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1. REPORT DATE	2. REPORT TYPE		3. [	DATES COVER	ED	
20220510	Technical Report, F	Final	STA	ART DATE June 2020	)	END DATE December 2021
4. TITLE AND SUBTITLE	1		I			
Obstructive Sleep Apnea	Surveillance and Ora	ll Appliance Therapy Evaluation, A	Active Duty I	J.S. Army, 20	14-2019	
5a. CONTRACT NUMBER		5b. GRANT NUMBER		5c. PROGRA		ENT NUMBER
N/A		N/A		N/A		
5d. PROJECT NUMBER		5e. TASK NUMBER		5f. WORK UI		BER
WS.0079064.3		N/A		N/A		
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8252 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5403

Technical Report No. S.0079064.3-21, May 2022 Clinical Public Health and Epidemiology Directorate

Obstructive Sleep Apnea Surveillance and Oral Appliance Therapy Evaluation, Active Duty U.S. Army, 2014–2019

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Approved for public release: distribution unlimited.

General Medical: 500A, Public Health Survey

APHC FORM 433-E, JAN 18

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'In peace and war, the lack of sleep works like termites in a house: below the surface, gnawing quietly and unseen to produce gradual weakening which can lead to sudden and unexpected collapse.'

Major General Aubrey Newman (Follow Me, 1981, p. 279)

The views expressed in this report are those of the author and do not necessarily reflect the official policy of the DoD, Department of the Army, U.S. Army Medical Department, or the U.S. Government.

# EXECUTIVE SUMMARY TECHNICAL REPORT NO. S.0079064.3-21 OBSTRUCTIVE SLEEP APNEA SURVEILLANCE AND ORAL APPLIANCE THERAPY EVALUATION, ACTIVE DUTY U.S. ARMY, 2014–2019

# 1. PURPOSE

This project serves as both a surveillance and treatment method evaluation. The purpose is threefold:

- Examine the incidence of obstructive sleep apnea (OSA) among active duty Army Soldiers from 2014 through 2019;
- Assess the identified Soldiers' subjective, self-reported impacts of OSA and one of its treatment methods oral appliance therapy; and
- Assess Soldiers' compliance and satisfaction with the oral appliance.

# 2. METHODS

The U.S. Army Public Health Center (APHC) Public Health Review Board determined this activity to be public health practice; it was assigned the APHC Office of Human Protections #19-744. The surveillance data presented were obtained from the Armed Forces Health Surveillance Division, which maintains the Defense Medical Surveillance System. All other data were self-reported through a survey distributed by the investigators via email to Soldiers diagnosed with OSA during the surveillance period.

Data analyses were restricted to the active component Army and covered the period from 2014 through 2019. OSA diagnoses were classified using the International Classification of Disease codes (ICD)-9 and -10. Analysis of surveillance data was conducted using Microsoft Excel 2016. Annual incidence rates were estimated by dividing the number of OSA cases by the number of active duty Army Soldiers reported in Defense Medical Epidemiology Database for that particular year. Incidence rates were further stratified by sex, age, and rank.

On 30 September 2020, an email containing an electronic survey link was sent to Soldiers identified as having been diagnosed with OSA; the survey closed on 28 December 2020. The survey asked questions pertaining to demographics, treatment methods, everyday wellness (e.g., sleep duration, alertness, fatigue, physical activity), as well as compliance and satisfaction with the oral appliance. Survey data were analyzed using SPSS Version 21.0 and Open Source Epidemiologic Statistics for Public Health, Version 3.01.

# 3. FINDINGS

# 3.1 Surveillance Findings

There were 87,404 incident diagnoses of OSA among active duty Army Soldiers from the years 2014 through 2019. Yearly incidence rates ranged from 274.3 to 330.3 cases per 10,000 person-years (p-yrs). The number of male cases (n=80,323) far exceeded that of female cases

(n=7,081). Male incidence rates (from 294.3 to 355.9 cases per 10,000 p-yrs) also exceeded that of females (from 155.2 to 189.2 cases per 10,000 p-yrs). Soldiers  $\geq$ 40 years old had the highest incidence rates of any age group (from 820.1 to 973.2 cases per 10,000 p-yrs). The greatest proportion (57.4%) of all OSA cases occurred among Soldiers in the ranks of E5–E9. However, Soldiers in the ranks of O4–O10 had the highest incidence rates (from 487.6 to 715.4 cases per 10,000 p-yrs). Soldiers in the ranks of E1–E4 had the lowest incidence rates (from 115.6 to 145.6 cases per 10,000 p-yrs). The greatest number of OSA diagnoses were among Soldiers in the Infantry (n=7,190) and Supply Administration (n=4,445).

# 3.2 Survey Findings

Out of 37,162 surveys distributed electronically, 8,740 surveys were returned. The majority of the respondents were men (95%; n=8,269) between 41 and 50 years of age (45%; n=3,930) in the ranks of E4–E9 (63%; n=5,469). The preponderance (93%; 402 women, 7,726 men) of respondents reported treatment with positive airway pressure (PAP) therapy, either in combination with other treatment modalities, or exclusively. Nine percent (n=795; 85 women, 710 men) reported treatment with the oral appliance. Of those treated with the oral appliance, 45% (n=360; 41 women, 319 men) were treated exclusively with the oral appliance; the remaining reported a combination of oral appliance therapy and other treatment periods, Soldiers treated with the oral appliance reported statistically significant improvements in sleep quality and duration, daily performance, cognition, alertness, physical activity, fatigue, and daytime sleepiness.

# 4. CONCLUSIONS AND RECOMMENDATIONS

OSA is a prevalent disorder among Army Soldiers that directly affects readiness. Additionally, Soldiers face many sleep-related challenges simply due to the nature of the profession. PAP therapy is the gold standard treatment for OSA, yet it is expensive, requires a power source and a great deal of maintenance, and presents with poor compliance. Oral appliance therapy is an effective treatment that can be used as an alternative to, or in conjunction with, PAP therapy. The oral appliance is small, lightweight, less expensive, and requires no electricity. The oral appliance's ease of use, particularly in austere environments, has the potential to improve the medical readiness of Soldiers with OSA. The results of this survey demonstrate that Army Soldiers are satisfied with oral appliance therapy; it has significantly improved their sleep quality and various aspects of daily life (e.g., alertness, cognition, performance, physical activity). Evaluation of long-term oral appliance therapy outcomes and cost-savings analyses may benefit the military and Soldiers with OSA.

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#### TECHNICAL REPORT NO. S.0079064.3-21 OBSTRUCTIVE SLEEP APNEA SURVEILLANCE AND ORAL APPLIANCE THERAPY EVALUATION, ACTIVE DUTY U.S. ARMY, 2014–2019

# 1. PURPOSE

Obstructive sleep apnea (OSA), while treatable, is a costly and highly prevalent disorder in the U.S. Army (reference 1). Additionally, it is associated with numerous chronic illnesses (references 1–6). Untreated OSA in the military is cause for concern, as is adherence to the prescribed treatment, both of which can have substantial implications on Soldier health, military medical readiness, and the military mission (references 1-6). Given the rising incidence of OSA and multitude of health complications that may accompany it, it is important that we determine the impact that both OSA and its lesser-known treatment, oral appliance therapy, have on Soldiers. Numerous studies have assessed OSA and the continuous positive airway pressure (CPAP) device in the Armed Forces. However, to our knowledge, there are no studies that assessed Army Soldiers' subjective, self-reported burdens of this disorder or their compliance and satisfaction with the oral appliance. This investigation will provide us with important information regarding the pre- to post-treatment effects of oral appliance therapy on sleep quality and duration, daily performance, cognition, alertness, physical activity, fatigue, and daytime sleepiness. In addition, this evaluation will serve to recognize the opportunity Army Dentistry has to support Army Medicine and the Army's Soldiers (reference Appendix C).

The objectives of this evaluation include the following:

- Identify active duty Army Soldiers diagnosed with OSA from 2014 through 2019. Included in this objective is to assess the incident diagnoses throughout this period by year, age, sex, and rank.
- Determine how the identified Soldiers were treated.
- Determine the extent to which OSA diagnosis affected deployment eligibility.
- Determine the impact OSA and the oral appliance have on sleep quality and duration, physical fitness level, cognitive behavior, alertness, and daily performance.
- Determine compliance and overall satisfaction with the oral appliance.

# 2. REFERENCES

See Appendix A for a comprehensive list of references.

# 3. BACKGROUND

As OSA is a serious and common sleep disorder, there is a rising health concern within both civilian and military populations (reference 1). The symptoms of this disorder are well characterized through its etymology; the Greek root of the term 'apnea' is 'apnos' which means 'without breath.'

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Medically speaking, apnea is defined as a cessation of airflow for at least 10 seconds. For those with OSA, this pause in breathing is caused by a physical obstruction; the pharynx collapses and blocks the upper airway (references 2–4). Depending on the severity of the disorder, this pause can last anywhere from 10 to 30 seconds (references 2–4). The result may be loud snoring or the production of choking noises as one attempts to breathe (references 2–4). Ultimately, the brain and body become deprived of oxygen causing the person to wake up (references 2–4). The person is often unaware this is happening as these pauses in breath do not trigger a full awakening (reference 4).

Due to interrupted breathing during sleep, an individual with OSA may feel extremely tired upon awakening in the morning and may experience excessive daytime sleepiness as a result (references 1–6). Poor sleep quality increases the risk of fatigue and depression, impairs physical performance, diminishes alertness, and decreases the ability to perform complicated cognitive tasks (references 1–6). In addition, those with OSA have increased rates of job-related and motor vehicle accidents, hypertension, cardiovascular disease, diabetes, and post-traumatic stress disorder (references 1–6).

Over the years, numerous population-based studies have assessed the prevalence of OSA in the United States as well as in other countries (reference 6). A recent study estimated that OSA affects 14% of men and 5% of women in the U.S. (reference 7). However, past studies have included a wide range of estimates, suggesting that the prevalence extends anywhere from 17%–27% of men and 3%–28% of women (references 6, 8–9). This variability is likely attributable to differences in study methods, some of which include differences in health status, age, and ethnicity, as well as differences in the methods to enroll participants and techniques used to measure airflow (references 6–9). In addition, it is estimated that at least 75% of severe OSA cases are undiagnosed (reference 6).

Sleep medicine physicians diagnose OSA; the standard for diagnosing this disorder is by polysomnography (PSG), commonly known as a sleep study (references 5, 6, 10). A PSG is a comprehensive test used to diagnose a variety of sleep disorders in addition to OSA, including narcolepsy, insomnia, restless leg syndrome, nocturnal seizures, and rapid eye movement sleep behavior disorder (references 5, 6, 10). During a PSG, the apnea-hypopnea index (AHI) is calculated; this measures the severity of OSA (reference 11). While apnea is a pause in breathing, hypopnea is a period of shallow breathing (reference 11). The AHI is the sum of all apneas and hypopneas that occur every hour, on average, during sleep (reference 11). An AHI of <5 is normal; 5–15 indicates mild OSA; 16–30 is moderate OSA; >30 is severe OSA (reference 11).

There are a myriad of risk factors for OSA. One major risk factor is elevated body mass index (BMI); however, OSA can occur in individuals of normal BMI as well (references 6, 12). Additional risk factors include age, sex, menopause, alcohol use, craniofacial abnormalities, hypertension, and family history of OSA (references 6, 12). OSA can occur at any age; nevertheless, it is most common between young adulthood and middle age (references 6, 12). The Sleep Heart Health Study shows a positive linear correlation between age and OSA up until roughly 65 years of age, after which the prevalence begins to plateau (references 6, 13). OSA is more common in men, but the risk for women increases with menopause due to a decrease in

the muscle tone in the upper airway (references 6, 12). Additionally, menopause is related to a change in the distribution of body fat. Both of these effects increase the likelihood of upper airway collapse during sleep (references 6, 12). Alcohol use increases upper airway resistance and causes a reduction of genioglossal muscle activity, thereby increasing the risk of OSA (references 6, 12). Various craniofacial abnormalities such as narrowing of the upper airway and increased upper airway collapsibility have been associated with the development of OSA (reference 6). Certainly, some OSA risk factors are modifiable (e.g., BMI, alcohol use), while others are not (e.g., family history, age).

PAP therapy, specifically the CPAP, is the gold standard treatment for moderate and severe cases of OSA (reference 14). There are also other variations of airway pressure devices in addition to the CPAP including auto-adjustable positive airway pressure (APAP), average volume-assured pressure support (AVAP), adaptive-servo ventilation (ASV), and bi-level positive airway pressure (BiPAP) devices (reference 5). The CPAP is the most prescribed machine as the American Academy of Sleep Medicine suggests clinicians use the CPAP or APAP over the BiPAP in the routine treatment of OSA (reference 5). The CPAP produces a steady stream of air through a mask which serves to keep the airway open (references 6, 15). The CPAP device is a highly effective method of treatment. However, studies have shown that adherence to this therapy is substandard in civilian patients and even more so among military personnel (references 16, 17). There are several other OSA treatment modalities available including oral appliance therapy, surgery, hypoglossal nerve stimulation, weight management, positional therapy, and lifestyle changes (e.g., avoiding alcohol, quitting smoking) (references 6, 15).

Oral appliance therapy is the leading alternative treatment to the CPAP for those with mild to moderate OSA (references 18, 19). These appliances, which appear very similar to a mouth guard, help keep the airway open by repositioning and/or stabilizing the lower jaw, and are delivered by qualified Dental Sleep Medicine (DSM) providers. The oral appliance is not suitable for all people with OSA. Should a sleep medicine physician feel a patient is a suitable candidate for this treatment method, the physician will provide the patient with a referral to a DSM provider (reference 20). In this situation, the DSM provider acts as the 'pharmacist' by delivering the custom-fabricated oral appliance only after receiving a prescription from the physician (reference 20). In some cases, the oral appliance is used in conjunction with the CPAP; this is known as combination therapy.

The incidence rates of OSA among Army Soldiers have drastically increased over the last 15 years (references 1, 21). According to a study by Rogers et al. (reference 1), the OSA incidence rate increased 600% from 2004 to 2013. As stated in the 2018 Health of the Force report (reference 22), OSA was the most frequently diagnosed sleep disorder among male Soldiers and the second most frequently diagnosed sleep disorder among female Soldiers. These are alarming facts, as Army Soldiers are otherwise healthy individuals when compared to similarly aged individuals in the U.S. population.

