SLEEP APNEA IN WOMEN AGED 50 YEARS AND OLDER. A CROSS SECTIONAL QUANTITATIVE SURVEY IN A RURAL CLINIC IN SOUTHERN ARIZONA

by

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Proverbs 3:5-6. Trust in the LORD with all your heart, and do not lean on your own understanding. In all ways acknowledge him and he will make your path straight.

DEDICATION

This project is dedicated to my lovely wife Alyssa, son Daniel and daughter Eliana. Your love is what brings the most joy in my life. You guys are my motivation, my world, my everything. I love you from the bottom of my heart.

This project is dedicated to my mother. The woman who worked tirelessly to ensure that as a child I always had a roof over my head, clothes to wear and food to eat. The woman that taught me compassion, faith and always demonstrated never ending support and encouragement. Thanks for always reminding me that through Christ all things are possible. I love you mom.

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ABSTRACT

Background

Sleep apnea is a common health disorder that is strongly associated with many serious comorbidities. At Patel Medical Clinic located in rural southwestern Arizona, the clinic director acknowledged the need to identify individuals that may have this condition but may go undetected. Presentation of symptoms in women can be misleading for diagnosis and conceals the need for further workup. Although men are more commonly recognized for having this condition, women of 50 years of age and older are vulnerable as the risk for sleep apnea increases significantly after menopause. In this study, women 50 years of age and older were asked to volunteer to determine sleep apnea risk and to identify barriers to diagnosis.

Methods

The purpose of this quality improvement project was to evaluate the use of a validated screening tool in identifying women 50 years of age and older in a rural southwestern internal medicine practice who are at moderate to high-risk of sleep apnea using a cross-sectional quantitative survey design. The study took place at Patel Medical Clinic, a private medical establishment located in rural Arizona. All clinic patients who are female and 50 years of age and older and patients of this clinic during data collection times were able to participate in the study, regardless of sleep apnea status.

Results

Most participants were of the 60-69 and 70-79 age groups. Study subjects consisted of 54 women. Of these, (37) 68.5% of participants scored at moderate or high-risk of sleep apnea. A total of (27) 50% participants scored as “moderate-risk,” (10) 18.5% scored as high-risk. Of the

54 participants, (13) 24% had a previous diagnosis of sleep apnea. Of those 13 with an established diagnosis, (7) 53% scored in the moderate-risk category, and (5) 38 % scored in the high-risk category. Out of those that were referred for sleep study but unable to participate, various barriers were identified that were unique to each individual participant.

Discussion/Recommendations

Symptoms of sleep apnea are vastly present among participants. Many participants that scored as having moderate to high-risk have not been referred for sleep study. A screening tool could potentially reduce the number of moderate-to-high-risk patients from going unrecognized. Additional long-term studies are necessary to further examine barriers for diagnostic testing and how to better ensure that these tests are completed. Women with sleep apnea often present with gender-specific symptoms and could greatly benefit from a female-focused questionnaire.

INTRODUCTION

The occurrence of sleep apnea continues to increase as does the obesity epidemic (National Healthy Sleep Awareness Project, 2014). Approximately 10% of the general population experience signs and symptoms of sleep apnea. More than 35% of men and just under 20% of all women suffer from some form or degree of sleep apnea; more than 90% of women with moderate to severe risk are not diagnosed (Floras, 2014; Redline, 2017). While sleep apnea is generally less common in women than it is in men, a woman's chances of developing this condition increase threefold once she reaches menopause (Strohl et al, 2017). This becomes a cause for concern in the primary care setting as studies indicate that many of these women are underdiagnosed in comparison to men (Wimms, Woehrle, Ketheeswaran, Ramanan & Armitstead, 2016). Women do not typically present with classic symptoms of sleep apnea; many of these cases go undetected and therefore, untreated. It is believed that more than 90% of women with moderate to severe symptoms have not been properly diagnosed. Women over the age of 50 are most vulnerable to this condition as their physiological and hormonal changes experienced post menopause significantly increase the severity of risk for sleep apnea.

The purpose of this quality improvement project is to evaluate the use of the STOP-BANG screening tool to determine the prevalence of women at moderate to severe risk of sleep apnea in a rural internal medical clinic in southern Arizona. This validated assessment tool provides the means to recognize those at risk and identify barriers present in diagnosis.

Background

Prevalence

Prevalence increases with age. The prevalence of sleep apnea in the elderly population is as high as 78% and as many as 49% of these cases are deemed moderate to severe in degree (Kapur et al., 2017). Community-based studies reported in the Journal of the American Medical Association (JAMA) indicate that sleep apnea is highly prevalent and underdiagnosed across specific population groups, particularly in women and minorities. Weight and age play a significant contribution to this problem. As obesity rates continue to grow, so too does the rate of sleep apnea. Among overweight women specifically, the prevalence is approximately five-fold higher in the elderly population as opposed to younger women (Kapur et al., 2017).

The occurrence of sleep apnea varies as specific disease populations have been found to have increased rates of sleep apnea. It is estimated that among diabetics, 75% have at least mild symptoms while 50% suffer symptoms from moderate to severe in degree (Bailes et al., 2017).

Sub-groups, specifically those with cardiovascular disease or metabolic syndrome have been reported to have much higher rates of sleep apnea (Bailes et al., 2017). The Hispanic Community Health Study reported in JAMA, focused on white, African American, Chinese, and Hispanics. Their data suggests that 25.8% of 14,440 participants tested positive for sleep apnea, with approximately 90% experiencing symptoms to moderate to severe in degree. This is compared to only 1.3% of participants that admitted to previous diagnosis. The data reveals a major gap in recognition and an area of opportunity particularly in areas where these minorities are commonly seen.

Definition

The increasing occurrence of sleep-disordered breathing threatens the well-being of millions of individuals across the United States and is steadily increasing in prevalence. Sleep disordered breathing is characterized by many clinicians as a wide spectrum of sleep-related breathing abnormalities. These anomalies are related to increased airway resistance including snoring, upper airway resistance syndrome and sleep apnea (Jordan, McSharry & Malhotra, 2017). A patient can move gradually through this spectrum with weight gain or other physiological changes. An individual who snores exhibits the first manifestation of sleep disordered breathing. Although generally addressed in this project, sleep apnea can be further broken down into three forms: mixed, central and obstructive sleep apnea (OSA) (Garcha, Aboussouan & Minai, 2013).

Mixed apnea is the combination effect of both central and obstructive sleep apnea (Garcha, Aboussouan & Minai, 2013). Central apnea causes a decrease in ventilatory drive without obstruction due to inherent properties of the respiratory control center or as result of a medical condition, drug use, or high altitude (Badr et al., 2017). Obstructive sleep apnea (OSA) the most common form, typically occurs during Rapid Eye Movement (REM) sleep. During REM sleep the velopharyngeal and oropharyngeal airway becomes obstructed by decreased genioglossus muscle tone causing the individuals' tongue to fall back and further prevent airflow despite an individual's breathing efforts (Strohl et al., 2017).

Apnea refers to a halt in breathing for 10 seconds or more as a result of complete obstruction of the airway. Hypopneas refer to slow and shallow breathing that reduces oxygen supply to the lungs. When recorded during sleep, the presence of these two is referred to the

apnea/hypopnea index (AHI). Obstructive sleep apnea is typically diagnosed by an AHI greater than or equal to a score of 5 on a polysomnography study (Nagappa, Liao, Wong, Auckley, Ramachandran, Memtsoudis, Mokhlesi & Chung, 2015). Moderate-to-severe sleep apnea is classified at an AHI greater than or equal to 15, and a score of 30 or more is considered severe in nature (Nagappa et al., 2015).

Clinically, sleep apnea is most commonly recognized by a declaration of snoring, long pauses between breaths, shallow breathing, or restlessness during sleep. In general, pauses in breathing during sleep can occur as often as 30 or more times per hour and last up to a few minutes at a time. This disruption in sleep leads to intermittent disturbances in gas exchange, leading to increased retention in carbon dioxide and impaired sleep patterns (NHLBI, 2012).

Sleep apnea, particularly in women, will often go undetected and consequently untreated causing excessive daytime sleepiness, fatigue, and lack of energy. Women with sleep apnea are less likely to be aware of witnessed apnea as opposed to men whose spouses commonly declare their snoring**. (**Shepertycky, Banno & Kryger, 2005). Often a spouse or other family member is the first to notice signs of sleep apnea in someone with this condition. The diagnosis of sleep apnea should only be based on the results of a polysomography or an at-home sleep apnea study (Kapur, Auckley, Chowdhuri, Kuhlmann, Mehra, Ramar & Harrod, 2017). Screening tools can be helpful in the clinical setting when the decision to further investigate sleep apnea is necessary.

Gender Differences

As many as 20-50% of the adult population experiences this problem to some degree and this number continues to grow in prevalence (Lorenzi-Filho, Genta, & Drager, 2017). Obstructive sleep apnea affects an estimated 18 million people within the United States, which is

equivalent to 1 in every 15 individuals (Lorenzi-Filho, Genta, & Drager, 2017). As many as 35% of all men and just under 20% of women are affected by this condition; prevalence difference narrows after women begin menopause as BMI increases in women (Bibbins-Domingo et al., 2017).

A woman's risk for developing sleep apnea increases significantly as they are three times as likely to experience this condition after they transition through menopause (Gooneratne & Vitiello, 2015). Women are also predisposed to partial airway collapse and airway flow breathing irregularities based on gender related differences in function and structure of the upper airway (Gooneratne & Vitiello, 2015). Middle-aged men with a high body mass index (BMI) are more likely than women to experience this condition but are also more likely to be properly diagnosed. This is true even as the gap in prevalence closes for women during menopause when they are at their highest risk for developing sleep apnea. This leads to speculate that many women will go undiagnosed throughout their lifetime.

Complications

In the female elderly population, observational studies have linked sleep apnea with an 85% increase in the risk of developing cognitive impairment or dementia. It is for this reason that primary care providers need to ensure women are properly screened, diagnosed, and appropriately treated (Gooneratne & Vitiello, 2015). Frequent hypoxic episodes that lead to REM sleep disruption cause increased cortisol levels and overstimulation of the sympathetic nervous system. It is for these reasons that sleep apnea has been established as a precursor for hypertension, diabetes, depression and coronary artery disease of which stem from inflammation and oxidative stress (Jehan et al., 2016). Therefore, a significant correlation is seen with patients

experiencing angina, myocardial infarction, stroke and immunodeficiency (Strohl et al., 2017). Sleep apnea also poses immediate threats along with its chronic risks. This disorder significantly increases the risk of day time accidents as result of lethargy (CDC, 2016). As many as 20% of all motor vehicle accidents are attributed to sleep disordered breathing (CDC, 2016).

