

4-29-2014

A Sleep Apnea Program for Commercial Drivers

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A Sleep Apnea Program for Commercial Drivers

A Clinical Scholarship Project

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A Clinical Scholarship Project Submitted to the Graduate School at the
University of Missouri-St. Louis in partial fulfillment of the requirements for
the degree
Doctorate of Nursing Practice

Spring 2014

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Abstract

Sleepy driving is a major contributing factor to the motor vehicle crash risk associated with commercial drivers (Pack et al., 2006). In commercial vehicles, approximately 31% to 41% of major crashes can be linked to sleepy driving (Gurubhagavatula et al., 2004). An average non-fatality crash involving a commercial motor vehicle costs about \$75,637 while a fatality crash averages about \$3.54 million (Gurubhagavatula et al., 2004). A contributing factor to sleepy driving is obstructive sleep apnea (Pack et al., 2006).

The purposes of this study were to: (1) determine how many commercial motor vehicle drivers referred to a sleep center as a result of a clinical positive screen by a commercial motor vehicle driver medical examiner had a true positive quantitative test for obstructive sleep apnea, and (2) to determine, on average, how many drivers treated for obstructive sleep apnea met minimum treatment requirements using positive airway pressure therapy at one week, one month, three months, six months and one year.

The electronic medical records of 128 commercial motor vehicle drivers were reviewed for diagnosis of obstructive sleep apnea with the following findings: 19 (14.9%) had no clinically significant obstructive sleep apnea, 51 (39.8%) had mild to moderate obstructive sleep apnea, and 58 (45.3%) had moderate to severe obstructive sleep apnea. Of the original 83 drivers prescribed positive airway pressure therapy, 25 (30.1%) were meeting the minimal adherence goal at 1 year of treatment. Of drivers with moderate to severe obstructive sleep apnea, 21 (36.2%) of the original 58 prescribed treatment were meeting the adherence goal at 1 year while 4 (16%) of the original 25 drivers with mild to moderate obstructive sleep apnea were meeting this goal.

Acknowledgements

I would like to thank Loretta Colvin, Advanced Practice Registered Nurse, of the Clayton Sleep Institute for her guidance and expertise in the field of obstructive sleep apnea. Mrs. Colvin was very knowledgeable in all aspects of diagnosis and treatment of sleep apnea especially in the commercial driver population. A special thank you is also extended to the Clayton Sleep Institute and Caduceus Corporation and to the staff that very graciously helped with the clinical aspects of this study.

I would also like to say thank you to Dr. Sue Farberman, Director of the Doctorate of Nursing Program, and Chairperson of my Committee. Dr. Farberman's time and assistance with this project encouraged me as I struggled with the obstacles of my Doctorate of Nursing Practice project.

A special thanks also goes out to Dr. Debbie Kiel for her expertise in the area of program evaluation. A special thanks also goes out to Dr. Kimberly Werner, statistician for the University of Missouri-St. Louis College of Nursing, for her help with data analysis and for taking the time to answer my hundreds of questions. Thanks to Dr. Jean Bachman PhD Program Director of Nursing at University of Missouri-St. Louis for her assistance with my project. Also, thanks to Dr. Nancy Magnuson Associate Dean for Advanced Nursing Education and Clinical Professor at University of Missouri-St. Louis for her assistance with this project. Both Dr. Bachman and Dr. Magnuson are members of my Clinical Scholarship Committee.

Lastly, I would like to thank my family for their support during the time consuming process of my clinical scholarship project. I am very grateful for everyone's assistance and support during my project.

Project Purpose

The primary purpose of this project was to determine the number of commercial motor vehicle drivers referred to the sleep center as a result of a positive clinical screen by a commercial motor vehicle driver medical examiner that had a true positive quantitative test for obstructive sleep apnea. A secondary objective for this project was to determine the number of those drivers with true obstructive sleep apnea that became adherent with positive airway pressure therapy at one week, one month, three months, six months and one year.

Issue and Rationale for the Project

Approximately 5,600 individuals are killed in motor vehicle crashes involving commercial drivers in the United States each year (Pack, Maislin, Staley, Pack, Rogers, George, & Dinges, 2006). Not only are crashes involving commercial vehicles costly in lives lost, the financial cost is also high (Gurubhagavatula, Maislin, Nkwuo, & Pack, 2004). An average non-fatality crash involving a commercial motor vehicle costs about \$75,637 while a fatality crash averages about \$3.54 million (Gurubhagavatula et al., 2004).

Baseline Data to Support the Issue

Obstructive sleep apnea plays a role in sleepy driving and sleepy driving is a major risk for crashes (Pack et al., 2006). In the general population, driving with obstructive sleep apnea, one cause of sleepy driving, can lead to a two to seven times increase in motor vehicle crashes (Hartenbaum., Collop, Rosen, Phillips, George, Rowley, Freedman, Weaver, Gurubhagavatula, Leaman, & Moffitt, 2006).

Approximately 20 % of motor vehicle crashes on roadways can be related to sleepy driving (Strohl et al., 2013).

The prevalence of commercial motor vehicle drivers with obstructive sleep apnea has been estimated at approximately 28.1 % but was dependent on age and obesity (Pack et al., 2006). In comparison, obstructive sleep apnea in the general population is estimated at approximately at 3% to 7% (Punjabi, 2008). Obstructive sleep apnea in commercial motor vehicle drivers is estimated to be four times higher when compared to the general population (Hiestand & Phillips, 2011).

Sleepy driving is a major contributing factor to motor vehicle fatalities (Centers for Disease Control and Prevention, 2012). This is of particular concern for the commercial motor vehicle driver population (Hartenbaum et al., 2006). Commercial motor vehicle drivers are especially at risk for such collisions due to the monotony of driving, and the excessive size and mass of their vehicles (Tregear, Reston, Schoelles, & Phillips, 2010). Sleepy drivers behind the wheels of large vehicles pose a great risk to the health of the general population by increasing motor vehicular collision risk and producing more destructive and costly outcomes due to financial and personal losses (Tregear et al., 2010).

Any sleepy driver can doze during driving and leave his/her lane of traffic leading to a traffic crash (Tregear et al., 2010). Excessive daytime sleepiness in drivers can contribute to these motor vehicle crashes (Tregear et al., 2006). A cause of daytime sleepiness can be caused by untreated obstructive sleep apnea (Tregear et al., 2010). Screening for obstructive sleep apnea during U.S. Department of Transportation

commercial driver's medical examination may reduce the risk of commercial drivers with untreated obstructive sleep apnea being on the roads (Hartenbaum et al., 2006).

Epidemiologic Relevance to Population Health Outcomes

In 2010, the U.S. Department of Health and Human Services and the Office of Disease Prevention and Health Promotion published their national health goals for the next ten years, Healthy People 2020 (Centers for Disease Control and Prevention, & National Institutes of Health 2010). Sleep related goals for Healthy People 2020 included reduction of the rate of vehicular crashes per 100 million miles traveled due to drowsy driving (Centers for Disease Control and Prevention, & National Institutes of Health 2010). The target is to have 2.1 or less vehicular crashes per 100 million miles traveled, which is a decrease from the baseline of 2.7 vehicular crashes per 100 million miles traveled (Centers for Disease Control and Prevention, & National Institutes of Health, 2010). Other sleep related goals for Healthy People 2020 were to increase students and adults who get sufficient sleep but were not directly related obstructive sleep apnea (Centers for Disease Control and Prevention & National Institutes of Health, 2010).

Review of Current Literature

Definition and History of Obstructive Sleep Apnea

As far back as the nineteenth century, observations depicting clinical manifestations of obstructive sleep apnea have been discussed in lay literature (Dickens, 1866). Early medical definitions of obstructive sleep apnea can be traced back to the Stanford University School of Medicine (Guilleminault, Tilkian, & Dement, 1976). Today, obstructive sleep apnea is recognized as an ever more prevalent condition that has multiple sequelae for the individual (American Academy of Sleep Medicine, 2005).

In 1999, the definition of obstructive sleep apnea was standardized (American Academy of Sleep Medicine Task Force, 1999). Obstructive sleep apnea is defined as a partial (hypopnea) or complete (apnea) obstruction of the upper airways during sleep (American Academy of Sleep Medicine, 2005). These events occur despite ongoing inspiratory efforts and can lead to inadequate alveolar ventilation resulting in oxygen desaturation (American Academy of Sleep Medicine, 2005). Hypopnic or apneic events are usually ended by brief awakenings from sleep (American Academy of Sleep Medicine, 2005).