The impact of OSA on Soldiers and their mission performance is cause for concern. According to the minimum standards of fitness for deployment (reference 23), Soldiers with symptomatic OSA and/or moderate to severe OSA require waivers to deploy. Furthermore, Soldiers

diagnosed with OSA and treated with the oral appliance must have documentation indicating that OSA is controlled with its use (reference 23). Those treated with CPAP must be prepared to deploy with the necessary supplies including rechargeable battery backup, air filters, tubing, and masks for the duration of the deployment (reference 23). Deployment to austere locations may make the logistical task of maintaining OSA treatment with the CPAP difficult or impossible. Soldiers with complex OSA (or OSA that requires advanced modes of ventilation such as the ASV or AVAP) are generally non-deployable. In addition, a history of OSA is a condition that does not meet the standards of medical fitness for flying duty. Therefore, OSA directly influences readiness (reference 23). Finally, OSA is considered a disqualifying condition (i.e., does not meet medical standards for military retention) should the condition persist despite treatment and impair function to the level that it inhibits satisfactory performance of military duties (reference 24).

# 4. METHODS

The U.S. Army Public Health Center (APHC) Public Health Review Board (PHRB) approved this surveillance study and survey as public health practice; it was assigned project #19-744.

#### 4.1 Surveillance Methods

The surveillance data were obtained from the Armed Forces Health Surveillance Division (AFHSD), which operates the Defense Medical Surveillance System (DMSS). DMSS is the central repository of medical surveillance data for the U.S. Armed Forces. It contains current and historical data on diseases and medical events, as well as longitudinal data on personnel and deployments.

From 2014 through 2019, data analyses were restricted to the active duty Army. A case of OSA was defined as:

- One hospitalization with any of the defining diagnoses (see codes in Table 1) in *any* diagnostic position; or
- Two outpatient medical encounters within 90 days of each other, with any of the defining diagnoses of OSA (see Table 1) in *any* diagnostic position.

For individuals who met the case definition:

- The incident date was considered the date of the first hospitalization or outpatient medical encounter that included a defining diagnosis of OSA.
- An individual was considered an incident case only once per lifetime.

This case definition was developed by AFHSD for the purpose of epidemiological surveillance. Analysis of surveillance data was conducted using Microsoft<sup>®</sup> Excel<sup>®</sup> 2016. Yearly incidence rates were calculated by dividing the number of incident diagnoses by the number of active duty Army Soldiers reported in Defense Medical Epidemiology Database (DMED) for that particular year. The population statistics reported by DMED are represented as cumulative person-years

(p-yrs) during the calendar year of interest. However, person-time was not censored at the date of diagnosis, which may have resulted in an overestimation of the subsequent years' denominators, and an underestimation of incidence rates. Incidence rates were further stratified by sex, age group, and rank.

Description	ICD-9 Code	ICD-10 Code
Obstructive sleep apnea, adult, pediatric	327.23	G47.33
Sleep apnea, unspecified	780.51, 780.57	G47.30
Other sleep apnea	780.53	G47.39

Legend:

ICD = International Classification of Diseases

#### 4.2 AFHSD Data Request

A discrepancy was found in the surveillance data following the initial stages of analysis. An inconsistency in the number of identified cases led to a re-investigation of the data requisition. It was determined that the incidence rule listed above (once per lifetime) was not initially taken into account by AFHSD. As such, prevalent cases were not excluded, and our case list consisted of some individuals who had initially been diagnosed with OSA prior to the surveillance period (2014–2019). This affected our survey population, as the survey was distributed prior to the identification of this problem. However, a Soldier diagnosed prior to the surveillance period *should* have immediately branched out of the survey after answering the exclusion question pertaining to diagnosis year.

A new data requisition, including the 'once per lifetime' incidence rule, was completed; the surveillance findings presented below reflect this. Following a cross-reference of the survey respondents' identities with the list of cases, it was determined that 15% (N=1,307) of the survey respondents were Soldiers initially diagnosed with OSA prior to 2014. Soldiers' self-reported impacts of this disorder and its treatment are extremely relevant to the Army, regardless of the diagnosis year. Accordingly, it was decided that all survey feedback should be included in this report.

#### 4.3 Survey Methods

A team of internal and external subject matter experts representing various scientific backgrounds developed the survey. Following approval from the APHC PHRB, the survey was published in Verint<sup>®</sup>, a secure electronic survey platform (see Appendix B: Obstructive Sleep Apnea Survey). Email addresses for Soldiers diagnosed with OSA during the surveillance period were obtained from the Defense Manpower Data Center (DMDC). DMDC serves under the Office of the Secretary of Defense to collate personnel, manpower, training, financial, and other data for the Department of Defense (DoD). The intent was to electronically distribute the survey to all previously identified Soldiers; however, email addresses were only available in DMDC for 34% (n=37,162). On 30 September 2020, an email containing the link to the survey

was sent to 37,162 Soldiers. Over the next several months, Soldiers who had not yet completed the survey received email reminders. The survey closed on 28 December 2020.

The survey began with three exclusion questions pertaining to survey consent, Active Duty status, and OSA diagnosis. The survey immediately ended for any Soldier that answered 'No' to one or more of the exclusion questions; the survey continued for those that answered 'Yes' to all three. Next, demographics including age, sex, rank, and military occupational specialty (MOS) were obtained. In addition, Soldiers were asked to report physical characteristics (height, weight), disorder severity, deployment eligibility, treatment method(s) discussed with provider(s), and current treatment method(s). Severity is not reflected in the diagnostic code. It is based on the AHI measured during the PSG, something Soldiers may or may not be aware of; therefore, severity was self-reported and unable to be validated.

The most effective treatment plans for managing OSA and other sleep-related breathing disorders are multidisciplinary and comprehensive (reference 14). Therefore, Soldiers had the option to select multiple methods. Treatments offered for selection in the survey included the following: oral appliance therapy, CPAP, lifestyle changes, surgery, no treatment, and other (fill-in-the blank option). Soldiers that reported treatment with anything *other* than the oral appliance were asked if they were aware of this alternative treatment method prior to taking the survey.

The following section gave Soldiers the opportunity to rate the impact of OSA on several subjective measures of every day wellness (measured on a 5-point Likert scale) prior to initiating any form of treatment, including sleep quality and duration, daily performance, cognitive level, alertness, level of physical activity, fatigue, and daytime sleepiness. The survey ended for those that reported treatment with any method *other* than the oral appliance. For Soldiers that reported treatment with the oral appliance (either exclusively, or in conjunction with other treatment modalities) the survey continued with an evaluation of treatment compliance and satisfaction. Soldiers were again asked to rate the impacts on every day wellness (sleep quality and duration, cognition, alertness, physical activity, daytime sleepiness, etc.); however, they were instructed to consider the impact post-treatment with the oral appliance for at least 1 month. The period of 1 month was selected as the oral appliance may require some adjustments in the first several weeks following delivery.

Data analyses were conducted using SPSS<sup>®</sup> Version 21.0 and Open Source Epidemiologic Statistics for Public Health, Version 3.01. Missing or invalid responses were excluded. Means and standard deviations for height and weight were calculated and stratified by sex. Body Mass Index (BMI) was calculated based on the reported height and weight (height/weight at the time the survey was taken, not at the time of disorder diagnosis). The following formula was utilized:

#### (weight (lb) $\div$ height (in)<sup>2</sup>)\*703.

Frequencies were calculated by sex for the following:

- Age,
- BMI,
- Rank,

- Disorder severity,
- Deployment eligibility,
- Treatment method(s) discussed with provider(s),
- Current treatment method(s), and
- Awareness of the oral appliance prior to taking survey.

Soldiers that reported any airway pressure device as current method of treatment were included in the 'PAP therapy' group for all analyses. These devices included the following: CPAP, AVAP, APAP, ASV device, and BiPAP.

For the analyses, Soldiers were placed into groups based on reported treatment method. Groups vary by table and include the following:

- Soldiers treated with the oral appliance,
- Soldiers treated with PAP therapy and the oral appliance, and
- Soldiers treated by means other than the oral appliance.

The latter category includes Soldiers that reported treatment with any method (or combination of methods) except the oral appliance. The purpose of this evaluation was not to compare the oral appliance to PAP therapy, or to any other treatment. PAP therapy has been studied extensively over the years; it remains the gold standard treatment for OSA. However, given that PAP therapy was the most commonly reported treatment, analyses were geared towards grouping those treated with PAP therapy or the oral appliance (as opposed to other treatment methods reported in far fewer numbers), but not for the purposes of statistically comparing them. The purpose was to determine if Soldiers who use the oral appliance (either exclusively or in combination with other methods) were satisfied and comfortable with it.

There is no standardized definition for oral appliance adherence within the dental sleep medicine community, and no validated questionnaire exists to measure adherence (reference 25). While the American Academy of Sleep Medicine recommends 7 or more hours of sleep per night for optimal health, it is acknowledged that this may vary greatly from person to person. To assess adherence, a definition was established specifically for this study. Coincidentally, this definition is very similar to a definition developed and published recently, after our data analyses were completed (reference 25). In our evaluation, adherence was defined as wearing the oral appliance for at least 80% of an average night of sleep; Soldiers wearing it less than 80% were considered non-adherent. Adherence was calculated by dividing the reported average number of hours slept per night by the average number of hours the oral appliance was worn per night. For example, if a participant reported sleeping 6 hours per night, on average, and reported wearing the oral appliance for 5 of the 6 hours per night, on average, then the participant wore the appliance 83% of an average night of sleep. Being ≥80%, this was considered adherent. If the Soldier reported wearing the appliance for only 4 of the 6 hours each night (66.7% of the night), he/she was considered non-adherent. Non-adherent Soldiers were excluded from select calculations in the analyses (Tables 13 – 22). In this study, adherence did not take into account the reported number of nights per week the oral appliance was used. This is because in the open-ended question of the survey, numerous Soldiers indicated that the oral appliance was

used as an 'alternate therapy' when deployed (or traveling), as they were unable to use the CPAP in those environments due to unreliable electricity and/or inability to obtain maintenance supplies. Alternating treatment methods is not uncommon, as it may help minimize side effects from either treatment.

Shapiro-Wilk normality tests were conducted, indicating that the data were not normally distributed; nonparametric tests were thus used for subsequent analysis of the survey data. Mann Whitney U tests were used to evaluate differences in oral appliance use, comfort, and satisfaction, by sex. Mann Whitney U tests were also used to evaluate differences in pretreatment variable ratings (sleep quality, performance, cognition, alertness, physical activity, etc.) by sex and reported treatment method. Wilcoxon Signed-Rank tests were conducted to evaluate differences in pre- to post-treatment variable ratings by sex, treatment method, and reported disorder severity. While these tests compare medians (or ranks) across groups, means, as well as percent change in means, are also reported in addition to medians in select tables (Tables 13 - 22). Consistent with convention, an alpha level of 0.05 was used as the cut off for defining statistical significance, (i.e.,  $p \le 0.05$ ).

# 5. FINDINGS

# 5.1 Surveillance Findings

There were 87,404 incident diagnoses of OSA among active duty Army Soldiers from the years 2014 through 2019. Table 2 lists these diagnoses by ICD-9/ICD-10 code. Yearly incidence rates ranged from 274.3 to 330.3 cases per 10,000 p-yrs (see Table 3). The number of male cases (n=80,323) far exceeded that of female cases (n=7,081). Male incidence rates (from 294.3 to 355.9 cases per 10,000 p-yrs) also exceeded that of females (from 155.2 to 189.2 cases per 10,000 p-yrs). Men accounted for 91.9% of incident OSA cases during this study period, and as of 2020, 84.6% of the Army (see Table 4). Incidence rates for the Army overall and by sex are illustrated in Figure 1.

# Table 2. Obstructive Sleep Apnea Diagnoses by ICD-9/ICD-10 Code, Active Duty Army, 2014–2019

Diagnosis Code and Description	N
327.23ª, G47.33 <sup>b</sup>	71,068
Obstructive sleep apnea, adult, pediatric	
780.51ª,780.57ª;G47.3 <sup>b</sup>	14,331
Sleep apnea, unspecified	
780.53ª,G47.39 <sup>b</sup>	2,005
Other sleep apnea	
Total Diagnoses	87,404
Logond:	

Legend:

ICD = International Classification of Diseases Notes: a ICD-9; b ICD-10

Table 3. Incident Diagnoses and Incidence Rates of Obstructive Sleep Apnea, Ov	verall
and by Sex, Active Duty Army, 2014–2019	

Year	Army N	Army Rate <sup>a</sup>	Male N	Male Rate <sup>a</sup>	Female N	Female Rate <sup>a</sup>
2014	14,778	290.4	13,685	312.1	1,093	155.2
2015	15,244	312.7	14,100	336.9	1,144	165.8
2016	15,560	330.3	14,332	355.9	1,228	179.5
2017	13,988	300.8	12,844	324.2	1,144	166.4
2018	12,812	274.3	11,694	294.3	1,118	160.4
2019	15,022	318.4	13,668	341.5	1,354	189.2
Total N	87	,404	80	,323	7,081	

Note:

<sup>a</sup> Rates per 10,000 person-years

Table 4. Percent of All Obstru	ctive Sleep Apnea Cases and
Percent of Army Population b	y Sex, Age Group, and Rank
Group	

	Percent of all Cases <sup>a</sup>	Percent of Army <sup>b</sup>
Sex		
Male	91.9	84.6
Female	8.1	15.4
Age Group		
< 20	0.3	7.5
20–24	8.6	30.7
25–29	15.2	23.6
30–34	17.5	15.4
35–39	22.3	11.9
>= 40	36.2	10.9
Rank Group		
E1–E4	19.6	43.1
E5–E9	57.4	37.4
O1–O3 (W1–W3)	10.1	12.8
O4–O10 (W4–W5)	12.9	6.7

Notes:

<sup>a</sup> 2014–2019

<sup>b</sup> As of 2020, reported in Defense Medical Epidemiology Database.



Figure 1. Obstructive Sleep Apnea Incidence Rates, Overall and by Sex, Active Army, 2014–2019

The greatest proportion (36.2%) of all OSA cases occurred among Soldiers  $\geq$ 40 years of age. As of 2020, this age group comprised the smallest proportion (10.9%) of the Army (see Table 4). Table 5 displays incident diagnoses and incidence rates by age group and year. Soldiers  $\geq$ 40 years of age had the highest incidence rates of any other age group (from 820.1 to 973.2 cases per 10,000 p-yrs); Soldiers  $\leq$ 20 years of age had the lowest rates (from 6.4 to 14.9 cases per 10,000 p-yrs). Figure 2 illustrates the incidence rates by age group throughout this study period.