Sleep apnea is a modifiable cardiovascular risk factor. In women especially, a strong correlation exists between severe sleep apnea and heart failure. Women with sleep apnea in mid-life have been found to be at a greater risk for left ventricular hypertrophy as compared to men. Recurrent cardiometabolic stress is induced when repetitively attempting to breathe against an occluded airway (Redline, 2017). In women with asymptomatic left ventricular dysfunction, sleep apnea and other forms of sleep disordered breathing can progress to symptomatic heart failure (Javaheri et al, 2017). Therefore, timely diagnosis is imperative for health outcomes.

When identified early, complications associated with sleep apnea can be greatly reduced. It is well known that serious health conditions can be prevented or better treated when sleep apnea is controlled. As many as 50–80% of patients with dementia, congestive heart failure, atrial fibrillation or cerebrovascular disease are identified as experiencing moderate to severe risk of sleep apnea and yet only 2% are diagnosed (Gooneratne & Vitiello, 2015). Women with sleep apnea are more likely to have a comorbid diagnosis including cardiovascular disease, hyperlipidemia, diabetes, asthma, hypothyroidism, arthropathy, and reflux/gastritis (Wimms et al, 2017).

Risk Factors

Hormonal regulation and body mass play an immense role in sleep apnea in women. An elevated Body Mass Index (BMI) is the largest known risk factor that equally affects women as it

does men (Force, 2017). Women with a neck circumference greater than 16 inches are at highest risk for developing sleep apnea (Cizza et al, 2014; Strohl et al., 2017). In women, progesterone and estrogen play a vital role in sleep health. The lack of production of these two hormones is a contributing factor of sleep apnea for women during and after menopause (Jehan et al., 2016; Strohl et al., 2017). Progesterone promotes respiration as women sleep and is often used as a supplement to treat mild obstructive sleep apnea (Jehan et al., 2016). Estrogen promotes quality sleep, total sleep time and decreases the number of breathing disruptions. Generally, menopause increases cardiovascular risk as does sleep apnea. Therefore, the combination of these two risk factors greatly increases cardiac workload and increases potential cardiometabolic stress.

Treatment

The aim of sleep apnea treatment is the improvement of shallow and or insufficient breathing patterns that cause complications during sleep. Prompt intervention is essential to prevent sleep apnea associated consequences. Various treatments for mild symptoms of sleep apnea exist. These include weight loss and several oral appliances that can contribute in improving symptoms of fatigue and quality of life. These therapies are commonly ineffective as standalone treatment options for moderate to severe symptoms. Surgery is an option that should only be considered when all pressure support therapies have been exhausted (Libman et al., 2017). The most common method of treatment comes from Continuous Positive Air Pressure (CPAP). CPAP is the most reliable, minimally invasive and cost-effective treatment available for moderate to severe symptoms (Libman et al, 2017).

Bilevel Positive Airway Pressure (BiPAP) is often used to treat individuals when removal of carbon dioxide is warranted. BiPAP is traditionally more expensive as it is often prescribed

for patients with heart failure, coronary artery disease and other pulmonary disorders and neurologic issues (Libman et al., 2017). It can also be used to treat sleep apnea when CPAP does not sufficiently meet the patients demands of pressure requirement (McArdle et al, 2015).

Local Problem

The city of Sierra Vista is located 70 miles southeast of Tucson, AZ and is approximately 35 miles north of the Naco border entry into Mexico. It is surrounded by the Huachuca, Dragoon, Whetstone, Mustang and Mule Mountains and is adjacent to the San Pedro River. This military town hosts Fort Huachuca Army post in the most northern part of the city and is also known for its retirement communities. As part of Cochise County, this town is the center of what is now considered the Sierra Vista-Douglas Metropolitan Area with surrounding cities of Tombstone, Bisbee, Benson, Wilcox and Douglas (Arizona's Economy: Economic and Business Research Center, 2015). Cochise County has an obesity rate of 22.4% (County Health Rankings and Roadmap, 2017). There are approximately 59 primary care physicians in practice in Cochise County with an estimated ratio of 2,160 patients per provider (County Health Rankings and Roadmap, 2017).

Sierra Vista has a reported population of 43,000 as per census records reported in 2015 (United States Census Bureau, 2015). In 2010, just under 20% of the population was identified as Hispanic, 10% as African American or Black, 4% Asian and 62.8% as white non-Hispanic (United States Census Bureau, 2015). There are approximately 15 clinics within the city that provide primary care services to the residents of this area and its surrounding cities. In this city alone, 33% of residents are considered overweight (City-data.com, 2017). The average time of

sleep was 6.8 hours per night which falls below the CDC's recommended 7-8, thus increasing the need for proper screening of sleep disordered breathing (City-data.com, 2017).

Patel Medical Clinic is an internal medicine practice located in Sierra Vista, Arizona that provides care to more than 5,000 male and female patients. The clinics' two providers, a physician and nurse practitioner provide primary care services to patients of various races and ethnicities. Patients range from ages 18 years of age and older with the majority over the age of 50. Patients assessed with symptoms that correlate with a sleep apnea diagnosis are typically sent for polysomnography or at-home sleep study testing; those that require intervention thereafter are usually treated with recommended dietary changes, exercise and other means of weight loss along with Continuous Positive Airway Pressure (CPAP). Although the clinic director identifies patients with typical presentations, it is those with non-traditional symptoms that he personally identifies as a concern. This brings forth the prospect of a quality improvement opportunity to identify those who have moderate to severe sleep apnea risk who might otherwise get overlooked for testing. It would also provide the opportunity to identify barriers associated with further diagnostic evaluation for sleep apnea. Because women are less likely to be identified as having this condition as opposed to men, the focus of this discourse was based on them specifically.

Purpose

The purpose of this Quality Improvement (QI) project is to evaluate the use of a validated screening tool to identify women 50 years of age and older in a rural Southwestern internal medicine practice who are at risk of sleep apnea and identify barriers to definitive diagnosis for those identified as moderate to high-risk. The intent is to promote timely diagnosis, as well as identifying barriers for diagnostic testing. Early diagnosis is vitally important and essentially the

ultimate goal towards improving patient outcomes. This project addresses the clinical directors concern that there are those that may be missed for diagnosis because of uncommon symptoms that may not be suspected in an individual experiencing sleep apnea. Currently there is no screening tool used for sleep apnea that is regularly used at this clinic. The results of this project will be used to support the implementation of a validated screening tool to achieve opportune diagnosis and address barriers that prevent diagnostic testing.

The intent of the study is to help bridge the gap in identification of symptoms and diagnostic evaluation in this specific population regardless of previous diagnosis and/or compliance with therapy. With the data collected, a quality improvement plan can be created and implemented to prevent under-identification of these individuals with moderate to severe degree symptoms.

Project Questions and Aims

1. Describe prevalence of sleep apnea symptoms in women 50 years of age and older in a rural Southwestern primary care practice.
2. Of the patients identified as having moderate to severe sleep apnea risk:
    a. What proportion have been identified as having had a previous diagnosis of sleep apnea?
    b. What are the barriers associated with patients getting further diagnostic evaluation for sleep apnea?

Theoretical Framework

Overview

The course of this project will follow the Ottawa Model of Research Use (OMRU) for its grounding in research, theory, and expert opinion (Rycroft-Malone & Bucknall, 2014, p. 83, 85). This model is a practical theoretical framework used for the purpose of promoting an evidence-based approach to the transfer and implementation of valid research findings into clinical practice. (Rycroft-Malone & Bucknall, 2014, p. 83). It is beneficial to use this model as a guide when translating knowledge from research into the clinical setting. It has been referred to as being a linear process, but its strengths secede its limitations. It has been referred to as being intuitive, reflecting practice and being useful with complex projects (Rycroft-Malone & Bucknall, 2014, p. 83).

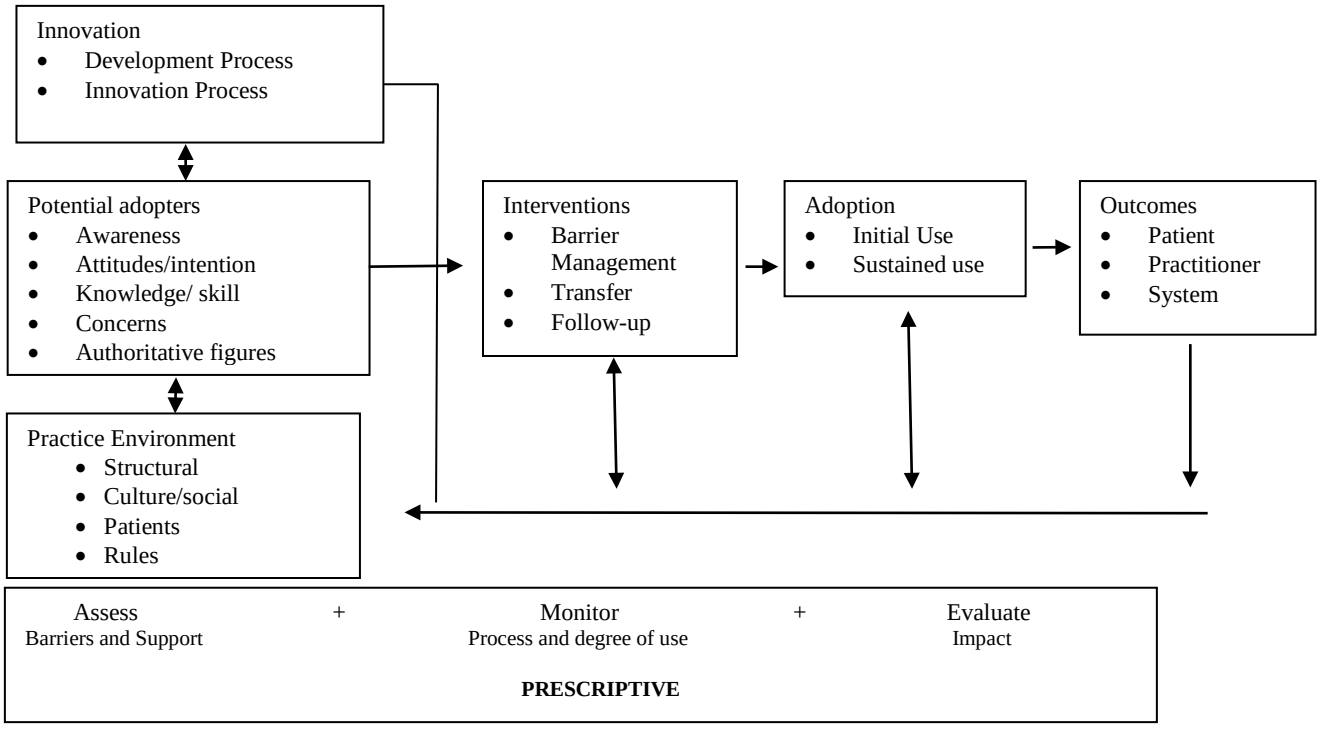

FIGURE 1. The Ottawa Model of Research Use. (Adapted from Rycroft-Malone & Bucknall, 2014, pp. 85)

As outlined in Figure 1, the Ottawa Model of Research Use (OMRU) consists of two portions that guide its processes. The first being six principal elements that are central to the research progression and the second to which a prescriptive portion facilitates implementation. The six elements include evidenced-based innovation, potential adopters, practice environment implementation, intervention strategies, adoption and health-related outcomes (Rycroft-Malone & Bucknall, 2014, p. 83). The prescriptive portion consists of assessing, monitoring, and evaluating (AME) (Rycroft-Malone & Bucknall, 2014, p. 83).

