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Effect of Telemonitoring and As Needed Patient Support on PAP Adherence

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Effect of Telemonitoring and As Needed Patient Support on PAP Adherence

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Abstract

Obstructive sleep apnea (OSA) is an increasingly recognized condition affecting patient health and public welfare. While positive airway pressure (PAP) therapy has remained the preferred treatment for OSA since 1981, PAP therapy adherence rates have also remained stubbornly suboptimal. Measures for improving PAP therapy adherence have been under constant study, and current literature demonstrates telemonitoring interventions to be promising. Furthermore, the American Academy of Sleep Medicine (AASM) suggests that telemonitoring interventions be integrated into standard practice to support patients as they initiate and acclimate to PAP therapy. This quality improvement project examined the effect of interval PAP data telemonitoring and as needed (data triggered) patient support via telephone consultation(s) at two- and/or four-weeks post therapy initiation in patients with moderate to severe OSA. Compared to standard practice, this intervention resulted in significantly higher mean PAP adherence and a greater percentage of participants demonstrating continued PAP usage at 90 days post therapy initiation. The project's results reflected those reported in the literature but did not result in a statistically significant increase in what is considered and defined as "good PAP adherence."

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Chapter 1: Introduction and Background

Background

Obstructive sleep apnea (OSA) is an increasingly recognized pathophysiological condition associated with significant morbidity and mortality (Frost & Sullivan, 2016; Patil et al., 2019). In OSA, upper airway patency is compromised by repeated obstructions within the pharynx leading to recurrent pauses in breathing (apneas and hypopneas) and oxygen desaturations. These obstructions and subsequent desaturations disrupt sleep and put undue stress on the body (Riha, 2021).

Risk factors for OSA include obesity, advanced age, male gender, post-menopausal status in women, race (with African Americans, Asians, and Hispanics disproportionally affected) and craniofacial dysmorphisms (Patil et al., 2019). Signs and symptoms of OSA include snoring, witnessed apneas, urinary frequency, insomnia, unrefreshing sleep, excessive daytime sleepiness, morning headaches or muscle aches, difficulty concentrating, and changes in mood (Frost & Sullivan, 2016; Patil et al., 2019). Untreated OSA is associated with compromised health and wellbeing, increased health care utilization, higher rates of accidents and errors, and reduced productivity (Frost & Sullivan, 2016; Patil et al., 2019; Wickwire et al., 2020). The personal and global effects of persistent untreated OSA are dire.

OSA is categorized as either mild, moderate, or severe based on the number of respiratory pauses observed per hour via in-laboratory polysomnography or in-home sleep apnea testing; however, how these respiratory pauses are captured, defined, and graded varies (Berry et al., 2022; CMS, n.d.). For in-laboratory polysomnograms (PSGs), there are currently two competing indices used to define respiratory pauses, Medicare's apnea

hypopnea index (AHI) and the American Academy of Sleep Medicine's (AASM's) respiratory disturbance index (RDI) (Berry et al., 2022; CMS, n.d.; Riha, 2021). Per Medicare, an apneic event is defined by a complete cessation of airflow for ≥ 10 seconds, and a hypopnea is defined as a 30% or greater reduction in airflow for 10 or more seconds with a ≥4% oxygen desaturation (CMS, n.d.; Riha, 2021). Per the AASM, an apnea is defined as a 90% or greater reduction in airflow for ≥ 10 seconds, and a hypopnea is defined as a 30% or greater reduction in airflow for 10 or more seconds with a ≥ 3% oxygen desaturation (Berry et al., 2022; Riha 2021). By these definitions, the AASM provides a more sensitive threshold for identifying and capturing respiratory events. Thus, a PSG's RDI will be either equal to or greater than its AHI, and it is argued that the clinical validity of these indices should be judged by their ability to identify symptomatic milder patients who would benefit from treatment. Furthermore, while dual scoring (PSG interpreted by both AHI and RDI) is recommended by the AASM, this is not standard practice for all laboratories (Berry et al., 2022).

In lab PSGs are the gold standard for diagnosing OSA, but in-home sleep apnea tests (HSATs) are increasingly preferred by payors and patients alike for their cost savings and convenience. HSATs are validated for the diagnosis of OSA and have high specificity but lower sensitivity as the data they provide is limited. Unlike PSGs, HSATs do not allow for electroencephalography (EEG) monitoring; and, consequently, total sleep time and arousals cannot be objectively measured. HSATs must rely on study recording time, not actual sleep time, when estimating the hourly respiratory event index (REI), which is calculated by dividing the total number of apneas and hypopneas captured during a study by the study's recording time. For this reason, HSATs often overestimate total sleep time and underestimate

OSA severity, increasing the risk for OSA misclassification and false negative results (Claman & Sunwoo, 2017).

All told, there are three indices by which respiratory pauses can be scored and OSA diagnosed (or misdiagnosed): AHI, RDI, and REI. Only two of these indices, however, are used to determine eligibility for treatment coverage, the PSG's AHI and HSAT's REI. Although the AASM's more sensitive RDI would allow a wider spectrum of symptomatic patients to qualify for treatment, this index is not currently acknowledged by payors (Berry et al., 2022; Riha, 2021). An AHI or REI of 5 to 14, 15 to 29, and ≥ 30 support the diagnosis of mild, moderate, and severe OSA, respectively. Treatment is recommended for patients with moderate to severe OSA regardless of comorbid status or symptomatology (CMS, n.d.). For those with mild OSA to qualify for treatment, associated symptoms (i.e., excessive daytime sleepiness, impaired cognition, insomnia, etc.) or comorbidities (i.e., hypertension, ischemic heart disease, or history of stroke) must be documented (CMS, n.d.).

For over 40 years, positive airway pressure (PAP) therapy has been the gold standard for OSA treatment (Patil et al., 2019). Unfortunately, although noninvasive and efficacious, PAP therapy adherence remains suboptimal, reported anywhere from 30% to 80% (Aardoom et al., 2020; Patil et al., 2019). Recent advances in PAP technology, however, may offer a solution to this predicament, with newer devices capable of remote electronic data transmission and manipulation (ResMed, 2021).

The AASM's "Good Practice Statements" (as cited by Patil et al., 2019), affirm that (1) "Treatment of OSA with PAP therapy should be based on a diagnosis of OSA established using objective sleep apnea testing" (p. 335), and (2) "Adequate follow-up, including troubleshooting and monitoring of objective efficacy and usage data to ensure adequate

treatment and adherence should occur following PAP therapy initiation and during treatment of OSA" (p. 335). It is important to objectively test patients screened to be at risk for OSA and, for those meeting the diagnostic criteria, provide the support required to promote successful PAP therapy adoption and adherence. Developing and integrating PAP telemonitoring protocols into current practice can provide additional support to OSA patients as they initiate and acclimate to therapy, ultimately, improving PAP therapy adherence (Patil et al., 2019).

Significance

Prevalence and Costs

Twelve percent of adults are estimated to have OSA, however 80% of these adults are untreated. Currently, an approximate 5.9 million adults within the United States (US) are diagnosed with OSA but 23.5 million remain undiagnosed (Frost & Sullivan, 2016). Per Frost and Sullivan (2016), untreated OSA cost the US approximately $149.6 billion in 2015; and, while the diagnosis and management of OSA can be expensive, treatment costs are estimated to be 33% of those associated with untreated OSA. In the US, older adult Medicare beneficiaries with untreated OSA have demonstrated increased healthcare utilization and costs across all points of service (inpatient, outpatient, emergency department, and prescription claims) (Wickwire et al., 2020). However, given the direct and indirect costs associated with untreated OSA, precisely defining the financial burden it poses to the individual, healthcare system, and nation can be challenging; despite clinical research demonstrating a strong correlation between OSA and quality of life indicators, it is difficult to quantify the effects and costs of this condition on these more abstract aspects (Frost &

Sullivan, 2016; Patil, 2019). Considering these factors, the personal, societal, and economic repercussions of untreated OSA are substantial.

Untreated OSA is associated with reduced quality of life, activation of the sympathetic nervous system, endothelial and metabolic dysfunction, cardiovascular disease, and neurocognitive impairment (Frost & Sullivan, 2016; Patil et al., 2019). Individuals with untreated OSA are at increased risk of hypertension, heart disease, diabetes, strokes, asthma and other pulmonary conditions, insomnia, daytime sleepiness, and mood disorders (e.g., anxiety, depression, etc.) as well as motor vehicle accidents (MVAs) and other work and non-work-related accidents, compromising the safety and well-being of those with OSA and those around them (Hirsch Allen, 2015; Frost & Sullivan, 2016; Patil, 2019). In 2015, the cost of OSA associated MVAs was estimated at $26.2 billion while the cost associated with non-vehicular workplace accidents (e.g., injuries and errors) were estimated at $6.5 billion (Frost & Sullivan, 2016).

Untreated OSA is linked to increased absenteeism and presenteeism, leading to reduced productivity. Productivity loss associated with untreated OSA was estimated at $86.9 billion in 2015 and, by this measure, accounts for 77.4% of the total cost burden of OSA. On average, for each adult receiving OSA treatment, work absences decline by 1.8 days and productivity rises by 17.3% per annum. Subsequently, the aggregate costs associated with untreated OSA are profound, while the successful management of OSA promises improved personal, social, and economic welfare (Hirsch Allen, 2015; Frost & Sullivan, 2016). Therefore, effective OSA screening, diagnosis, and treatment is critical to curtailing the considerable repercussions of this condition.

Intention to Treat

Prior to the introduction of positive airway pressure (PAP) therapy in 1981, the most effective means of treating OSA was by tracheostomy (Patil et al., 2019). Today, alternate treatment options for OSA include weight loss, oral appliances (mandibular advancement devices), positional therapy, nasal resistance devices, upper airway surgery (uvulopalatopharyngoplasty), muscle stimulation, hypoglossal nerve stimulation (Inpsire), maxillomandibular advancement, genioglossus advancement, pharmacotherapy, and combination therapy; yet, despite these many alternatives, PAP therapy remains the preferred and most consistently effective mode of treatment (Patil et al., 2019; Randerath et al., 2022).

Although the preferred and most effective treatment for OSA, PAP therapy adherence rates remain suboptimal and, while promoting OSA screening is important, if effective treatment cannot be meaningfully implemented, improved diagnostics hold limited value. Consequently, the medical community's ongoing battle to improve PAP therapy adherence persists (Patil et al., 2019; Shaukat et al., 2022).

Nonadherence has been linked to a variety of factors, including lack of patient awareness of and appreciation for the risks of untreated OSA and the importance of treatment, complexity of treatment, provider-patient communication, and patient education (Shaukat et al., 2022). Predictors of nonadherence include lower socioeconomic status, poor self-efficacy, social isolation, younger age, and OSA severity (moderate to severe OSA) (Shaukat et al., 2022). Additionally, treatment success (or lack thereof) is often established within days to weeks of initiating therapy, with an average nightly PAP usage of <4 hours predictive of treatment failure (Patil et al., 2019; Shaukat et al., 2022). Conversely, it is

considered well established that those who demonstrate good PAP adherence in the short-term will demonstrate good PAP adherence in the long-term (Patil et al., 2019).

With PAP therapy continually evolving, the newest devices use machine learning technology to automatically adjust pressure delivery according to individual needs and wireless technology to transmit therapy data and manipulate device settings (ResMed, 2021). Thus, PAP therapy can be monitored and titrated remotely; and this telemonitoring capability offers healthcare providers the opportunity to observe the AASM's recommendation to better support patients as they initiate and acclimate to treatment (Patil et al., 2019).

Clinical Question

In adult patients initiating PAP therapy for the management of OSA, how do telemedicine guided interventions in conjunction with current practice, compared to current practice alone, affect PAP therapy adherence?

Current research literature indicates that telemonitoring protocols can enhance patient care and improve PAP therapy adherence (Aardoom et al., 2020; Carlucci & Thanavaro, 2019; Chen et al., 2020; Hoet et al., 2017; Hwang et al., 2018; Kotzian et al., 2019; Labarca et al., 2021; Sedkaoui et al., 2015; Patil et al., 2019). Furthermore, the 2019 American Academy of Sleep Medicine's (AASM's) (as cited in Patil et al., 2019) clinical practice guideline "suggests that clinicians use telemonitoring guided interventions during the initial period of PAP therapy in adults with OSA" (p. 341). However, while PAP therapy telemonitoring protocols are supported, the details of these protocols and methods for implementation have yet to be established.