			Age Group					
Year		<20	20–24	25–29	30–34	35–39	>=40	
2014	N	19	1,080	2,243	2,791	3,169	5,476	
2014	Rate <sup>a</sup>	6.4	73.9	188.9	320.3	522.4	820.1	
0045	N	32	1,255	2,326	2,845	3,343	5,443	
2015	Rate <sup>a</sup>	10.3	89.0	209.7	344.9	570.1	856.6	
0010	N	27	1,233	2,273	2,793	3,427	5,807	
2016	Rate <sup>a</sup>	8.3	89.4	214.9	357.4	600.8	973.2	
0017	N	45	1,194	2,015	2,330	3,167	5,237	
2017	Rate <sup>a</sup>	12.5	85.6	193.7	314.2	567.7	941.7	
0010	N	43	1,166	1,950	2,087	2,884	4,682	
2018	Rate <sup>a</sup>	11.5	81.5	183.7	289.8	517.7	888.0	
0010	N	55	1,567	2,463	2,460	3,458	5,019	
2019	Rate <sup>a</sup>	14.9	107.6	224.7	342.5	616.6	972.4	
Total N		221	7,495	13,270	15,306	19,448	31,664	

Table 5. Incident Diagnoses and Incidence Rates of Obstructive Sleep Apnea
by Age Group and Year, Active Duty Army, 2014–2019

Note:

<sup>a</sup> Rates per 10,000 person-years



Figure 2. Obstructive Sleep Apnea Incidence Rates by Age Group and Year, Active Army, 2014–2019

The greatest proportion (57.4%) of all OSA cases occurred among Soldiers in the ranks of E5– E9 (Table 4). In 2020, Soldiers in the ranks of O4–O10 comprised the smallest proportion (6.7%) of the Army, yet this group had the highest OSA incidence rates (from 487.6 to 715.4 cases per 10,000 p-yrs). Those in the ranks of E1-E4 had the lowest incidence rates ranging from 115.6 to 145.6 cases per 10,000 p-yrs (see Table 6). Figure 3 illustrates the incidence rates by rank group throughout this period.

		Rank Group			
Year	Year E1–E4 E5–E9 O1–O3 (W1–		01–03 (W1–W3)	O4-O10 (W4–W5)	
2014	N	3,045	8,705	1,322	1,706
2011	Rate <sup>a</sup>	139.3	452.9	209.5	487.6
2015	Ν	3,051	8,983	1,450	1,755
2010	Rate <sup>a</sup>	145.0	494.3	234.4	524.0
2016	Ν	3,030	8,984	1,607	1,939
2010	Rate <sup>a</sup>	145.6	527.8	264.4	606.1
2017	Ν	2,690	8,061	1,431	1,806
	Rate <sup>a</sup>	129.9	482.9	238.9	582.2
2018	Ν	2,379	7,148	1,425	1,860
	Rate <sup>a</sup>	115.6	421.7	235.3	596.4
2019	Ν	2,914	8,264	1,598	2,246
	Rate <sup>a</sup>	142.1	474.3	262.1	715.4
Total N <sup>b</sup>		17,109	50,145	8,833	11,312

Table 6. Incident Diagn	oses and Incidence Rates of Obstructive Sleep Apnea
by Rank Group and Ye	ar, Active Duty Army, 2014–2019

Notes:

<sup>a</sup> Rates per 10,000 person-years <sup>b</sup> Five cases of unknown rank



Figure 3. Obstructive Sleep Apnea Incidence Rates by Rank Group and Year, Active Army, 2014–2019

Department of Defense Primary Occupation Codes (DoDPOC) were utilized to categorize occupations of Soldiers diagnosed with OSA during the study period. The top 20 occupations are listed in Table 7, each with a minimum of 1,300 cases. Occupations with less than 1,300 cases are included in the 'other' category. The occupations with the greatest number of cases were Infantry, General (n=7,190), Supply Administration (n=4,445), and Automotive, General (n=3,879).

Occupation	N
Infantry, General	7,190
Supply Administration	4,445
Automotive, General	3,879
Medical Care and Treatment, General	3,238
Ground and Naval Arms	2,951
Motor Vehicle Operators	2,611
Combat Operations Control, General	2,520
Law Enforcement, General	2,183
Aircraft, General	2,153
Artillery and Gunnery	1,753
Helicopter Pilots	1,747
Special Forces	1,683
General Logistics	1,662
Communications Radio	1,659
Recruiting and Counseling	1,578
Missile Fuel and Petroleum	1,575
Combat Engineering, General	1,571
Food Service, General	1,482
Missile Artillery, Operating Crew	1,470
Personnel, General	1,331
Other <sup>a</sup>	38,723
Total	87,404

# Table 7. Obstructive Sleep Apnea Diagnoses by PrimaryOccupation Code, Top 20 Occupations, Active Duty Army,2014–2019

Note:

<sup>a</sup> Remaining occupations have <1,300 cases each, or are unknown.

# 5.2 Survey Findings

The electronic survey was initiated by 12,090 of the 37,162 Soldiers that received it, for an initial response rate of 33%. However, the survey was not completed by all that initiated it. Those that answered 'No' to one of the exclusion questions regarding consent, active duty status, and diagnosis were immediately excluded, as were Soldiers that exited prior to completing the entire survey. The final number of Soldiers that submitted the survey totaled 8,740 for a final response rate of 24% (Figure 4).



Figure 4. Survey Response Flow Chart

Table 8 displays the demographics of survey respondents. Table 9 lists reported OSA severities, deployment eligibilities, and treatment methods. Given that oral appliance therapy is the focus of this evaluation, variables in Tables 8 and 9 are displayed by sex for two groups of respondents including those that reported treatment with the oral appliance (identified by superscript b), as well as *all* survey respondents, regardless of treatment method (identified by superscript a). The majority of all survey respondents were men (95%; n=8,269), between 41

and 50 years of age (45%; n=3,930), and in the ranks of E4 through E9 (63%; n=5,469). When observing only the respondents treated with the oral appliance, similar sex, age, and rank distributions were found. Fifty-three percent (n=4,298) and 51% (n=241) of all male and female survey respondents, respectively, were considered overweight; 40% (n=3,255) and 26% (n=121) were considered obese. Sixty-four percent (n=446) and 53% (n=45) of male and female oral appliance users, respectively, were considered overweight; 27% (n=191) and 24% (n=20) were considered obese.

OSA is a disorder that may require multiple treatment methods; therefore, Soldiers were given the opportunity to select multiple treatment methods in the survey. The vast majority (93%; 402 women, 7,726 men) reported treatment with PAP therapy, either in combination with other treatment modalities, or exclusively. Nine percent of Soldiers (n=795; 85 women, 710 men) reported treatment with the oral appliance. Of these Soldiers treated with the oral appliance, 45% (n=360; 41 women, 319 men) were treated with it exclusively; the remaining reported a combination of the oral appliance and other treatments modalities (e.g., PAP therapy, lifestyle changes, medication). Soldiers that reported treatment with anything other than the oral appliance were asked if they were aware of this alternative treatment method prior to taking the survey. The majority (76%, n=5,234) reported that they were not aware of the oral appliance as a method of treating OSA.

The majority (43%) of all respondents reported moderate OSA. Twenty-eight percent reported severe OSA; 13% were unaware of the severity of their disorder. When assessing only those that reported treatment with the oral appliance, few (15%) reported severe OSA; most reported moderate (48%) or mild (27%) OSA. The vast majority of all survey respondents (63%) as well as those that reported treatment with the oral appliance (71%) indicated that their deployment eligibility was not impacted by their OSA diagnosis. Sixteen percent (n=1,470) of all respondents and 11% (n=88) of those treated with the oral appliance indicated that a waiver was required for deployment.

	Men <sup>a</sup> (N=8,269)	Men OAT <sup>ь</sup> (N=710)	Women <sup>a</sup> (N=471)	Women OAT <sup>b</sup> (N=85)
	N (%) or Mean±SD	N (%) or Mean±SD	N (%) or Mean±SD	N (%) or Mean±SD
Age (years)				
20–30	480 (6)	42 (6)	43 (9)	9 (10)
31–40	3,302 (40)	291 (41)	139 (30)	27 (32)
41–50	3,712 (45)	299 (42)	218 (46)	37 (44)
51–69	775 (9)	78 (11)	71 (15)	12 (14)
Height (inches)	70±3	70±3	65±3	65±3
Weight (Ibs)	204±28	199±27	166±25	163±23
BMI				
Underweight/normal (18.5-24.9)	584 (7)	59 (9)	109 (23)	20 (23)
Overweight (25.0-29.9)	4,298 (53)	446 (64)	241 (51)	45 (53)
Obese (30.0+)	3,255 (40)	191 (27)	121 (26)	20 (24)
Rank				
E1–E3	7 (<1)	-	47 (10)	13 (15)
E4–E6	2,667 (32)	213 (30)	386 (82)	66 (78)
E7–E9	2,416 (29)	247 (35)	-	-
01–03	751 (9)	63 (9)	37 (8)	6 (7)
O4–O6	1,606 (19)	129 (18)	1 (<1)	-
O7–O10	30 (<1)	-	-	-
W1–W3	599 (7)	45 (6)	-	-
W4–W5	191 (2)	13 (2)	-	-

#### Table 8. Demographics of Survey Respondents by Sex and Reported Treatment Method

Notes:

N includes only valid responses; missing or invalid entries excluded. <sup>a</sup> All respondents regardless of reported treatment method.

<sup>b</sup> Respondents who reported treatment with oral appliance therapy.

Table 9. Self-Reported Severity,	Deployment Eligibility, and	Treatment Methods of Survey
Respondents by Sex		

	Men <sup>a</sup> (N=8,269)	Men OAT <sup>ь</sup> (N=710)	Women <sup>a</sup> (N=471)	Women OAT <sup>b</sup> (N=85)
	N (%)	N (%)	N (%)	N (%)
Self-reported disorder severity				
Mild	1,302 (16)	178 (25)	135 (29)	33 (39)
Moderate	3,540 (43)	347 (49)	205 (43)	36 (42)
Severe	2,343 (28)	115 (16)	74 (16)	5 (6)
Unknown	1,084 (13)	70 (10)	57 (12)	11 (13)
Deployment eligibility				
Eligibility not impacted by diagnosis	5,151 (63)	504 (71)	315 (67)	60 (71)
Must obtain waiver to deploy	1,430 (17)	82 (12)	40 (9)	6 (7)
Not eligible to deploy	94 (1)	6 (1)	11 (2)	5 (6)
Deployment eligibility unknown	1,594 (19)	118 (16)	105 (22)	14 (16)
Treatment(s) discussed with provider				
PAP therapy <sup>c</sup>	7,995 (97)	562 (79)	430 (91)	58 (68)
Oral Appliance Therapy	1,638 (20)	626 (88)	136 (29)	74 (87)
Lifestyle changes	1,773 (21)	210 (30)	104 (22)	19 (22)
Surgery	936 (11)	111 (16)	41 (9)	8 (9)
Did not remember	78 (1)	3 (<1)	4 (1)	1 (1)
Other	173 (2)	19 (3)	17 (4)	1 (1)
Current treatment method(s)				
PAP therapy <sup>c</sup>	7,726 (93)	329 (46)	402 (85)	33 (39)
Oral Appliance Therapy	707 (9)	-	85 (18)	-
Lifestyle changes	1,134 (14)	141 (20)	70 (15)	17 (20)
Not treated	11 (<1)	-	1 (<1)	-
Other	161 (2)	25 (4)	18 (4)	3 (4)
Awareness of oral appliance therapy				
prior to receiving survey <sup>d</sup>				
Yes	1,590 (24)	-	63 (19)	-
No	4,972 (76)	-	262 (81)	-

Notes:

N includes only valid responses; missing or invalid entries excluded.

<sup>a</sup> All respondents regardless of reported treatment method.

<sup>b</sup> Respondents reported treatment with oral appliance therapy.

<sup>c</sup> Includes CPAP, AVAP, APAP, ASV, BiPAP.

<sup>d</sup> This question did not apply to all survey participants.

Table 10 displays survey respondents by reported military occupational specialty. The top 20 reported specialties are listed in the table; the remaining reported specialties had either less than 110 respondents, or the entry was invalid. Thirty-seven percent (n=3,192) of respondents reported one of the following five occupational specialties: Ammunition Mechanical Maintenance & Ordnance Branch, Quartermaster Corps Branch, Military Intelligence Branch, Aviation, and Signal Corps Branch.

Table 10. Survey Respondents by Military Occupational
Specialty, Top 20 Reported Specialties

Military Occupational Specialty				
Ammunition, Mechanical Maintenance & Ordnance Branch	663			
Quartermaster Corps Branch	647			
Military Intelligence Branch	640			
Aviation	627			
Signal Corps Branch	615			
Adjutant General Corps	552			
Medical CMF	546			
Infantry Branch	538			
Field Artillery Branch	433			
Corps of Engineers	324			
Military Police Branch	278			
Transportation Branch	275			
Logistics Corps	271			
Armor Branch	255			
Air Defense Artillery	223			
Special Forces	178			
Chaplain Branch	153			
Chemical Corps	136			
Nurse Corps Branch	128			
Army Acquisition Corps	113			
Other <sup>a</sup>	1,145			
Total	8,740			

Note:

<sup>a</sup> Remaining specialties have < 110 respondents each, or entry is invalid.

Table 11 displays oral appliance adherence by sex. Eighty-eight percent (n=636; 64 women, 572 men) of Soldiers were considered adherent to the treatment (i.e., they met the minimum 80% adherence requirement discussed in Methods). When observing this by sex, adherence among men (88%) was equal to that of women (88%).

	Men (N=650)	Women (N=73)
Adherence <sup>a</sup>	N (%)	N (%)
100% of the night	513 (79)	55 (75)
80–99% of the night	59 (9)	9 (12)
50–79% of the night	50 (8)	7 (10)
<50% of the night	28 (4)	2 (3)

Notes:

N includes only valid responses; missing or invalid entries excluded.

<sup>a</sup> Adherence was calculated by dividing the reported average number of hours slept per night by the average number of hours the oral appliance was worn per night. Respondents were considered adherent if they reported wearing the oral appliance at least 80% of a typical night of sleep, on average.