During planning and implementing of this project, facilitators are guided by the AME process prior to, during and after implementation. A proper assessment of the innovation will help develop an outline of characteristics that either support or create barriers for its' integration into practice. Assessment of the adopters' perceptions will provide insight to acceptance as the adopters' knowledge, concerns and overall awareness may change. An assessment of the practice environment is aimed at evaluating outside barriers that could influence adoption other than from the innovation itself.

Monitoring of the implementation strategies is essential to ensure that no new barriers have arisen and to determine if strategies require modifying (Rycroft-Malone & Bucknall, 2014, p. 93). Adoption is monitored to evaluate the type and degree of use by adopters as outcomes cannot be evaluated until correct application of the innovation is ensured (Rycroft-Malone & Bucknall, 2014, p. 96).

Evaluating outcomes is done using quantitative and qualitative designs to determine if the impact of the adoption is worth required resources and time. During this process, it is imperative to ensure that professional standards are met and not vulnerable to compromise. Evaluating

outcomes can include surveys, audits, analysis as well as interviews of administrators and providers. (Rycroft-Malone & Bucknall, 2014, pp. 96-97).

Framework Elements and Implementation

The evidenced based innovation represents something new to be implemented and is informed by valid research findings (Rycroft-Malone & Bucknall, 2014, p. 86). The STOP BANG screening tool serves as the research-informed, evidenced based innovation.

This tool offers the clinicians in practice a quick assessment score as to the patient's degree of risk for sleep apnea. Because of its simple functionality, it is expected to garner support from potential adopter's. These individuals' perceptions of the innovation will attribute most to the adoption or rejection of the innovation (Rycroft-Malone & Bucknall, 2014, p. 89).

These potential adopters are the practitioners, policy makers and patients who will use the innovation (Rycroft-Malone & Bucknall, 2014, p. 90). Sub elements of the potential adopter that are considered include the awareness of the screening tool, the intention to adopt, and the concerns that may arise about it (Rycroft-Malone & Bucknall, 2014, p. 90).

The potential adopters are identified as the clinic director, office manager and clinicians. These individuals are the authority figures who will see the usefulness of the innovation first hand and approve the implementation of this questionnaire. Potential adopters will be interviewed to better understand what their perceptions are towards screening this specific population and the potential use of a survey tool in their practice.

The practice environment includes the structural factors of the setting. These consist of the physical environment, the decision-making structure, workload, rules and regulations of current practice. This is where recommended changes in the current practice will occur (Rycroft-

Malone & Bucknall, 2014, p. 91). A situational assessment of the current practice environment will be performed to establish a baseline understanding of the current progression and processes in the clinic. This method will be used to identify any barriers that encumber the current method.

Intervention strategies and implementation interventions should be tailored to the specifics of the situation based on the assessment of the innovation, potential adopters and the practice environment. Interventions should be classified into barrier management, passive and active implementation strategies and follow up activities (Rycroft-Malone & Bucknall, 2014, p. 92). Implementation interventions will begin with the introduction of the survey tool during staff meetings. Education about the tool will be presented in power point format where its usefulness and limitations will be explained. Staff will be instructed to educate patients on the use of the survey tool and how it will be used by the providers to determine a patient's need for further evaluation. These staff members will serve as agents of change responsible for implementing the innovation.

Adoption refers to sequences by potential adopters where the innovation is initially tried and then use is continual. Initial use is apparent until the learning curve is over, and a degree of competence is achieved. The innovation is new information and knowledge to adopters. Adoption is a form of knowledge use. It is either conceptual or general enlightenment, symbolic or strategic; when knowledge is used to legitimate predetermined positions, and instrumental use where knowledge is applied directly and is reflected in changes in practice. Instrumental use is preferred to achieve patient centered outcomes (Rycroft-Malone & Bucknall, 2014, p. 93).

Staff members involved in this process will be interviewed periodically to better grasp the attitudes and understanding of the implemented change. It is essential to recognize barriers

hindering efficacy and to discourse management strategies for improvement. Daily follow up meetings will occur to ensure smooth transitioning and a full grasp of the application is widely received by adopters and change agents as recommended per the Ottawa model.

Outcomes are based on patients, practitioners or financial results. This element represents the impact of the implementation and is focused on the specific innovation recommendations. It should not be evaluated until the adopters learning curve is primarily completed (Rycroft-Malone & Bucknall, 2014, p. 93).

Weekly reviews of data collected will be performed. Interviews with providers and staff will assess the progress and outcome of the implementation. The goal is to have this tool considered as a normal part of the patient check-in process. The outcome of the project will result in a better understanding of the prevalence of sleep apnea in women. The data collected will be presented to the clinic director and staff with recommendations for potential utility in adopting a screening tool in practice.

Concepts and Definitions

1. Sleep apnea- general term used to describe cessation of breathing or decreased airflow during sleep due to impaired ventilator effort or obstruction, intrinsic factors or both (NHLBI, 2012).
2. Providers -licensed medical practitioners including nurse practitioners, physicians and physician assistants
3. Screening tool – instrument used to collect data on illness specific criteria

Synthesis of Evidence

A literature search was conducted using the following databases: PubMed, CINAHL, and Google Scholar. Using the search terms: “sleep apnea,” “screening tools,” “women,” “central sleep apnea,” “obstructive sleep apnea,” “STOP BANG,” “rural healthcare,” “primary care,” “sleep,” “undiagnosed,” “CPAP,” “prevalence,” and “screenings.” A total 27,600 articles via Google Scholar were identified for the general search for sleep apnea with the date range from October 2013 until October 2017. This search was further refined to include the terms “women,” “undiagnosed,” “50 and older,” “rural healthcare,” which produced 2,030 results. This search was again refined by adding “stop bang” from which 135 results were produced. Similarly, PubMed produced 2084 results for the term sleep apnea. This search was then further refined by adding “stop bang” from which 135 results were produced. This search was further refined to include the terms “women”, and 0 results were found. CINHAL produced 12,261 articles for sleep apnea and reduced to 631 when refined with “women” as additional search criteria. Adding the term “screening” returned 39 articles.

There are discrepancies between gender in the prevalence of sleep apnea. Prevalence data supports that men more so than women are affected by sleep apnea; however, these differences are not evident within clinical trial populations. This is indicative of an underdiagnosed population as women are being diagnosed and treated for sleep apnea less frequently than males (Wimms et al., 2016). Women are frequently being misdiagnosed or underdiagnosed due to report of atypical symptoms that clinicians may not find (Wimms et al., 2016). Report of symptoms such as depression and anxiety adds to the difficulty in correctly diagnosing female patients (Wimms et al., 2016). At the time of diagnosis, women with are more likely to be treated

for depression, insomnia, and hypothyroidism than are men with the same degree of sleep apnea (Wimms et al., 2016). Data also suggests that although the prevalence and severity of sleep apnea may be lower in women than in men, the consequences of this disease are at least the same, if not worse in severity.

The current practice of screening and assessing for sleep apnea lacks structure and is ineffective specifically in women. Primary care providers do not routinely screen or refer patients to a sleep specialist (Miller & Berger, 2016). The high prevalence of untreated OSA requires improved recognition. Under recognition of sleep apnea is at least in part related to clinicians not routinely looking for signs of sleep apnea in patients who may not have symptoms (Redline, 2017).

The family practice journal from Oxford Academic (Bailes et al., 2017) studied 295 participants, to examine the sleep characteristics and likelihood of obstructive sleep apnea. The sample consisted of both men and women 45 years and older in two family practices. Patients studied had no previous sleep apnea testing nor had they ever been suspected of having sleep apnea. Participants completed a sleep apnea symptom questionnaire and were offered an overnight polysomnography study, regardless of questionnaire results. Of the total number of women that underwent polysomnography, 75% were diagnosed with sleep apnea (Bailes et al., 2017).

It was concluded that greater gender equality in sleep apnea rates can be achieved in family practice if sleep apnea assessments are frequently offered to older patients (Bailes et al, 2017). By doing so, many more patients with moderate to severe sleep apnea will be identified particularly in women. The difficulty with sleep apnea is that its diagnosis relies on the

willingness of participants to undergo demanding testing procedures that are expensive. This may limit sample sizes that are feasible for population-wide studies (Bailes et al., 2017).

In current practice, most primary care clinicians do not routinely screen for sleep apnea. Sleep apnea is under diagnosed due to lack of formal training in sleep medicine, low pro active questions addressing sleep issues in the office or low access to sleep studies (Lorenzi-Filho, Genta, & Drager, 2017). Barriers to screening cited by clinicians include being unsure about how to identify and diagnose sleep apnea, uncertainty regarding which type of sleep monitors are best for the diagnosis of sleep apnea, and how to follow up patients who have been diagnosed with sleep apnea (Bibbins-Domingo et al., 2017).

METHODS

Design

The purpose of this QI project is to evaluate the use of a validated screening tool in identifying women 50 years of age and older in a rural Southwestern internal medicine practice who are at moderate to high-risk of sleep apnea. This study used a cross-sectional quantitative survey design including use of a validated screening tool. The STOP-BANG sleep apnea questionnaire is used to identify women over the age of 50 with moderate to severe risk of sleep apnea and assess barriers to diagnosis.

Setting

Patel medical clinic is a rural Southwestern internal medicine practice in Sierra Vista, Arizona. Sierra Vista is home to approximately 43,000 people. It is considered partially rural with urban areas. Sierra Vista is the largest of seven incorporated cities in Cochise County, accounting for one-third of the county's population. Care is provided by two clinicians: the

director who is a physician and a nurse practitioner. Between both providers an average of 45 patients are provided services each day.

