Use of STOP-BANG Screening Questionnaire in Outpatient Setting: Increasing Both Identification of Obstructive Sleep Apnea Patients and Polysomnography Referral Accuracy

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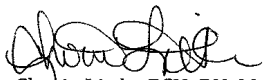

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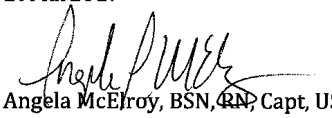

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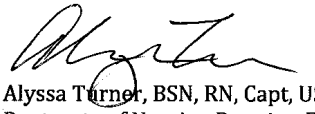

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Abstract

There are 29.4 million people affected by obstructive sleep apnea (OSA) in the United States (AASM, 2016b). This disorder is classified as a chronic illness and is directly associated with a multitude of serious health sequelae. The risks for developing these sequelae increase if OSA is not diagnosed and treated (Badran, Ayas, & Laher, 2012). The American Association of Sleep Medicine (AASM) estimates 23.5 million people with OSA are undiagnosed, resulting in $149.6 billion in associated annual healthcare costs (AASM, 2016b). Among active duty military members the incidence of OSA may be as high as 50% (Wood, 2013).

The AASM recommends early identification and timely treatment of OSA using polysomnography as the gold standard for diagnosis (Agency for Healthcare Research and Quality [AHRQ], 2011). Current recommendations for identifying high-risk OSA patients are subjective and do not include an evidence-based guideline (Aurora & Quan, 2016). PSG costs averaging $1100-$2500 per patient make utilizing PSG to screen patients for OSA neither cost effective nor an efficient use of limited resources (CMS, 2015; Aurora & Quan, 2016). Use of a validated evidence-based screening tool to identify and triage OSA patients could ensure early diagnosis, increased referral accuracy, and potential monetary health care savings.

This doctor of nursing practice (DNP) project utilized a systematic review of available literature, consisting of 36 randomized control trials (RCTs) and over 11,800 patients. The STOP-BANG questionnaire (SBQ) was identified as the evidence-based screening tool with highest sensitivity and specificity. Training of clinic staff and implementation of SBQ was employed in a military outpatient setting. Results demonstrated a 180% increase in SBQ utilization and 60% increase in PSG referral accuracy. Results for these two outpatient clinics equate to approximately $405,000 in annual savings on PSG referrals.

Obstructive Sleep Apnea Screening Tool

Introduction

Obstructive sleep apnea (OSA) is a sleep disorder characterized by recurrent blockage of the airway due to pharyngeal muscle relaxation, tongue occlusion, and/or an anatomic obstruction of the airway (Ho & Brass, 2011). These airway obstructions result in periods of hypopnea, and in severe cases, apnea (AHRQ, 2011). For affected individuals, these recurrent periods of de-oxygenation can contribute to multiple cardiovascular comorbidities including hypertension, coronary artery disease, deep vein thrombosis, stroke, and sudden cardiac death. (Ramachandran & Josephs, 2009; AHRQ, 2011). OSA also contributes to metabolic dysfunction, affecting glucose regulation and lipid metabolism. This can result in the development of diabetes, hyperlipidemia, and/or fatty liver disease (Stansbury & Stroll, 2015; AASM, 2016a). Early diagnosis and proper treatment of OSA can mitigate or prevent worsening of these associated sequelae (AASM, 2016a), reinforcing the importance of early diagnosis and treatment for this condition.

Significance of the Problem

Prevalence of OSA/Undiagnosed OSA

Current epidemiology of OSA has been studied in North America, Europe, and Australia. In the United States OSA affects approximately 20% of the adult population (AASM, 2016b). This equates to 29.4 million Americans, with 1 in 5 adults diagnosed with mild OSA and 1 in 15 adults affected with severe OSA (Bouloukaki et al., 2013). Recent longitudinal epidemiology studies reflect OSA prevalence has been increasing for at least two decades (Jonas, Amick, & Feltner, 2017). In a combined study from the Wisconsin Sleep Cohort Study and the U.S. National Health and Nutrition Examination Survey database, OSA increased in every age bracket

and body mass index (BMI) category, though not at the same rate (Jonas et al., 2017).

Increased OSA incidence among genders has remained constant with males affected 2-3 times more than females. This ratio decreases as females approach menopause but both genders have increased risk of OSA with aging until age 60-70 years old (Jonas et al., 2017). For both genders BMI and weight demonstrate a significant association with OSA diagnosis. Specifically, individuals with a 10% weight gain experienced a six time greater risk of OSA (Jonas et al., 2017). No clear relationship between race or ethnicity and OSA has been established.

The prevalence of undiagnosed OSA in the United States affects 82% of males and 93% of females (Ramachandran & Josephs, 2009; Bouloukakai, 2013). This equates to 23.5 million undiagnosed adults in the United States affected with moderate to severe OSA. Without diagnosis and treatment, undiagnosed OSA results in increased risk for cardiovascular and metabolic sequelae (AASM, 2016b). The increasing prevalence of OSA with a significant undiagnosed OSA population suggests a need for evaluation into current screening and diagnostic criteria.

Polysomnography

Clinical guidelines from the American Academy of Sleep Medicine (AASM) identify polysomnography (PSG) as the gold standard for OSA diagnosis. This diagnosis is made by measuring occurrences of decreased or absent breathing per hour during a patient's sleep (AASM, 2016a). These measurements are expressed as an apnea-hypopnea index or AHI. Patients with AHI $\geq$ 5-15 are classified as having mild OSA, patients with AHI>15-30 are classified as having moderate OSA, and patients with AHI>30 are classified with severe OSA (AASM, 2016b).

Polysomnography requires extensive, in-laboratory monitoring. During this procedure

patients are monitored for eye movements, oxygen saturation, body movement, nasal airflow, and electrical activity in the brain, muscles, and heart (Gong et al., 2016). Specialized technicians are needed to monitor patients throughout the overnight study. Acquired PSG data requires interpretation by a physician specialist to determine the patients' OSA diagnosis (Gong et al., 2016). PSG is considered a routine and necessary procedure for OSA diagnosis. Utilizing this expensive and limited resource as a first-line screening tool for OSA is not practical.

Currently, the limited resources for PSG testing have led to extensive wait lists. Wait times for PSG differ by region with a national range from 2 to 10 months (AHRQ, 2007). The average wait time from referral to definitive treatment is 26 weeks (AHRQ, 2007). These long wait times contribute to increased missed appointments, ultimately worsening delays in diagnosis and treatment (IOM, 2006). Within the military population, similar OSA prevalence and PSG delays can be even more pronounced.

Military Relevance

Prevalence. The military health care system currently provides screening, treatment, and management of healthcare for 9.5 million military members, dependents, and retirees (Tricare, 2014). The number of military members meeting criteria for OSA is estimated to be 50% for members with previous deployments (Wood, 2013). The prevalence of OSA amongst the active duty military population has increased 4.5% in contrast to a two percent increase in the civilian population (AFHSC, 2010; Ramachandran & Josephs, 2009). From 2000 to 2009, "there were 96,922 diagnoses of obstructive sleep apnea among active component service members, most diagnoses were made in outpatient settings" (AFHSC, 2010, p. 9). The increasing number of OSA diagnoses reflects the sheer number of patients presenting to military treatment facilities (MTF) for OSA screening and potential diagnosis.

All active duty components have seen a six fold increase in OSA diagnosis over the past 10 years. Service members over 40 years old with OSA have increased eight fold (AFHSC, 2010). Additionally, military personnel returning from deployment have an increased incidence of OSA (Mysliwiec et al., 2013). Mysliwiec et al. conducted a cross-sectional study of 110 military members returning from combat deployment with sleep disturbances. Of those 110 military members, 62.7% met the criteria for OSA (Mysliwiec et al., 2013). This incidence of OSA amongst military members reinforces the importance of early and efficient diagnosis of OSA is critical. The availability of PSG in MTFs is similar to the civilian healthcare market.

Sleep center. The location of this DNP project, Wilford Hall Ambulatory Surgical Center (WHASC) in San Antonio, Texas, currently provides healthcare services for the Joint Base San Antonio (JBSA) region (Rankin, Carroll, Walz & Stubbs, 2016). The WHASC Sleep Center utilizes a ten-bed capacity sleep lab to provide PSGs to beneficiaries within the JBSA catchment area. Sleep Center staff report a staggering request of approximately 700 PSGs monthly, a level that far exceeds the Sleep Center's capability (Rankin et al., 2016). PSG request wait lists have been established, however, significant delay in diagnosis can result in development or complication of comorbidities (AASM, 2016b). To avoid these delays many patients are deferred to civilian sleep centers for PSG. WHASC estimates outsourced PSG costs in the local San Antonio area to be $750 to $2,500 (E. Mckenna, personal communication, July 29, 2016). In 2014, the WHASC Sleep Center outsourced 4,175 of 7,800 referrals to the civilian network, resulting in over $6 million in healthcare expenditures (Rankin et al., 2016). These similar findings in military and civilian healthcare can be attributed to the same barriers to OSA diagnosis.

Barriers to OSA Diagnosis

No current clinical practice guideline or evidence based practice. While new information regarding prevalence and associated complications with OSA has been discovered, much controversy remains regarding the best avenue to identify and diagnose those affected. The AASM and American College of Physicians (ACP) are currently the only two governing agencies with a documented guideline or approach to screening patients at risk for OSA (AASM, 2016a; Qaseem et al, 2014). These guidelines provide similar algorithms for identifying risks, referring for PSG, and proposed treatment modalities. Both guidelines utilize a subjective screening of patients without identifying a standard method or evidence-based tool (AASM, 2016a; Qaseem et al, 2014). The AASM and the ACP however, disagree on criteria needed to refer patients for PSG.

The ACP guideline suggests utilizing patient symptoms as a rationale for PSG testing (Qaseem et al., 2014) Conversely, the AASM cautions this may lead to a superficial emphasis on daytime sleepiness as the main reason for PSG testing (Morgenthaler, 2014). While daytime sleepiness may be a sign of OSA, 37% of OSA patients don't experience this symptom. Referring patients for PSG based off this symptom alone would effectively exclude two-thirds of patients with OSA while simultaneously referring for excessive and unnecessary PSGs (Morgenthaler, 2014; AASM, 2016b). Moreover, this approach would delay prudent evaluation for patients affected by other disorders responsible for somnolence, such as insomnia, medication side effects, or other neurological conditions (Morgenthaler, 2014)

Providers need an evidenced-based screening tool to identify patients needing diagnostic testing for OSA (AASM, 2016b). Use of an evidence-based screening tool, in addition to clinical discretion would ensure early identification of OSA, help to mitigate associated sequelae, and decrease costs associated with unnecessary PSG testing (Morgenthaler, 2014). Currently,

there are a variety of validated screening tools or methods available, however there are not established guidelines for their application (Redline, 2017). Instituting a single evidence-based screening guideline would provide a stable standard of care, improve consistency of care, and decrease potential patient harms (IOM, 2006). The selected screening tool and standardized guideline would have extensive value in the outpatient setting where patients are most likely to initially present for evaluation.

Outpatient Care Presentation. From 1993 thru 2010 there was a 15-fold increase in outpatient visits for OSA (Namen et al., 2015). In 2010, 6.7 million Americans were seen in outpatient clinics for OSA. This represents 0.3% of all outpatient visits with primary care providers responsible for 34% of these visits (Namen et al., 2015). These figures confirm outpatient clinics, particularly primary care, are the most common entry point for patients affected with OSA (Aurora & Quan, 2016). Unfortunately, the majority of primary care providers do not regularly assess patients for OSA symptoms. This has been partially attributed to provider uncertainty in diagnosis, treatment, and follow-up for OSA patients (Jonas et al., 2017).

Many providers report this uncertainty develops from lack of emphasis on sleep medicine during their medical school training (AASM, 2016b). Cited most often are difficulties in identification of OSA symptoms and associating linked comorbidities with OSA (AASM, 2016b). This results in sporadic, inconsistent use of available validated screening tools contributing to the inability to capture 80% of undiagnosed OSA patients (Aurora & Quan, 2016). Without the ability to identify these subtle manifestations, providers will be unable to mitigate the long-term health impacts of OSA (Stansbury & Stroll, 2015).

Overcoming the lack of screening in outpatient care is a critical step in changing the

number of people with undiagnosed OSA. Primary care providers will benefit from a standardized tool with prescribed criteria, diagnostics, and treatment progression (IOM, 2006). Additionally, providing education to providers on the importance and positive impact of OSA screening is crucial to any successful screening program (Aurora & Quan, 2016). Increasing provider knowledge and confidence on OSA will promote patient education on the topic and begin addressing the barrier of inadequate patient awareness.