Figures 5 and 6 display the frequencies of overall satisfaction and comfort of oral appliance therapy. These figures represent all respondents who reported treatment with the oral appliance, either exclusively or in combination with other methods, regardless of treatment adherence. The majority (58%, n=439) of all respondents rated satisfaction as either 3 (n=218) or 4 (n=221) on a scale of 1 to 5 (1-not at all satisfied; 5- completely satisfied). Similarly, the majority (61%, n=457) rated overall comfort as either 3 (n=280) or 4 (n=177) on a scale of 1 to 5 (1-extremely uncomfortable; 5-extremely comfortable).



Figure 5. Oral Appliance Therapy Satisfaction Ratings, All Oral Appliance Users



Figure 6. Oral Appliance Therapy Comfort Ratings, All Oral Appliance Users

Figure 7 displays the frequencies of reported side effects related to oral appliance use, regardless of treatment adherence. The most common reported side effect was jaw soreness (73%, n=546). Overall, a greater proportion of Soldiers did not experience teeth shifting or bite changes compared to those that did. Of those that experienced *any* problem(s) with the appliance, 296 sought help from a dentist. Sixty-two percent (n=185) of those Soldiers reported that the dentist was able to successfully address the problem.



Figure 7. Reported Side Effects of Oral Appliance Therapy, All Oral Appliance Users

Table 12 displays the reported side effects (teeth shifting, bite changes, jaw soreness) from oral appliance use by adherence and sex. A greater proportion of non-adherent male and female Soldiers reported teeth shifting, bite changes, and jaw soreness compared to adherent male and female Soldiers. Soldiers that sought help from the dentist regarding *any* problem(s) with the appliance were asked if their dental provider was able to resolve the problem(s) to their satisfaction; the majority (62%) of all Soldiers responded 'yes.' When observing this response by sex and adherence, a greater proportion of adherent male and female Soldiers reported 'yes' compared to non-adherent male and female Soldiers.

Men					
	Response	<b>Adherent</b> <sup>a</sup>	Non-adherent <sup>b</sup>		
		N (%)	N (%)		
Teeth shifting	No	357 (62)	57 (56)		
	Yes	215 (38)	45 (44)		
Bite changes	No	323 (57)	54 (53)		
	Yes	249 (43)	48 (47)		
Jaw soreness	No	172 (30)	19 (19)		
	Yes	400 (70)	83 (81)		
Dentist addressed problem					
to satisfaction <sup>c</sup>	No	78 (35)	19 (49)		
	Yes	147 (65)	20 (51)		
Women					
	Response	<b>Adherent</b> <sup>a</sup>	Non-adherent <sup>b</sup>		
Teeth shifting	No	43 (67)	8 (53)		
	Yes	21 (33)	7 (47)		
Bite changes	No	32 (50)	7 (47)		
	Yes	32 (50)	8 (53)		
Jaw soreness	No	16 (25)	-		
	Yes	48 (75)	15 (100)		
Dentist addressed problem		, <i>i</i>			
to satisfaction <sup>c</sup>	No	13 (42)	3 (100)		
	Yes	18 (58)	-		

 Table 12. Reported Side Effects of Oral Appliance Therapy by Sex and

 Adherence

Notes:

N includes only valid responses; missing or invalid entries excluded.

<sup>a</sup> Participants that reported wearing oral appliance ≥80% of a typical night of sleep

<sup>b</sup> Participants that reported wearing oral appliance <80% of a typical night of sleep.

<sup>c</sup> Only the respondents that reported they sought help from their dentist were asked this question.

Table 13 displays oral appliance use, comfort, and satisfaction by sex among adherent respondents only. At the time the survey was completed, the mean number of months that male and female Soldiers reported using the oral appliance was 29 and 27 months, respectively. There were no statistically significant differences between men and women in regards to the total length of treatment time, average nights per week the device was worn, comfort, or satisfaction. Both the median male and female comfort scores were 3, as were the median male and female satisfaction scores. On average, men reported sleeping significantly more hours per night than did women. In addition, male Soldiers reported wearing the appliance significantly more hours per night compared to female Soldiers.

		Men Women		Mann-Whitney U Test	
	N	Median; Mean±SD	N	Median; Mean±SD	p- value <sup>b</sup>
Length of time wearing appliance (months)	551	24; 29.21±21.08	59	23; 27.86±22.16	0.42
Comfort <sup>c</sup>	572	3; 2.98±1.04	64	3; 3.03±1.04	0.69
Satisfaction <sup>d</sup>	571	3; 3.30±1.14	64	3; 3.23±1.08	0.54
Average nights worn per week	572	6; 5.35±1.92	64	5.5; 5.11±1.91	0.20
Average hours worn per night	572	6; 5.97±1.11	64	5.5; 5.42±1.04	<0.001
Average hours of sleep per night	572	6; 6.08±1.10	64	5.5; 5.56±1.02	<0.001

Table 13. Oral Appliance Use and Satisfaction by Sex, Adherent<sup>a</sup> Respondents Only

Notes:

N includes only valid responses; invalid or missing entries and oral appliance non-adherent respondents excluded.

<sup>a</sup> Participants that reported wearing oral appliance ≥80% of a typical night of sleep (total 636; 572 men, 64 women)

<sup>b</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>c</sup> 1-extremely uncomfortable 5-extremely comfortable

<sup>d</sup> 1-not at all satisfied 5-completely satisfied

Tables 14 and 15 display pre-treatment wellness ratings (sleep quality and duration, performance, cognition, physical activity, etc.) of men and women, respectively, treated with the oral appliance compared to those treated with any method other than the oral appliance. Wellness ratings were compared in this manner because the symptoms of the disorder may influence the treatment decisions of the provider. The goal of this particular analysis was to evaluate differences in the reported effects of the disorder on wellness among those that later began treatment with the oral appliance, compared to those that later began treatment by other methods. Overall, both the men and women that were eventually treated by methods *other* than the oral appliance reported worse effects of OSA on all wellness measures: poorer sleep quality, fewer hours of sleep per night, more difficulty performing tasks, more impaired cognition, lower levels of alertness, more fatigue, more excessive daytime sleepiness, and feeling rested less often. All of the observed differences among men were statistically significant. Differences among women were statistically significant only for the following: sleep quality, performance, physical activity, fatigue, and excessive daytime sleepiness. Cognition was borderline significant (p=0.06).

Wellness Variable	Men treated by methodsWellness Variable		Men treated exclusively with oral appliance		Mann-Whitney U Test
	N	Median; Mean±SD	N	Median; Mean±SD	p-value <sup>a</sup>
Sleep quality <sup>b</sup>	7,559	2; 1.80±0.88	272	2; 2.10±0.91	<0.001
Hours of sleep/night	6,513	5; 5.08±1.15	257	5; 5.35±1.15	<0.001
Performance <sup>c</sup>	7,559	3; 2.75±0.94	272	3; 3.13±.97	<0.001
Cognition <sup>d</sup>	7,559	3; 2.84±0.97	272	3; 3.16±1.04	<0.001
Alertness <sup>e</sup>	7,558	3; 2.85±0.93	272	3; 3.10±0.97	<0.001
Physical activity <sup>f</sup>	7,558	3; 3±1.03	272	3; 3.36±1.10	<0.001
Fatigue <sup>g</sup>	7,558	2; 1.76±0.85	272	2; 1.99±0.95	<0.001
Excessive daytime sleepiness <sup>g</sup>	7,532	2; 1.91±0.94	269	2; 2.24±1.06	<0.001
Feeling rested <sup>h</sup>	7,552	2; 2.06±0.77	272	2; 2.24±0.82	<0.001

 Table 14. Comparison of Male Pre-Treatment Wellness Ratings by Reported Treatment

 Method

Notes:

N includes only valid responses; invalid or missing entries and oral appliance non-adherent participants excluded.

<sup>a</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>b</sup> 1-extremely poor 5-excellent

<sup>c</sup> 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

<sup>e</sup> 1-severe lack of alertness 5-highly alert

<sup>f</sup> 1-extremely difficult 5-no difficulty

<sup>g</sup> 1-most days 5-never

h 1-never 5-always
Wellness Variable	methods	n treated by other than oral pliance	exclusiv	en treated vely with oral pliance	Mann-Whitney U Test	
	N	Median; Mean±SD	N	Median; Mean±SD	p-value <sup>a</sup>	
Sleep quality <sup>b</sup>	386	1; 1.70±0.88	33	2; 2.27±0.94	<0.001	
Hours of sleep/night	311	4; 4.76±1.04	25	4; 4.88±1.09	0.62	
Performance <sup>c</sup>	386	3; 2.70±0.99	33	3; 3.06±0.86	0.02	
Cognition <sup>d</sup>	386	3; 2.80±1.00	33	3; 3.09±0.95	0.06	
Alertness <sup>e</sup>	386	3; 2.84±0.96	33	3; 2.91±0.77	0.73	
Physical activity <sup>f</sup>	386	3; 2.82±1.00	33	3; 3.30±0.89	0.01	
Fatigue <sup>g</sup>	386	1; 1.61±0.81	33	2; 2.03±0.98	0.01	
Excessive daytime sleepiness <sup>g</sup>	386	2; 1.85±0.98	33	2; 2.39±1.00	0.001	
Feeling rested <sup>h</sup>	386	2; 2.03±0.86	32	2; 2.06±0.84	0.68	

 Table 15. Comparison of Female Pre-Treatment Wellness Ratings by Reported Treatment

 Method

Notes:

N includes only valid responses; invalid or missing entries and oral appliance non-adherent participants excluded.

<sup>a</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>b</sup> 1-extremely poor 5-excellent

° 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

e 1-severe lack of alertness 5-highly alert

<sup>f</sup> 1-extremely difficult 5-no difficulty

<sup>g</sup> 1--most days 5-never

h 1-never 5-always

Tables 16 and 17 summarize a comparison of pre- to post-treatment wellness ratings among men treated with the oral appliance exclusively, as well as men treated with both the oral appliance and PAP therapy. On average, both groups of men reported statistically significant improvements in all wellness variables from pre- to post-treatment. Medians, means, as well as the percent change in means are reported. For the oral appliance group, the percent change in means ranged from 16% to 64% improvement. For the oral appliance and PAP therapy group, the percent change ranged from 19% to 79% improvement. The wellness metric with the greatest percent improvement in both groups of men was sleep quality.

		Before	After	Wilcoxon Signed- Rank	Change in mean	
Wellness Variable	Ν	Median; Mean±SD	Median; Mean±SD	p-value <sup>a</sup>	(%)	
Sleep quality <sup>b</sup>	272	2; 2.10±0.91	4; 3.45±0.93	<0.001	+64	
Hours of sleep/night	257	5; 5.35±1.15	6; 6.23±1.06	<0.001	+18	
Performance <sup>c</sup>	272	3; 3.13±0.97	4; 3.85±0.91	<0.001	+23	
Cognition <sup>d</sup>	272	3; 3.16±1.04	4; 3.84±0.95	<0.001	+22	
Alertness <sup>e</sup>	272	3; 3.10±0.97	4; 3.83±0.91	<0.001	+24	
Physical activity <sup>f</sup>	272	3; 3.36±1.09	4; 3.89±0.99	<0.001	+16	
Fatigue <sup>g</sup>	272	2; 1.99±0.95	3; 3.04±1.03	<0.001	+53	
Excessive daytime sleepiness <sup>g</sup>	269	2; 2.24±1.06	3; 3.22±1.09	<0.001	+44	
Feeling rested <sup>h</sup>	272	2; 2.24±0.82	3; 3.22±0.93	<0.001	+44	

 Table 16. Comparison of Pre- to Post-Treatment Wellness Ratings, Men Treated with Oral

 Appliance Exclusively

Notes:

N includes only valid responses; invalid or missing entries and oral appliance non-adherent participants excluded.

<sup>a</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>b</sup> 1-extremely poor 5-excellent

<sup>c</sup> 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

<sup>e</sup> 1-severe lack of alertness 5-highly alert

<sup>f</sup> 1-extremely difficult 5-no difficulty

g 1--most days 5-never

<sup>h</sup> 1-never 5-always

Table 17. Comparison of Pre- to Post-Treatment Wellness Ratings, Men Treated with Oral
Appliance and Positive Airway Pressure Therapy

		Before	After	Wilcoxon Signed- Rank	Change in
Wellness Variable	Ν	Median; Mean±SD	Median; Mean±SD	p-value <sup>a</sup>	mean (%)
Sleep quality <sup>b</sup>	183	2; 1.83±0.88	3; 3.28±1.01	<0.001	+79
Hours of sleep/night	161	5; 5.04±1.13	6; 6.01±1.1	<0.001	+21
Performance <sup>c</sup>	183	3; 2.77±0.95	4; 3.59±0.97	<0.001	+30
Cognition <sup>d</sup>	183	3; 2.80±0.95	4; 3.64±0.92	<0.001	+30
Alertness <sup>e</sup>	183	3; 2.89±0.93	4; 3.61±0.92	<0.001	+25
Physical activity <sup>f</sup>	183	3; 3.07±1.07	4; 3.66±0.98	<0.001	+19
Fatigue <sup>g</sup>	183	2; 1.80±0.91	4; 2.87±1.04	<0.001	+59
Excessive daytime sleepiness <sup>9</sup>	183	2; 1.97±0.98	4; 3.01±1.13	<0.001	+53
Feeling rested <sup>h</sup>	183	2; 2.12±0.72	4; 3.16±0.91	<0.001	+49

Notes:

N includes only valid responses; invalid or missing entries and oral appliance non-adherent participants excluded.

<sup>a</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>b</sup> 1-extremely poor 5-excellent

° 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

<sup>e</sup> 1-severe lack of alertness 5-highly alert

<sup>f</sup> 1-extremely difficult 5-no difficulty

g 1--most days 5-never

h 1-never 5-always

Tables 18 and 19 are similar to the previous two tables; however, comparison of pre- to posttreatment wellness ratings are stratified by reported disorder severity. All men, regardless of treatment or disorder severity, reported statistically significant improvements in all wellness variables from pre- to post-treatment. The variable with the greatest improvement in both groups of men, of all severities, was sleep quality.