Co-morbidities and Sequelae of Obstructive Sleep Apnea

Obstructive sleep apnea can contribute to a wide range of medical problems (American Academy of Sleep Medicine, 2005). Physiologic effects of sleep apnea include elevated blood pressure, cardiovascular changes, impaired glucose metabolism, and decreased insulin sensitivity (American Academy of Sleep Medicine, 2005). Additional consequences include snoring, sleep fragmentation, sleep-related cardiac dysrhythmia, nocturnal angina, gastroesophageal reflux, and insomnia (American Academy of Sleep Medicine Task Force, 1999). Other comorbidities can be worsened by obstructive sleep apnea (American Academy of Sleep Medicine, 2005). These conditions include pulmonary hypertension, cor pulmonale, dilated cardiomyopathy, ischemic heart disease, congestive heart failure, sleep fragmentation, gastroesophageal reflux, nocturnal seizures and cerebral anoxic attacks (American Academy of Sleep Medicine, 2005).

Cholesterol abnormalities can also be seen in individuals with obstructive sleep apnea (Berry, 2008). Individuals with obstructive sleep apnea have a tendency to have lower high density lipoproteins and elevated triglycerides causing an increased risk of

cardiovascular disease (Berry, 2008). Increased insulin resistance is also found in individuals with more severe sleep apnea causing an increased risk of diabetes (Berry, 2008). Snoring, is common in obstructive sleep apnea individuals, and has also been associated with increased risk of stroke and myocardial infarction due to the hypoxia-reoxygenation cycle, sleep fragmentation, and increase sympathetic nervous system activity (Berry, 2008). Individuals with heart failure and obstructive sleep apnea have also been found to have an increased mortality rate (Berry, 2008).

Predisposing features for obstructive sleep apnea include “obesity (especially upper body adiposity), male gender, craniofacial abnormalities including mandibular/maxillary hypoplasia, increased pharyngeal soft or lymphoid tissue including tonsillar hypertrophy, nasal obstruction, endocrine abnormalities (hypothyroidism, acromegaly), and familial history” (Masood, & Phillips, 2000, p. 480). Other findings that are also associated with obstructive sleep apnea include snoring, excessive daytime sleepiness, hypertension, witnessed apneas, body mass index greater than 35 kg/m^2 , and neck circumference greater than or equal to 17 inches in men and greater than or equal to 16 inches in women (Hartenbaum et al., 2006).

Epidemiology of Obstructive Sleep Apnea

In 1979, Block and colleagues conducted one of the first studies to compare obstructive sleep apnea in men and women (Block, Boysen, Wynn, & Hunt 1979). This study monitored sleep disordered breathing in normal individuals and found that more males than females had episodes of nocturnal oxygen desaturation and abnormal breathing (Block, et al, 1979). Also, the incidence of nocturnal oxygen desaturation increased with age and obesity in men (Block, et al, 1979).

In 1993, the Wisconsin Sleep Cohort Study estimated that about 2% of the female workforce and about 4% of the male workforce met the minimal diagnostic criteria for obstructive sleep apnea (Young, Palta, Dempsey, Skatrud, Weber, & Bader, 1993). Being male and being obese were found to be strongly associated with the presence of sleep-disordered breathing (Young et al., 1993). Upon additional analysis, an estimate found that at least 80% of moderate to severe sleep apnea is missed in middle-aged men and women (Young, Evans, Finn, & Palta, 1997).

A later follow-up to the Wisconsin Sleep Cohort Study reviewed eighteen year mortality rates in this population (Young et al., 2008). This review found that sleep disordered breathing, including obstructive sleep apnea, tripled mortality from all causes of death (Young et al., 2008). Young and colleagues also found that treatment of obstructive sleep apnea with a positive airway pressure device decreased mortality due to cardiovascular and cerebrovascular deaths (Young et al., 2008).

Diagnosis of Obstructive Sleep Apnea

When an individual is suspected of having obstructive sleep apnea, a sleep study is conducted using the polysomnogram (also known as a sleep study) which is typically performed in a sleep testing facility with a technologist present, and measures the apnea and hypopnea events as well as other neurophysiologic and respiratory variables (Kryger et al., 2000). Attended polysomnography can confirm the diagnosis of obstructive sleep apnea, determine the severity of obstructive sleep apnea, and can, in certain types of studies, evaluate response to positive airway pressure therapy (Kryger et al., 2000). During a sleep study using polysomnography with electroencephalography, the apnea hypopnea index is measured. The apnea hypopnea index is the number of episodes of

apneas or hypopneas per hour of sleep (Kryger et al., 2000). The apnea hypopnea index is classified as mild obstructive sleep apnea (5 to 15 events per hour), moderate obstructive sleep apnea (greater than 15 to 30 events per hour), or severe obstructive sleep apnea (greater than 30 events per hour) (American Academy of Sleep Medicine, 2005).

An alternative to the sleep center based attended polysomnogram is the out of center test, commonly referred to as a home sleep study (Collop, 2010). These limited channel out of center tests can be done in any environment where the individual sleeps, most commonly at home (Collop, 2010). Although more convenient and less costly than the attended polysomnogram, commonly used out of center tests are unable to measure as many parameters as the center based attended polysomnogram (Collop, 2010). One such parameter is total sleep time and this produces some limitations to the information gathered from this testing method (Collop, 2010).

A typical out of center sleep study measures a disordered breathing parameter similar to the apnea hypopnea index called the respiratory disturbance index (Collop, 2010). Because sleep time is not available, the parameter cannot be defined as the apnea hypopnea index (Collop, 2010). Out of center sleep studies may not be adequate for all patients suspected of having sleep apnea (Collop, 2010). This type of test does offer a faster alternative than traditional testing and may be used to determine if further sleep center monitored testing is required (National Institutes of Health, 2012; Begany, 2002).

Treatment of Obstructive Sleep Apnea

Treatment options for obstructive sleep apnea include mandibular advancement devices, weight loss, surgery, and positive airway pressure devices (Agency for Healthcare Research and Quality, 2011). Mandibular advancement devices are hard

plastic devices that cover the upper and lower teeth, and tongue protruding the jaw forward to widen the posterior oropharyngeal airway (Agency for Healthcare Research and Quality, 2012). Usually these devices are fitted by a dentist or orthodontist (Agency for Healthcare Research and Quality, 2012). Mandibular advancement devices have been found to have a 52% rate of success at decreasing the apnea hypopnea index to below 10 events per hour (Woodson, 2010). At this time, mandibular advancement devices are not considered adequate treatment for obstructive sleep apnea by the Motor Carrier Safety Advisory Committee due to inability to monitor adherence (2012).

Weight loss can also reduce or eliminate obstructive sleep apnea (Motor Carrier Safety Administration, 2012). Bariatric surgery, commonly known as weight loss surgery, is an option for obese individuals with obstructive sleep apnea (Motor Carrier Safety Administration, 2012). Some obese individuals have decreased or even cured their apnea by losing significant amounts of weight (Motor Carrier Safety Administration, 2012).

Other surgical interventions can help alleviate obstructive sleep apnea symptoms (Agency for Healthcare Research and Quality, 2011). Oropharyngeal surgery to help remove tissue from the posterior pharynx helps widen the area and decrease obstruction (Motor Carrier Safety Administration, 2012). A last resort, tracheostomy, will eliminate symptoms by providing a new breathing route that bypasses the posterior oropharynx (Motor Carrier Safety Administration, 2012).

Positive airway pressure therapy is the most commonly prescribed treatment for obstructive sleep apnea (Agency for Healthcare Research and Quality, 2011). Positive airway pressure devices include continuous (single setting), bi-level (dual setting), and

auto-titrating (automatically adjusting) positive airway pressure devices (Agency for Healthcare Research and Quality, 2011). The positive airway pressure device has an interface that fits into the nostrils (nasal pillows), over the nose (nasal mask), or nose and mouth (full face mask), and forces air through the nose or nose and mouth to keep the airway open (Agency for Healthcare Research and Quality, 2011).

In 2003, Weaver and colleagues, found that about half of the subjects in their study of continuous positive airway adherence had limited understanding of the comorbidities and other possible risks related to obstructive sleep apnea (Weaver et al., 2003). The majority of patients in this study were not capable of linking adverse effects such as problems with sexual dysfunction, attention, depression, or driving sleepy to obstructive sleep apnea (Weaver et al., 2003). In 2005, Lindberg and colleagues studied the treatment effects of positive airway pressure therapy on the metabolic profile in patients with an apnea hypopnea index greater than 10 (Lindberg, Berne, Elmasry, Hedner, & Janson, 2006). This study found that insulin resistance may be improved after positive airway pressure treatment without change of body weight and suggests that insulin resistance may be induced by sleep apnea unrelated to obesity (Lindberg et al., 2006). The subjects in this study reported improvements in vitality and mental health after treatment with positive airway pressure devices (Lindberg, et. al, 2006). Unfortunately this study also found that even though positive airway pressure therapy is highly effective at treating obstructive sleep apnea, success is hampered by adherence (Lindberg et al., 2006).