Evidence Based Practice

In controlled trials, Carlucci & Thanavaro (2019), Hoet et al. (2017), Hwang et al. (2018), Kotzian et al. (2019), and Sedkaoui et al. (2015) demonstrated improved PAP therapy adherence in OSA patients who received supplemental telemedicine interventions, in addition to standard practice, compared to those who received standard practice alone. While Chumpangern et al. (2021), Contal et al. (2021), Fernandes et al. (2019), Fields et al. (2016), Isetta et al. (2015), Luto et al. (2019), Murase et al. (2020), Rattray et al. (2020), Schoch et al. (2019), Tamisier et al. (2020), and Turino et al. (2017) demonstrated telemedicine replacement interventions to be noninferior to standard practice. Aardoom et al. (2020), Chen et al. (2020), Labarca et al. (2021), and Patil et al.'s (2019) systematic reviews with meta-analysis evaluated studies exploring various telemedicine technologies as either add-on or replacement protocols; and each of these reviews demonstrated subsequent improvement in PAP adherence.

With telemedicine as replacement care appearing to be, at least, equivalent to standard practice and telemedicine as add-on care appearing to be superior to standard practice, the effect of follow-up frequency and intensity on PAP adherence has also been studied. Askland et al. (2020), Bakker et al. (2016), Bouloukaki et al. (2014), Murase et al. (2020), and Patil et al. (2019) demonstrated that closer follow-up and the additional support it offers resulted in improved PAP adherence. Thus, telemedicine interventions can be used to enhance care by providing additional support to OSA patients initiating PAP therapy and, ultimately, improving treatment adherence.

Given this evidence as well as the AASM's (2019) suggestion that telemonitoring guided interventions be utilized during PAP initiation, a quality improvement (QI) project

was proposed, implemented, and evaluated at the Thomas Jefferson University Sleep Disorders Center in Philadelphia, Pennsylvania to evaluate the effect of telemonitoring and as needed patient support on PAP therapy Adherence.

Goals of Project

The proposed QI project examined the effect of interval telemonitoring of PAP therapy data at two and four weeks after treatment initiation in adult patients with moderate to severe OSA with as needed patient support and troubleshooting by telephone consultation in addition to standard practice of a 30-to-90-day in-office or telemedicine follow-up visit on 90-day PAP therapy adherence. The effect of this telemonitoring intervention (telemonitoring alongside standard practice) on 90-day PAP therapy adherence was compared to standard practice alone. In addition to PAP adherence, therapy effect (apneic control) and patient reported daytime sleepiness was also monitored and evaluated.

Conceptual Model

Introduced in 1966, Donabedian's conceptual model provides a framework for examining health care services and evaluating quality of care, and this model was used to guide the project's development, implementation, and evaluation (Donabedian, 2005; Donabedian 2014). The Donabedian model directs the design and implementation of health care interventions in a manner that seeks to identify a cause-and-effect relationship and aims to deduce the probability of a relationship between an intervention and its effect quantitatively and qualitatively. To do this, Donabedian (2005) proffers three categories by which health care interventions can be assessed and compared: structure, process, and outcomes. Structure refers to the context in which the care is delivered; process refers to the transactions which occur between two parties (the providers and recipients of care or

beneficiaries of an intervention); and outcome refers to the effect of a healthcare delivery system or intervention. Donabedian emphasizes that each of these categories does not exist in isolation; rather, each influences the other, and only together do they offer a comprehensive framework for evaluating quality of care (Donabedian, 2005; Donabedian, 2014).

Moreover, although the Donabedian model was developed and is proposed as a means for evaluating quality of medical care, Donabedian cautions that quality of care is a remarkably difficult notion to define. What is considered good quality of care may vary depending on context, culture, and community or individual values. Further complicating this task, Donabedian (2014) warns, is human bias; and, as such, asks that "the distinction between values, and elements of structure, process or outcome, [be] recognized and maintained; and that both [be] subjected to equally critical study" (p. 721). By better understanding and appreciating the intricacies and nuances of health care delivery, quality of care can, in turn, be better understood and more accurately evaluated (Donabedian, 2014). Today, Donabedian's thoughtful and dynamic approach to evaluating quality of care remains a primary paradigm utilized in healthcare (Finkelman, 2022).

Summary

The personal, societal, and economic repercussions of untreated OSA are substantial. It is associated with higher rates of morbidity and mortality; it risks both individual health and public safety; and its associated costs well exceed those of OSA treatment (Frost & Sullivan, 2016; Patil et al., 2019). For over 40 years, PAP therapy has remained the preferred and most effective treatment for OSA, but therapy adherence remains suboptimal. Improving therapy adherence is necessary to reduce the threat posed by untreated OSA, and

recent advances in PAP technology may offer a solution. The integration of PAP telemonitoring protocols alongside current practice can provide additional support to patient's initiating therapy and improve treatment adherence (Patil et al., 2019). Consequently, the effect of interval telemonitoring of PAP therapy data at two and four weeks after treatment initiation in adult patients with moderate to severe OSA with as needed patient support by telephone consultation in addition to standard practice of a 30-to-90-day in-office or telemedicine follow-up visit on 90-day PAP therapy adherence was studied and evaluated.

Chapter 2: The Literature Review

Introduction

Obstructive sleep apnea (OSA) is an increasingly recognized chronic condition affecting 26% of the United States population and is associated with unrefreshing sleep, daytime sleepiness, motor vehicle accidents, obesity, diabetes, cardiovascular disease, stroke, and many other conditions including death (Patil et al., 2019). Positive airway pressure (PAP) therapy, first introduced in 1981, has become and remains the gold standard of treatment despite advances in surgical interventions and the availability of various validated devices serving as potential alternative treatment options. Unfortunately, patients often struggle to acclimate to PAP therapy, resulting in poor adherence and treatment discontinuation (Patil et al., 2019). The direct and indirect costs of untreated OSA are considerable. Consequently, improved PAP adherence can reduce the health-related complications and costs associated with untreated OSA, relieving demands on our healthcare system and the corresponding economic burden (work absences and sleep related accidents and errors) (Bouloukaki et al., 2014, De Benedetto et al., 2017; Frost & Sullivan, 2016; Wickwire et al., 2020). To enhance the care and support available to patients initiating PAP therapy for the management of OSA, telemedicine holds immense potential.

Translated, telemedicine means healing at a distance. The World Health Organization (WHO) defines telemedicine as the delivery of healthcare services at a distance, using information and communication technologies (ICT) to exchange “information for diagnosis, treatment and prevention of disease and injuries... in the interest of advancing the health of individuals and their communities” (WHO, 2010, p. 9). Today, advances in technology have enabled remote monitoring of PAP therapy data (device usage and therapy effect). PAP

usage is measured by the number of hours per night and proportion of nights the device is worn (Aardoom, 2020). PAP adherence is determined by the proportion of nights the device is used for four or more hours with "good PAP adherence" defined as a minimum of four hours of PAP usage a day, ≥ 70% of days (CMS, n.d.). Therapy effect is measured by the control of airway obstructions – by the residual apnea hypopnea index (AHI); a baseline AHI of less than five is considered within normal limits. Consequently, a residual AHI of less than five indicates effective therapy (Berry & Wagner, 2015). The ability to monitor PAP data remotely, coupled with the growing acceptance of telemedicine, offers new opportunities to support and care for patients initiating PAP therapy. In fact, the 2019 American Academy of Sleep Medicine's (AASM's) clinical practice guideline "suggests that clinicians use telemonitoring guided interventions during the initial period of PAP therapy in adults with OSA" (Patil et al., 2019, p. 341); and, in recent years, the effect of telemedicine interventions on PAP therapy adherence has been widely studied.

In this chapter, the literature exploring the effect of telemedicine interventions on PAP adherence will be synthesized and reviewed. Study duration, participant demographics, standard practices, telemedicine technologies as well as the effect of telemedicine interventions and follow-up intensity and support on PAP adherence will be evaluated and the implications of study findings to clinical practice discussed.

Literature Search

A comprehensive search of the literature was performed from February 2022 through March 2022. Seeking to answer the PICOT question, "In adult patients initiating PAP therapy for the management of OSA, how does telemedicine guided intervention in conjunction with current practice compared to current practice alone affect PAP adherence

within the first 90 days of therapy?," the CINAHL, PubMed, Cochrane library, and TRIP databases were searched. Search terms included: *obstructive sleep apnea, obstructive sleep apnoea, OSA, telemonitor, telemonitoring, telehealth, telecare, telemedicine, positive airway pressure therapy, continuous positive airway pressure therapy, PAP, CPAP, adherence, compliance, follow-up, intensity, and frequency*. Search limiters included: *literature published no later than 2015, academic literature, peer-reviewed, English language, and all adults*.

Combined, the database searches exposed 151 potentially relevant articles which, upon removal of duplicates and articles identified as ongoing research, condensed to 49. Additional articles were excluded that demonstrated a substandard level of evidence (< level III), were non-research (opinion or correspondence) publications, or compared telemedicine technologies without a standard practice (usual care) arm.

Finally, although the search was limited to articles published from 2015 onwards, an exception was made for Bouloukaki et al.'s (2014) identified through the final selection of articles, amongst which it was frequently cited and referenced. Of note, many of the articles selected for this literature review referenced each other – that is, later works often cited and referenced earlier works included in this review.

Ultimately, 25 robust journal articles were included: three controlled trials without randomization (Carlucci & Thanavaro, 2019; Frasnelli et al., 2016; Rattray et al., 2020), sixteen randomized controlled trials (RCTs) (Bakker et al., 2016; Bouloukaki et al., 2014; Chumpangern et al., 2021; Contal et al., 2021; Fernandes et al., 2021; Fields et al., 2016; Hoet et al., 2017; Hwang et al., 2018; Isetta et al., 2015; Kotzian et al., 2019; Lugo et al., 2019; Murase et al., 2019; Schoch et al., 2019; Sedkaoui et al., 2015; Tamisier et al., 2020;

Turino et al., 2017), and six systematic reviews with meta-analysis (Aardoom et al., 2020; Askland et al., 2020; Chen et al., 2020; Labarca et al., 2021; Murphie et al., 2019; Patil et al., 2019). Twenty of the articles primarily explored the effect of various telemedicine interventions as either replacement or add-on to standard practice (usual care) on PAP adherence (Aardoom et al., 2020; Carlucci & Thanavaro, 2019; Chen et al., 2020; Chumpanger et al., 2021; Contal et al., 2021; Fernandes et al., 2021; Fields et al., 2016; Frasnelli et al., 2016; Hoet et al., 2017; Hwang et al., 2018; Isetta et al., 2015; Kotzian et al., 2019; Labarca et al., 2021; Lugo et al., 2019; Murphie et al., 2019; Rattray et al., 2020; Schoch et al., 2019; Sedkaoui et al., 2015; Tamisier et al., 2020; Turino et al., 2017). Three of the articles primarily focused on the influence of follow-up intensity and support on PAP adherence (Askland et al., 2020; Bakker et al., 2016; Bouloukaki et al., 2014). One systematic review sought to answer several PICO questions, two of which were pertinent to this review: (1) the effect of troubleshooting interventions and (2) PAP monitoring interventions on PAP adherence (Patil et al., 2019). Another study compared the effect of telemedicine and follow-up visit frequency on PAP adherence (Murase et al., 2020).

Although the literature is plentiful, no study replications were found. However, while the studies were diverse, each evaluated some variation of telemedicine and a specified follow-up protocol. Despite designs and methodologies varying widely, when combined and compared, certain trends emerged.

Study Duration (Length of Follow-up)

Most studies examining PAP adherence focused on patients newly diagnosed with OSA and initiating PAP therapy for the first time (PAP naïve patients). This trend is seen in the systematic reviews and controlled trials selected for this review. Of the included

controlled trials, 18 of the 19 studies focused on PAP naïve patients. Only one study by Murase et al. (2020) sought to explore the effect of telemedicine interventions on PAP adherence in established patients – patients currently on PAP therapy for a minimum of three months. Additionally, most studies were short-term, none of the studies extended beyond two years and most were limited to a follow-up of less than six months (15 of the 19 controlled trials). Specifically, follow-up was limited to one month in three studies (Chumpangern et al., 2021; Fernandes et al., 2019; Frasnelli et al., 2015), three months in six studies (Carlucci & Thanavaro, 2019; Fields et al., 2016; Hoet et al., 2017; Hwang et al., 2018; Lugo et al. 2019; Turino et al., 2017), four months in one study (Sedkaoui et al., 2015), six months in five studies (Isetta et al., 2015; Murase et al., 2020; Rattray et al., 2020; Schoch et al., 2019; Tamisier et al., 2020), one year in three studies (Contal et al., 2021; Bakker et al., 2016; Kotzian et al., 2019), and two years in one study (Bouloukaki et al., 2014) .

