Requisite Work Day Rest Periods for Anesthesia Providers Working 24-hour-shifts: A Quantitative Study

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ABSTRACT

The purpose of this study was to measure fatigue scores for anesthesia providers working twenty-four-hour shifts. This study took place at two hospitals within The Henry Ford Health System. The experimental group, that will be referred to as Group 1, from Henry Ford Wyandotte Hospital was composed of five Certified Registered Nurse Anesthetists (CRNA) that work twenty-four-hour shifts on a regular basis. They were allotted a work place free rest period from 1300-1530 during their shift. The control group, that will be referred to as Group 2, from Henry Ford Macomb Hospital was composed of five CRNAs that work twenty-four-hour shifts on a regular basis. They did not alter their practice. The CRNAs were provided a Readiband ™ by Fatigue Science, Vancouver, BC. The ten CRNAs that participated, were asked to wear the data collection device for twelve consecutive days. The Readiband ™ measured the provider's activity, sleep depth, sleep interruptions and sleep effectiveness. The demographic data collected from each provider was age, number of years as a CRNA and their work schedule throughout the twelve days of data collection.

Fatigue in health care has been studied by the Accreditation Council for Graduate Medical Education (ACGME), regarding the safety of resident work hours. Studies involving anesthesia providers and fatigue have been done using subjective data collection tools. The Readiband ™ provides an objective measure for data collection. Fatigue scores in Group 2, the group without the intervention, were lower, they averaged 86.64 during twenty-four-hour shifts. Fatigue scores in Group 1, the group that was allowed a rest period, averaged 89.07 during twenty-four-hour shifts. The higher score in Group 1 did not show a statistically significant difference. However, the scores in this sample supported the research question. The group having the intervention had higher fatigue scores, meaning they were less tired, overall. The average fatigue scores showed no statistical significance between providers when working twenty-four-hour shifts and not working twenty-four-hour shifts. All scores fell within the range considered unimpaired (80-100). As a secondary finding this sample demonstrated that anesthesia providers remain within a safe fatigue level to provide care while working twenty-four-hour shifts

Keywords: Fatigue in anesthesia, sleep medicine, ACGME resident regulations, fatigue and patient safety.

INTRODUCTION

Sleep is a physiologic drive for humans akin to hunger and thirst.[1] Lack of restorative sleep affects the immune system, mood, ability to concentrate and reaction time.[2] Lack of sleep can negatively impact professions where long work hours are required, and where rigor and vigilance are necessary for performing their requisite duties. Examples of professions that require long work hours and attention to detail are airline pilots, professional truck drivers and anesthesia professionals.

Fatigue is the loss of strength or energy resulting from hard physical or mental labor.[1] Fatigue can result from a single disruption, multiple disruptions or total sleep deprivation. Sleep deprivation and fatigue may be present in professions that demand long work hours. Airline pilots flying long routes through the night, professional truck drivers making long cross-country hauls and anesthesia providers working twenty-four-hour shifts, may experience some level of fatigue. Inattention to detail in any of the above examples may lead to catastrophic outcomes.

The American Association of Sleep Medicine (AASM) reports that fatigue can be mitigated through certain interventions.[3] Naps are one such intervention. A nap is defined by the Oxford dictionary as "sleep lightly or briefly, especially during the day".[4] In a laboratory simulated study comparing groups of experienced registered nurse shift workers, a group allowed to nap was compared to those with no nap before their shift. Napping resulted in improved reaction times later in the shift.[5] These results may translate to professions such as anesthesia, where a decrease in reaction time may jeopardize patient safety.

Anesthesia services are required twenty-four hours a day, seven days a week in most hospital settings. Emergency surgeries, placement of labor epidurals and urgent intubations can present at any time. Anesthesia providers must be in optimal condition to provide required services at any time. Research has been conducted correlating sleep deprivation with poor

judgement and clinical errors.[1] Studies on the effects of sleep deprivation on performance have shown that sleep loss causes subjects to exhibit a decrease in reaction time.[6]

Anesthesia providers may work an average of sixty to seventy hours per week.[7] These hours may be comprised of shifts consisting of up to twenty-four hours consecutively. The demands on anesthesia providers are unique. The operating room elective schedule does not normally run continuously for twenty-four hours. Cases are typically boarded and completed before midnight, leaving the night hours for emergency cases only. There may be opportunities for rest, provided emergency surgeries, airway emergencies or the obstetrics unit does not require anesthesia services. Since an anesthesia provider must be available at any time, and twenty-four-hour shifts are an accepted cultural norm, sleep disruption is common.

Anesthesia providers experience interrupted sleep patterns during twenty-four-hour shifts. Interrupted sleep patterns create fatigue.[2] Lack of vigilance or inattention to detail may result. "It is obligatory that an anesthesiologist stays vigilant at every step of patient care."[7] One study allowing for a day time rest period for nurse anesthetists working twenty-four hour shifts showed positive results.[8] The providers involved that were given a rest period, suffered less fatigue and showed less impairment of cognitive function.[8] This was an older study, a subjective data collection tool was used, along with a small sample size, and an abbreviated data collection period. Fatigue also negatively impacts the anesthesia provider leaving work after completion of a twenty-four-hour shift. Fatigue at this level can affect the anesthesia provider's safety and the safety of others on the road. The results however, contribute to the overall body of knowledge and the effects of fatigue.[9]

The Federal Aviation Administration (FAA) and The National Aeronautics and Space Administration (NASA), have instituted policies to make flights safer for customers and pilots by ensuring time off between shifts.[10] Anesthesia practice currently lacks the safe guards that other

professions have implemented. Anesthesia departments do not historically offer interventions, or work hour restrictions to mitigate the effects of fatigue, caused by sleep deprivation.

A gap in the literature exists in the objective measurement of fatigue research and utilizing this data by improving the provision of anesthesia in the United States (US). Patient monitoring and safety features utilized by practitioners have been enhanced, however interventions to promote provider vigilance and attention through the reduction of fatigue are not standard for many health care organizations.[11] NASA, the FAA, and other multi-billion dollar organizations have adopted fatigue lessening policies and procedures. A change in the culture for anesthesia may aid in further increasing patient safety and improving quality outcomes.

Research Question

The research question investigated for this study was, "Will an intervention such as a rest period, free from work life responsibility, for a minimum period of two and one half hours, during a twenty-four-hour shift, decrease the level of fatigue in Certified Registered Nurse Anesthetists (CRNAs) working this shift"? This study aims to show a statistically significant improvement in CRNA fatigue scores for those receiving the intervention, compared to those scores in the control group without the benefit of the intervention.

LITERATURE REVIEW

A literature review was conducted using Scholar Google; PubMed; Cumulative Index to Nursing and Allied Health Literature (CINAHL); Ovid and Medline databases. This review provided an in depth understanding of the most recent research done in the area of fatigue among anesthesia providers working twenty-four hour shifts. Search terms/phrases used: sleep inertia; mitigating fatigue in anesthesia; fatigue and sleep loss mitigation; sleep debt; fatigue and sleep quality in anesthesia and google employee perks. The search produced greater than 60,000 studies and articles. Literature reviewed included studies from the past ten years, written in

English, with research done in the United States (US). Other articles utilized described sleep deprivation, current health trends in sleep medicine, health issues associated with lack of sleep and correlations between sleep debt and accidents.