Poor Public Awareness. A significant contributor to undiagnosed OSA burden can be attributed to a lack of public awareness (AASM, 2016b). The general public does not understand the signs and symptoms of OSA. Further, they do not understand the multitude of serious comorbidities including heart disease, stroke, and diabetes (Morgenthaler, 2014). Additionally, many patients have begun to accept certain symptoms such as snoring and sleepiness as a normal part of aging (AASM, 2016b). This belief system has led many patients to underreport or not report sleep-related symptoms to their provider (Redline, 2017). Currently only 20% of patients who routinely see their primary care provider spontaneously report OSA symptoms (AASM, 2016). Underreporting can prolong time-to-diagnosis, resulting in poor patient outcomes (Redline, 2017).

Poor awareness of OSA significance among the general population results in poor compliance in completed diagnostic PSG testing. The Institute of Medicine (IOM) found many patients do not complete PSG due to intrusive monitoring and the requirement to spend one or more nights outside the home (2006). This was highly concerning for populations with young children or dependent parents in the home (IOM, 2006). Providers need to recognize this knowledge deficit exists and educate patients to acknowledge OSA as a chronic disease similar to hypertension or diabetes. OSA is associated with increased mortality and should be managed

as any other chronic illness (AASM, 2016b; Aurora & Quan, 2016). Patient education and enhancing OSA awareness has the potential to improve patient understanding of associated comorbidities and increase compliance with diagnosis and treatment (AASM, 2016b).

Concentration on increasing public awareness and education on OSA should be a priority for providers (AASM, 2016b). This is especially important for those in outpatient clinics,as this is the gateway to care for most patients (Namen et al., 2015). Full understanding of the presentation and serious complications of undiagnosed OSA will assist in early identification and diagnosis of OSA (AASM, 2016b). Emphasis on the seriousness of OSA comorbidities may also help combat the cost-barrier keeping patients from seeking care.

Costs. For patients meeting criteria for OSA testing, the cost of multiple appointments and PSG testing can create financial burden (AASM, 2016b). For diagnosis, patients will incur multiple appointments for screening, testing, and titration. These appointments create direct costs of outpatient patient appointments, cost of testing, and specialist fees (AASM, 2016b). Other indirect costs such as time lost from work and travel expenses can also contribute to financial burden.

The AASM estimated OSA diagnosis and treatment costs in 2015 at approximately $12.4 billion (2016b). Approximately 57% of these expenditures came from outpatient care visits, diagnostic testing, and non-surgical treatments. These costs averaged $2,105 per person annually (AASM, 2016b). For patients covered by insurance programs, some portion of cost is usually covered. For example, the Center for Medicare and Medicaid Services (CMS) authorized 2016 PSG reimbursement at $1100 (CMS, 2016). For patients without insurance or CMS benefits these costs may be insurmountable. Amelioration of these cost barriers begins with increased awareness directed toward insurance companies and employers on the economic and health

impacts from undiagnosed and untreated OSA (AASM, 2016b). This collaborative awareness could serve to mitigate the associated health and economic impacts.

Impact on Health

Research studies have consistently demonstrated a link between OSA and significant medical comorbidities including hypertension, cardiovascular disease, and diabetes (Badran et al., 2012; AASM, 2016b). Current estimates reflect 14.1 million people with undiagnosed OSA have hypertension and 3.1 million have heart disease (AASM, 2016b). This has been associated with an increased diagnosis of congestive heart failure and atrial fibrillation (Worsnop et al., 1998; Wolk, Kara, & Somers, 2003; Jean-Louis et al., 2008). These diagnoses further contribute to a 150 % increased risk of cerebral vascular accident (CVA) or stroke (Stansbury & Strollo, 2015). Additionally, in males OSA is an independent risk factor for stroke. Individually these associated cardiovascular sequelae increase both morbidity and mortality. Collectively they contribute to a four-fold increase in risk of premature death (Enciso & Clark, 2011).

The sleep disturbances associated with OSA have also been shown to affect glucose metabolism. This has resulted in the increased insulin resistance and glucose intolerance contributing to type-two diabetes (AASM, 2016b; Stansbury & Strollo, 2015). In the United States there are currently 5.6 million people with undiagnosed OSA affected with diabetes (AASM, 2016b). Additionally, researchers at John Hopkins found OSA impacted insulin sensitivity independent of age, gender, race, or body habitus (Stansbury & Strollo, 2015). OSA also impacts lipid absorption, and hepatic steatosis contributing to non-alcoholic fatty liver disease. These sequelae are the major components of metabolic syndrome, suggesting OSA may also be contributing to this syndrome (Stansbury & Strollo, 2015).

Research has also correlated OSA with mental health disorders including depression and increased addictive behaviors. These addictive behaviors can include increased alcohol intake, tobacco use, and consumption of pills to both promote alertness and induce sleep (AASM, 2016b). These maladaptive behaviors are attributed to fatigue, low energy levels, and decreased alertness experienced by those with untreated OSA. Additionally, lack of education on OSA diagnosis leads to provider misdiagnosis and unnecessary prescriptions for psychiatric and sleeping medications (AASM, 2016b). Currently 8.7 million Americans with undiagnosed OSA are affected by depression, anxiety, or other mental health disorder (AASM, 2016b). If left undiagnosed or untreated these multiple health comorbidities can have significant economic impacts.

Impact on Healthcare Cost Burden

The comorbidities associated with undiagnosed OSA have a substantial impact on national healthcare costs. These expenditures arise from medical visits, treatment, medications, and inpatient care for associated sequelae. Annual costs for undiagnosed OSA were estimated at $30 billion and included $5.4 billion for hypertension, $6.7 billion for heart disease, $6.4 billion for diabetes, and $7.1 billion for mental health (AASM, 2016b). Research has consistently proven treatment of OSA reduces or eliminates these associated comorbidities (Stansbury & Strollo, 2015).

Additional economic burdens associated with undiagnosed OSA include motor vehicle accidents (MVAs) and their associated medical treatment costs. The National Highway Traffic Safety Administration (NHTSA) estimated $26.2 billion in undiagnosed OSA associated MVAs in the United States in 2015 (AASM, 2016b). These patients not only have an increased risk of MVA but a subsequent increased risk of personal injury. MVAs have an additional economic

cost burden accumulated from property damages, loss of productivity from work-related absenteeism, and rising insurance premiums (AASM, 2016b). Further contributors to economic costs are suspected to include workplace accidents. While data is limited in this component, associated costs within the occupational sector are estimated at $6.5 billion.

The total costs associated with undiagnosed OSA in 2015 were $149.6 million or $6,336 per undiagnosed individual (AASM, 2016b). In contrast, treatment costs for OSA in 2015 were $12.4 billion or $2,105 per diagnosed individual. This represents untreated OSA costs are 67% higher than treated OSA costs (AASM, 2016b). This is consistent with research demonstrating treatment of OSA reduces or eliminates associated comorbidities.

As outlined above, OSA can have significant health consequences and subsequent economic impacts. Cost effective mitigation of these sequelae can only occur with early and accurate diagnosis of OSA. Primary care providers will see most undiagnosed patients, thus referral for diagnostic PSG should occur in outpatient care clinics (Aurora & Quan, 2016; Namen et al., 2015). The expense and resource burden of PSG renders it impractical to employ as a screening tool for OSA (Bianchi, Hershman, Bahadoran, Ferguson & Westover, 2014; Ramachandran & Josephs, 2009). To combat this researchers have actively sought an alternative and efficient examination to screen for OSA (Gong et al., 2016). This has resulted in a number of validated screening tools (Redline, 2017). The United States Preventative Task Force (USPTF) and AHRQ have determined standardized screening using validated questionnaires with subjective and objective findings should be used to prioritize the need for PSG (Jonas et al., 2016). Evaluation of available screening tools should be performed to determine the most sensitive and specific tool for implementation.

Clinical Question

In the adult population aged 18 years and older at risk for OSA, does implementation of a standardized evidence-based screening tool affect PSG referral accuracy?

Focus Areas

Identified Stakeholders. Stakeholders for this project were identified as outpatient care providers, Sleep Medicine providers, outpatient clinic staff, sleep laboratory staff, hospital administration, and empaneled patients.

Identified evidence based screening tool. Using a systematic review of current literature, an evidence-based screening tool to increase PSG referral accuracy was identified. This selected screening tool, the SBQ, demonstrated superior sensitivity and specificity, as well as a relative potential for employment in regards to cost and/or availability.

Identified barriers to practice. Discussion with stakeholders and pre-implementation surveys identified barriers to practice. These included, (a) no established protocol or guideline to screen patients for OSA or determine need for PSG; (b) individual provider preference for screening tool or method; (c) lack of knowledge on OSA presentation and severity of sequelae; (d) lack of knowledge on available screening tools; (e) lack of training on OSA screening; (f) perceived lack of time for utilizing screening tools; and (g) decreased access/resources for PSG.

Implemented training. Training dates and locations were coordinated with outpatient care clinic administration and incorporated into designated training time to maximize clinic staff attendance. Training was conducted at each outpatient clinic location with combined provider and technician staff. Information was presented using PowerPoint presentation, an open question and answer session, and screening tool handouts. Training topics focused on increasing OSA knowledge, discussion of evidence based screening tool selection, and SBQ screening tool usage and implementation. Alternative training was provided via email for staff unable to attend.

Post Survey Data. Staff attending training was provided post-surveys to determine effectiveness of training. Questions were focused on whether staff found training valuable, received sufficient information and training on SBQ screening tool, and whether staff would utilize and recommend the selected evidence based screening tool. All responses received were greater than 90% positive.

Implemented screening tool. Preparation for SBQ implementation began with identification of a *go-live* date. This start date was relayed to staff during their scheduled training and through email notifications. Blank SBQ screening forms were provided and distributed to each clinic team. Forms were also sent to all staff members via email to ensure capability to print SBQ screening forms as needed. Staff was provided phone numbers and emails for all project members for any arising questions.

Collected referral data and PSG results. All PSG referrals from associated clinics were queried for similar time periods in 2015 (pre-implementation of SBQ) and 2016 (post-implementation of SBQ). Project team members screened identified referrals and relevant data was extracted from military electronic medical record (EMR). Data was compiled for evaluation of pre- and post-implementation comparative data. Consultation with hospital statisticians was accomplished for final analysis and determination for extended relevance.

Relevance to Military Nursing

Accomplishment of the described focus areas can contribute numerous implications to clinical practice. This is directly related to the establishment of a standardized evidence-based screening tool for screening at-risk for OSA patients. As noted earlier, current available guidelines do not allocate a specific screening tool for outpatient care use. By identifying an evidence-based screening tool with high specificity and sensitivity, our facility and patient

population will benefit in the following ways:

- Earlier identification of patients with OSA due to improved referral accuracy and decreased PSG wait times.
- Improved patient outcomes due to early avoidance/decreased development of associated sequelae.
- Decreased costs attributed to OSA associated sequelae.
- Decreased costs associated with improved PSG referral accuracy.

Further anticipated impacts involve leveraging the findings of this project, to impact the entire Air Force Medical System (AFMS). The utilization of the SBQ screening tool in outpatient clinics can produce expedient, efficient, and cost effective OSA diagnosis. Extended implementation of the SBQ screening tool can subsequently improve referral accuracy, expedite OSA diagnosis, and result in early intervention and reduction of associated comorbidities across the entire AFMS.

Organizing Framework

The focus of our project was to identify an evidence-based screening tool that demonstrated improved PSG referral accuracy for at risk OSA patients. The Knowledge-To-Action framework was well suited for implementing a screening tool into an outpatient care clinic. This framework utilizes knowledge generation, or research to produce products or tools for clinical use (Lobiondo-Wood & Haber, 2014). In this project, research led to the identification of the SBQ screening tool for implementation in the outpatient setting.

Employing the action portion of this framework ensures maximized success of the implementation of the intervention (White & Dudley-Brown, 2012). This involves the following seven steps:

1. Identifying the problem and performing a literature search.
2. Adapting the knowledge to the local context.
3. Assessing barriers to knowledge use.
4. Selecting, tailoring, and implementing the interventions.
5. Monitoring knowledge use.
6. Evaluating the outcome.
7. Sustaining the knowledge use.

A detailed description of each step, as well as their relevant application to the DNP project, is further explained in the *Procedural Steps* section of this proposal.