Of note, it is generally accepted that patients who achieve good adherence in the first weeks to months of PAP therapy will demonstrate good adherence in the long-term (Patil et al., 2019). However, given the paucity of long-term studies, this theory has yet to be truly tested and validated. Long-term studies would offer greater insight on the variables affecting PAP adherence over time.

Participant Demographics and Sample Sizes

All the controlled trials for this review included adult patients (≥18 years) diagnosed with OSA by in laboratory polysomnogram (PSG) or home sleep apnea testing (HSAT). Also, as mentioned, baring Murase et al.'s (2020) study examining therapy adherence in PAP established patients, the studies included in this review focused on adherence in PAP naïve patients. Most studies excluded patients with central sleep apnea (CSA), parasomnias,

significant cardiovascular and lung disease, obesity hypoventilation syndrome, cognitive impairment, psychiatric disorders, and/or language barriers. The only exceptions were Kotzian et al. (2019) who studied the effect of proactive telemedicine monitoring on PAP adherence in stroke patients and Bakker et al. (2016) who studied the effect of motivational enhancement on PAP adherence in patients with or at risk for cardiovascular disease. Thus, as studies largely excluded patients with advanced comorbidities and/or coexisting sleep disorders, the applicability of these studies to increasingly complex, multimorbid patient populations is unknown.

Although the literature search was limited to include only articles published in English, the studies included were performed across the globe from the United States to Switzerland, Spain, France, Portugal, Austria, Greece, Thailand, and Japan. Varying cultural norms as well as healthcare systems and standards of care may have influenced individual study findings and, subsequently, limit their generalizability. Furthermore, with all included controlled trials conducted through urban healthcare centers, most study findings may not be applicable to more rural populations. Rattray et al. (2020) was the only study with a patient population classified as either rural or highly rural.

Fourteen of the controlled trials were single center, conducted at one specific clinical practice or within a particular hospital system (Carlucci & Thanavaro, 2019; Chumpangern et al., 2021; Contal et al., 2021; Bouloukaki et al., 2014; Fernandes et al., 2019; Fields et al., 2016; Frasnelli et al., 2015; Hoet et al., 2017; Hwang et al., 2018; Kotzian et al., 2019; Lugo et al., 2019; Rattray et al., 2020; Schoch et al., 2019; Turino et al., 2017), while five were multicenter, performed at multiple unaffiliated practices or hospital institutions (Bakker et al., 2016; Isetta et al., 2015; Murase et al., 2020; Sedakaoui et al., 2015; Tamisier et al.,

2020). Sample sizes ranged widely from 28 to 31000 participants. Thirteen of the 19 controlled trials describe using power analysis to determined sample size, setting alpha at < 0.05 ($p = 0.05$) and power at 70% to 80% (Bakker et al., 2016; Chumpangern et al., 2021; Contal et al., 2021; Fields et al., 2016; Hwang et al., 2018; Isetta et al., 2015; Kotzian et al., 2019; Lugo et al., 2019; Murase et al., 2019; Schoch et al., 2019; Sedkaoui et al., 2015; Tamisier et al, 2020; Turino et al., 2017). With anticipated drop-out rates of five to 15%, most studies succeeded in capturing their estimated sample size. Bakker et al. (2016), Hwang et al. (2018), and Murase et al.'s (2020) samples well exceeded their calculated estimates by 329, 273, and 183 subjects respectively; however, Tamisier et al. (2020) failed to reach their estimated sample size, reducing the validity, and limiting the utility of this study's findings. Bouloukaki et al. (2014) conducted the longest and largest study, recruiting 31000 patients over the course of 4 years (with each subject followed for two years). Although no power analysis is mentioned in the publication, the large sample size likely allowed for a small effect size and sufficient sensitivity to detect any significant relationships between the variables under investigation – giving its findings statistical power.

Standard Practice

Standard practice, typically referred to as "usual care," was diverse between studies. All participants were diagnosed with OSA either by in-laboratory PSG or HSAT and were typically seen in-office prior to PAP initiation to review their study results and receive education on OSA and PAP therapy. PAP device setup and education was performed in person either through the sleep provider's office or the durable medical equipment (home care) company. However, some studies performed in laboratory PAP titrations to assess pressure settings (fixed or automated) and determine appropriate mask interface prior to

setup (Chumpangern et al., 2021; Hoet et al., 2017; Isetta et al., 2015; Lugo et al., 2019). When specified, many studies reported using ResMed devices (Chumpangern et al., 2021; Fernandes et al., 2015; Hwang et al., 2018; Kotzian et al., 2019; Rattray et al., 2020; Turino et al., 2017), two studies used Philip Respironics devices (Fields et al., 2016; Lugo et al., 2019), one study used Srett devices (Hoet et al., 2017), and another study used a Fisher & Paykel model (Schoch et al., 2019). Two studies used a mix of device brands from ResMed, Philips Respironics, Srett, Weinmann, and/or Fisher & Paykel (Bakker et al., 2016; Frasnelli et al., 2015) and other studies did not specify device brand or model (Bouloukaki et al., 2014; Carlucci & Thanavaro, 2019; Contal et al., 2021; Isetta et al., 2015; Murase et al., 2020; Sedkaoui et al., 2015; Tamisier et al., 2020).

Follow-up protocols after PAP device setup ranged widely, with initial follow-up appointments scheduled anywhere from within days, weeks, or months after therapy initiation. Most participants allocated to usual care were seen at least once within the first month of therapy, but no participant was seen later than three months post initiation. Hwang et al. (2018) and Kotzian et al. (2019), provided a one-week trial on PAP therapy before device setup and therapy initiation for all their participants regardless of study arm allocation. Murase et al. (2020) evaluated three study arms, (1) those receiving telemedicine care to (2) those receiving in-office follow-up visits every month versus (3) every 3 months for a total of 6 months. Differing cultural norms and healthcare systems may account for the variations in standards of care described within the literature and may, in turn, have influenced individual study findings, confounding the results and limiting their generalizability.

Telemedicine Technologies

Telemedicine technologies varied across the studies and ranged from video conferencing, telephone calls, texting, and emailing to the use of mobile applications and websites. Studied in isolation or in combination, the chosen telemedicine technology/technologies enabled remote synchronous and/or asynchronous patient care.

Amongst the 19 controlled trials, 10 studies utilized asynchronous telemonitoring (remote PAP data monitoring) with predefined data triggers - such as mask air leakage, residual apnea hypopnea index, and nightly PAP usage (hours/night) – prompting as needed patient phone calls for troubleshooting (Bouloukaki et al., 2014; Chumpangern et al., 2021; Fernandes et al., 2019; Frasnelli et al., 2015; Hoet et al., 2017; Kotzian et al., 2019; Murase, et al., 2020; Schoch et al., 2019; Tamisier et al., 2020; Turino et al., 2017). Whether by phone or video, these data triggered tele-visits occurred at predetermined intervals where remote PAP data was reviewed, patient concerns were discussed, and therapy issues were addressed in real-time. Six of the controlled trials also incorporated telephone consultations (Bakker et al., 2016; Carlucci & Thanavaro, 2019; Contal et al., 2021; Fields et al., 2016; Rattray et al., 2020; Sedkaoui et al., 2015) and two used video conferencing (Isetta et al., 2015 and Lugo et al., 2019) to provide additional subject support and, if needed, to address therapy issues but were not data triggered by remote telemonitoring. In these studies, all subjects allocated to the telemedicine intervention study arms were contacted at their study's predetermined intervals regardless of their PAP therapy data reports. Of note, Isetta et al. (2015) and Lugo et al. (2019) offered web accessible patient education and questionnaires in addition to video conferences. Lastly, Hwang et al. 2018 examined the effect of an automated

feedback system where patients received messages via a method of their choosing (text, email, etc.), either encouraging improved usage or reinforcing good adherence.

Of the six systematic reviews, three (Aardoom et al., 2020; Askland et al., 2020; Laborca; 2021) included studies researching a wide range and combination of telemedicine technologies while the other three (Chen et al., 2020; Murphie et al., 2019; Patil et al., 2019) included only studies evaluating these same remote telemonitoring interventions.

All studies evaluated their chosen telemedicine interventions against standard practice. However, the diversity in telemedicine technologies and intervention algorithms as well as baseline standards of practice across the studies may have influenced study findings.

Telemedicine Interventions

Despite the variety of telemedicine interventions explored and the study protocols employed, certain trends were revealed. Depending on how telemedicine was integrated into patient care, it was demonstrated to have an equivalent (non-inferior) or better effect on PAP adherence. All five of the controlled trials exploring telemedicine as add-on interventions to standard practice demonstrated improved PAP adherence compared to standard practice alone in the first one to four months of therapy (Carlucci & Thanavaro, 2019; Hoet et al., 2017; Hwang et al., 2018; Kotzian et al., 2019; Sedkaoui et al., 2015). However, while Kotzian et al. (2019), the only study of these five to evaluate PAP adherence at 3 and 12 months, demonstrated improved PAP adherence in the telemedicine add-on arm compared to standard practice at both time points, this finding did not remain statistically significant at 12 months.

Eleven of the 12 controlled trials evaluating telemedicine as replacement care were seen to be noninferior or to have an insignificant effect on PAP adherence when compared to

standard practice (Chumpangern et al., 2021; Contal et al., 2021; Fernandes et al., 2019; Fields et al., 2016; Isetta et al., 2015; Lugo et al., 2019; Murase et al., 2020; Rattray et al., 2020; Schoch et al., 2019; Tamisier et al., 2020; Turino et al., 2017). Frasnelli et al. (2016) was the only trial to demonstrate improved PAP adherence resulting from telemedicine as replacement care. Additionally, Murphie et al.'s (2019) systematic review (narrative synthesis) of five studies evaluating telemedicine care as replacement care included three studies which did not demonstrate a significant improvement in PAP adherence and two which did.

The four systematic reviews with metanalysis evaluating telemedicine care included various telemedicine technologies and study designs exploring both add-on and replacement protocols. All of these studies demonstrated significant improvement in PAP adherence (Aardoom et al., 2020; Chen et al., 2020; Labarca et al., 2021; Patil et al., 2019). However, Chen et al. (2020), similar to Kotzian et al. (2019), found telemedicine interventions to influence PAP adherence positively and significantly in the short term (<3 months) but not the long-term (>3 months).

Follow-up Intensity and Support

If telemedicine as replacement care is equivalent to standard practice (with no significant effect on PAP adherence) but telemedicine as add-on care is superior (significantly improving PAP adherence), it is plausible that telemedicine is not the variable on which PAP adherence is dependent. The intensity or frequency of follow-up care post PAP initiation may be the true independent variable influencing adherence.

Askland et al. (2020), Bakker et al. (2016), and Bouloukaki et al. (2014) evaluated the effect of follow-up intensity and support on PAP adherence. Askland et al.'s (2020)

metanalysis demonstrated a rise in nightly PAP usage of 0.7 hours and an 11.6% increase in PAP adherent participants in those who received supportive interventions (additional clinical follow-up) during PAP initiation. Bakker et al. (2016) demonstrated that motivational enhancement (provided at two additional in-office follow-up appointments and by six telephone consultations over 32 weeks) increased nightly PAP usage by 99 minutes per night at 6 months and 97 minutes at 12 months. Similarly, Bouloukaki et al. (2014) showed intensive patient care (two telephone consultations within the first week of therapy and remote evaluation of PAP data on days 15 and 30 of PAP initiation) resulted in a significantly improved mean nightly PAP usage of 1.7 h/night and adherence by 13%.

Murase et al. (2020) and Patil et al. (2019) also provided insight on PAP follow-up support and frequency. As previously noted, Murase et al. (2020) evaluated three study arms (1) in-office visits every three months accompanied by monthly telemonitoring (TM), (2) in-office visits every month (1M), and (3) in-office visits every 3 months (3M). The study revealed monthly telemonitoring (TM) to be equivalent to monthly in-office visits (1M), with both arms demonstrating improved PAP usage and adherence when compared to follow-up visits limited to every 3-months (3M). Finally, Patil et al. (2019), who sought to answer several PICO questions in their systematic review, queried the effects of troubleshooting and education interventions on PAP adherence. They explored how close patient communication could assist in the identification of PAP related issues and offer opportunities to resolve these issues. Their metanalysis of 9 RCTs demonstrated a significant increase in PAP usage by 0.7 hours per night in patients receiving troubleshooting and education interventions.

Implications

Study designs and methodologies varied widely, but, while heterogenous, the literature reveals telemedicine interventions to be noninferior to standard practice – traditional in-office, face-to-face care – and strongly indicates that closer, more intensive follow-up support improves PAP adherence. Which telemedicine intervention most effectively augments and compliments standard practice as well as how and when it should be implemented has yet to be determined. Replications of studies comparing distinct and/or specific combinations of telemedicine technologies along with strict, predefined follow-up protocols need to be performed to further inform evidence-based practice.