A Task Force from the American Academy of Sleep Medicine reviewed literature pertaining to the treatment of sleep disordered breathing in adults with positive airway

pressure treatment (Gay, Weaver, Loubé, & Iber, 2006). The Task Force reported that positive airway pressure therapy is an effective therapy, eliminating respiratory disturbances and reducing the apnea hypopnea index as compared to placebo, or other therapies (Gay et al., 2006). Gay et al. also found that the first few weeks of treatment are key to determining the benefit and adherence to positive airway pressure therapy, and determined that there was no evidence that bi-level positive airway pressure devices, a two pressure setting device, improved effectiveness or usage in the treatment of obstructive sleep apnea in initial use of positive airway pressure therapy but the evidence supports equivalency for effectiveness and adherence compared to continuous positive airway pressure therapy (Gay et al., 2006).

George and colleagues conducted a study in 1996 evaluating nasal continuous positive airway pressure therapy (George, Boudreau, & Smiley, 1997). This study found that treatment of this nature resulted in significant improvement in simulated driving performance in a group of patients with obstructive sleep apnea (George et al., 1997). In another study, usage of positive airway pressure therapy reportedly reduced crash risk in commercial drivers diagnosed with severe obstructive sleep apnea (Gurubhagavatula et al., 2004).

Adherence to Positive Airway Pressure Therapy

The currently accepted minimum adherence treatment standard for positive airway pressure devices in individuals with obstructive sleep apnea is use of the device for at least 4 hours per night for at least 70% of nights (Motor Carrier Safety Advisory Committee, 2012). Unfortunately, minimum adherence rates of 30% to 60% have been found for continuous positive airway devices in the general population (Weaver &

Sawyer, 2009). In commercial vehicle drivers, adherence is estimated to be even less (Parks, Durrand, Tsismenakis, Vela-Bueno, & Kales, 2009). Parks and colleagues estimated adherence to positive airway pressure therapy in the commercial driver population to be about 1 in 20 but this result may be skewed due to individuals' non-compliance with sleep testing and loss to follow-up (Parks, et al., 2009).

Commercial Vehicle Drivers and Obstructive Sleep Apnea

The trucking industry has the third highest rate of worker fatality in the United States' workforce accounting for about 12% of all worker deaths (Tregear et al., 2010). In 1999, the U.S. Department of Transportation established the Federal Motor Carrier Safety Administration to decrease collisions, damages, and deaths by large commercial vehicles (Tregear et al., 2010). A part of U.S.'s Federal Motor Carrier Safety Administration's goals were to develop and maintain medical fitness standards for commercial vehicle drivers (Tregear et al., 2010). In 2009, Tregear and colleagues conducted a literature review regarding the effect of continuous positive airway pressure treatment on motor vehicle collision risk among drivers with obstructive sleep apnea and also reviewed time on continuous positive airway pressure treatment required to increase driver safety (Tregear et al., 2010). Tregear et al. (2010) reported use of continuous positive airway pressure decreased crash risk among all drivers with moderate-to-severe obstructive sleep apnea. Excessive daytime sleepiness symptoms could often be relieved within one day of treatment (Tregear et al., 2010).

In 2002, the U.S. Federal Motor Carrier Safety Administration and the American Transportation Research Institute of the American Trucking Association sponsored a study at the University of Pennsylvania and found that approximately "17.6% of

commercial motor vehicle license holders had mild sleep apnea, 5.8% had moderate sleep apnea and 4.7% had severe sleep apnea” (Federal Motor Carrier Safety Administration, 2002, p. 3). Gurubhagavatula et al. (2004) attempted to identify commercial drivers with severe sleep apnea thru subjective, reported, and objective, measured, screening methods and found that combining subjective symptoms and body mass index plus sleep oximetry resulted in a “91% sensitivity and specificity and yielded a negative likelihood ratio of 0.10” (Gurubhagavatula et al., 2004). Additionally, the researchers were able to exclude severe apnea and this was valuable since confirmatory polysomnography testing is costly and potentially unobtainable (Gurubhagavatula et al., 2004).

The U.S. Federal Motor Carrier Safety Administration states that a commercial vehicle driver must have “no established medical history or clinical diagnosis of respiratory dysfunction likely to interfere with the ability to control and drive a commercial motor vehicle safely” (Federal Register, 2000, p. 5). In 2006, a Task Force comprised of representatives from the following specialty organizations: the American College of Chest Physicians, the American College of Occupational and Environmental Medicine, and the National Sleep Foundation was convened to address concerns related to obstructive sleep apnea risk in commercial drivers (Hartenbaum et al., 2006). The Task Force recommended assessment of drivers for possible sleep apnea and evaluation for “fitness for duty of commercial drivers with possible or probable sleep apnea” (Hartenbaum et al., 2006, p. 903). The Joint Task Force for screening criteria of commercial motor vehicle drivers for obstructive sleep apnea listed the following as risk factors: hypertension, body mass index greater than 35 (lbs/in²), and neck circumference

greater than or equal to 17 inches for males and greater than or equal to 16 inches for females (Talmage et al., 2008).

In 2008, Talmage and colleagues conducted a study, to evaluate criteria for screening commercial motor vehicle drivers for obstructive sleep apnea (Talmage, Hudson, Hegmann, & Thiese, 2008). This study found that the criteria yielded a high probability for detecting the condition with a positive predictive value of 94.8% (Talmage et al., 2008). Unfortunately, little published knowledge beyond this study is available regarding effectiveness of screening methods for obstructive sleep apnea in commercial drivers.

Regulations for Commercial Drivers with Obstructive Sleep Apnea

Recommendations have been made regarding screening criteria for obstructive sleep apnea in commercial motor vehicle drivers (Hartenbaum et al., 2006). Although use of these recommendations is encouraged, it is not mandated by statute. Evolving regulations are urging increased use of the recommendations of the Joint Task Force (Talmage et al., 2008).

In 1991, the Office of Motor Carriers, the Federal Highway Administration, and the U.S. Department of Transportation conducted a conference to expand medical criteria for commercial motor vehicle drivers with conditions of the respiratory tract (Office of Motor Carriers, 1991). The 1991 conference suggested that commercial motor vehicle drivers with probable obstructive sleep apnea or with “proven but untreated sleep apnea be medically disqualified for commercial motor vehicle operation until the diagnosis has been eliminated or adequately treated” (Office of Motor Carriers, 1991). This Task Force recommended that “individuals with known sleep apnea be allowed to obtain certification

to drive only after successful therapy has resulted in multiple sleep latency testing values within the normal range or repeat sleep study during treatment shows resolution of apnea” (Office of Motor Carriers, 1991. p. 41).

After treatment for sleep apnea, commercial drivers that meet the medical qualifications to operate a commercial motor vehicle must continue positive airway pressure therapy treatment in a continuous pattern to retain operator’s certification (Office of Motor Carriers, 1991). The Task Force also recommended annual re-certification and yearly multiple sleep latency testing (a test to measure how quickly an individual falls asleep in a quiet environment during normal wakeful hours) or repeat sleep study in drivers who have been diagnosed with obstructive sleep apnea to confirm adequate treatment (Office of Motor Carriers, 1991). Since the original Task Force in 1991, the recommendations regarding multiple sleep latency testing and annual sleep study, or polysomnography, have been removed (Motor Carrier Safety Advisory Committee, 2012).

The latest endorsements from the Motor Carrier Safety Advisory Committee, a group of sleep experts that advise the Federal Motor Carrier Safety Administration, state that a driver with obstructive sleep apnea may be certified to drive if he or she has an “apnea hypopnea index of less than 20” and “no excessive sleepiness during the major wake period or the driver” has been “effectively treated” (Motor Carrier Safety Advisory Committee, 2012, p. 1). This criteria is used because moderate to severe sleep apnea with an apnea hypopnea index greater than 20 events per hour, has a statistically higher crash risk than for drivers with mild to moderate obstructive sleep apnea, an apnea

hypopnea index of 5 to 20 events per hour (Motor Carrier Safety Advisory Committee, 2012).

The rules and regulations established by the U.S. Department of Transportation's Federal Motor Carrier Safety Administration for medical qualifications for commercial drivers are published under rule 391.41 of the medical program and states a driver may be medically "qualified if he/she has no established medical history or clinical diagnosis of respiratory dysfunction likely to interfere with his/her ability to control and drive a commercial motor vehicle safely" (Federal Registry, 2012, p. 2). The current medical examination report used for the U.S. Department of Transportation physicals includes one question on the history regarding sleep disorders (Federal Register, 2000). The patient history form has a single yes or no question that asks if the driver has "a sleep disorder, pauses in breathing while asleep, daytime sleepiness, or loud snoring" (Federal Register, 2000, p. 1). This is a self-reported subjective response question that may or may not be answered truthfully by the respondent (Federal Register, 2000).