Sample

The clinic patients are largely Caucasian with many Hispanic and African Americans. A smaller percentage of Native American or Asian patients also seek care at this clinic. Patients of ages 18 and older are provided care with the majority being over the age of 50. Most patients are within a 15-minute drive to the clinic from any point in Sierra Vista, while others reside in its neighboring towns that are usually within a 45-minute radius. Given that the focus of this project is improving identification of sleep apnea in post -menopausal women, the study included women 50 years of age and older. All clinic patients who are female and 50 years of age and older were eligible to participate in the study, regardless of sleep apnea status. Inclusion criteria included ability to read and write in English or in Spanish. If assistance was needed with the questionnaire, only the ability to speak English or Spanish was acceptable. All female patients 50 and older who present for care to the clinic during data collection were invited to participate.

With approximately 200 patient visits per week and with half or more being women, a minimum of 50 questionnaires was targeted to provide a fair representation of the patients seen in one weeks' time. This sample provided a broad range of socio-demographic characteristics including, race/ethnicity, socioeconomic status, and insurance status. It also provided several patients that had never been diagnosed or fully evaluated for sleep apnea despite having an increased risk of experiencing this condition.

Data Collection

Tools

The paper quantitative survey tool used to collect data includes three parts, a social-demographics portion, a section that addresses history and barriers and finally the STOP BANG questionnaire.

In the social-demographics portion, the survey first addressed the participant's ethnicity and age. The next portion questions if the participant has ever had a previous diagnosis of sleep apnea, a previous sleep study and addresses barriers that may have prohibited a study from occurring. The STOP BANG questionnaire addressed problems regarding snoring, tiredness, observed apnea and high blood pressure. It also included four questions regarding BMI, age, neck circumference and gender. A common clinic tape measure was provided to participants needing to measure their neck circumference.

The STOP-BANG questionnaire is commonly recognized as having the highest validity among most studies and is sensibly accurate (Redline, 2017). The STOP-Bang questionnaire is regarded as having the highest value for sensitivity and is fairly easy to fill out. It is considered as one of the best measures to predict risk and the presence of moderate to severe sleep apnea (Miller & Berger, 2016). It is for these reasons, that this tool was selected for this study.

This questionnaire is commonly used in pre-operative settings when a baseline respiratory assessment is necessary prior to anesthesia administration. Although current literature does not support the use of a screening tools, these recommendations have not been subject to random control trials (Pendharkar & Clement, 2017). The *Journal of the American Medical Association* (JAMA) emphasizes that if this recommendation is misinterpreted, it could

negatively influence public health to discourage direct questioning or deployment of short screening questionnaires for identifying patients at high-risk for sleep apnea which have had a proven degree of effectiveness (Redline, 2017).

Data Collection Process

All female patients 50 years of age and older who presented to the clinic for routine care during data collection times, mutually agreed upon by the investigator and medical director, were invited to participate in the project. After check-in at the front desk, the investigator introduced himself to potential participants. At this time, he thoroughly explained what the project entails and the purpose of the study. The investigator then explained the criteria required to participate and explained that little to no risk was posed to them as no personal identifiers would be collected should they choose to participate. It was explained to the individual that they had the option to withdraw from the study at any time. After consent was obtained, with a waiver attained from the IRB to protect confidentiality, participant completion of the survey indicated consent to participate. Patients that agreed to participate and who met criteria were then given a paper survey to fill out in the lobby sitting area while they waited for their appointment. Signed consent was not obtained nor required for participants to take part in the study as actively completing the survey demonstrated consent to participate. Surveys were available in English and Spanish, translated by the primary investigator who is fluent and practices in both languages. Participants requiring assistance to fill out the form were then aided by the primary investigator as necessary. Once the survey was completed, the investigator then collected the completed questionnaire and explained to the participant that if they wished to share their results with their medical provider, a copy of their questionnaire would be provided for them once their scores had

been tallied. Participants had the opportunity to then choose whether to present their results with their medical provider at their next appointment. This element was added at the request of the medical director who was concerned primarily about potentially missing at risk patients. It was the sole responsibility of the participant to provide their copy to their provider, as no identifiable information was recorded. A minimum of 50 to 75 surveys were aimed to be collected. A total of 54 complete survey tools were collected by the end of the data collection time frame. Completed surveys were kept in a manilla folder for later evaluation.

Data Analysis

The gathered data was organized using quantitative methods to depict data in a concise manner. Data was then entered into an Excel spreadsheet for data management and analysis. No Spanish surveys were collected by the investigator therefore translation was not required. Once the information was transferred into Excel, paper copies were then shredded. Although no personal information was collected, information was password protected, locked and secured by the investigator. Sociodemographic data was analyzed using descriptive statistics to better label the prevalence of sleep apnea symptoms in women 50 years of age and older in a rural Southwestern primary care practice. Risk assessments using the tallied score of the STOP-BANG questionnaire were performed to identify patients as having moderate to severe sleep apnea risk. Descriptive statistics are used to determine what proportion of patients identified, have had a previous diagnosis of sleep apnea what are the barriers associated with patients getting further diagnostic evaluation for this condition.

Ethical Issues

Ethical considerations for this project revolved around the privacy of the participants in this study. Beneficence, justice and respect for persons guides this projects' focus. There was no identifiable data collected. Data collected was locked and password protected by the investigator. Contributors were notified prior to going that the director of the clinic would have access to the complete results of the study but that no personal information would be collected nor distributed. Participants identities remained anonymous as participants did not share their personal information thus demonstrating respect for persons. In the event that participants did choose to share their results with their provider, options were provided so that they could obtain a copy of their completed survey with test results to discuss them with their provider when they chose to.

The basis of this project is grounded on the principle of beneficence. Ultimately, improving patient outcomes is the desired goal. Beneficence addresses the notion that actions should promote good and that the intent of doing good and acting in kindness is to benefit others (American Nurses Association, 2011).

All data collected will be treated equally. Justice implies that all individuals have an equal right to the goods distributed, regardless of what they have contributed or who they are (American Nurses Association, 2011). Justice is to be upheld as surveys are to be distributed without partition to all women over the age of 50 regardless of ethnicity, previous diagnosis of sleep apnea or previous failure to get testing done.

Dissemination

An executive summary and PowerPoint presentation of key findings and evidence-based recommendations are being created based on the information collected. A meeting will be held

with the program director of the clinic to share the results of the study. During this meeting, the primary investigator will provide an overview of the results and share evidenced-based recommendations for incorporation of the screening tool in this primary care setting.

RESULTS

Participant Characteristics

Study subjects consisted of 54 women. All participants were screened regardless of previous diagnosis or current treatment of sleep apnea. Participants were established patients of Patel Medical Clinic, 50 years of age and older, and predominantly Caucasian, although various ethnicities were represented.

Sleep Apnea Risk Scores

Stop-Bang survey tool scores were tallied and varied by severity. These results identified many “at risk” patients among most age groups that would warrant a sleep study exam. Results revealed that out of 54 participants, (37) 68.5% scored at moderate to high-risk of sleep apnea.

A total of (27) 50% of participants scored in the moderate-risk category alone while (10) 18.5% scored as “high-risk” for sleep apnea (Figure 2). The rest of the surveys collected made up (17) 31.5% of the total and scored as “low-risk.”

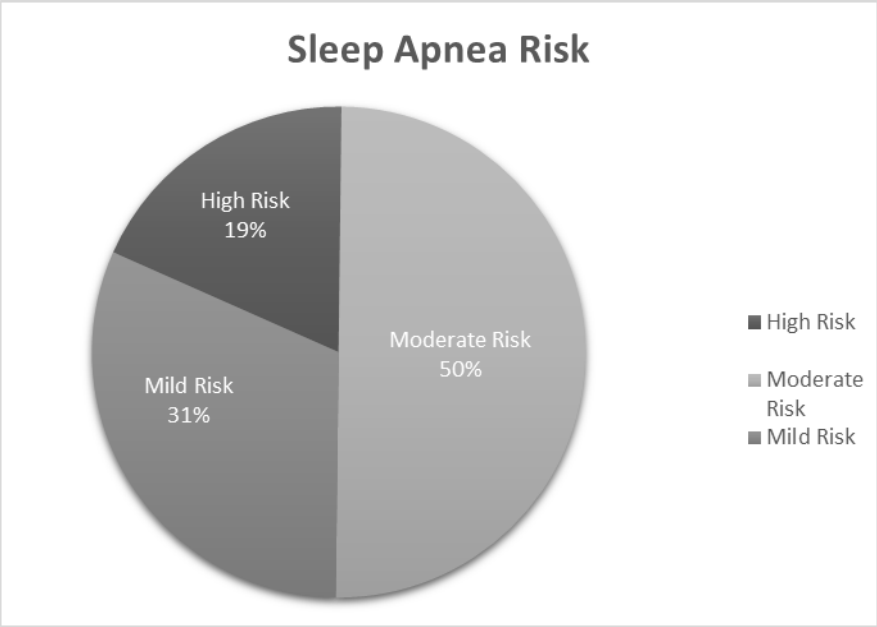

FIGURE 2. Sleep apnea risk by severity

Demographics

Risk Stratification and Current Diagnosis

Between the 22nd and the 26th of January 2018, 54 eligible female participants at Patel Medical Clinic were invited to participate in this study. Out of these 54 individuals, (54) 100% of participants willingly agreed to fill out the survey tool.

Of the 54 that participated, (13) 24% admitted to being previously diagnosed with sleep apnea. Among these 13, all sleep studies were completed without complications. Interestingly, a substantial proportion of patients with significant symptoms and an additional established diagnosis of sleep apnea was discovered. Of those 13 with an established diagnosis, (7) 53% scored in the moderate-risk category, and (5) 38 % scored in the high-risk category represented in Table 1.

TABLE 1. *Sleep study and diagnosis*

Severity	Total	Sleep Study Ordered	Sleep Study Completed	Sleep Apnea Diagnosis
Low	17	1	1	1
Moderate	27	8	7	7
High	10	8	5	5

As previously mentioned, a total of (27) 50% of participants scored as moderate-risk. A breakdown of this group reveals that just (8) 29% out of the 27 total were referred for sleep study. This indicates the greatest area of opportunity requiring further inquiry. One individual of the 27 had been referred for a sleep study but did not complete it because of their unwillingness to go through with the study itself.

Out of the 54 total participants, (10) 18% had high-risk scores. Of these 10, (8) 80% were referred for sleep study but only (5) 62% of these eight, completed their study. One individual stated that she never received a phone call from the sleep center to confirm her appointment and she never followed up, so her referral fell through. One participant stated that the unusualness and unfamiliarity of the testing center prohibited her from going through with the exam. Another participant stated that although she made it to her appointment, feelings of claustrophobia prohibited successful completion of her study.

Ethnic Characteristics

Of the sample group (48) 88% of participants identified as Caucasian. Of these 48, (7) 14% self-identified as Hispanic, Latino or of Spanish origin. There was a total of (6) 12% that were self-described as Mexican while (1) 2% identified as Hispanic of "other" origin.

