two largest FEV1s within 0.2L of each other?
Number of trials: <ul style="list-style-type: none">• A minimum of 3 acceptable FVC maneuvers should be performed.• If a subject is unable to perform a single acceptable maneuver after 8 attempts, testing may be discontinued. However, after additional instruction and demonstration, more maneuvers may be performed depending on the subject's clinical condition and tolerance.

(Adapted from American Association for Respiratory Care. AARC Clinical Practice Guideline: Spirometry, 1996 Update. Respiratory Care, Volume 41, Number 7, 629-636)

5.3 Statistical Analysis

The role of statistical analysis in research is vital because it gives meaning to the data that is collected. The goal in any data analysis is to extract from raw information the accurate estimation (Alexopoulos, 2010). The appropriate statistical tests chosen for this research are described in the paragraphs below.

To determine if the worker population experienced abnormal pulmonary function compared to the standard population, mean values were produced for FEV1 and FVC and the significance of the differences were evaluated using the students t-test. These analyses were further stratified by median age, median height, gender, and smoking history. To determine which factors were most predictive of pulmonary function, multivariate linear regression analysis was performed for the outcomes of FEV1 and FVC. Linear regression is the procedure that estimates the coefficients of the linear equation, involving one or more independent variables that best predict the value of the dependent variable which should be quantitative (Alexopoulos, 2010). Multivariate analysis evaluated the following variables as predictors of pulmonary function outcomes: age, gender, height, pack-years of smoking, and status as a worker.

There is currently an active debate regarding the use of the FEV1/FVC ratio as a definitive criterion for the diagnosis of obstructive disorders, but it is generally acknowledged that lowered FEV1/FVC ratio is indicative of obstruction when taken into context with other pulmonary function testing data for the individual and patient demographics (Mohamed, 2011). This research evaluated the study population for deficits at the higher end of the normal FEV1/FVC range, 0.80. A categorical approach

was used to evaluate potential pre-clinical pulmonary obstruction using logistic regression to evaluate associations with producing an abnormal FEV1/FVC ratio, defined as less than 0.80. Logistic regression coefficients can be used to estimate odds ratios for each of the independent variables in the model (Alexopoulos, 2010). Categories for independent variables were defined as above and below median height and median age, females vs. males, nonsmokers vs. those with a smoking history. Statistical significance was determined by a p-value less than 0.05 for all analytical tests. All statistical analyses were performed using SAS version 9.1.2.

Chapter 6

Pulmonary Function Testing in Boat Manufacturer Workers

6.1 Data Source

A record review was conducted on seventy-five pulmonary function tests from the workers of three boat manufacturing companies in the state of Florida based upon the inclusion criteria provided in the Chapter 5.1. Restriction of the NHANES III data and removal of unacceptable spirometry tests resulted in a final control population of 4,729 subjects.

6.2 Results

6.2.1 Univariate Analysis

The population demographics for both the study population (boat manufacturer workers) and the NHANES III segment used for analysis are reported in Table 5. The study population was largely male and approximately forty-one percent had a history of tobacco smoking. The study population was somewhat younger overall, compared to the NHANES III median age.

Figure 6 provides the results of means testing for FEV1 and FVC comparing the total study population to the NHANES III segment. The study population demonstrated a modestly higher mean FEV1, while no statistically significant differences were found

between mean FVC values when comparing the populations as a whole. The differences in age and disproportionate gender represented in the study population necessitated the use of stratified analysis to determine the effect of these population differences on evaluating the effect of boat manufacturer worker status on pulmonary function.

Stratification by age (below median), height, and smoking status yielded statistically significant larger mean values for FEV1 and FVC measurements for the study population. When analyzing females and those at or above median age, no statistically significant differences were found. The results of the analysis are reported in Figures 7 through 14.

Table 5: Summary of Study Population and NHANES III Control Population

	<u>Study Population</u>	<u>NHANES III</u>
Total population n =	75	4,729
Males n =	66	3,446
Females n =	9	1,283
Smoking History (YES)	31	2,897
Smoking History (NO)	44	1,832
Median Height (Inches)	67	69
Median Age (Years)	29	40

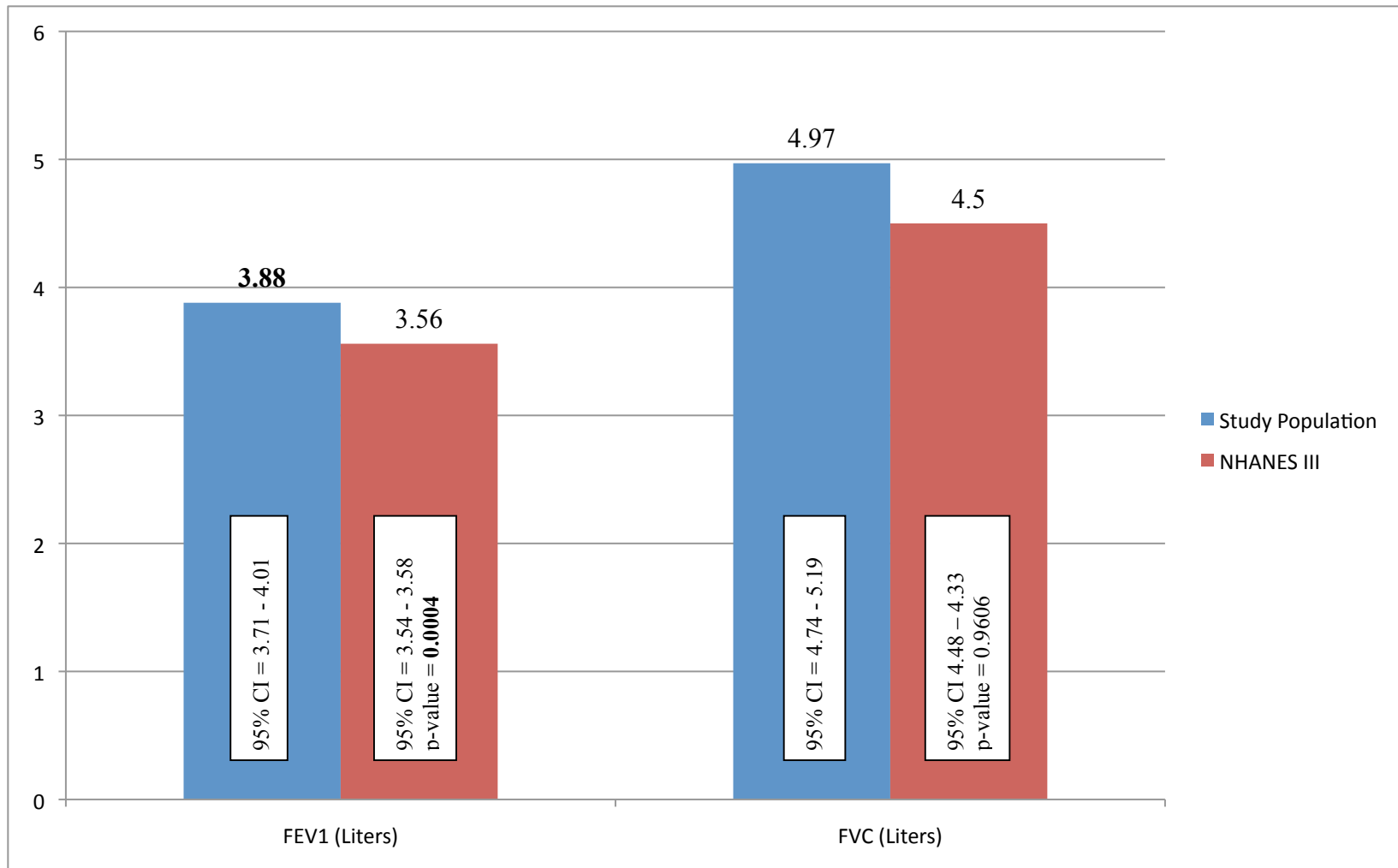


Figure 6: Pulmonary Function Mean for the Total Population. *Bolded values are statistically significant.*

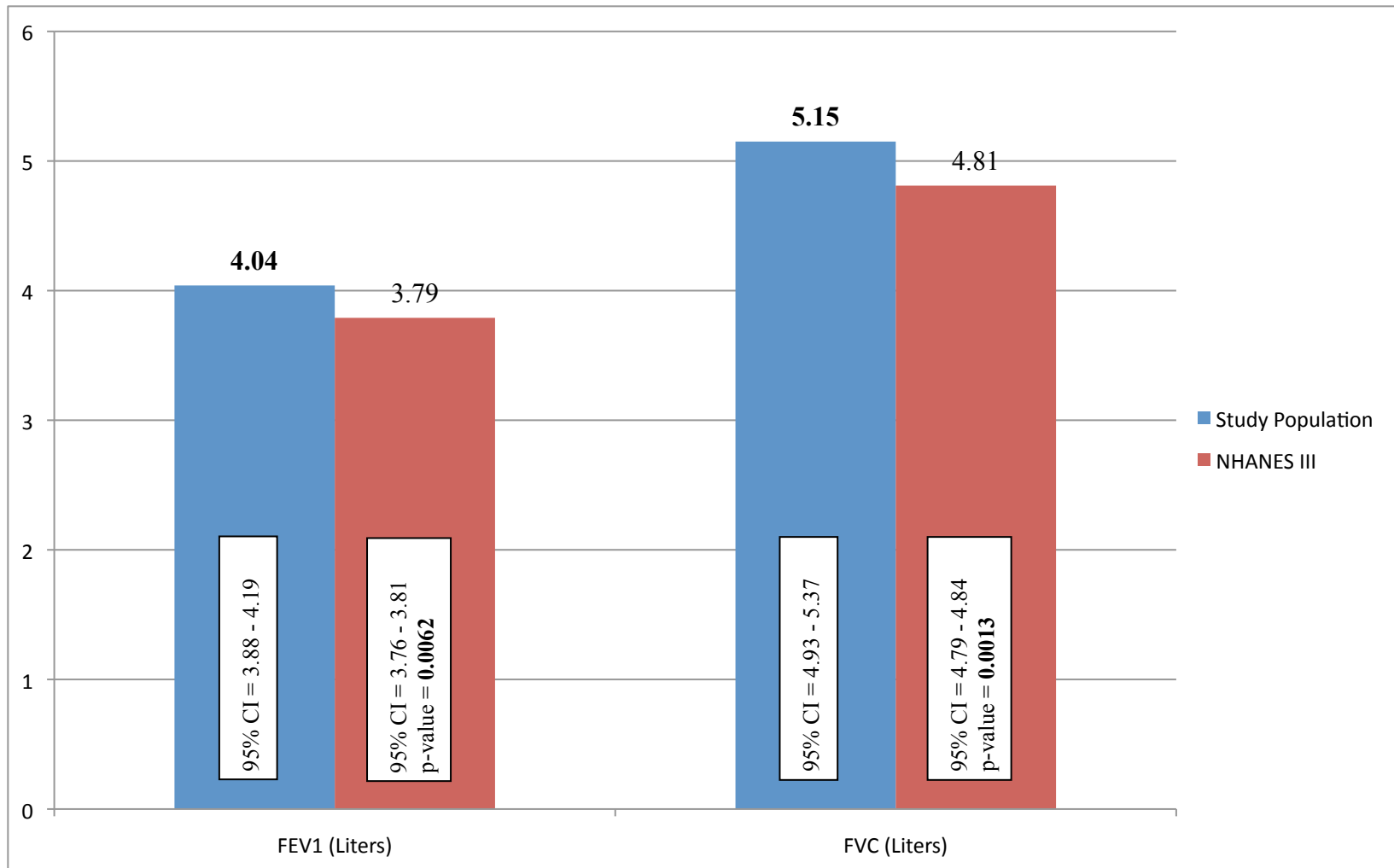


Figure 7: Pulmonary Function Mean for Males. *Bolded values are statistically significant*