At this time, the U.S. Department of Transportation physical examination form does not provide examiners with guidance as to which drivers need to be screened more thoroughly for obstructive sleep apnea (Federal Register, 2000). Very few conditions exist that are automatic failures for the examination (Federal Register, 2000). Loss of a limb is an automatic failure but a waiver can be obtained after a skill performance evaluation certificate has been issued (Federal Register, 2000). Individuals using insulin to control diabetes cannot be "qualified to drive a commercial vehicle" (Federal Register, 2000, p. 4). Cardiac, respiratory, musculoskeletal, neurologic, and psychologic conditions that are "likely to interfere with the ability to operate a motor vehicle" are

disqualifiers (Federal Register, 2000, p. 2). Distance vision must be at least 20/40 as tested by a Snellen chart and the driver must be able to distinguish between red and green traffic lights (Federal Register, 2000). The driver must be able to hear a forced whisper at five feet, must not use a schedule I controlled substance unless “prescribed by a licensed medical practitioner who is familiar with the driver”, and must not have a current diagnosis of alcoholism (Federal Register, 2000, p. 3). Unfortunately, most driver examinations are not performed at the individual’s primary care provider so past medical records are not available.

Summary

The medical condition known as obstructive sleep apnea has developed over the course of the past century (American Academy of Sleep Medicine, 2005). Co-morbidities can be worsened by or even caused by obstructive sleep apnea (American Academy of Sleep Medicine, 2005). Driving with untreated sleep apnea puts both the driver and the public at greater risk for collisions due to sleepy driving (Centers for Disease Control and Prevention & National Institutes of Health, 2010). Commercial vehicle drivers must remain vigilant during hours of vehicle operation so that the public’s health is not compromised (Centers for Disease Control and Prevention & National Institutes of Health, 2010).

Project Design

Project Description

This study was a retrospective electronic health record review utilizing existing electronic health records and commercially available online adherence software to gather data for analysis. These records were reviewed for adherence with the U.S. Federal

Motor Carrier Safety Administration's Motor Carrier Safety Advisory Committee's (2012) proposed recommendations for positive airway pressure therapy in commercial motor vehicle drivers. The length of time for drivers to meet U.S. Federal Motor Carrier Safety Administration's adherence goals was recorded and analyzed.

Definition of Terms

Adiposity. "Obesity" (Venes (ed.), 2013).

Afterload. "In cardiac physiology, the force that impedes the flow of blood out of the heart. The heart contracts against a resistance primarily composed of the pressure in the peripheral vasculature, the compliance of the aorta, and the mass and viscosity of blood" (Venes (ed.), 2013).

Alveolar ventilation. "The movement of air into and out of the alveoli. It is a function of the size of the tidal volume, the rate of ventilation, and the amount of dead space present in the respiratory system. It is determined by subtracting the dead space volume from the tidal volume and multiplying the result by the respiratory rate" (Venes (ed.), 2013).

American Academy of Sleep Medicine. "Headquartered in Darien, Illinois, the American Academy of Sleep Medicine is the only professional society dedicated exclusively to the medical subspecialty of sleep medicine. As the leading voice in the sleep field the American Academy of Sleep Medicine sets standards and promotes excellence in health care, education and research. Established in 1975 as the Association of Sleep Disorders Centers, the American Academy of Sleep Medicine has a combined membership of nearly 12,000 accredited member sleep centers and individual members,

including physicians, scientists and other health care professionals” (American Academy of Sleep Medicine, 2013).

Apnea. “Temporary cessation of breathing and, therefore, of the body’s intake of oxygen and release of carbon dioxide. It is a serious symptom, especially in patients with other potentially life-threatening conditions” (Venes (ed.), 2013).

Apnea hypopnea index: “The number of episodes of apneas or hypopneas per hour of sleep” (Kryger et al., 2000).

Apneic. The act of having apnea.

Biostatistician. “An individual that systematically collects, organizes, analyzes, and interprets numerical data pertinent to biological subjects” (Venes (ed.), 2013).

Body mass index. “A measure of body fat that is the ratio of the weight of the body in kilograms to the square of its height in meters” (Merriam-Webster, 2013).

Cardiac dysrhythmia. Abnormal heart rhythm.

Catecholamines. “Many biologically active amines, including metanephrine, dopamine, epinephrine, and norepinephrine, derived from the amino acid tyrosine. They have a marked effect on the nervous and cardiovascular systems, metabolic rate, temperature, and smooth muscle” (Venes (ed.), 2013).

Cerebral anoxic attacks: Episodes within the cerebrum when oxygen is completely absent (Venes (ed.), 2013).

Commercial motor vehicle. Large trucks and buses used to transport people and goods across state lines (Federal Motor Carrier Safety Administration, 2013).

Controlled schedule I substance. “Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for

abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Some examples of Schedule I drugs are: Heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote” (United States Drug Enforcement Agency, 2013).

Cor pulmonale. “Hypertrophy or failure of the right ventricle resulting from disorders of the lungs, pulmonary vessels, chest wall, or respiratory control center. Living for an extended period at a high altitude may occasionally cause this condition” (Venes (ed.), 2013).

De-identified. All identifying information removed.

Department of Transportation (United States). Synonymous with the U.S. Department of Transportation. “The Department of Transportation was established by an act of Congress on October 15, 1966. The Department’s first official day of operation was April 1, 1967. The mission of the Department is to: Serve the United States by ensuring a fast, safe, efficient, accessible and convenient transportation system that meets our vital national interests and enhances the quality of life of the American people, today and into the future. Leadership of the DOT is provided by the Secretary of Transportation, who is the principal adviser to the President in all matters relating to federal transportation programs” (United States Department of Transportation, 2013).

Diabetes (mellitus). “A chronic metabolic disorder marked by hyperglycemia” (Venes (ed.), 2013).

Dilated cardiomyopathy. “Diminished cardiac performance caused by greatly enlarged heart chambers and thinning of ventricle walls” (Venes (ed.), 2013).

Dysregulation. “Impairment of a physiological regulatory mechanism” (Miriam-Webster, 2013).

Endothelial. “Pertaining to or consisting of a form of squamous epithelia-like tissue consisting of flat cells that line the blood and lymphatic vessels, the heart, and various other body cavities. Endothelia differ from epithelia in that the former is derived from mesoderm while the latter is derived from ectoderm or endoderm. Taken together, the endothelium throughout the body has a surface area more than twice that of the skin. Endothelial cells are metabolically active and produce a number of compounds that affect the vascular lumen and platelets. Included are endothelium-derived relaxing factor, prostacyclin, endothelium-derived contracting factors 1 and 2, endothelium-derived hyperpolarizing factor, and thrombomodulin” (Venes (ed.), 2013).

Federal Motor Carrier Safety Administration. “An agency established within the United States Department of Transportation on January 1, 2000, by the Motor Carrier Safety Improvement Act of 1999. The primary purpose of this agency is to prevent commercial motor vehicle-related fatalities and injuries” (Federal Motor Carrier Safety Administration, 2013).

High density lipoproteins. “Plasma lipids bound to albumin, consisting of conjugated chemicals in the bloodstream consisting of simple proteins bound to fat. A high level of high density lipoproteins is desirable” (Venes (ed.), 2013).

Hypercoagulation. “An increased ability of anything to coagulate, but especially the blood” (Venes (ed.), 2013).

Hypertension. “In adults, a condition in which the blood pressure is higher than 140 mm Hg systolic or 90 mm Hg diastolic on three separate readings recorded several

weeks apart. Hypertension is one of the major risk factors for coronary artery disease, heart failure, stroke, peripheral vascular disease, kidney failure, and retinopathy. It affects about 50 million people in the United States. Considerable research has shown that controlling hypertension increases longevity and helps prevent cardiovascular illness” (Venes (ed.), 2013).

Hypertrophy. “Excessive development of an organ or part; specifically an increase in bulk (as by thickening of muscle fibers) without multiplication of parts” (Miriam-Webster, 2013).

Hypopnea. “Decreased rate and depth of breathing” (Venes (ed.), 2013).

Hypopnic. “The state of having hypopnea which is a decreased rate and depth of breathing” (Venes (ed.), 2013).

Hypoxia. “An oxygen deficiency in body tissues. A decreased concentration of oxygen in inspired air” (Venes (ed.), 2013).

Inspiration. “Inhalation; drawing air into the lungs; the opposite of expiration. The average rate is 12 to 18 respirations per minute in a normal adult at rest” (Venes (ed.), 2013).

Insulin. “A hormone secreted by the beta cells of the pancreas. As a drug, insulin is used principally to control diabetes mellitus. Insulin therapy is required in the management of type 1 diabetes mellitus because patients with this illness do not make enough insulin on their own to survive. The drug also is used in the care of patients with gestational diabetes to prevent fetal complications caused by maternal hyperglycemia (insulin itself does not cross the placenta or enter breast milk). In type 2 diabetes

mellitus, its use typically is reserved for those patients who have failed to control their blood sugars with diet, exercise, and oral drugs” (Venes (ed.), 2013).

Interstate. “Of, connecting, or existing between two or more states especially of the United States” of America (Merriam-Webster, 2013).

Intrastate. “Existing or occurring within a state such as within the United States” (Merriam-Webster, 2013).

Intrathoracic. “Within the thorax. The thorax is the part of the body between the base of the neck superiorly and the diaphragm inferiorly” (Venes (ed.), 2013).