Sleep and Health

Sleep is necessary to maintain health.[12] A joint consensus statement was issued by the American Society of Sleep Medicine and the Sleep Research Society stating that adults should sleep seven hours or more per night on a regular basis to promote optimal health.[12] This recommendation was issued as a part of the federal initiative to improve our nation's health by 2020, called the sleep objective, issued by the US Department of Health and Human Services.[12]

The goal of the sleep objective is to improve health within our nation. The American Society of Sleep Medicine (AASM) and the Sleep Research Society list several adverse outcomes if proper sleep is not obtained. These adverse outcomes include weight gain, diabetes, hypertension, heart disease, stroke, depression, impaired immune function, increased pain, impaired performance, an increased amount in errors and an increased risk for accidents.[12]

Sleep deprivation, and sleep disruption cause fatigue and have resultant health implications. Sleep disruption is defined as any interruption in a normal sleep cycle.[13]

Disruption of the normal sleep cycle refers to waking a sleeping person during one of the five stages of sleep. Stage 1 is the stage of light sleep. It is during this stage that a person may experience jerky leg movements or muscle contractures called hypnic myoclonia.[15] Stage 2 of the sleep cycle is associated with slow brain waves.[13] Stages 3 and 4 are the deep sleep stages. It is during the deep stages, that people may not immediately adjust, and often feel "groggy" if awakened.[13] Stage 5 or REM (rapid eye movement) is the stage where dreams occur, and heart rate and blood pressure both increase. This stage usually happens within 90 minutes of falling asleep.[13]

When a person is awakened during stages 3, 4 or 5 it is likely that they will experience a period called sleep inertia or sleep drunkenness.[6] This is the period upon immediate awakening when someone may feel "groggy" or not quite awake. This can increase in length dependent upon the amount of sleep debt the person is experiencing.[6] Sleep debt is the effect of not getting enough sleep. It can be due to partial or total sleep deprivation.[13] Increasing interruptions throughout the night increase the amount of sleep inertia and the amount of sleepiness the person experiences the next day.[14] It has been reported that when daytime sleepiness increases, the likelihood of near miss accidents at work may increase by 14%.[15] Sleep serves a vital physiologic need. Increases in daytime sleepiness can be the result of decreased sleep quantity.[16]

The lack of sleep creates a sleep debt.[16] The American Association of Sleep Medicine (AASM), The Journal of Sleep Medicine and Sleep Journal have defined the cure for sleep debt. This cure is sleep.[17] Sleep debt can be paid proactively before a long shift or before a night where sleep disruption is likely. The recommendation is a daytime nap period.[17]

Measuring Sleep

Sleep has been a topic of investigation by physicians and research scientists for years. The measurement of sleep has evolved over the years. The studies from 1980s to present have been evaluated using such tests as the Multiple Sleep Latency Test (MSLT), the Epworth Sleepiness Scale (ESS) and the Maintenance of Wakefulness Test (MWT).[12] These tools evaluated subject's sleepiness relative to rested individuals. They are all validated and reliable tools used in numerous studies.[18,19,20]

The gold standard diagnostic tool, for fatigue and sleep related concerns, is polysomnography.[12] A polysomnographic evaluation must be administered in a sleep lab, and is able to diagnose sleep disorders and potential health problems related to inadequate sleep. The data derived from polysomnography has been incorporated into new technology. This technology

is a bio mathematical analytical model. When it is given accurate sleep data, it can measure, quantify and predict human fatigue impairment. It was developed by the United States Army Research Lab. Fatigue Science of Vancouver, BC combines the United States Army- developed bio mathematical fatigue modelling with laboratory-tested sleep data capture to predict human fatigue.

These contributions have created the technology known as **S**leep, **A**ctivity, **F**atigue, **T**ask **E**ffectiveness (SAFTE)^{TM}. The SAFTE^{TM} model is used to analyze sleep data via a band worn on the wrist called a Readiband^{TM}. Wearing the Readiband^{TM} enables capture of high-resolution sleep data, which has been validated against polysomnography with 93% accuracy, per manufacturer claim. The band eliminates subjectivity in evaluation while analyzing fatigue levels. It evaluates the amount of daylight usual for the time of year, via global positioning software, the wearer's activity throughout the day and the level of sleep obtained, along with interruptions in sleep. This data is uploaded to the cloud and analyzed to give a fatigue score and projection of future fatigue if rest is not obtained. The SAFTE^{TM} Fatigue Model detects all periods of sleep, including short periods, such as a nap. This information is then calculated into the sleep algorithm. This data will have a corresponding effect on a person's SAFTE^{TM} Alertness Score.

Consequences of Inadequate Sleep

Wide ranges of catastrophic phenomena have been the result of sleep deprivation. The commercial power plant on Three-Mile Island came close to melt down. Root cause analysis concluded that mechanical error precipitated the incident, but human error of omission due to sleep deprivation, caused the disaster.[21] The nuclear disaster in Chernobyl, Russia was attributed to human error and suspected sleep deprivation. The space shuttle Challenger crash was determined by NASA to be a result of human error and poor judgement related to sleep loss.[21]

The near loss of the space shuttle Columbia in 1986 was investigated after the launch was cancelled within 35 seconds of blast off and certain catastrophe. The root cause analysis discovered operator fatigue to be the key contribution.[21]

The Sleep Advisory Board concluded that circadian rhythm has two troughs in a twenty-four-hour cycle. These troughs occur from 1300-1600 and 0100-0600. This is where the body becomes naturally more tired and vulnerable to errors.[22] The recommendations of this board were to recognize that inadequate sleep can greatly exaggerate this error tendency and that the physiologic needs of workers must be considered.[21,22]

CRNAs are required to operate during the night, at irregular hours, on weekends and on holidays. The demands for anesthesia services are great, and every reasonable avenue to ensure employees are fit, alert and rested should be considered. Interventions preventing fatigue in anesthesia are not typically employed. Science has shown that a natural trough in human circadian rhythm occurs between 1300 and 1600 daily. A rest period during this time frame makes sound physiologic sense for the fitness and well-being of the CRNA, and assist in preventing errors that may jeopardize patient safety.

Mitigating Fatigue in High Risk Professions

Research has been conducted in professions at risk of experiencing fatigue. Non-health care studies have looked at professions that require vigilance and safety such as professional drivers and pilots.[25,10] Drivers and pilots must log their trips, then turn logs in to their employers for evaluation of compliance.[25,10] Pilots must not exceed a maximum of 60 hours of flight duty per week, as mandated by the Federal Aviation Administration (FAA).[10]

Driving logs for professional drivers, must be accurate, consistently maintained, and submitted on a regular basis. These logs are evaluated for violations and errors upon submission. Errors are brought to the attention of the corporation's administration and reconciled. If the error

is clerical, it is corrected. If the error is a true violation, such as driving over allowable mandated hours of service, the driver is issued a fine.[25] If a driver receives several fines, then he/she will be suspended. The hours of service rules are developed and dictated by the Federal Motor Carrier Safety Administration (FMCSA).[25] Logs are routinely checked in the event of an accident; a traffic stop or at a weigh station.[25] The FMCSA performs random audits of driver's logs to ensure corporate compliance.[25] Drivers reaching a maximum 70 hours of driving within a week may resume driving only after resting for 34 consecutive hours.[48]

These companies have used research and technology to create a more profitable business model while maintaining very high employee satisfaction and safety. Rested employees work with higher accuracy, healthy employees miss less work, and medical bills remain low.[26,27] Rested and satisfied employees stay healthy, remain loyal, and have decreased job turnover.[27] Large corporations acknowledge that sleep deprivation becomes a public health hazard.[26] Naps improve alertness and productivity.[26] Despite the trends in big business, less than 1% of companies allow employees to take a nap on the job.[26]

Patient Safety in Anesthesia

Significant advancements towards patient safety have been made in the practice of anesthesia. Over the last five decades, there have been considerable decreases in perioperative mortality, defined as a death within 48 hours of the induction of anesthesia.[11] Out of almost three million cases reviewed between January 1, 2010 and May 31, 2014, 944 deaths were noted. This equates to an average of 33 deaths per 100,000 cases.[11] This reporting did not take into account the patient's physical status or their co-morbities.[11]

In an effort to continue to further improve the quality of anesthesia care, the Anesthesia Quality Institute (AQI) was been established.[11] Cases are reported to this database where quality measures and outcomes are assessed and compared to other practitioners, and practices across

the country.[11] Standards of care are developed based upon these reports and practice is continually made safer. Improved standards of care aim to continue to increase the safety of anesthesia despite escalating challenges related to an increasingly aging society.