Other aspects of telemedicine interventions requiring consideration include technology literacy and accessibility, privacy concerns regarding personal electronic data, and hospital infrastructure and staffing (Pepin et al. 2017; Rattray et al., 2020). However, as technology continues to advance in concert with the public's technology literacy, telemedicine will likely become increasingly applicable and more acceptable. Most patients view telemedicine as offering greater flexibility in and accessibility to care as well as cost and time savings which, for most patients, appear to outweigh privacy concerns (Pepin et al., 2017). Finally, to effectively benefit from telemedicine interventions, new practice protocols will need to be developed, specifying each health care discipline's (team member's) role and responsibilities (Rattray et al., 2020).

The findings of this review as well as the current practice guidelines proposed by the AASM, as cited in Patil et al. (2019), "suggest that behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy in adults with OSA [and]… that clinicians use telemonitoring guided interventions during the initial period of PAP

therapy in adults with OSA" (p. 341). Telemedicine can enhance current practice. Greater patient support facilitated by telemedicine promises to help patients acclimatize to PAP therapy and achieve sustained good adherence.

Summary and Proposal

Telemedicine is not superior but comparable to standard practice when employed as replacement care; however, when used to enhance and support standard practice in patients initiating PAP therapy, adherence improves. Consequently, telemedicine serves to increase patient access to care and support as they acclimate to PAP therapy, facilitating early intervention and troubleshooting. This literature review supports the integration of telemedicine interventions alongside standard practice to improve PAP adherence. It was, therefore, proposed that telemonitoring technology be used to observe patients initiating PAP therapy so that those in need of additional assistance be identified and supported, helping more patients achieve and maintain good PAP adherence.

The following research question was put forth: In adult OSA patients initiating PAP therapy, how does interval telemonitoring (at two and four weeks) with as needed telephone consultations in addition to the standard practice of a 30-to-90-day follow-up office visit, compare to standard practice alone, affect PAP adherence within the first 90 days of therapy?

It was hypothesized that the proposed telemonitoring intervention and the additional support it offers to patients would result in improved PAP adherence at 90 days after therapy initiation. Furthermore, this proposed intervention may not only improve PAP adherence in the short term (90 days) but also in the long-term, reducing the risks untreated OSA poses to patients, the health care system, public safety, and the economy over time.

Chapter 3: Methodology

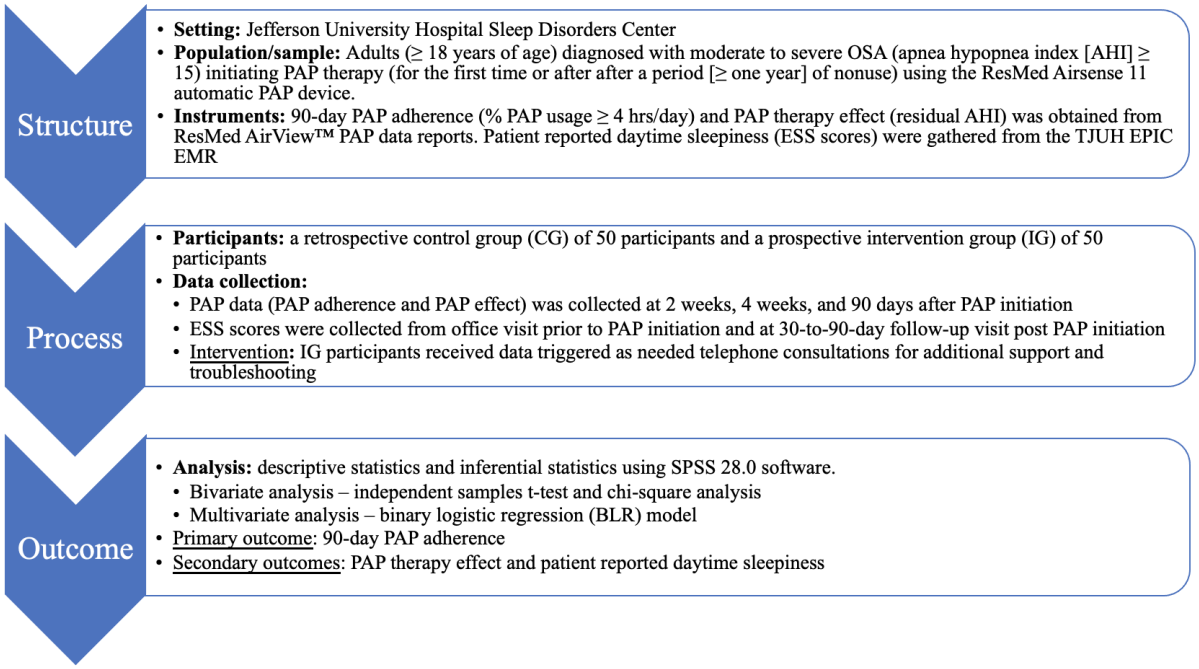
Introduction

This quality improvement (QI) project evaluated the effect of interval telemonitoring of positive airway pressure (PAP) therapy data at two and four weeks after treatment initiation in patients with moderate to severe obstructive sleep apnea (OSA) with as needed patient support and troubleshooting by telephone consultation in addition to standard practice of a 30-to-90-day in-office or telemedicine follow-up visit on 90-day PAP therapy adherence. The effect of this telemonitoring intervention (telemonitoring alongside standard practice) was compared to standard practice alone.

The Donabedian conceptual model provides a framework for examining health care services and evaluating quality of care (Donabedian, 2005; Donabedian,2014). It identifies three categories by which healthcare interventions can be assessed and compared: structure, process, and outcome. Structure refers to the context in which the care is delivered. Process refers to the transactions which occur between two parties (the providers and recipients of care or beneficiaries of an intervention). Outcome refers to the effect of a healthcare delivery system or intervention (Donabedian, 2005; Donabedian,2014). Chapter three details the structure, process, and outcome measures of this QI project (see Figure 1).

Figure 1

Donabedian Model



Structure

Setting

The project was conducted through the Sleep Disorders Center at the Thomas Jefferson University Hospital in Philadelphia, Pennsylvania. Established in 1978, the Sleep Disorders Center was the first such program in the Philadelphia area and is accredited by the AASM. It serves Philadelphia's urban population and that of its surrounding suburbs within Pennsylvania and its neighboring states, New Jersey and Delaware. The principal investigator, Saoirse Owens CRNP, has served as an advanced practice provider within the Jefferson Sleep Disorders Center since July 2018 and was responsible for the implementation of this QI project.

Population/Sample

Participants included adult patients (≥ 18 years of age) diagnosed with moderate to severe OSA (apnea hypopnea index [AHI] ≥ 15) initiating PAP therapy (for the first time or after a period [> one year] of nonuse) using the ResMed Airsense 11 automatic continuous PAP device. Individuals with cognitive delay, decisional impairment, pregnant women, prisoners, Jefferson employees, and those without telephone access were excluded.

Although 100 participants were initially enrolled in the project, the final sample size totaled 99 participants and comprised two groups, a retrospective control group (CG) of 50 participants and a prospective intervention group (IG) of 49 participants. In terms of statistical power, the Power and Precision software program indicated that a medium effect size effect (OR=3.34) would be detected between a dichotomous independent and dependent variable (with a projected event rate of .26 and .54 among the 2 groups) with power set at .80 and alpha set at .05, using a sample size of 100 participants. The G*Power software program indicated that a medium effect size effect (*f*=.25) would be detected for a repeated measures between group analysis with power set at .80 and alpha set at .05, using a sample size of 34 participants per group. Thus, the final sample of 99 participants provided sufficient statistical power for the analysis (W. Bannon, personal communication, March 11, 2023).

Participants were given an identification code (e.g., CG01 - CG50 and IG01 - IG50) under which project data points were recorded. Upon completion of the data collection, it was de-identified by permanently deleting the participant identifiers from the dataset, thus destroying any direct or indirect identifiers linking the data to any individual participant.

Participants were followed for 90 days after their PAP device set up dates. They were not recruited and there was no compensation for participation.

Instruments

Ninety-day PAP therapy adherence was the primary endpoint of interest while therapy effect and patient reported daytime sleepiness served as secondary endpoints. PAP therapy adherence and effect was monitored and obtained using the ResMed AirView™ secure, cloud-based system for remote monitoring of patient PAP therapy data, a tool previously integrated into standard practice (ResMed, n.d.) (see Appendix A).

Patient reported daytime sleepiness was captured using Dr. Murray Johns' validated Epworth Sleepiness Scale (ESS) (The Epworth Sleepiness Scale, n.d.) (See Appendix B). A user license agreement was obtained (effective as of 17 October 2022) from Dr. Johns' agents, Mapi Research Trust (eProvide, n.d.) (see Appendix C). ESS scores are obtained during all office visits (whether new or return patient visits) as standard practice. Scores from participant visits before and after (at their 30-to-90-day follow-up visit) PAP therapy initiation were collected. ESS scores along with participant name, date of birth (DOB), medical record number (MRN), age, gender, race, OSA diagnosis (i.e., moderate OSA or severe OSA), baseline AHI, and contact information were obtained through the Thomas Jefferson University Hospital patient electronic medical record software (EPIC).

Process

Participants

Prior to implementing the proposed QI project, the previous 50 patients meeting the project's inclusion and exclusion criteria were enrolled in the control group (CG) and their pertinent data collected. Upon implementing the proposed QI project, 50 patients meeting

the project's inclusion and exclusion criteria were enrolled in the intervention group (IG) and their pertinent data subsequently collected. However, of the one hundred participants initially enrolled in the project, one of the intervention group participants passed away prior to the project's completion. This reduced the final total participant count to the aforementioned 99, with 50 control and 49 intervention participants followed for the full and intended 90 days after PAP therapy initiation.

Standard of care was observed for all participants within this project. Standard practice included PAP therapy set up (education and training) by the participant's durable medical equipment (home care) company and a 30-to-90-day insurance mandated follow-up visit with the Jefferson Sleep Disorders Center conducted in the office as a face-to-face visit or via telemedicine as a video conference. The control group received standard of care alone, while those in the intervention group received as needed, data triggered (per predetermined data threshold variants) additional support and troubleshooting via telephone consultation at two and/or four weeks after PAP therapy initiation (see Appendix D).

Data Collection

Data was recorded and tracked on a spreadsheet, including each participant's information and data points under investigation. The PI had sole access to the data which was stored electronically on the PI's laptop and desktop computers protected by data encryption software. Finally, data documentation adhered to the Food and Drug Administration's (FDA's) ALCOA-C (Attributable, Legible, Contemporaneous, Original, Accurate, and Complete) guidelines (U.S. FDA, 2018).

Whether assigned to the control group or the intervention group, each participant's remote PAP data was evaluated at two weeks (14-day PAP data report), four weeks (28-day

PAP data report) and 90 days (30-day PAP data report, encompassing days 61 to 90) after PAP therapy initiation. Air leak (L/min), residual AHI, average nightly usage (minutes/night), and PAP therapy adherence (% days worn ≥ 4 hours) were also monitored and recorded. At two and four weeks, if an air leak of > 30 L/min, a residual AHI of >5 events per hour, average nightly usage of < 4 hours, and/or PAP adherence of < 70% was observed, participants in the intervention group were contacted by telephone. These telephone consultations were used to review participant sleep study results, diagnosis, and the recommendation for PAP therapy in addition to discussing the participant's experience with PAP therapy and troubleshoot any issues indicated by the data or expressed by the participant, including but not limited to mask fit, pressure settings, and climate controls (see Appendix E). Telephone consultations were documented in the EMR and recorded on the QI project data spreadsheet. Post therapy initiation ESS scores were obtained during each participant's 30-to-90-day follow-up visit, and final PAP data were captured at 90 days (i.e. the final PAP therapy data were captured remotely on each participant's 90th day of therapy) (Appendix D).

The QI project was conducted over three and a half months, from 24 October 2022 to 8 February 2023 with the proposed intervention (PAP therapy data telemonitoring and as needed, data triggered telephone consultations) implemented over 6 weeks, from 24 October 2022 through 2 December 2022. Final PAP therapy data were collected on 1 February 2023, and chart reviews were completed on 8 February 2023.

Outcome

Analysis

The latest version of the Statistical Product and Service Solutions software (SPSS 28.0) was used for all statistical analysis. The data analysis plan was conducted in three phases. First, all project variables were presented using descriptive statistics, such as, means, standard deviation, and minimum/maximum values for continuous variables (Interval/Ratio level) and frequencies and percentages for categorical variables (Nominal/Ordinal level) (W. Bannon, personal communication, July 28, 2022).