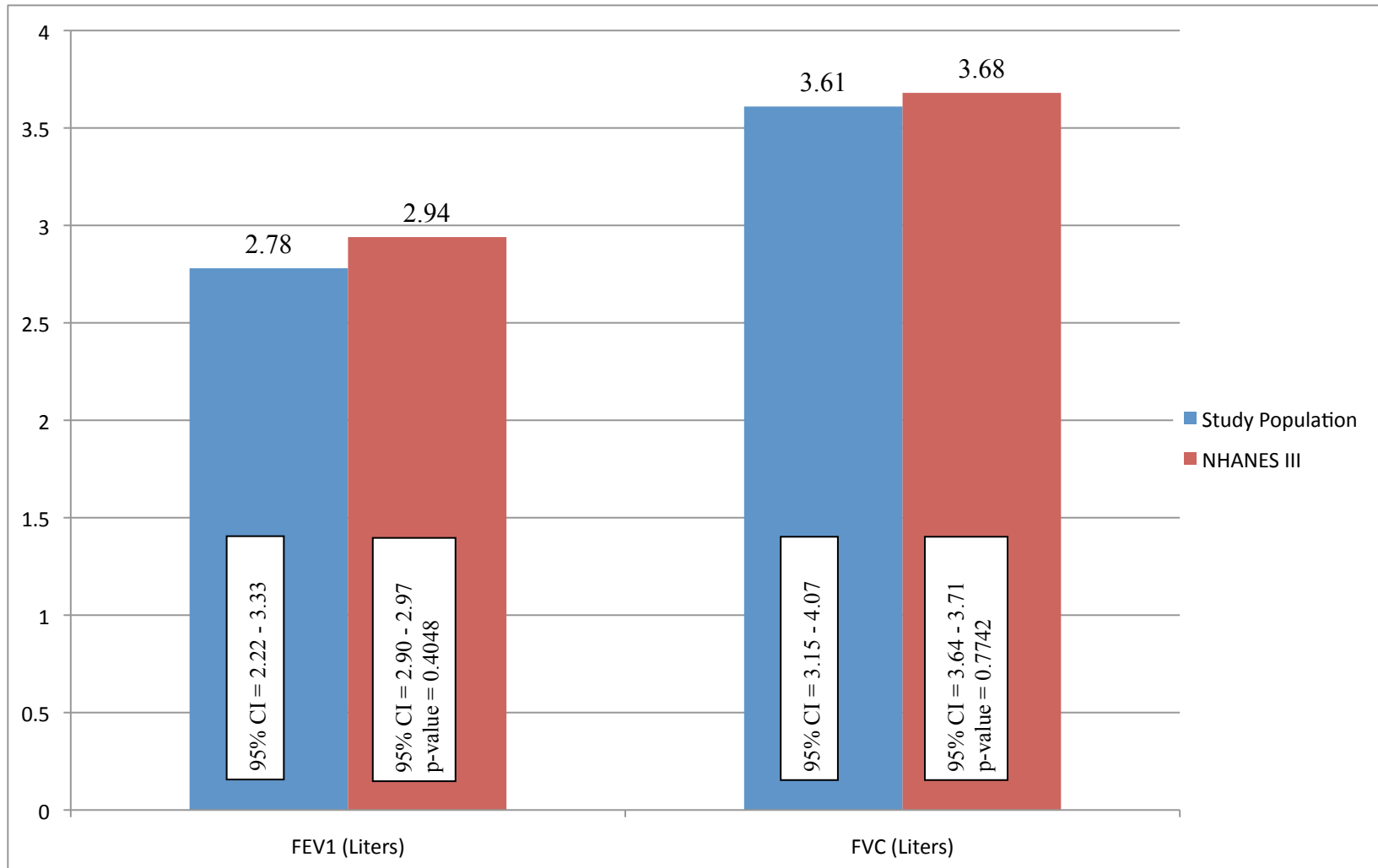


Figure 8: Pulmonary Function Mean for Females

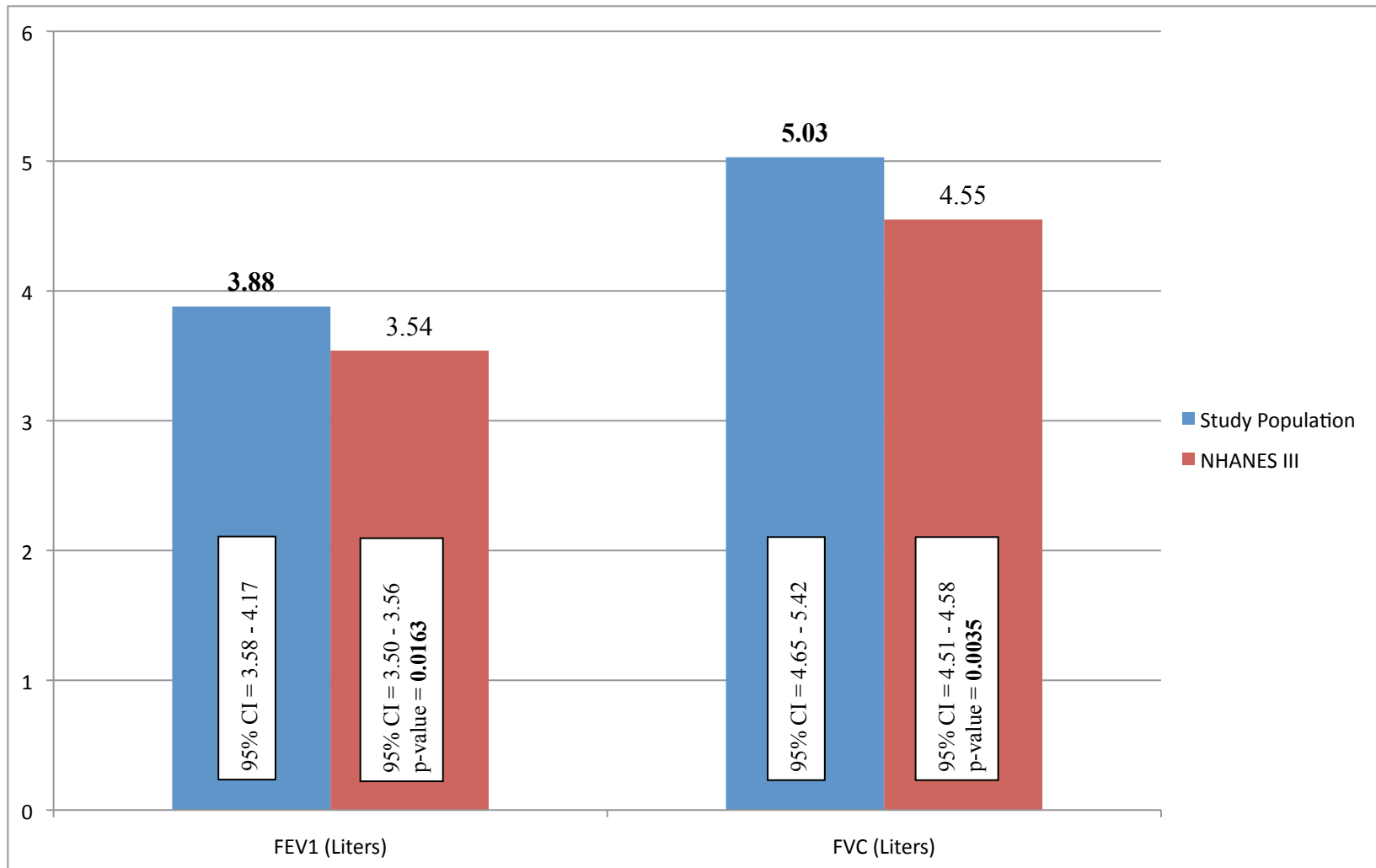


Figure 9: Pulmonary Function Mean for Smoking History (YES). *Bolded values are statistically significant.*

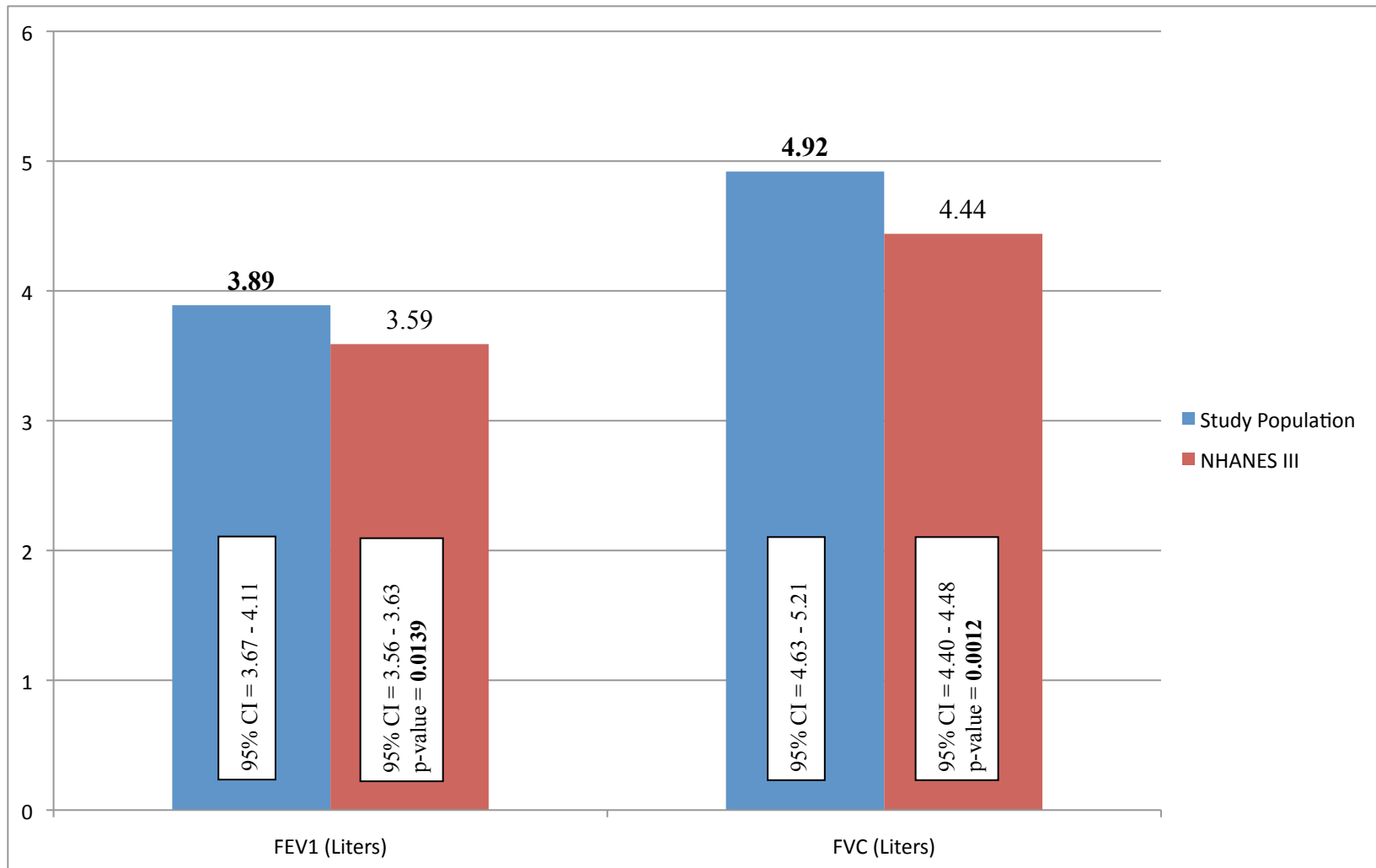


Figure 10: Pulmonary Function Mean for Smoking History (NO). *Bolded values are statistically significant*

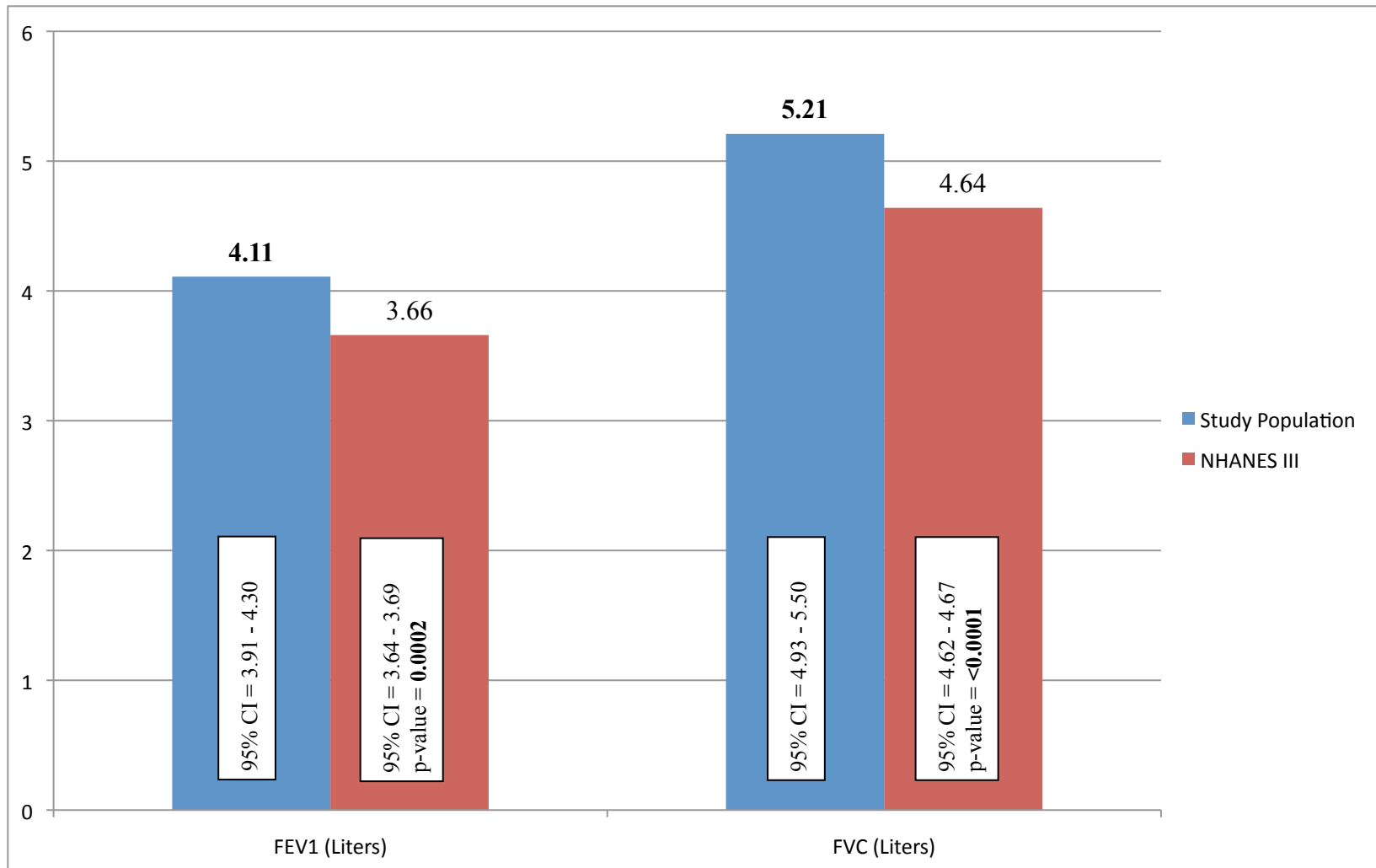


Figure 11: Pulmonary Function Mean for Height At or Above Median (67 inches). *Bolded values are statistically significant.*

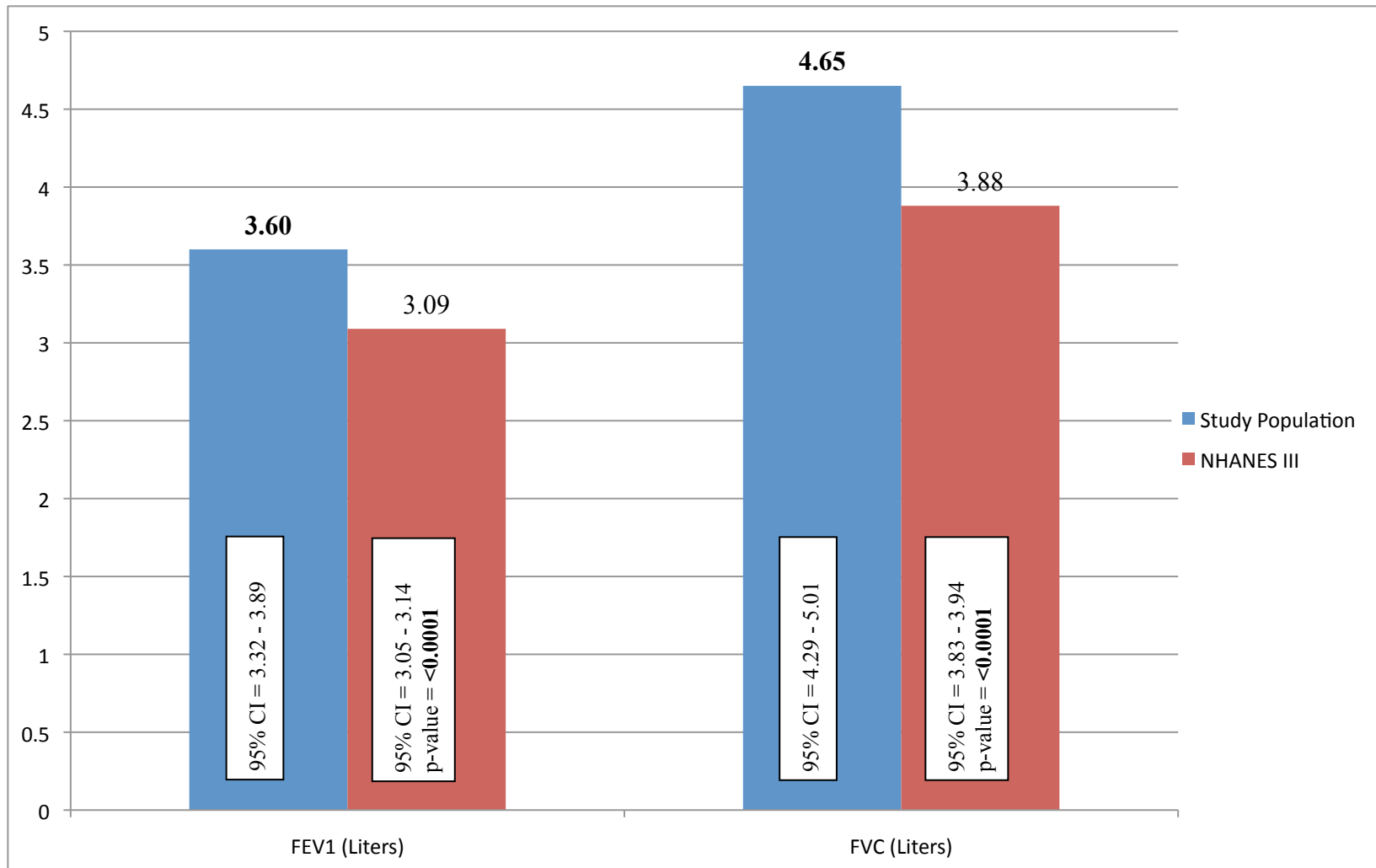


Figure 12: Pulmonary Function Mean for Height Below Median (67 inches). *Bolded values are statistically significant.*