Project Design

General Approach

This project design focused on quality improvement (QI) of screening methods for PSG referral. Through systematic review an evidence-based OSA screening tool was identified and implemented within the WHASC and Randolph Air Force Base (RAFB) Primary Care Clinics. Pre-implementation surveys were utilized to determine potential barriers and knowledge gaps. Training was provided within each outpatient clinic to increase general OSA knowledge, discuss evidence based screening tool selection, provide training on SBQ screening tool usage, and provide guidance on implementation of the SBQ screening tool within each clinic. Alternative training was provided via email for staff unable to attend. Post-surveys were collected to evaluate the effectiveness of training and staff perceptions of the SBQ implementation. Comparative data was collected and evaluated using PSG referrals from pre- and –post implementation time periods. This data was compiled to determine effectiveness of SBQ implementation. Further comparisons were made using pre-and post-implementation survey

data. Consultation with hospital statisticians was utilized to determine statistical significance of QI results.

Setting

This DNP project was conducted at WHASC, Lackland Air Force Base (LAFB), San Antonio, Texas and Randolph Clinic, RAFB, Universal City, Texas. WHASC is the largest medical wing in the Air Force and "provides the full spectrum of primary care, specialty care, and outpatient surgery" (59th Medical Wing, 2015, par. 2). This facility serves a substantial population within the greater San Antonio area including joint service personnel, dependents, and retirees (59th Medical Wing, 2015). Further, its close proximity to Joint Base Randolph allowed for extension of this QI project implementation.

Currently, the WHASC Sleep Center is the largest Pulmonology Sleep Lab in the Air Force (59th Medical Wing, 2015). The facility provides services to the surrounding joint military healthcare facilities, as well as some Veterans Affairs (VA) entitled members. With responsibility for such a large population, the WHASC Sleep Center strives to be at the forefront of identification and treatment of OSA. The sleep center has attained and maintained certification from the AASM, and functions as a center of excellence (59th Medical Wing, 2015).

Procedural Steps

Systematic Review of Available Evidence

This literature review was performed to identify an evidence-based tool to screen at risk OSA patients in prior to PSG referral. The search engines used to identify articles and abstracts included in this review were Public/Publisher Medical Literature Analysis and Retrieval System Online (PubMed), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and

Embase. Learning Resource Center (LRC) research librarians located at Uniformed Services University of Health Sciences (USUHS) were utilized to assist with developing strong, valid search criteria. Universal search criteria and limits were established to ensure an unbiased search strategy and selection process.

Search criterion. Databases were searched using universal search criteria and limits to ensure an unbiased search strategy and selection process. Search terms included *apnea, obstructive sleep apnea, predictive, efficient, referral,* and *diagnostic*. Medical Subject Heading (MeSH) terms included *obstructive sleep apnea* (multiple variations; e.g. *apnea, obstructive sleep*), *questionnaire, screening assess primary care,* and *family health*. Initial search results provided 1342 articles matching specified search criteria. Further title review revealed 19 duplicates, resulting in a net search result of 1323 articles.

Limits for these retrieved articles were defined as (a) published within the last 10 years; (b) peer-reviewed; (c) research articles; (d) human subjects; and (e) minimum age of 18 years. Application of these limits resulted in 153 articles meeting criteria. The title and abstracts of these 153 articles were screened for exclusion criteria including:

- Study designed for treatment of OSA.
- Not obstructive sleep apnea (e.g. central sleep apnea).
- Study included pediatric patients.
- Study included pregnant patients.
- Wrong publication type.
- Study included patients with other sleep comorbidities besides OSA (e.g. sleep paralysis, insomnia).
- Study included hospitalized patients.

- Study utilized alternative diagnostic test in lieu of gold standard PSG.
- Study included patients with significant preexisting chronic illness (e.g. Chronic Obstructive Pulmonary Disease, stroke)

This exclusion criterion resulted in the removal of 135 articles. The remaining 18 articles were divided among group members for complete article screening and review. Seven additional articles were excluded for previously identified exclusion criteria through full text review. The most common exclusion factors were use of alternate testing for OSA diagnosis, and participants with significant chronic illness. Complete search criteria, limitations, and exclusion criteria are presented in Table 1.

The resulting 11 articles were reviewed using Evidence Appraisal Forms from John Hopkins Evidenced Based Nursing Practice (Appendix E). Articles were then rated using John Hopkins Evidenced Based Nursing Practice Rating Scale for Level and Quality of Evidence (QOE). Complete article selection is presented in Figure 1, using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses or PRISMA Diagram.

Search results.

Quality. Completion of the literature search resulted in (a) two, level-one studies; (b) two, level-two studies; and (c) seven, level-three studies (Table 2). Specifically, the level of evidence (LOE) of results consisted of two meta-analyses, 36 randomized control trials (RCTs), two quasi-experimental studies, and seven cohort studies. In addition, QOE evaluation resulted in two *A* studies, and nine *B* studies.

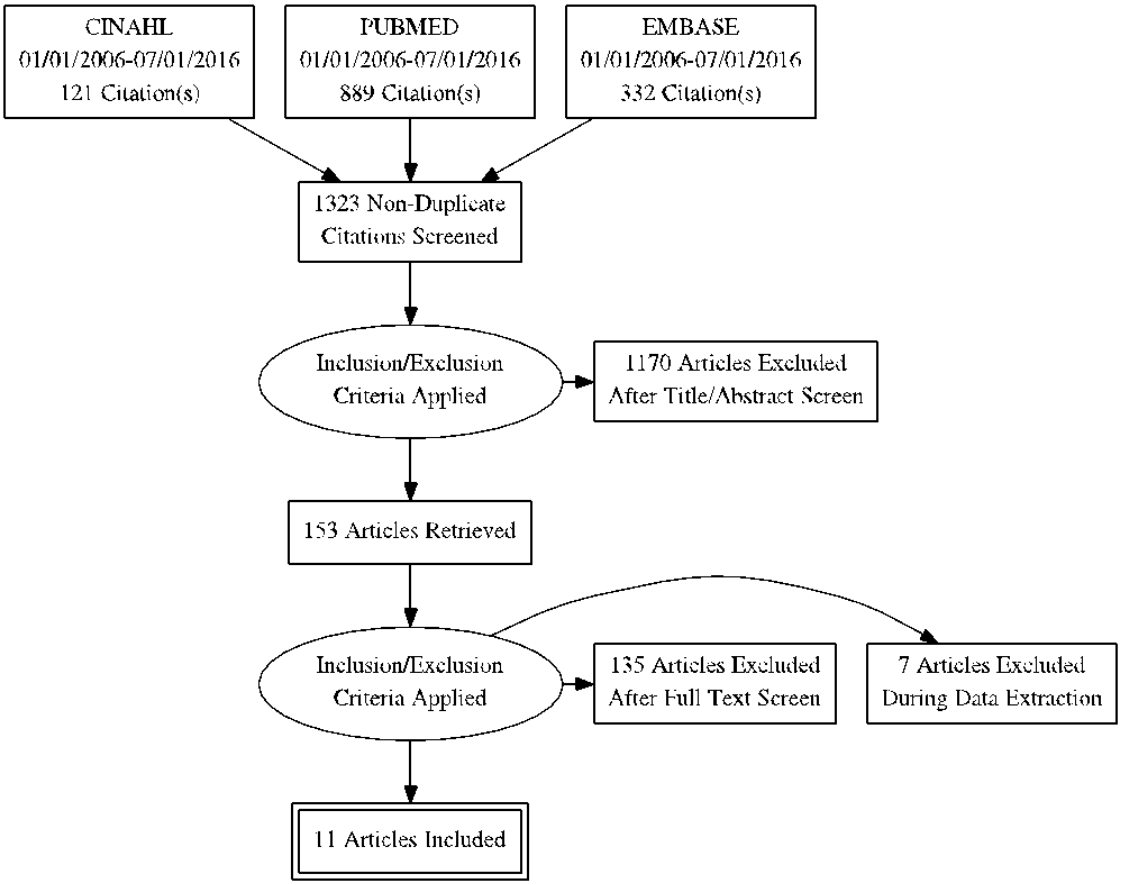

Figure 1. Flow diagram of the systematic review process.

Quantity. The 11 articles identified using systematic review provided a vast quantity of information. Specifically, the selected articles provided data from 36 RCTs, and tracked the data of over 11,800 participants. In depth individual article information is provided in Table 3. These studies identified eight validated screening tools for further evaluation.

Identified tools.

STOP-BANG questionnaire. The SBQ is a questionnaire composed of eight dichotomous questions. These questions broadly assess subjective data (snoring, tired, observed

apnea) with objective data (hypertension, BMI, age, neck size, gender). Simple scoring conveys one point for each affirmative answer. Scores are segregated into ranges as follows:

- Low Risk: 0 to 2
- Intermediate Risk: 3 to 4
- High Risk: 5 to 8

Review of seven retrieved studies, including two meta-analyses and over 10,000 patients consistently recognized the SBQ for high sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Averages for these values (Table 4) were, sensitivity 91%; specificity of 74%; PPV 83%; and NPV 81% (Abrishami, Khajehdehi, & Chung, 2010; Chung, Abdullah, & Liao, 2016; Chung, Yang, Brown & Liao, 2014; Farney et al., 2011; Luo, Rong, Xu, Yi, & Jiong, 2014a; Luo, Rong, Xu, Yi, & Jiong, 2014b; Vana, Silva, and Goldberg, 2013; Ramachandran & Joseph, 2009). Abrishami et al. (2010) also recognized this questionnaire for superior methodological validity, simplicity, and ease of use.

Additionally, in a retrospective study by Farney et al. (2011), linear regression demonstrated a proportional correlation between AHI and SBQ score. The diagnosis diagnostic odds ratio (DDOR) was also superior with a value of 141.48. In a study by Chung et al., (2014) the SBQ demonstrated poor specificity, though further clinical evaluation with gender, BMI, and age increased sensitivity to 95%

Berlin questionnaire. The Berlin questionnaire is composed of 10 multiple-choice questions addressing subjective symptomatology. Answers are scored based on assigned categories and correlated with a risk level. Available literature provided data from seven studies, including two meta-analyses and more than 8,000 patients. This tool demonstrated inconsistent results across varied studies with superior sensitivity and specificity identified by Ramachandran

& Joseph (2009), and PPV of only 50% in other studies (Karakoc et al., 2014; Subramanian, Hesselbacher, Aguilar, & Surani, 2011). Averages for these values (Table 4) were, sensitivity 75%; specificity of 59%; PPV 81%; and NPV 96%.

Table 4

Comparisons of Sensitivity, Specificity, Predictive Value, and Diagnosis Diagnostic Odds Ratio for OSA Screening Tools

					Average		
Screening Tool	Ease of Use	AHI Threshold	Sensitivity Average	Specificity Average	NPV	PPV	DDOR Average
SBQ	Questionnaire & Measurements	5	0.91	0.74	0.83	0.81	141.48 Excellent
Berlin	Questionnaire	5	0.75	0.59	0.81	0.96	1.20-117.78 Poor to Excellent
Kushida Index	Complex methodology; Cumbersome for routine use	5	0.93-1.00	0.88-0.97	-	-	>81 Excellent
ESS	Questionnaire	5	0.38	0.52	0.46	0.60	0.43 Poor
NAMES	Combined Questionnaire	15	0.91	0.23	0.63	0.62	-
ARES	Combined Questionnaire	5	0.90	.43	0.57	0.73	-
Wisconsin	Combined Questionnaire	5	-	-	0.89	0.46	-
ASA	Subjective Assessment	5	-	-	0.38	0.72	-

Note. AHI=apnea-hypopnea index; DDOR=diagnosis diagnostic odds ratio; PPV=positive predictive value; NPV=negative predictive value

Limitations on this screening tool were attributed to subjectivity of questions. In two studies, multiple Berlin questionnaires were incomplete (Friedman et al., 2011; Karakoc et al., 2014). This may be attributed to a lack of dichotomous questioning that leads participants to

spend excessive time completing the questionnaire. Karakoc et al. (2014), also found lack of time limits on subjective questions allowed for tremendous variance in patient scores. Specifically, allowing patients to recall symptoms from many years ago, likely not relevant to current disorder.

Kushida index. This tool is a morphometric model using measurements of mouth, cervical circumference, and BMI. In a meta-analysis reviewing 6794 participants this method demonstrated high sensitivity, specificity, and DDOR (Ramachandran & Joseph, 2009). Averages for these values (Table 4) were sensitivity 93% to 100%, specificity 88% to 97%, and a DDOR greater than 81%. In many instances, these values were superior to other tools. Methodology for this tool requires radiographs, prolonged time to complete, and specialized training for interpretation (Ramachandran & Joseph, 2009). These limitations result in a very poor ease of use and make it cumbersome to utilize within an outpatient environment.

Epworth sleepiness scale. This questionnaire consists of eight subjective questions scored from 0 to 3 based on degree of intensity. The higher the patient ranks each question, the higher the overall score. A score of greater than 12 indicates daytime sleepiness requiring further evaluation. This tool, designed to detect daytime sleepiness, is frequently used in clinics due to its ease of use and provider familiarity (Quan, 2013).