Next, a series of bivariate tests were used to produce inferential findings. Bivariate tests (independent samples t-test, chi-square analysis) were used to examine if any explanatory variables, including the covariate variables age, race, etc. and the independent variable, telemonitoring with as needed support by telephone consultation, were significantly related to the dependent variable, PAP therapy adherence. Any explanatory variables related to the dependent variable at a statistically significant level ($p<.05$), were included in the third phase of data analysis, multivariate analysis (W. Bannon, personal communication, July 28, 2022) (see Appendix F).

Third, a multivariate model, specifically a binary logistic regression model, was used to model the dependent variable as a function of all explanatory variables significantly related to the dependent variable in bivariate analysis. The model was assessed in terms of overall statistical significance, chi-square value, the percentage of cases categorized correctly, the significance of individual predictors, and the odds ratio effect size values along with the 95% confidence interval for each odds ratio value. Final hypothesis testing

was based upon the findings of the multivariate analysis (W. Bannon, personal communication, July 28, 2022) (see Appendix G).

A binary logistic regression model would have been considered if the independent variable, p*articipant group,* was related to the dependent variable, *follow-up visit* (Yes/No) at a statistically significant level at the bivariate level. However, this multivariate test was not necessary as there was no significant bivariate relationship between these variables (W. Bannon, personal communication, March 11, 2023).

Within the final inferential analysis presented, all test assumptions related to parametric testing were examined, including normality, linearity, and multicollinearity. For any missing data values, patterns of missingness were examined (MCAR, MAR, NMAR) and accounted for based upon the pattern of missing data, as well as the number of values missing overall and the percentage of participants that evidenced missing data (W. Bannon, personal communication, July 28, 2022).

Protection of Human Subjects/IRB

As this QI project involved no more than minimal risk to its participants, the West Chester University (WCU) and Thomas Jefferson University Hospital (TJUH) Institutional Review Boards (IRBs) deemed it exempt (see Appendices H &I) and a waiver of participant authorization was granted (see Appendix J). Also, to reiterate, this QI project assessed the implementation of the AASM's 2019 clinical practice guideline which suggests the use of telemonitoring-guided interventions to support adult OSA patients as they initiate and acclimate to PAP therapy (Patil et al., 2019).

Anticipated and Actual Barriers

PAP data is routinely accessed remotely in current practice but its telemonitoring potential has yet to be realized. This project sought to further exploit this potential, providing a pathway for providers to identify patients in need of additional support and enabling them to tailor patient care accordingly. This opportunity, however, was not without its challenges and potential barriers.

First, variable patient PAP device set up timelines – which, at the time of implementation were exacerbated by supply chain issues and device backorders related to the COVID-19 pandemic and the Philips PAP device recall of 2021 – could have influenced the execution of this project. Second, increased monitoring and consultations required additional provider time and added to the sleep center's workload. Third, telephone consultations also demand more patient time and might have been seen as a disruption and inconvenience by patients. Moreover, patients were not always available for the unplanned, as needed telephone consultations which, on occasion, resulted in failed attempts to connect with patients who demonstrated the need for additional support. Finally, although none were expressed, participant privacy concerns regarding increased protected health information (PHI) access may have arisen and risked patient satisfaction (Pépin et al., 2017; Rattray et al., 2020).

Despite these challenges and concerns, however, the benefits and advantages of this telemonitoring intervention may outweigh its potential barriers and disadvantages (Pépin et al., 2017). In all instances, of course, institutions and providers must be tactful in their use of PHI and sensitive to patient preferences.

Summary

As a supplement to standard practice, this QI project sought to determine the effect of interval PAP therapy data telemonitoring and as needed, data triggered patient support on PAP therapy adherence. Participants included adults with moderate to severe OSA initiating PAP therapy, and all participants were set up through the durable medical equipment company Adapt Health with the latest ResMed Airsense 11 PAP device. Project approval was granted by TJUH's and WCU's IRBs prior to implementation, and PAP therapy data as well as EMR documented ESS scores were collected and analyzed for statistical significance.

Chapter 4: Results

Introduction

This quality improvement (QI) project examined the effect of interval positive airway pressure (PAP) data telemonitoring and as needed (data triggered) patient support by telephone consultation in addition to standard practice on PAP therapy adherence at 90 days. The effect of this intervention on PAP adherence as well as therapy effect (residual AHI), patient reported daytime sleepiness (pre and post PAP therapy initiation Epworth Sleepiness Scale [ESS] scores), follow-up visit status, and PAP therapy usage (continued vs discontinued PAP usage) was examined and compared to standard practice alone.

Data Collection

There was completed data for 99 participants regarding the primary outcome variable, adherence, as well as the secondary outcome variables, PAP therapy usage (usage [yes/no]) and follow-up visit status (follow-up visit completed, scheduled [to be completed], not scheduled, cancelled, and no show). A sub-analysis involving 78 of the 99 participants was conducted for the outcome variables AHI, air leak, and nightly usage (time used per night) as there was no PAP usage and, thus, no PAP data for these variables at 90 days for the remaining 21 participants. Similarly, a sub-analysis involving 46 of the 99 participants was conducted for the pre and post PAP initiation Epworth Sleepiness Scale (ESS) scores. This analysis was limited to 46 participants as pre and/or post scores for this variable were either not available or incomplete for the remaining 53 participants.

Statistical Results

Descriptive analysis of the categorical variables of this QI project are presented in Table 1. Data indicated that the sample was a little less than half female (*n*=43, 43.4%), predominantly of a White (*n*=39, 38.9%) and African-American/Black (*n*=40, 40.8%) racial identity and had an average age of 53.45 (*SD*=13.84, MIN/MAX=23.49-83.15) years. Per protocol, the project included only those with moderate (*n*=39, 39.4%) to severe (*n*=60, 0.6%) OSA.

Table 1

Descriptive Analysis of Categorical Project Variables (n=99)

Variable	N	%
Gender		
Female	43	43.4
Male	56	55.6
Race		
White	39	38.9
African-American/Black	40	40.8
Latinx	9	9.2
Asian	9	9.2
Native American/Native Alaskan	1	1.0
Missing	*1*	
Race (Collapsed for analysis as a covariate)		
White	39	39.4
Other	60	60.6
Diagnosis		
Moderate OSA	39	39.4
Severe OSA	60	60.6
Age	*M*=53.45, *SD*=13.84, *MIN/MAX*=23.49-83.15	

At both two- and four-weeks post PAP initiation, 77.6% (*n*=38) of the intervention group participants met the threshold (predetermined data triggers) for telephone consultation (see Table 2). Data triggers included insufficient nightly PAP usage (average usage of <4

hrs/day), suboptimal PAP adherence (<4 hrs PAP usage 70% of days), a high air leak (> 30 L/min), and/or an elevated residual apnea hypopnea index (AHI ≥ 5). Coupled or in isolation, suboptimal adherence was the most frequent trigger observed; however, it was most commonly associated with insufficient usage. In combination, adherence and usage accounted for 29% and 26% of the calls triggered at two and four weeks, respectively (see Figure 2).

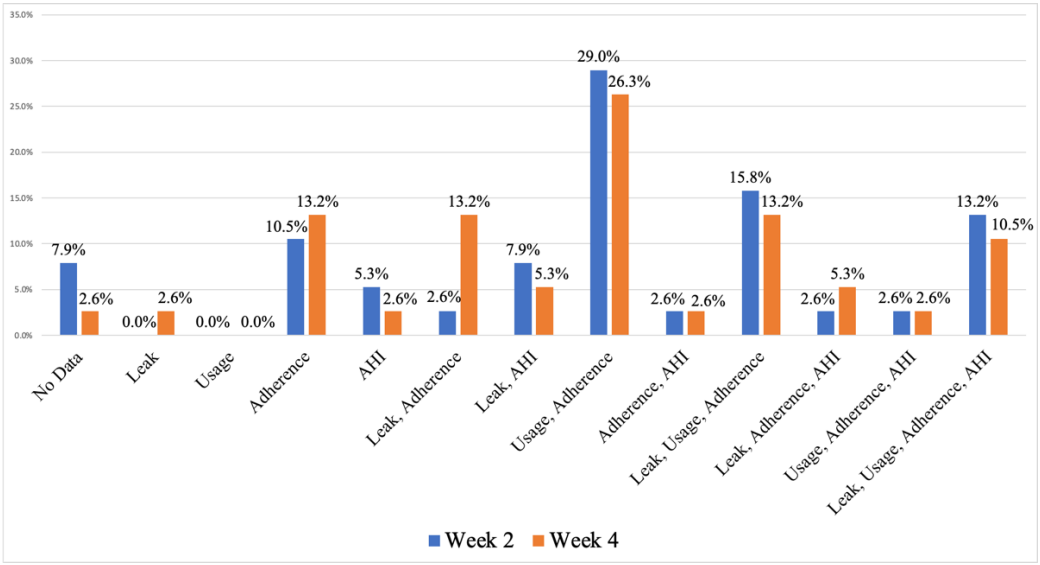
Table 2

Data Triggered Calls and Telephone Consultations (Applies to Intervention Group only) (n=49)

Variable	N	%
Data triggered call at 2 weeks.		
Yes	38	77.6
No	11	22.4
Participant successfully contacted for telephone consultation at 2 weeks.		
Yes	29	77.3
No	9	23.7
Data triggered call at 4 weeks.		
Yes	38	77.6
No	11	22.4
Participant successfully contacted for telephone consultation at 4 weeks.		
Yes	27	71.1
No	11	28.9

Figure 2

PAP Data Items Triggering Telephone Consultations (Applies to Intervention Group only)



Of the data triggered telephone consultations, 77.3% (*n*=29) and 71.1% (*n*=27) of the intervention group participants, at two and four weeks respectively, were successfully contacted and consulted by phone (see Figure 3). During each consultation performed, participant sleep study results (diagnosis) and the recommendation for PAP therapy were reviewed. Mask fit, pressure settings, and climate controls were also discussed; and, if indicated, avenues to explore alternate mask options were discussed, pressure changes were made remotely, and climate control features were reviewed. Of these potential issues, mask fit was the most common to arise (see Figure 4).

Figure 3

Data Triggered Calls (Applies to Intervention Group only)

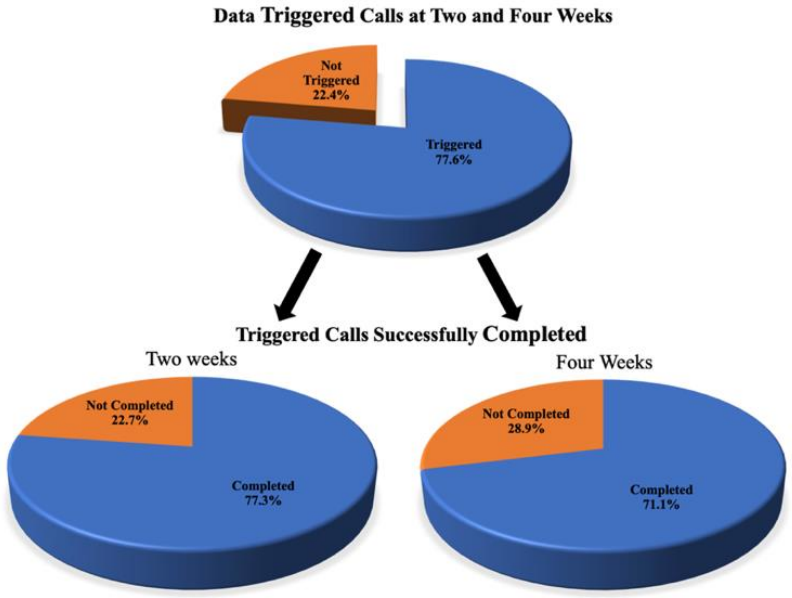
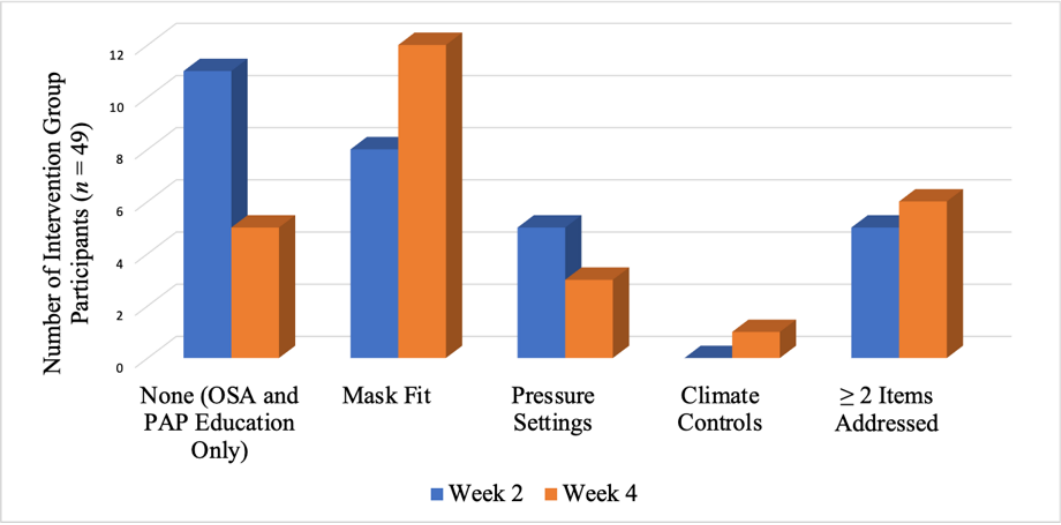


Figure 4

PAP Therapy Issues Addressed During Data Triggered Telephone Consultations (Applies to Intervention Group only)



A repeated measures MANOVA examining PAP adherence scores and continued PAP usage (Yes/No) over time by participant group is presented in Table 3. Analysis of PAP adherence scores indicated that this model was statistically significant, $F(1.16, 112.21) = 4.84$, $p<.05$, PES=.05. Mean PAP adherence scores for each group remained similar at two- and four-weeks post PAP initiation but diverged at 90 days with the intervention group having a significantly higher mean score (M=49.24, SD=38.18) relative to the control group (M=36.38, SD=37.69) (see Figure 5).