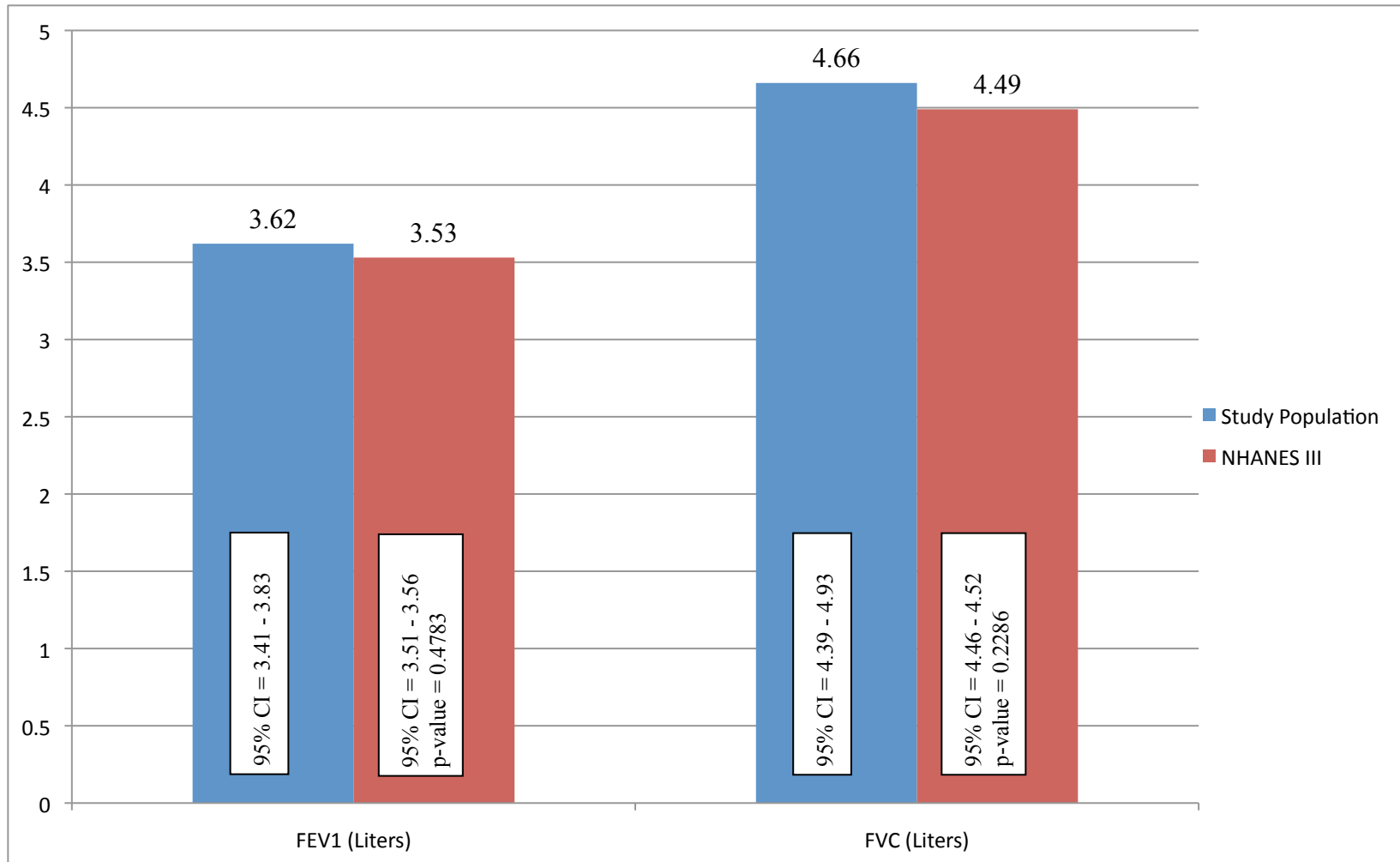


Figure 13: Pulmonary Function Mean for Age at or Above Median (29 years)

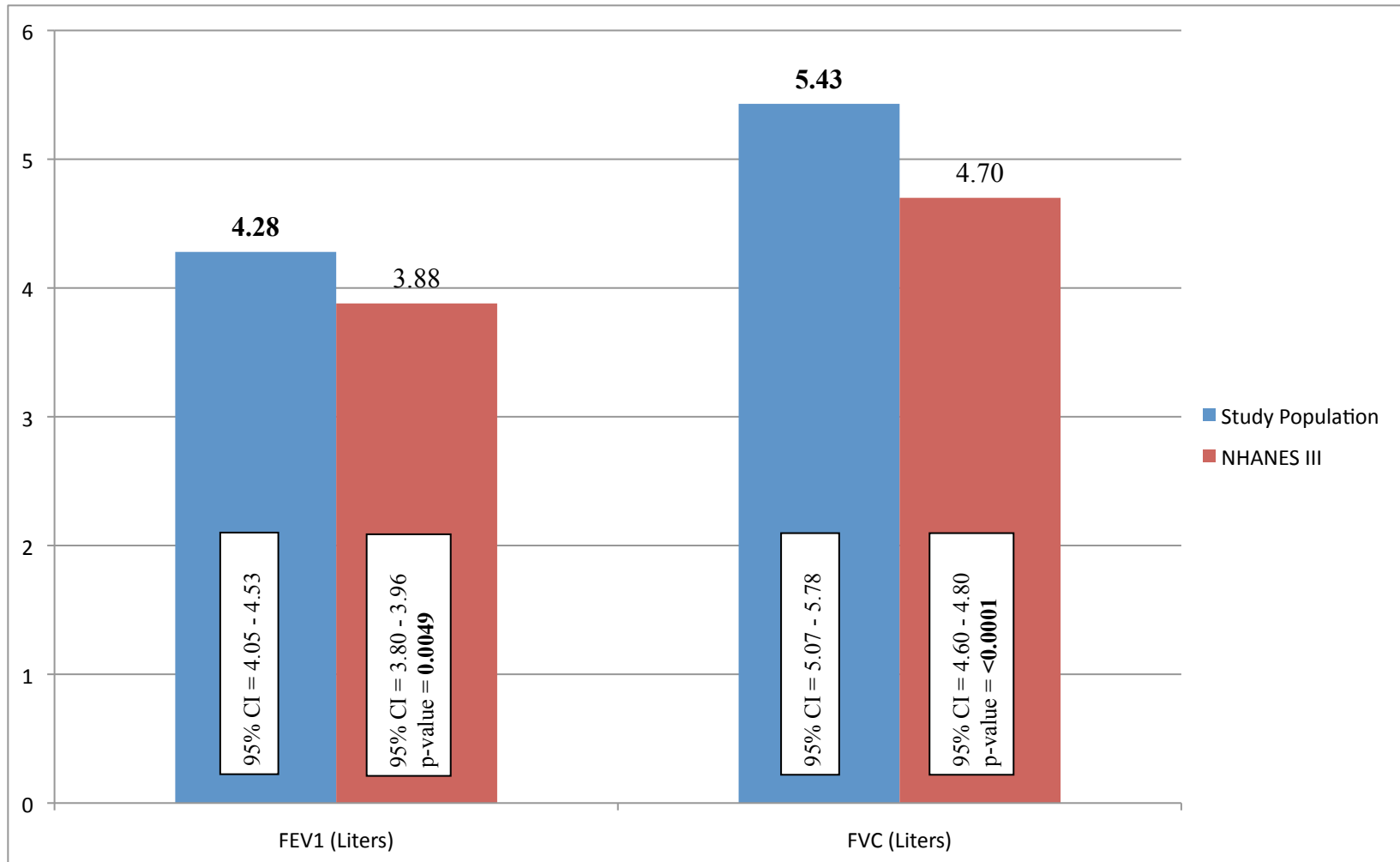


Figure 14: Pulmonary Function Mean for Age Below Median (29 years). *Bolded values are statistically significant*

6.2.2 Multivariate Analysis

Multivariate analysis was conducted by constructing linear regression models including all data elements known to impact pulmonary function including age, height, gender, and smoking history. The parameter estimates identify the magnitude of effect each predictor has on either increasing or decreasing pulmonary function in the total population. Statistically significant predictors were identified as having a p-value less than 0.05. The results of the linear regression analysis for FEV1 are reported in Table 6. The analysis identified age, height, gender, and smoking pack-years as statistically significant predictors of FEV1. The adjusted outcome for status as a boat manufacturer worker was not a statistically significant predictor of FEV1.

The results of the linear regression analysis for FVC are reported in Table 7. The analysis identified age, height, gender, but not smoking pack-years as statistically significant predictors of FVC. The adjusted outcome for status as a boat manufacturer worker was also a significant predictor of FVC in this analysis. With a parameter estimate of 0.2957, status as a boat manufacturer conferred a modest increase to FVC compared to the control population.

Logistic regression analysis was used to determine the effect of pulmonary function predictors on generating an FEV1/FVC ratio less than 0.80 (Table 8). From this analysis, two statistically significant factors impacted the FEV1/FVC ratio: age and smoking history. Height, gender, and status as a boat manufacturer worker were not associated with the production of a FEV1/FVC ratio less than 0.80. Those in the population over the median age for boat manufacturer workers (29) were approximately

twice as likely to produce an FEV1/FVC ratio less than 0.80. Similarly, those with no smoking history were nearly half as likely to produce an FEV1/FVC ratio less than 0.80.

Table 6: Predictors of FEV1 from Linear Regression Analysis

<u>FEV1</u>			
Predictor	Parameter Estimate	Standard Error	p-value
Age at test	-0.0394	0.0017	<0.0001
Height at test (in)	0.0829	0.0057	<0.0001
Gender (females vs. males)	-0.6491	0.0376	<0.0001
Smoking History (pk-yrs)	-0.0034	0.0011	0.0030
Boat Manufacturer Status	0.1077	0.0706	0.1276

Bolded values are statistically significant.

Table 7: Predictors of FVC from Linear Regression Analysis

<u>FVC</u>			
Predictor	Parameter Estimate	Standard Error	p-value
Age at test	-0.0328	0.0021	<0.0001
Height at test (in)	0.1063	0.0070	<0.0001
Gender (females vs. males)	-0.8538	0.0461	<0.0001
Smoking History (pk-yrs)	0.0023	0.0014	0.0951
Boat Manufacturer Status	0.2957	0.0865	0.0006

Bolded values are statistically significant.

Table 8: Logistic Regression Analysis of FEV1/FVC to Examine the Effect of Predictors on Producing an Abnormal Ratio (<0.80 FEV1/FVC)

<u>FEV1/FVC <0.80</u>		
Predictor	Odds Ratio	95% Confidence Limit
Age above median >29 years	2.16	1.82 – 2.56
Height above median >67 inches	1.11	0.97 – 1.27
Gender (females vs. males)	0.92	0.80 – 1.07
Smoking History (effect on non-smoking)	0.55	0.48 – 0.62
Boat Manufacturer Status	0.96	0.59 – 1.56

Bolded values are statistically significant.

6.3 Discussion

This research examined the feasibility of conducting a cross sectional surveillance evaluation of workers in the boat manufacturing industry from three boat manufacturing facilities in the state of Florida, which had maintained records of pulmonary function testing for workers required to use respiratory protection. Statistical comparisons between the occupational population and the NHANES III population segment, limited by age and height to reflect the occupational population's demographics, demonstrated the putative factors that altered pulmonary function in our population of interest.

The results of this research indicated that the boat manufacturer workers experienced a modest, but statistically significant, increase in FEV1 mean values over the NHANES III population in both total and stratified analyses, including stratification by gender, age, height, and smoking history. While the analysis of the total population for FVC mean values did not demonstrate a difference from the control population, stratified analyses demonstrated modest, significant increases in mean FVC for some stratified analyses by gender, age, height, and smoking history. No analysis that examined mean values demonstrated better pulmonary function in the control group versus the target worker population.

In the linear regression analysis performed to examine the effect of salient cofactors on pulmonary function, FEV1 analysis demonstrated that age, height, gender, and smoking pack-years all significantly affected pulmonary function of the population in the expected direction. That is to say, increased age, female gender, and increased pack-years of smoking decreased FEV1, while increased height increased FEV1. Status as a

boat manufacturer worker was not found to have a statistically significant effect on FEV1.

Similar results were reported for the analysis of FVC, with the exception of pack-year history of smoking, which did not demonstrate statistical significance in this analysis. As well, status as a boat manufacturer worker conferred a modest, significant increase in FVC. The results of the linear regression analysis for FEV1 and FVC outcomes indicate that the predominate factors that affect pulmonary function values are those traditionally known to impact lung volume and clearance, e.g. age, height, gender, and smoking history. A modest positive effect on FVC was observed for boat manufacturer workers in both the stratified analysis, as well as the linear regression analysis. This may indicate the presence of the 'healthy worker effect' in the occupational population related to more time spent in active labor compared to the NHANES III population which may contain unemployed persons or those engaged in more sedentary labor.

Logistic regression was performed for the outcome of the FEV1/FVC ratio to evaluate the potential for obstructive disorders among the target occupational population compared to the NHANES III population. A cutoff point of less than 0.80 FEV1/FVC was used to classify persons with abnormal FEV1/FVC values that could potentially be an indicator of pre-clinical pulmonary obstruction. In this analysis, status as a boat manufacturer worker was not significantly associated with an FEV1/FVC value of less than 0.80. However, the analysis clearly demonstrated that the older half of the population was twice as likely to produce a lower FEV1/FVC ratio, and non-smokers

were half as likely to produce a lower FEV1/FVC ratio compared to the smokers in the population.

Through the use of OSHA mandated pulmonary function testing and the available NHANES III spirometry data set, this study was able to efficiently evaluate the pulmonary health of a substantive cross section of a specific industry: boat manufacturer workers. The data collected in both the OSHA mandated testing and the NHANES III spirometry data allows for the control of confounding factors that impact measures of pulmonary function so that statistical comparisons can identify deficits in pulmonary function and indicate whether or not those deficits are associated with an occupational sector. This research did not identify any pulmonary function deficits in the target occupational population and it demonstrated that in all cases boat manufacturer workers had equivalent or modestly superior pulmonary function compared to a baseline population.

Chapter 7

Pulmonary Function Testing in Utility Workers

7.1 Data Source

A record review was conducted on 227 pulmonary function tests from a population currently employed as utility workers in the state of Florida based upon the inclusion criteria provided in Chapter 5.1. Restriction of the NHANES III data and removal of unacceptable spirometry tests resulted in a final control population of 4,958 subjects. There were only two females in the worker population; therefore females were removed from both the worker and NHANES III population for analysis.

7.2 Results

7.2.1 Univariate Analysis

The population demographics for both the study population (utility workers) and the NHANES III segment used for analysis are reported in Table 9. Approximately forty-one percent of the study population had a history of tobacco smoking and was slightly older overall, compared to the NHANES III mean age.

Figure 15 provides the results of means testing for FEV1 and FVC comparing the total study population to the NHANES III segment. The study population demonstrated modestly higher (statistically significant) mean values for FEV1 and FVC when

compared to the NHANES III control population. The difference in age represented in the study population necessitated the use of stratified analysis to determine the effect of the population difference on evaluating the effect of utility worker status on pulmonary function.

No significant differences were found between mean pulmonary function test values of utility workers and NHANES III study subjects when stratified by age, height, and smoking status except among older utility workers, who demonstrated modestly better pulmonary function values compared to their NHANES III counterparts. The results of the analysis are reported in Figures 15 through 21.