The ESS did not perform well in any of the reviewed studies (Karakoc et al., 2014; Subramanian et al., 2011; Luo et al., 2014a; Vana et al., 2013; Ramachandran & Joseph, 2009). Scores for sensitivity, specificity, PPV and NPV ranked last when compared to other screening tools (Table 4). Averages for these values were sensitivity 38%, specificity 52%, PPV 60%, and NPV 46%. Additionally, the average DDOR for the ESS was 43%, with one study by Luo et al. (2014a) finding an AUC at 30%.

The poor performance of the ESS is known to Sleep Medicine Physicians. Dr. Stuart Quan, an AASM physician revealed the ESS "was never designed as a sole instrument to determine whether a patient is or is not sleepy for the purpose of approving diagnostic testing. For this purpose, it is actually a poor instrument" (Quan, 2013, p. 987). Dr. Quan expounded stating the ESS is inappropriate for evaluation of OSA and sleep medicine physicians should stop being complicit in its use. The limitations of the ESS combined with AASM physician evaluations make the ESS a poor choice for screening for OSA.

NAMES. This screening method involves neck circumference, airway classification, comorbidities, ESS score, and snoring (NAMES). This is the only screening tool to formally consider comorbidities into OSA risk calculation (Subramanian et al., 2001). In a meta-analysis with 509 patients, the average sensitivity, specificity, PPV, NPV were identified using an AHI of 15 (Subramanian et al., 2001). Results were sensitivity 91%, specificity 23%, PPV 62%, and NPV 63%.

The NAMES screening tool has only been validated in one setting and does not provide a method of evaluation for patients with mild OSA scoring (AHI 5 to 15). Additionally, this tool requires specialized training for evaluation of airway classification and comorbidity evaluation can be subjective. These limitations make the NAMES a poor choice to employ in a busy outpatient setting.

ARES. This screening tool stands for the Apnea Risk Evaluation System (ARES). It is comprised of 20 questions and includes use of the ESS. In a study by Encisco and Clark (2011), the ARES demonstrated a superior sensitivity of 96.6%. Specificity was low at 43.2% with PPV and NPV at 73%. This study only included 84 participants and questions on the questionnaire were reported as complicated or in-depth. Further studies would be required to determine

employability within an outpatient setting.

Wisconsin. The Wisconsin Sleep Questionnaire is a screening tool with both dichotomous and multiple-choice questions. This tool was designed to evaluate for multiple sleep disorders, not specifically for OSA. Abrishami et al. (2010) reviewed the Wisconsin screening tool in a meta-analysis. Available data for the Wisconsin came from only two prospective studies involving 753 participants. This tool demonstrated a superior NPV of 89%, but a minimal PPV of 46%. Additionally, this tool is time consuming for patients and allows for subjectivity on many questions. The limitations of this tool make it difficult to employ in an outpatient setting.

ASA. The American Society of Anesthesiologists (ASA) checklist has been used on surgical patients for many years and has recently been studied as a screening tool for OSA (Vasu, Grewal, & Doghramji, 2012). This tool contains 12 items for review and requires specialized training to complete. Studies available for meta-analysis determined a PPV 72% and a NPV of 38% (Abrishami et al., 2010). Usefulness of this checklist as an OSA screening tool and its employability in an outpatient setting will need further investigation.

Selection of SBQ. A systematic review of available literature compared available data for eight validated OSA screening methods. Compiled data came from 11 studies including two meta-analyses, 36 RCTs and over 11,800 patients. The SBQ was identified as the evidence-based screening tool providing highest combination of sensitivity, specificity, PPV, NPV, and DDOR. Further, this tool is feasible, available, and provides simple dichotomous questioning for all genres of patients. To determine the potential for improved OSA screening in the outpatient setting, the SBQ was chosen for this project.

Methodology

Education and training. Initial implementation within the outpatient setting began with scheduling training for all assigned staff at WHASC and RAFB clinic primary care clinics. Training was scheduled through clinic managers, outside of patient care hours to facilitate maximum staff attendance. Separate training sessions were scheduled at each location for staff convenience.

Training sessions began with pre-surveys to solicit baseline OSA and SBQ knowledge. This hardcopy survey (Appendix E) contained seven questions aimed at identifying stakeholders, determining normal quantity of OSA patient interactions, determining current screening practices, and identifying any perceived or actual barriers. Surveys remained anonymous to promote honest feedback. Surveys were collected prior to beginning the training presentation.

Training was delivered at both facilities via PowerPoint presentation. All DNP project team members participated in delivery of training at both assigned locations. Instruction focused on, (a) OSA definition, prevalence, sequelae, and military relevance; (b) diagnosis requirements, costs, and availability; (c) costs associated with the MTFs current process; (d) literature review results and selection of the evidence-based SBQ; (e) potential benefits of SBQ within assigned clinics; (f) SBQ familiarization and training (including neck measurement training); and (g) implementation date and strategy. All questions were accepted and addressed upon completion of training. All clinic staff members not present for training were provided a copy of the PowerPoint presentation via email. Staff members were also provided with email and phone numbers for all project team members and DNP site director for further questions.

Upon completion of training, staff were administered post-surveys (Appendix E). These surveys assessed training topics including (a) value of training; (b) increased SBQ knowledge; (c) likelihood of increased SBQ use or recommended use; (d) most influential section of training;

and (e) suggestions for improvement. All surveys were distributed and collected anonymously to encourage honest feedback. Staff members not in attendance for live training were excluded from survey data collection. All pre- and post-survey data was entered into an excel spreadsheet for analysis.

SBQ implementation. All clinic teams were provided with both hardcopy (Appendix E) and computer versions of the SBQ for implementation. Paper tape measures were supplied and available for use in both clinics. Providers and ancillary staff were instructed to utilize SBQ for any patient with OSA risk from October 01, 2016 to November 30, 2016. SBQ scores were manually entered or scanned into the EMR. This decision was determined by each clinic team in order to minimize the impact in daily operations. Staff members were advised SBQs were not needed for patients with previous diagnosis of OSA or patients needing titration studies.

Data Collection. All referrals for PSG from October 01, 2015 to November 30, 2015 were queried utilizing resource management staff. An identical query for October 01, 2016 thru November 30, 2016 was also retrieved. Data was filtered to include only PSG referrals from WHASC and RAFB primary care clinics. Retrieved PSG referral data was utilized to locate the originating patient encounter in the EMR. Patient EMRs were then evaluated to identify referring provider, referral diagnosis, use of screening tool, screening tool score, prior diagnosis of OSA, and the clinical reasoning for PSG referral. Available demographic data including patient age, gender, BMI, and active duty status were also collected. PSG diagnosis outcome, and AHI score was confirmed using EMR patient encounters and/or clinical notes. Pertinent referral data and EMR information were placed into a de-identified excel spreadsheet. Records were excluded for (a) patients not completing PSG; (b) patients with prior OSA diagnosis; (c) currently pregnant; (d) under 18 years old; and (e) unable to locate PSG result or evidence of

OSA determination.

Statistical Analysis. Statistical significance between SBQ training, use of SBQ, and number of negative PSGs were evaluated in separate pairs using a two-by-two contingency table and cross-tabulation (Table 5). Significance was established using Pearson's chi-square. Binary relationships were evaluated using bivariate correlation and nonparametric related K samples. Significance was established using McNemar's Exact and Linear Association. A Receiver Operating Characteristic (ROC) was established to analyze the Area Under the Curve (AUC) for sensitivity, specificity, positive predictive value, and negative predictive value (Table 6). All tests were two-tailed with $p < 0.05$ considered statistically significant. All data was analyzed using SPSS 18.0.

Table 5

Results of Statistical Analysis When Comparing Relational Factors

Relational Factors	Valid Cases (Providers)	PPV	NPV	Pearson Chi-Square Sig.* □	Fisher's Exact Sig.*	McNemar Test Sig.*	Likelihood Ratio Sig.* □	Linear-by-Linear Sig.* □
Increased SBQ with Decreased PSGS	32	.950	.330	.033	.049	.039[a]	.033	.035
Attended Training and Increased SBQ Use	32	.770	1.00	.000	.001	.033[a]	.000	.001
Attended Training and Decrease in PSGs	32	.960	.800	.000	.002	.001[a]	.001	.000

Note. Correlations utilized a 2x2 contingency table with 2-sided asymptotic significance. PPV=Positive Predictive Value; NPV=Negative Predictive Value;
[a] Binomial distribution used.
*p<0.05.
□df=1.

Table 6
Area Under the Curve For Attending Training and Increased PSG Referral Accuracy

					Asymptotic 95% Confidence Interval	
Decreased Negative PSGs	Valid	Area	Std. Error[a]	Asymptotic Sig.[b]	Lower Bound	Upper Bound
Positive	27	0.863	0.110	0.011	0.647	1.000
Negative	5					

Note. Positive actual state is YES
a. Under the nonparametric assumption
b. Null hypothesis: true area = 0.5

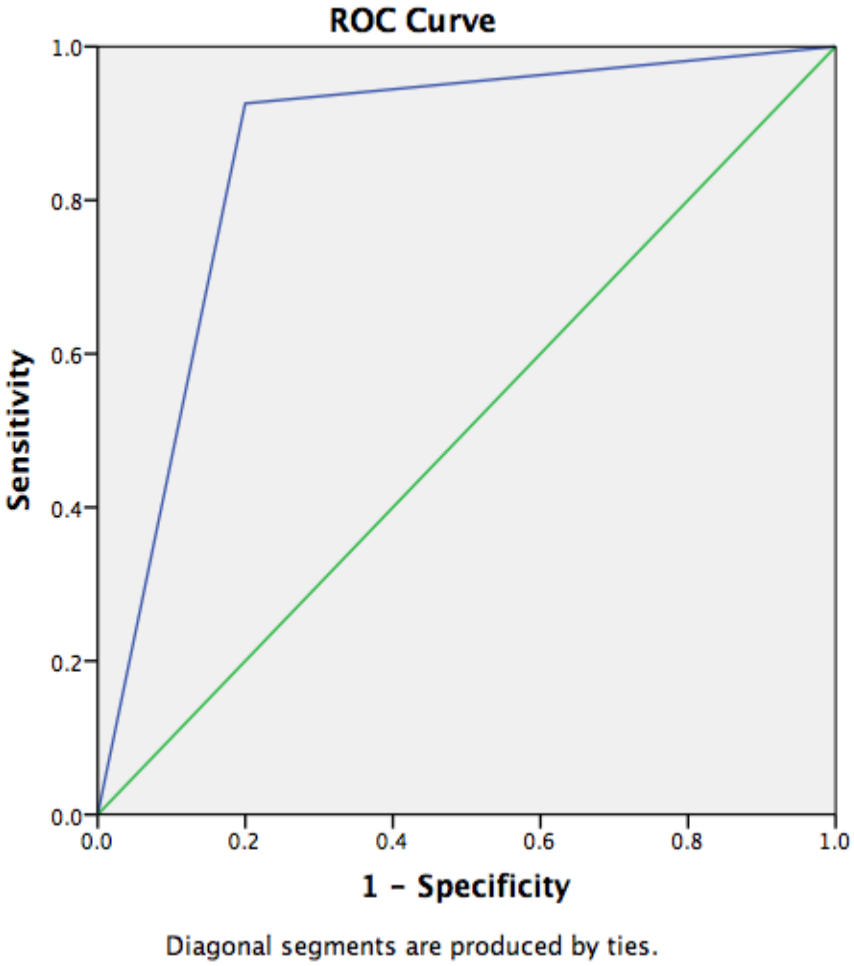

Figure 2. Receiver Operating Characteristic for Training Attendance and Increased Use of SBQ.

HIPAA Concerns

This DNP group obtained Institutional Review Board (IRB) approval based on the federal definition of human subjects research. Specifically, the definition states "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge..."(DHHS, 2014). The primary concern for our DNP project was protection of patients' personal information due to (a) chart reviews of current practice at WHASC; (b) data collection from patient encounters for OSA screening, PSG referral, and potential OSA diagnosis; and (c) temporary collection of patient personal identifiable information (PII) for data collection.

Health Insurance Portability and Accountability Act (HIPAA) concerns were mitigated by de-identifying PII collected from data extraction. This data was stored on a government computer assigned to Principle Data Collectors. All government computers required a common access card (CAC), and were firewall protected to prevent a possible breach. Data was not linked with external databases, nor transmitted for collaborative use. All data was stored and/or destroyed in compliance with WHASC Institutional Review Board policies.