		Mild			Moderate	9	Severe			
		Before	<u>After</u>		Before	<u>After</u>		Before	<u>After</u>	
Wellness Variable	N	Median; Mean±SD	Median; Mean±SD	N	Median; Mean±SD	Median; Mean±SD	N	Median; Mean±SD	Median; Mean±SD	
Sleep quality <sup>a</sup>	87	2; 2.23±0.87	4; 3.55±0.86	140	2; 2.05±0.96	4; 3.46±0.9	15	2; 1.67±0.62	3; 3.27±1.22	
Hours of sleep/night	82	6; 5.63±1.15	6; 6.46±0.88	130	5; 5.21±1.13	6; 6.27±1.05	15	5; 5.07±0.96	7; 6.2±1.08	
Performanceb	87	3; 3.3±0.97	4; 4.05±0.83	140	3; 3.05±0.88	4; 3.79±0.86	15	3; 2.67±1.05	4; 3.47±1.19	
Cognition <sup>c</sup>	87	3; 3.39±1.03	4; 4.02±0.86	140	3; 2.99±0.96	4; 3.76±0.88	15	3; 3±1.07	3; 3.47±1.13	
Alertness <sup>d</sup>	87	3; 3.32±0.96	4; 3.97±0.88	140	3; 3±0.91	4; 3.76±0.85	15	2; 2.6±1.12	4; 3.47±1.19	
Physical activity <sup>e</sup>	87	3; 3.56±1.11	4; 3.98±1	140	3; 3.25±1.01	4; 3.84±0.95	15	3; 3.2±1.26	4; 3.8±1.26	
Fatigue <sup>f</sup>	87	2; 2.15±0.95	3; 3.11±0.98	140	2; 1.90±0.9	3; 2.99±1.05	15	1; 1.87±1.25	3; 2.93±1.1	
Excessive daytime sleepiness <sup>f</sup>	87	2; 2.44±1.06	3; 3.37±0.99	138	2; 2.13±1.01	3; 3.14±1.11	15	2; 2.07±1.1	3; 3±1.2	
Feeling rested <sup>g</sup>	87	2; 2.28±0.84	3; 3.24±0.95	140	2; 2.21±0.82	3; 3.2±0.92	15	2; 1.93±0.7	3; 3.13±0.99	

 Table 18. Comparison of Pre- to Post-Treatment Wellness Ratings by Reported Sleep Apnea Severity, Men Treated

 with Oral Appliance Exclusively

Notes: N includes only valid responses; missing or invalid entries excluded; participants non-adherent with oral appliance or who did not report sleep apnea severity were excluded.

All pre- to post-treatment differences were statistically significant (p≤0.02), Wilcoxon Signed-Rank.

All scales 5-point Likert: a1-extremely poor 5-excellent; b1-extremely difficult 5-no difficulty; c1-cognition extremely impaired 5-normal cognition; d1-severe lack of alertness 5-highly alert; e1-extremely difficult 5-no difficulty; f1-most days 5-never; g1-never 5-always.

	Mild				Moderat	e	Severe		
Wellness		<u>Before</u>	<u>After</u>		<u>Before</u>	<u>After</u>		<u>Before</u>	<u>After</u>
Variable	N	Median; Mean±SD	Median; Mean±SD	Ν	Median; Mean±SD	Median; Mean±SD	N	Median; Mean±SD	Median; Mean±SD
Sleep quality <sup>a</sup>	27	2; 1.93±0.78	3; 3.44±0.89	93	2; 1.91±0.9	3; 3.38±0.92	47	1; 1.72±0.93	3; 3.02±1.22
Hours of sleep/night	26	5; 5.15±1.32	6; 6.54±1.07	86	5; 5.03±1.08	6; 6.07±1.07	36	5; 4.83±0.94	6; 5.89±1.09
Performanceb	27	3; 2.96±1.06	4; 3.81±0.92	93	3; 2.77±0.92	4; 3.65±0.95	47	3; 2.68±0.98	3; 3.38±1.01
Cognition <sup>c</sup>	27	3; 3.07±1.07	4; 3.89±0.89	93	3; 2.81±0.91	4; 3.69±0.91	47	3; 2.68±0.98	3; 3.47±0.95
Alertness <sup>d</sup>	27	3; 2.93±1.17	4; 3.81±0.88	93	3; 2.94±0.87	4; 3.69±0.9	47	3; 2.85±0.93	3; 3.4±0.99
Physical activity <sup>e</sup>	27	3; 3.33±1.3	4; 3.93±0.87	93	3; 3.09±0.99	4; 3.69±0.97	47	3; 3.02±1.13	4; 3.53±0.97
Fatigue <sup>f</sup>	27	2; 2.07±1.04	3; 3.26±1.02	93	2; 1.81±0.91	3; 2.84±0.97	47	2; 1.77±0.87	3; 2.77±1.13
Excessive daytime sleepiness <sup>f</sup>	27	2; 2.19±0.96	3; 3.33±1	93	2; 1.91±1.01	3; 2.97±1.1	47	2; 2.02±0.99	3; 2.91±1.25
Feeling rested <sup>g</sup>	27	2; 2.37±0.74	3; 3.37±0.79	93	2; 2.13±0.68	3; 3.12±0.91	47	2; 1.98±0.79	3; 3.11±1.03

 Table 19. Comparison of Pre- to Post-Treatment Wellness Ratings by Reported Sleep Apnea Severity, Men Treated with Oral Appliance and Positive Airway Pressure Therapy

Notes: N includes only valid responses; missing or invalid entries excluded; participants non-adherent with oral appliance or who did not report sleep apnea severity were excluded.

All pre- to post-treatment differences were statistically significant (p≤0.02), Wilcoxon Signed-Rank.

All scales 5-point Likert: <sup>a</sup>1-extremely poor 5-excellent; <sup>b</sup>1-extremely difficult 5-no difficulty; <sup>c</sup>1-cognition extremely impaired 5-normal cognition; <sup>d</sup>1-severe lack of alertness 5-highly alert; <sup>e</sup>1-extremely difficult 5-no difficulty; <sup>f</sup>1-most days 5-never; <sup>g</sup>1-never 5-always.

Tables 20 and 21 display a comparison of pre- to post-treatment wellness variables among women treated with the oral appliance exclusively, as well as women treated with both the oral appliance and PAP therapy. Both groups of women reported statistically significant improvements in all variable ratings from pre- to post-treatment. For the oral appliance group, the percent change ranged from 14% to 54% improvement. For the oral appliance and PAP therapy group, the percent change ranged from 22% to 107% improvement. The variable with the greatest improvement among the oral appliance group was fatigue; among the oral appliance and PAP therapy group, sleep quality ratings improved the most.

 Table 20. Comparison of Pre- to Post-Treatment Wellness Ratings, Women Treated

 with Oral Appliance Exclusively

		Before	After	Wilcoxon	
Wellness Variable	N	Median; Mean±SD	Median; Mean±SD	Signed- Rank p-value <sup>a</sup>	Change in mean (%)
Sleep quality <sup>b</sup>	33	2; 2.27±0.94	3; 3.48±0.83	<0.001	+53
Hours of sleep/night	25	4; 4.88±1.09	6; 5.67±1.08	0.001	+16
Performance <sup>c</sup>	33	3; 3.06±0.86	4; 3.73±0.88	0.004	+22
Cognition <sup>d</sup>	33	3; 3.09±0.95	4; 3.85±0.94	0.001	+25
Alertness <sup>e</sup>	33	3; 2.91±0.77	4; 3.88±0.82	<0.001	+33
Physical activity <sup>f</sup>	33	3; 3.30±0.89	4; 3.76±0.83	0.018	+14
Fatigue <sup>g</sup>	33	2; 2.03±0.98	3; 3.12±0.86	<0.001	+54
Excessive daytime sleepiness <sup>9</sup>	33	2; 2.39±1.00	3; 3.33±0.92	<0.001	+39
Feeling rested <sup>h</sup>	32	2; 2.06±0.84	3; 3.16±0.92	<0.001	+53

Notes:

N includes only valid responses; missing or invalid entries excluded; participants non-adherent with oral appliance excluded.

<sup>a</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>b</sup>1-extremely poor 5-excellent

° 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

e 1-severe lack of alertness 5-highly alert

<sup>f</sup>1-extremely difficult 5-no difficulty

g 1-most days 5-never

<sup>h</sup> 1-never 5-always.

Table 21. Comparison of Pre- to Post-Treatment Wellness Ratings, Women Treated
with Oral Appliance and Positive Airway Pressure Therapy

		Before	After	Wilcoxon	
Wellness Variable	N	Median; Mean±SD	Median; Mean±SD	Signed- Rank p-value <sup>a</sup>	Change in mean (%)
Sleep quality <sup>b</sup>	20	1; 1.45±0.69	3; 3.0±0.73	<0.001	+107
Hours of sleep/night	15	4; 4.33±0.72	5; 5.5±1.0	0.002	+29
Performance <sup>c</sup>	20	3; 2.3±0.98	3; 3.2±0.89	0.003	+39
Cognition <sup>d</sup>	20	2.5; 2.45±0.89	3; 3.25±0.91	0.001	+33
Alertness <sup>e</sup>	20	3; 2.9±1.29	3.5; 3.55±1.15	0.008	+22
Physical activity <sup>f</sup>	20	2; 2.35±0.88	3; 3.05±0.94	0.007	+30
Fatigue <sup>g</sup>	20	1; 1.55±0.76	3; 2.65±0.81	0.001	+71
Excessive daytime sleepiness <sup>g</sup>	20	2; 2.05±1.15	3; 2.6±0.99	0.043	+27
Feeling rested <sup>h</sup>	20	2; 1.75±0.72	3; 2.5±0.83	0.007	+43

Notes:

N includes only valid responses; missing or invalid entries excluded; participants non-adherent with oral appliance excluded.

<sup>a</sup> Statistically significant if p<0.05

All scales 5-point Likert:

<sup>b</sup>1-extremely poor 5-excellent

° 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

e 1-severe lack of alertness 5-highly alert

<sup>f</sup>1-extremely difficult 5-no difficulty

g 1-most days 5-never

h 1-never 5-always

Table 22 displays a comparison of pre- to post-treatment wellness variables among women treated with the oral appliance, by reported disorder severity. There were no women treated with the oral appliance that reported severe OSA. Additionally, very few women reported treatment with both the oral appliance and PAP therapy (n<10 for each severity group). Therefore, those two categories were excluded from the presentation of results. Women with mild OSA and treated with the oral appliance reported statistically significant improvements in all variables, with the exception of physical activity. Those with moderate OSA reported statistically significant improvements in the following: sleep quality, hours of sleep/night, cognition, alertness, fatigue, and excessive daytime sleepiness.

		Mild			Moderate				
		Before	After	Wilcoxon Signed-		Before	After	Wilcoxon Signed-	
Wellness Variable	N	Median; Mean	Median; Mean	Rank p-value <sup>a</sup>	N	Median; Mean	Median; Mean	Rank p-value <sup>a</sup>	
Sleep quality <sup>b</sup>	15	2; 2.53	4; 3.73	0.004	13	1; 1.92	3; 3.23	0.011	
Hours of sleep/night	12	5.5; 5.58	6; 6.13	0.023	10	4; 4.3	5; 5.4	0.015	
Performance <sup>c</sup>	15	3; 3.2	4; 4.07	0.008	13	3; 3	3; 3.38	0.26	
Cognition <sup>d</sup>	15	3; 3.47	4; 4.13	0.026	13	3; 2.85	4; 3.69	0.016	
Alertness <sup>e</sup>	15	3; 3	4; 4	0.004	13	3; 2.85	4; 3.62	0.046	
Physical activity <sup>f</sup>	15	3; 3.47	4; 3.87	0.141	13	3; 3.31	3; 3.62	0.28	
Fatigue <sup>g</sup>	15	2; 2.2	3; 3.53	0.005	13	2; 1.85	3; 2.69	0.026	
Excessive daytime sleepiness <sup>g</sup>	15	2; 2.53	4; 3.6	0.001	13	2; 2.38	3; 3.15	0.021	
Feeling rested <sup>h</sup>	14	2; 2.14	4; 3.36	0.004	13	2; 2.08	3; 3	0.071	

Table 22. Pre- to Post-Treatment Wellness Ratings by Reported Sleep Apnea Severity,
Women Treated with Oral Appliance Exclusively

Notes:

N includes only valid responses; missing or invalid entries excluded; participants non-adherent with oral appliance or who did not report sleep apnea severity were excluded.

There were no women adherent with the oral appliance that reported severe sleep apnea.

<sup>a</sup> Statistically significant if p<u><</u>0.05

All scales 5-point Likert:

<sup>b</sup> 1-extremely poor 5-excellent

<sup>c</sup> 1-extremely difficult 5-no difficulty

<sup>d</sup> 1-cognition extremely impaired 5-normal cognition

<sup>e</sup> 1-severe lack of alertness 5-highly alert

<sup>f</sup>1-extremely difficult 5-no difficulty

<sup>g</sup> 1-most days 5-never

<sup>h</sup> 1-never 5-always.

## 5.3 Summary of Open-Ended Survey Responses

At the conclusion of the OSA survey, Soldiers were presented with an open-ended question that provided them with the opportunity to share any additional information they chose regarding their experiences, diagnoses, treatment methods, etc. Many Soldiers (n=1,280) took advantage of this opportunity and chose to provide generous amounts of feedback. All responses were reviewed and placed into the following categories based on recurring themes: comments related to the effects of the disorder itself, including the process for its diagnosis, positive oral appliance comments, negative oral appliance comments, positive PAP therapy comments, negative PAP therapy comments, and recommendations. Numerous Soldiers provided very lengthy comments that contributed to all six categories.

The top five most common comments related to the overall effects of OSA and/or its diagnosis included the following:

- 1. Excessive daytime sleepiness.
- 2. Waking up choking/gasping for air or Soldier reports his/her spouse witnessed the choking/gasping for air.
- 3. Cognition impairments, including memory loss and inability to focus.
- 4. Challenges with receiving medical help from Army medical providers regarding sleep problems.
- 5. Difficult to fall and/or stay asleep.

The top five most common positive oral appliance comments included the following:

- 1. Overall satisfaction with the oral appliance improved sleep quality and/or quantity.
- 2. Easy to travel with, including deployments and/or field training exercises.
- 3. Works very well in conjunction with the PAP device.
- 4. Reduction (or elimination) of snoring.
- 5. Spouse sleeps better.

The top five most common negative oral appliance comments included the following:

- 1. Appliance is uncomfortable including general oral pain and/or soreness.
- 2. Overall dissatisfaction- no (or very little) improvement in sleep quality and/or quantity.
- 3. Jaw soreness and/or temporomandibular joint (TMJ) problems.
- 4. Uses the oral appliance only when the PAP device is not convenient or possible (i.e., traveling, deployed, PAP replacement parts not available).
- 5. Teeth shifting and/or altered bite.