Other races represented out of the 54 include (2) 3% American Indian or Alaskan Native, (1) 1.8%African-American, (1) 1.8% Filipino, (1) 1.8% Asian-American and (1) 1.8% Vietnamese, respectively (Table 2).

TABLE 2. *Race by percentage*

Variable	**Severity**	**N**		**Total**	**%**
Race	**Low**	**Moderate**	**High**		
Caucasian or white	15	25	8	48	88.8%
Black or African American	1	0	0	1	1.8%
American Indian or Alaska Native	0	1	1	2	3%
Filipino	0	0	1	1	1.8%
Vietnamese	0	1	0	1	1.8%
Asian Indian	1	0	0	1	1.8%
Chinese	0	0	0	0	0%
Japanese	0	0	0	0	0%
Korean	0	0	0	0	0%
Native Hawaiian	0	0	0	0	0%
Guamanian or Chamorro	0	0	0	0	0%
Samoan	0	0	0	0	0%

**(7) 14% Hispanic women identified as Caucasian; (6) Mexican (1) of other Hispanic origin*

There was a wide range in age among participants, beginning with age 50 (Figure 3). Out of 54 participants, (10) 18.5% were of the 50-59 age range, (18) 33.3% were of the 60-69 age range, (16) 29.6% were of the 70-79 age range, (8) 14.8% were of the 80-89 age range, and lastly (2) 3.7% were of the 90 and over age range.

From the 10 individuals within the 50-59 age range, (6) 60% scored as moderate to high-risk. Among the 18 individuals within the 60-69 age group, (13) 72% scored moderate to high-

risk. Among the 16 in the 70-79 age group, (12) 75% scored as moderate to high-risk. The eight individuals in the 80-89 age group were represented by (6) 75% in the moderate to high-risk category. Among the two individuals within the 90 and older group, both were of low-risk per the survey tool.

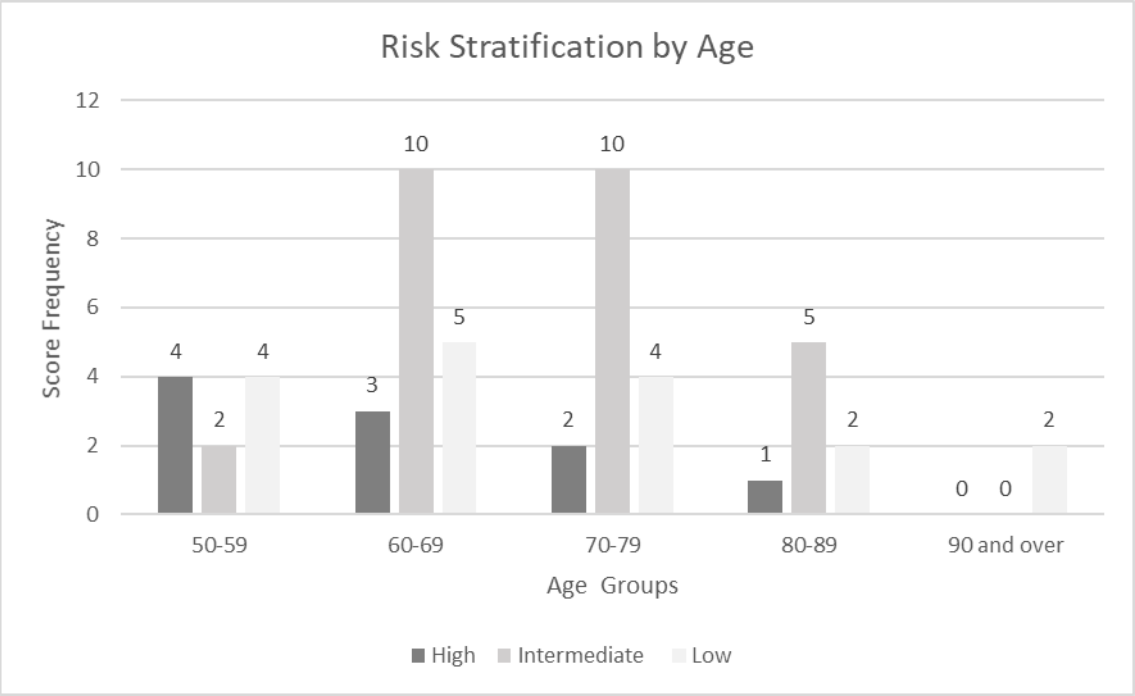

FIGURE 3. *Risk stratification by age*

Discussion

This quality improvement study evaluated the use of a validated screening tool in identifying women 50 years of age and older with moderate to severe risk of sleep apnea in a rural Southwestern internal medicine practice. As stated, women are often overlooked for workup and proper diagnosis, often due to unreported or unidentified symptoms. Because a woman's chances of developing this condition significantly increase after menopause, the purpose of this quality improvement project was to evaluate and recognize the prevalence of

sleep apnea risk using a validated survey tool and to identify barriers that prevent timely diagnosis in this population.

Participants

Most participants were predominantly Caucasian; many of which identified as Hispanic. This seems to represent the community of Sierra Vista accurately and would likely mirror other primary care practices. Nearby cities, such as Bisbee and Douglas for example, lie along the U.S-Mexico border and may have a larger representation of the Hispanic population.

There was no difficulty when prompting individuals for participation. Complete cooperation and willingness to contribute was encountered during data collection as all potential participants agreed to take part in the study. Interest in the project was apparent, but a lack of follow-through on the topic of sleep apnea was evident as only one participant requested a copy of her results to share with her provider. It can be speculated that women may experience embarrassment or shame while discussing symptoms that include snoring with their provider. The inconvenience of having to potentially need CPAP or a sleep study alone could also deter a patient from receiving a complete workup.

Sleep Apnea Risk

It is estimated that just under 20% of all women suffer from sleep apnea and the prevalence continues to grow. (Bibbins-Domingo et al., 2017). In the United States, as many as 16% suffer from mild symptoms and 10% experience them at a moderate to severe degree (Bibbins-Domingo et al., 2017). This study reveals that sleep apnea symptoms were quite prevalent in women over the age of 50 in this rural primary care practice. Opportunities to better identify patients at risk exist and should be looked at closely. Although sleep apnea risk varies

with each age range, risk scores are predominantly higher between the 60-69 and 70-79 age groups.

As previously mentioned, out of all patients surveyed, (37) 68.5% of the 54 tallied scores were moderate to severe risk. Just (16) 43.2% of these patients have ever been referred for a sleep study and out of 10 participants with high-risk scores, (8) 80% had been referred for sleep study but only (5) 62%of these had been completed. Identification of these individuals was not an issue; rather, follow-through on completion of diagnostic testing was recognized as a greater obstacle. Polysomnography should always be considered in patients with a high pretest likelihood of moderate to severe sleep apnea (Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine, 2009). Therefore, a sleep apnea screening tool could potentially narrow or close the gap in the moderate group and improve identification in symptoms and potentially lead to timely diagnosis and treatment (Bailes et al., 2017).

A similar study took place in Canada in a family practice clinic that used polysomnography to confirm results of their screening tool. In participants aged over 60, sleep apnea rates were over 60%, and over 80% in those over age 70, for both men and women (Abrishami, Khajehdehi, & Chung, 2010). The study revealed that 13 participants with an established diagnosis of sleep apnea still scored as having moderate to high-risk regardless of their established diagnosis. Of these, (7) 53% scored in the moderate-risk category, and (5) 38 % scored in the high-risk category regardless of previous diagnosis (Abrishami, Khajehdehi, & Chung, 2010).

Potential explanations include difficulty getting equipment, effective use of the equipment, or other potential intrinsic factors that need to be addressed. The fact that so many of

these individuals recognized having this condition yet were still demonstrating symptoms opens further opportunity for research to determine why this is the case.

Barriers

Various barriers were identified that could potentially deter or prolong timely diagnosis. The first barrier was recognized in communication between testing center and patient. Some individuals admitted to having poor communication, if any, with their testing center. Coordinating dates and times that are convenient for both parties is also essential to ensure diagnostic testing is fulfilled. At the time of referral, it could be recommended that the clinic provide coordinating actions between patient and testing center with follow-up phone calls to ensure testing is executed.

A second barrier identified was individual intrinsic factors; unfamiliarity and the inconvenience of sleeping away from home were some reasons given that prohibited the completion of these tests. One high-risk participant admitted to experiencing symptoms of claustrophobia when attempting the study. The unusualness of the testing environment made it difficult for some to see this diagnostic test to completion. Others stated that a lack of privacy at the testing center made it unusually awkward for the patient to rest. Perhaps the intrusiveness of the potential treatment plan (such as using CPAP) regarding couple intimacy could further explain the participants' reluctance toward pursuing the matter beyond the scope of this study.

Portable at-home monitoring is a method that can improve convenience with high efficacy for patients unable or unwilling to undergo a sleep study away from home (Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine, 2009). The National Institute for Health and Care Excellence states that moderate to severe OSA can be

diagnosed from an evaluation and an in-home sleep study using oximetry monitoring devices. At home testing may decrease the barrier in scheduling issues but may not be the best option for those with comorbidities. This option can be used as an alternative to polysomnography in patients with a high pretest probability of moderate to severe sleep apnea without serious comorbid conditions such as congestive heart failure and chronic obstructive pulmonary disease (Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine, 2009).

An important barrier was evident in the data collection process. While interest in participation was high, concern in discussing results was nearly nonexistent. Only one individual of all 54 participants chose to share their results with their provider regardless of risk score. Implementation of a screening tool prior to patient and provider interaction could begin conversations about symptoms that may be difficult for the patient to discuss. This could also assist in discovery of signs that may not be commonly recognized or that may seem benign to the patient.

Strengths and Limitations

Strengths of this project include the racial/ethnic diversity within the sample and 100% participation that although limited, largely represents the clinic patient population. A strength of this study is the collection of rural data particularly of Hispanic/Latina women which suffer from various health disparities, but which data is limited.

Limitations of this study include the underrepresented ethnicities known to this southwestern city and the self-reporting of data that could disrupt accuracy. The short amount of time used to collect data proved to be another limitation.

Conclusions and Recommendations

- There were four participants who were not able to complete their sleep study. This small number is concerning for the purposes of this project. Because of the small representation size, this patient population at Patel Medical Clinic is likely not represented accurately. A larger sample size would prospectively increase the number of participants unable to see their study to completion. This would also provide further information towards identifying barriers preventing successful completion of sleep studies. This is a unique area of need, that requires long term monitoring and frequent evaluation. A recommendation for this clinic would be to assign referral clerks and front desk office staff the duty of assisting patients with sleep study appointments. This would also involve phone call follow-ups between patient and sleep clinics to ensure that this process is thoroughly executed. At the same time, and perhaps the best method for capturing data would be to additionally assign referral clerks and front desk staff the responsibility of keeping track of why patients are not completing their sleep studies and evaluating this data on a weekly basis.
- An additional recommendation would focus on the long-term usefulness of the questionnaire. Future research can be aimed on routine screening which could help demonstrate the effectiveness of pre-sleep study screening. Results can be compared six months to one year later using a retrospective chart review. This could help determine if more patients are then better recognized with this condition. It is recommended to consider the clinic providers' opinions regarding the tool to determine if they find it

effective in their own practice. This information can be useful to adjust the process to better serve the needs of the clinic.