Project Results

Survey Results

Pre-Survey Results. Data was collected from surveys distributed prior to SBQ training (Table 7). Results revealed 100% of providers felt OSA screening was valuable, yet only 23% reported screening every patient. Additionally, 23% of providers reported time as a barrier to OSA screening. This may correlate with the 46% using the ESS (reported as fast and easy). An additional 12% of providers reported using no screening tool. Lack of CPG or training was reported by 20% of staff as a barrier to OSA screening.

Table 7

STOP-BANG Training Pre-Survey Results

	WHASC		RAFB	
Pre SBQ Training Survey	Provider	Nurse/Technician	Provider	Nurse/Technician
Number in Attendance	15	26	11	18
Value OSA Screening				
Yes	15	21	5	12
No	-	1	-	-
How Often Using a Screening Tool				
0-25 percent	1	3	1	5
25-50 percent	5	1	-	4
50-75 percent	6	2	2	1
Every patient	4	17	2	2
Screening Tool Used				
SBQ	4	5	2	4
ESS	10	13	2	3
None	2	-	1	-
Barriers to Screening				
No CPG/No Training	1	1	1	2
Patient lacks Knowledge	-	2	-	1
Not enough Time	4	-	2	-
None	11	20	2	9

Note. WHASC = Wilford Hall Ambulatory Surgery Clinic; RAFB = Randolph Air Force Base; SBQ = STOP-BANG Questionnaire; OSA = Obstructive Sleep Apnea; CPG = Clinical Practice Guideline; ESS = Epworth Sleepiness Scale

Post-Survey Results. Post training surveys were collected immediately upon SBQ training completion (Table 8). Data revealed 49 out of 50 staff members found the training valuable to their practice, with only one provider disclosing no value in the training. All staff members reported the training provided an appropriate amount of information. One provider reported no intention to utilize SBQ in future practice. Conversely, 23 providers reported they were likely to implement the SBQ into their practice. Twelve providers identified the presentation of evidence and general SBQ information as the most effective training elements. Nursing and technician staff reported SBQ information and neck circumference training as the most valuable training elements. Pre- and post-survey data was utilized in conjunction with collected referral data for analysis.

Table 8

STOP-BANG Training Post-Survey Results

	WHASC		RAFB	
Post SBQ Training Survey	Provider	Nurse/Technician	Provider	Nurse/Technician
Number in Attendance	15	26	11	18
Training was Valuable				
Yes	15	6	8	18
No	-	-	1	-
SBQ Information Appropriate				
Yes	15	6	9	18
No	-	-	-	-
Likely to Implement				
Yes	15	6	8	6
No	-	-	1	-
Most Effective Training Element				
SBQ Information	5	1	-	6
Evidence Presentation	6	-	1	2
Neck Circumference Training	-	-	1	1

Note. WHASC = Wilford Hall Ambulatory Surgery Clinic; RAFB = Randolph Air Force Base; SBQ = STOP-BANG Questionnaire

Referral Data

A final count of 129 referrals from 2015 and 100 referrals from 2016 were available for data evaluation (Table 9). Of these 229 patients there were 164 males and 65 females, ranging in age from 20 years to 62 years (mean 38 years). Body mass index ranged from 19kg/m^2-52kg/m^2 with a mean BMI of 29.43kg/m^2. There were 196 active duty members and 33 civilians. Fifty-three of these referrals originated from RAFB clinic, while 176 referrals came from WHASC.

Table 9

Characteristics of Study Population for Selected Timeframe 2015 and 2016

	Age		BMI	
Frequencies	2015	2016	2015	2016
Number	129	100	129	97
Mean	37.72	38.36	28.95	29.99
Median	38.00	38.00	29.00	30.00
Mode	38.00	44.00	27.00	29.00[a]
Range	42.00	36.00	36.00	31.00
Minimum	20.00	22.00	19.00	21.00
Maximum	62.00	58.00	55.00	52.00

Note. BMI = body mass index; M = male; F = female
[a]Multiple modes exist. The smallest value is shown

Referral data was evaluated for referring provider, referral diagnosis, SBQ usage, SBQ score, PSG diagnosis outcome, and AHI score. A total of 53 primary care providers ordered PSG referrals within the selected 2015 and 2016 time periods. Due to military deployment absence, attrition, or incoming/outgoing relocations, 21 providers did not have referral data from both periods. Only providers with referral data in both specified time frames were included for statistical review to enable evaluation of the educational program impact. Final data included 32 providers and 229 PSG referrals for analysis.

Analysis of the Results

Acquired referral data was evaluated with pre-implementation training attendance, use of SBQ, number of negative PSGs, and number of positive PSGs. This data was evaluated to determine statistical significance and correlation between (a) SBQ training and use of SBQ; (b) SBQ use and PSG referral accuracy; and (c) SBQ training and number of negative PSGs. Statistically significant results were discovered with the potential to impact future OSA screening and diagnosis.

SBQ Training and Use of SBQ.

Received training. 26 providers attended pre-implementation training for SBQ screening. Of the 26 providers who received training, 20 demonstrated an increased use of SBQ for OSA evaluation, while six providers did not increase SBQ usage. This training attendance demonstrated a 76.9% PPV (Table 5) for increased use of SBQ ($p<0.05$).

Did not receive training. Six providers were not available for SBQ training. Lack of SBQ training resulted in a zero percent (Table 5) increase in SBQ usage ($p<0.05$). This data demonstrated a reciprocal correlation between SBQ training and increased SBQ utilization. Specifically, those receiving SBQ training increased their utilization of the tool, while those not

receiving training did not use the SBQ.

Use of SBQ and Decrease in Negative PSG.

Increased use of SBQ was seen in 20 clinic providers. Of those, 19 had an increase in PSG referral accuracy. This represents a 95% PPV for increased PSG referral accuracy for providers increasing utilization of the SBQ ($p<0.05$). Additionally, there were 12 providers who did not increase use of the SBQ. This resulted in a NPV of 33.3% for negative PSGs referred by them ($p<0.05$). Complete data for this correlation is presented in Table 6.

SBQ Training and Number of Negative PSGs.

A final correlation was made between attendance at pre-implementation training and total number of negative PSGs. This revealed a 96.2% PPV for providers attending training to decrease the number of negative PSGs referred ($p<0.05$). Conversely, there was a NPV of 66.6% for providers not attending training to realize no decrease in negative PSGs ($p<0.05$). Further correlations using ROC curve and AUC, confirmed SBQ training is positively correlated with a decrease in negative PSGs (AUC=0.863). Complete data is available in Table 6 and Figure 2.

Analysis of Findings

The analysis of this project demonstrates the potential for increased PSG accuracy through the use of the SBQ. While SBQ is a widely accepted screening tool throughout the healthcare community, many providers report decreased knowledge and training regarding OSA screening (Lou et al., 2014b). The same barrier was identified via the pre-implementation surveys conducted during the education program. The majority of surveyed providers identified utilizing the ESS or no screening tool when determining need for PSG referral. This decision was largely determined due to amount of time available and ease of ESS use. This correlates

with the pre-implementation survey data that revealed a majority of providers identified lack of time, lack of training, and no CPG as barriers to using screening tools. Post-training data, however confirmed providers were likely to employ the SBQ after receiving information, training, and statistical evidence including sensitivity and specificity.

Finally, our study demonstrated a correlation between SBQ training and increased PSG referral accuracy. This finding is consistent with the employment of the Knowledge-to-Action framework procedural steps. Specifically, by identifying training needs, biases, and gaps in knowledge, training was specifically tailored to address the clinic's individual needs (Melnyk & Finout-Overholt, 2011). Implementing a specialized training program resulted in improved PSG referral accuracy for 96% of providers attending. Results of this project demonstrate potential impacts for providers, patients, and organizations.

Organizational Impact / Implications to Practice & Policy

Organizational Impacts

For facilities, the increased accuracy of PSG referral increases access to both Sleep Medicine providers and PSG testing (AASM, 2016b; Rankin et al., 2016). The effects of this increased resource efficiency is two-fold. First, by decreasing the number of unneeded PSGs, an estimated $2,105 per patient can be saved (AASM, 2016b). On a national level, even a modest projection of a 10% increase in referral accuracy would amount to $1.2 million in healthcare cost savings.

Additional cost savings will result from improved patient health outcomes. Specifically, increased access would lead to identifying undiagnosed OSA patients earlier. This can prevent or mitigate associated sequelae such as hypertension, diabetes, or mental health disorders resulting in a potential annual cost savings of $6336 per patient (AASM, 2016b). These improvements to

PSG referral accuracy have further associated impacts for patient health and well-being.

Patient Impacts

Increased PSG referral accuracy in the healthcare system impacts patients in a variety of ways. For high-risk patients, improved access to specialists and PSG reduces the average 2 to 3 month waiting period. This leads to a quicker diagnosis and treatment for affected patients. Early diagnosis and treatment are proven to prevent or mitigate comorbidities associated with OSA (Redline, 2017; Jonas et al., 2016; AASM, 2016b). This results in decreased costs for the patient, as well as improved physical and mental health (AASM, 2016b). Redline (2017) found early treatment also prevents interim appointments patients may seek for untreated OSA symptoms (e.g. fatigue, depression). Avoiding these appointments would result in an estimated annual cost savings of $4,231 per patient (AASM, 2016b). Patients with a low risk OSA score per the SBQ could experience similar benefits.

For patients found to have a low-risk of OSA on SBQ, providers may choose to focus on other differential diagnoses such as insomnia, poor sleep hygiene, and/or psychiatric or medical contributors (Morgenthaler, 2014). This can translate into quicker identification of their true diagnosis and decrease the personal time and associated costs with unnecessary PSG testing. The estimated cost savings for avoiding unnecessary PSG are $2,105 (AASM, 2016b, Rankin et al., 2016). Savings associated with avoiding loss of work wages for time spent in sleep center will vary (AASM, 2016b). Ultimately, increased referral accuracy results in decreased patient costs, improved health, and increased patient satisfaction. This improved accuracy can also have positive impacts for providers in the outpatient setting.

Provider Impacts

The SBQ provides positive impacts to providers by addressing barriers that previously

hampered the ability to provide OSA care. The most commonly identified barrier for OSA screening is time and manpower burden (AASM, 2016b). Using the SBQ providers in the outpatient setting can increase PSG referral accuracy without compromising time or manpower. Screening with the SBQ is easy to complete for both patients and staff with 91% of patients able to complete the survey autonomously (Lou et al., 2014a). This reduces the burden on manpower while increasing the identification of patients with undiagnosed OSA. This efficient identification of patients with probable untreated OSA ultimately leads to improved patient outcomes.

While the healthcare value of improving patient outcomes is important to providers, patient outcomes also have a monetary value. The Healthcare Effectiveness Data Information Set (HEDIS) is a tool utilized by the National Committee for Quality Assurance (NCQA) to determine reimbursements for healthcare costs. These measures include patient satisfaction, preventative care, and benchmarks for diseases such as hypertension and diabetes (NCQA, 2017). As previously discussed, early diagnosis and treatment of OSA can improve associated comorbidities such as those measured (Redline, 2017; Jonas et al., 2016; AASM, 2016b). Federal and state reimbursements through HEDIS measures have been estimated at up to $17 million per 100,000 members evaluated (BioIQ, 2015). These figures combined with the estimated 2.28 million (Namen et al., 2015) undiagnosed OSA patients seen annually in primary care amounts to potential reimbursements of $387 million. These profound impacts can also be realized within the military healthcare environment.

Military Specific Impacts

Improved utilization. Since fiscal year (FY) 2014, approximately 50% of all PSG referrals to WHASC Sleep Center are outsourced to the civilian network (Rankin et al., 2016).

This outsourcing is due to insufficient resources to assume the volume of PSG referrals in a timely manner (Rankin et al., 2016). While this is partially attributed to the limited number of military Sleep Centers available to beneficiaries (Sleep Disorders Center, 2015), it is further complicated by poor referral accuracy. In FY 2015, nearly 40% of PSG referrals from WHASC and RAFB primary care clinic were not found to have OSA (Rankin et al., 2016). This study demonstrated that use of the SBQ resulted in a 60% decrease in unnecessary referrals. For these facilities, the increased accuracy of PSG referral translates into improved utilization, patient satisfaction, as well as improved patient outcomes (AASM Adult OSA Task Force, 2009). While the benefit to sleep center utilization is apparent, further impacts for outpatient clinic also exist.

Increasing the ability to identify and treat undiagnosed OSA results in a decrease of clinic appointments for untreated OSA symptoms. This subsequent decrease in clinic appointments results in improved access for the empaneled provider. In a PCMH environment, increased access is directly correlated with improved patient satisfaction, improved health outcomes, and improved HEDIS measures (NCQA, 2017). Improvement in these elements and increased referral accuracy can have a significant impact on MTF cost-savings.