The top five most common positive PAP device comments reported by Soldiers included the following:

- 1. Overall satisfaction with PAP device improved quantity and/or quality of sleep.
- 2. Improved quality of life.
- 3. Feeling well rested in the morning.

- 4. Improvement in overall daily function and/or work performance.
- 5. More energy on a daily basis.

The top five most common negative PAP device comments included the following:

- 1. Difficult to use and/or get used to.
- 2. Difficult to maintain and/or obtain the necessary maintenance supplies.
- 3. Overall dissatisfaction- it has not improved sleep quality and/or quantity.
- 4. Difficult to use while traveling, including deployments and field training exercises.
- 5. Difficulty with falling and/or remaining asleep.

The top five most common recommendations made by Soldiers included the following:

- 1. Travel-sized PAP devices should be issued.
- 2. A battery pack should be issued with the PAP device.
- 3. Cleaners/sanitizers should be issued with the PAP device.
- 4. The Army should assess the impact of burn pits and blast exposures on the development of sleep apnea.
- 5. The Army should review the time required for authorization of a replacement PAP device.

## 6. **DISCUSSION**

#### 6.1 Surveillance Discussion

This report documents the incidence of OSA in active duty Army Soldiers from 2014 through 2019. Incidence rates per 10,000 p-yrs were calculated for each year and stratified by sex, age, and rank. OSA constitutes a substantial burden for the Army, particularly among its older Soldiers, with 87,404 diagnoses during this 6-year evaluation period. The year-to-year incidence rates exhibited only minor fluctuations; however, despite the consistency throughout this study period, there has been a considerable rise in OSA diagnoses over the last 15 years (references 1, 21). According to one study (reference 1), the incidence of OSA among active duty Army Soldiers increased 600% from 2004 to 2013. Likewise, the percentage of Soldiers classified as overweight or obese has been increasing over the past several decades. In a study of active duty military personnel, the combined overweight and obesity prevalence increased from 50.6% in 1995 to 60.8% in 2008 (reference 26). Additionally, an investigation of U.S. Army recruits showed a 19% increase in body fat mass among both men and women from 1975 to 2013 (reference 27). The increase in the prevalence of overweight and obese Soldiers may have contributed to the aforementioned increase in OSA diagnoses. Additionally, a greater awareness of this disorder, its symptoms, and its risk factors may have led to a greater number of PSG referrals, and ultimately a greater number of diagnoses.

OSA diagnoses are more common among men, both in the general population and active Army. The vast majority of the cases (92%) were among male Soldiers. Given the gender distribution in the Army, this is to be expected. In 2020, males represented 85% of the active duty Army.

Nevertheless, when assessing risk, male Soldiers consistently had higher incidence rates compared to female Soldiers. The 6-year male incidence rate (327.5 per 10,000 p-yrs) was almost double the 6-year female incidence rate (169.4 per 10,000 p-yrs). OSA is a result of upper airway collapse during sleep. A 1999 editorial published in the journal *Thorax* (reference 28) suggested the higher prevalence of OSA among men may be attributed to sex-related differences in the structure and physiological behavior of the upper airway (reference 28). Literature suggests women have augmented genioglossal muscle activity compared to men, as well as a different upper airway shape (references 28, 29). This increased activity results in greater upper airway stability, making upper airway closure during sleep less likely (references 28, 29).

In the general population, OSA is most commonly diagnosed between young adulthood and middle age. Research shows a positive linear correlation between age and OSA diagnosis up until roughly 65 years, after which the prevalence begins to plateau (references 6, 13). The vast majority of active duty Army Soldiers (89%) are 39 years of age or younger. Soldiers 40 years or older comprise the smallest proportion of the Army (11%), yet, this age group experienced the greatest proportion of cases (36.2%) and the highest incidence rates. The 6-year incidence rate of Soldiers 40 years or older was 1.6 times that of Soldiers 35 to 39 years, and 85 times that of Soldiers younger than 20 years. Therefore, while the preponderance of active duty Army Soldiers are under the age of 40, those over 40 years of age have a substantially higher risk of an OSA diagnosis. As discussed previously, obesity is a major risk factor for OSA. Consequently, the age and sex distribution of obesity among active duty Army Soldiers is highly relevant when considering the sex and age distribution of OSA among active duty Army Soldiers. The last three iterations of the APHC's Health of the Force Report (references 22, 30, 31) stated that 17% of active duty Army Soldiers were obese; the prevalence of obesity increased with age, and in all age groups men were more likely to be obese than women. Therefore, the higher rates of OSA among older male Soldiers may be associated with the higher likelihood of obesity among this group.

As of 2019, enlisted Soldiers represented the vast majority of the Army (80.5%). Predictably, enlisted Soldiers represented the greatest proportion of OSA diagnoses during this study period (77.0%). However, when considering risk, officers in the ranks of O4 through O10 had the highest incidence rates. The 6-year OSA incidence rate of Soldiers in the rank group of O4 through O10 was 585.3 cases per 10,000 p-yrs; this rate is over 4 times the incidence rate of Soldiers in the ranks of E1 through E4 (136.2). This greater risk is likely attributed to the differing age distributions among ranks. As of 2020, almost a third (29%) of officers were 40 years or older while only 7% of enlisted Soldiers were in this age group. Alternatively, officers may be more likely to seek medical attention, which may lead to a greater number of PSG referrals and therefore, more diagnoses.

As reported by DMDC in 2021, combat-related occupational positions (e.g., infantry) accounted for 29% of enlisted Soldiers' occupations. Not surprisingly, the occupation with the greatest number of OSA diagnoses (n=7,190) was infantry. Infantry would require more deployments than, for example, administrative-related occupations. Deployment history may be relevant when considering the occupations with the most OSA diagnoses. A recent study evaluated the association of OSA with deployment and combat exposure among Army Soldiers from 1997 to 2011 (reference 21). Soldiers who were deployed were found to have more than twice the risk of

being diagnosed with OSA compared to non-deployed Soldiers. Additionally, the authors found that the association observed between deployment and OSA diagnosis remained statistically significant after controlling for obesity in a multivariable analysis (reference 21).

#### 6.2 Survey Discussion

This survey had an initial response rate of 33% (based on surveys initiated), and a final response rate of 24% (based on surveys completed). What may be considered a good or acceptable response rate depends on various factors including the survey method (e.g., telephone, electronic, in-person), type (e.g., consumer satisfaction, patient satisfaction), length, and demographics of the target group. When regarding health-related surveys specifically, literature (reference 32) suggests that younger men (29–44 years of age) of poor health and health behaviors are factors commonly associated with non-response. In this case, the target group included Soldiers diagnosed with OSA, the majority of which were men, 40 years of age and older. The initial response rate of 33% indicates that OSA is an area of importance; however, the response rate could have potentially been higher had the target audience been of a different demographic.

In this study, deployment eligibility was self-reported, and as such, may have been inaccurate. Furthermore, a Soldier may not be aware of deployment eligibility until the time he/she is assigned to deploy. Soldiers were also asked to report disorder severity, which is based on the AHI measured during the PSG. As PSG results are not readily available, severity could not be validated. Some Soldiers may not have been aware of their AHI and instead based the severity of their disorder using a subjective view of the severity of the impact on day-to-day life.

Survey respondents had the opportunity to select more than one current treatment method. The responses in the open-ended question indicated that some patients alternate treatment methods (i.e., use of PAP therapy at home and oral appliance during deployments or when traveling), while others use them in conjunction with each other. This is not unusual, as the alternating of treatments may help to minimize side effects of either therapy. However, the survey did not inquire about alternating treatment methods versus combining them. Therefore, whether or not the respondents who reported use of both treatment methods alternated them or used them in conjunction with each other is unknown. Certainly, this may influence the overall impact, and in turn, the wellness variable ratings. However, the purpose was not to compare the effectiveness of the oral appliance when used alone, to its effectiveness when used in conjunction with other methods; nor was the purpose to compare the oral appliance to PAP therapy. The purpose was to learn if overall, Soldiers who use the oral appliance (either exclusively, or in combination with other treatments) are satisfied and comfortable with it.

#### 6.2.1 Adherence

The vast majority (88%) of oral appliance users were considered adherent to the treatment. However, it must be pointed out that there is no standardized definition of oral appliance adherence (reference 25). The determination of compliance included the use of a definition constructed specifically for this investigation. Additionally, it is based on self-reported data, which may be accompanied by potential validity problems. Adherence to treatment may be based on a

multitude of factors, including comfort and satisfaction. The majority of oral appliance users rated overall appliance satisfaction as 4 (1-not at all satisfied; 5- completely satisfied); the majority rated overall appliance comfort as 3 (1-extremely uncomfortable; 5-extremely comfortable). Yet, when assessing side effects by treatment adherence, a greater proportion of non-adherent Soldiers reported side effects from the appliance (teeth shifting, bite changes, and jaw soreness) compared to adherent Soldiers. This finding is to be expected, as patients experiencing side effects from a prescribed treatment would be less likely to comply with it.

#### 6.2.2 Pre-Treatment Wellness Comparisons

Differences in wellness-related impacts of the disorder (prior to starting treatment) among those that later began treatment with the oral appliance were compared to those that later began treatment by other methods. This comparison was made because the symptoms (severity) of the disorder may influence the future method(s) of treatment. The literature has shown that the oral appliance is an effective treatment for patients with mild to moderate OSA (references 14, 18, 19, 33), as opposed to severe OSA. Consequently, there might be fewer cases of severe OSA in the 'oral appliance treatment group' compared to the 'other' treatment group. This may explain why overall, Soldiers treated by methods other than the oral appliance reported worse effects from the disorder.

#### 6.2.3 Pre- to Post-Treatment Wellness Comparisons

When observing the percent change in the men's wellness ratings pre- to post-treatment, the improvement in each rating was greater for those treated with the oral appliance and PAP device, compared to those treated exclusively with the oral appliance. Similar findings were observed among women, with the exception of three variables (alertness, daytime sleepiness, and feeling rested). These findings suggest that combination therapy may provide more relief from the disorder than just the oral appliance alone. Alternatively, those in the oral appliance and PAP therapy group have more severe OSA, and therefore have more room for symptom improvement. However, it must be repeated that whether or not the respondents that reported use of both the oral appliance and PAP therapy alternate the treatment methods or use them in conjunction with each other is unknown.

Overall, this survey demonstrated that oral appliance therapy, when used alone or combined with PAP therapy, resulted in statistically significant improvements in sleep quality, sleep duration, and various other wellness-related aspects of daily life (physical performance, alertness, cognition, etc.). To our knowledge, few studies have investigated wellness-related aspects of daily life both before and after oral appliance therapy. A recent study measured hypersomnolence (excessive sleepiness) and fatigue in 58 patients with OSA and treated with the oral appliance, specifically the mandibular advancement device (reference 34). Both hypersomnolence and fatigue were significantly reduced following 3 months of oral appliance therapy. Severe fatigue measured at baseline was reduced to mild fatigue. Additionally, the AHI decreased from  $28.9 \pm 17.6$  events per hour at baseline to  $10.0 \pm 11.8$  events per hour (AHI of 5-15 indicates mild OSA; 16-30 is moderate; >30 is severe). Therefore, these data suggest the oral appliance is an effective treatment resulting in improved health outcome characteristics (reference 34).

## 6.2.4 Awareness

Despite the fact that oral appliance therapy is not a newly developed treatment method, it has taken a backseat to PAP therapy for many years, most likely due to lack of awareness. The vast majority (76%, n=5,234) of Soldiers who reported any treatment method other than the oral appliance indicated they were not aware of this treatment prior to taking the survey. Perhaps some medical providers do not discuss oral appliance therapy with Soldiers because they themselves are not aware of it, or they do not believe it is an effective method for treating this disorder. Nevertheless, the oral appliance may gain more attention since Philips Respironics, a principal military PAP device supplier, recently issued a device recall (reference 35) (specifics of recall detailed below in paragraph 6.3). This recall notification was released 4 months after the close of the survey. Therefore, the specific impact the recall had, and continues to have, on Soldiers suffering from OSA is unknown at this time.

## 6.2.5 Insights from Additional Survey Comments

Fifteen percent (n=1,280) of the Soldiers that completed this survey took the time to provide additional comments. A great deal of those comments were exceedingly lengthy, clearly indicating they had something to say regarding this disorder, its impact on them and their spouses, their struggles, and their successes (or lack thereof) with the treatment method(s) prescribed to them. Numerous Soldiers described in detail the arduous process of being evaluated for OSA. Some stated it took months (or years) of pleading with healthcare providers before finally being referred for a PSG. Some Soldiers indicated their provider was reluctant to refer them for a PSG because they did not 'fit the profile' of someone with OSA (i.e., the Soldier was young, fit, and athletic as opposed to older and overweight). Alternatively, numerous other Soldiers experienced problems with treatment rather than diagnosis. Some that did not find relief through the prescribed treatment reported they 'learned to cope' with OSA by utilizing other methods. It was disconcerting to read that for a number of them, these 'other methods' included large amounts of alcohol, over the counter sleep aids, and caffeine. Other common complaints included 'no follow-up' and 'no continuity of care.' Some reported that after being informed of the PSG results and issued a PAP device, there was no further contact from the doctor and/or sleep clinic. Many Soldiers indicated they were never shown how to properly use (or maintain) the PAP device. Others indicated that following a permanent change of station (PCS) they encountered great difficulty obtaining the supplies necessary to maintain the device.

When considering the volume of thorough comments provided by Soldiers in this survey, one can assuredly conclude there are multiple barriers within the Army health system as it relates to this disorder. Dentists have an opportunity to pave the way for a streamlined process when it comes to the diagnosis and treatment of OSA. While a dentist cannot diagnose this disorder, the required yearly dental exam provides the dentist with the opportunity to screen for it. The American Academy of Dental Sleep Medicine's (AADSM) Standards of Practice Committee has established methods for identifying adults suspected of a sleep-related breathing disorder (reference 14). These methods include the collection of information regarding the demographic and anatomic (oral) factors most often associated with OSA. Some anatomical considerations of importance when assessing risk of OSA include the soft palate, uvula, tonsils, circumference of the neck, as well as the size and placement of the tongue. The dentist may also use a questionnaire (e.g.,

STOP-BANG questionnaire) to evaluate a patient's risk of having a sleep-related breathing disorder. This screening tool inquires about various characteristics and symptoms (e.g., snoring, tiredness, blood pressure, BMI) that are often associated with OSA. Additionally, the information that is routinely gathered during comprehensive dental examinations (e.g., health of hard and soft tissues of the mouth, location and integrity of teeth) can be used to help determine if a patient is a candidate for the oral appliance, should that patient be diagnosed with OSA in the future (reference 14).