Table 9: Summary of Study Population and NHANES III Control Population

	<u>Study Population</u>	<u>NHANES III</u>
Total population n =	225	4958
Males n =	225	4958
Females n =	0	0
Smoking History (YES)	93	3144
Smoking History (NO)	132	1814
Mean Height (Inches)	70	69
Mean Age (Years)	45	41

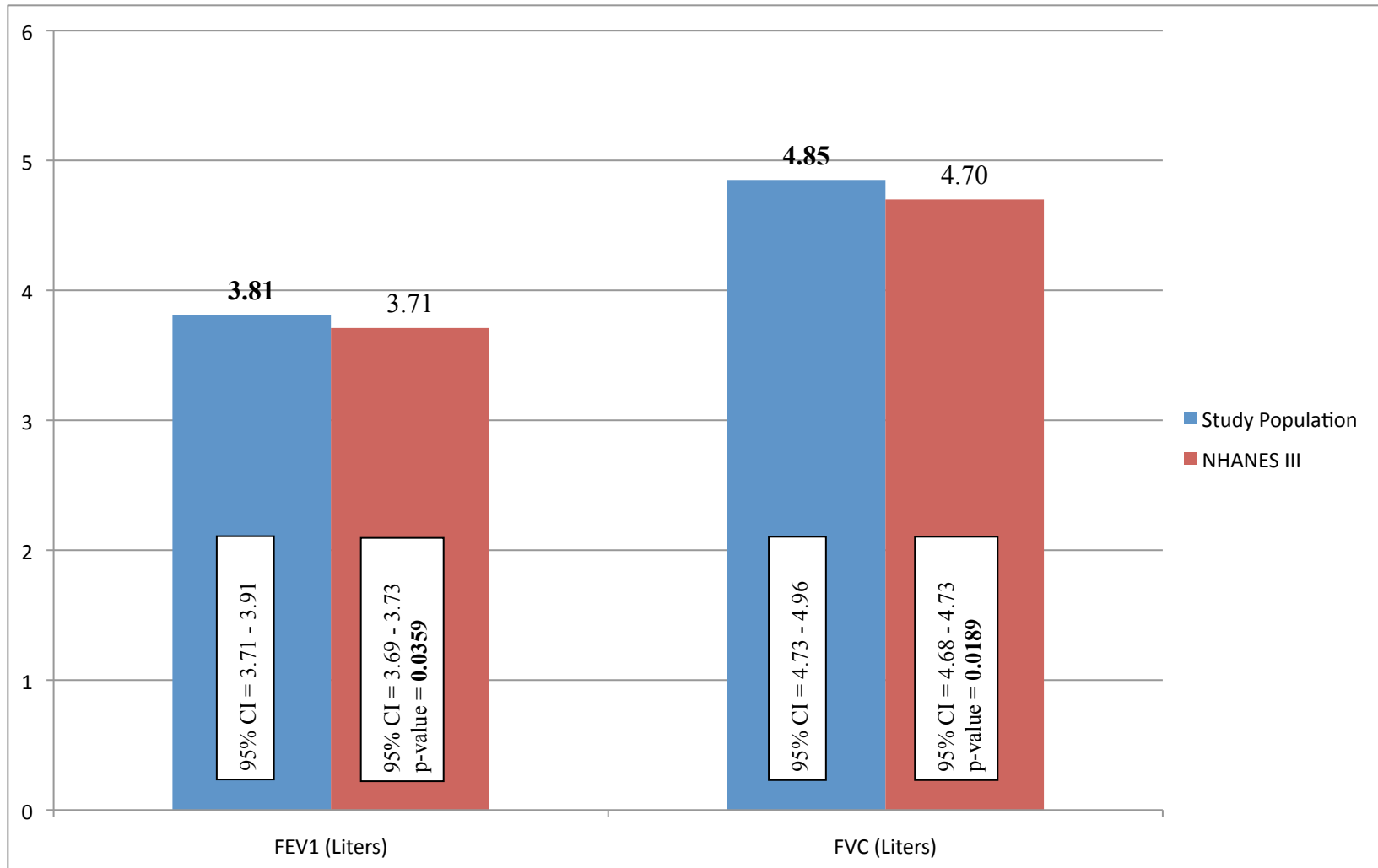


Figure 15: Pulmonary Function Mean for the Total Population. *Bolded values are statistically significant.*

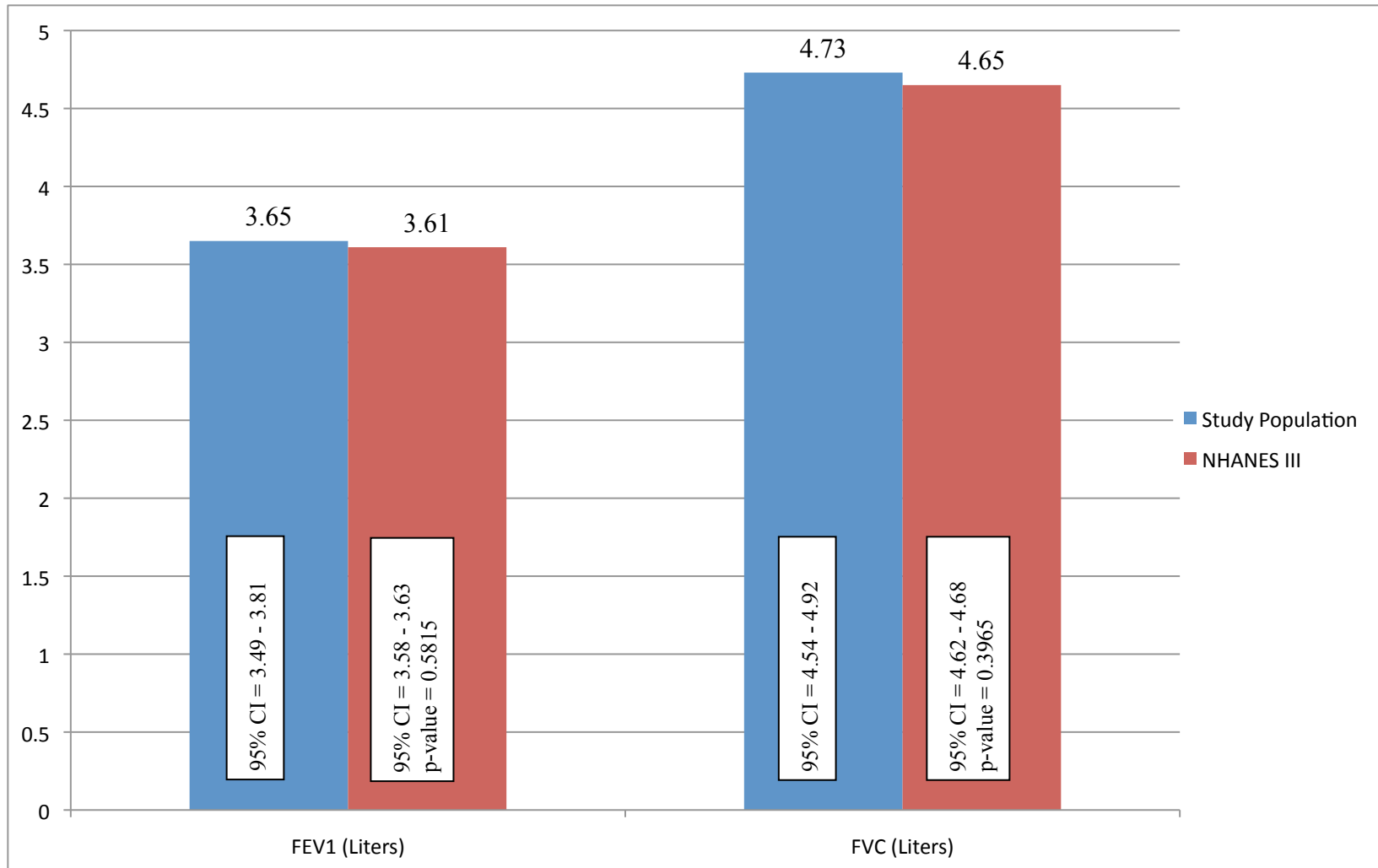


Figure 16: Pulmonary Function Mean for Smoking History (YES)

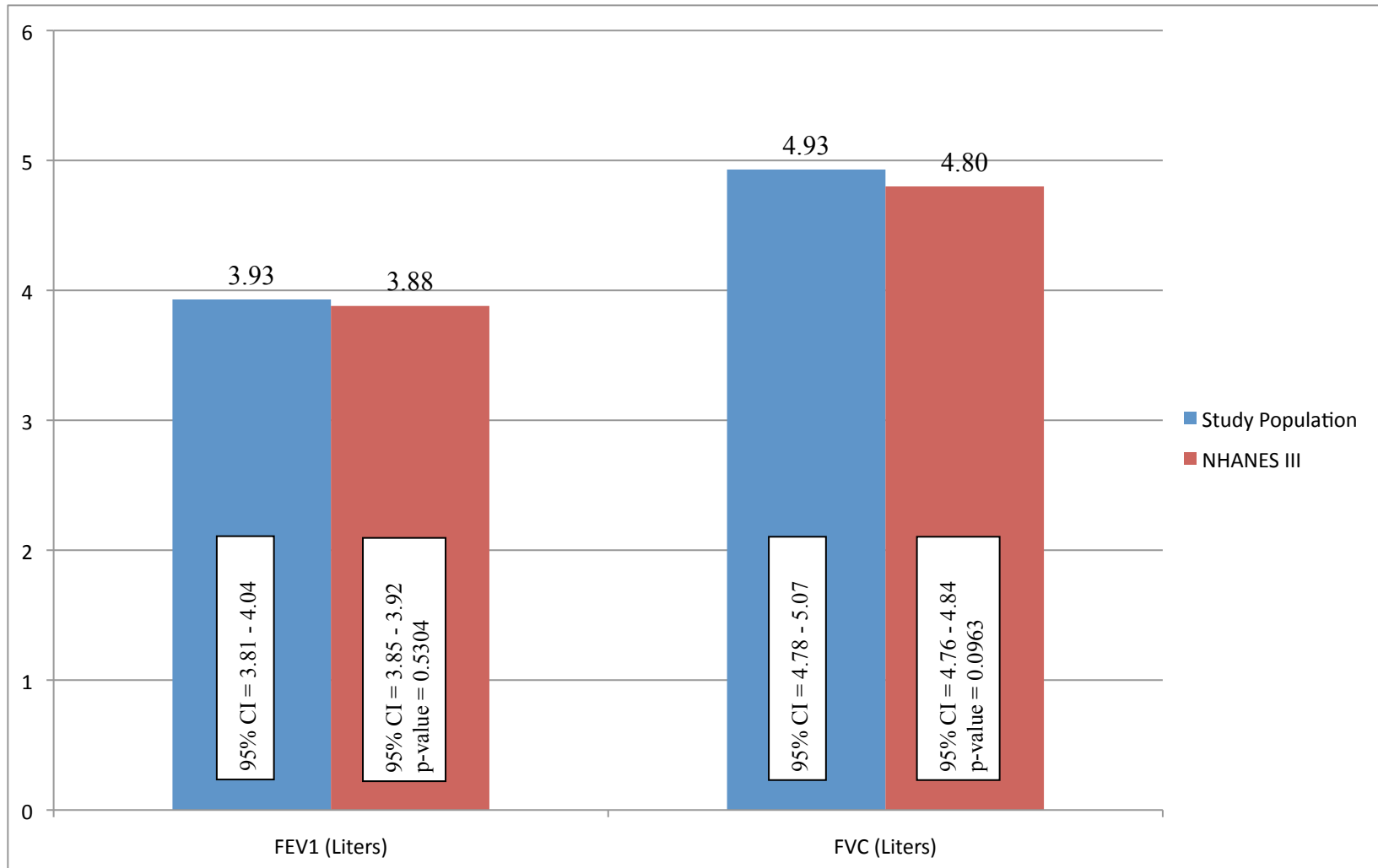


Figure 17: Pulmonary Function Mean for Smoking History (NO)

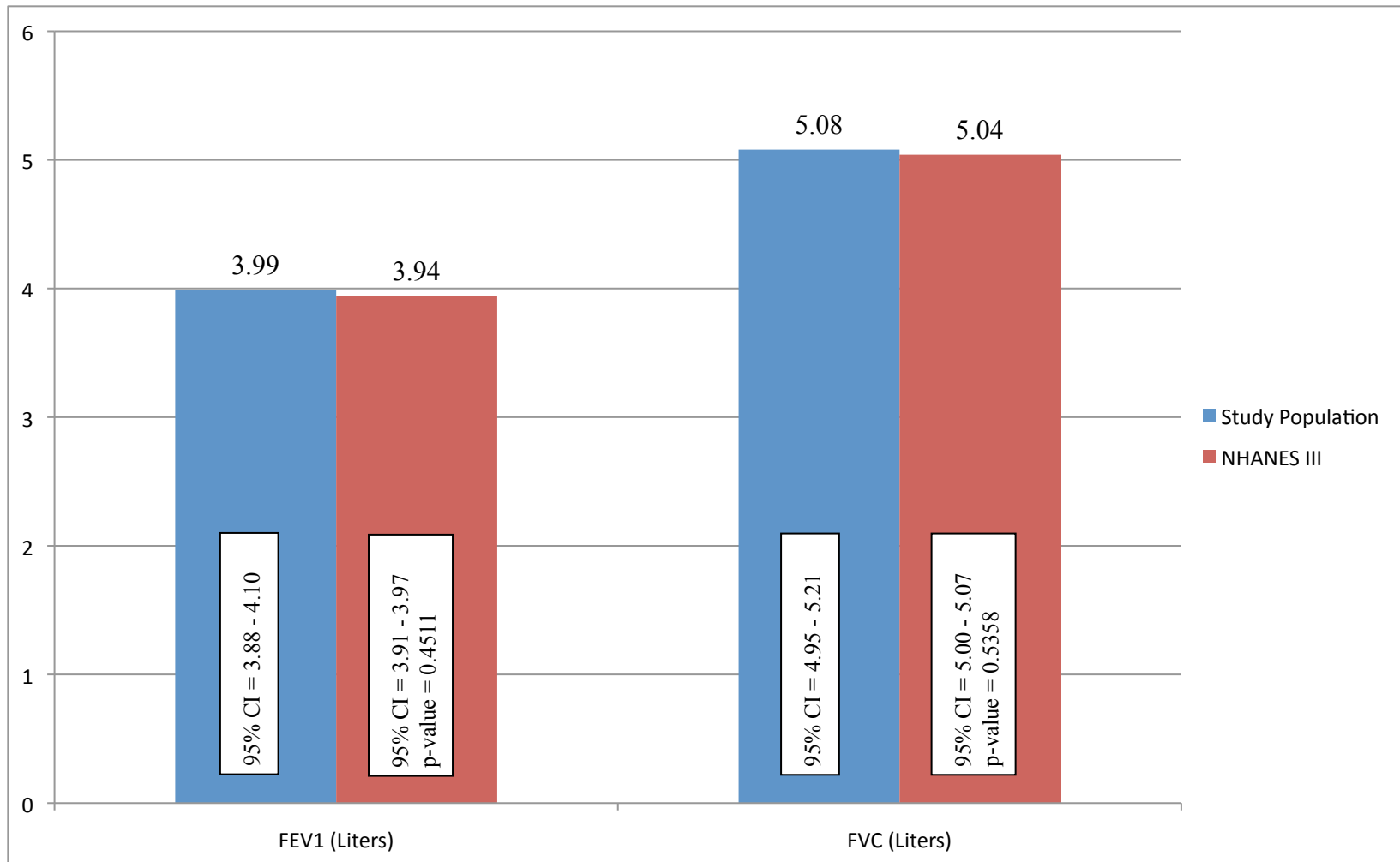


Figure 18: Pulmonary Function Mean for Height At or Above Median (70 inches)

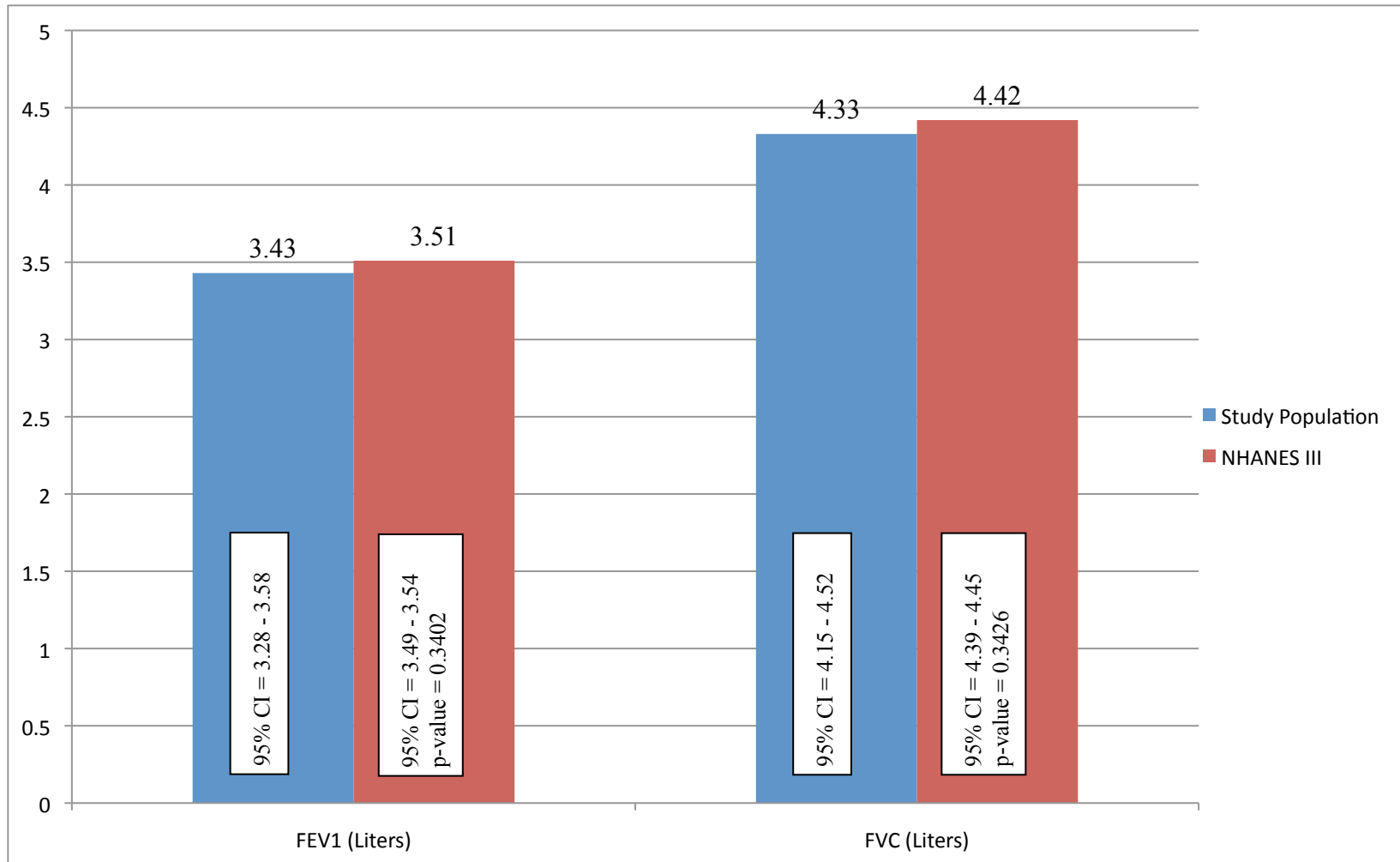


Figure 19: Pulmonary Function Mean for Height Below Median (70 inches)