Table 3

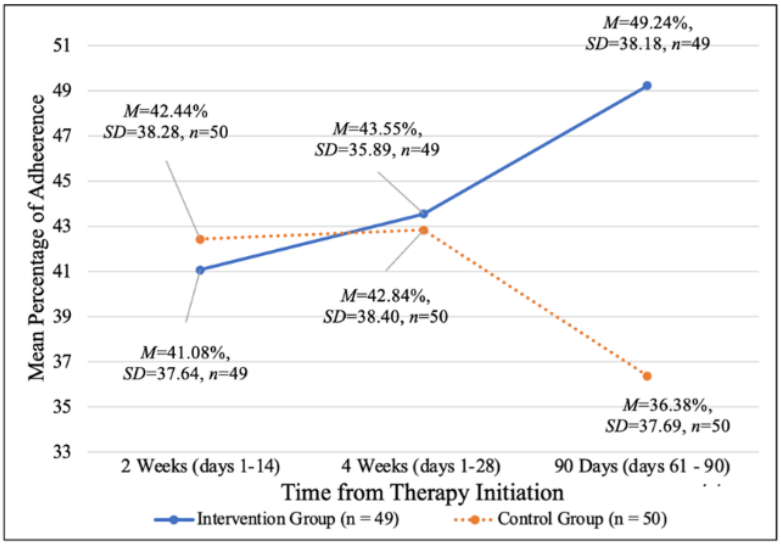
Repeated Measures MANOVA Examining PAP Adherence Scores and Usage (Yes/No) Over Time by Participant Group (n=99)

	Intervention Group (*n*=49)	Control Group (*n*=50)			
Variable	**M (SD)**	**M (SD)**	**F(df)**	**p**	**PES[1]**
Adherence by Study Group			**4.84 (1.16, 112.21)**	**.03**	**.05**
Adherence at 2 weeks	41.08 (37.64)	42.44 (38.28)			
Adherence at 4 weeks	43.55 (35.89)	42.84 (38.40)			
Adherence at 90 days	49.24 (38.18)	36.38 (37.69)			
Usage (Yes/No) by Study Group			**5.91 (1.32, 125.66)**	**.01**	**.06**
Usage at 2 weeks	93.88 (24.22)	98.00 (14.14)			
Usage at 4 weeks	97.96 (14.29)	98.00 (19.80)			
Usage at 90 days	89.80 (30.58)	72.00 (45.36)			

[1]PES: 0.01 indicates a small effect, 0.06 indicates a medium effect, 0.14 indicates a large effect

Figure 5

Display of Adherence Scores Over Time by Participant Group (n=99)[1]

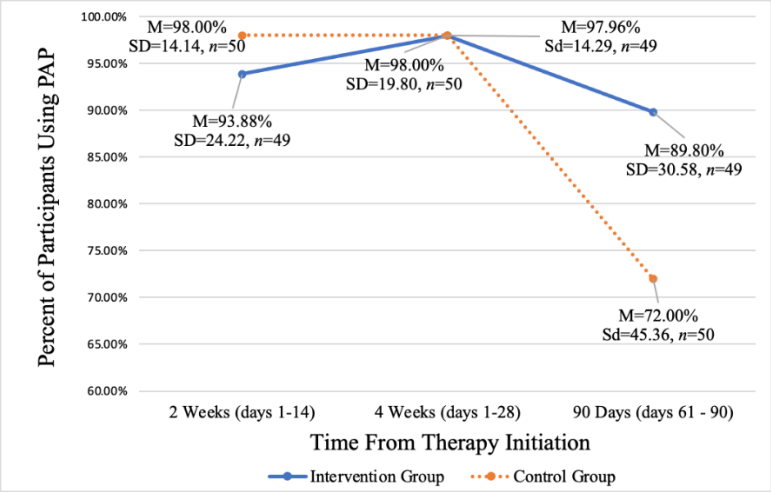


[1]For the Repeated Measures GLM Model: $F(1.16, 112.21)=4.84$, $p<.05$, PES=.05

This variance between participant groups is also reflected in the percentage of participants demonstrating continued PAP usage (yes/no) at 90 days (any usage within the last 30 days, from day 61 to 90) after therapy initiation. Analysis of continued PAP usage over time also revealed a statistically significant divergence between the participant groups, $F(1.32, 125.66) = 5.91$, $p<.05$, PES=.06. As with adherence scores, continued PAP usage for each group remained similar at two- and four-weeks post PAP initiation but diverged at 90 days with the intervention group having a significantly higher mean score (M=89.80, SD=30.58) relative to the control group (M=72.00, SD=45.36). As seen in Figure 6, 89.8% of the intervention group compared to 72% of the control group demonstrated continued usage at 90 days. Alternately, 10% of the intervention group compared to 28% of the control group had discontinued PAP usage at 90 days (no data = no usage = 0% adherence).

Figure 6

Percent of Participants Using PAP Over Time by Participant Group (n=99)



A chi-square analysis of follow-up visit status by participant group was conducted (see Table 4). Bivariate analysis indicated that the dependent variable follow-up visit status did not vary by participant group at a statistically significant level, $X^2(4)=4.84$, $p=.53$. This is illustrated in Figure 7.

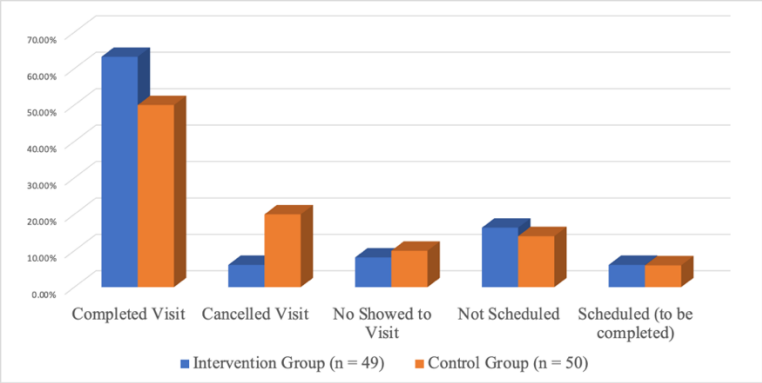
Table 4

Chi-Square Analysis of Follow-up Visit Status by Participant Group

	Intervention Group (*n*=49)	**Control Group (*n*=50)**		
Variable	**n (%)**	**n (%)**	**X²(df)**	**p**
Follow-up Visit Status			**4.58 (4)**	**.33**
Completed	31 (55.40)	25 (44.60)		
Scheduled	3 (50.0)	3 (50.0)		
Not Scheduled	8 (53.30)	7 (46.70)		
Cancelled	3 (23.1)	10 (76.9)		
No Show	4 (44.40)	5 (55.60)		
Follow-up Visit Status (Collapsed Categories)			**1.77 (1)**	**.18**
Completed	31 (55.40)	25 (44.60)		
Not Completed	18 (41.9)	25 (58.1)		

Figure 7

Follow-up Visit Status by Participant Group



A subsample analysis, involving a repeated measures MANOVA, examined outcome variables over time by participant group for participants with complete data (see Table 5). Analysis indicated that mean scores did not vary over time by participant group at a statistically significant level regarding AHI, $F(1.11, 84.61)=1.07$, $p=.31$, Air Leek, $F(1.26, 95.73)=1.13$, $p=.30$, or Usage Time Per Night, $F(1.42, 108.05)=.71$, $p=.45$.

Table 5

Subsample Analysis: Repeated Measures MANOVA Examining Outcome Variables Over Time by Participant Group for Participants with Complete Data (n=78)

	Intervention Group (*n*=42)	Control Group (*n*=36)		
Variable	**M (SD)**	**M (SD)**	**F(df)**	**p**
AHI by Participant Group			**1.07 (1.11, 84.61)**	**.31**
Baseline AHI	38.09 (19.31)	44.22 (28.41)		
Residual at 2 weeks	4.00 (4.87)	4.11 (8.55)		
Residual at 4 weeks	3.77 (4.72)	4.41 (9.70)		
Residual at 90 days	2.30 (2.32)	2.40 (2.59)		
Air Leek (L/min) by Participant Group			**1.13 (1.26, 95.73)**	**.30**
Air leek at 2 weeks	33.19 (31.35)	28.60 (19.11)		
Air leek at 4 weeks	30.42 (28.24)	27.52 (16.70)		
Air leek at 90 days	27.34 (24.02)	28.59 (20.00)		
Usage Time Per Night (minutes) by Participant Group			**.71 (1.42, 108.05)**	**.45**
Usage at 2 weeks	261.38 (158.51)	281.72 (144.88)		
Usage at 4 weeks	269.88 (128.02)	286.08 (129.04)		
Usage at 90 days	282.10 (123.64)	279.92 (112.76)		

Finally, a subsample analysis, involving a repeated measures MANOVA, examining the outcome variable pre and post PAP initiation ESS scores indicated that mean ESS scores did not vary between the two time points at a statistically significant level, $F(1, 44)=.48$, $p=.49$ (see Table 6).

Table 6

Subsample Analysis: Repeated Measures MANOVA Examining Epworth Sleepiness Scale Scores Over Time by Participant Group for Participants with Complete Data (n=46)

	Intervention Group (*n*=25)	Control Group (*n*=21)		
Variable	**M (SD)**	**M (SD)**	**F(df)**	**p**
Epworth Sleepiness Scale (ESS scores) by Participant Group			**.48 (1, 44)**	**.49**
Pre PAP Initiation	8.28 (4.26)	9.24 (4.39)		
Post PAP Initiation	4.96 (3.67)	6.57 (3.80)		

Summary

The results of this QI project revealed a significantly higher mean PAP adherence (p = 0.3) within the intervention group (49.24%, SD 38.18) compared to the control group (36.38%, SD 37.69) at 90 days after therapy initiation. This divergence was also seen in the variable PAP usage (yes/no), with a significantly greater percentage (p = 0.1) of the intervention group demonstrating continued PAP usage at 90 days (89.80, SD 30.58) relative to the control group (72.00, SD 45.36). However, while PAP adherence and usage were significantly higher in the intervention group relative to the control group at 90 days, no significant difference was observed between the participant groups regarding “good PAP adherence” as defined by the Centers for Medicare and Medicaid Services (CMS) (CMS, n.d.). There was no significant bivariate relationship identified between participant group and

follow-up visit status, and no significant difference was seen in average nightly PAP usage, air leak, residual AHI, or pre and post PAP therapy initiation ESS scores between the participant groups.

Chapter 5: Discussion

Review of the Problem

Obstructive sleep apnea (OSA) is an increasingly recognized condition estimated to affect 12% of adults. It not only threatens individual health and wellbeing but also public safety and welfare (Frost & Sullivan, 2016). It is associated with reduced productivity and increased health care utilization, costing the Unites States $149.6 billion in 2015 (Frost & Sullivan, 2016; Patil et al., 2019; Wickwire et al., 2020); and, while the diagnosis and management of OSA can be expensive, treatment costs are estimated to be 33% of those associated with untreated OSA (Frost & Sullivan, 2016).