Ischemic heart disease. “An inadequate supply of blood to meet the metabolic demands of the heart muscle” (Venes (ed.), 2013).

Joint Task Force. “A task for comprised of individuals from the American College of Chest Physicians, the American College of Occupational and Environment Medicine, and the National Sleep Foundation” (Hartenbaum, et a., 2006).

Leptin. “A helical peptide hormone produced by adipose tissue. Leptin acts on cells in the hypothalamus in response to increases in body fat storage to suppress appetite and increase energy expenditure. It also contributes to the onset of puberty and to the secretion of insulin by the pancreas” (Venes (ed.), 2013).

Lipoproteins. “Any of the conjugated chemicals in the bloodstream consisting of simple proteins bound to fat. Cholesterol, phospholipids, and triglycerides are all fatty components of lipoproteins. Analyzing the concentrations and proportions of lipoproteins in the blood can provide important information about patients’ risk of atherosclerosis, coronary artery disease, and death” (Venes (ed.), 2013).

Low density lipoproteins. “Any of the plasma lipids that carry most of the cholesterol in plasma. Bound to albumin, low density lipoproteins are a proven cause of atherosclerosis. Lowering low density lipoproteins with a low fat diet or with drugs help prevent and treat coronary disease” (Venes (ed.), 2013).

Motor Carrier Safety Administration. Synonymous with the Federal Motor Carrier Safety Administration.

Multiple sleep latency testing. “A test to diagnose any of several causes of excessive daytime sleepiness. Causes include insomnia, narcolepsy, and obstructive sleep apnea” (Venes (ed.), 2013).

Nocturnal angina. “An oppressive pain or pressure in the chest caused by inadequate blood flow and oxygenation to heart muscle that occurs at night” (Venes (ed.), 2013).

Objective. “Able to be analyzed, measured, or counted. Objective findings are those findings that are obtained during the physical examination. Opposite of subjective” (Venes (ed.), 2013).

Obstructive sleep apnea. “The temporary absence of breathing during sleep. In obstructive sleep apnea, vigorous respiratory efforts are present during sleep but the flow of air in and out of the airways is blocked by upper airway obstruction” (Venes (ed.), 2013). In obstructive sleep apnea hypopnea syndrome, this also includes a reduction in breathing.

Oxidative stress. “Stress that occurs with oxidation. Oxidation is “the process of a substance combining with oxygen and also is the loss of electrons in an atom with an accompanying increase in positive valence” (Venes (ed.), 2013).

Oxygen desaturation. A decrease in “the percent of arterial hemoglobin saturated with oxygen. Usual arterial hemoglobin saturation is 96%” (Venes (ed.), 2013).

Polysomnogram. “The simultaneous monitoring of respiratory, cardiac, muscle, brain, and ocular function during sleep. It is used most often to diagnose sleep apnea” (Venes (ed.), 2013).

Preload. “In cardiac physiology, the end-diastolic stretch of a heart muscle fiber. In the intact ventricle, this is approximately equal to the end-diastolic volume or pressure. At the bedside, preload is estimated by measuring the central venous pressure or the pulmonary capillary wedge pressure” (Venes (ed.), 2013).

Reoxygenation: “The process of resaturation or recombination with oxygen” (Venes (ed.), 2013).

Respiratory disturbance index. The average number of respiratory disturbances (obstructive apneas, hypopneas, and respiratory event–related arousals) per hour of recording time (Centers for Medicare and Medicaid Services, 2013).

Retrospective study design. “A clinical study in which patients or their records are investigated after the patients have experienced the disease, condition, or treatment” (Venes (ed.), 2013).

Sleep center. A health care agency that is equipped with staff to recognize, diagnose and treat all sleep-related issues (Clayton Sleep Institute, 2013).

Sleep fragmentation. Interrupted sleep.

Statistician. “An individual that systematically collects, organizes, analyzes, and interprets numerical data pertinent to any subject” (Venes (ed.), 2013).

Subjective. “Arising from or concerned with the individual; not perceptible to an observer; the opposite of objective” (Venes (ed.), 2013).

Tonsillar. “Pertaining to a tonsil, especially the faucial or palatine tonsil” (Venes (ed.), 2013).

Triglycerides. “Any combinations of glycerol with three of five different fatty acids. These substances, triacylglycerols, are also called neutral fats. In the blood, triglycerides are combined with proteins to form lipoproteins. The liver synthesizes lipoproteins to transport fats to other tissues, where they are a source of energy” (Venes (ed.), 2013).

Project Questions

This study attempted to answer the following research questions pertaining to the drivers of commercial motor vehicles referred to the sleep center for sleep disorder assessment.

1. How many commercial motor vehicle drivers referred to the sleep center as a result of a positive screen for sleep disorders by a commercial motor vehicle driver medical examiner had a true positive test for obstructive sleep apnea based on results from either an attended polysomnogram or an out of center sleep test?
2. How many commercial motor vehicle drivers with a true positive test for obstructive sleep apnea treated with positive airway pressure therapy achieved minimum expectations of adherence at 1 week, 1 month, 3 months, 6 months, and 1 year?

3. Did a difference exist in the ability of commercial motor vehicle drivers with an apnea hypopnea index or respiratory disturbance index of 5 to 20 events per hour compared to subjects with an apnea hypopnea index or respiratory disturbance index of more than 20 events per hour to reach treatment goals?

Methodology

Electronic health records were reviewed from a sleep center located in a Midwest metropolitan city. The sleep center is a testing facility credentialed by the American Academy of Sleep Medicine (Clayton Sleep Institute, 2013). The sleep center treats a variety of sleep problems for individuals of all ages and provides educational resources for patients, medical professionals, scientists and the general public (Clayton Sleep Institute, 2013).

Subjects in this study consisted of commercial motor vehicle drivers referred to the sleep center and evaluated for sleep disorders including obstructive sleep apnea via clinical evaluation, attended polysomnography or out of center sleep study. The respiratory disturbance index, measured during out of center sleep studies, is similar to the apnea hypopnea index, measured during attended polysomnograms, but does not quantify total sleep time. The drivers' charts were reviewed for presence and severity of obstructive sleep apnea as determined by the apnea hypopnea index and respiratory disturbance index and for usage of positive airway pressure therapy, if any. Patients' charts from January 1, 2012 thru December 31, 2012 were reviewed. Drivers' charts that were prescribed positive airway pressure therapy were reviewed for one year of data when available. The initial number of charts to be reviewed in this study was 140.

Commercial motor vehicle drivers that had a true positive test for obstructive sleep apnea were divided into two groups. The first group consisted of drivers with an apnea hypopnea index or respiratory disturbance index of 5 to 20 events per hour (mild to moderate obstructive sleep apnea). The second group consisted of drivers with an apnea hypopnea index or respiratory disturbance index greater than 20 events per hour (moderate to severe obstructive sleep apnea). Comparisons between these two groups were made to determine if any differences in adherence existed.

For this study, the apnea hypopnea index and respiratory disturbance index was set at greater than 20 events per hour because the current recommendations from the U.S. Federal Motor Carrier Safety Administration suggest crash risk in the moderate-to-severe obstructive sleep apnea range is statistically higher in this group than for drivers with mild to moderate obstructive sleep apnea (Motor Carrier Safety Advisory Committee, 2012). Adequate treatment for obstructive sleep apnea for the purpose of this study was the minimum requirement defined by the Expert Panel Recommendations for Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety (Ancoli-Israel, Czeisler, Guilleminault, & Pack, 2008). Current minimally accepted adherence to positive airway pressure therapy is defined by the Expert Panel Recommendations as use of positive airway pressure for at least 4 hours per night for at least 70% of nights (Ancoli-Israel et al., 2008). This minimally accepted adherence is considered adequate but not ideal.

Protection of Human Subjects

Permission to initiate this project was obtained from the Midwest Sleep Center, located in St. Louis, Missouri (see Appendix A). Permission was also obtained from the

University of Missouri-St. Louis's Internal Review Board prior to initiating this study. All efforts have been made to eliminate any confidentiality violations during this study.

Procedure for Data Collection

Data was extracted from the electronic health records utilizing the programs AllscriptsMyWay® and Practice Partners®. The data was related to obstructive sleep apnea diagnosis based on apnea hypopnea index or respiratory disturbance index. Apnea hypopnea index or respiratory disturbance index was determined by the aforementioned criteria and was recorded as number of events per hour (Hartenbaum et al., 2006).

Individual usage data for positive airway pressure therapy was recorded by the treatment device and uploaded into commercially available software for data review. The software, Encore Pro™ and EncoreAnywhere™, from Philips® was utilized to access usage data on Resironics® positive airway pressure devices (Philips Resironics, 2013). ResScan™ or Easy Care Online™ Patient Management System was used for ResMed™ positive airway pressure devices to gather data (ResMed, 2013). Lastly, the Fisher & Paykel® software, InfoSmart™ or InfoSmart Web™, was used for positive airway pressure devices compatible with this program (Fisher & Paykel Healthcare, 2013). With every proprietary software, the calculations of the percentage of days with usage more than 4 hours were provided.