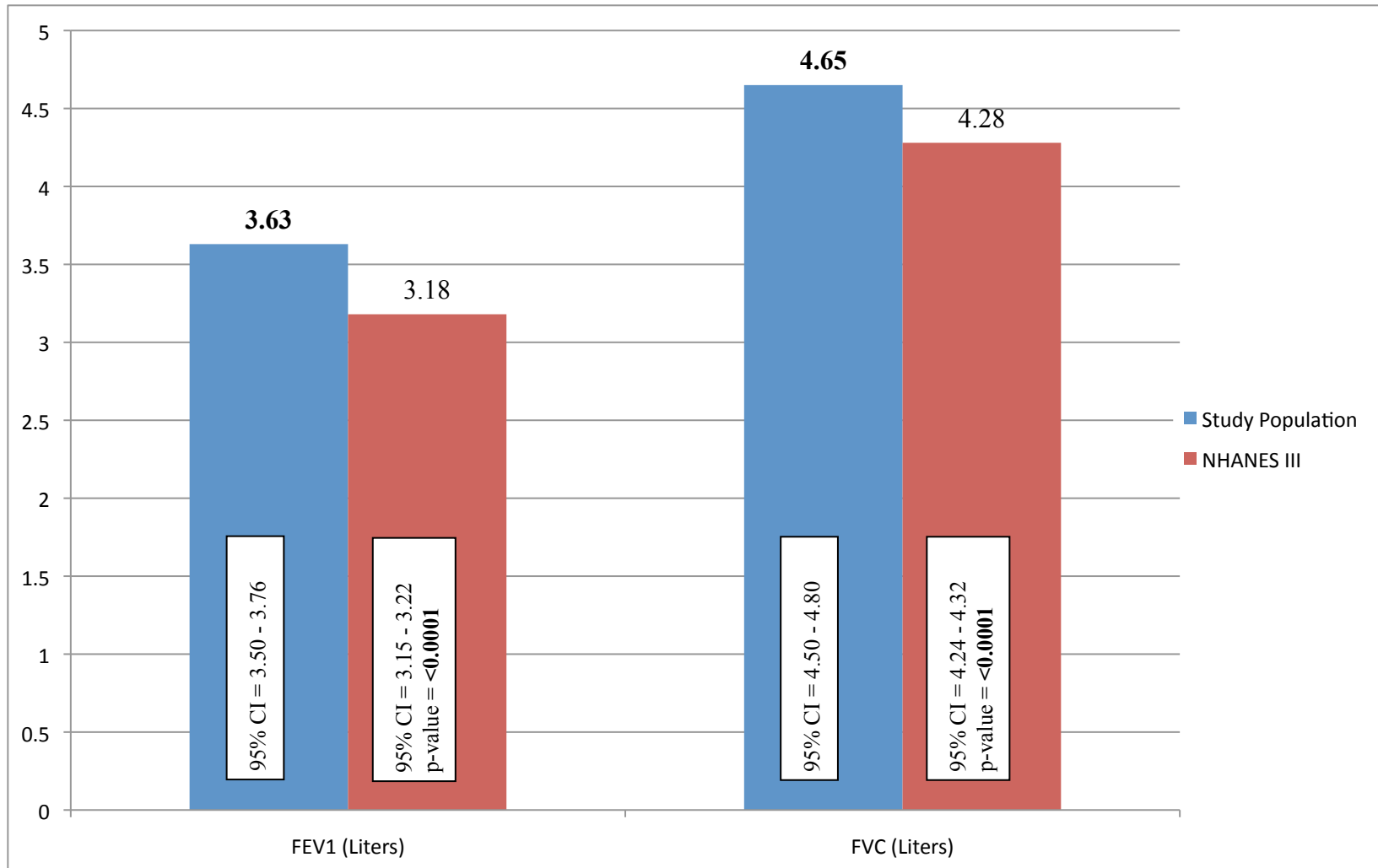


Figure 20: Pulmonary Function Mean for Age At or Above Median (46 years). *Bolded values are statistically significant.*

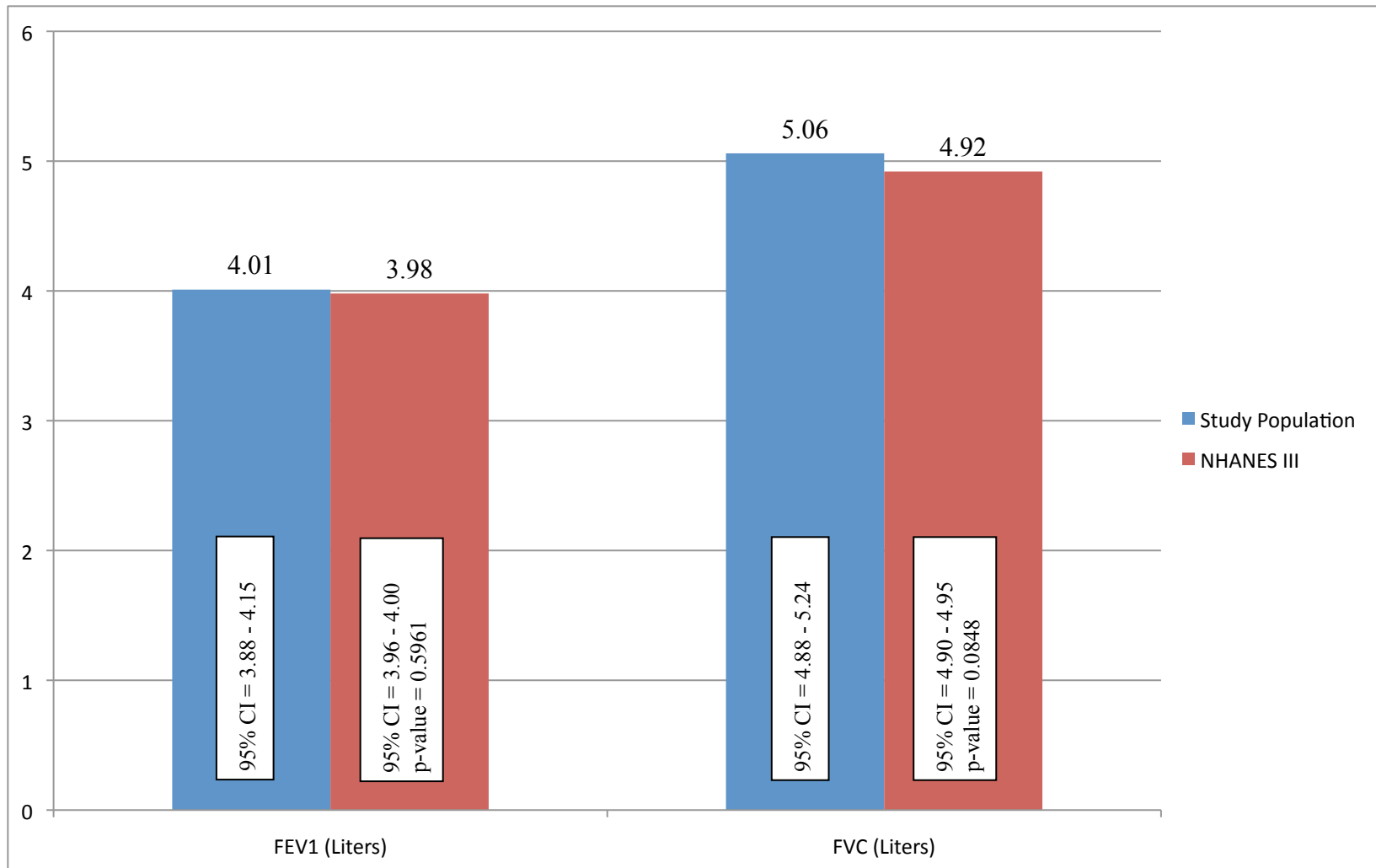


Figure 21: Pulmonary Function Mean for Age Below Median (46 years)

7.2.2 Multivariate Analysis

Multivariate analysis was conducted by constructing linear regression models including all data elements known to impact pulmonary function including age, height, and smoking history. The parameter estimates identify the magnitude of effect each predictor has on either increasing or decreasing pulmonary function in the total population. Statistically significant predictors were identified as having a p-value less than 0.05. The results of the linear regression analysis for FEV1 are reported in Table 10. The analysis identified age, height, pack-years of smoking, and utility worker status as statistically significant predictors of FEV1.

The results of the linear regression analysis for FVC are reported in Table 11. The analysis identified age and height, but not smoke pack-years as statistically significant predictors of FVC. The adjusted outcome for status as a utility worker was also a significant predictor of FVC in this analysis. With a parameter estimate of 0.2460, status as a utility worker conferred a modest increase to FVC compared to the control population.

Logistic regression analysis was used to determine the effect of pulmonary function predictors on generating an FEV1/FVC ratio less than 0.80 (Table 12). From this analysis, three statistically significant factors impacted the FEV1/FVC ratio: age, height, and smoking history. Status as a utility worker was not associated with the production of a FEV1/FVC ratio less than 0.80. Those in the population over the median age for utility workers (forty-six) were approximately four times as likely to produce an FEV1/FVC ratio less than 0.80. Those in the population over the median height for

utility workers (seventy-one) were approximately one and a half times as likely to produce an FEV1/FVC ratio less than 0.80. Similarly, those with no smoking history were nearly half as likely to produce an FEV1/FVC ratio less than 0.80.

Table 10: Predictors of FEV1 from Linear Regression Analysis

<u>FEV1</u>			
Predictor	Parameter Estimate	Standard Error	p-value
Age at test	-0.03842	0.00141	<0.0001
Height at test (in)	0.08397	0.00486	<0.0001
Smoking History (pk-yrs)	-0.00314	0.00107	0.0034
Utility Worker Status	0.30053	0.04526	<0.0001

Bolded values are statistically significant.

Table 11: Predictors of FVC from Linear Regression Analysis

<u>FVC</u>			
Predictor	Parameter Estimate	Standard Error	p-value
Age at test	-0.03168	0.00169	<0.0001
Height at test (in)	0.11685	0.00583	<0.0001
Smoking History (pk-yrs)	0.00199	0.00128	0.1221
Utility Worker Status	0.24602	0.05425	0.0006

Bolded values are statistically significant.

Table 12: Logistic Regression Analysis of FEV1/FVC to Examine the Effect of Predictors on Producing an Abnormal Ratio (<0.80 FEV1/FVC)

<u>FEV1/FVC <0.80</u>		
Predictor	Odds Ratio	95% Confidence Limit
Age above median >29 years	3.86	3.39 – 4.40
Height above median >67 inches	1.48	1.30 – 1.70
Smoking History (effect on non-smoking)	0.57	0.51 – 0.65
Utility Worker Status	1.30	0.97 – 1.74

Bolded values are statistically significant.

7.3 Discussion

This research examined the feasibility of conducting a cross sectional surveillance evaluation of workers in the utility industry from seven utility facilities in the state of Florida, which had maintained records of pulmonary function testing for workers required to use respiratory protection. Statistical comparisons between the occupational population and the NHANES III population segment, limited by age and height to reflect the occupational population's demographics, demonstrated the putative factors that altered pulmonary function in the population of interest.

The results of this research indicated that the utility workers experienced a modest, but statistically significant, increase in FEV1 and FVC compared to the NHANES III population for the total analysis. No significant differences were found between mean pulmonary function test values of utility workers and NHANES III study subjects when stratified by age, height, and smoking status except among older utility workers, who demonstrated modestly better FEV1 and FVC values compared to the study population.

In the linear regression analysis performed to examine the effect of salient cofactors on pulmonary function, FEV1 analysis demonstrated that age, height, smoking history, and utility worker status significantly affected pulmonary function. As expected, increased age and increased pack-years of smoking decreased FEV1, while increased height increased FEV1. The results of this analysis also revealed that status as a utility worker was associated with a significant increase in FEV1.

Similar results were reported for the analysis of FVC, with the exception of smoking history, which did not demonstrate statistical significance in this analysis. As with FEV1, status as a utility worker conferred a modest, significant increase in FVC. The results of the linear regression analysis for FEV1 and FVC outcomes indicate that the predominate factors that affect pulmonary function values are those traditionally known to impact lung volume and clearance, e.g. age, height, and smoking history. A modest positive effect on FEV1 and FVC was observed for utility workers in both the stratified analysis, as well as the linear regression analysis. This may indicate the presence of the 'healthy worker effect' in the occupational population related to more time spent in active labor compared to the NHANES III population which may contain unemployed persons or those in more sedentary labor.

Logistic regression was performed for the outcome of the FEV1/FVC ratio to evaluate the potential for obstructive disorders among the target occupational population compared to the NHANES III population. A cutoff point of less than 0.80 FEV1/FVC was used to classify persons with abnormal FEV1/FEV values that could potentially be an indicator of pre-clinical pulmonary obstruction. In this analysis, status as a utility worker was not significantly associated with an FEV1/FVC value of less than 0.80. However, the analysis clearly demonstrated that the older half of the population and those above the median height were more likely (odds ratio of 3.86 and 1.48 respectively) to produce a lower FEV1/FVC ratio, and non-smokers were approximately half as likely to produce a lower FEV1/FVC ratio compared to the smokers in the population.

Through the use of OSHA mandated pulmonary function testing and the available NHANES III spirometry data set, this study was able to efficiently evaluate the pulmonary health of a substantive cross section of a specific industry: utility workers. The data collected in both the OSHA mandated testing and the NHANES III spirometry data allows for the control of confounding factors that impact measures of pulmonary function so that statistical comparisons can identify deficits in pulmonary function and indicate whether or not those deficits are associated with an occupational sector. This research did not identify any pulmonary function deficits in the target occupational population and it demonstrated that in all cases, electric utility workers had equivalent or modestly superior pulmonary function compared to a baseline population.

Chapter 8

Pulmonary Function Testing in Emergency Responders

8.1 Data Source

A record review was conducted on 127 pulmonary function tests from emergency responders in the state of Florida based upon the inclusion criteria provided in Chapter 5.1. Restriction of the NHANES III data and removal of unacceptable spirometry tests, resulted in a final control population of 9,792 subjects.

8.2 Results

8.2.1 Univariate Analysis

The population demographics for both the study population (emergency responders) and the NHANES III segment used for analysis are reported in Table 13. The study population was largely male and approximately 16 percent had a history of tobacco smoking. The study population was slightly younger and taller overall, compared to the NHANES III mean age and height.