Despite efforts to improve patient safety, many institutions have not adequately addressed ways of mitigating anesthesia provider fatigue. Caring for an anesthesia provider's needs, such as implementing procedures adopted by other professions may decrease morbidity and mortality. The culture must be changed within the anesthesia specialty to acknowledge physical demands, and limitations such as the need for rest, so practitioners can provide the safest care possible.

Vigilance in Anesthesia

Several studies have addressed the relationship between anesthesia provider fatigue and patient safety.[31,7,1] Three studies investigated for this project, demonstrated that reaction time and vigilance were negatively impacted by fatigue. The countermeasures offered to the experimental group in each, involved some form of sleep. The type of sleep may include a later start to the day of a long shift, or a nap offered during the work day.[31,7,1]

The administration of anesthesia requires constant vigilance. Vigilance is defined as, "a state of readiness to detect and respond to certain specified, small changes occurring at random intervals in the environment."[29] The care of a patient receiving an anesthetic requires a very small margin of error, and vigilance is key to safety and quality outcomes.[30] A single night of sleep loss can significantly decrease performance of skilled cognitive tasks.[1] Significant decrements begin to show after 18 hours of awakening.[1] This poses a threat to provider and patient safety.

Performance on a hand-eye tracking task was measured in anesthesia providers after an extended shift.[8] A decline in hand-eye tracking after 17 hours of wakefulness was such that it was equivalent to those observed doing this task with a blood alcohol level of 0.05%.[31] The

decline worsened after 24 hours of wakefulness, making the level of psychomotor function equivalent to that of someone with a blood alcohol level of 0.1%.[31]

A decline in psychomotor function may significantly affect provider performance and lead to adverse outcomes. It is imperative that providers and their employers are aware of circumstances, which may lead to a degradation of performance. The adoption of policies and procedures to detect and improve practitioner performance should be a high priority. This study was designed to answer the question: Will an intervention such as a rest period, free from work life responsibility, for a period of two hours, decrease an anesthesia provider's fatigue during an extended shift? Answering this question may assist in developing a strategy for reducing CRNA performance degradation, enhancing patient safety.

THEORETICAL MODELS

Dorthea Orem was a well-respected nurse practicing in the 20th century. She developed a formal model of self-care.[32] Orem deems self-care as necessary to maintain life, health and development.[32] Orem theorized that by having a better understanding of a patient's specific needs, both physical and psychological, a plan of care could be implemented that promotes health and healing.[32] The importance of self-care can be adopted when addressing employee needs. Something as simple as an encouraged nap by employers during a twenty-four-hour shift may provide for both the physical and psychological needs of an employee.

Abraham Maslow created "Maslow's Hierarchy of Needs" (Figure 1). This theory is based on the fundamentals for personal motivation.[33] In his hierarchy, the initial level describes the basic physiologic needs, which include food, air, water, shelter, the need to be active, rest and the need to sleep.[33] Safety is the next level; this encompasses the desire to be safe from harm, both physical and psychological.[33] Once primary needs are met, a person's focus becomes love and belonging.[33]

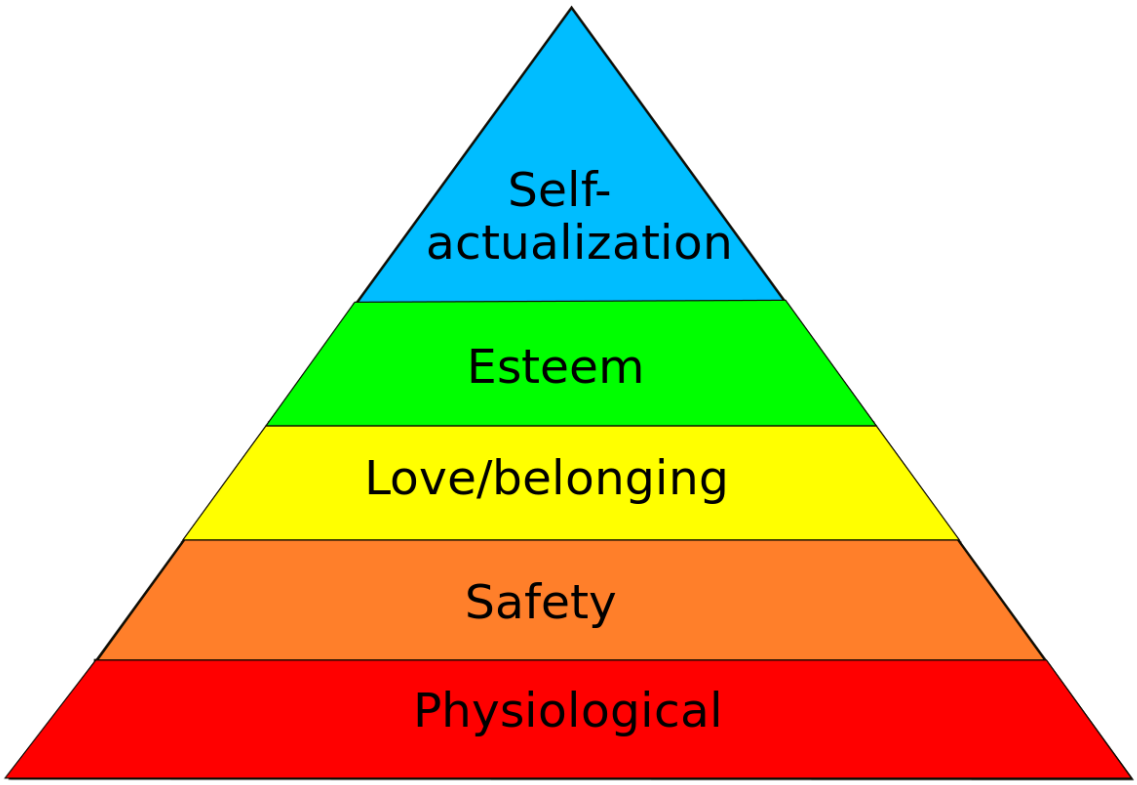


Figure 1. Maslow's Hierarchy of Needs

The love and belonging level of the hierarchy can be accomplished in the working environment via social support between employees, co-workers and bosses.[33] The concept of feeling needed and supported in the workplace meet the criteria for this level. Esteem is the next level that must be achieved in the hierarchy. This includes the need for responsibility, reputation, prestige recognition and respect.[33] Offering a perk such as a nap during the workday may allow the employee to work up to their maximum potential, thus building esteem.[33] Self-actualization is the fifth and most important level in Maslow's hierarchy.[33] Accomplishment of this need allows one to be the best person that they are capable of becoming.