A team composed of this researcher, the biostatistician, and a clinician familiar with the programs at the sleep center was responsible for analyzing the data. The clinician at the sleep center's office acted as a facilitator to help access data collection and retrieval. The health system biostatistician served as a consultant and director for data retrieval, preparation and analysis. The analytic software, SPSS® latest version, was

used for data analysis (IBM, 2013). The biostatistician assisted with data manipulation relevant to measurements for comparisons.

Resources Utilized

Access to the sleep center's electronic health records was necessary for this project. A biostatistician familiar with SPSS® was necessary to help with data analysis. This individual assisted with data analysis and interpretation. Data from the electronic health records was turned into meaningful data with the assistance of the biostatistician.

Time to complete the necessary interpretation of the data was necessary for this project. The charts of less than 200 (n~138) subjects were reviewed for data retrieval. The amount of time to review and analyze these charts was also a necessary resource.

Stakeholders, Team Members, and Project Involvement

The key stakeholders of this study included drivers with a positive screen for obstructive sleep apnea by U.S. Department of Transportation commercial motor vehicle driver medical examiners, drivers that had a true positive test for obstructive sleep apnea, drivers that did not have a true positive test for obstructive sleep apnea, trained staff and healthcare providers at the sleep center, positive airway pressure equipment suppliers, families of commercial motor vehicle drivers with a positive screen for obstructive sleep apnea, families of commercial motor vehicle drivers with a positive diagnosis of obstructive sleep apnea, referring providers, insurance providers, employers, and governing bodies such as the U.S. Department of Transportation and the Federal Motor Carrier Safety Administration. More far-reaching stakeholders related to obstructive sleep apnea in commercial drivers include the National Institutes of Health, the National Transportation Safety Board, the National Institutes of Nursing Research, the American

Academy of Sleep Medicine, occupational medicine organizations, and the Centers for Disease Control and Prevention.

During the planning of this study, select stakeholders were interviewed to determine the most useful data to collect. Discussions and interviews were conducted to accommodate stakeholders' schedules. The stakeholders chose the focus of the study to be on the commercial vehicle drivers' adherence to positive airway pressure data. This was deemed to be the most relevant data for the sleep institute to evaluate in regards to their commercial motor vehicle driver program.

As the Federal Motor Carrier Safety Administration began recommending more in-depth screening for obstructive sleep apnea, the sleep center has been performing more evaluations on commercial motor vehicle drivers. The time period of January 1, 2012 thru December 31, 2012, was a convenient specific time period of drivers that were evaluated during the time of the study and were followed up on for at least three to six months afterward and in many cases a full year.

Extracting data from the electronic health records and from the positive airway pressure device software adherence programs provided opportunities for data collection and manipulation that were previously unobtainable. Since October of 2011, the sleep center has utilized electronic health records. The electronic health records allowed specific areas of data to be gathered and analyzed. The advanced practice nurse at the sleep center acted as a liaison. She assisted with access to electronic health records, sleep center, and sleep laboratory data as well as positive airway pressure adherence data. Assistance from statisticians and research analysts was incorporated as the need arose.

Barriers and Challenges to Project

Archived data from the electronic health records of the sleep center was utilized for data in this study. Access and ability to use the programs at the facilities was a challenge. Health Insurance Portability and Accountability Act of 1996 rules and regulations were followed. These rules are in place to protect an individual's privacy but can also be a hindrance when gathering data. Care was taken in data collection to ensure anonymity.

Technology can facilitate a project. Unfortunately, that same technology can also prove to be a barrier. As long as the technology functioned as planned, data collection was not problematic. If the technology failed in any fashion, from programming and hardware to electrical supply, data collection would have been halted either for the current subject or for the entire data set depending on the occurrence. Also, many drivers stopped follow-up with the sleep center and were lost to data collection.

Ethical Issues and Concerns

Data files for this study did not contain any identifying patient information. The archived electronic data was extracted by this researcher and the research team had legitimate access to the electronic health records. The analytic team was composed of this researcher, the biostatistician, and the research analyst. Mandatory Health Insurance Portability and Accountability Act of 1996 training was completed prior to collection of any research data. The policies for data collection at the sleep center and the university were adhered to with strict compliance. No patient, provider names, locations, or any other identifying information was linked to any of the study variables. Data files contained a unique identifier to enable cross-referencing with subject charts. A key of

identifiers was kept at the sleep center and was not removed from the facility so that protected data was not compromised. Once data collection and analysis was complete, one copy of the key was kept in a secured location at the sleep center. No other copies exist.

The data utilized in this study was de-identified and the risks to the individual were minimal. No direct contact with subjects occurred. Contact with providers was limited to data collection within the host sleep center. All identifying patient information was removed prior to data removal from the sleep center location and data analysis. The patient data gathered from the electronic health record included the presence of obstructive sleep apnea, severity of obstructive sleep apnea, test type, the amount of time spent on positive airway pressure therapy, the amount of time needed to reach minimum adherence to positive airway pressure therapy, and descriptive data such as body mass index, sex and neck circumference. No individually identifying information chart was extracted from the patients' electronic health records except to produce the "key". Because this was a retrospective study, no changes in the workflow at the sleep center occurred.

Although current patients will not benefit directly from this study due to the retrospective nature, clinicians will benefit from the program evaluation and will work to improve the quality of the obstructive sleep apnea program for commercial motor vehicle drivers at the sleep center. U.S. Department of Transportation commercial motor vehicle driver medical examiners will gain knowledge from the outcomes of this study. Also, the sleep medicine and occupational medicine communities will benefit from the information

gathered regarding the effectiveness of screening programs for obstructive sleep apnea in the commercial vehicle driver.

Final Institutional Review Board approval was granted from the office at the University of Missouri-St. Louis, then data collection and extraction began. Permission to use the sleep institute's electronic health records was previously obtained (see Appendix A). Data collection and data analysis occurred from fall 2013 to winter of 2014 with the final presentation and project defense to be completed in spring 2014.

Project Results

Descriptive statistics were used to characterize the sample in this study. One-hundred forty charts were reviewed at the sleep center. Of these 140, two charts were not used because the drivers had not been referred by a U.S. Department of Transportation medical examiner, one was a clinic patient, one did not fit screening criteria for obstructive sleep apnea, and three were prior positive airway pressure device users. Data was not available for 5 drivers. One refused sleep apnea testing, and four did not have results for sleep apnea testing even though testing was ordered. Thus, 128 drivers referred to the sleep center met criteria for inclusion in this project. The majority of drivers (95, 74.2%) were male and 33 (25.8%) were female. Age of the drivers ranged from 23 to 67 years with a mean age of 47.85 years. Only 40 (31.3%) of the drivers did not have a previous diagnosis of hypertension while 88 (68.8%) did have a prior diagnosis of hypertension. Average neck circumference for the drivers in this study was 17.58 inches with a range of 14.0 inches to 24 inches. Average neck circumference for females was 15.91 inches and for males was 18.16 inches. Average body mass index for drivers in this study was 42.8 kg/m^2 with a range of 29.3 kg/m^2 to 76.1 kg/m^2 .

Project question 1. How many commercial motor vehicle drivers referred to the sleep center as a result of a positive screen for sleep disorders by a medical examiner had a true positive test for obstructive sleep apnea based on results from either an attended polysomnogram or an out of center sleep test?

Electronic health records of commercial motor vehicle drivers were reviewed from January 1, 2012 thru December 31, 2012. Of those reviewed, 128 drivers met criteria for a positive clinical screen by a U.S. Department of Transportation commercial motor vehicle driver medical examiner and were tested with a sleep study by polysomnogram, out of center sleep study or both (see Table 1). This project sought to determine how many of these drivers would have a true positive test for obstructive sleep apnea. Of the drivers clinically evaluated and quantitatively tested, 19 (14.8%) had an apnea hypopnea index or respiratory disturbance index less than five events per hour and 109 (85.2%) had an apnea hypopnea index or respiratory disturbance index greater than or equal to five events per hour, and thus a true positive test for obstructive sleep apnea. Of the 109 that had a true positive test for obstructive sleep apnea, 51 (39.8%) were found to have an apnea hypopnea index or respiratory disturbance index between 5 to 20 events per hour (mild to moderate obstructive sleep apnea) and 58 (45.3%) were found to have an apnea hypopnea index or respiratory disturbance index greater than 20 events per hour (moderate to severe obstructive sleep apnea) (see Table 2).