Figure 22 provides the results of means testing for FEV1 and FVC comparing the total study population to the NHANES III segment. The study population demonstrated modestly higher mean FEV1 and FVC values when comparing the populations as a whole. The differences in age and disproportionate gender represented in the study

population necessitated the use of stratified analysis to determine the effect of these population differences on evaluating the effect of emergency worker status on pulmonary function.

Stratification by age, gender, height and smoking history yielded statistically significant larger mean values for FEV1 and FVC measurements for the study population. The results of the analysis are reported in Figures 23 through 30.

Table 13: Summary of Study Population and NHANES III Control Population

	<u>Study Population</u>	<u>NHANES III</u>
Total population n =	127	9792
Males n =	105	4659
Females n =	22	5133
Smoking History (YES)	20	5176
Smoking History (NO)	107	4616
Mean Height (Inches)	69	66
Mean Age (Years)	38	40

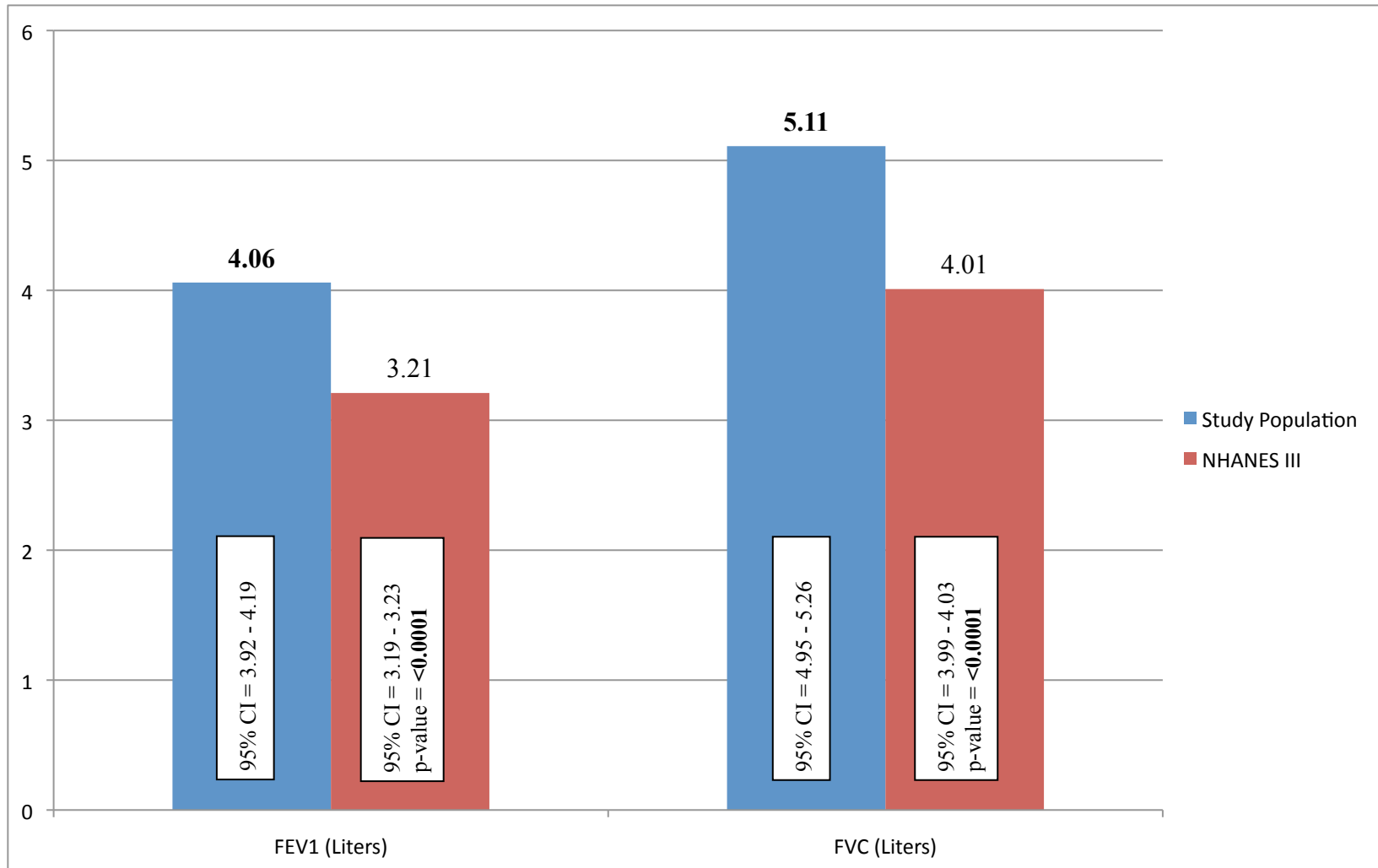


Figure 22: Pulmonary Function Mean for the Total Population. *Bolded values are statistically significant.*

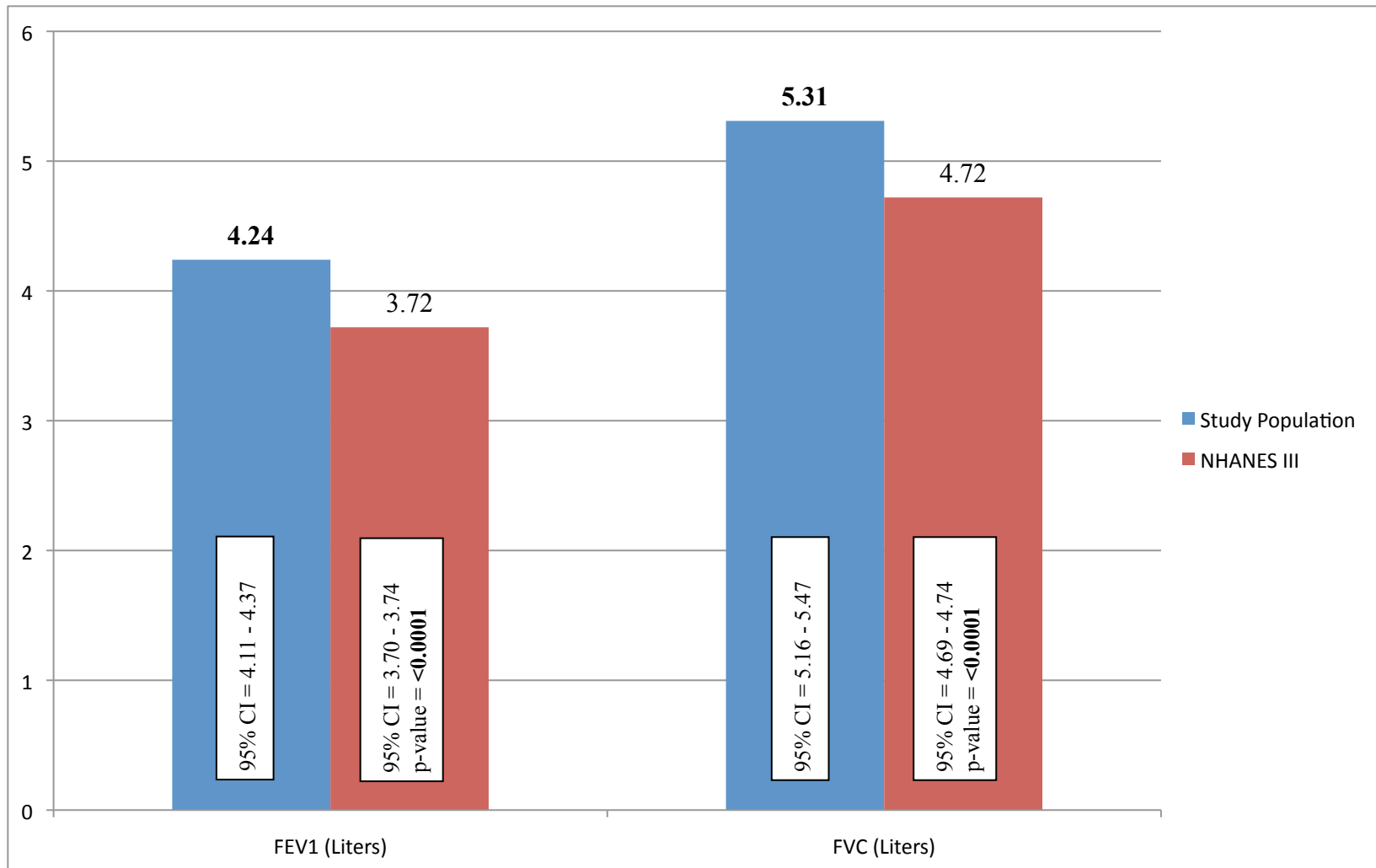


Figure 23: Pulmonary Function Mean for Males. *Bolded values are statistically significant.*

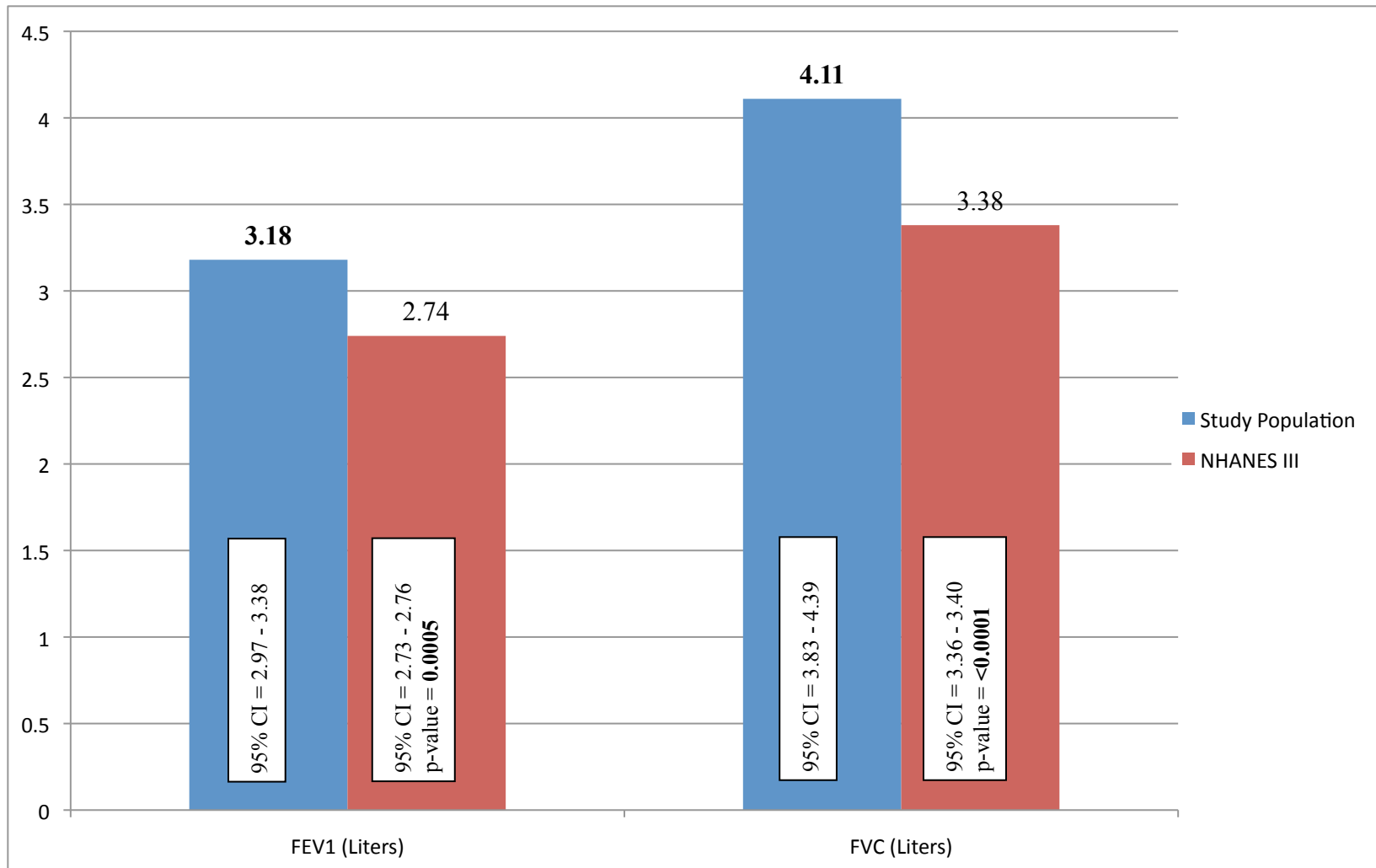


Figure 24: Pulmonary Function Mean for Females. *Bolded values are statistically significant.*

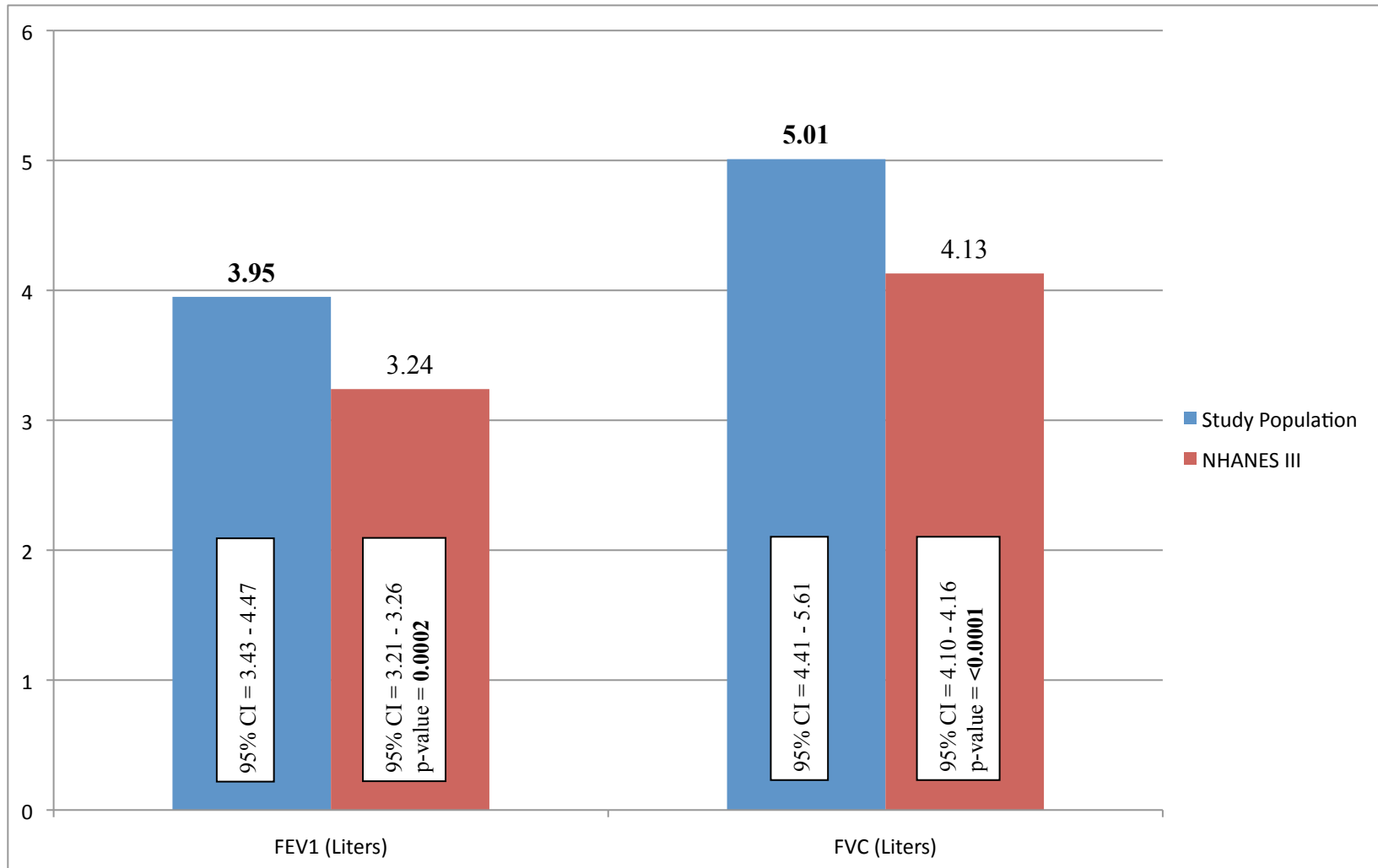


Figure 25: Pulmonary Function Mean for Smoking History (YES). *Bolded values are statistically significant.*