Cost savings. For WHASC and RAFB primary outpatient care, a decrease in unnecessary referrals results in improved cost savings through improved sleep center utilization. A decrease in outsourced PSGs reduces costs associated with civilian network costs. In the JBSA area PSG costs range from $750 to $2,500 with the civilian network typically charging toward the higher end of the spectrum (Rankin et al., 2016). This study demonstrated a 60% decrease in unnecessary PSG. This decrease applied to referral estimates from 2015 reflect a potential decrease in total PSGs, decrease in outsourced PSGs, and average cost savings of $3

million (Table 10). Additional cost savings within the military environment can be estimated when evaluating the effect of appropriate OSA screening related to overall mission impact.

Table 10
Actual and Potential Costs Associated with PSG Referrals

	WHASC Sleep Center Reported 2015 PSGs	Estimated 2016 with Project Findings	Cost Savings with SBQ
Total PSGs	7800	7800	-
Total PSGs Outsourced to Civilian Network	4175	2927	-
Costs of Outsourced PSGs (Civilian Network $2000/PSG)[a]	$8,350,000	$5,854,000	$2,496,000
Total PSGs without OSA Diagnosis	3120	1248	-
Costs of PSGs without OSA Diagnosis (CMS Reimbursement $1100/PSG)[b]	$3,432,000	$1,372,800	2,059,200
Costs of PSGs without OSA Diagnosis (Civilian Network $2000/PSG)[a]	$6,240,000	$2,496,000	$3,744,000

Note. WHASC = Wilford Hall Ambulatory Surgery Clinic; SBQ = STOP-BANG Questionnaire; PSG = Polysomnograph; JBSA = Joint Base San Antonio; CMS = Centers for Medicare and Medicaid Services
[a]Average for JBSA network estimates
[b]Based off CMS reimbursements

Mission Impact. From a military perspective PSG referral accuracy can have impacts on mission accomplishment. As previously mentioned, PSG diagnostic testing most commonly requires overnight stays at a sleep laboratory. For military members this can result in time lost from duties. Additionally, if the patient is found to have a normal PSG, additional time will be needed to determine an accurate diagnosis (Jonas, et al., 2016). This will require additional clinic visits, possible diagnostics, and potential referrals to other specialists (Redline, 2017). These situations can result in excessive absence from duties and subsequent impact to the service member's' mission (AASM, 2016b). For the military outpatient care population this is of significant concern as nearly 86% of patients in this study were active duty service members. The positive and negative impacts associated with this study suggest the opportunity for policy and practice improvements.

Potential Implications

Implications to policy and practice should focus on instituting measures to increase PSG referral accuracy. Acquired survey results demonstrated SBQ training established buy-in with clinic stakeholders (Figure 3). This is evidenced by a 150% increased use of SBQ by providers attending training. Further development and implementation of an education program to advocate SBQ use could increase knowledge and evidence of the tool. In this study, education proved to address common barriers identified by providers and ancillary staff. Through mitigation of barriers additional steps should be taken to establish a standard screening protocol for OSA.

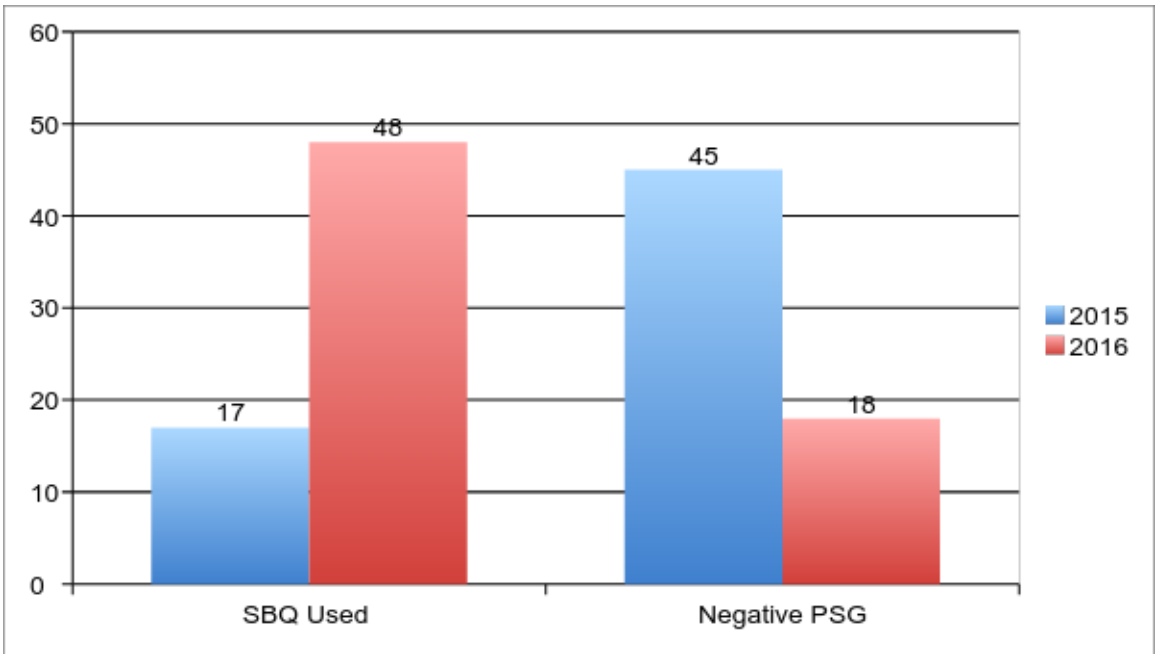

Figure 3. Results of SBQ Training on SBQ Use and Negative PSGs.

While the SBQ should not be seen as a replacement for clinical judgment, establishing a consistent OSA screening process within the outpatient care setting would likely result in sustained or improved PSG referral accuracy. Additionally, CPGs or standard protocols are recognized by numerous agencies including NCQA, CMS, and DOD Congressional Budget Office (CBO) as providing improved patient outcomes and decreasing healthcare costs. With

OSA emerging as a significant chronic illness, implementation of a standard screening protocol is needed.

Limitations

Some potential limitations in this project were identified. First, there was population bias, as all patients were military beneficiaries. Additionally, the majority of our population was active duty and may have been required to undergo PSG for different military requirements (e.g. retirement, medical evaluation board). Military population nuances combined with a small sample of 229 referrals may hinder the ability to generalize these findings to the general population. This is further complicated by location bias.

This project was conducted utilizing only two outpatient clinics. Both clinics were primary care clinics located at Air Force MTFs. These findings may prove difficult to apply to a non-military facility or different outpatient care specialty. Additional limitations were identified in retrieval of post-implementation data.

With current wait times for PSG, some referrals remained uncompleted at the end of the study. Additional results were unable to be retrieved due to difficulty in acquiring civilian results. This made the comparison between civilian PSG findings and military PSG findings difficult to determine. With available information however, there are identifiable opportunities for future research and practice.

Future Directions for Research and Practice

This project demonstrated the utility and potential positive health and economic impacts with using the SBQ. Results from this small project should be validated and extended with continued research on OSA screening. Future attention can be directed at varying specialties, different populations, or other available screening tools.

Future studies evaluating varying specialties should focus on extended evaluation of the SBQ within other outpatient care areas. Since our project focused on implementing the SBQ in a primary care setting, future studies could evaluate the results seen in internal medicine clinics, women's health clinics, and pediatrics for example. Evaluation in these other clinics may also provide a gateway to evaluating OSA screening in different populations.

Since the primary care population in the MTF is largely segregated from both pediatric and geriatric patients, our project did not collect data on any extremes. Some investigation should be aimed at the ability to reproduce SBQ findings within these populations. This could lead to important findings, as OSA diagnosis and screening has different nuances when evaluating those at age extremes, as well as those with significant comorbidities (AASM, 2016b). Through these various populations, studies might investigate augmentation of the SBQ or utilization of different OSA screening questionnaires.

Additional focus on the SBQ itself may prove to further increase the sensitivity or specificity of the tool. Specifically, some studies evaluated in our systematic review discussed employment of additional factors to augment the SBQ (Lou et al., 2014a). In one study, some improvements to the SBQ specificity were recorded (Lou et al., 2014a). These augmented tools could be compared to the SBQ, or compared to other validated OSA screening tools. Comparative studies would assure stakeholders are gaining the full benefits of improved OSA screening.

Conclusion

There are 29.4 million people affected by obstructive sleep apnea (OSA) in the United States (AASM, 2016b). Among active duty military members the incidence of OSA is estimated to be 20% higher (Wood, 2013). This disorder is classified as a chronic illness and is directly

associated with a multitude of serious health sequelae. The risks for developing these sequelae increase if OSA is not diagnosed and treated (Badran et al., 2012). The AASM estimates 23.5 million people with OSA are undiagnosed, resulting in $149.6 billion dollars in associated annual healthcare costs (AASM, 2016b).

This project used a systematic review of available literature to identify an evidence-based screening tool for identifying patients at risk for OSA. The SBQ was identified as a superior screening tool, recognized as easy to employ, and developed with solid methodology (Lou, 2014). Using the SBQ in primary care clinics at WHASC and RAFB demonstrated a decrease in unnecessary PSG referrals by 60%. This efficient use of PSG resources can decrease costs associated with outsourced care, decrease prolonged wait times, and improve the diagnosis and early treatment for those with OSA (Chung et al., 2016). Employment of this evidence-based practice in primary care resulted in $405,000 annual cost savings. If applied to all PSG referrals, cost savings could approach $2 to $3 million annually. The impact of applying an evidence-based OSA screening tool is evident. Both a reduction in cost and improved overall health can be realized if the SBQ is employed as a first line screening tool for OSA in the outpatient arena.

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Appendix A

Citi Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

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- **Curriculum Group:** CITI Good Clinical Practice
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 14949419
- **Completion Date:** 02/20/2015
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID:1350)	01/20/15
Overview of New Drug Development (ID:1351)	01/20/15
Overview of ICH GCP (ID:1352)	01/20/15
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID:1354)	01/26/15
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID:1355)	01/26/15
Investigator Obligations in FDA-Regulated Research (ID:1356)	01/26/15
Managing Investigational Agents According to GCP Requirements (ID:1357)	02/06/15
Overview of U.S. FDA Regulations for Medical Devices (ID:1358)	02/06/15
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID:1359)	02/06/15
Detecting and Evaluating Adverse Events (ID:1360)	02/06/15
Reporting Serious Adverse Events (ID:1361)	02/06/15
Audits and Inspections of Clinical Trials (ID:1363)	02/20/15
Monitoring of Clinical Trials by Industry Sponsors (ID:1362)	02/20/15
Completing the CITI GCP Course (ID:1364)	02/20/15

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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Appendix A

Citi Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

OUSD P&R HUMAN RESEARCH (CURRENT) CURRICULUM COMPLETION REPORT

Printed on 08/25/2014

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BIOMEDICAL INVESTIGATORS AND KEY STUDY PERSONNEL

COURSE/STAGE:	Stage 1/1
PASSED ON:	08/25/2014
REFERENCE ID:	13755088

REQUIRED MODULES	**DATE COMPLETED**
Belmont Report and CITI Course Introduction	08/24/14
History and Ethics of Human Subjects Research	08/25/14
Basic Institutional Review Board (IRB) Regulations and Review Process	08/25/14
Informed Consent	08/25/14
Social and Behavioral Research (SBR) for Biomedical Researchers	08/25/14
Genetic Research in Human Populations	08/25/14
Research With Protected Populations - Vulnerable Subjects: An Overview	08/25/14
Research and HIPAA Privacy Protections	08/25/14
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	08/25/14
Conflicts of Interest in Research Involving Human Subjects	08/25/14
Avoiding Group Harms - U.S. Research Perspectives	08/25/14
Office of the Under Secretary of Defense (Personnel and Readiness)	08/25/14
ELECTIVE MODULES	**DATE COMPLETED**
Stem Cell Research Oversight (Part II)	08/25/14

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Citi Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

OUSD P&R HUMAN RESEARCH (CURRENT) CURRICULUM COMPLETION REPORT

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REFERENCE ID:	13743289

REQUIRED MODULES	**DATE COMPLETED**
Belmont Report and CITI Course Introduction	08/20/14
History and Ethics of Human Subjects Research	08/20/14
Basic Institutional Review Board (IRB) Regulations and Review Process	08/20/14
Informed Consent	08/20/14
Social and Behavioral Research (SBR) for Biomedical Researchers	08/20/14
Genetic Research in Human Populations	08/20/14
Research With Protected Populations - Vulnerable Subjects: An Overview	08/21/14
Research and HIPAA Privacy Protections	08/21/14
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	08/21/14
Conflicts of Interest in Research Involving Human Subjects	08/21/14
Avoiding Group Harms - U.S. Research Perspectives	08/21/14
Office of the Under Secretary of Defense (Personnel and Readiness)	08/21/14
ELECTIVE MODULES	**DATE COMPLETED**
Hot Topics	08/21/14