OSA does not discriminate; it can affect men and women of all ages, body types, and athletic abilities. While risk factor-based OSA screening is justified and recommended, the idea that someone with OSA must fit a stereotype (i.e., older, overweight man) should no longer be entertained. Additionally, a successful treatment method for one Soldier may be an unsuccessful treatment method for another. PAP therapy is no longer the only treatment option for OSA. Furthermore, given the nature of the military profession (i.e., frequent moves, deployments, assignments in austere environments), ensuring continuity of care is essential. It would be appropriate and beneficial to mission readiness for dentists to take advantage of the yearly-required dental examination by screening for sleep-related breathing disorders, in addition to assessing dental readiness. Ultimately, all of the information collected during the dental exam will assist the dentist in determining if the patient is suspected of having OSA, and in turn requires a referral to a physician. The creation of this collaborative nature between dentists and physicians will serve to simplify and improve the OSA diagnostic and treatment processes.

The Military Health System (MHS) Quadruple Aim represents the ultimate goal for the MHS – to ensure a medically ready force through better health, better care, and lower cost (reference 36). Oral appliances are much less expensive to provide when compared to a PAP device. A recent study (reference 33) outlined in detail the potential cost savings for the military that oral appliance therapy offers. There were roughly 4,800 oral appliances issued Army-wide between August 2016 and August 2020, the cost of which was \$2.1 million (reference 33). Had the PAP device been issued to those patients instead of the oral appliance, the cost would have been \$4.8 million (reference 33).

The literature showing the effectiveness of oral appliance therapy in treating OSA is extensive (references 14, 18, 19, 33). The oral appliance presents with an ease of use that PAP therapy lacks; this is a significant quality given the nature of the military profession. Additionally, it offers considerable cost savings (reference 33). Ultimately, oral appliance therapy aligns with the MHS Quadruple Aim by successfully treating OSA, thereby improving readiness and deployability, at a lower financial cost.

## 6.3 Medical Device Recall Notification

On 26 April 2021, Philips Respironics provided an update regarding issues the company discovered with certain products in their Sleep & Respiratory Care portfolio (reference 35). Following extensive analysis, the company issued a recall notification on 14 June 2021. The potential health risks are related to the sound abatement foam used in specific Philips CPAP and BPAP devices, as well as mechanical ventilators. The notification (reference 35) reads as follows:

- The notification informs customers and users of potential impacts on patient health and clinical use related to this issue. Possible health risks include exposure to degraded sound abatement foam, for example caused by unapproved cleaning methods such as ozone, and exposure to chemical emissions from the foam material. High heat and high humidity environments may also contribute to foam degradation in certain regions.
- For patients using BPAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks.
- For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.
- Phillips is recommending that customers and patients do not use ozone-related cleaning products.
- Additionally, Phillips is reminding customers and patients to review the age of their BPAP and CPAP devices, as they are recommended to be replaced after 5 years of use.

In November 2021, Philips updated this guidance, which 'is based on the same test results up to June 2021 and is intended to provide broader options for physicians advising patients of affected devices, to better account for a wide variety of clinical use cases for patient medical conditions' (reference 35). The guidance reads as follows:

- For patients using BiLevel PAP and CPAP devices, consult with your physician on a treatment plan. This guidance has been updated from our previous recommendation to stop therapy before consulting with your physician. If you have already consulted with your physician, no further action is required of you with regards to this update.
- For patients using life-sustaining ventilation, continue prescribed therapy. There is no update to this guidance. Consult with your physician as soon as possible to determine appropriate next steps.

## 7. LIMITATIONS

The utilization of ICD diagnostic codes for surveillance studies, in *any* position, comes with limitations. These codes may not always translate into an official diagnosis. This was evident once the survey was administered to the Soldiers who were previously identified as OSA cases. Numerous Soldiers (n=71) responded to the survey via email indicating they did not have OSA. Some reported they had been tested for it in the past (i.e., PSG), after which they were informed that they did not have OSA. Some Soldiers indicated they were diagnosed with other sleep-related disorders (e.g. restless leg syndrome, insomnia), while others reported that if they did in fact have OSA, they were never informed of it. When these 71 Soldiers were cross referenced with the list of cases provided by AFHSD, it was determined that 18% of them did not display the OSA diagnostic code in the *primary* diagnostic position, but instead in a higher position (i.e., second through fourth positions). Therefore, the position of the ICD code may be of relevance when attempting to determine the true incidence (or prevalence) of a medical disorder or disease.

Self-reported studies, in general, present with multiple validity problems including the following:

respondents may exaggerate symptoms, they may under- or over-report frequencies, or they may simply misremember specific details. Therefore, while it was very important to capture Soldiers' subjective, self-reported burdens of this disorder, and their comfort and satisfaction with treatment, the confines of this specific type of study are well recognized and appreciated.

#### 8. CONCLUSIONS AND RECOMMENDATIONS

Quality sleep is critical to mission readiness. It is a valuable contributor to mental and physical health, and provides the body with an opportunity to restore and rejuvenate itself. Consequences of poor sleep quality include emotional distress, impaired cognition, risk of injury, and multiple other short- and long-term health complications (references 1–6). Unfortunately, sleep-related breathing disorders among Soldiers are not uncommon (references 1, 22, 30, 31). Additionally, the nature of the profession in and of itself presents with many sleep-related challenges (reference 37).

This report demonstrates that OSA remains a prevalent disorder, particularly among older U.S. Army Soldiers. To our knowledge, this is the first survey assessing Soldiers' subjective burdens from this sleep disorder, as well as their compliance and satisfaction with oral appliance therapy. Follow-up sleep studies are very useful for determining the efficacy of a particular treatment (i.e., how well it works under ideal, controlled conditions). However, they do not measure the treatment's effectiveness (i.e., how well it performs in real world conditions). PAP therapy is the gold standard treatment for OSA. Its efficacy has been thoroughly studied and proven. Yet, it is expensive, requires a great deal of maintenance, and presents with poor compliance (references 16–17). For many, PAP therapy is difficult to adhere to under ideal circumstances; in a deployed environment, its use can be thoroughly burdensome and inconvenient (references 16–17). Oral appliance therapy is an effective treatment that can be used as an alternative to, or in conjunction with, PAP therapy (references 14, 18, 19, 33). The oral appliance is small, lightweight, and requires no electricity. Its ease of use in austere environments provides it with the ability to improve Army readiness.

This survey indicates that overall, Soldiers are satisfied with oral appliance therapy. Additionally, this treatment has significantly improved their sleep quality, duration, and various aspects of daily life. However, the multitude of comments recounting the struggles to receive an OSA diagnosis and obtain effective treatment clearly indicate that some barriers remain within the military health care system. Consequently, an assessment of the current processes for screening, diagnosis, and treatment of Soldiers with sleep-related breathing disorders is well founded. Army Dentistry has the opportunity to support Army Medicine in the streamlining of these processes. Furthermore, evaluation of long-term oral appliance therapy outcomes and cost-savings analyses may benefit the military and Soldiers with OSA.

## 9. POINT OF CONTACT

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### Appendix A References

1. Rogers A, S Stahlman, D Hunt, G Oh, and L Clark. 2016. Obstructive sleep apnea and associated attrition, active component, U.S. Armed Forces, January 2004-2016. *MSMR* 23(10):2–11. PMID: 27792352

2. "Sleep Education – Sleep Apnea, Overview and Facts," American Academy of Sleep Medicine, last modified 2020. http://www.sleepeducation.org/essentials-in-sleep/sleep-apnea/overview-facts

3. "Sleep Medicine – What is Sleep Apnea?" Academy of Clinical Sleep Disorders Discipline, last modified 2021. https://acsdd.org/sleep-medicine

4. "What is Sleep Apnea?" American Sleep Apnea Association, last modified 2021. https://sleepapnea.org/learn/sleep-apnea/obstructive-sleep-apnea

5. Kapur VK, DH Auckley, S Chowdhuri, DC Kuhlmann, R Mehra, K Ramar, and CG Harrod. 2017. Clinical practice guideline for diagnostic testing of adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med* 13(3):479–504. DOI: 10.5664/jcsm.6506

6. Gharibeh T and R Mehra. 2010. Obstructive sleep apnea syndrome: natural history, diagnosis, and emerging treatment options. *Nat Sci Sleep* 2:233–255. DOI: 10.2147/NSS.S6844

7. Peppard PE, T Young, JH Barnet, M Palta, EW Hagen, and KM Hla. 2013. Increased prevalence of sleep-disordered breathing in adults. *Am J Epidemiol* 177(9):1006–1014. DOI: 10.1093/aje/kws342

8. Punjabi NM. 2008. The epidemiology of adult obstructive sleep apnea. *ProcAm Thorac Soc* 5(2):136–143. DOI: 10.1513/pats.200709-155MG

9. Young T, L Evans, L Finn, and M Palta. 1997. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. *Sleep* 20(9):705–706. DOI: 10.1093/sleep/20.9.705

10. Rundo JV and R Downey. 2019. Polysomnography. *Handb Clin Neurol* 160:381–392. DOI: 10.1016/B978-0-444-64032-1.00025-4

11. "What Does AHI Represent?" American Sleep Apnea Association, last modified 2021. https://sleepapnea.org/what-does-ahi-represent/

12. "Sleep Education – Sleep Apnea, Symptoms and Risk Factors," American Academy of Sleep Medicine, last modified 2016. http://www.sleepeducation.org/essentials-in-sleep/sleep-apnea/symptoms-risk-factors

13. Young T, E Shahar, FJ Nieto, et al. 2002. Predictors of sleep-disordered breathing in community-dwelling adults: the sleep heart healthy study. *Arch Intern Med* 162(8):893–900. DOI: 10.1001/archinte.162.8.893

14. Levine M, K Bennett, M Cantwell, K Postol, and D Schwartz. 2018. Dental sleep medicine standards for screening, treating, and managing adults with sleep-related breathing disorders. *J Dent Sleep Med* 5(3):61–68. DOI:10.15331/jdsm.7030

15. "Sleep Education – Sleep Apnea - Treatment," American Academy of Sleep Medicine, last modified 2016. http://www.sleepeducation.org/essentials-in-sleep/sleep-apnea/treatment

16. Lettieri CJ, N Paolino, AH Eliasson, AA Shah, and AB Holley. 2011. Comparison of adjustable and fixed oral appliances for the treatment of obstructive sleep apnea. *J Clin Sleep Med* 7(5):439–445. doi: 10.5664/JCSM.1300

17. Mysliwiec V, V Capaldi, J Gill, T Baxter, B O'Reilly, P Matsangas, and B Roth. 2015. Adherence to positive airway pressure therapy in the U.S. military personnel with sleep apnea improves sleepiness, sleep quality, and depressive symptoms. *Mil Med* 180(4):475–482. doi: 10.7205/MILMED-D-14-00197

18. Lim J, TJ Lasserson, J Fleetham, J Wright. 2006. Oral appliances for obstructive sleep apnea. *Cochrane Database Syst Rev* 25(1):CD004435. doi: 10.1002/14651858.CD004435.pub3

19. Sutherland K, C Phillips, and P Cistulli. 2015. Efficacy versus effectiveness in the treatment of obstructive sleep apnea: CPAP and oral appliances. *J Dent Sleep Med* 2(4):175-181. DOI:10.15331/jdsm.5120

20. OTSG/MEDCOM Policy Memo 18-043, Dental Sleep Medicine Therapy (Obstructive Sleep Apnea and Severe Snoring Oral Appliance Therapy) in the U.S. Army Dental Care System, 3 August 2018.

21. Caldwell J, J Knapik, T Shing, J Kardouni, and H Lieberman. 2019. The association of insomnia and sleep apnea with deployment and combat exposure in the entire population of U.S. Army soldiers from 1997–2011: a retrospective cohort investigation. *Sleep* 42(8):1–10. DOI:10.1093/sleep/zsz112

22. APHC. 2018. *Health of the Force*. https://phc.amedd.army.mil/Periodical%20Library/2018HealthoftheForceReport.pdf

23. USCENTCOM. 2020. Modification Fifteen (Tab A): Amplification of the Minimal Standards of Fitness for Deployment to the CENTCOM AOR; to Accompany Modification Fifteen to USCENTCOM Individual Protection and Individual/Unit Deployment Policy, April 2020.

24. DoD. 2020. Department of Defense Instruction 6130.03, *Volume 2: Medical Standards for Military Service: Retention.* Effective 4 September 2020.

25. Radmand R, H Chiang, M Giosia, M Galang-Boquiren, R Rohatgi, D Silk, O Vanderveken, and M Adame. 2021. Defining and measuring compliance with oral appliance therapy. *J Dent Sleep Med* 8(3). http://dx.doi.org/10.15331/jdsm.