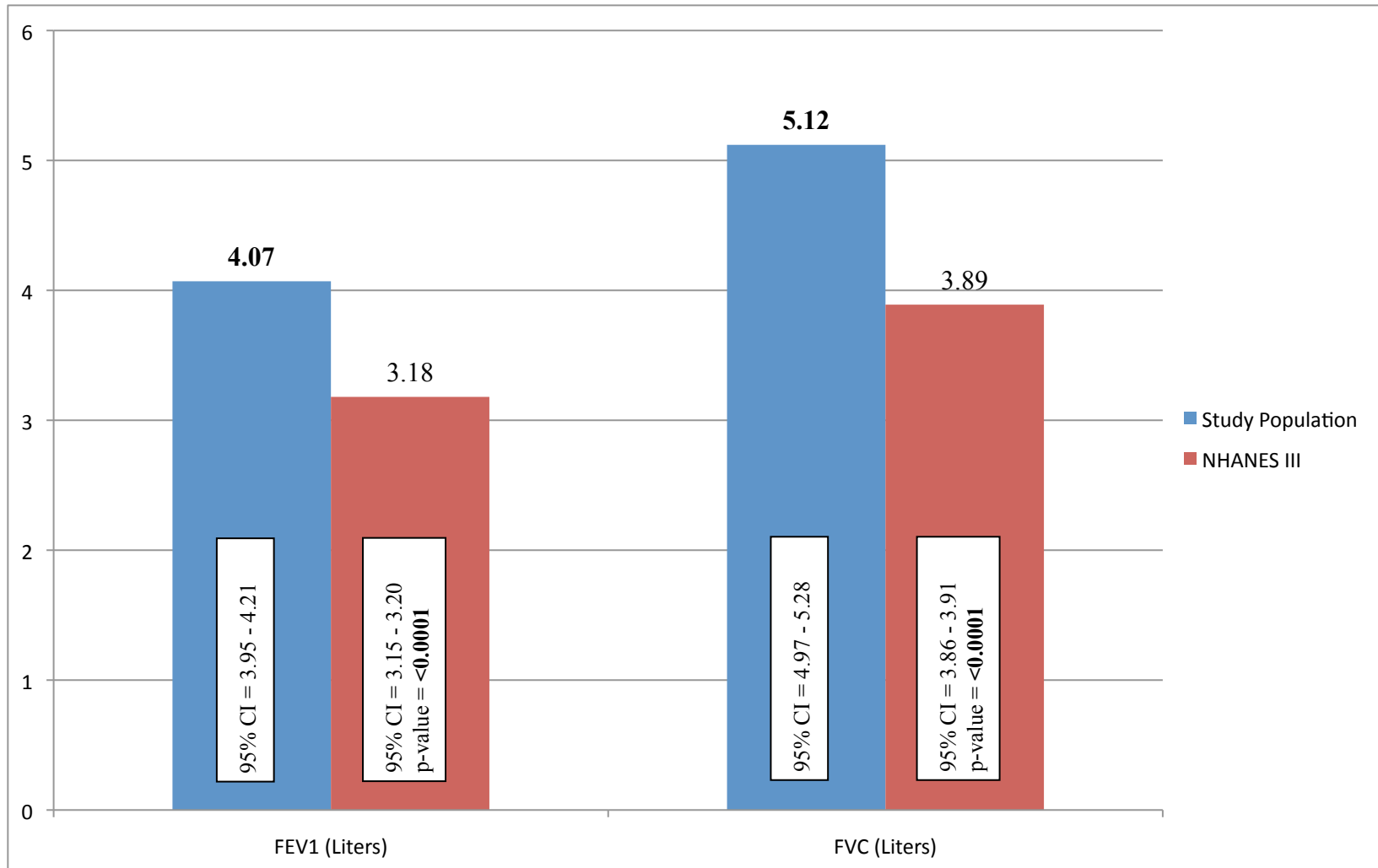


Figure 26: Pulmonary Function Mean for Smoking History (NO). *Bolded values are statistically significant.*

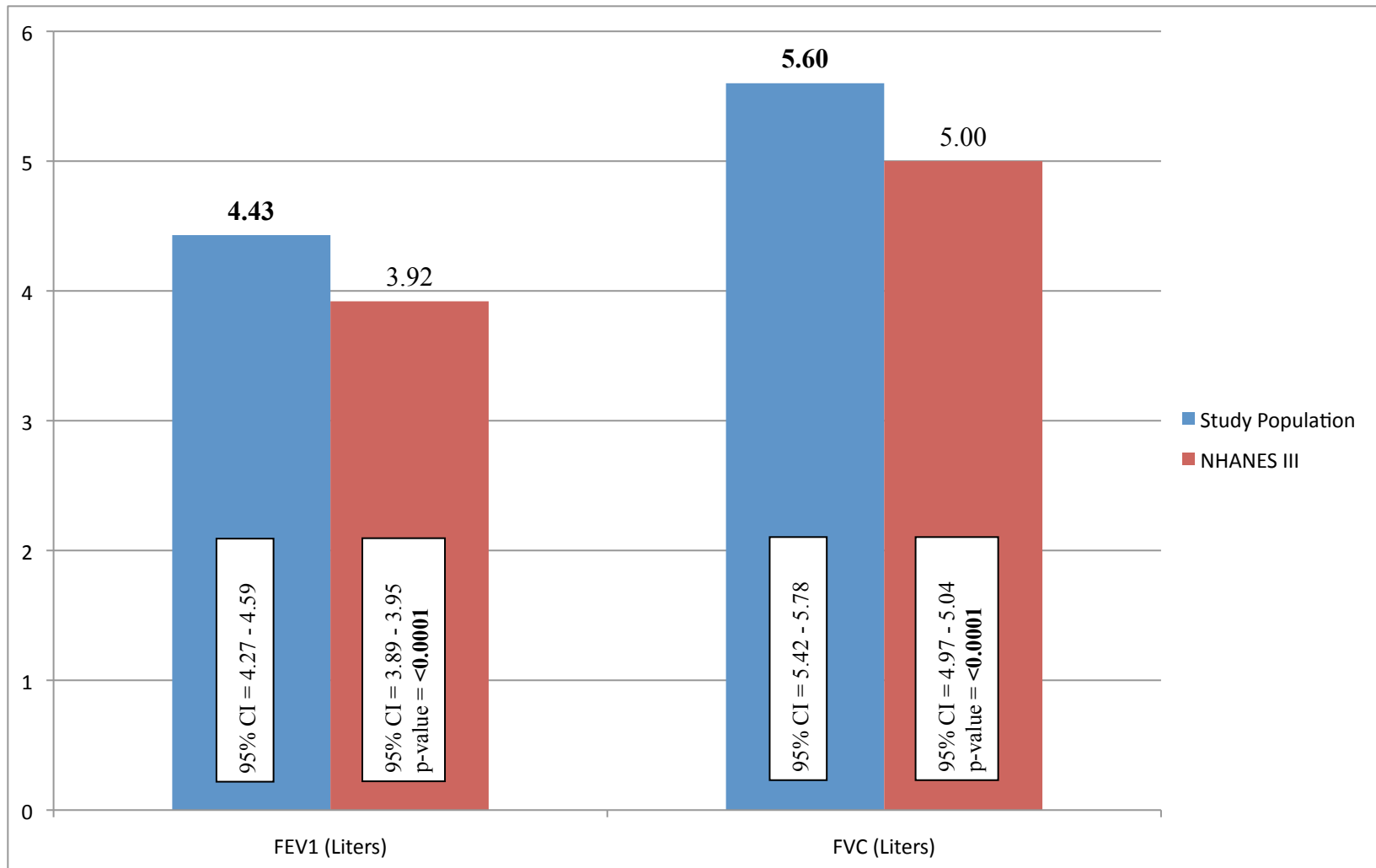


Figure 27: Pulmonary Function Mean for Height At or Above Median (70 inches). *Bolded values are statistically significant.*

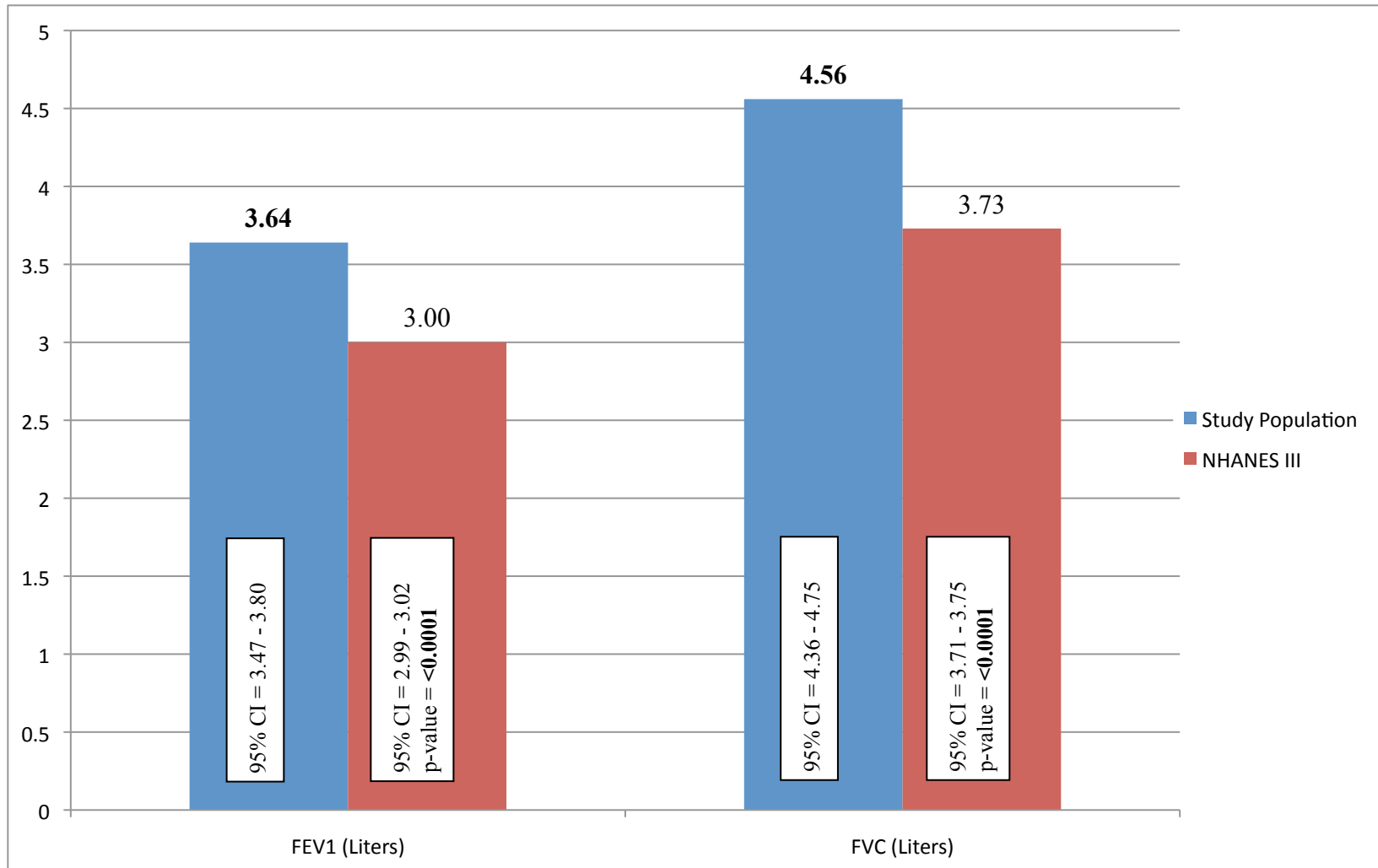


Figure 28: Pulmonary Function Mean for Height Below Median (70 inches). *Bolded values are statistically significant.*

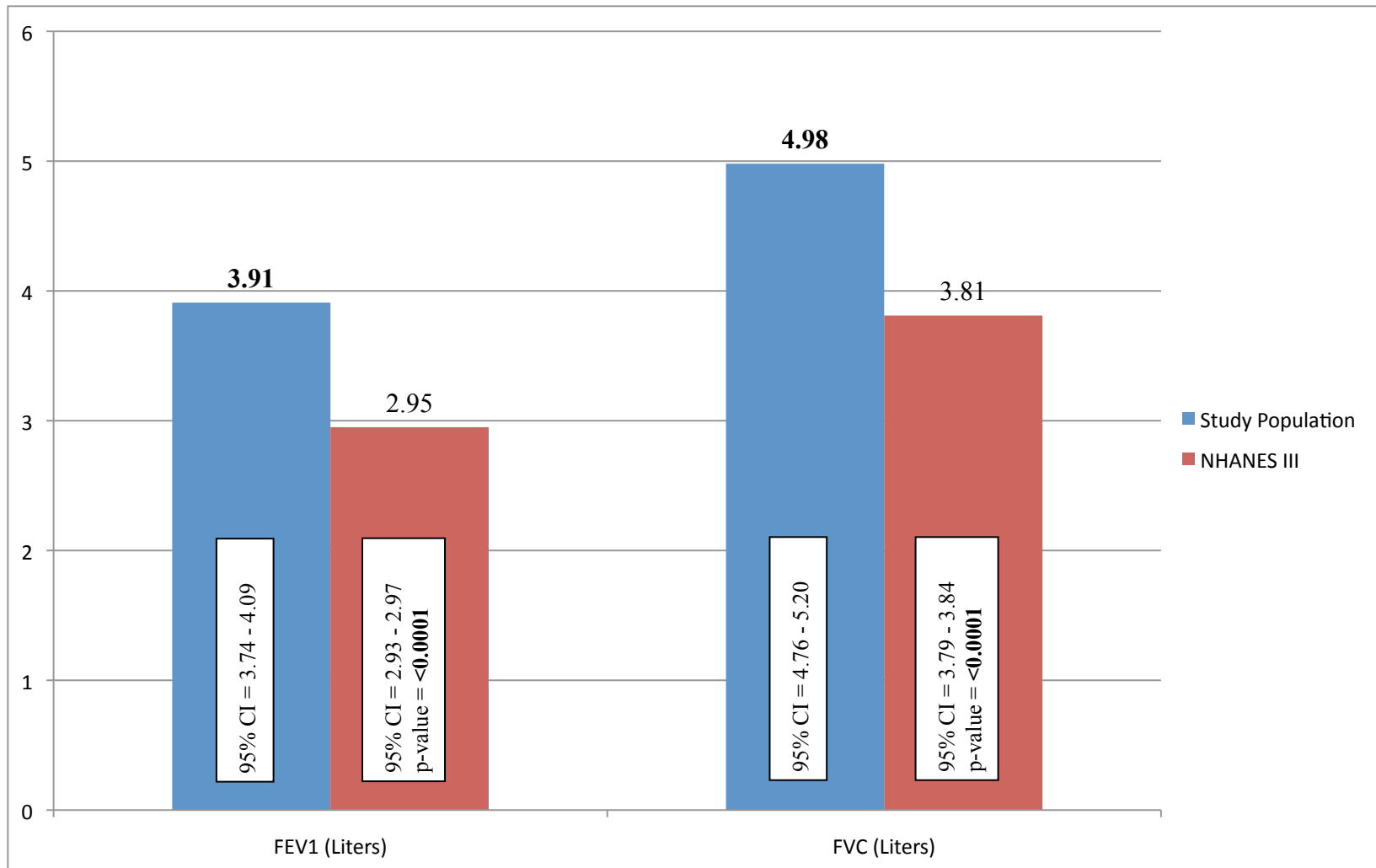


Figure 29: Pulmonary Function Mean for Age At or Above Median (38 years). *Bolded values are statistically significant.*