Table 1

Type of Test, Frequency and Percent (N=128)

Type of Test	Frequency	Percent
Polysomnogram	116	90.6
Out of clinic sleep study	9	7.0
Both	3	2.3

Table 2

Diagnosis and Severity of Obstructive Sleep Apnea (N=128) as Measured by Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI)

Variable	n	Percent
AHI or RDI < 5 events per hour	19	14.8
AHI or RDI ≥ 5 events per hour	109	85.2
AHI or RDI 5 to 20 events per hour	51	39.8
AHI or RDI ≥ 20 events per hour	58	45.3

Project question 2. How many commercial motor vehicle drivers with a true positive test for obstructive sleep apnea and treated for obstructive sleep apnea with positive airway pressure therapy achieved minimum treatment expectations at 1 week, 1 month, 3 months, 6 months and 1 year?

Data were gathered from the positive airway pressure device software for drivers with a true positive test for obstructive sleep apnea at the sleep center between January 1, 2012 and December 31, 2012 and received positive airway pressure therapy. Data were analyzed for minimal adherence at 1 week, 1 month, 3 months, 6 months and 1 year points. Table 3 presents the number of commercial motor vehicle drivers with an apnea hypopnea index or respiratory disturbance index of 5 to 20 events per hour (mild to moderate sleep apnea) and the number of commercial motor vehicle drivers with an apnea hypopnea index or respiratory disturbance index greater than 20 events per hour (moderate to severe sleep apnea) that did or did not meet the adherence goal for positive airway pressure therapy at specified time points.

Table 3

Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) at Time Intervals with Goal met versus Goal Not Met

Variable	<u>1 Week</u> n (%)	<u>1 Month</u> n (%)	<u>3 Months</u> n (%)	<u>6 Months</u> n (%)	<u>1 Year</u> n (%)
AHI or RDI 5 to 20 events/per hour	33	18	11	9	7
Goal Met	11(47.8%)	11(61.1%)	8(66.7%)	7(77.8%)	4(57.1%)
Goal Not Met	12(52.2%)	7(38.9%)	3(27.3%)	2(22.2%)	3(42.9%)
AHI or RDI > 20 events/per hour	58	56	50	42	35
Goal Met	40(69.0%)	35(62.5%)	33(62.3%)	28(66.7%)	21(60.0%)
Goal Not Met	18(31.0%)	21(37.5%)	17(32.1%)	14(33.3%)	14(40.0%)

Note. The number of drivers reporting back at the specified time points decreased. At the beginning, 83 drivers were treated with positive airway pressure therapy but only 42 drivers reported back at 1 year.

Project question 3. Did a difference exist in the ability of commercial motor vehicle drivers with an apnea hypopnea index or respiratory disturbance index of 5 to 20 events per hour compared to subjects with an apnea hypopnea index or respiratory disturbance index of more than 20 events per hour to reach treatment goals?

Drivers were compared at each time point for achievement of minimum treatment goals as defined by the Motor Carrier Safety Advisory Committee (2012) of least 4 hours per night of positive airway pressure usage for at least 70% of nights (Hartenbaum et al., 2006). Chi square statistical analysis was utilized to compare drivers with an apnea hypopnea index or respiratory disturbance index of 5 to 20 events per hour (mild to moderate obstructive sleep apnea) with the group of subjects that had an apnea hypopnea index or respiratory disturbance index of more than 20 events per hour (moderate to severe obstructive sleep apnea). No statistically significant differences ($p < 0.05$) were found at any time period between the two groups (See Table 4) of drivers continuing to utilize continuous positive airway pressure therapy.

Table 4

Chi-Square Values at Time interval for drivers with an Apnea Hypopnea Index or Respiratory Disturbance Index of 5 to 20 or Greater Than 20

Statistic	<u>1 Week</u>	<u>1 Month</u>	<u>3 Months</u>	<u>6 Months</u>	<u>1 Year</u>
Chi-Square Value $p < 0.05$	0.09	0.916	0.667	0.514	0.888

Note. Chi-square level of significance for this study was set at 0.05.

Discussion

For this study, sleep apnea was defined as an apnea hypopnea index or respiratory disturbance index greater than or equal to 5 events per hour. Drivers with an apnea hypopnea index or respiratory disturbance index greater than or equal to 5 events per hour were considered to have sleep apnea in this study. Commercial motor vehicle drivers were referred for further evaluation if two of the following three screening criteria were positive, as recommended by the Joint Task Force: body mass index greater than 35 kg/m²; neck circumference greater than 17 inches in males and 16 inches in females, and presence of treated or untreated hypertension (Hartenbaum, et al., 2006).

Parks and colleagues (2009) found that 17% of all drivers seen at an occupational medical clinic that did screen for obstructive sleep apnea using to the Joint Task Force guidelines, did have positive tests for obstructive sleep apnea. A previous study by Talmage and colleagues (2008) found that use of the Joint Task Force's screening criteria for obstructive sleep apnea in commercial motor vehicle drivers had a positive predictive value of 94.8% (Hartenbaum, et al., 2006). This project found similar results in that 109 out of 128 (85.2%) subjects had some amount of obstructive sleep apnea in patients with a prior positive screen using the Joint Task Force's screening criteria. Of the drivers referred to the sleep center, 51 (39.8%) had mild to moderate obstructive sleep apnea and

58 (45.3%) had moderate to severe obstructive sleep apnea. According to Hartenbaum (2010), treatment is highly recommended in the last group.

In this study, 84 drivers initially had positive airway pressure therapy prescribed. One driver had been evaluated with an out of center sleep study and was prescribed a positive airway pressure device but returned for further evaluation with a polysomnogram. This driver was found to not have clinically significant obstructive sleep apnea and his positive airway pressure device was discontinued. Thus the number for further evaluation in this study was decreased to 83 drivers. Of the remaining subjects, 25 had an apnea hypopnea index or respiratory disturbance index of 5 to 20 events per hour (mild to moderate obstructive sleep apnea) and did start positive airway pressure therapy. All of the 58 drivers with an apnea hypopnea index or respiratory disturbance index greater than 20 events per hour (moderate to severe obstructive sleep apnea) did start positive airway pressure therapy which is consistent with the Hartenbaum and colleagues (2006) recommendations.

At the 1 year time point, 42 (50.6%) drivers were continuing to use positive airway pressure therapy with 25 (30.1%) of the drivers meeting minimal treatment expectations. Of the drivers with an apnea hypopnea index or respiratory disturbance index greater than 20 events per hour (moderate to severe obstructive sleep apnea), 21 (36.2%) of the 58 originally prescribed positive airway pressure therapy were meeting the minimal adherence goal at 1 year of therapy. Of the original 25 drivers with an apnea hypopnea index of 5 to 20 events per hour (mild to moderate obstructive sleep apnea), 4 (16%) were meeting the minimal adherence goal at 1 year of therapy. Of the original 83 drivers prescribed positive airway pressure therapy, 25 (30.1%) were meeting minimal

adherence goals at the one year time point. From this data, drivers with moderate to severe obstructive sleep apnea (36.2%) were more adherent with positive airway pressure therapy at one year of treatment than those with mild to moderate obstructive sleep apnea (16%). Drivers in this project were also more adherent than drivers in the Parks and colleagues (2009) study, where only 1 driver out of 20 (5%) that were prescribed positive airway pressure therapy became adherent with treatment.

Positive airway pressure usage in commercial motor vehicle drivers is a newer area of study in this patient population. Limited published material is available for comparison of the results found in this study. As more commercial motor vehicle driver medical examiners become listed on the Federal Registry of Medical Examiners, evaluation for obstructive sleep apnea is expected to increase as recommendations become standards of care.

Project Outcomes

The de-identified data extracted from the electronic health records at the sleep center were analyzed. Standard descriptive statistics were used to analyze the described population. Minimum adherence goals between the two groups were analyzed using the Chi-Squared test. These electronic health records were from patients initially evaluated for obstructive sleep apnea between January 1, 2012 thru December 31, 2012.

The short term goal of this project was to identify the commercial motor vehicle drivers who were referred to the sleep center that did have obstructive sleep apnea as diagnosed by sleep study. For this study, sleep apnea was defined as an apnea hypopnea index or respiratory disturbance index greater than or equal to 5 events per hour. Drivers

with an apnea hypopnea index or respiratory disturbance index greater than or equal to 5 events per hour were considered to have sleep apnea in this study.

The intermediate goal for this project was to determine the number of commercial motor vehicle drivers seen at the sleep center that were using positive airway pressure therapy and meeting minimum adherence recommendations. This was completed by review of electronic health records for appropriate use of the device as recorded by the appropriate monitoring software. Minimally acceptable adherence criteria were defined by the Federal Motor Carrier Safety Administration as at least 4 hours positive airway pressure usage per night for at least 70% of the time (Motor Carrier Safety Advisory Committee, 2012).

The long term goal of this project was to determine adherence to positive airway pressure therapy as recommended by the Federal Motor Carrier Safety Administration's minimally accepted criteria. Adherence with treatment as previously described, ensures a driver with obstructive sleep apnea will be allowed to continue to drive a commercial motor vehicle. Treatment adherence may increase public and occupational safety for the commercial motor vehicle driver and is considered the goal of therapy.