26. Reyes-Guzman CM, RM Bray, VL Forman-Hoffman, and J Williams. 2015. Overweight and obesity trends among active duty military personnel, a 13-year perspective. *Am J Prev Med* 48(2):145-153. doi: 10.1016/j.amepre.2014.08.033

27. Knapik JJ, MA Sharp, and RA Steelman. 2017. Secular trends in the physical fitness of United States Army recruits on entry to service, 1975–2013. *J Strength Cond Res* 31(7):2030–2052. doi: 10.1519/JSC.00000000001928

28. Schwab RJ. 1999. Sex differences and sleep apnoea. *Thorax* 54(4):284–285. doi: 10.1136/thx.54.4.284

29. Popovic RM and DP White. 1995. Influence of gender on waking genioglossal electromyogram and upper airway resistance. *Am J Respir Crit Care Med* 152(2):725–31. doi:10.1164/ajrccm.152.2.7633734

30. APHC. 2019. *Health of the Force.* https://phc.amedd.army.mil/PHC%20Resource%20Library/2019\_Health-of-the-Force.pdf

31. APHC. 2020. *Health of the Force.* https://phc.amedd.army.mil/PHC%20Resource%20Library/2020-hof-report.pdf

32. Lallukka T, O. Pietilainen, S Jappinen, M Laaksonen, J Lahti, O Rahkonen. 2020. Factors associated with health survey response among young employees: a register-based study using online, mailed and telephone interview data collection methods. *BMC Public Health* 20(1):184. https://doi.org/10.1186/s12889-020-8241-8

33. Knowles S, M Dekow, M Williamson. 2021. Oral appliances for OSA treatment: meeting the quadruple aim. *Mil Med* usab316. doi: 10.1093/milmed/usab316

34. Kazemeini E, M Braem, G Moorkens, S Balina, C Kastoer, S Op de Beeck, OM Vanderveken, and M Dieltjens. 2019. Scoring of hypersomnolence and fatigue in patients with obstructive sleep apnea treated with a titratable custom-made mandibular advancement device. *J Clin Sleep Med* 15(4):623-628. doi: 10.5664/jcsm.7728

35. "Medical Device Recall Information, Phillips Respironics Sleep and Respiratory Care Devices." Philips USA, 14 June 2021. https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

36. "MHS Quadruple Aim." 2017. The Defense Health Agency. https://www.health.mil/Reference-Center/Glossary-Terms/2017/08/23/MHS-Quadruple-Aim

37. Troxel W, R Shih, E Pedersen, L Geyer, M Fisher, B Griffin, A Haas, J Kurz, and P Steinberg. 2015. Sleep in the military – promoting healthy sleep among U.S. servicemembers. Santa Monica CA: RAND Corporation. https://www.rand.org/pubs/research\_reports/RR739.html

### Appendix B Obstructive Sleep Apnea Survey

Why am I being asked to complete this survey?

This survey is specifically for Army Soldiers with sleep apnea (SA). If you have not been diagnosed with SA, please do not complete this survey. SA is a very common sleep disorder. Poor sleep quality can impair physical performance, increase fatigue and diminish alertness. The Army Public Health Center would like to learn more about how this disorder has impacted you. In addition, we would like to determine your compliance and satisfaction with a particular form of treatment called Oral Appliance Therapy (OAT), if that is your current method of treatment. OAT is a small oral device similar to a night guard and delivered by a certified dental sleep medicine provider. OAT is not a method of treatment suitable for all people with SA. Should OAT not be your current method of treatment, you still have the opportunity to help us understand the level to which this disorder has impacted your daily life, mission performance, and deployment eligibility.

Who is eligible to participate?

Only Army Active Duty Soldiers who have been diagnosed with SA within the years 2014 through 2019 are eligible to participate.

What will I be asked?

You will be asked questions related to your SA diagnosis including its severity and your current method of treatment. You will also be asked to rate the impact this disorder has on your daily life including sleep quality and duration, mission performance, physical activity level, etc. Should OAT be your current method of treatment, you will also be asked to rate the impact this particular treatment has had on the same aspects of your daily life.

How long will it take?

This survey is expected to take anywhere from 10 to 15 minutes – the total time depends on your current treatment method and the amount of thought you put into each answer. The survey must be completed in one sitting. Please make sure you have sufficient time to complete it.

How will my information be used?

In addition to the questions discussed above, we will be asking you some demographic questions, including identifying questions (e.g., your DoD ID). However, all information you provide will be kept private and secure; it will not be shared. You will not be personally contacted after completing this survey. The information we are collecting is necessary in order to confirm diagnoses and treatment methods. In addition, it will be utilized to compare responses and identify trends in the data between the various people who have completed this survey. All identifying information will be removed from any products that are produced from this project (e.g. reports, presentations, articles, etc.).

What are the risks and benefits of participating?

This survey is voluntary; you can stop at any time. The main benefit of participating is that your responses will help us to better understand how this disorder has impacted you, personally. Given how common this disorder is, that is very important information. In addition, should OAT be your current treatment method, we would like to know your personal satisfaction and compliance with it.

A risk associated with completing this survey is that participation provides you with the opportunity to really think about how you have personally been affected by this disorder; depending on the level to which you have been impacted, this may be accompanied by additional feelings of anxiousness or distress. Should that be the case, please contact your primary care physician, sleep medicine

physician/dental provider, or your local behavioral health clinic.

What is the incentive for participating?

Unfortunately, there is no incentive for your participation; however, please know that we greatly appreciate it.

Who should I contact if I have questions?

If you have any questions about this survey, feel free to contact MAJ Christa E. Hirleman DMD, at the U.S. Army Public Health Center by email christa.e.hirleman.mil@mail.mil. The APHC Office of Human Protections has reviewed and approved this survey as Public Health Practice and is tracking the project as #19-744.M2. You may also contact Ms. Dawn (Eslinger) Gyory, Human Protections Administrator, at dawn.m.gyory.civ@mail.mil or 410-417-2611 if you have any questions about this effort.

Do you agree to participate in this assessment?

Yes, begin asessment No, end assessment

Are you Active Duty Army?

Yes No

Were you diagnosed with Sleep Apnea (SA) within the years 2014 through 2019?

Yes No

DoD ID number

Military Occupational Specialty (MOS) (e.g., 11B)

\_\_\_\_\_

Army Grade

\_\_\_\_\_

E1 E2 E3 E4 E5 E6 E7 E8 E9 O1 O2 O3 04 O5 06 07 08 O9 O10 W1 W2 W3 W4 W5

Sex

Male Female

Age (years)

Height (feet)

Height (inches)

Weight (lbs)

What degree (severity) of Sleep Apnea (SA) were you diagnosed with?

*Mild Moderate Severe I don't know I do not have SA* 

How has your diagnosis with SA impacted eligibility to deploy?

My diagnosis with SA has not impacted my eligibility to deploy Since being diagnosed with SA, I am required to obtain a waiver to deploy Since being diagnosed with SA, I am not eligible to deploy I do not know the status of my eligibility to deploy

When you were diagnosed with SA, what treatment method(s) did your providers(s) discuss with you?

Select all that apply: Continuous Positive Airway Pressure (CPAP) Oral Appliance Therapy (OAT) - an oral device similar to a night guard Lifestyle changes (e.g. weight loss, no smoking, no drinking alcohol) Surgery I do not remember Other treatment \_\_\_\_\_

How are you currently being treated for SA?

Select all that apply: Continuous Positive Airway Pressure (CPAP) Oral Appliance Therapy (OAT) - an oral device similar to a night guard Lifestyle changes (e.g. weight loss, no smoking, no drinking alcohol) I am not currently being treated for SA Other treatment \_\_\_\_\_

Prior to initiating this survey, were you aware of Oral Appliance Therapy (OAT) as an alternative method used to treat SA?

Yes No

# Consider the three months before you started treatment for your SA:

How would you rate your sleep quality, in general, on a scale of 1 to 5?

1- Extremely poor 2 3 4 5- Excellent

How many hours of sleep per night, on average, were you getting?

How would you rate, in general, your daily performance (ability to function, accomplish tasks, complete your work duties, etc.) on a scale of 1 to 5?

1- Extremely difficult

- 2
- 3
- 4
- 5- No difficulty

How would you rate, in general, your daily cognitive level (perception, memory, judgement, comprehension and reasoning) on a scale of 1 to 5?

1- Cognition extremely impaired

2

3

4

5- Normal cognition, no impairments

How would you rate, in general, your alertness (state of awareness of what is going on in your surroundings; ability to sustain attention) on a scale of 1 to 5?

Severe lack of alertness
 3
 4
 5- Highly alert

How would you rate, in general, your physical activity level (ability to endure moderate to vigorous aerobic exercise such as running, biking, swimming, climbing, etc. for 20-30 minutes) on a scale of 1 to 5?

1- Extremely difficult

2

3

4

5- No difficulty

How often did you feel fatigued (lack of energy and motivation)?

Never Rarely (once or twice per month, on average) Sometimes (three or four times per month, on average) Frequently (two to three times per week, on average) Most days

How often did you experience excessive daytime sleepiness?

Never Rarely (once or twice per month, on average) Sometimes (three or four times per month, on average) Frequently (two to three times per week, on average) Most days

After a typical night's sleep, did you feel refreshed and well-rested?

Never Rarely Sometimes Frequently Always

If you have any additional information you would like to share with us about your experience with sleep apnea, including your diagnosis and/or treatment(s), please write your comments below:

# SURVEY ENDS FOR THOSE NOT TREATED WITH ORAL APPLIANCE

In this section, please indicate the total amount of time (approximately) in years AND months you have been using the oral appliance. *If you have been using the oral appliance for less than 1 year, please enter "0" for number of years.* 

How many years have you been using the oral appliance?

Enter number of years and months 0 1 2 3 4 5 6 I don't know

How many months have you been using the oral appliance?

11

I don't know

Over the past month:

How many nights per week, on average, have you worn the oral appliance?

1 night 2 nights 3 nights 4 nights 5 nights 6 nights 7 nights

Over the past month:

On the nights that you wore the oral appliance, how many *hours per night*, on average, did you wear it?

The following questions will allow you to rate your comfort and satisfaction with the oral appliance:

On a scale of 1 to 5, how comfortable is your oral appliance?

Extremely *un*comfortable
 3

4

5- Extremely comfortable

Have you ever noticed any teeth shifting due to wearing the oral appliance?

Yes No

Have you ever noticed any bite changes due to wearing the oral appliance?

Yes No

Have you ever noticed any jaw soreness, including clicking or popping, due to wearing the oral appliance?

Yes No

If you experienced any problem(s) with your oral appliance, did you contact your dental provider?

Yes

No

N/A - I have never experienced problems with the oral appliance

Was your dental provider able to address the problem(s) to your satisfaction?

Yes No

The following questions allow you to rate the same things you rated previously (sleep quality/duration, daily performance, alertness, etc.) However, now you will consider these ratings after use of the oral appliance for *at least one month*.

# Consider use of the oral appliance for at least one month:

How would you rate your sleep quality, in general, on a scale of 1 to 5?

1- Poor

2

3 4

4 5 Ev

5- Excellent

How many hours of sleep per night, on average, are you getting?

How would you rate, in general, your daily performance (ability to function, accomplish tasks, complete your work duties, etc.) on a scale of 1 to 5?

1- Extremely difficult

2

3

4

5- No dificulty

How would you rate, in general, your daily cognitive level (perception, memory, judgement, comprehension and reasoning) on a scale of 1 to 5?

1- Cognition extremely impaired

2

3

4

5- Normal cognition, no impairments

How would you rate, in general, your alertness (state of awareness of what is going on in your surroundings; ability to sustain attention) on a scale of 1 to 5?

1- Severe lack of alertness

2

3

4

5- Highly alert

How would you rate, in general, your physical activity level (ability to endure moderate to vigorous aerobic exercise such as running, biking, swimming, climbing, etc. for 20-30 minutes) on a scale of 1 to 5?

- 1- Extreme difficulty
- 2
- 3
- 4

5- No difficulty

How often do you feel fatigued (lack of energy and motivation)?

Never

Rarely (once or twice per month, on average) Sometimes (three or four times per month, on average) Frequently (two to three times per week, on average) Most days

How often do you experience excessive daytime sleepiness?

Never Rarely (once or twice per month, on average) Sometimes (three or four times per month, on average) Frequently (two to three times per week, on average) Most days

After a typical night's sleep, do you feel refreshed and well-rested?

Never Rarely Sometimes Frequently Always

On a scale of 1 to 5, how would you rate your current overall satisfaction with the oral appliance?

1- Not at all satisfied 2 3 4

5- Completely satisfied

If you have any additional information you would like to share with us about your experience with the oral appliance, please write your comments below:

### Appendix C Letter of Request

DEPARTMENT OF THE ARMY U.S. ARMY DENTAL ACTIVITY FORT BLISS U.T. 128 CHAFFEE ROAD EL PASO, TX 79916

MCDS-ME-CDC

January 30, 2019

MEMORANDUM FOR Director, U.S. Army Public Health Center, 8252 Blackhawk Road, Aberdeen Proving Ground, MD 21010

SUBJECT: Request U.S. Army Public Health Center (APHC) support to evaluate the burden of Obstructive Sleep Apnea (OSA) among Army Soldiers and satisfaction with Oral Appliance Therapy (OAT)

1. Purpose. The Army Dental Corps, Dental Sleep Medicine, requests the U.S. Army Public Health Center conduct a disease surveillance evaluation of OSA among Soldiers followed by an evaluation of those treated with OAT, an oral appliance/mandibular advancement device which keeps the jaw held forward thereby preventing collapse of the upper airway. Currently very little information exists regarding the satisfaction of these appliances among the military population. This is a disease which directly impacts mission performance and Soldier readiness. This evaluation will serve to not only measure the burden of this disease, but the impact of OAT on the sleep quality and mission readiness among our Soldiers. Army Dentistry has a valuable opportunity to support Army Medicine when it comes to the treatment of OSA.

2. Background. Contacted the APHC Disease Epidemiology Division on 25 January 2019. The purpose was to discuss assistance with disease surveillance and therapy satisfaction. Objectives discussed:

Determine number of Soldiers diagnosed with OSA Determine number of Soldiers informed of the OAT option Determine number of Soldiers treated with OAT vs Positive Airway Pressure Therapy Determine OAT compliance among Soldiers Determine Soldier satisfaction with OAT – to include improvements in sleep duration and quality as well as impact on daily/cognitive performance.

3. Request that the APHC Disease Epidemiology Division assist with the design of an evaluation, survey administration, analysis, interpretation, and reporting necessary to assess the burden of OSA and satisfaction with OAT among Army Soldiers.

4. The point of contact for this request is the undersigned at <u>phillip.w.neal2.mil@mail.mil</u>, please advise if more information is needed.

Phillip W Neal LTC, DC Chief, Army Dental Sleep Medicine

# Glossary

AFHSD Armed Forces Health Surveillance Division

AHI Apnea-hypopnea Index

APAP Auto-adjustable Positive Airway Pressure

**APHC** U.S. Army Public Health Center

AR Army Regulation

ASV Adaptive-servo Ventilation

AVAP Average Volume-assured Pressure Support

**BiPAP** Bi-level Positive Airway Pressure

BMI Body mass index

**CPAP** Continuous Positive Airway Pressure

DMDC Defense Manpower Data Center

**DMED** Defense Medical Epidemiology Database

DMSS Defense Medical Surveillance System

**DoD** Department of Defense

**DSM** Dental Sleep Medicine

ICD International Classification of Disease

MHS Military Health System

**PAP Therapy** Positive Airway Pressure Therapy

**PCS** Permanent Change of Station

**PHRB** Public Health Review Board

**PSG** Polysomnography

**p-yrs** person-years