Integrating Orem's self-care theory with that of Maslow's hierarchy of needs creates a hybrid approach to caring for employees, and gives further basis to the theory that an individual may obtain maximum health, and ability when basic needs are met.[33] Safety concerns may be lessened and health may improve, thus decreasing the need for time off due to illness. Large corporations have begun to lead a change of culture in the work force. Both the FAA and FMCSA see the value of rest concerning safety and health of employees and customers.

Large corporations, companies who employ professional drivers and airlines, have subscribed to concepts described in Orem and Maslow's theories. Many of these entities enforce rules and regulations to ensure the safety of their employees and customers.[34,35] The ACGME has investigated fatigue among resident physicians and made changes to their mandatory work hours.[36] Companies are adopting the concepts described in theoretical models, by meeting employee's needs while on the job. Productivity increases when employee self-care needs are met.[26]

Meeting basic needs such as food, sleep, and fitness make employees feel valued, and alleviates stress.[26] Less stress, and feelings of value and safety, have manifested themselves as more productivity among those afforded these measures.[26] Companies that offer free food, eliminate the employee's need to pack food or buy food at work. Providing a "nap pod" with the understanding that taking a nap during the workday is not only accepted but also encouraged, decreases fatigue.[27] Another approach companies use to motivate employees to obtain high productivity is offering, "perks". Google, Zappos, NASA and Huffington Post have used research and internal metrics to guide the development of "perks." Perks were implemented to increase employee satisfaction and productivity.[26]

MATERIALS AND METHODS

This study was conducted in two anesthesia departments within the Henry Ford Health System. One department was at Henry Ford Macomb Hospital (Clinton Township, MI) and the second was at Henry Ford Wyandotte Hospital (Wyandotte, MI). The Institutional Review Board (IRB) process within the Henry Ford Health System is centralized. The application was submitted to the IRB in full, along with the proposed methods and literature review as rationale for the importance of this research.

Each participant read a consent form authorizing his or her willingness to be involved in this study. They were informed that they were able to withdraw at any time for any reason without fear of retribution. IRB approval from the University of Michigan-Flint and Henry Ford Health System was obtained. A copy of permission granted by the University of Michigan-Flint IRB can be found in Appendix A. Henry Ford Health System IRB approval is documented in Appendix B. The IRB at Henry Ford Health System recommended that no consent need be signed. Consent was implied by donning the Readiband™. A decision to withdraw from the study was done by doffing the Readiband™.

Study Design

This is a quantitative study consisted of a control and an experimental group utilizing two separate community based anesthesia departments at two large health system business units. The experimental group, Group 1, consisted of Certified Registered Nurse Anesthetists (CRNA) at Henry Ford Wyandotte Hospital, who work 24-hour shifts. Twenty-four-hour shifts are those that begin at 0700 one day and finish at 0700 the next day. The experimental group, Group 2, consisted of Certified Registered Nurse Anesthetists (CRNA) at Henry Ford Macomb Hospital, who worked comparable shifts.

Setting

Two separate anesthesia departments participated in this study. Both anesthesia departments operate in the Henry Ford Health System. The two departments investigated in this study were similar in size. Henry Ford Wyandotte Hospital is a 401- bed hospital, and Henry Ford Macomb Hospital is a 435-bed facility. Both have a similar payer mix and case mix. Henry Ford Macomb Hospital employs 47 CRNAs and Henry Ford Wyandotte Hospital employs 37 CRNAs.

CRNAs from both business units were given a training session lasting approximately 30 minutes explaining the study, and the Readiband™ data collection tool. Informed consent forms were distributed and read by those willing to participate. The data collection devices were collected in person at the end of the 60-day data collection period, and sent directly to the manufacturer for analysis. Permission for the use of this tool was granted, and a copy of approval was documented in Appendix C. A copy of the informed consent utilized is shown Appendix D.

Study Population

The study population investigated in this study consisted of 10 CRNAs that work in two separate departments in the Henry Ford Health System. Each of the two anesthesia departments included in this study have a total of ten CRNAs that regularly rotate to cover the 24-hour-shifts. Two Readibands™ were obtained for the study. Each department was given one band. All ten CRNAs that work regular 24-hour-shifts, in each department were informed of the study. They were asked if they would like to participate. Inclusion criteria was willingness to wear the band for twelve days, and have at least one 24-hour-shift within the twelve-day period. Exclusion criteria was an unwillingness to participate or not having a 24-hour-shift within the period of

data collection. The data collection period was 60 days. That allowed five CRNAs to be a part of the study in each of the departments participating.

Data Collection Tools

Each department was issued a Readiband™ from Fatigue Science™. An individual mental fatigue analysis was done using this tool. The data from the Readiband™ was independently and blindly analyzed by the manufacturer of the Readiband™, Fatigue Science™.[22] The Readiband™ works by incorporating actigraphy technology.[22]Actigraphy monitors movement and can be used to assess sleep wake cycles or circadian rhythms over an extended period of time.[22] The band was worn continuously by each CRNA working regular 24-hour-shifts within a twelve-day period.

The employee's sleep and awake periods and the quality of sleep were recorded. The employee wore the Readiband™ continuously, even while showering or exercising. Continuous wear of this device allowed for a more accurate assessment of awake and rest periods of the employee working 24-hour-shifts. Following the twelve-day period the band is doffed and unpaired by the primary investigator, and the next CRNA working regular 24-hour- shifts within a twelve-day period donned the band. This procedure occurred five times, once for each of the providers at each facility.

The Readiband™ has proven to be 93% as accurate as an in-lab sleep study, per the manufacturer. The polysomnography had always been dubbed as "the gold standard" of sleep tests. Due to its accuracy, this device was used and proven worthy in many prior studies. It is a noninvasive measure of sleep and wake intervals.[37]

Fatigue Science™ uses the acronym SAFTE that stands for **S**leep, Activity, **F**atigue, and **T**ask **E**ffectiveness. This model has been validated to predict performance degradation effects of fatigue and the rate of recovery. This technology calculates the person's performance

effectiveness and rates them on a scale of 0-100.[37] A rating of 100 depicts someone fully awake and unimpaired. A rating of 60 would be analogous to a blood alcohol level of 0.11%.[37] The effectiveness score has been correlated to blood alcohol level, and has been further validated to accurately predict the influences of sleep and scheduling on human factor accident risk.[37] The SAFTE™ model is currently being used by the US Department of Defense, the US Army, the US Air Force, the US Navy, the US Marine Corps and the Federal Railroad Association.[22]

The SAFTE™ model prediction is a computer application. It provides continuous record of predicted fatigue levels at all times during measurement periods. The Fatigue Science™ software calculates an individual's amount of sleep, quality of sleep, time needed to fall asleep and sleep interruptions. It then analyzes the total time functioning at a specific fatigue level and calculates the overall risk of error compared with a well-rested person.[37] The Readiband™ devices were shipped to the manufacturer where they were independently and blindly analyzed.[37]

Implementation

The CRNA group at Henry Ford Macomb Hospital was considered the control group, Group 2, and did not change their current practice. Each participant was asked wear the Fatigue Science Readiband™ from 0700 upon arrival for work, for twelve consecutive days. The band was then handed off to the next person working regular 24-hour-shifts, for the subsequent twelve-day period. The Henry Ford Macomb Hospital anesthesia department does not currently offer interventions to mitigate fatigue.