- Women with sleep apnea often present with gender-specific symptoms including fatigue, insomnia, restless leg syndrome, headache, mood disturbances and/or other issues. For this reason, they may benefit more from a focused questionnaire. The screening tool used, although proven effective in the past, is general and used for both men and women. However, a female focused questionnaire that includes female-specific questions addressing atypical symptoms could be beneficial in improving recognition of sleep apnea in women.
- The same process will be recommended as it was performed during this study. As patients check into the clinic for their visit, the medical assistant at the front desk can have each patient who is due to renew their screen fill out the selected paper survey tool. This can be done while they wait to be seen by their provider or at the time they enter the patient room and vital signs are collected. The Electronic Health Record accessed by the medical assistant should have a record of the patients last survey and when it was last completed. Paper surveys filled out by each patient should be returned to the front desk to be entered in to the EHR by staff to keep track of changes that may occur over time. The physical copy can be returned to the patient, so they may have it at hand during their visit. In the EHR, the results of the survey tool should be easily visible and available for review by the provider caring for their patient.

Recommendations for Survey Tool Implementation

- General recommendation
    - The survey tool should be filled out at least once per year for patients meeting criteria with standing order from providers.
    - Or as filled out as recommended by clinic providers
- Staff Training
    - Implementation will begin with the introduction of the survey tool during staff meetings.
    - Provide brief in-services to ensure staff are educated on usefulness of survey.
    - Staff should be instructed to educate patients how it will be used by the providers to determine a patient's need for further evaluation.
    - Ensure that patients understand that this is a not a method of diagnosing sleep apnea.
- Recommendation for Follow-Up
    - Daily follow-up meetings with staff during the first week of implementation to ensure smooth transition.
        - Discuss what is hindering the process
        - Discuss positives and problems encountered because of the tool
    - Encourage discussion of what value the tool has to provider's practice.
        - Daily interviews of clinic providers for first week of implementation

One month, six months and one year follow up with providers and staff to determine if the process requires adjusting.

APPENDIX A:

SURVEY TOOL WITH STOP-BANG QUESTIONNAIRE

1. **Please specify the race you associate as (please check one)**

White or Caucasian	
Black or African American	
American Indian or Alaska Native	
Asian Indian	
Chinese	
Filipino	

Japanese	
Korean	
Vietnamese	
Native Hawaiian	
Guamanian or Chamorro	
Samoan	

Are you a person of Hispanic Latino or Spanish origin?

YES (Please specify)	
No	

Mexican American	
Puerto Rican	
Cuban	
Other Hispanic Latino or Spanish origin	

2. **Please select your age range**

50-59 yrs. of age	60-69 yrs. of age	70-79yrs. of age	80-89 yrs. of age	90yrs. of age and older

3. **Have you ever been diagnosed with sleep apnea?**

YES	NO

4. **Have you ever been recommended to have a sleep study If YES, Did you complete your study? in the past?**

(please check one)

YES	NO

YES	NO

If you answered no, please identify why you were unable to have your study performed

Test Location	Financial Concerns	Scheduling	Transportation	Insurance	Other (please specify)

STOP-Bang Questionnaire

Please answer the following questions below to determine if you might be at risk.

Snoring ?
Do you **Snore Loudly** (loud enough to be heard through closed doors or your bed-partner elbows you for snoring at night)?
Yes

No

Tired ?
Do you often feel **Tired, Fatigued, or Sleepy** during the daytime (such as falling asleep during driving or talking to someone)?
Yes

No

Observed ?
Has anyone **Observed** you **Stop Breathing** or **Choking/Gasping** during your sleep ?
Yes

No

Pressure ?
Do you have or are being treated for **High Blood Pressure** ?
Yes

No

Body Mass Index more than 35 kg/m^2?

Yes

No

Age older than 50?
Yes

No

Neck size (Measured around Adams apple)
For male, is your shirt collar 17 inches / 43cm or larger?
For female, is your shirt collar 16 inches / 41cm or larger?
Yes

No

Gender = Female

1. ¿Cual es el origen étnico que asocia esta persona? (por favor, marque una)

Blanca	
Negra o Africana Americana	
India americana o nativa de Alaska	
India asiática	
China	
Filipina	

Japonesa	
Coreana	
Vietnamita	
Nativa de Hawaii	
Guamaña or Chamorro	
Samoana	

¿Es usted de origen hispano, latino o español?

Si (favor de espicifiquar)	
No	

Mexicano Americano	
Puertorriqueño	
Cubano	
Otro origen hispano, latino o español	

2. **Favor de selector rango de edad**

50-59 años de edad	60-69 años de edad	70-79 años de edad	80-89 años de edad	90 años de edad

3. **¿Alguna vez le han diagnosticado apnea del sueño??**

SI	NO

¿Alguna vez te han recomendado tener un estudio de sueño? Si contesto que si, Pudo completer su studio?

SI	NO

SI	NO

Si contesto que no, cual es la razon que no pudo tener su studio?

Ubicación de prueba	Financial Concerns	Preocupaciones financieras	Transportacion	Seguro	Otras Razones

Cuestionario STOP-Bang actualizado

Ronquidos
¿Ronca fuerte (tan fuerte que se escucha a través de puertas cerradas o su pareja lo codea por roncar de noche)?
SI

No

¿Cansado?
¿Se siente con frecuencia cansado, fatigado o somnoliento durante el día (por ejemplo, se queda dormida mientras conduce)?
SI

No

¿Lo observaron? ¿Alguien lo observó dejar de respirar o ahogarse/jadear mientras dormía?
SI

No

¿Presión arterial elevada?
¿Tiene o está recibiendo tratamiento para la presión arterial elevada?
SI

No

¿Índice de masa corporal de más de 35 kg/m2?
SI

No

¿Tiene más de 50 años?
SI

No

¿El tamaño de su cuello es grande? (Medido alrededor de la nuez de Adán) Si es hombre, ¿el cuello de su camisa mide 17 pulgadas/43 cm o más? Si es mujer, ¿el cuello de su blusa mide 16 pulgadas/41 cm o más?
SI

No

Sexo = Femenino

APPENDIX B:

LICENSE FOR STOP-BANG QUESTIONNAIRE

UHN 2017-0647

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab

Technology Development & Commercialization

NON-EXCLUSIVE ACADEMIC LICENSE

DEFINITIONS:

Organization name (**"Licensee"**): University of Arizona, College of Nursing

Address: PO Box 210203 1305 N Martin, AZ 85721

(**"Licensee Site"**)

Contact person: **Christy Pacheco, DNP, FNP-BC** Job Title: **University of Arizona College of Nursing, DNP Project Committee Chair; CON Rural Health Professions Program Director**

Jesus Arballo RN BSN **DNP-FNP Student**

Contact information:

Christy Pacheco, DNP, FNP-BC
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(o) 520.626.4039
(c) 928.600.7557

Jesus Arballo RN BSN
DNP-FNP Student
jarballo87@hotmail.com
520 249 3076

Proposed Use (check applicable):

☒ Paper questionnaire ☐ Website ☐ Downloadable app

Please elaborate on Proposed Use:

With your permission, this tool would be used in my doctoral project entitled "Sleep apnea in women aged 50 years and older. A cross sectional quantitative survey in a rural clinic in southern Arizona." This project will be used to assess the prevalence of moderate to high risk sleep apnea in women over 50 years of age in a rural internal medicine clinic in southern Arizona. This project is focused on identifying sleep apnea in patients who otherwise may go undetected, as well as help identify associated barriers for timely diagnosis and treatment.

Language(s): English and Spanish

(collectively, the **"Permitted Use"** means Proposed Use and Language,)

"Effective Date": August 15th, 2017

License **"Term"**: One (1) year from the Effective Date.

Licensor: "UHN"
UNIVERSITY HEALTH NETWORK
having a business office at:
Technology Development & Commercialization
101 College Street, Suite 150,
Heritage Building, MaRS Centre,
Toronto, Ontario M5G 1L7
Canada

Notices. Notices must be sent to the attention of:
Director, Technology Development & Commercialization

This license agreement ("Agreement"; and as further defined herein) is made effective as the Effective Date and is between **UHN** and **Licensee** with a business address at **Licensee Site.**

(In this Agreement, UHN and Licensee may be referred to individually as a "Party", or collectively as the "Parties".)

Whereas, UHN owns and controls certain rights, title and interest in the STOP-Bang tool (version 2014) (the "Technology", as further defined herein) developed by UHN Principal Investigator, Dr. Frances Chung, and

Whereas, Licensee wishes to utilize the Technology for specific purposes (the "Permitted Use", as further defined herein), and as such, wishes to license the Technology from UHN for such purposes.