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Citi Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

OUSD P&R HUMAN RESEARCH (CURRENT) CURRICULUM COMPLETION REPORT

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COURSE/STAGE:	Stage 1/1
PASSED ON:	08/22/2014
REFERENCE ID:	13768464

REQUIRED MODULES	**DATE COMPLETED**
Belmont Report and CITI Course Introduction	08/22/14
History and Ethics of Human Subjects Research	08/22/14
Basic Institutional Review Board (IRB) Regulations and Review Process	08/22/14
Informed Consent	08/22/14
Social and Behavioral Research (SBR) for Biomedical Researchers	08/22/14
Genetic Research in Human Populations	08/22/14
Research With Protected Populations - Vulnerable Subjects: An Overview	08/22/14
Research and HIPAA Privacy Protections	08/22/14
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	08/22/14
Conflicts of Interest in Research Involving Human Subjects	08/22/14
Avoiding Group Harms - U.S. Research Perspectives	08/22/14
Office of the Under Secretary of Defense (Personnel and Readiness)	08/22/14
ELECTIVE MODULES	**DATE COMPLETED**
Vulnerable Subjects - Research Involving Prisoners	08/22/14

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Appendix A

Citi Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

OUSD P&R HUMAN RESEARCH (CURRENT) CURRICULUM COMPLETION REPORT

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COURSE/STAGE:	Stage 1/1
PASSED ON:	08/18/2014
REFERENCE ID:	13728083

REQUIRED MODULES	**DATE COMPLETED**
Belmont Report and CITI Course Introduction	08/18/14
History and Ethics of Human Subjects Research	08/18/14
Basic Institutional Review Board (IRB) Regulations and Review Process	08/18/14
Informed Consent	08/18/14
Social and Behavioral Research (SBR) for Biomedical Researchers	08/18/14
Genetic Research in Human Populations	08/18/14
Research With Protected Populations - Vulnerable Subjects: An Overview	08/18/14
Research and HIPAA Privacy Protections	08/18/14
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	08/18/14
Conflicts of Interest in Research Involving Human Subjects	08/18/14
Avoiding Group Harms - U.S. Research Perspectives	08/18/14
Office of the Under Secretary of Defense (Personnel and Readiness)	08/18/14
ELECTIVE MODULES	**DATE COMPLETED**
The Regulations - SBE	08/18/14

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Appendix B

Form 3202N

Joint Base San Antonio + Keesler #2

USUHS FORM 3202N
DANIEL K. INOUYE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: T0614041 (VPR will assign)
Project Title: Obstructive Sleep Apnea Screening Tools

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): **Turner, Alyssa** Student E-mail: **Alyssa.turner@usuhs.edu**
2. Home Address: **6521 Greentree Rd. Bethesda, MD 20817** Cell Number: **719-351-9509**

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): **Dillon, Douglas**
4. Telephone: **301-295-0742** Fax: E-mail: **douglas.dillon@usuhs.edu**
5. USUHS Building/ Room No.: **E/1029**

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐ Yes ☒ No
   If yes, complete below; if no, proceed to Part 8.
   Project Number:
   Project Title:
   Project Start Date: Project End Date:
8. Anticipated period of performance: Project Start Date: **June 2016** Project End Date: **March 2017**
9. Performance Site(s): **Wilford Hall Medical Center, San Antonio TX**
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No
11. Do you have a funding source for this project? ☐ Yes ☐ No ☒ NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

The following signatures attest to the validity of the above information:

CAPT ALYSSA TURNER (Student (Project Point of Contact for the Group))	9Dec15 (Signature and Date)	(Chair/Senior Mentor)	9 Dec 15 (Signature and Date)
(Chair/Program Director)	3/2/16 (Signature and Date)	(Chair/Program Director)	(Signature and Date)
(DNP Project Director or PhD Director)	12 Feb 2016 (Signature and Date)	(Associate Dean for Academic Affairs, GSN)	3-9-16 (Signature and Date)
(Associate Dean for Research, GSN)	14 Mar 2016 (Signature and Date)	(Dean, DKI Graduate School of Nursing)	3-16-16 (Signature and Date)

In light of the above signatures, the project is approved.

for (USUHS Vice President for Research) April 7, 2016 (Date)

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

Appendix C

IRB Approval Letter

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

14 Sep 2016

FINAL IRB APPROVAL (EXPEDITED - MINIMAL RISK)

IRB Approval Date: 14 Sep 2016

Principal Investigator: LTC Brian Kittelson/SGVT

59 MDW IRB Reference Number: FWH20160100H

Assurance Number: DoD Assurance: F50007, Expires: 9/8/2016

Protocol Title: "Investigating and Optimizing Obstructive Sleep Apnea (OSA) Screening in the Air Force Primary Care Setting"

1. Your Expedited Approval of a New Human Research Protocol (Initial Review) was **approved** by the 59th MDW IRB Chair or designee on **14 Sep 16**. Expedited approvals are available for review by the other board members as appropriate at a subsequent IRB meeting. Documents Reviewed:

- Form A – Signature Sheet
- Form A-2 – Study Personnel List
- Clinical Data Protocol
- Form F – Waiver or Alteration of Consent
- Form J – HIPAA Waiver
- OSA Screening Data Collection
- PI CV
- CITI (Kittelson, Little, McElroy, Smith, Turner)

A waiver of the requirement to obtain a valid authorization to access, use and disclose PHI was approved by an Expedited review procedure. It was determined that the following criteria as required by 45 CFR 164.512 (i) were satisfied:

- ∀ The PHI use or disclosure involves no more than minimal risk to the privacy of individuals base on at least the presence of (1) an adequate plan presented to the Privacy Board to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- ∀ The research could not practicably be conducted without the requested waiver or alteration.
- ∀ The research could not practicably be conducted without access to and use of the PHI.

The waiver permits the investigators to access potential subjects' health records for purposes of determining eligibility and recruitment as specified in the reviewed HIPAA Waiver Request form. The waiver permits the investigators to access the subjects' health records for purposes of collecting research data, as specified in reviewed HIPAA Waiver Request form.

32 CRF 219.110(b)(1) Category 5: Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Appendix C

IRB Approval Letter

2. Your study will be reviewed in about **11 months for continuing review, based on its IRB approval date, not to exceed 1 year**. It is the 59th MDW IRB's decision that this study will expire as of **9/14/2017**, unless you submit a continuing review report, using the most current template provided by the Protocol Office located on Knowledge Exchange. If your study is not re-approved, **9/14/2017** is the first day you may not perform any research activity. Your first progress report, which is a request for continuation of the study, will be due to the Protocol Office no later than **7/11/2017.** An annual continuing review report will be due every year thereafter in order for the 59th MDW IRB to approve continuance of the study. Your expiration date will continue to be the 14 Sep anniversary date so long as the IRB approves your study within 30 days of each expiration. Upon completion of your study you must submit a final closeout report to the 59th MDW Protocol Office using the most current template.

3. It is the PI's responsibility to keep and maintain a New Study Binder. You will be sent an email with the study binder table of contents, Info Sheet, Belmont Report, the final IRB study approval letter, original date-stamped ICD, and any other IRB-approved documents needed for the study binder.

4. Only investigators listed below are approved to participate in the study (e.g., obtain consent and to interact with and/or collect identifiable information on research subjects as delegated in Form A-2):

- Lt Col Brian Kittelson, PI
- Maj Cherie Little, AI
- Capt Kenneth Smith, AI
- Capt Angela McElroy, AI
- Capt Alyssa Turner, AI

These are the only investigators identified by the 59th MDW IRB to have completed "IRB approved" investigator training. Any additions to this list must first be approved by the IRB by submitting an amendment, along with a revised Form A-2, Study Personnel List and copy of the investigator's training certificate.

5. Your **MINIMAL RISK** will be forwarded to the Surgeon General's Research Compliance and Oversight Office (SGE-C) for information and concurrence.

6. The 59th MDW IRB must be notified immediately of any additional information, or changes to the approved protocol. All modifications to approved research activities (e.g., the protocol, the ICD) must be reviewed and approved by the 59th MDW IRB prior to their inception.

7. You must comply with the information contained in the Form A Signature Sheet (Principal Investigator's Agreement section).

8. If funds were requested for your study, you will be notified by the 59th Clinical Research Division Resource Manager (292-7295) concerning the status of the requested funds. **YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.**

9. Send all questions regarding your new study to 59crd.protocol@us.af.mil. Please include your project title and reference number in all correspondence or inquiries.

Rocky D. Calcote, PhD
Clinical Research Administrator

Appendix D

PAO Clearance /Level of Dissemination Classification

DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

18 APR 2017

MEMORANDUM FOR SGVT
ATTN: MAJ CHERIE LITTLE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Use of STOP-Bang Questionnaire in Outpatient Setting: Increasing Both Identification of Obstructive Sleep Apnea Patients and Polysomnography Referral Accuracy** presented at/published to **Uniformed Services University of Health Sciences Research Day (Abstract), Research Day Events (Poster), & USU Archives (Final Report)/Colloqium, Bethesda, MD, 16-18 May 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17184.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

Warrior Medics — Mission Ready — Patient Focused

Appendix E

STOP-BANG Questionnaire

Name _____
Height _____ Weight _____
Age _____ Male / Female _____

STOP BANG QUESTIONNAIRE

Do you **snore loudly** (loud enough to be heard through closed doors or your bed-partner elbows you for snoring at night)?	Yes	No
Do you often feel **tired, fatigued, or sleepy** during the daytime (such as falling asleep during driving or talking to someone)?	Yes	No
Has anyone **observed** you **stop breathing** or choking/gasping during your sleep?	Yes	No
Do you have or are being treated for **high blood pressure?**	Yes	No
BMI > 35kg/m^2?	Yes	No
Age older than 50?	Yes	No
Neck size --For males, shirt collar 17 inches/43cm or larger? --For females, shirt collar 16 inches/41cm or larger?	Yes	No
Male Gender	Yes	No

Patient Score: _____

Low risk of OSA: Yes 0 - 2

Intermediate risk of OSA: Yes 3 – 4

High risk of OSA: Yes 5 – 8

Adapted from:
STOP Questionnaire
A Tool to Screen Patients for Obstructive Sleep Apnea. Chung F et al. Anesthesiology 2008; 108: 812-821, Chung F et al Br J Anaesth 2012; 108: 768-775, Chung F et al J Clin Sleep Med Sept 2014.

Appendix E

Training Pre-Survey

Pre-survey

Investigating and Optimizing Obstructive Sleep Apnea Screening in the Air Force Primary Care Setting.

1. What is your occupation?
   a. Provider
   b. Nurse
   c. Technician
   d. Other
2. Approximately how many patients do you encounter per week with signs or symptoms of obstructive sleep apnea (OSA)?
   a. <5
   b. 5-10
   c. 10-15
   d. 15-20
   e. >20
3. Screening for OSA in Primary Care is important to me as a healthcare professional
   a. True
   b. False
4. How consistently do you screen patients with OSA symptoms using a screening tool? Examples of commonly used screening tools include: STOP-Bang, Berlin, Epworth Sleepiness Scale (ESS), etc...).
   a. Rarely (0-25%)
   b. Sometimes (25-50%)
   c. Most of the time (50-75%)
   d. All of the time (100%)
5. What OSA screening tool do you currently use, and why? (validity, ease of use, etc.)

_____

6. What barriers, if any, do you have to using a screening tool?

_____

_____

7. What recommendations do you have that would increase the screening of patients with OSA risk factors or symptoms?

_____

_____

Appendix E

Training Post-Survey

Post-survey

Investigating and Optimizing Obstructive Sleep Apnea Screening in the Air Force Primary Care Setting.