The CRNA group at Henry Ford Wyandotte Hospital was considered the experimental group, Group 1, and was asked to alter their practice. Each participant was asked to wear the Fatigue Science Readiband™ from 0700 upon arrival for work, for twelve consecutive days. The band was then handed off to the next person working regular 24-hour-shifts for the next twelve-day period. Those participating in Group 1, having read and understood the consent for study

participation, were given a work life free sleep period at 1:00 pm lasting until the end of dayshift at 3:30 pm. They were asked to surrender all hospital issued pagers and phones during the rest period. They were dismissed to the provided anesthesia call room.

There were no additional resources required in order to allow for this rest period. The float (charge) CRNA was tasked with maintaining the integrity of this study. He or she ensured that each CRNA working a 24-hour-shift, that met the study criteria, was afforded a rest period. After 60 days of data from each department was collected, the scores were compared and analyzed. The Fatigue Science™ databank independently and blindly calculated the fatigue scores. A statistician was given this fatigue data for further analysis of statistical significance. A conceptual model for the project can be viewed in Figure 2.

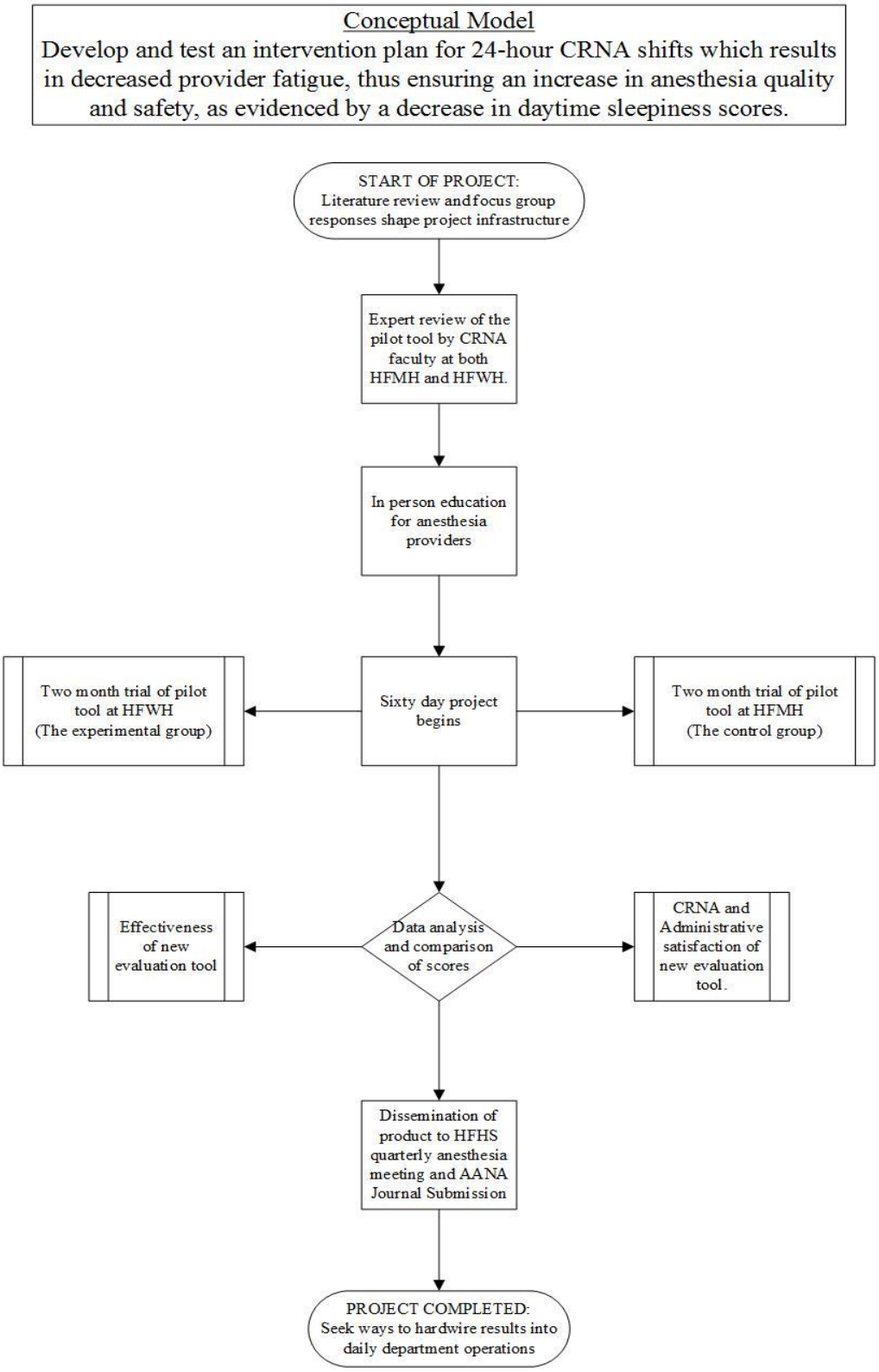


Figure 2. Conceptual Model Describing the Methodology of this Study

RESULTS

Unpaired Student's t tests showed that the CRNAs in Group 1 were about 14 years older, and had about 15 more years' experience as CRNAs, than participants in Group 2.

Table 1. Age and Years of Experience as a CRNA

	Control (Group 2)	Experimental (Group 1)	Significance	Difference (95% Confidence Interval for the difference)
Age (years)	41.8 (7.26)[1]	55.6 (8.32)	.023[2]	13.8 (25.19 to 2.41)
CRNA Experience (years)	10.2 (4.76)	25.8 (11.0)	.03[3]	15.6 (29.1 to 2.1)

Notes:

1. Values are Mean (SD) throughout. *P* values are two-tailed, and considered significant if less than .05 throughout.
2. $t = -2.794$, df = 8
3. $t = -2.90$, df = 5.4

A split-plot analysis of variance was conducted on the average fatigue score, with groups 2 & 1 (control, experimental) and 24-hour shift (working= yes, not working= no) as independent variables, with repeated measures on subjects within groups. This showed that average fatigue score did not differ between the experimental and control groups ($F = 0.004$, df = 1), nor by whether the person was working a 24 hour shift ($F = 0.00$, df = 1). The interaction between groups and 24 hour shift was also non-significant ($F = 0.041$, df = 1).