In this study, the primary purpose for the driver to seek treatment for obstructive sleep apnea was to continue to drive a commercial vehicle. By treating obstructive sleep apnea, the risk of sleepy driving may be decreased. By decreasing the risk for drowsy driving, the risk for motor vehicle accidents related to sleepy driving decreases (Tregear, Reston, Schoelles, & Phillips, 2009). This also ensures continued employment for the commercial motor vehicle driver and provides a positive impact to the economy by decreasing crash costs.

Cost Benefit Analysis

Screening for obstructive sleep apnea in commercial drivers Hartenbaum and colleagues (2006) have outlined specific screening and treatment guidelines for commercial motor vehicle drivers with confirmed or suspected obstructive sleep apnea. The average cost for an in-lab polysomnogram is approximately \$800 but can be as much as \$1500 depending on the facility (L. J. Colvin, personal communication, February 26, 2014). The average cost of an out of center or home out of center test is about \$250 (L. J. Colvin, personal communication, February 26, 2014). Even though the costs associated with obstructive sleep apnea testing seem extravagant, one fatality accident prevented can offset the cost of more than 2000 polysomnograms and prevent a family from being without a parent or a child.

Ethical Concerns in Practice

Commercial motor vehicle drivers raise concerns that the recommendations for more in-depth obstructive sleep apnea screening will cause many drivers to be medically disqualified from commercial motor vehicle operation. Many commercial drivers feel that the United States government is taking away their right to pursue their chosen occupation. Many of these drivers have voiced concerns to this researcher that they feel their right to self-determination and autonomy is being impinged upon by more regulations to an already over-regulated occupation. These commercial drivers worry they will not be allowed to drive as a result of these new regulations and fear they will no longer be able to provide an income for their families.

From a public health viewpoint, many personally and financially costly crashes involving commercial motor vehicle drivers may be prevented. Finding and treating the

drivers with obstructive sleep apnea should decrease the number of commercial drivers on the roadways that are driving sleepy. Encouraging diagnosis and treatment of commercial motor vehicle drivers with obstructive sleep apnea is a goal for the U.S. Department of Transportation medical examination.

Application to Practice

The information from data analysis will be disseminated to stakeholders at completion of this study. Understanding current trends in patient utilization of equipment may give insights as to the areas of needed improvement so that adherence goals can be accomplished. By improving adherence to positive airway pressure therapy for commercial motor vehicle drivers, excessive daytime sleepiness of drivers with moderate to severe obstructive sleep apnea may be decreased. As excessive daytime sleepiness decreases, motor vehicle accidents related to sleepy driving may diminish. The costs associated with these accidents may decrease as the numbers decrease. By decreasing the number of commercial vehicle driver accidents attributed to obstructive sleep apnea, an increase in the safety of America's roadways may occur. Information gathered in this study may also be helpful for employers to obtain a better understanding of adherence and utilization to positive airway pressure therapy patterns in their commercial vehicle drivers.

Integration to Practice on Larger Scale

Other sleep centers that track patient response to treatment should be able to gather and analyze data similar to what was gathered and analyzed in this project. Analyzing commercial motor vehicle driver patient's response to treatment for obstructive sleep apnea can be followed regularly until minimal adherence to therapy is

met and then annually thereafter. These drivers must be seen annually to comply with the requirement of the commercial driver U.S. Department of Transportation physical examination. Multiple sleep facilities should be able to combine data for analysis on an even larger scale.

Target Population and Demographic

The primary target population for this project is commercial motor vehicle drivers. This study directly evaluates a medical condition that can cause an increased hazard related to large vehicles on roadways. Decreasing this hazard will increase the safety for all those that travel on America's roads. Although the target population is commercial motor vehicle drivers, all drivers and travelers can benefit from a safer journey. Safer travel is as a result of a decrease in the number of motor vehicle crashes is a goal for Healthy People 2020 (Centers for Disease Control and Prevention, & National Institutes of Health, 2010).

All drivers would benefit from being better informed about the hazards of drowsy driving. Encouraging all drivers to learn about the dangers associated with sleepy driving and obstructive sleep apnea may help decrease personal and financial costs of the roadways. Targeting the entire motor vehicle operator population would be extremely difficult due to the cultural and economic diversity of the general population. Medical providers need to be aware of the risks associated with driving sleepy and the comorbidities worsened by obstructive sleep apnea. These providers must screen their patient population appropriately.

Role of Doctorate of Nursing Practice in Research

In any discipline, the creative process is directly related to project development. Differences in individual's creativity can directly influence these processes. Although nurses can be inventive in finding ways to solve problems, creating new problems to solve can be difficult.

Because the Doctorate of Nursing Practice education is a practice based degree, evidence based practice is combined with creativity and theory to advance nursing practice. Graduates of Doctorate of Nursing Practice programs will have broader knowledge bases for expanding nursing science. Expanding nursing science will lead to better outcomes for the larger population.


Doctorate of Nursing Practice Education in Nursing Practice

Designing, organizing and implementing a program has revealed what goes into project development. Utilizing the skills learned in the Doctorate of Nursing Practice degree program will enhance the skills needed for this process. Communicating the results of this process has increased data dissemination to shareholders and has promoted enhancement of communication skills. Enhancement of the researcher's role enables clinicians to become more personally involved in the research process. The Doctorate of Nursing Practice enhances clinicians understanding of the research process and the importance of the researcher's role to nursing science.

Appendix A

Permissions and Confidentiality

Clayton Sleep Institute and Caduceus Corporation gives permission for Gayla Dace, doctoral student at University of Missouri-St. Louis, to review and gather data from charts. This data will be kept confidential. Unique patient identifying data, such as name, social security numbers and dates of birth, will not be associated with the gathered data. Each patient will be given a unique identifier for tracking purposes and data analysis and no identifying demographic information will be removed from Clayton Sleep Institute or Caduceus Corporation. Ms. Dace may access electronic medical records as necessary to gather data. Access of patient data not intended for use in the doctoral project will not be permitted.



Joseph Ojle, MD
Chief Executive Officer, Clayton Sleep Institute
Physician Partner, Caduceus Corporation



Date

Gayla Dace

Date

Caduceus Corporation

CONFIDENTIALITY AGREEMENT

I understand that Caduceus has a legal and ethical responsibility to maintain patient privacy, including obligations to protect the confidentiality of patient information and to safeguard the privacy of patient information. In addition, I understand that during the course of my employment/assignment/affiliation at Caduceus I may see or hear other confidential information such as financial data and operational information pertaining to this practice and that Caduceus is obligated to keep that information confidential.

As a condition of my employment/assignment/affiliation with Caduceus I understand that I must sign and comply with this agreement. By signing this document I understand and agree that:

- I will disclose patient information and/or confidential information only if such disclosure complies with Caduceus policies, and is required for the performance of my job.
- My personal access code(s), user ID(s), access key(s) and password(s) used to access computer systems or other equipment are to be kept confidential at all times.
- I will not access or view any information other than what is required to do my job. If I have any question about whether access to certain information is required for me to do my job, I will immediately ask my supervisor for clarification.
- I will not discuss any information pertaining to the practice in an area where unauthorized individuals may hear such information.
- I understand that it is not acceptable to discuss any practice information in public areas even if specifics such as a patient's name are not used.
- I will not make inquiries about any practice information for any individual or party who does not have proper authorization to access such information.
- I will not make any unauthorized transmissions, copies, disclosures, inquiries, modifications, or purging of patient information or confidential information. Such unauthorized transmissions include, but are not limited to; removing and/or transferring patient information or confidential information from Caduceus' computer system to unauthorized locations (for instance, home).
- Upon termination of my employment/assignment/affiliation with Caduceus I will immediately return all property (e.g. keys, documents, ID badges, etc.) to Caduceus.
- My obligations under this agreement regarding patient information will continue after the termination of my employment/assignment/affiliation with Caduceus.

I understand if I inadvertently use or disclose PHI in violation of Caduceus policies and procedures that I have a duty to provide that information to my supervisor or the Privacy Officer in order to mitigate (soften) the harm done.

I understand that I have the right to inform my supervisor and the Privacy Officer of any observed violations and will not experience any intimidation, threats, coercion or discrimination or receive any retaliatory action for:

- exercising any of my rights included within our Privacy Notice,
- filing complaints to our Privacy Officer or the Secretary of HHS,
- testifying, or participating in any investigation,
- opposing any act or practice that is unlawful related to HIPAA Privacy Rules or Caduceus Privacy Notice.

I understand that violations of this Agreement may result in disciplinary action, up to and including termination of my employment/assignment/affiliation with Caduceus and/or suspension, restriction or loss of privileges, in accordance with Caduceus' policies, as well as potential personal civil and criminal legal penalties.

I understand that any confidential information or patient information that I access or does not belong to me.

I have read the above agreement, the Notice of Privacy Practices, Caduceus' Policies and Procedures and agree to comply with all its terms as a condition of continuing employment.

Name of employee/physician/student/volunteer

Signature of employee/physician/student/volunteer

Date

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