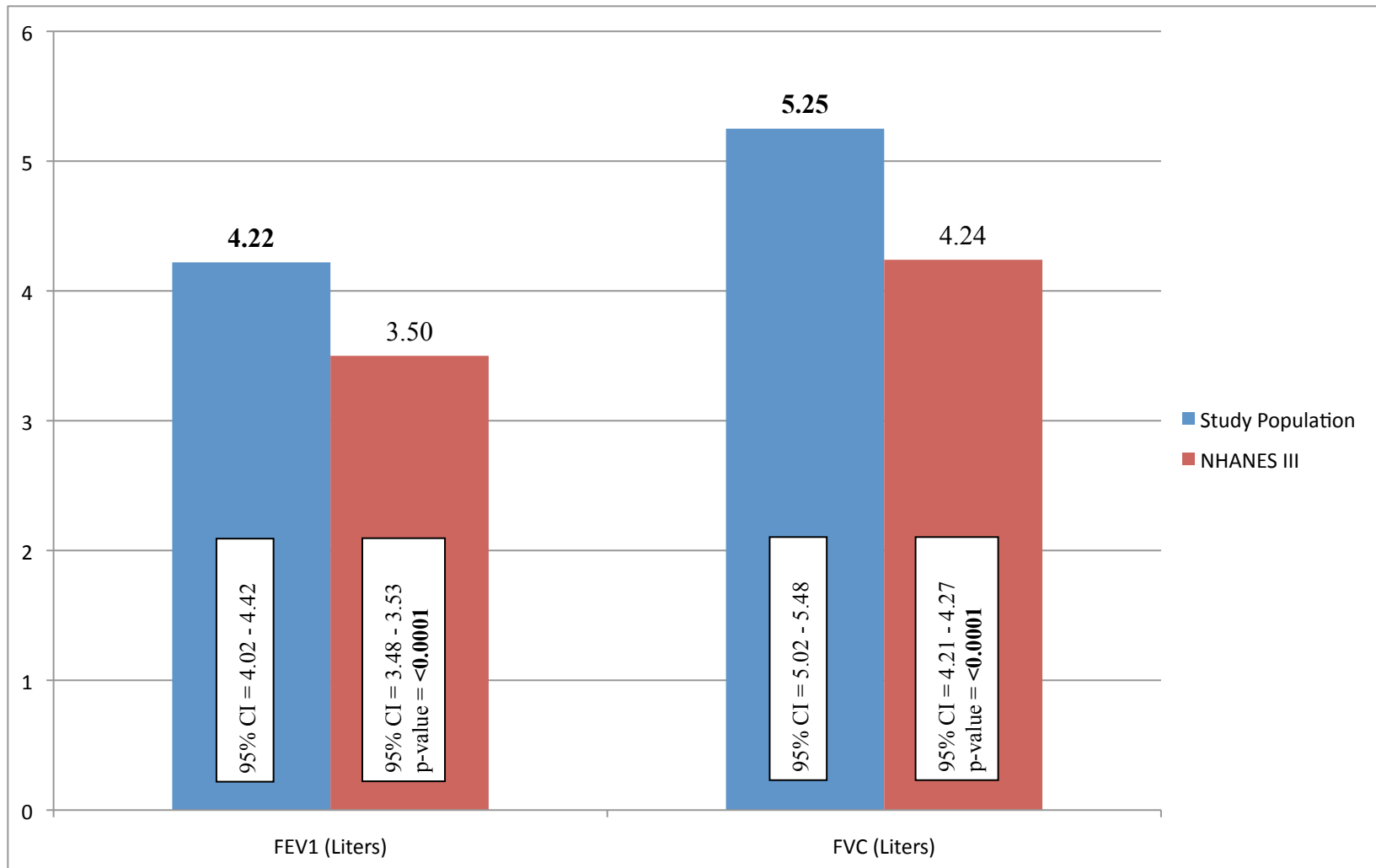


Figure 30: Pulmonary Function Mean for Age Below Median (38 years). *Bolded values are statistically significant.*

8.2.2 Multivariate Analysis

Multivariate analysis was conducted by constructing linear regression models including all data elements known to impact pulmonary function including age, height, gender, and smoking history. The parameter estimates identify the magnitude of effect each predictor has on either increasing or decreasing pulmonary function in the total population. Statistically significant predictors were identified as having a p-value less than 0.05. The results of the linear regression analysis for FEV1 are reported in Table 14. The analysis identified age, height, gender and smoking history as statistically significant predictors of FEV1. The adjusted outcome for status as an emergency responder was also a significant predictor of FEV1 in this analysis. With a parameter estimate of 0.44757, status as an emergency responder conferred a modest increase to FEV1 compared to the control population.

The results of the linear regression analysis for FVC are reported in Table 15. The analysis identified age, height, gender, but not smoking history as statistically significant predictors of FVC. The adjusted outcome for status as an emergency responder was also a significant predictor of FVC in this analysis. With a parameter estimate of 0.53683, status as an emergency responder conferred a modest increase to FVC compared to the control population.

Logistic regression analysis was used to determine the effect of pulmonary function predictors on generating an FEV1/FVC ratio less than 0.80 (Table 16). From this analysis, four statistically significant factors impacted the FEV1/FVC ratio: age, height, smoking history, and gender. Status as an emergency responder was not

associated with the production of a FEV1/FVC ratio less than 0.80. Those in the population over the median age (thirty-eight years) and height (seventy inches) were more likely to produce an FEV1/FVC ratio less than 0.80. Similarly, those with no smoking history and gender is female were less likely to produce an FEV1/FVC ratio less than 0.80.

Table 14: Predictors of FEV1 from Linear Regression Analysis

<u>FEV1</u>			
Predictor	Parameter Estimate	Standard Error	p-value
Age at test	-0.03571	0.00105	<0.0001
Height at test (in)	0.07459	0.00357	<0.0001
Gender	-0.62706	0.02694	<0.0001
Smoking History (pk-yrs)	-0.00391	0.00083	<0.0001
Emergency Responder Status	0.44757	0.05049	<0.0001

Bolded values are statistically significant.

Table 15: Predictors of FVC from Linear Regression Analysis

<u>FVC</u>			
Predictor	Parameter Estimate	Standard Error	p-value
Age at test	-0.02927	0.00124	<0.0001
Height at test (in)	0.10485	0.00423	<0.0001
Gender	-0.81338	0.03188	<0.0001
Smoking History (pk-yrs)	-0.00102	0.00098	0.2987
Emergency Responder Status	0.53683	0.05974	<0.0001

Bolded values are statistically significant.

Table 16: Logistic Regression Analysis of FEV1/FVC to Examine the Effect of Predictors on Producing an Abnormal Ratio (<0.80 FEV1/FVC)

<u>FEV1/FVC <0.80</u>		
Predictor	Odds Ratio	95% Confidence Limit
Age above median >38 years	3.5	3.20 – 3.80
Height above median >70 inches	1.4	1.24 – 1.59
Gender (females vs. males)	0.55	0.50 – 0.60
Smoking History (effect on non-smoking)	0.76	0.69 – 0.84
Emergency Responder Status	0.93	0.66 – 1.35

Bolded values are statistically significant.

8.3 Discussion

This research examined the feasibility of conducting a cross sectional surveillance evaluation of workers in the emergency response industry in the state of Florida, which had maintained records of pulmonary function testing for workers required to use respiratory protection. Statistical comparisons between the occupational population and the NHANES III population segment, limited by age and height to reflect the occupational population’s demographics, demonstrated the putative factors that altered pulmonary function in the population of interest.

The results of this research indicated that the emergency responders experienced a modest, but statistically significant, increase in FEV1 and FVC mean values over the NHANES III population in both total and stratified analyses, including stratification by age, gender, height, and smoking history. No analysis that examined mean values demonstrated better pulmonary function in the control group versus the target worker population.

In the linear regression analysis performed to examine the effect of salient cofactors on pulmonary function, FEV1 analysis demonstrated that age, gender, height and smoking history all significantly affected pulmonary function of the population in the expected direction. That is to say, increased age, female gender, and increased pack-years of smoking decreased FEV1, while increased height increased FEV1. As well, status as an emergency responder conferred a modest, significant increase in FEV1.

Similar results were reported for the analysis of FVC, with the exception of smoking history, which did not demonstrate statistical significance in this analysis. The results of the linear regression analysis for FEV1 and FVC outcomes indicate that the predominate factors that affect pulmonary function values are those traditionally known to impact lung volume and clearance, e.g. age, gender, height, and smoking history. A modest positive effect on FEV1 and FVC was observed for emergency responders in both the stratified analysis, as well as the linear regression analysis. This may indicate the presence of the ‘healthy worker effect’ in the occupational population related to more time spent in active labor compared to the NHANES III population which may contain unemployed persons or those engaged in more sedentary labor.

Logistic regression was performed for the outcome of the FEV1/FVC ratio to evaluate the potential for obstructive disorders among the target occupational population compared to the NHANES III population. A cutoff point of less than 0.80 FEV1/FVC was used to classify persons with abnormal FEV1/FVC values that could potentially be an indicator of pre-clinical pulmonary obstruction. In this analysis, status as an emergency responder was not significantly associated with an FEV value of less than

0.80. However, the analysis clearly demonstrated that the older and taller half of the population was more likely to produce a lower FEV1/FVC ratio, and non-smokers and the female gender were less likely to produce a lower FEV1/FVC ratio compared to the smokers and males in the population.

Through the use of OSHA mandated pulmonary function testing and the available NHANES III spirometry data set, this study was able to efficiently evaluate the pulmonary health of a substantive cross section of a specific industry: emergency responders. The data collected in both the OSHA mandated testing and the NHANES III spirometry data allows for the control of confounding factors that impact measures of pulmonary function so that statistical comparison can identify deficits in pulmonary function and indicate whether or not those deficits are associated with an occupational sector. This research did not identify any pulmonary function deficits in the target occupational population and it demonstrated that in all cases, emergency responders had modestly superior pulmonary function compared to a baseline population.

Chapter 9

Conclusion

Occupational health surveillance in the United States is a rising priority and a new focus has been established on the health and welfare of the workforce. Health surveillance in the past has typically been associated with communicable diseases such as polio and influenza. However, as Baker et al. (1988) states:

Although certain aspects of the communicable disease surveillance model are applicable for surveillance of occupational conditions, there are basic differences between communicable diseases and occupational disorders which impact on the strategy for surveillance:

- Strong disincentives exist for reporting occupational conditions by employers, physicians, and most importantly affected individuals. Such disincentives do not characterize communicable disease surveillance.
- Health professionals lack knowledge regarding the nature of health risks in the workplace. Generally, they are more familiar with communicable disease surveillance.
- Many common occupational conditions are also caused or aggravated by non-occupational factors unrelated to work.

- The latency period between exposure onset and disease occurrence is frequently great for occupational disorders.

While the history of occupational diseases may go back for centuries, numerous diseases and ailments go unrecognized in modern times. Currently, the nation's workforce is exposed to more potential hazards than ever before. In the past, the points listed above have hindered the identification of the occupational origin of numerous diseases. Fortunately, a new emphasis on worker health has been established at the corporate level, employee level, and in academic institutions. Corporations recognize the economic impact and loss of productivity that can occur when an employee has to miss work or becomes disabled. Employees now more than ever realize the negative impact associated with being out of work and how it affects not only them, but also other household members dependent on both their physical and monetary support.

Increased awareness of the importance of a healthy workforce has created a need for public health practitioners specialized in occupational health. Companies are now seeking individuals that have knowledge of the health risks associated with the workplace and the ability to monitor their workforce and implement controls when needed. This has led to the development of occupational health courses and degrees being offered to a variety of disciplines including physicians, toxicologists, industrial hygienists, and epidemiologists. Better understanding of occupational settings, occupational diseases, and surveillance strategy has led to the advancement of occupational health surveillance.

The stated objectives of this study were to:

- Identify industries in the State of Florida that have the potential for increased pulmonary impairment amongst workers.
- Evaluate the feasibility of using pulmonary function data collected for purposes of compliance and/or best practices for workers who use respiratory protection because they are potentially exposed to pulmonary toxicants in the workplace.

OSHA mandated pulmonary function testing as well as testing included as a best practice or standard operating procedure represents a potentially powerful surveillance tool to evaluate at-risk populations who have known inhalation exposures that require respiratory personal protective equipment and regular spirometry evaluations. Evaluation of this type of occupational health data can lead to the advancement of occupational exposure controls as well as regulatory and policy changes that can lead to safer workplace environments. In addition, this type of research can be expanded and or tailored to include additional indicators of occupational disease, which allows for greater utility and the potential to identify various adverse health effects associated with occupational exposure to toxicants.

The methodology presented in this study provided an opportunity to determine the feasibility of using pulmonary function data collected for purposes of compliance and/or best practices for workers who use respiratory protection. The various methods used for data collection and data analysis in this study indicated the feasibility of using occupational health data to quickly and efficiently conduct a population level analysis and draw conclusions. Limitations of the interpretation of surveillance data can include under-reporting, reporting bias, and inconsistent case definitions. While procedures were

established to address such limitations, further methods could be included to enhance the results. For example, additional analyses for consideration could include time comparative studies that track health outcomes through out a work history. Inclusion of this additional analysis may help address biases associated with a one time study. This study not only demonstrates the feasibility of using occupational health data for population level analysis but also illustrates the flexibility provided by the methodology presented.

Two main limitations to conducting this line of research include data collection and data warehousing. The first principal limitation to conducting this line of research is access to occupational health data. While all states require disease reporting, state and federal laws do not mandate that all occupational health data is reported and pooled for analysis. Convincing industry to share this type of data is necessary to perform wide scale analyses and draw strong conclusions. Ethical issues and legal issues related to occupational health surveillance include right of access, public trust, confidentiality, informed consent, etc. Such concerns by industry need to be addressed and safeguards need to be established to ensure that dissemination of such data is only provided to those who need it for surveillance purposes. Cooperation and education between governmental and private sectors to create acceptable data collection procedures that ensure ethical and legal concerns must be addressed and are key in the promotion of occupational health surveillance.

The second principal limitation to conducting this line of research is the current lack of infrastructure to aggregate both required and voluntary pulmonary function

testing data. OSHA required pulmonary function testing is conducted under standard pulmonary function testing guidelines and the resulting data is maintained with employers for compliance purposes. If this data were also transmitted to a local, state, or federal database to be used in population level analysis, the availability and efficacy of this method of surveillance would be greatly enhanced. Data sharing has many limitations, which include coding, formatting, definitions, etc. Standardization of occupational health data for the purpose of data sharing and data processing need to be addressed and guidance created to eliminate the many different inconsistencies that exist in the equipment used and the data produced. Advancement in technology and the increased awareness of the importance of data sharing should drive the needed advancements and collaboration to ensure that occupational health surveillance can be used to monitor health, which is in everyone's best interest.

There is a need to develop and utilize surveillance methodologies that are capable of efficiently evaluating occupational populations for health status, identifying changes in health status over time, and comparing the health status of occupational populations to baseline populations. As shown by the methodology described in this study, the use of spirometry data to quickly evaluate the pulmonary health status of selected occupational populations is both a feasible and efficient way to conduct occupational health surveillance.

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APPENDIX I:

IRB APPROVAL LETTER



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

August 24, 2010

Giffe Johnson, MPH, PhD
Environmental and Occupational Health
13201 Bruce B. Downs Blvd., MDC 56
Tampa, FL 33612

RE: **Expedited Approval** for Initial Review
IRB#: Pro00001348
Title: Occupational Health Monitoring Database Development

Dear Dr. Johnson:

On 8/24/2010, the Institutional Review Board (IRB) reviewed and **APPROVED** the above referenced protocol. Please note that your approval for this study will expire on 08/24/2011.

Approved Items:
Protocol Document(s):

[Study Protocol.doc](#)

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It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

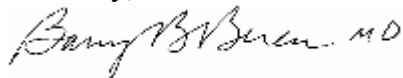
Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Your study qualifies for a waiver of the requirement for signed authorization as outlined in the HIPAA Privacy Rule regulations at 45 CFR 164.512(i) which states that an IRB may approve a waiver or alteration of the authorization requirement provided that the following criteria are met (1) the PHI use or disclosure involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the requested waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,

A handwritten signature in black ink that reads "Barry B. Berlin, MD". The signature is written in a cursive style.

USF Institutional Review Board

Cc: Sarah Croker

USF IRB Professional Staff