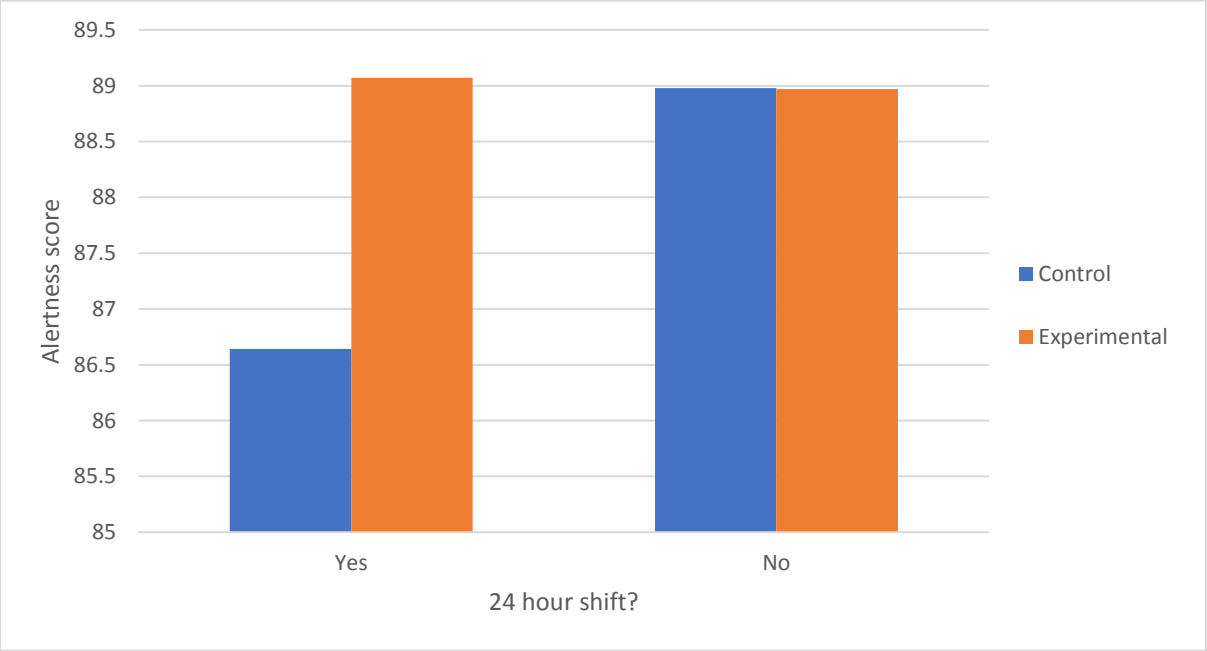
Table 2 and Figure 3 illustrate that differences in fatigue scores, though small and not statistically significant, are in the direction provided by theory (less change in fatigue scores during 24-hour shifts in Group 1- they showed less fatigue).

Table 2. Alertness Scores by Group and Shift Type

***(Yes- scores obtained during a 24hr shift No- scores obtained with no 24hr shift)**

	24-hr Shift?	
	Yes	No
Control (Group 2)	86.64 (9.9)	88.98 (8.6)
Experimental (Group 1)	89.07 (3.6)	88.97 (7.1)

Figure 3. Graph of Alertness Scores by Group and Shift Type



***Graphed fatigue scores for those working 24-hour shifts (Yes) - Those not working 24-hour shifts that day (No)**

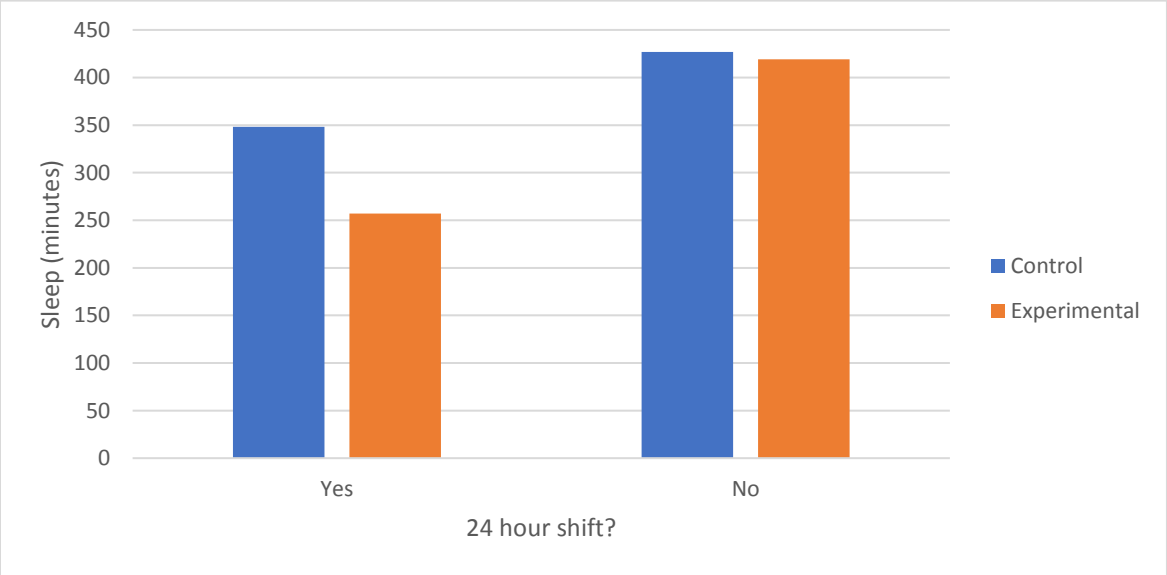
A second, similar split-plot ANOVA showed that minutes asleep were less during 24 hour shifts than on days without a 24 hour shift (F = 17.03, df = 1). The interaction between group and 24 hr. shift was not significant (F = 2.93, df = 1), and the groups did not differ (F = 1.735, df = 1). The means are shown in Table 3 and Figure 4.

Table 3. Minutes Asleep by Group and Shift Type

	24-hr Shift?	
	Yes	No
Control (Group 2)	348.3 (133)	426.8 (123)
Experimental (Group 1)	257 (118)	419 (113)

***Yes= minutes asleep during a 24-hour shift No= minutes asleep not working a 24-hour shift**

Figure 4. Minutes Asleep by Group, and Whether Obtained During a 24 hr. Shift



DISCUSSION

There was a statistical significance between the demographics in Group 1 and Group 2. Group 1 had a median age of 55.6 years old with an average of 25.8 years of anesthesia experience. Group 2 had a median age of 41.8 years old with an average of 10.2 years of

anesthesia experience. The older, more experienced experimental group, Group 1, scored higher on fatigue scores (were less fatigued), with less minutes asleep than the younger, less experienced control group, Group 2, who had more minutes asleep. Statistically there was no significant difference between either group's fatigue scores. This was despite implementation of the intervention. The sample size and duration of the study may have impacted this result. An assumption can be made that the rest period (intervention) had a positive impact on the CRNAs fatigue scores.

The experimental group, Group 1, at Henry Ford Wyandotte Hospital experienced more disruptions in their sleep and less overall minutes asleep during their twenty-four hour shifts than the Henry Ford Macomb Hospital CRNAs. The Henry Ford Macomb Hospital CRNAs, Group 2, do not respond to labor and delivery. This greatly reduces the number of interruptions during the night. The Henry Ford Wyandotte Hospital CRNAs, Group 1, averaged four interruptions per twenty-four hour shift between the hours of 0000-0600. The fatigue scores of Group 1, with more sleep disruptions still remain higher. This indicates that the experimental group were less fatigued, regardless of having had more sleep disruptions.

Table 3 and Figure 4 depict the difference between minutes asleep between the groups. No statistical significance relating to the intervention occurred. However, assumptions based on data trends can be made regarding the effectiveness of the rest period. The experimental group, Group 1, was older, had a greater amount of sleep disruptions and less overall minutes of sleep than the control group, Group 2. Yet, they remained less fatigued per objective data.

Fatigue and its impact on anesthesia providers has been studied in past research. The data collection tools utilized for previous studies were subjective tools such as the Epworth Sleepiness Scale (ESS) and the Multiple Sleep Latency Test (MSLT). This study used an objective data collection tool, the Fatigue Science Readiband ^{TM}. The fatigue scores for each

provider, regardless of having had the benefit of intervention, fell at or above 80. The Fatigue Science SAFTE™ model created a fatigue score from 0-100. Scores of 80-100 reflect levels that are considered unimpaired and are said to have a zero percent decrease in reaction time.