NOW THEREFORE in consideration of the mutual promises, representations, covenants and agreements of the Parties contained herein, the Parties agree as follows:

ARTICLE 1 – INTERPRETATION

1.1 **Further Defined Terms**. For the purposes of this Agreement, unless the context otherwise requires, the following terms shall have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

(a) "**Agreement**" means this license agreement, and all of its Schedules, and the terms "herein", "hereunder", "hereto" and such similar expressions shall refer to this Agreement;

(b) "**Confidential Information**" of a Party means any and all information of and disclosed by, a Party (a "Disclosing Party") which has or will come into the possession or knowledge of the other Party (a "Receiving Party") in connection with or as a result of entering into this Agreement and which is marked as confidential or is identified as confidential at the time of disclosure, including information concerning the Disclosing Party's past, present and future business, research and development, technology, customers and suppliers. Information shall not be considered "Confidential Information" to the extent that the information:

(i) is part of the public domain at the time of disclosure,

(ii) subsequently becomes part of the public domain through no act or fault of the Receiving Party or its agents or employees,

(iii) can be demonstrated by the Receiving Party's written records to have been known or otherwise available to the receiving party prior to the disclosure by the Disclosing Party,

(iv) can be demonstrated by the Receiving Party's written records to have been provided to the Receiving Party, without restriction, by a third party who is not under a duty of confidentiality respecting the information disclosed and who has a legal right to disclose it,

(v) can be demonstrated by the Receiving Party's written records was independently developed by or on behalf of the Receiving Party by persons who had no knowledge of or access to the information disclosed,

(vi) is required to be disclosed by law or an order of a court, tribunal, or government agency, provided that the Receiving Party gives to the Disclosing Party prompt notice of the required disclosure in order to allow the Disclosing Party reasonable opportunity to seek a confidentiality order or the like, or

(vii) is identified in writing by the Disclosing Party as no longer constituting Confidential Information;

(c) **"Generated Data"** means all data, information and any other matter or deliverable arising from the performance of the Permitted Use by the Licensee;

(d) **"Intellectual Property"** or **"IP"** mean inventions (whether patentable or unpatentable), discoveries, written material, information, know-how, trade secrets, designs, formulae, algorithms, concepts, proprietary data, techniques, instructions, processes, procedures, flow charts, logic diagrams, manuals, specifications, instructions, or any copies of the foregoing in any medium, or the expression thereof;

(e) **"License"** shall have the meaning provided in Section 2.1;

(f) **"Licensed Technology"** means the Technology and the UHN Intellectual Property Rights;

(g) **"Technology"** means the processes, procedures and other relevant technical information pertaining to the STOP-Bang Tool (version 2014), including without limitation, the software, data, know-how, drawings, product specifications and other specifications, all as further described in Section II of Schedule "A";

(h) **"UHN Intellectual Property Rights"** or **"UHN IP Rights"** means any rights in which UHN owns, seeks to own and/or seeks to enforce in Technology, including without limitation those rights described in Subsections I(A), (B) and (C) of Schedule "A"

ARTICLE 2 - GRANT OF RIGHTS

2.1 **License Grant**. Subject to the terms and conditions of this Agreement, UHN grants to Licensee a non-exclusive license to use the Licensed Technology solely for the Permitted Use at Licensee Site(s) for the Term (the "License").

2.2 **Prohibited Uses**. Unless otherwise explicitly stated in this Agreement, the Licensed Technology may only be used for information purposes. Licensee shall not have any rights to grant sublicenses to any third party. Licensee shall not use the Licensed Technology in any product or service made available to a third party for purposes of consulting, sale, lease, license or transfer, other than as expressly allowed per the Permitted Use. THE LICENSED TECHNOLOGY MAY NOT BE USED FOR PURPOSES OF THERAPEUTIC OR DIAGNOSTIC USE.

ARTICLE 3 – REPRESENTATIONS, WARRANTIES, LIABILITY AND INDEMNIFICATION

3.1 **REPRESENTATIONS, WARRANTIES AND LIABILITY.** EXCEPT AS OTHERWISE EXPRESSLY SET OUT IN THIS AGREEMENT:

(A) UHN EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, SAFETY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE LICENSED TECHNOLOGY AND IN RESPECT OF ANY GENERATED DATA;

(B) UHN SHALL PROVIDE LICENSED TECHNOLOGY "AS IS". UHN DOES NOT WARRANT OR REPRESENT THAT ISSUED PATENTS ARE VALID, OR PENDING PATENT APPLICATIONS WILL ISSUE, OR WHEN ISSUED WILL BE VALID, OR THAT THE PRACTICE OR EXPLOITATION OF ANY LICENSED TECHNOLOGY, TECHNICAL INFORMATION OR KNOW-HOW DISCLOSED TO LICENSEE PURSUANT TO THIS AGREEMENT DOES NOT, OR WILL NOT, CONSTITUTE INFRINGEMENT OF RIGHTS OF PERSONS NOT PARTIES HERETO;

(C) UHN SHALL NOT BE LIABLE TO LICENSEE FOR ANY DAMAGE, INCLUDING (WITHOUT LIMITATION) ANY DIRECT, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGE SUFFERED BY LICENSEE RESULTING FROM THE USE OF THE LICENSED TECHNOLOGY, TECHNICAL INFORMATION OR KNOW-HOW DISCLOSED TO LICENSEE PURSUANT TO THIS AGREEMENT. FURTHERMORE, UHN MAKES NO REPRESENTATION THAT THE LICENSED TECHNOLOGY, TECHNICAL INFORMATION OR KNOW-HOW DISCLOSED TO LICENSEE PURSUANT TO THIS AGREEMENT, ARE FREE FROM DEFECT OR LIABILITY OF INTELLECTUAL PROPERTY INFRINGEMENT;

(D) LIMITED LIABILITY. UHN'S ENTIRE LIABILITY TO LICENSEE FOR DAMAGES OR ALLEGED DAMAGES HEREUNDER, WHETHER IN CONTRACT, TORT OR ANY OTHER LEGAL THEORY, IS LIMITED TO, AND WILL NOT EXCEED AN AMOUNT EQUAL TO THE SUM OF TOTAL AMOUNTS PAID TO UHN UNDER THIS AGREEMENT. LICENSEE ACKNOWLEDGES THAT UHN LICENSE FEE (IF ANY) REFLECTS THE ALLOCATION OF RISK UNDER THIS AGREEMENT AND THE LIMITATION OF LIABILITY SPECIFIED HEREIN.

3.2 **Indemnification**. Licensee assumes all risks associated with Licensee's use of, or inability to use, the Licensed Technology and in all respects associated with Generated Data. Licensee, for and in consideration of and as a condition to the granting of the License, agrees to indemnify, save harmless, and defend UHN and its directors, officers, research/clinical staff, employees, research trainees, students, and agents (collectively the

"UHN Indemnitees"), against any and all claims, suits, losses, damages, costs, fees, liabilities and expenses (including reasonable legal expenses; collectively the "Indemnified Damages") arising from Licensee's use of the Licensed Technology and in respect of all matters associated with the Generated Data, and otherwise any material breach of this Agreement by Licensee, except and to the extent that such Indemnified Damages arise from the negligence or willful misconduct of the UHN Indemnitee(s). In no event shall UHN (and its directors, officers, research/clinical staff, employees, research trainees, students, and agents) be liable to Licensee for special, indirect or consequential damages, even if UHN has been advised of the possibility thereof, including but not limited to lost profits, lost revenues, failure to realize expected savings or any other commercial or economic loss of any kind.

ARTICLE 4 – FURTHER COVENANTS

4.1 **Licensee.** Licensee covenants and agrees for the benefit of UHN that it shall:

(a) exercise the License granted herein or otherwise use the Licensed Technology and the Generated Data in accordance with all applicable laws, statutes, ordinances, regulations, guidelines and rules, including, all applicable statutes and regulations and applicable guidelines set forth by the Canadian Institutes of Health Research (CIHR), National Institutes of Health (NIH) or other governmental agencies where applicable; and

(b) cause to be applied to, where appropriate, any markings required by applicable government statutes and laws to maintain continued validity and enforcement of UHN Intellectual Property Rights in the Technology; and

(c) ensure that any of its research/clinical staff, employees, research trainees, students, and agents involved with the performance of this Agreement on its (ie. Licensee's) behalf are aware of any and all obligations under this Agreement, including any and all confidentiality obligations and Permitted Use obligations and restrictions, and have agreed to be legally bound by them.

4.2 **UHN.** UHN covenants and agrees for the benefit of Licensee that it shall ensure that any of its research/clinical staff, employees, research trainees, students, and agents involved with the performance of this Agreement on its (ie. UHN's) behalf are aware of any and all obligations under this Agreement, including any and all confidentiality obligations, and have agreed to be legally bound by them.

ARTICLE 5 - INTELLECTUAL PROPERTY

5.1 **UHN Ownership and Patent Prosecution.** Nothing contained in this Agreement shall be construed to convey any right, title or interest of UHN in the Licensed Technology to Licensee other than as specifically stated in this Agreement. Any registration, associated prosecution and maintenance of UHN IP Rights and all other legal rights in the Licensed Technology shall be managed solely by UHN in its discretion.

5.2 **Infringement.** The Licensee shall promptly notify UHN if it has knowledge of any third-party use and/or infringement of Licensed Technology. In the event that a third party brings or asserts a claim against Licensee or UHN that the use of the Licensed Technology infringes rights in Intellectual Property owned or otherwise controlled by such third party, the Parties shall mutually cooperate and/or otherwise provide reasonable assistance in connection to any defence against such claim.

5.3 **No Actions and Challenges.** Licensee agrees to not knowingly take any action which would jeopardize the obtaining or maintaining of UHN Intellectual Property Rights in the Technology. Licensee shall not challenge the validity of any UHN Intellectual Property Rights in the Technology or otherwise any right of UHN to the Licensed Technology.

5.4 **Generated Data.** Licensee shall own all Generated Data. Licensee agrees to furnish UHN with a written report encompassing the Generated Data arising from the Permitted Use on expiration or earlier termination of this Agreement.

5.5 **Translations.** Licensee agrees to provide UHN Principal Investigator and UHN with copies of any language translations of the Licensed Technology along with any relevant validation certificates. Licensee shall grant Dr. Chung and UHN a non-exclusive, perpetual, royalty-free license to use any such language translations for teaching and/or academic research purposes, with a further right to grant sublicenses to third parties for similar such purposes.

ARTICLE 6 – PUBLICATIONS

6.1 **Publications.** Licensee agrees to furnish UHN with a preprint of any publication, or an advance copy of any other disclosure encompassing the Generated Data or other research findings arising from the use of the Licensed Technology. Licensee shall acknowledge Dr. Frances Chung and UHN as the owner of the Licensed Technology in any publication or disclosure, and shall cite the following website www.stopbang.ca.

ARTICLE 7 - CONFIDENTIAL INFORMATION

7.1 **Use of Confidential Information.** The Parties agree that they will only use the Confidential Information of the other solely for the purposes contemplated and in accordance with this Agreement and for no other purpose. The Parties will ensure that their research/clinical staff, employees, research trainees, students, and agents to whom the Confidential Information is disclosed further to performance under this Agreement are informed of the confidential nature of the information and are legally bound to retain such information in confidence. The Parties further agree that, except as required to do so by applicable law or court order, they will not disclose the Confidential Information (or any part therof) of the other Party, and will promptly provide to said other Party written notice if said first Party is legally compelled or otherwise required by law or court order to disclose any part of the Confidential Information, so that said other Party may seek a protective order or take other appropriate action. A Party in receipt of Confidential Information from the other shall maintain any such received Confidential Information in confidence for a period of **three (3) years** from the date of receipt of such Confidential Information.

ARTICLE 8 - TERM & TERMINATION

8.1 **Termination for Breach.** UHN may earlier terminate this Agreement in its sole discretion if the Licensee materially breaches any of its obligations under this Agreement, and upon written notification of such breach fails to, refuses, or cannot remedy the breach to the satisfaction of UHN within thirty (30) days of receipt of such written notice from UHN.

8.3 **Termination by Mutual Consent.** The Parties may earlier terminate this Agreement at any time by mutual consent, which consent shall be evidenced by a written agreement duly executed by the Parties.