Since 1981, positive airway pressure (PAP) therapy has remained the preferred and most effective mode of treatment for OSA (Patil et al., 2019; Randerath et al., 2022). Unfortunately, this popular mode of treatment remains unpopular amongst patients, with adherence rates reported anywhere from 30% to 80% (Aardoom et al., 2020; Patil et al., 2019). However, although the preference for PAP therapy has not changed, PAP devices have. Newer devices offer remote telemonitoring capabilities which can be utilized to better support patients as they initiate and acclimate to therapy (Patil et al., 2019; ResMed 2021).

Findings and Limitations

This quality improvement (QI) project evaluated a PAP data telemonitoring intervention providing as needed, data triggered patient support at two- and four-weeks post therapy initiation. Statistical analysis demonstrated significantly higher mean adherence rates in the intervention group relative to the control group. The percentage of participants who demonstrated continued PAP usage (i.e. any PAP usage within the final 30 days of this project's 90 day duration) was also significantly higher within the intervention group relative

to the control group. Yet, while PAP adherence and continued usage were significantly higher in the intervention group at 90 days, no significant difference was observed between project groups with respect to "good PAP adherence" as defined by the Centers for Medicare and Medicaid Services (CMS). CMS defines good PAP adherence as a minimum of four hours of PAP usage a day, ≥ 70% of days (CMS, n.d.).

Regarding follow-up visit status, while more intervention group participants completed their visits prior to final data collection on 8 February 2023, this variance between project groups was not statistically significant. Despite this, it is important to note that, having initiated therapy and been enrolled in the project after the control group, there was a shorter timeframe in which to capture the intervention group's visits. Thus, follow-up visits scheduled or rescheduled beyond the intended 90 days from PAP initiation may have disproportionally affected the intervention group's dataset, possibly rendering this finding misrepresentative.

An ESS score of > 10 is considered indicative of excessive daytime sleepiness (EDS) (The Epworth Sleepiness Scale, n.d.); however, neither the intervention nor control groups' mean baseline ESS scores prior to initiating PAP therapy (8.28 [SD 4.26] and 9.24 [SD 4.39], respectively) were indicative of excessive daytime sleepiness. Moreover, while the mean scores for both groups decreased after PAP initiation (4.96 [SD 3.67] and 6.57 [SD 3.80], respectively), this difference was insignificant. This is particularly interesting as the project included participants with moderate (39.4%) to severe OSA (60.6%) only and excluded those with mild OSA. Subjective daytime sleepiness is often associated with untreated OSA and, along with OSA severity, is considered an independent positive predictor of PAP adherence (Jacobsen et al., 2016). This project's results suggest that EDS was not pronounced amongst

the project participants; and, if only mildly symptomatic, participants may have been less inclined to adhere to and remain on PAP therapy. The validity and reliability of this finding may be limited, however, due to the number of missing ESS scores.

Finally, this QI project was conducted by a single provider (the principal investigator) through a single center (the Jefferson Sleep Disorders Center in Center City Philadelphia, Pennsylvania), and included only patients set up through the durable medical equipment company, Adapt Health, with the ResMed Airsense 11 automated CPAP device. These limitations may restrict the generalizability of this project's findings.

Implications for Practice, Education, and Research

The results of this project mirror those reported within the literature; telemonitoring interventions provided in supplement to standard practice result in improved PAP therapy adherence (Aardoom et al., 2020; Carlucci & Thanavaro, 2019; Chen et al., 2020; Hoet et al., 2017; Hwang et al., 2018; Kotzian et al., 2019; Labarca et al., 2021; Patil et al., 2019; Sedkaoui et al., 2015). However, this project's results did not demonstrate a significant increase in 'good PAP adherence' (adherence of ≥ 70%), the metric by which insurance companies determine (approve or deny) continued PAP coverage. Furthermore, this project was time intensive, and with no significant increase in 'good PAP adherence' observed, the diminished return on time and effort invested may render this intervention impractical.

Telemonitoring required dedicated time each day to screen PAP data and identify patients needing additional support, and telephone consultations varied, lasting upwards of 15 to 20 minutes. Recruiting the assistance of ancillary staff (to screen data for the predetermined data triggers) and sharing the volume of data triggered telephone consultations among all providers might render this intervention less burdensome and more feasible.

Billing for these telephone consultations would also improve financial viability, but billing patient's insurances for unplanned and unscheduled consultations may not be well received by patients and would require patient consent in advance. Another challenge presented by these unplanned telephone consultations was patient availability; in this project, approximately 25% of attempted calls were unsuccessful.

Continued evaluation of telemonitoring protocols is necessary to clarify the value of such interventions and identify best practices. Perhaps performing telemonitoring data triggered consultations at one time point (i.e. four weeks) as opposed to two time points (i.e. two and four weeks) would render equivalent results without impacting workload. Healthcare patient portals (i.e. MyChart) also offer avenues to support and educate patients through electronic communications (i.e. portal messages) providing standardized explanations of OSA pathophysiology and the importance of PAP adherence, tips for acclimating to therapy, as well as methods of and resources for addressing issues commonly encountered during therapy initiation. Links to websites, educational videos, and frequently asked questions (FAQs) could also be embedded in these messages for reinforcement.

Collaborative telemonitoring protocols integrated into standard practice can provide supplementary support to those in need and improve PAP therapy adherence. Future QI projects will need to explore the intervals, avenues, and protocols to best achieve this goal.

Conclusion

As technology advances, new opportunities to assist patients emerge; telemonitoring interventions can augment and enhance the pathways by which providers educate, motivate, and promote treatment in patients diagnosed with OSA. Measures supporting PAP therapy acclimation and adherence can help preserve patient health, reduce health care costs, protect

public safety, and bolster the economy (through increased productivity, reduced work absences, and fewer sleep related accidents and errors) (Frost & Sullivan, 2016; Patil et al., 2019; Wickwire et al., 2020). This project's telemonitoring intervention resulted in improved PAP therapy utilization and adherence in patients initiating treatment for moderate to severe OSA. Subsequent iterations of this project's telemonitoring intervention promise to support improved PAP adherence and, in turn, protect patient health and public welfare.

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Appendix A

ResMed Airview PAP Therapy Compliance/Adherence Data Report

ResMed

AirView™

Patient ID:
DOB:
Age: years

Compliance Report

Usage		
Usage days		**/30 days (%)**
>= 4 hours		**days (%)**
< 4 hours		**days (%)**
Usage hours		hours minutes
Average usage (total days)		hours minutes
Average usage (days used)		hours minutes
Median usage (days used)		hours minutes
Total used hours (value since last reset - 07/27/2022)		hours

AirSense 11 AutoSet	
Serial number	
Mode	AutoSet
Min Pressure	cmH2O
Max Pressure	cmH2O
EPR	Ramp Only
EPR level	
Response	Standard

Therapy			
Pressure - cmH2O	Median:	95th percentile:	Maximum:
Leaks - L/min	Median:	95th percentile:	Maximum:
Events per hour	AI:	HI:	AHI:
Apnea Index	Central:	Obstructive:	Unknown:
RERA Index			
Cheyne-Stokes respiration (average duration per night)			**minutes (%)**

Usage - hours

ResMed. (n.d.) *ResMed Airview report guide - resmed*. Retrieved from https://airview.resmed.com/resources/welcome-page/pdf/1018991_airview-report-guide_usa_eng.pdf

Appendix B

Epworth Sleepiness Scale (ESS)

Name:_____ Today's date:_____

Your age (yrs):_____ Your gender (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired?

This refers to your usual way of life recently.

Even if you haven't done some of these things recently, try to figure out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = **no chance** of dozing
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each item as best as you can.

Situation	**Chance of Dozing (0-3)**
Sitting and reading	___
Watching TV	___
Sitting inactive in a public place (e.g., a theater or a meeting)	___
As a passenger in a car for an hour without a break	___
Lying down to rest in the afternoon when circumstances permit	___
Sitting and talking to someone	___
Sitting quietly after a lunch without alcohol	___
In a car, while stopped for a few minutes in traffic	___

THANK YOU FOR YOUR COOPERATION

ESS - United States/English - Version of 01 Feb 2021 - Mapi
ID037309 / ESS_AU1.0_eng-US2.doc

The Epworth Sleepiness Scale. (n.d.). *About the ESS*. Epworth Sleepiness Scale. (n.d.).

Retrieved from https://epworthsleepinessscale.com/about-the-ess/

Appendix C

ESS User license Agreement Special Terms

SPECIAL TERMS No77670

These User License Agreement Special Terms (Special Terms) are issued between Mapi Research Trust ("MRT") and Saoirse Owens (User).

These Special Terms are in addition to any and all previous Special Terms under the User License Agreement General Terms.

These Special Terms include the terms and conditions of the User License Agreement General Terms, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the Special Terms Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the User License Agreement General Terms.

These Special Terms, including all attachments and the User License Agreement General Terms contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of these Special Terms or any attachment conflict with the terms and conditions of the User License Agreement General Terms, the terms and conditions of the User License Agreement General Terms will control, unless these Special Terms specifically acknowledge the conflict and expressly states that the conflicting term or provision found in these Special Terms control for these Special Terms only. These Special Terms may be modified only by written agreement signed by the Parties.

1. User information

User name	Saoirse Owens
Category of User	Student
User address	211 South 9th Street, Suite 5, Philadelphia, 19107, Pennsylvania, United States
User VAT number	
User email	so277692@wcupa.edu
User phone	2159102853
Billing information	211 South 9th Street, Suite 5, Philadelphia, 19107, Pennsylvania, United States

eProvide. (n.d.). *Epworth Sleepiness Scale (ESS).* Retrieved from https://eprovide.mapi-trust.org/instruments/epworth-sleepiness-scale

2. General information

Effective Date	Date of acceptance of these Special Terms by the User : 17 Oct 2022
Expiration Date (Term)	Upon completion of the Stated Purpose
Name of User's contact in charge of the request	Saoirse Owens

3. Identification of the COA

Name of the COA	ESS - Epworth Sleepiness Scale
Author	Johns MW
Copyright Holder	Johns Murray W.
Copyright notice	ESS © MW Johns 1990-1997. Used under License.

eProvide. (n.d.). *Epworth Sleepiness Scale (ESS).* Retrieved from https://eprovide.mapi-trust.org/instruments/epworth-sleepiness-scale

Bibliographic reference	Johns MW. The clinical assessment of daytime sleepiness in patients with obstructive sleep apnea. In:Surgery for snoring and obstructive sleep apnea syndrome, ed. Fabiani M. Kugler publications, The Hague, 2003: 283-295 Johns MW. Sensitivity and specificity of the multiple sleep latency test (MSLT), the maintenance of wakefulness test and the epworth sleepiness scale: failure of the MSLT as a gold standard. J Sleep Res. 2000 Mar;9(1):5-11 (PubMed abstract) Johns MW. Sleepiness in different situations measured by the Epworth Sleepiness Scale. Sleep. 1994 Dec;17(8):703-10 (PubMed abstract) Johns MW. Daytime sleepiness, snoring, and obstructive sleep apnea. The Epworth Sleepiness Scale. Chest. 1993 Jan;103(1):30-6 (PubMed abstract) Johns MW. Reliability and factor analysis of the Epworth Sleepiness Scale. Sleep. 1992 Aug;15(4):376-81 (PubMed abstract) Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep. 1991 Dec;14(6):540-5 (PubMed abstract)
Module(s)/version(s) needed	• ESS

4. Context of use of the COA

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Other project

Title	DNP Quality Improvement Project: Effect of Telemonitoring and As Needed Patient Support on PAP Adherence

eProvide. (n.d.). *Epworth Sleepiness Scale (ESS).* Retrieved from https://eprovide.mapi-trust.org/instruments/epworth-sleepiness-scale

Disease or condition	Obstructive Sleep Apnea
Planned Term*	Start: 10/2022 End: 03/2023
Description (including format or media)	

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:

Version/Module	Language	For use in the following country
ESS	English	the USA

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

5. Specific requirements for the COA

- The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.
- In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.
- In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into a technical file provided by the User or IT Company. The User or IT Company will upload the translations from the technical file into the User's or IT Company's system and shall send the Screenshots of the translations of the COA to ICON LS for review and approval. The update (if needed), the population of the versions into the technical file and the Screenshots review may incur additional fees.