The subjects of this study remained in the unimpaired category up until the completion of their twenty-four-hour shifts. The impact that this research will have on the anesthesia community may be positive. There have been speculations made about the safety of practitioners participating in extended shifts. This research supplies unobjectionable evidence that impairment was not demonstrated in the providers in this sample.

The intervention was implemented without use of extra resources. The float (charge) CRNA relieved the twenty-four hour person after all breaks and lunches were given. This rest period was well received by the rest of the anesthesia department as well as administration. The Chief Nursing Officer at Henry Ford Wyandotte Hospital believes strongly that taking care of the needs of our employee's is paramount to success. When presented with this rest period, the decision to allow this was accepted and encouraged. The CRNAs within the department believed that this was a beneficial plan, and a way of showing that we care for each other's needs. The timing of the rest period was not coincidental. The human circadian rhythm dips between 1300-1600 hours.[22] This is why people frequently feel tired within this time frame. The CRNA group receiving the rest period commented how easy it was to actually sleep during this time.

The research question: "Will an intervention such as a rest period, free from work life responsibility, for a minimum period of two and one half hours, during a twenty-four-hour shift, decrease the level of fatigue in Certified Registered Nurse Anesthetists (CRNAs) working this shift"?

Although the results did not achieve statistical significance, the fatigue scores in this sample, were higher in Group 1, this was the group receiving the intervention. The higher the

fatigue score, the less fatigued the provider. The study aimed to show a statistically significant improvement in CRNA fatigue scores for those receiving the intervention, compared to those scores in the control group without the benefit of the intervention. This did not occur and may be explained through the limitations of this study.

This study was considered a pilot study. In order to achieve statistically significant results, it is necessary to repeat this implementation with a larger group of CRNAs working twenty-four hour shifts. Optimally, CRNAs would all wear the Readibands™ for a longer period of time, and all of those in the study would experience the rest period, as well as experience no rest period. The use of Readibands™ for longer periods with more participants most likely would require obtaining a research grant due to significant costs related to data collection for a larger study group.

Dissemination

This study was presented to the Entire Henry Ford Health System anesthesia community on 12/13/2017 at 1300, as a first of three means of dissemination. This group includes the leaders of the anesthesia departments from all five-business units within the health system. This group meets quarterly to discuss new business, new research, current and upcoming practice trends. A PowerPoint presentation commenced with the added assistance of a large poster representation of the study as a whole. The presentation was followed by a question and answer period. This project was submitted to the Henry Ford Quality Expo for 2018. The third means of dissemination was submission to the Henry Ford Research Department for publishing in the Henry Ford newsletter, and perhaps recommendation for funding of a larger scale study in this area.

Study Strengths

This study utilized the first objective data collection tool in the field of anesthesia fatigue research to date. The data collection tool could not be altered by any outside input or subjective interpretation. An outside statistician, not involved in any part of the study design or data collection period, analyzed the results. The sample size from each group was equal. The case mix, department size and hospital size were similar. Both provider groups routinely work twenty-four-hour shifts.

Limitations of Study

The demographic differences of each provider group was not taken into account. There was a statistically significant difference between the age and years of practice. The sample size was smaller than required for an ideal study analysis. The period for data collection was limited due to the time frame allotted for this study. A longer data collection period would have provided more data for analysis, and allow further conclusions to be drawn.

CONCLUSION

Research on fatigue has shown that sleep is necessary for health, function and work place safety. Anesthesia, like many other fields, requires attention to detail and constant vigilance. This study focused on fatigue levels among anesthesia providers that work twenty-four-hour shifts. Two hospital anesthesia departments made up the control and experimental groups. Each department had ten CRNAs that regularly work twenty-four-hour shifts. The data collection period allotted was sixty days. Five CRNAs at each hospital, out of the group that work regular twenty-four-hour shifts, wore the Readiband™ for twelve consecutive days each. Those wearing the Readiband™ supplied their age, years of practice as a CRNA and shifts worked throughout the data collection period. These statistics were submitted to the statistician along with the data obtained from Fatigue Science™ .

The CRNAs at Henry Ford Wyandotte Hospital were the experimental group, or Group 1. They were given an intervention aimed at improving their fatigue scores throughout their twenty-four-hour shifts. The intervention was a rest period that was strategically placed between the hours of 1300-1530. This timing correlates the dip in human circadian rhythm that happens each afternoon. The CRNAs at Henry Ford Macomb Hospital were the control group, or Group 2. The CRNAs wearing the Readiband™ did not have any disruption in their usual routine.

Results did not indicate that the intervention created a statistical significance when the groups were compared. However, the fatigue scores in this sample were higher in Group 1, indicating a decreased level of fatigue. The data does lean in the direction of the research question. A secondary finding showed that the fatigue scores for all providers involved in the study showed no statistical significance between the days working twenty-four-hour shifts and the days regular shift hours were worked. The average fatigue scores for both groups working twenty-four-hour shifts remained at a score above 86. Henry Ford Macomb, Group 2, scored an average of 86.64 and Henry Ford Wyandotte, Group 1, scored an average of 89.07 while working twenty-four-hour shifts. Fatigue scores greater than 80 equate to no decrease in reaction time and are considered unimpaired per the Fatigue Science guidelines. The implications of this research are that anesthesia providers in this study were providing care within a safe fatigue range with or without the benefit of intervention. This data was objective and unique to the study of fatigue in anesthesia. A new study with an improved design may show significance with intervention.

Improvement of this study for future research would include a repeated measures design on the participants. This type of design would help to control for the personal differences that were encountered with the current study such as age, years of experience, sleep needs and ability to sleep. Additionally each participant would wear the band for multiple weeks within each

condition. This would reduce the impact from avoidable interruptions, and improve generalizability and significance of findings.

APPENDIX A. University of Michigan Institutional Review Board Approval

Flint Institutional Review Board • 530 French Hall, 303 E. Kearsley St, Flint, MI 48502 • phone (810) 762-3383 • fax (313) 593-0526 • research@umflint.edu

To: Jennifer Havenstein

From:

Kazuko Hiramatsu

Cc:

Jane Motz
Jennifer Havenstein

Subject: IRB Flint Acknowledgement of Study Conducted Under a Non-UM IRB, [HUM00133934]

SUBMISSION INFORMATION:
Study Title: Requisite work day rest periods
Full Study Title (if applicable): Requisite word day rest periods for anesthesia providers working 24-hour-shifts: a quantitative study
Study eResearch ID: HUM00133934
Date of this Notification from IRB: 9/11/2017
Date of IRB Flint Registration Review: 9/11/2017
Non-UM ID Number: 11385
Current Non-UM Approval Period: Jul 13, 2017 - Jul 12, 2018
Current UM Acknowledgement Period: Sept 11, 2017-Jul 12, 2018
UM Federalwide Assurance: FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)

NOTICE OF IRB ACCEPTANCE AND CONDITIONS:
Following applicable internal review(s), this application to conduct human subjects research is acknowledged as meeting the criteria of the University of Michigan for ceding oversight to a non-UM IRB and is considered to be registered with IRB Flint for purposes of institutional record-keeping. You must conduct this study in accordance with the approval criteria of the external IRB.

APPROVAL PERIOD:
The UM acknowledgement period for this study is listed above. Please note the UM expiration date as it may differ from the IRB approval period of the non-UM IRB. If the external IRB approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as

necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, notify the external IRB and the IRB Flint Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

AMENDMENTS, RENEWALS, AND TERMINATIONS:
The non-UM IRB is now the IRB of Record for the conduct of this study at the University of Michigan. However, you must utilize eResearch to:

- Submit amendments to the registered application if any changes to the protocol will require re-review by an ancillary committee (e.g., IDS, CRAO, RDRC/SHUR)
- Annually renew (SCR) the registration of this research study with IRB Flint
- Terminate the IRB Flint registration of this study when the study is terminated at the non-UM IRB

AEs/ORIOs:
Although the non-UM IRB is now the IRB of Record for the conduct of this study, you must report related Serious Adverse Events and Unanticipated problems in accordance with the division of labor as agreed upon by the University of Michigan and the non-U-M IRB.

This should be done through eResearch following the same procedures as for an IRB Flint-approved study. These include, but are not limited to, events and/or information that may have physical, psychological, social, legal, or economic impact on local research subjects.

APPROVED STUDY DOCUMENTS:
You must use the study documents approved by the non-UM IRB.

SUBMITTING VIA eRESEARCH:
The online forms for continuing review, amendments, and AE/ORIO reporting can be accessed in the eResearch workspace for this Non-UM IRB-approved, IRB Flint-accepted study, referenced above.

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at http://research-compliance.umich.edu/human-subjects.

Kazuko Hiramatsu
Chair, IRB Flint

Research Administration

Henry Ford Health System

1 Ford Place – 2F

Detroit, MI 48202-2689 (313) 874-4464 Office (313) 874-4288 Fax

APPENDIX B. Henry Ford Health System Institutional Review Board Approval

To: Jennifer L. Havenstein
Anesthesiology

Fm: Timothy Roehrs, Ph.D., Chair
Jonathan Ehrman, Ph.D., Vice Chair
Adrian Ormsby, M.D., Vice Chair
Institutional Review Board (IRB)

Re: **Requisite Work Day Rest Periods for Anesthesia Providers Working 24-hour-shifts: A Quantitative Study** (IRB No. 11385)

Period of IRB Approval: **July 13, 2017 – July 12, 2018**

This is to apprise you that the above-named project was re-reviewed through the expedited procedure on **July 13, 2017**. The human rights aspects of the above-referenced protocol were reviewed and approved. This approval is based on Title 45, Section 46.110 of the HHS Code of Federal Regulations related to no more than minimal risk to the subject. The approval of this project will be presented as an informational item at a subsequent IRB meeting.

The Institutional Review Board and Federal Regulations require that each research proposal involving human subjects be reviewed at intervals appropriate to the degree of risk but not less than once per year and that a final report is submitted at the termination of the project. ***Therefore, a continuation or final report for this proposal is due in one year. The report must be submitted to and approved by the IRB by July 12, 2018 to avoid a lapse in your approval. As the Principal Investigator, you are ultimately responsible for timely submissions of continuation and final reports. You are encouraged to create a tracking mechanism to ensure timely submissions.***

Revisions to the protocol must be approved by the IRB prior to implementation. In addition, our IRB is expected to review all documents and activities that bear directly on the rights and welfare of participants of research. A copy of the signed and stamped application, indicating approval by the Institutional Review Board, is enclosed for your files.

Forms for progress reports, final reports, modification and adverse/unexpected event are available on the IRB website. Please contact the Research Office at 874-4464 if you have questions regarding these matters.

Appendix C. Letter of Permission to Use Fatigue Science Readiband™

DocuSign Envelope ID: 48FB2A54-5FF2-426C-A073-D82D114D9EC2

FATIGUE SCIENCE

Phone (604) 408.0085
Fax (778) 331.0402
www.fatiguescience.com

Dear Jennifer Havenstein,

Fatigue Science provides you permission to use the Readiband™ in your research 'Requisite Work Day Rest Periods for Anesthesia Providers Working 24-hour- shifts', and other research you may be conducting.

The Readiband captures high-resolution sleep data, validated against the clinical gold standard of polysomnography with 92% accuracy. With the data collected by the Readiband, you are able to see sleep quantity, interruptions to sleep, sleep latency, sleep onset time, sleep wake time, variance around wake and onset, and also each wearer's SAFTE score.

The SAFTE algorithm developed by the US Army Research Lab, is used to predict human reaction time, likelihood of lapsed judgement, and fatigue risk. It has been extensively validated as an accurate predictor of fatigue related accident risk by the US Department of Transportation.

Best regards,

DocuSigned by:
Karl Woll

6/6/2017

Karl Woll
Account Manager

APPENDIX D. Informed Consent for Study Participation

Consent to participate in a research project

Requisite Work Day Rest Periods for Anesthesia Providers Working 24-hour-shifts: A Quantitative Pilot Study

Researcher: Jennifer L. Havenstein CRNA, MS affiliated with The University of Michigan/Flint
Doctoral program: Doctor of Anesthesia Practice (DrAP)

This research project aims to decrease the level of fatigue in CRNAs working regular twenty-four-hour shifts instituting an intervention. It is theorized that the intervention will show that those in the experimental group will show statistically significant improvement on the fatigue continuum as issued by Fatigue Science™ after the intervention is implemented.

This study requires human subject involvement. The CRNAs working regular twenty-four-hour shifts at Henry Ford Macomb Hospital will be required to wear a Readiband™ for twelve consecutive days during which regular 24-hour-shifts will be worked. No other changes will be made to their workday. The CRNAs enrolled in the study working regular 24-hour-shifts in a consecutive twelve-day period at Henry Ford Wyandotte Hospital will be required to wear a Readiband™ and participate in a work-life-free rest period from 1300-1530 during their shift.

The Readiband™ is advised to be worn on the CRNA's non-dominant hand for the entire duration of the twelve-day period. It is made of rubber and can be worn while washing hands, showering or any other activity. There is no extra risk involved in this study, no paperwork to complete past filling out a generic subject demographic form. This project has been deemed as having no more than minimal risk. The researcher does not foresee or anticipate any direct risk to the subjects.

Although you are not receiving a direct benefit from your participation, others may ultimately benefit from the knowledge obtained in this study

The cost of this research will be on the researcher (Jennifer Havenstein). There shall be no financial burden on the Henry Ford Health System or the participants involved in this study.

You will not be identified in any reports on this study. The aggregate fatigue scores for both departments will be collected and analyzed as a group. There will be no records kept of participants other than the demographics sheet. Forms will be kept confidential to the extent provided by federal, state, and local law. However, the Institutional Review Board, and the University and government officials responsible for monitoring this study may inspect these records.

Primary Researcher:

Jennifer L. Havenstein CRNA, MS Doctoral Candidate (313)363-8189

Faculty Advisor:

Jane Motz CRNA, DrAP Program Director (810)262-9264

Should you have questions regarding your rights as a research participant, or wish to obtain information, ask questions, or discuss with someone other than the researcher, please contact Mary Mandeville in the Institutional Review Board. 4204 William S White Bldg., Flint, MI. 48502 (810)762-3383 or email: irb-flint@umflint.edu

Your participation in this project is voluntary. Even after you read the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise be entitled.

Participant Demographics

Age: _____

Sex: M F (Circle one)

Number of years in Anesthesia practice: _____

Average number of shifts per week/hours worked: _____

Average number of hours worked prior to 24-hour shift_____

Hospital Name (where employed):_____

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