1. What is your occupation?
   a. Provider
   b. Nurse
   c. Technician
   d. Other

2. Was this presentation valuable to your practice?
   a. Yes
   b. No

3. Did the presentation provide enough information on the STOP-Bang screening questionnaire?
   a. Yes
   b. No
   c. Somewhat

4. Are you now more likely to utilize the STOP-Bang screening questionnaire for a patient with OSA signs/symptoms or risk factors?
   a. Yes
   b. No
   c. Somewhat

5. How likely are you to recommend STOP-Bang screening questionnaire use to someone for whom it would be suitable?
   a. Very likely
   b. Somewhat likely
   c. Neither likely nor unlikely
   d. Somewhat unlikely
   e. Very unlikely

6. What component of the training was most effective and why?

_____

_____

7. What changes in the training would have made it more effective?

_____

_____

Appendix E

John Hopkins Evidence Appraisal Form

Johns Hopkins Nursing Evidence-Based Practice
Appendix E: Research Evidence Appraisal Tool

Evidence Level and Quality:_____

Article Title:	Number:
Author(s):	Publication Date:
Journal:	
Setting:	Sample (Composition & size):
Does this evidence address my EBP question?	☐Yes ☐No Do not proceed with appraisal of this evidence

Level of Evidence (Study Design)

A. Is this a report of a single research study? ***If No, go to B.***	☐Yes	☐No
1. Was there manipulation of an independent variable?	☐Yes	☐No
2. Was there a control group?	☐Yes	☐No
3. Were study participants randomly assigned to the intervention and control groups?	☐Yes	☐No
If Yes to all three, this is a Randomized Controlled Trial (RCT) or Experimental Study → ☐ LEVEL I		
If Yes to #1 and #2 and No to #3, OR Yes to #1 and No to #2 and #3, this is Quasi Experimental (some degree of investigator control, some manipulation of an independent variable, lacks random assignment to groups, may have a control group) → ☐ LEVEL II		
If No to #1, #2, and #3, this is Non-Experimental (no manipulation of independent variable, can be descriptive, comparative, or correlational, often uses secondary data) **or Qualitative** (exploratory in nature such as interviews or focus groups, a starting point for studies for which little research currently exists, has small sample sizes, may use results to design empirical studies) → ☐ LEVEL III		
NEXT, COMPLETE THE BOTTOM SECTION ON THE FOLLOWING PAGE, "STUDY FINDINGS THAT HELP YOU ANSWER THE EBP QUESTION"		

Appendix E

John Hopkins Evidence Appraisal Form

Johns Hopkins Nursing Evidence-Based Practice
Appendix E: Research Evidence Appraisal Tool

B. Is this a summary of multiple research studies? ***If No, go to Non-Research Evidence Appraisal Form.*** ☐Yes ☐No

1. Does it employ a comprehensive search strategy and rigorous appraisal method **(Systematic Review)?** ***If No, use Non-Research Evidence Appraisal Tool; if Yes:*** ☐Yes ☐No

   a. Does it combine and analyze results from the studies to generate a new statistic (effect size)? **(Systematic review with meta-analysis)** ☐Yes ☐No
   b. Does it analyze and synthesize concepts from qualitative studies? **(Systematic review with meta-synthesis)** ☐Yes ☐No

   If Yes to either a or b, go to #2B below.

2. For Systematic Reviews and Systematic Reviews with meta-analysis or meta-synthesis:
   a. Are all studies included RCTs? → ☐ LEVEL I
   b. Are the studies a combination of RCTs and quasi-experimental or quasi-experimental only? → ☐ LEVEL II
   c. Are the studies a combination of RCTs, quasi-experimental and non-experimental or non-experimental only? → ☐ LEVEL III
   d. Are any or all of the included studies qualitative? → ☐ LEVEL III

COMPLETE THE NEXT SECTION, "STUDY FINDINGS THAT HELP YOU ANSWER THE EBP QUESTION"
STUDY FINDINGS THAT HELP YOU ANSWER THE EBP QUESTION:

NOW COMPLETE THE FOLLOWING PAGE, "QUALITY APPRAISAL OF RESEARCH STUDIES", AND ASSIGN A QUALITY SCORE TO YOUR ARTICLE

Appendix E

John Hopkins Evidence Appraisal Form

Johns Hopkins Nursing Evidence-Based Practice
Appendix E: Research Evidence Appraisal Tool

Quality Appraisal of Research Studies			
• Does the researcher identify what is known and not known about the problem and how the study will address any gaps in knowledge?	☐Yes	☐No	
• Was the purpose of the study clearly presented?	☐Yes	☐No	
• Was the literature review current (most sources within last 5 years or classic)?	☐Yes	☐No	
• Was sample size sufficient based on study design and rationale?	☐Yes	☐No	
• If there is a control group:			
○ Were the characteristics and/or demographics similar in both the control and intervention groups?	☐Yes	☐No	☐NA
○ If multiple settings were used, were the settings similar?	☐Yes	☐No	☐NA
○ Were all groups equally treated except for the intervention group(s)?	☐Yes	☐No	☐NA
• Are data collection methods described clearly?	☐Yes	☐No	
• Were the instruments reliable (Cronbach's α [alpha] ≥ 0.70)?	☐Yes	☐No	☐NA
• Was instrument validity discussed?	☐Yes	☐No	☐NA
• If surveys/questionnaires were used, was the response rate ≥ 25%?	☐Yes	☐No	☐NA
• Were the results presented clearly?	☐Yes	☐No	
• If tables were presented, was the narrative consistent with the table content?	☐Yes	☐No	☐NA
• Were study limitations identified and addressed?	☐Yes	☐No	
• Were conclusions based on results?	☐Yes	☐No	

Quality Appraisal of Systematic Review with or without Meta-Analysis or Meta-Synthesis		
• Was the purpose of the systematic review clearly stated?	☐Yes	☐No
• Were reports comprehensive, with reproducible search strategy?	☐Yes	☐No
○ Key search terms stated	☐Yes	☐No
○ Multiple databases searched and identified	☐Yes	☐No
○ Inclusion and exclusion criteria stated	☐Yes	☐No
• Was there a flow diagram showing the number of studies eliminated at each level of review?	☐Yes	☐No
• Were details of included studies presented (design, sample, methods, results, outcomes, strengths and limitations)?	☐Yes	☐No
• Were methods for appraising the strength of evidence (level and quality) described?	☐Yes	☐No
• Were conclusions based on results?	☐Yes	☐No
○ Results were interpreted	☐Yes	☐No
○ Conclusions flowed logically from the interpretation and systematic review question	☐Yes	☐No
• Did the systematic review include both a section addressing limitations and how they were addressed?	☐Yes	☐No

QUALITY RATING BASED ON QUALITY APPRAISAL

A **High quality:** consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence

B **Good quality:** reasonably consistent results; sufficient sample size for the study design; some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

C **Low quality or major flaws:** little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn

Appendix F

DNP Project Completion Verification Form

Appendix J: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Use of STOP-BANG Screening Questionnaire in Outpatient Setting: Increasing Both Identification of Obstructive Sleep Apnea Patients and Polysomnography Referral Accuracy was completed at Joint Base San Antonio Lackland Air Force Base by the following student(s):

Cherie Little	_____	29Mar17
Angela McElroy	_____	29Mar17
Kenneth Smith	_____	29Mar17
Alyssa Turner	_____	29Mar17

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix I*), and
- DNP Project written report.

Verified by:

LtCol Douglas Dillon	_____	30 Mar 17	Senior Mentor
LtCol Brian Kittelson	_____ *(signature)*	29 Mar 2017 *(date)*	Team Mentor & Phase II Site Director

Form Version: 4 Sept 2016

Table 1

Literature Search Terms Used, MeSH Terms Used, Search Limitations, and Exclusion Criterion

Literature Search Limits		
Search Terms	Apnea Predictive Efficient	Obstructive Sleep Apnea Referral Diagnostic
MeSH Terms	Apnea, Obstructive Sleep Apnea, Sleep Apneas, Obstructive Sleep Obstructive Sleep Apnea Obstructive Sleep Apnea Syndrome	Questionnaire Screening Assess Primary Care Family Health
Search Limits	2006-2016 English Language Peer Reviewed	Research Article Age ≥ 18 years Human Subjects
Exclusion Criterion		
● Article designed for treatment of OSA ● Not Obstructive sleep apnea (central sleep apnea) ● Pediatric patients ● Pregnant patients ● Wrong publication type ● Other sleep comorbidities besides OSA ● Hospitalized patients ● Use of alternate diagnostic test (not gold standard PSG) ● Aimed at patient with significant preexisting comorbidities		

Table 2

Level and Grade of Evidence for Studies Identified in Systematic Review of Literature

John Hopkins University Level and Grade of Evidence			
Grade of Recommendation	**Level of Evidence**	**Interventions**	**Total**
A	1a	Systematic Review of Randomized Control Trials	2
	1b	Individual Randomized Control Trial	0
B	2a	Systematic Review of Cohort Study	2
	2b	Individual Cohort Study	0
	3a	Systematic Review of Case-Control Studies	6
	3b	Individual Case Control Study	1
C	4	Case Series	0
D	5	Expert Opinion without explicit critical appraisal or based on physiology or bench research	0

Table 3

Evaluation of Studies Identified in Systematic Review of Evidence

Citation	Purpose of Article	Type	Sample	Variables	Quality/Relevance Rating
Abrashami et al., 2010	The objective of this systematic review is to identify and evaluate the available questionnaires for screening OSA.	Meta-Analysis/Systematic Review	10 RCTs 1484 Patients	IV=OSA Screening Tools DV=Ability to predict OSA	Level I; A
Chung et al., 2014	The objective of this study was to explore the predictive performance of the different combinations of items from "Bang" with the STOP component..	Quasi-experimental	516 Patients	IV=STOP-BANG DV=Ability to predict OSA	Level II; B
Encisco & Clark, 2011	To compare the sensitivity and specificity of two questionnaires to identify patients with obstructive sleep apnea (OSA).	1 Prospective Case Control Study	85 patients	IV=Berlin;ARES Screening Tool DV=Ability to predict OSA	Level III; B
Farney et al., 2011	Explore the possibility of using the STOP-Bang model (SBM) to classify severity of OSA into 4 categories ranging from none to severe.	Retrospective Cohort Study	1426 patients	IV=STOP-BANG DV=Ability to classify OSA severity	Level III; B
Friedman et al., 2010	To determine the sensitivity and specificity of the Berlin Questionnaire.	Cross Sectional Study	223 Patients	IV=Berlin DV=Ability to predict OSA	Level II; B
Karakoc et al., 2014	To investigate the value of the Berlin Questionnaire (BQ) for screening at-risk patients for obstructive sleep apnea (OSA).	Retrospective	217 patients	IV=Berlin; ESS DV=Ability to predict OSA	Level III; B

Table 3 Continued

Citation	Purpose of Article	Type	Sample	Variables	Quality/Relevance Rating
Lou et al., 2014	This study aimed to evaluate the value of the STOP-Bang questionnaire (SBQ) in screening OSAHS in sleep-disordered breathing clinic by comparing it with the Epworth sleepiness scales (ESS), Berlin questionnaire, and STOP questionnaire.	Prospective Study	212 Patients	IV=STOP-BANG, Berlin, ESS, STOPDV=Ability to predict OSA	Level III; B
Lou et al., 2014	To evaluate the value of the STOP-Bang questionnaire (SBQ) in screening OSA.	Prospective Study	212 patients	IV= STOP-BANG DV=Ability to predict OSA	Level III; B
Ramachandran & Josephs, 2009	Compare clinical screening tests for osa and establish an evidence base for use.	Meta-Analysis	26 RCTs 6794 patients	IV=OSA Screening Tool DV=Ability to predict OSA	Level I ; A
Subramanian et al., 2011	To develop a novel screening tool for identification of patients with OSA.	Retrospective Study	579 patients	IV=NAMES screening tool DV=Ability to predict OSA	Level III; B
Vana et al., 2013	This study compared the predictive abilities of the STOP-Bang and Epworth Sleepiness Scale (ESS) for screening for OSA.	Cross Sectional Study	60 patients	IV=STOP-BANG;ESS DV=Ability to predict OSA	Level III; B

Project Year 1 (2015)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Project Planning	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	
Project Data Collection	**X**	**X**	**X**									
Evidence Review	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**				
USUHS DNP Proposal Approval									**X**	**X**	**X**	
Site IRB Submission and Approval												**X**
USUHS VPR Submission and Approval												

Project Year 1 (2016)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
USUHS VPR Submission and Approval	**X**	**X**										
Site IRB Submission and Approval			**X**	**X**								
Introduction Meeting w/Stakeholders					**X**	**X**						
Chart Reviews					**X**	**X**						
Evidence Meeting w/Stakeholders							**X**					
Collaboration Meeting with Clinic Staff							**X**					
Protocol Design							**X**	**X**				
Clinic (Team) Training for Protocol								**X**				
Implementation of Protocol to Select Teams								**X**	**X**			
Post-Implementation Meeting with Clinic									**X**	**X**		
Post-implementation Chart Review										**X**	**X**	**X**

Timeline

Timeline

Project Year 2 (2017)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Post-implementation Chart Reviews	**X**	**X**	**X**									
Data Compilation/Comparison Pre&Post			**X**	**X**								
Post-Implementation Meeting with Stakeholders				**X**								
Meeting with Future DNP Team			**X**	**X**								
USUHS Presentation					**X**							
Final Meeting with new DNP Team					**X**							