8.4 **Post-Termination.** On the expiration or earlier termination of this Agreement:
(a) Licensee shall immediately stops any further use of, and otherwise cease to derive any benefit from, the Licensed Technology; and
(c) if and/or as required, the Parties shall take all necessary steps in a prudent business manner to effect the orderly earlier termination of this Agreement.

ARTICLE 9 – GENERAL

9.1 **Entire Agreement.** The Parties acknowledge that the Agreement and its Schedule is the entire agreement and understanding of the Parties as to the use of the Licensed Technology, and supersedes all prior discussions, agreements and writings in respect hereto.

9.2 **General Assurances.** The Parties agree to do all such things and to execute such instruments and documents as may be necessary or desirable in order to carry out the provisions and intent of this Agreement.

9.3 **Enure to Benefit.** This Agreement shall enure to the benefit of and be binding upon the respective Parties and, where the context admits or requires, their respective permitted successors or assigns.

9.4 **Assignment.** This Agreement cannot be assigned, sold, transferred or encumbered in any manner by Licensee without the expressed written consent of UHN, which consent will not be unreasonably withheld, but any such consent shall be subject to and conditional on the receipt by UHN of any payment owed to UHN.

9.5 **No Use of Names.** Except as required for the purposes of complying with the provisions of this Agreement, Licensee shall not use the name, logo, trade-mark or trade-name of UHN in connection with any publication, publicity, promotion news release, advertising or similar public statements or otherwise without the prior written consent of UHN.

9.6 **Waiver.** No amendment, supplement or waiver of any provision of this Agreement shall be binding on any Party unless consented to in writing by such Party. No waiver of any provision of this Agreement shall constitute a

waiver of any other provision, nor shall any waiver constitute a continuing waiver unless otherwise expressly provided. Further, no failure or delay by any Party in exercising any right or remedy shall operate as a waiver thereof, nor shall any single or partial exercise or waiver of any right or remedy preclude its further exercise or the exercise of any other right or remedy.

9.7 **Severability of Provisions**. In the event that any provision of this Agreement is determined to be invalid or unenforceable by a court of competent jurisdiction in any jurisdiction, the remainder of the Agreement shall remain in full force and effect without said provision in said jurisdiction and such determination shall not affect the validity or enforceability of such provision or the Agreement in any other jurisdiction. The Parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement.

9.8 **Survival**. Articles 1, 3, 6, 7 and 9 in their entirety, and Sections 2.2, 5.1, 5.4, 5.5, 8.4, 9.1, 9.3 through 9.6 and 9.8 shall

survive expiration or earlier termination of this Agreement until such time as specifically stated in a particular Article/Section or until the Parties agree to the release of the obligations (in whole or in part) contained therein.

9.9 **Counterparts**. This Agreement may be executed in counterparts each of which shall be deemed an original but all of which together shall constitute one and the same instrument. The Parties further agree to the exchange of execution of the Agreement in electronic format (e.g. as a "pdf" document).

The Parties are executing this Agreement so as to be effective on the Effective Date.

UNIVERSITY HEALTH NETWORK	**LICENSEE**
Per:	Per:
Name: Dr. Bradly Wouters	Name: Christy Pacheco, DNP, FNP-BC
Title: EVP, Science and Research	Title: University of Arizona College of Nursing, DNP Project Committee Chair
Date:	Date: 8/14/17

SCHEDULE A

Licensed Technology

I. **UHN Intellectual Property Rights**

A. Patent Applications/Issued Patents:

United States Provisional Patent Application No. 61/974,319

Title: SYSTEM AND METHOD FOR SLEEP APNEA ASSESSMENT

Priority date: April 2, 2014.

B. Foreign & Domestic Dependent Applications:

All patent application(s) or issued patents claiming priority to the applications listed in Subsection I(A) of this Schedule A.

C. Continuations, Continuations-in-Part, Divisionals, Renewals, Extensions:

For greater certainty, the UHN Intellectual Property Rights of this Section I shall include:

(i) all continuations and continuations-in-part applications to the patent applications in Subsections I(A) and (B), and all patents issuing therefrom, with the proviso that ownership rights in any continuation-in-part applications and or patents shall only apply to issued claims containing subject matter which can claim the benefit of a priority date of any patent or patent application described in Subsections I(A) or (B);

(ii) all foreign counterparts of any of the foregoing (including without limitation, any European Supplementary Protection Certifications or equivalents);

(iii) all divisionals, patents of addition, reissues, renewals, and/or extensions of any of the patents, patent applications, continuation and continuation-in-part applications set out in any of the foregoing Subsections I(A), (B), (C)(i) and (ii).

II. **Other Intellectual Property**

Processes, procedures and other relevant technical information pertaining to STOP-Bang Tool (version 2014) including without limitation, the software, data, know-how, drawings, product and other specifications, and the like, regardless of format or media or mode or representation.

APPENDIX C:

SITE AUTHORIZATION LETTER

November 30, 2017

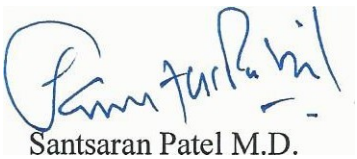
University of Arizona
Human Subjects Protection Program
1618 E. Helen St. P.O. Box 210409
Tucson AZ, 85721

Dear Human Subjects Protection Program Members,

This is to certify that Jesus Arballo RN BSN, Doctor of Nursing Practice, Family Nursing Practitioner student at the University of Arizona College of Nursing, has permission to conduct a quality improvement project entitled Sleep Apnea in Women aged 50 Years and Older: A Cross Sectional Quantitative Survey in a Rural Clinic in Southern Arizona.

The study will be physically conducted at our facility, Patel Medical Clinic, located at 1620 East Wilcox Drive in Sierra Vista, Arizona. Mr. Arballo will be conducting an on-site survey of our clinic patients. It is anticipated that data will occur during the Winter 2017/ Spring 2018. I understand that Mr. Arballo will be conducting this quality improvement following IRB review from the University of Arizona.

Sincerely,



Santsaran Patel M.D.
Clinic Director/ Owner
Patel Medical Clinic
520 459 0362

APPENDIX D:

DISCLOSURE FORM

DISCLOSURE FORM

Introduction

My name Jesus Arballo. I am a Doctor of Nursing Practice, Family Nurse Practitioner student at the University of Arizona, College of Nursing.

Purpose of Project

I am doing a Quality Improvement project at Patel Medical Clinic to see how effective it is to screen for sleep apnea in women 50 years of age and older. This project will be used to identify women that are at risk of having sleep apnea and identify which women are at highest risk so that they are not overlooked.

Why are you being asked to participate?

You are being invited to participate because you may fit the criteria of the patients this project is focused on.

Description of the project:

We will survey a minimum of 50 women using a questionnaire. The results from this questionnaire will provide information that will help better evaluate women who may be at risk for sleep apnea in hopes of achieving early diagnosis and treatment. This project will also help get an understanding of what difficulties people have getting treated for sleep apnea.

Are there any risks?

Risks are minimal. The survey is anonymous and only summary findings will be shared with the providers at Patel Medical Clinic.

This project is being reviewed by the University of Arizona Institutional Review Board to be sure participants are protected.

What are the benefits?

The benefits of the study will be to improve identification of sleep apnea in women so that timely diagnosis and treatment is possible.

You may request a copy of you questionnaire to further discuss with your provider at your discretion.

The study is voluntary

You may decide not to participate or stop participating at any time. By completing the survey, you are consenting (agreeing) to participate.

For any questions, please contact

Jesus Arballo RN BSN
(520) 249 3076

FORMA DE DIVULGACION

Introduccion

Mi nombre es Jesus Arballo. Soy estudiante de la Escuela de Enfermeria de la Universidad de Arizona.

Proposito del Proyecto

Estoy haciendo un proyecto de mejoramiento en la Clinica Medica de Patel para demonstrar que tan efectivo es examinar a las mujeres de 50 anos o mayor de edad para la detecion de apnea del sueno. Este proyecto sera utilizado para identificar a las mujeres que estan a riesgo de tener apnea del sueno y para identificar a cuales mujeres tienen el mayor riesgo de ser pasadas por alto.

Porque le piden que participe?

Usted es invitada a participar porque puede ser que usted cumpla con los criterios de los pacientes en los que este proyecto esta enfocado.

Descripcion del Proyecto

Vamos a encuestar un minimo de 50 mujeres utilizando un cuestionario. Los resultados de este cuestionario proporcionaran informacion que ayudara para evaluar mejor a las mujeres que estan a riesgo de apnea del sueno con la esperanza de adquirir a tiempo un diagnostico y tratamiento. Este proyecto tambien ayudara a obtener un mejor entendimiento de cuales dificultades tienen las personas que estan recibiendo tratamiento para apnea de sueno.

Hay Riesgos?

Los riesgos son minimos. La encuesta es anonima y solamente las conclusiones resumidas seran compartidas con los proveedores de la Clinica Medica de Patel.

Este proyecto sera revisado por la Junta de Revision Institucional de la Universidad de Arizona para asegurar que los derechos de los participantes esten protegidos.

Cuales son los Beneficios?

Los beneficios de este estudio seran para mejorar la identificacion de apnea de sueno en las mujeres para que el diagnostico y el tratamiento sean posibles y se adquiran a tiempo.

Puede usted solicitar una copia de la encuesta para discutir ampliamente con su proveedor a su propia discrecion.

El estudio es voluntario

Usted puede decidir no participar o puede dejar de participar en cualquier momento. Al completar la encuesta, usted esta consintiendo a participar en este estudio.

Si tiene preguntas, favor de ponerse en contacto con:

Jesus Arballo RN BSN
(520) 249-3076

APPENDIX E:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

Research
Office for Research & Discovery

Human Subjects Protection Program

1618 E. Helen St.
P.O. Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	December 22, 2017
Principal Investigator:	Jesus Marvin Arballo
Protocol Number:	1712143894
Protocol Title:	SLEEP APNEA IN WOMEN AGED 50 YEARS AND OLDER: A CROSS SECTIONAL QUANTITATIVE SURVEY IN A RURAL CLINIC IN SOUTHERN ARIZONA
Determination:	Human Subjects Review not Required

The project listed above does not require oversight by the University of Arizona because the project does not meet the definition of 'research' and/or 'human subject'.

- **Not Research as defined by 45 CFR 46.102(d):** As presented, the activities described above do not meet the definition of research as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "research means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge".
- **Not Human Subjects Research as defined by 45 CFR 46.102(f):** As presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention ***or*** interaction with the individual, or identifiable private information".

Note: Modifications to projects not requiring human subjects review that change the nature of the project should be submitted to the Human Subjects Protection Program (HSPP) for a new determination (e.g. addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the research question). Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

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