By accepting these Special Terms, the User acknowledges and confirms that it has read and approves the User Agreement General Terms.

eProvide. (n.d.). *Epworth Sleepiness Scale (ESS).* Retrieved from https://eprovide.mapi-trust.org/instruments/epworth-sleepiness-scale

Appendix D

Quality Improvement Project Timetable

The control group data will be collected and recorded retrospectively but at the same intervals as that of the intervention group. Capturing PAP therapy average nightly usage (in hours and minutes), adherence, effect (average residual AHI), and average nightly air leak (L/min) at 2 weeks, 4 weeks, and 90 days after PAP initiation/set-up; and, capturing ESS scores from each subject's visit prior to PAP set up and at their 30-to-90-day follow-up visit, either in-office (face-to-face) or by telemedicine (video conferencing).

Intervention will be implemented over an 8-week time frame. Subject ResMed Airview PAP therapy data will be evaluated at two and four weeks after PAP initiation/set up. Subjects in the intervention group whose PAP data indicate an average nightly usage of < 4 hours, non-adherence (<70%), suboptimal therapy effect (average AHI of > 5), and/or poor mask fit/large air leak (> 30 L/min) will be contacted by telephone for consultation (support and troubleshooting). However, final data will be reviewed at 90 days.

Intervention:
Week 1 (Intervention group subject enrollment):
1. Weekly, the investigator will obtain a list of the Jefferson Sleep Disorders Center's established patients/subjects set up with ResMed Airsense 11 devices from the durable medical equipment companies Adapt Health and Premier medical.
2. The first 50 patients meeting the study's inclusion and exclusion criteria will be enrolled in the intervention group (IG).

Week 2 through 4 from subject enrollment/PAP initiation:
3. The remote PAP therapy data of those in the intervention group will be evaluated by the investigator at 2 and 4 weeks after PAP therapy initiation/set up.
4. Subjects in the intervention group will be contacted by the investigator for troubleshooting at two and four weeks after PAP therapy initiation/set-up if any of the following data triggers are observed on their remote PAP therapy data:

Average nightly usage of < 4 hrs
Adherence of < 70% (≥ 4 hrs of PAP usage < 70% nights) Average Residual AHI of > 5
Average Air leak of > 30 L/min

Telephone consultations/interview will include the following (see attached script):

subject reeducation on their OSA diagnosis, the medical indication for treatment, and the risks of untreated OSA
evaluation of subject's comfort with mask and pressure settings. Discuss and evaluate climate settings (humidification and temperature). Address data and any patient specific concerns.

Standard practice:

Week 5 to 12 (30 to 90 days follow-up visit per standard practice):

5. Intervention group subjects will be seen (as were those in the control group [CG]), per standard practice, for their 30-to-90-day follow-up visit either in-office (face-to-face) or by telemedicine (video conferencing). At this visit their post-treatment initiation Epworth Sleepiness Scale (ESS) scores will be obtained (also per standard practice).

Week 12 (90 days):

6. 90-day PAP therapy adherence and effect will be obtained for all subjects (intervention and control subjects).

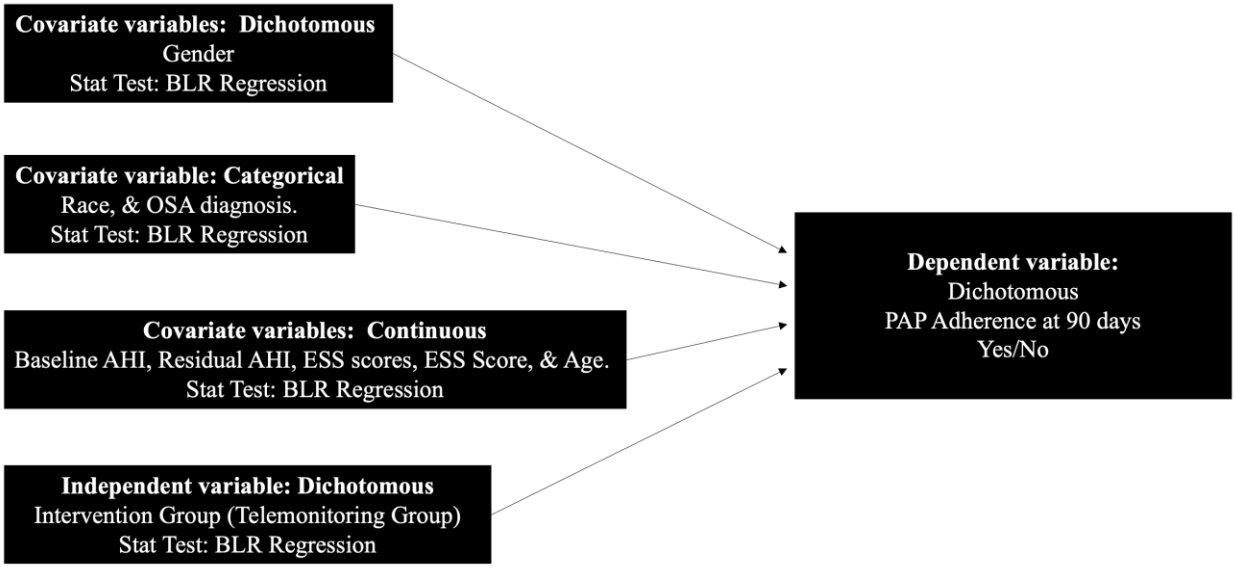
Appendix E

Phone Script: Telephone Consultation/Interview Talking Points

1) PAP experience since therapy initiation.
2) Review subject's diagnosis and indication for treatment.
3) Discuss subject's comfort with PAP therapy: climate settings mask fit. pressure parameters.
4) Recommendations per discussion:
    a. Mask change: Yes/No
       If yes, subject will be advised to call their durable medical equipment company or come to sleep center office for consultation with durable medical equipment affiliated respiratory therapist staffed CPAP clinic to discuss mask fitting.
    b. Pressure change: Yes/No
       If yes, Changes will be made remotely on ResMed Airview
    c. Climate setting change: Yes/No
       If yes, Changes can be made remotely through ResMed Airview or patient can adjust directly on their PAP device.
5) Reinforce recommendation to use PAP therapy every day with all sleep.
   (PAP compliance is defined as a minimum PAP usage of at least 4 hrs per day, 70% of days.)

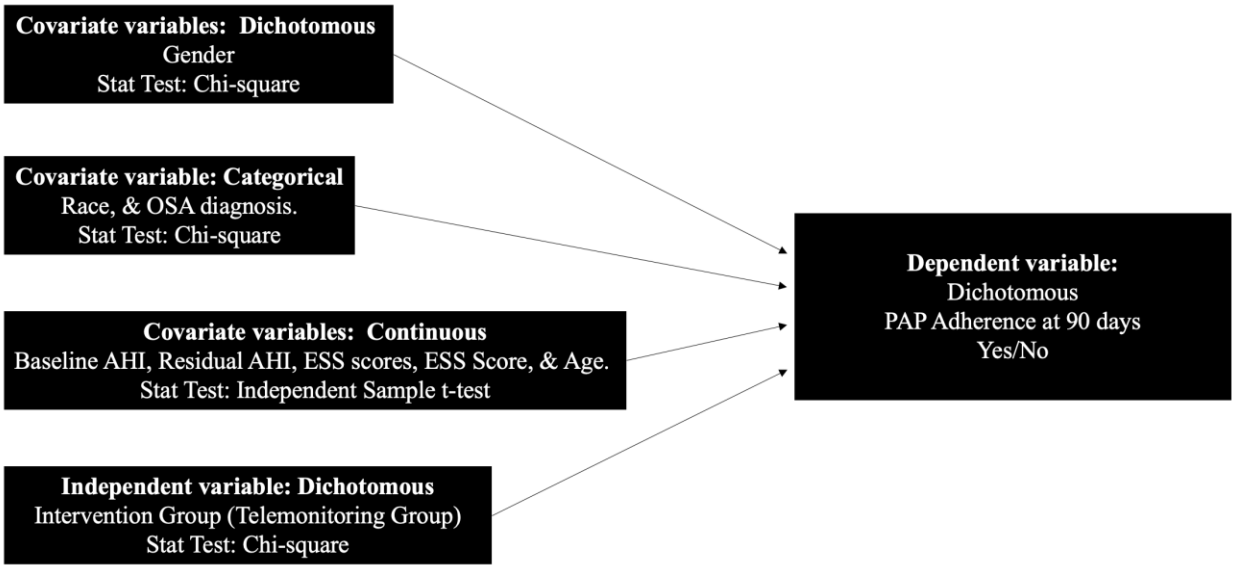
Appendix F

Bivariate Analysis Study Map



Appendix G

Multivariate Analysis Study Map



Appendix H

West Chester University of Pennsylvania Institutional Review Board Approval Letter

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Oct 3, 2022 3:21:31 PM EDT

To: Saoirse Owens
Department: School of Nursing

Re: Exempt - Initial - IRB-FY2023-61 Effect of Telemonitoring and As Needed Patient Support on PAP Adherence

Dear Saoirse Owens:

Thank you for your submitted application to the WCUPA Institutional Review Board. We have had the opportunity to review your application and have rendered the decision below for Effect of Telemonitoring and As Needed Patient Support on PAP Adherence.

Decision: Exempt

Selected Category: Category 2.(i). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
Category 3.(i)(A). Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

If there are any questions, please don't hesitate to reach out to irb@wcupa.edu

Sincerely,
WCUPA Institutional Review Board

IORG#: IORG0004242
IRB#: IRB00005030

Appendix I

Thomas Jefferson University Hospital Institutional Review Board Approval Letter

Office of Human Research
Institutional Review Board

Jefferson Alumni Hall
1020 Locust Street, Suite M-34
Philadelphia, PA 19107
T 215-503-8966
F 215-503-5738

October 4, 2022

Karl Doghramji, MD
Jefferson Sleep Disorders Center

Dear Dr. Doghramji,

The **Institutional Review Board (IRB)** has reviewed the involvement of human subjects in the proposed research study entitled:

"Effect of Telemonitoring and As Needed Patient Support on PAP Adherence" (Departmental)
***45 CFR 46.110* Control #22D.806**

In accordance with Federal-Wide Assurance #00002109 to the U.S. Department of Health and Human Services, this **study** was **administratively approved** on **9/8/2022.** Board #153 was notified at its **9/8/2022** meeting.

(X) EXPEDITED/NEW

PURSUANT TO TITLE 45 CODE OF FEDERAL REGULATIONS PART 46.116 (D), THE IRB HAS GRANTED A WAIVER OF INFORMED CONSENT.

As per 45 CFR 46.109(f)(1), this minimal risk research study requires **no further review and approval** by the IRB as long as the study is conducted as proposed. Any proposed revision to this study will necessitate submission of an OHR-12 to the IRB for further consideration prior to implementation.

Please notify the IRB in writing when the study has been completed.

This approval verifies that the IRB operates in accordance with applicable federal, local and institutional regulations that govern IRB operations.

Sincerely yours,

Walter Kraft, MD
Director
Office of Human Research
/sm

Appendix J

Thomas Jefferson University Hospital Waiver of Authorization

Jefferson
Philadelphia University + Thomas Jefferson University

Office of Human Research
Institutional Review Board

Jefferson Alumni Hall
1020 Locust Street, Suite M-34
Philadelphia, PA 19107
T 215-503-8966
F 215-503-5738

WAIVER OF AUTHORIZATION FOR USE /DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR HUMAN SUBJECTS RESEARCH

Please present this letter and your IRB approval letter to the appropriate personnel when requesting protected health information (PHI) from data sources outside your own practice.

Approval Date: 9/8/2022	PI:Karl Doghramji, MD	Control: 22D.806
Study Title: Effect of Telemonitoring and As Needed Patient Support on PAP Adherence		

IRB 153 has approved or been informed of this waiver. This waiver was reviewed by:

( ) Convened IRB **( ) Expedited** Review **(x) Exempt** Review

The requested waiver of authorization satisfies the criteria set forth in 45 CFR 164.512(i)(2)

X The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least the presence of the following elements:

X An adequate plan to protect the identifiers from improper use and disclosure;

X An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for regaining the identifiers or such retention is otherwise required by law;

X Adequate verbal/written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be otherwise permitted.

X The research could not be practicably conducted without the waiver of authorization.

X The research could not be practicably conducted without access to and use of the PHI.

This waiver applies to the following "minimum necessary" PHI:

Name, DOB, MRN, Age, gender, marital status, race, OSA diagnosis (moderate OSA, Severe OSA), baseline AHI, residual AHI (events per hour with PAP usage), % days of PAP usage, % days of PAP usage equal to or greater than 70%, average nightly use of PAP therapy (hours), 95% air leak (L/min), Epworth Sleepiness Scale score, contact information

Signature
Walter Kraft, MD
Director, OHR

10/4/2022
Date

Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation