Commercial Motor Vehicle Drivers and Obstructive Sleep Apnea

A Systematic Review and Meta-Analysis of Prevalence, Diagnosis, Treatment, and Risk Factors for OSA

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Executive Summary

Introduction

Driving a large commercial truck is dangerous work. Truck drivers have a high fatal work injury rate.[1] Large trucks were involved in 3,568 fatal crashes in 2011, killing 4,108 people and costing the U.S. $39 billion.[2]

The primary mission of the FMCSA is to reduce these crashes, injuries, and fatalities. As a part of this mission, the Medical Programs Division works to ensure that commercial motor vehicle (CMV) drivers engaged in interstate commerce are physically qualified and able to safely perform their work. In order to improve safety the FMCSA commissions systematic reviews on a variety of topics. These findings, together with input from FMCSA's Medical Expert Panel, are used to inform policy and decision-making.

This systematic review focuses on obstructive sleep apnea (OSA). OSA is a medical condition that impairs the quality of sleep and may lead to daytime sleepiness. FMCSA is interested in investigating the prevalence of OSA among CMV drivers and how OSA risk factors relate to CMV crashes. FMCSA is also investigating current best practices for diagnosing and treating OSA, as well as how these strategies have been applied to populations of commercial motor vehicle drivers.

This study builds on the findings of two previous FMCSA reports (2007[3] and 2011[4]).

Research Questions

FMCSA has identified the following research questions for this study:

1. **Based on studies of commercial motor vehicle driver populations, how many CMV drivers would be expected to have untreated OSA?**
2. **Based on studies of CMV crashes related to human factors, what is the relationship of those crashes to OSA risk factors such as high body mass index, neck circumference, snoring and excessive daytime sleepiness, and previous diagnosis of OSA?**

[1] Bureau of Labor Statistics: "Census of Fatal Occupational Injuries, data for 2012," accessed February 2014: http://www.bls.gov/iif/oshwc/cfoi/cfch0011.pdf
[2] FMCSA: "Commercial Motor Vehicle Facts, March 2013," accessed February 2014: http://www.fmcsa.dot.gov/documents/facts-research/CMV-Facts.pdf
[3] ECRI and Manila (2007). "Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety (Comprehensive Review)." Available at http://ntl.bts.gov/lib/30000/30100/30187/Final_Sleep_Disorders_Evid_Report_Vol._1.pdf
[4] Williams, Amana, and Tregear (2011). "Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety: Updated Review." Available at http://ntl.bts.gov/lib/44000/44600/44638/OSA_Update_11302011-p.pdf

3. **What is the cost and diagnostic accuracy of various options for diagnosing OSA, including paper-based questionnaires, home studies and overnight sleep studies?**
4. **What is the cost and effectiveness of current treatment options for individuals diagnosed with OSA?**
5. **Looking specifically at CMV drivers: Which diagnostic strategies have been tested with a population of CMV drivers? Which treatment options have been tested with a population of CMV drivers? How can treatments be tracked to ensure CMV driver compliance?**

Search Methodology

To identify relevant findings, Acclaro Research Solutions, Inc. (Acclaro) searched several large databases (Academic Search Premier, Business Source Complete, the Cochrane Library, CINAHL, Embase, Health Business Elite, the National Guideline Clearing House, PubMed, PsychINFO, Proquest Research Library, Science Direct, and TRID). Acclaro also identified relevant unpublished reports by searching the websites of various governmental, commercial, and non-profit organizations. The references of identified materials were also searched.

Databases were searched using a set of identified keywords. Abstracts were reviewed against a set of *a priori* retrieval criteria, and then the full text of potentially relevant items was reviewed against a set of defined inclusion criteria. All studies which met the criteria were abstracted and included in this review.

Findings for each identified study are presented and summarized by research question, along with a characterization of whether the identified evidence is strong, moderate, weak, or unacceptably weak.

A total of n=91 relevant studies were identified via the search process.

Findings are described using one of four categories (see Table 4 for more information):

- **Strong:** Evidence is convincing
- **Moderate:** Evidence is somewhat convincing
- **Weak:** There is some evidence, but it is tentative
- **Unacceptably weak:** Evidence is insufficient to warrant a conclusion

Findings

Research Question 1

Based on studies of commercial motor vehicle driver populations, how many CMV drivers would be expected to have untreated OSA?

The evidence base for Question 1 consists of n=15 studies.

There is moderate evidence that OSA is prevalent among CMV drivers at a higher rate than in the general population. Using a conservative definition for OSA of AHI≥5, two U.S.-based studies found 28% and 90% had at least mild OSA when a census approach was used to conduct polysomnography (PSG) on all participating drivers. Approaches where all participating drivers are given PSG are viewed as most appropriate to determine OSA prevalence, since screening approaches followed by PSG will necessarily miss some cases, and since many drivers referred for PSG using a screening approach will fail to follow-up (see below and question 5 for more information).

Studies from other nations employing a census approach to administering PSG found a quarter to forty percent or more of commercial drivers testing positive.

Data are insufficient to put a point estimate on how many drivers may have at least mild OSA: however, it is not unreasonable to expect that the number of drivers with at least mild OSA is greater than one in five and perhaps as many as nine out of ten. This is consistent with the recent finding that more than two-thirds of CMV drivers are obese.[5]

There is strong evidence that at least one in ten CMV drivers will screen as at-risk for OSA according to Joint Task Force Criteria, and weak evidence that the number of drivers screening positive according to this criteria may be up to three times higher. Four recent studies found that 12-32% of all drivers screened according to the criteria were at high-risk of having OSA. **However, current screening guidelines may be insufficiently sensitive to detect all drivers with OSA.** See question 5 for more information.

Research Question 2

Based on studies of CMV crashes related to human factors, what is the relationship of those crashes to OSA risk factors such as high body mass index, neck circumference, snoring and excessive daytime sleepiness, and previous diagnosis of OSA?

The evidence base for Question 2 consists of n=5 studies.

[5] Sieber, W. K., Robinson, C. F., Birdsey, J., Chen, G. X., Hitchcock, E. M., Lincoln, J. E., Nakata, A. and Sweeney, M. H. (2014), "Obesity and other risk factors: The National Survey of U.S. Long-Haul Truck Driver Health and Injury." Am. J. Ind. Med.

There is moderate evidence that OSA risk factors including BMI, AHI, daytime sleepiness, and scores on the Berlin questionnaire are associated with increased crash risk for CMV drivers. Studies both within and outside the United States have found elevated risks for those factors. There are insufficient data to quantify these risks, however, due to small number of available studies, and the different factors and investigative approaches used by these studies.

Research Question 3

What is the cost and diagnostic accuracy of various options for diagnosing OSA, including paper-based questionnaires, home studies and overnight sleep studies?

The evidence base for Question 3 consists of n=40 studies.

There is strong evidence that lab-based diagnostic approaches are the most sensitive and specific way to diagnosis OSA. Other diagnostic approaches, including home-based studies and questionnaires plus biometric data, are acceptable approaches when a lab-based option is not available. Questionnaires are a less sensitive and specific way to diagnosis OSA, although some questionnaires perform better than others (see question 5 for additional discussion)**.** These findings are based on a meta-analysis of recent research findings.

There is strong evidence that a screening program to identify drivers at-risk for OSA, followed by selective PSG, is more cost-efficient related to immediate short-term costs. Screening programs allow for the identification of drivers who are likely to be at higher risk for OSA, and reduce the number of PSGs performed, thus reducing immediate costs.

However, there is insufficiently weak evidence to identify whether screening is more cost-effective than universal PSG in the long-term, especially for a population like CMV drivers that is highly at-risk for OSA. This is because long-term cost savings are highly dependent on the cost of missed cases. Only one study has investigated this relationship, and it was based on a definition of OSA that includes Epworth scores in addition to AHI.

There is strong evidence that home-based PSG is more cost-efficient related to immediate short-term costs than lab-based PSG. Home-based PSG appears to cost 65-75% of lab-based PSG. However, one study suggests that lab-based monitoring may be more cost effective in the long-term, especially among audiences likely to have moderate to severe OSA. Additional research is required to investigate this topic.

Research Question 4

What is the cost and effectiveness of current treatment options for individuals diagnosed with OSA?

The evidence base for Question 4 consists of n=40 studies.

There is strong evidence that air pressure treatment is an effective way to treat OSA. This is based on the results of a meta-analysis of recent studies.

There is moderate evidence that medicine is an effective way to treat OSA. While medicine had a large effect size in the meta-analysis, there were fewer studies looking at the effects of medicine, and the confidence interval on this finding is large.

There is moderate evidence that surgery and dental appliances can be an effective way to treat OSA, although they appear to be not as effective as air pressure treatment or medicine. However, these treatment approaches may offer the advantage of permanence (in the case of surgery) and possibly higher adherence rates (in the case of dental appliances). Further study is required.

There is strong evidence that behavioral interventions approaches were the least effective approach to treat OSA.

There is weak evidence that CPAP treatment is cost effective. One study found that such treatment has a positive effect, but further research is needed. A major factor affecting the cost-effectiveness of CPAP is adherence rate, as CPAP is not an effective treatment if patients do not comply with treatment. **There is weak evidence that cost of treatment may be a barrier to CPAP adherence, based on the results of one study.**

There is weak evidence that OSA treatment can be conducted effectively in a primary care setting. One study found treatment was non-inferior and substantially more affordable in a primary care setting; however, this study used only Epworth scores as its outcome metric, and further research is required.

Research Question 5

Looking specifically at CMV drivers: Which diagnostic strategies have been tested with a population of CMV drivers? Which treatment options have been tested with a population of CMV drivers? How can treatments be tracked to ensure CMV driver compliance?

The evidence base for Question 5 consists of n=12 studies.

There is strong evidence that FMCSA's Commercial Driver Fitness Form (used on its own) will underestimate cases of OSA among CMV drivers compared to other methods. Very few drivers screen as at-risk using the question on the current form, and several studies show that the actual rate of OSA among the CMV driver populations is much higher than that identified by the current form.

There is weak evidence that questionnaires can be used to identify OSA among a population of CMV drivers; however, the sensitivity and specificity of each instrument varies considerably. Many of the instruments have only been tested in one study with CMV drivers; additional research is required to validate their use for this purpose.

There is weak evidence that BMI on its own may be a useful criteria to identify drivers at-risk for OSA. One study looked at the sensitivity and specificity of using BMI≥30 and BMI≥35 as criteria for OSA screening. It found that BMI (especially BMI≥35) has moderate sensitivity and specificity. Additional research is required.

There is strong evidence that the Joint Task Force Criteria are highly sensitive, and that most drivers screening at-risk according to these criteria will be confirmed by PSG to have OSA. There is weak evidence that these guidelines may not be very specific (based on the results of one study).

There is insufficiently weak evidence to identify preferred OSA treatment among CMV drivers. Only one study discussed treatment approaches, and only two types of approaches were discussed. Further study is needed to better understand how CMV drivers will respond to OSA treatment.

There is strong evidence that many drivers will not voluntarily complete requested PSG follow-up. Six studies found drop-out rates from 24-66%, with most studies averaging an attrition rate of over half of all drivers identified as at-risk. High loss to follow-up may significantly impact the identified rate of OSA among CMV drivers.

There is insufficiently weak evidence related to CMV driver compliance with treatment. Only one study directly addressed this question (and found low compliance); another study indirectly suggested compliance was high enough to reduce medical claims among drivers undergoing treatment.

Preface

Introduction

Driving a large commercial truck is dangerous work. Truck drivers have a fatal work injury rate of 22.1 per 100,000 workers, the eighth highest in the nation.[6] According to the Federal Motor Carrier Safety Administration (FMCSA), large trucks were involved in 3,568 fatal crashes in 2011, killing 4,108 people and costing the U.S. $39 billion.[7]

The primary mission of the FMCSA is to reduce these crashes, injuries, and fatalities. As a part of this mission, the Medical Programs Division works to ensure that commercial motor vehicle (CMV) drivers engaged in interstate commerce are physically qualified and able to safely perform their work. In order to improve safety the FMCSA commissions systematic reviews on a variety of topics. These findings, together with input from FMCSA's Medical Expert Panel, are used to inform policy and decision-making.

This systematic review of the literature focuses on obstructive sleep apnea (OSA). OSA is a medical condition that impairs the quality of sleep and may lead to daytime sleepiness. FMCSA is interested in investigating the prevalence of OSA among CMV drivers and how OSA risk factors relate to CMV crashes. FMCSA is also investigating current best practices for diagnosing and treating OSA, as well as how these strategies have been applied to populations of commercial motor vehicle drivers.

This study builds on the findings of two previous FMCSA reports (2007[8] and 2011[9]). Key findings from these previous reports include:

- There are currently no screening/diagnostic algorithms that enable medical screeners to identify CMV drivers at higher risk for OSA (2011).
- CMV drivers with OSA are at increased risk for a crash compared to drivers who do not have OSA, but the magnitude of this risk cannot be estimated at the present time (2007).

[6] Bureau of Labor Statistics: "Census of Fatal Occupational Injuries, data for 2012," accessed February 2014: http://www.bls.gov/iif/oshwc/cfoi/cfch0011.pdf
[7] FMCSA: "Commercial Motor Vehicle Facts, March 2013," accessed February 2014: http://www.fmcsa.dot.gov/documents/facts-research/CMV-Facts.pdf
[8] ECRI and Manila (2007). "Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety (Comprehensive Review)." Available at http://ntl.bts.gov/lib/30000/30100/30187/Final_Sleep_Disorders_Evid_Report_Vol._1.pdf
[9] Williams, Amana, and Tregear (2011). "Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety: Updated Review." Available at http://ntl.bts.gov/lib/44000/44600/44638/OSA_Update_11302011-p.pdf

- The following four factors are associated with increased crash risk among individuals with OSA: presence and degree of daytime sleepiness, severity of disordered respiration during sleep, lower blood SaO2 (arterial oxygen saturation) levels, and higher BMI (2007).
- Individuals with OSA may not be aware of the extent to which daytime sleepiness increases their crash risk (2007).
- Portable sleep monitoring systems may offer an acceptable and lower-cost alternative to OSA diagnosis than lab-based sleep studies, but further study is required (2011 & 2007).
- Continuous positive airway pressure (CPAP) is proven to reduce crash risk among individuals with moderate to severe OSA (2007).
- The use of CPAP reduces crash risk almost immediately (after as little as one night of treatment), and stopping treatment likewise negatively impacts driving ability almost immediately (2007).

Purpose of Report

The focus of this study is on identifying and describing the prevalence of OSA among CMV drivers, as well as how OSA risk factors relate to CMV crashes. The study also continues FMCSA's investigations into how OSA may be diagnosed and treated, especially among CMV drivers. FMCSA contracted with Acclaro Research Solutions, Inc. (Acclaro) to conduct a systematic review of the literature and identify relevant studies that address this topic.

This report addresses the following research questions:

1. **Based on studies of commercial motor vehicle driver populations, how many CMV drivers would be expected to have untreated OSA?**
2. **Based on studies of CMV crashes related to human factors, what is the relationship of those crashes to OSA risk factors such as high body mass index, neck circumference, snoring and excessive daytime sleepiness, and previous diagnosis of OSA?**
3. **What is the cost and diagnostic accuracy of various options for diagnosing OSA, including paper-based questionnaires, home studies and overnight sleep studies?**
4. **What is the cost and effectiveness of current treatment options for individuals diagnosed with OSA?**
5. **Looking specifically at CMV drivers: Which diagnostic strategies have been tested with a population of CMV drivers? Which treatment options have been tested with a population of CMV drivers? How can treatments be tracked to ensure CMV driver compliance?**

Report Organization

This evidence report and systematic review contains four major sections:

1) Background information on CMVs and Obstructive Sleep Apnea
2) Comparison of Relevant Regulations
3) Methodology
4) Evidence Summary

The Background section briefly summarizes risk factors for OSA and how it is diagnosed and treated. It also discusses the cost of OSA and why OSA is a particular concern for CMV drivers.

The Comparison of Relevant Regulations provides relevant information on current federal regulations for CMV drivers and offers equivalent standards from four English-speaking countries as a comparison. Additionally, equivalent regulations from the Federal Aviation Administration (FAA), the Federal Railroads Administration (FRA), and the Maritime Administration (MARAD) are summarized, providing a view of how obstructive sleep apnea is treated in the wider transportation industry.

The Methodology section describes in detail the sources that were searched, as well as the search terms used for each research question and the overall evidence base. This section also describes the evaluation criteria for determining the quality of the evidence for each study.

Finally, the Evidence Summary provides a detailed description of the evidence base for each research question, and includes summaries for each included study, grouped by question.

Report Funding and Role of Funders

This review was funded via contract DTMC75-13-R-00007 from the Federal Motor Carrier Safety Administration (FMCSA). FMCSA reviewed the report and provided comments. However, all research was conducted independently by Acclaro Research Solutions, Inc. and all findings are our own.

All authors declare no financial or other conflicts of interest.

Background

Obstructive Sleep Apnea

Sleep apnea is a disorder characterized by the cessation of normal breathing during sleep. These pauses in breathing can last several seconds or more, and in severe cases can occur more than 30 times per hour. Normal breathing typically resumes suddenly, accompanied by loud snoring, snorting, or choking sounds. Sleep apnea reduces the overall quality of sleep, disrupting normal sleep cycles. Because it is a chronic disorder, these disruptions happen night after night. This may result in excessive daytime sleepiness and a corresponding lack of alertness, as well as contribute to a range of health problems.

Obstructive sleep apnea (OSA) is the most common type of sleep apnea, affecting more than 18 million Americans according to the National Sleep Foundation.[10] OSA is more common in men than in women.[11] OSA occurs when muscles and tissue in the upper throat relax during sleep and block the flow of air. Symptoms usually include excessive daytime sleepiness and heavy snoring. Untreated OSA can exacerbate high blood pressure and the effects of diabetes, and increase the risks associated with cardiovascular disease.

Risk Factors

Risk factors associated with OSA include:[12,13]

- Obesity
- Neck circumference (> 17 inches for men and > 16 inches for women)
- High blood pressure
- Diabetes
- Age (OSA effects people of all ages, but is most common in adults aged 40-60)
- Smoking

Diagnosing OSA

There are a variety of methods used to diagnosis OSA. A physical exam can be conducted by a physician to assess risk factors (such as BMI and neck circumference); doctors may also look at nose and throat tissue for signs of potential obstructions. A doctor might also recommend further examination by a sleep specialist.

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[10] National Sleep Foundation: "Sleep Apnea and Sleep," accessed March 2014: http://sleepfoundation.org/sleep-disorders-problems/sleep-related-breathing-disorders/obstructive-sleep-apnea

[11] University of Maryland Medical Center: "Obstructive Sleep Apnea," accessed March 2014: http://umm.edu/health/medical/reports/articles/obstructive-sleep-apnea

[12] National Heart, Lung, and Blood Institute: "Who Is At Risk for Sleep Apnea?" accessed March 2014: http://www.nhlbi.nih.gov/health/health-topics/topics/sleepapnea/atrisk.html

[13] University of Maryland Medical Center: "Obstructive Sleep Apnea," accessed March 2014: http://umm.edu/health/medical/reports/articles/obstructive-sleep-apnea

Sleep studies are one of the primary methods for diagnosing OSA in a patient and assessing its severity. Overnight polysomnography (PSG) is considered to be the gold standard for OSA diagnosis. During PSG, a wide range of data is recorded while a patient sleeps, including brain activity, heart rate, breathing, arm and leg movements, and blood oxygen levels. Sleep experts then examine this data to diagnose OSA. Portable at-home monitors may also be used, though they do not monitor as many variables as lab-based tests.

A variety of questionnaires and screeners have also been developed to help identify OSA and other sleep-related disorders. These include:

- **The Epworth Sleepiness Scale (ESS):** This self-administered questionnaire consists of eight questions to assess how likely people are to fall asleep in various daytime situations, for a score ranging from 0-24. A score above 10 is frequently considered high.
- **The Berlin questionnaire:** This self-administered questionnaire consists of ten questions on a variety of topics related to snoring, witnessed apneas, restfulness, and physical characteristics such as BMI and high blood pressure. Patients scoring high in at least two of three domains are considered at high risk.
- **The Joint Task Force Recommendations:** These guidelines for OSA screening for CMV drivers were released in 2006 by the American College of Chest Physicians, the American College of Occupational and Environmental Medicine, and the National Sleep Foundation. The guidelines call for an expanded screening process for drivers, including a medical exam, a family/health/sleep history, and identification of risk factors such as high BMI, large neck circumference, or hypertension. Examiners determine whether the driver should be certified as fit to drive and given a two-year certificate, given a three-month temporary approval, or immediately suspended.
- **The Commercial Driver Fitness Determination:** FMCSA has developed a form for examiners to use, which includes one question about whether drivers experience sleep disorders, pauses in breathing, daytime sleepiness, or loud snoring.

Drivers scoring high on some of these measures are often referred for follow-up PSG examination.

Treatment Options for OSA

Once diagnosed, there are a variety of treatment options available, including:

- Air pressure treatments
- Behavior modifications
- Dental appliances
- Medication
- Surgery

The most common air pressure treatment is continuous positive airway pressure (CPAP). A CPAP user attaches a mask which then provides enough air pressure to prevent the airway from becoming blocked as the user sleeps. CPAP delivers constant air flow at a pre-set pressure. Other air pressure treatments include autotitrating positive airway pressure (APAP), bilevel positive airway pressure (BPAP), auto bilevel pressure release-positive airway pressure (ABPR-PAP), expiratory positive airway pressure (EPAP), and nasal continuous positive airway pressure (nCPAP). CPAP and its variants are generally considered to be effective treatments for OSA, though not all patients can use the device comfortably.

Behavior modifications include weight loss, increased exercise or physical activity, reduction of alcohol use, quitting smoking, or changing sleeping positions.

Dental appliances are another treatment option, particularly for patients who are unable to use or tolerate air pressure devices. Dental appliances work by changing the shape or position of the mouth and throat. Common devices include the mandibular advancement device (MAD), which opens the airway by forcing the jaw forward, and the tongue retraining device (TRD), which opens the airway by holding the tongue in a fixed position. Dental devices can be effective, particularly when the apnea is not severe.

Medications may also be effective in a limited number of cases. Modafinil, for example, is approved by the FDA to treat daytime sleepiness that results from OSA, though it does not treat the apnea itself.

Finally, there are several surgical procedures that can treat severe cases of OSA by reshaping or removing tissue from the soft palette, changing the shape and position of the jaw, altering the position of the tongue, or implanting devices to steady the soft palette.

Cost of OSA

A 2010 study conducted by the Harvard Medical School Division of Sleep Medicine estimated that moderate to severe OSA costs the U.S. between $65 and $165 billion dollars each year.[14] This is a potentially higher annual cost than both drunk driving ($60 billion) and driving without a seatbelt ($150 billion[15]). However, because the costs are often indirect and difficult to measure, and because OSA is often difficult and expensive to diagnose, there is limited public awareness about this condition and its costs.

[14] Harvard Medical School and McKinsey & Company: "The Price of Fatigue," 2010. Available at: https://sleep.med.harvard.edu/file_download/100
[15] Ibid

What OSA Means for Commercial Motor Vehicle Drivers

Driver fatigue has long been a concern in the trucking industry. The nature of the work—long hours, infrequent or low physical activity, repetitive tasks—mean that even healthy drivers may sometimes face sleepiness on the road.

However, OSA is a particular concern for commercial motor vehicle (CMV) drivers who—as a group—tend to be older males engaged in largely sedentary work. A recent study[16] compared long-haul truck drivers with a representative population of working adults: 1,670 drivers were surveyed, and findings indicate that over two thirds of drivers were obese, and 17% were morbidly obese (compared with one third and 7% respectively among working adults). CMV drivers also reported smoking at a rate more than twice that of the working adult population (51% vs. 19%), and 88% of drivers reported at least one of three OSA risk factors: hypertension, smoking, or obesity. Moreover, 9% reported all three (compared to 54% and 2% respectively for working adults). These findings are concerning, because excessive daytime sleepiness caused by OSA can increase the risk of serious motor vehicle accidents.[17]

Regulatory Review

FMCSA Regulations

FMCSA regulations establishing the physical qualifications of CMV drivers can be found in 49 Code of Federal Regulations (CFR) 391.41. One of the qualifying factors determining if an individual is fit to operate a CMV is that the individual "has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with his/her ability to control and drive a CMV safely."

Comparative Analysis for Other Nations

Like the United States, many other nations consider the potential impact of OSA on CMV operations. When looking at other major English-speaking nations, Canada, the United Kingdom, Australia, and New Zealand all address the risks of OSA in their regulations governing driver fitness; while US regulations do not refer to OSA specifically, guidance provided to medical examiners cites OSA as a risk. Specific regulation and guidance related to driver licensing and the responsibility of the driver to report medical conditions differs from nation to nation. A brief summary of national regulations is presented in Table 1, below.

[16] Sieber, W. K., Robinson, C. F., Birdsey, J., Chen, G. X., Hitchcock, E. M., Lincoln, J. E., Nakata, A. and Sweeney, M. H. (2014), "Obesity and other risk factors: The National Survey of U.S. Long-Haul Truck Driver Health and Injury." Am. J. Ind. Med.

[17] ECRI and Manila (2007). "Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety (Comprehensive Review)." Available at http://ntl.bts.gov/lib/30000/30100/30187/Final_Sleep_Disorders_Evid_Report_Vol._1.pdf

Table 1: Comparison of national regulations as they relate to commercial motor vehicles and obstructive sleep apnea

United States	Canada	United Kingdom	Australia	New Zealand
Regulations address risk of respiratory conditions	Regulations address risks of OSA	Regulations address risks of OSA	Regulations address risks of OSA	Regulations address risks of OSA
Medical examiner guidance covers OSA risk factors	Commercial drivers must file periodic mandatory medical reports assessing fitness to hold a commercial license	Drivers must report OSA symptoms that may affect safe driving	Drivers with OSA may not be able to hold an unconditional license	Drivers must declare medical conditions when applying for a license
Medical examination to determine fitness to drive is required	Treated OSA is subject to annual medical review by licensing agency	Drivers subject to fines up to £1000 for failure to report conditions that affect driving and may be prosecuted for involvement in accidents	Drivers with OSA who are compliant with treatment and display satisfactory response may hold a conditional license, subject to periodic review	Drivers who meet the high-risk profile should not drive until the condition has been treated.
	Licensing agencies determine if drivers with OSA risk factors are fit to hold a license pending a sleep assessment			License may be issued conditionally, subject to annual review

Sources: http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.aspx?reg=391.41 (United States); http://ccmta.ca/en/publications/resources-home/category/medical-standards-for-drivers (Canada); https://www.gov.uk/obstructive-sleep-apnoea-and-driving (UK); http://austroads.com.au/images/stories/assessing_fitness_to_drive_2013_rev2.pdf (Australia); http://www.nzta.govt.nz/resources/medical-aspects/ (New Zealand)

Comparative Analysis: Other Modes of Transportation

Regulations and guidance for other U.S. modes of commercial transportation vary. OSA is a disqualifying condition for pilots, whereas it is considered potentially disqualifying for merchant mariners. Regulations for both industries require consultation with a medical practitioner. There are no specific regulations or guidelines for the Federal Railroad Administration (FRA) or the Pipeline and Hazardous Materials Safety Administration (PHMSA), though the National Transportation Safety Board (NTSB) has issued recommendations related to sleep apnea and the risk of fatigued operations to all DOT agencies. Based on these recommendations, The Federal Transit Administration has developed training to increase awareness of sleep apnea and fatigue. Table 2, below, summarizes regulations and guidance for each industry.

Table 2: Comparison of Federal regulations related to obstructive sleep apnea in various transportation modes

FMCSA	Railroad	Air	Merchant Marine	FTA	PHMSA
Regulations address risk of respiratory conditions Medical examiner guidance covers OSA risk factors Medical examination to determine fitness to drive is required	No specific regulation or guidance NTSB has issued recommendations	Untreated OSA is a disqualifying condition for airmen Airmen who have OSA actively treated by a physician and an Aviation Medical Examiner may fly	"Sleep disorders or therapy which would result in gradual deterioration of performance of duties, sudden incapacitation otherwise compromise shipboard safety, including required response in an emergency situation" may be potentially disqualifying	No specific regulation Untreated OSA is recognized as a high-risk vulnerability Training has been developed and implemented	No specific regulation or guidance NTSB has issued recommendations

Sources: http://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=15474
http://www.uscg.mil/hq/cg5/nvic/pdf/1998/n2-98.pdf
http://www.fta.dot.gov/newsroom/12910_15546.html
http://www.ntsb.gov/doclib/speeches/rosekind/Rosekind_140219.pdf

Research Methodology and Evidence Base

Research Questions

FMCSA has identified several research questions for this study, which we have refined and further subdivided into discrete research questions to focus our search strategies. These questions are:

1. **Based on studies of commercial motor vehicle driver populations, how many CMV drivers would be expected to have untreated OSA?**
2. **Based on studies of CMV crashes related to human factors, what is the relationship of those crashes to OSA risk factors such as high body mass index, neck circumference, snoring and excessive daytime sleepiness, and previous diagnosis of OSA?**
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4. **What is the cost and effectiveness of current treatment options for individuals diagnosed with OSA?**
5. **Looking specifically at CMV drivers: Which diagnostic strategies have been tested with a population of CMV drivers? Which treatment options have been tested with a population of CMV drivers? How can treatments be tracked to ensure CMV driver compliance?**

Sources Searched

We searched thousands of peer-reviewed journals using precisely defined key search terms to locate materials for this study. We searched the following electronic databases:

- **Academic Search Premier:** Full-text publications from all academic areas of study, including the sciences, social sciences, humanities, and medical sciences
- **Business Source Complete:** Full-text business publications and hundreds of scholarly, peer-reviewed journals covering all aspects of business
- **The Cochrane Library:** A collection of six databases that contain high-quality information to inform healthcare decision-making, including:
    - Cochrane Database of Systematic Reviews
    - Cochrane Central Register of Controlled Trials
    - Cochrane Methodology Register
    - Database of Abstracts of Reviews of Effects
    - Health Technology Assessment Database
    - NHS Economic Evaluation Database

- **Cumulative Index to Nursing & Allied Health (CINAHL):** Over 700 journals on topics related to nursing and allied health
- **Embase (Excepta Medica):** An index to pharmacological and biomedical literature from over 6,500 journals from 70 countries, including most MEDLINE records
- **Health Business Elite:** Articles in management, medical, general business, and industry specific topics
- **National Guideline Clearinghouse (NGC)**: Designed to provide physicians and other health professionals with an accessible mechanism for obtaining information on clinical practice
- **PubMed**: The National Library of Medicine's MEDLINE and PreMEDLINE databases; MEDLINE encompasses information from Index Medicus, Index to Dental Literature, and International Nursing Index, as well as other sources of coverage in the areas of allied health, biological and physical sciences, humanities and information science as they relate to medicine and health care
- **Proquest Research Library:** Indexing, abstracting, and many full-text entries for over 2,800 scholarly and general-interest periodicals; covers a very broad range of topics and sources
- **PsycINFO**: Including over 2,500 journals covering psychology and its related fields
- **Science Direct:** Web database for scientific research that contains abstracts, tables of contents, and full text of Elsevier journal articles mainly in science and medicine, with some coverage of social sciences and humanities, particularly business, economics and psychology
- **TRID**: More than one million records related to worldwide transportation research

In addition, we also searched the "grey literature," which consists of unpublished reports, studies, and other materials which are not commercially available. We sought out these materials by searching the Web sites of various Federal agencies, as well as related commercial and non-profit organizations. We searched:

- American Academy of Dental Sleep Medicine http://www.aadsm.org
- American Academy of Sleep Medicine http://www.aasmnet.org
- American Association of Sleep Technologists http://www.aastweb.org
- American Board of Sleep Medicine http://www.absm.org
- American Sleep Association http://www.sleepassociation.org
- American Sleep Apnea Association http://sleepapnea.org
- American Thoracic Society - Sleep Assembly http://thoracic.org/assemblies/srn/index.php
- American Trucking Association http://www.truckline.com/
- Centers for Disease Control and Prevention http://www.cdc.gov
- Commercial Vehicle Safety Alliance http://www.cvsa.org/home.php
- DOT Bureau of Transportation Statistics http://www.rita.dot.gov/bts/

- Drowsy Driving http://drowsydriving.org/
- Federal Motor Carrier Safety Administration http://fmcsa.dot.gov
- National Sleep Awareness Roundtable http://www.nsart.org
- National Sleep Foundation http://www.sleepfoundation.org
- NIH National Heart, Lung, and Blood Institute http://www.nhlbi.nih.gov
- NIH National Center on Sleep Disorders Research http://www.nhlbi.nih.gov/about/ncsdr/index.htm
- National Transportation Safety Board http://www.ntsb.gov
- SLEEPClinician http://sleepclinician.com
- Sleep Research Society http://www.sleepresearchsociety.org
- Society of Anesthesia and Sleep Medicine http://anesthesiaandsleep.org
- Transportation Research Board http://www.trb.org/Main/Home.aspx

Finally, we fully reviewed the references of retrieved articles in order to locate any additional relevant materials.

Search Terms Used

We searched for information using a set of specific keywords and text word combinations. These search terms varied according to our key questions and the sources being searched. For Questions 1, 2, and 5, all identified articles needed to include both an OSA term and a CMV term. Questions 3 and 4 had their own unique search terms which were paired with at least one OSA term. Search terms are presented in Table 3 below.

All searches were limited to the English language. For databases where large numbers of results were returned (e.g., Science Direct) search terms were further limited to header/subject/keywords. Searching was done in November and December 2013.

Table 3: Search Terms

OSA Terms	("obstructive sleep apnea" OR "obstructive sleep apnoea" OR "sleep disordered breathing")
CMV Terms	("truck driver" OR "trucking" OR "commercial motor vehicle" OR "CMV" OR "commercial driving" OR "commercial driver")
Q3 Terms	("diagnosis" OR "screening" OR "clinical guideline" OR "clinical guidelines" OR "evaluation" OR "polysomnography" OR "home sleep study" OR "anthropometric parameters" OR "cephalometry" OR "nocturnal oximetry" OR "Epworth Sleepiness Scale" OR "Sleep Apnea Clinical Score" OR "Berlin questionnaire" OR "Multivariate Apnea Detector Questionnaire" OR "Functional Outcomes of Sleep Questionnaire") AND ("cost" OR "efficacy" OR "diagnostic accuracy" OR "sensitivity" OR "specificity" OR "false positive" OR "false negative")
Q4 Terms	("treatment" OR "adherence" OR "compliance" OR "health outcome" OR "health outcomes" OR "noncompliance" OR "non-adherence" OR "nonadherence" OR "tracking" OR "SleepWatch" OR "Copilot" OR "SafeTRAC") AND ("cost" OR "effectiveness" OR "efficacy")

Complete sample search terms for the database PubMed appear as Appendix A to this report.

Reviewers read the title and abstract for each article, and decided whether to retrieve it in full-text using the retrieval criteria described in Appendix B which were established *a priori*. If an article met the retrieval criteria, it was retrieved in full-text and added to a reference manager program (Zotero) for additional analyses. Items were not added if they were already in the reference program; many items were identified in multiple sources.

Once all searching was complete, the items were again reviewed (this time using full-text) against a set of inclusion criteria which appear as Appendix C to this report. Reviewers made a decision about whether each article should be included or excluded. In cases of uncertainty, the article was flagged for follow-up and reviewed by the Principle Investigator. Where articles were excluded, reviewers also made a notation summarizing the reason for exclusion.

As a part of this process, reviewers were also asked to identify potentially relevant references in the identified studies. Reference items were retrieved and reviewed following the same procedures analyzed above.

The initial searching for questions 3 and 4 returned a high volume of studies, and the decision was made to analyze these findings using meta-analysis. Thus, studies were further limited based on whether their findings were presented in a manner which would enable meta-analysis.

Evaluation of Quality of Evidence

Once the final set of articles was identified, each included article was reviewed for quality based on the standards used by the Cochrane Bias Method Group. Original research articles were given a bias rating (high risk, low risk, or unclear risk) on each of seven domains (see http://bmg.cochrane.org/assessing-risk-bias-included-studies). These domains are:

- **Selection bias/random sequence generation:** This reflects whether subjects between groups are systematically different; randomization mitigates against selection bias.
- **Performance bias/allocation concealment:** This reflects whether subjects between groups are systematically different in the care provided or in other interventions of interest. Blinding of participants and personnel mitigates against this risk.
- **Detection bias/blinding of participants and personnel:** This reflects whether participants and personnel know assignment to condition. Blinding or masking reduces the risk of this bias.
- **Detection bias/blinding of outcome assessment:** This reflects whether systematic differences between groups are present in how outcomes are determined. Blinding or masking of outcome assessors reduces the risk of this bias.
- **Attrition bias/incomplete outcome data addressed:** This reflects whether there are systematic differences between groups on withdrawal rates.
- **Reporting bias/selective reporting:** This reflects whether there are systematic differences between reported and unreported findings.

- **Other biases:** These reflect other potential areas of concern in study design, implementation, analysis, or reporting.

Using this method, studies are not given an overall score, but are rated separately in each domain.

Statistical Methods

Identified data were reviewed by question topic and sub-topic. Data were abstracted by members of the research team and reviewed by the Principle Investigator. For each original research study data were gathered on the location of the study, design of the study, objective, procedures and protocol, sample size and demographics, overall conclusions, and specific findings.

For research questions 1, 2, and 5, insufficient data were available to conduct a meta-analysis, so findings are discussed qualitatively. For questions 3 and 4, data were sufficient to conduct a meta-analysis. For question 3, we categorized each diagnostic approach as relating to questionnaires, in-home devices, lab devices, or biometric information plus a questionnaire. We also collected information on the sensitivity or specificity of each type of treatment, using PSG or AHI as the standard of comparison. For question 4, we categorized each treatment as relating to air pressure, behavior modification, dental appliance, medication, surgery, or various combination treatments. We also recorded information on the effect size, sample size, and control variables related to BMI for each study. For both questions 3 and 4, we used the MIX 2.0 meta-analysis software to calculate mean effect sizes for each type of intervention.

Each finding is rated as strong, moderate, weak, or unacceptably weak, as show in Table 4 below.

Table 4: The criteria for each evidence rating

Strong	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion.
Weak	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions.
Unacceptably Weak	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion.

Overall Evidence Base

A total of n=91 relevant studies were identified via our search process. These studies were identified via database searches, Web site searches, and reference list searches. The entire search process is diagrammed below in Figure 1.

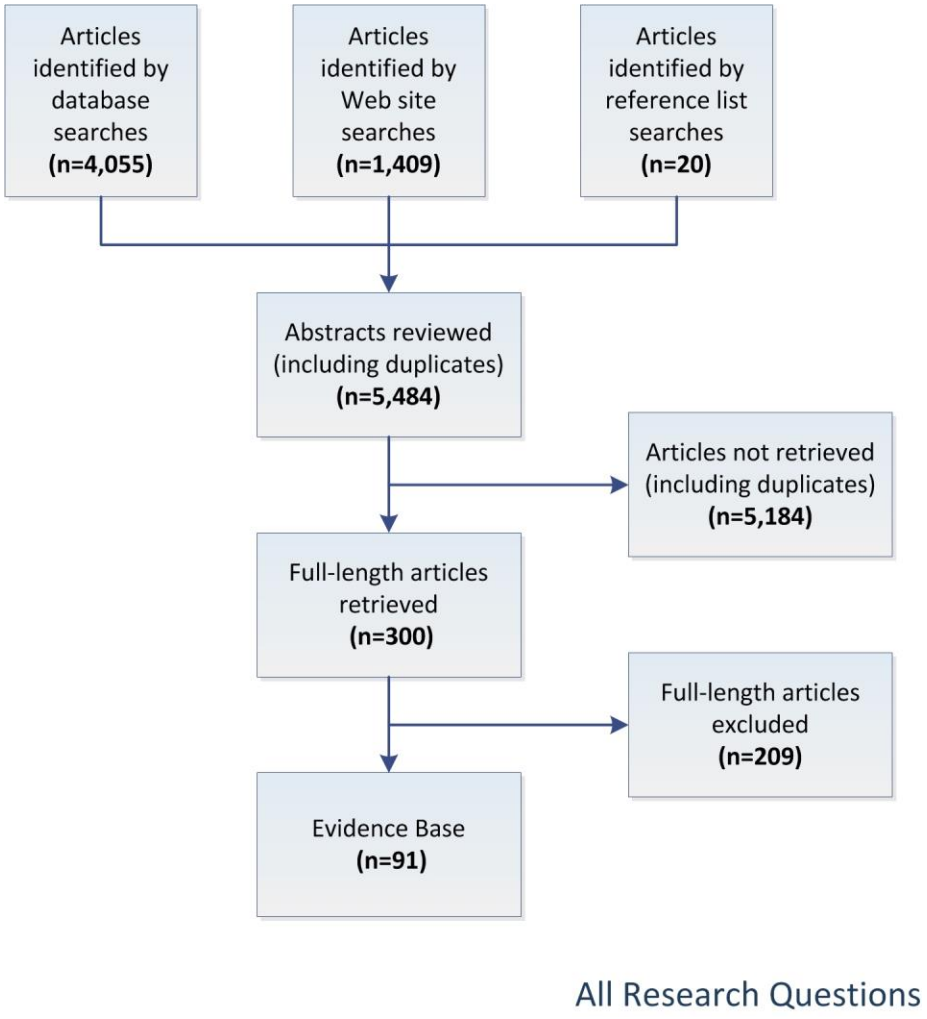


Figure 1: Evidence base, all questions

Evidence Summary

This section of the report presents findings for each research question.

Research Question 1

Question 1 asks: Based on studies of commercial motor vehicle driver populations, how many CMV drivers would be expected to have untreated OSA?

Evidence Base for Question 1

The evidence base for Question 1 consists of n=15 studies, as shown in Figure 2.

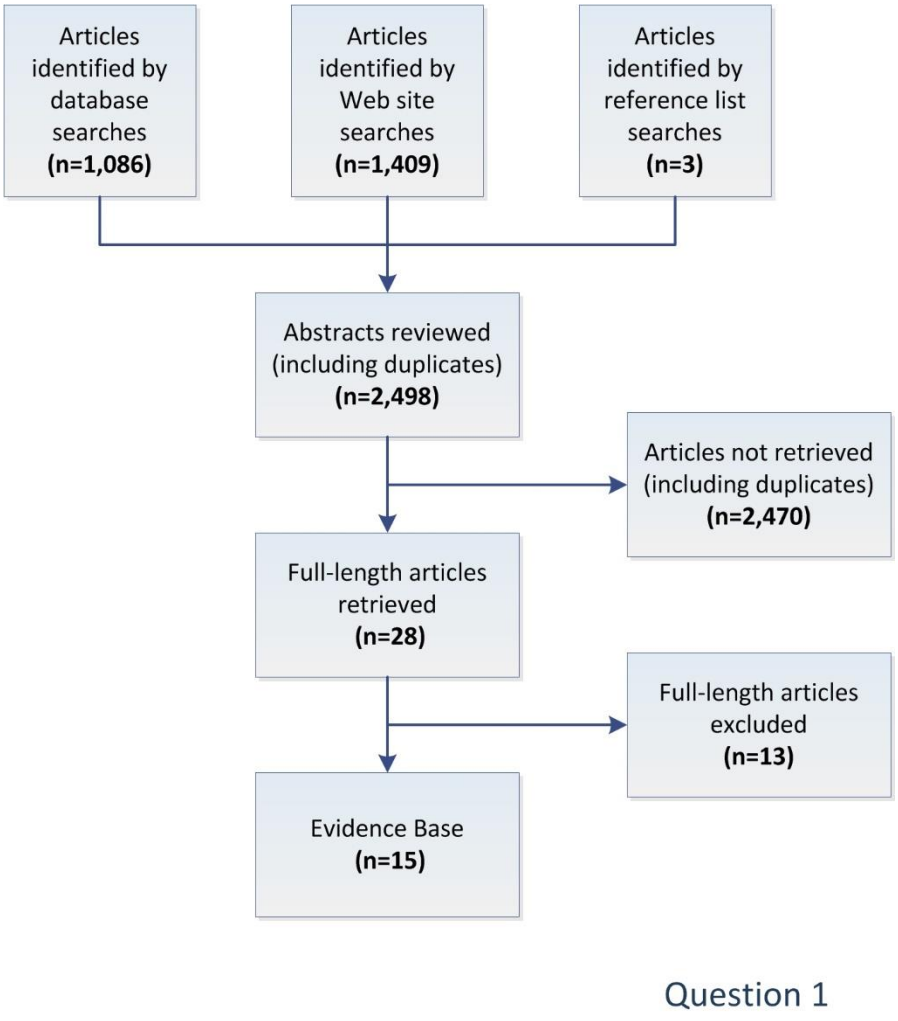


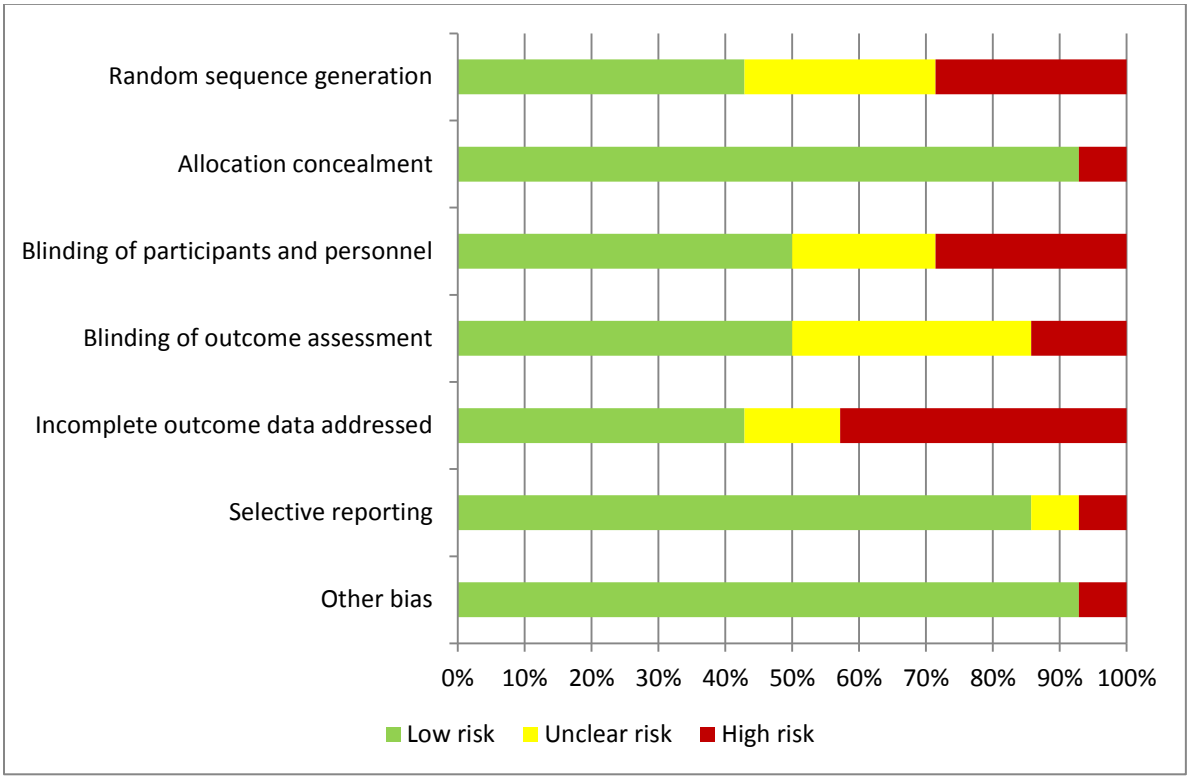
Figure 2: Evidence base, Question 1

Quality of Included Studies

Each identified item was ranked for quality using the categories described in the research methodology section. The ratings for the original research articles are presented in Table 5.

While the studies were generally of acceptable quality, they suffer in the area of incomplete outcome data. This is due to the high amounts of attrition and loss to follow-up in the studies due to drivers declining PSG or other follow-up measures. This attrition rate likely means that the prevalence of OSA is under-reported among this population.

Table 5: Study Quality for Q1 Research Articles



Summaries of Included Studies

Original research articles that address Q1 are shown in the tables below. Table 6 shows information about the study design and conclusions. Table 7 shows detailed findings for each of the articles. Note that two of the studies shared the same data collection effort, so these studies are treated as one unit for the purposes of our analysis.

Table 6: Study Design and Conclusions for Original Articles that Address Q1

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Berger et al. (2012) [1]	USA, Survey; retrospective analysis	Investigate the prevalence of OSA among CMV drivers	Commercial drivers were screened for OSA with an online questionnaire through employer mandates. Questionnaire and PSG results were analyzed retrospectively.	n=19,371 (male: 91.1%, age 41.2 ± 11.2, BMI 30.9 ± 6.6, neck size 17 ± 1.6; female: 7.6%, age 41.2 ± 9.7, BMI 31.0 ± 7.4)	Online screening followed by PSG for high-risk drivers finds a conservative estimate for OSA among commercial drivers is 21%
Gurubhagavatula et al. (2008) [2]	USA, Case control study	Investigate the cost effectiveness of different approaches to screening for OSA and the treatment adherence rate necessary to make treatment cost effective	CMV drivers answered a questionnaire to screen for OSA risk and then completed PSG.	n=247 high-risk drivers; n=159 low-risk drivers (average age 45.4±11.0 years, BMI 29.9±5.2 kg/m2)	A substantial number of drivers had AHI≥5 (28.1%) or Epworth Sleepiness Scale>10 (32.6%); nearly one in 10 (8.7%) had both, which is called Obstructive Sleep Apnea Syndrome
Parks et al. (2009) [3]	USA, Questionnaire-based cross-sectional study	Evaluate Joint Task Force criteria for screening commercial drivers for OSA	All drivers received a commercial driver medical examination. Patients that presented a high likelihood according to the Joint Task Force OSA screening criteria were instructed to receive a PSG to determine whether or not they had OSA.	n=456 (mean age 39.22, mean BMI 29.07, mean neck circumference 16.36)	Prevalence of OSA is estimated at 12% based on application of Joint Task Force guidelines and PSG
Platt et al. (2013) [4]	USA, Prospective cohort study	Evaluate Joint Task Force criteria-based screening for	Subjects self-reported demographics, apnea symptoms, tobacco and alcohol use, and Epworth Sleepiness Scale. A pre-employment physical exam was simulated,	n=100 drivers with active commercial driver's licenses (94% male, mean	Thirty percent of drivers screened had severe-OSA based on AHI scores; OSA is also commonly found among those

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
		severe OSA in commercial drivers	using DOT's Medical Examination Report. PSG was conducted in-home, set up and scored by registered technologists. Primary analyses considered severe OSA as AHI of 30 or more per hour.	age 44.0 ± 8.6, BMI 34.3 ± 8.0, neck circumference (cm) 43.2 ± 4.0)	drivers classified as being at "low" risk by various BMI or symptom-related screening criteria
Smith & Phillips (2011) [5]	USA, Online survey	Establish a tool that truck drivers can use to assess their risk for OSA and determine if commercial drivers would employ an online tool to assess risk	Data was collected from an online survey designed for commercial truck drivers to determine whether or not they were at a high risk for OSA. The survey was developed from a version of the Berlin questionnaire.	n=595 self-selected participants (91.8% male, BMI 33.94 kg/m2)	The primary findings are that some commercial drivers willingly assess their OSA risk anonymously online, and a majority of those who do so are obese, have positive Berlin screening questionnaires, and would be required to undergo PSG according to guidelines
Talmage et al. (2008) [6]	USA, Consecutive case series	Validate the recently published consensus criteria for screening commercial drivers for OSA	Federal Commercial Driver Medical Examinations were administered; each driver completed the history section, a questionnaire about factors that would suggest sleep apnea, and an Epworth Sleepiness Scale. A physical exam included blood pressure, BMI, and neck circumference. If the driver met the examined criteria they were informed they would have a limited 3-month certification and would be required to have a PSG.	n=134 completed PSG (no OSA: BMI 35.9, mean neck circumference 17.0; Mild OSA: BMI 39.7, neck 17.7; Moderate OSA: BMI 40.1, neck 17.9; Severe OSA: BMI 41.6, neck 18.1)	Thirteen percent of drivers screened at risk for OSA according to the consensus guidelines and were referred for follow-up PSG; among those who completed the referral, almost all (94.8%) had OSA that was mild, moderate, or severe

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Watkins et al. (2009) [7]		Compare the accuracy of portable monitoring for OSA with PSG in commercial drivers	Newly hired drivers underwent commercial driver certification exams; drivers screening positive on history and physical exam by the consensus criteria were scheduled for PSG. PSG results were interpreted as positive if the AHI was ≥ 10, or if sleep specialist recommended treatment with CPAP due to severe nocturnal hypoxia, regardless of AHI. Drivers screening positive were requested to use a single-channel portable apnea monitor device for one night (RUSleeping) to compare the accuracy of portable monitoring screening to the formal PSG scheduled 3 months later.	n=346 drivers	Almost a third of new hires screened at risk for OSA according to the consensus guidelines and were referred for follow-up PSG
Xie et al. (2011) [8]	USA, Cross-sectional, retrospective, case-control design	Identify factors associated with OSA risk during commercial driver medical examinations	Each driver completed the health history section of the federal CDME form. Blood pressure, height, weight, and neck circumference were measured. The examining physician determined whether the driver met the consensus criteria for PSG. Drivers with suspected OSA were issued a 3-month medical certification and referred for PSG evaluation. The AHI or respiratory disturbance index and lowest recorded oxygen saturation were extracted from PSG reports to indicate the presence and severity of OSA.	n=1,890 (91.6% male, average age 43.7 ±11.52 years, average BMI 30.5 (±6.6))	A conservative estimate of drivers with OSA is 6.1%; the actual rate is likely higher, perhaps as much as 11% or more

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Sharwood et al. (2012) [9]	Australia, Cross-sectional study	Determine the relationship between subjective and objective assessments of OSA in CMV drivers	Drivers were interviewed regarding their driving experience, personal health, shift schedules, and various questions on sleep and tiredness in order to describe their sleep health across a range of variables. In addition, home recordings using a flow monitor were used during one night of sleep for all participants.	n=517 recruited (50% obese); n=325 completed data and flow monitoring	Objective testing for OSA needs to be considered, as symptom reports and self-identification appear insufficient to accurately identify those at risk; flow monitor detected much higher rates of OSA than other tests
Wahida et al. (2013) [10]	Malaysia, Cross-sectional study	Identify the prevalence of OSA among truck drivers in Malaysia using the Berlin questionnaire and among express bus drivers using Berlin questionnaire and PSG	Commercial truck drivers were given the Berlin questionnaire to determine the prevalence of OSA. These drivers were not given a PSG because of budget constraints. Express bus drivers were given the Berlin questionnaire and completed PSG.	n=130 truck drivers (high risk for OSA: mean age 40.2, mean BMI 30.6, mean neck circumference 40.9; low risk of OSA: mean age 38.7, mean BMI 24.8, mean neck circumference 40.9); n=292 bus drivers (OSA: mean age 45.4, mean BMI 29.4, mean neck circumference 40.0; non-OSA: mean age 42.5, mean BMI 25.7, mean neck circumference 37.4)	Found that 14.6% of commercial truck drivers were categorized as high risk for OSA based on Berlin questionnaire; among express bus drivers the prevalence of OSA (measured by PSG) was 44.3%

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Catarino et al. (2013) [11]	Portugal, Cross-sectional study	Determine prevalence of sleep disorder symptoms among truck drivers and identify individual traits and work habits associated with sleepiness and accident risk	Forty-five companies were contacted about distributing questionnaires to their employees. Eighteen companies responded and distributed questionnaires. Respondents answered questions related to sociodemographic data, personal habits, previous accidents, Epworth Sleepiness Scale, and the Berlin questionnaire. This data was used to determine the prevalence of various sleep disorders.	n=714 (all male, mean age 43.1±10.0, mean BMI 28.5±3.8, 47.1% overweight, 34.6% obese)	More than one in ten drivers had a witnessed sleep apnea, and over a quarter were at high risk based on the Berlin questionnaire
Karimi et al. (2013) [12]	Sweden, Cohort study	Investigate the prevalence of sleep disorders among public transport operators and assess the interventional effects on hyper somnolence and neurocognitive function in those with OSA	Overnight PSG and questionnaire data were collected from employees of a transportation company. Treatment was offered in cases with newly detected OSA. Daytime sleep episodes and neurocognitive function were assessed before and after intervention.	n=101 evenly split between bus and tram drivers (72% male, median age 48, BMI 27)	Public transit officers had a high prevalence of sleep disorders, particularly OSA

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Li et al. (2008) [13]	Sweden, Retrospective analysis	Investigate whether there is an association between socioeconomic status, occupation and OSA	Data from the Swedish population census was compared with the Hospital Discharge Register and Cause of Death Register to obtain data on all first adult hospitalizations for OSA diagnosed during the study period from 1997 to 2001. Standardized incidence ratios (SIRs) were calculated for socioeconomic status (three educational status groups) and different occupations as the ratio of the observed to the expected number of cases.	n=12,938 (10,336 males); n=707 commercial driver incidents; all aged 35 and older	Occupational driving increased the risk of OSA
Akkoyunlu et al. (2013) [14]	Turkey, Cross-sectional study	Assess the prevalence of OSA in long-distance drivers located in the Zonguldak area of Turkey	Participants answered a questionnaire about demographic data, time driving, number of accidents, symptoms associated with OSA, snoring, Epworth Sleepiness Scale, and Berlin questionnaire. Annual accident rates were calculated by dividing the number of accidents by the number of years in occupation. Subjects suspected of OSA were offered PSG, conducted according to standard guidelines.	n=241 long-distance drivers (all male; mean age 42 ± 9.85; BMI 27.3 ± 4.2; neck circumference (cm) 39.7 ± 2.9; waist-neck ratio 0.93 ± 0.4)	Obstructive sleep apnea is common in long-distance drivers; PSGs from patients exhibiting some symptoms revealed that 14.1% have OSA
Firat et al. (2012) [15]	Turkey, Cohort study	Assess the usefulness of four standardized questionnaires (Berlin, STOP, STOP-BANG, and OSA50) in identifying bus drivers at high risk for OSA	Questionnaires for predicting OSA were translated and adapted to Turkish and completed by subjects with the help of a physician. Subjects completed a 5 hour PSG after working a full night shift.	n=85 bus drivers (all male; < 45 years of age: BMI 27.7 ± 2.9; neck circumference (cm) 40.1 ± 2.5; AHI 14.4 ± 11.6; ≥ 45 years of age: BMI 29.7 ± 4.0; neck circumference 41.5 ± 2.9; AHI 23.6 ± 18.5)	Over half of all bus drivers in the study had OSA, with an AHI>15. Drivers over age 45 were particularly at risk.

Table 7: Detailed Findings for Original Articles that Address Q1

Author (Year)	Findings
Berger et al. (2012) [1]	1. Estimated prevalence of OSA (AHI>10) among commercial motor vehicle drivers: 21% 2. Categorized as high-risk based on online questionnaire: 30.5% 3. Drivers screened into a high risk category having definite OSA (AHI>10): 67.7% 4. Drivers in high risk category having possible or definite OSA (AHI>5): 79.7% 5. Among drivers with OSA, those with clinically severe OSA (AHI>30): 47.7%
Gurubhagavatula et al. (2008) [2]	1. Drivers with OSAS (defined as AHI≥5 and Epworth score>10)=8.7% 2. Drivers with AHI≥5: 28.1%; Average AHI=6.0±11.5 events/h 3. Drivers with excessive daytime sleepiness (Epworth Sleepiness Scale>10): 32.6% (CI: 28.2–36.9); Mean Epworth score = 8.8 (CI: 8.4–9.2)
Parks et al. (2009) [3]	1. Drivers screening positive using Joint Consensus Criteria: 17.1% 2. Drivers referred for PSG examination who followed-up and tested positive for OSA: 100% 3. Conservative estimate of OSA prevalence in the study population: 12% (CI: 8.68-14.56%)
Platt et al. (2013) [4]	1. ESS score>10: 13%; ESS score>16: 8%; Mean ESS=6.6 ± 4.0 2. AHI ≥5 per hour: 90%; AHI ≥20 per hour: 53%; Mean AHI: 26.6 ± 22.6 3. Proportions of OSA: mild (30%), moderate (30%), and severe (30%)
Smith & Phillips (2011) [5]	1. Participants that screened positive on the Berlin questionnaire: 55.9% 2. Participants that were at increased risk due to BMI/Hypertension: 78.3% 3. Participants that reported a witnessed apnea: 21% 4. Participants that answered positively that they sometimes fall asleep while driving: 20.5% 5. Participants that reported falling asleep at stoplights: 20.5%
Talmage et al. (2008) [6]	1. Drivers screening positive based on Joint Consensus Criteria: 13% 2. Among drivers undergoing PSG, those who had Mild OSA (AHI 5-14.9): 31.5%; Moderate OSA (AHI 15-29.9): 26.8%; Severe OSA (AHI≥30): 41.7% 3. Drivers screening positive based on Joint Consensus Criteria who had an Epworth Score>10: 1
Watkins et al. (2009) [7]	1. New hires screening positive based on Joint Consensus Criteria: 32% 2. Among drivers undergoing PSG, mean AHI=18.5; 74% had AHI>5 and 24% had AHI>30
Xie et al. (2011) [8]	1. Confirmed prevalence of OSA among participants: 6.1%; includes drivers with a history and confirmed via PSG, but does not include drivers lost to follow-up 2. Potential rate of OSA (assuming drivers lost to follow-up had tested positive with the same frequency as those who presented for testing (78%)): 11%

Author (Year)	Findings
Sharwood et al. (2012) [9]	1. Epworth Sleepiness Scale>10: 12.2%; Mean ESS=5.6 (CI: 5.3-5.9) 2. Self-report any trouble staying awake while driving in last month: 40.5%; experience this twice a week or more: 17% 3. Mean AHI=19.5 (CI: 17.85-21.12); OSA (defined as AHI ≥18 and <30)=24.6%; Severe OSA (defined as AHI ≥30)=16% 4. Overall prevalence of possible OSA detected by the at-home monitor: 43% (41% previously undiagnosed + 2% currently using CPAP)
Wahida et al. (2013) [10]	1. Prevalence of commercial truck drivers being categorized as high risk according to the Berlin questionnaire: 14.6% 2. Prevalence of OSA in express bus drivers as determined by PSG testing: 44.3% 3. Prevalence of mild OSA in express bus drivers (AHI 5-15) as determined by PSG testing: 28.7% 4. Prevalence of moderate OSA (AHI 16-30) in express bus drivers as determined by PSG testing: 9.0% 5. Prevalence of severe OSA (AHI>30) in express bus drivers as determined by PSG testing: 6.6%
Catarino et al. (2013) [11]	1. Prevalence of excessive daytime sleepiness as determined by the Epworth Sleepiness Scale (score ≥11): 20.0% 2. Prevalence of being high risk on the Berlin questionnaire: 28.8% 3. Prevalence of history of apnea: 1.8% 4. Prevalence of witnessed apnea: 11.6%
Karimi et al. (2013) [12]	1. Public transit drivers with complete PSG data screening positive for OSA: 25%
Li et al. (2008) [13]	1. Standardized incident ratio (SIR) for being hospitalized for OSA among male occupational drivers: 1.24 (CI: 1.15-1.34) 2. Standardized incident ratio (SIR) for being hospitalized for OSA among male occupational drivers (second model adjusted for obesity): 1.20 (CI: 1.12-1.29)
Akkoyunlu et al. (2013) [14]	1. Prevalence of long distance drivers with positive PSG for OSA (AHI ≥ 5 w/symptom or AHI>15): 14.1% 2. AHI results among drivers screened at-risk and completing PSG: AHI < 5: 19%; AHI 5–15: 26%; AHI 15–30: 21%; AHI > 30: 34% 3. Reporting witnessed sleep apnea: 11.6%
Firat et al. (2012) [15]	1. Bus drivers under age 45 with AHI>15: 30.4% 2. Drivers over age 45 with AHI>15: 62.9% 3. All drivers with AHI>15: 54.1%

Findings

Findings are presented first for U.S.-based studies, and then for other nations.

United States

About half of the identified studies (n=8) studied the prevalence of OSA among U.S. CMV drivers.

Two of these studies had all drivers complete PSG as a part of the study. Gurubhagavatula et al. [2] found that nearly a third of all drivers had AHI≥5 and that almost a third had high Epworth Sleepiness Scores (ESS>10). However, only one in ten had both a high AHI and a high ESS, which the authors defined as OSA syndrome. Data from this study were collected from 1996-1998, so the findings may be out of date. A more recent study by Platt et al. [4] asked all drivers to answer a series of questions (including the Epworth scale) and to consent to a physical exam. Drivers were then asked to complete home-based PSG. This study found that 30% of all drivers had severe OSA (with AHI>30), and 90% of drivers had AHI≥5. Only 13%, however, had elevated Epworth scores. The authors concluded that OSA is common even among CMV drivers who might screen as "low" risk.

The majority of the studies (n=5) used screening criteria to make an initial determination of whether PSG should occur. The primary screening criteria used were the Joint Task Force Criteria [3,6–8]. These studies found that 12% [8], 13% [6], 17% [3], and 32% [7] of drivers screened positive for further testing according to the criteria. Almost all of these drivers who completed testing (attrition was significant in some studies, see question 5 findings for more details) tested positive for OSA. Across the four studies, AHI≥5 was found at least three quarters of the time, and up to 100% of the time. Many of these identified cases were severe, with one study reporting 42% [6] of those undergoing PSG had AHI>30 and another reporting 24% of drivers under-going PSG with AHI>30 [7]. One of these studies also found that high Epworth scores were not related to testing at-risk according to the Joint Task Force Criteria [6].

The other screening method used to screen participants for further testing was the Somni-Sage® Questionnaire [1]. This questionnaire identified almost a third of all drivers as at-risk for OSA, and these drivers were then asked to complete further testing. Eight in ten of these had AHI≥5; and, among those with AHI>10, nearly half had severe OSA (AHI>30).

The remaining U.S.-based study we identified was a self-selected sample of drivers completing an online questionnaire only. Smith and Phillips [5] found that this sample screened at-risk on a number of factors, including over 50% who scored high on the Berlin questionnaire, and more than one in five who reported witnessed sleep apneas, falling asleep while driving, or falling asleep at a stoplight.

Outside the United States

Seven additional studies investigated the prevalence of OSA among CMV drivers for five additional countries.

An Australian study where all drivers completed PSG found more than four in ten had OSA (AHI>18), while only one in ten (12%) had an Epworth score greater than ten [9]. About four in ten also said they had recently had trouble staying awake while driving.

A study of express bus drivers in Malaysia found that four in ten had AHI≥5 [10].

A study from Portugal did not use PSG to confirm OSA diagnosis, but found that one in ten drivers reported a witnessed sleep apnea [11].

Karimi et al. [12] found that a quarter of Swedish transit operators tested positive for OSA, while Li et al. [13] found that those who drove for a living in Sweden were at higher risk for OSA.

Finally, two studies in Turkey investigated the prevalence of OSA. In Akkoyunlu et al. [14], 17% of long-distance drivers screened as higher risk for OSA, and 81% of these screened with an AHI≥5, including 34% who screened with AHI>30. In the second study [15], all bus drivers underwent PSG, and over half (54.1%) had AHI>15; OSA was even more pronounced among drivers aged 45 and up.

Conclusions

As described in Table 4, conclusions are presented as strong, moderate, weak, or unacceptably weak.

There is moderate evidence that OSA is prevalent among CMV drivers at a higher rate than in the general population. Using a conservative definition for OSA of AHI≥5, two U.S.-based studies found 28% and 90% had at least mild OSA when a census approach was used to conduct PSG on all participating drivers. Approaches where all participating drivers are given PSG are viewed as most appropriate to determine OSA prevalence, since screening approaches followed by PSG will necessarily miss some cases, and since many drivers referred for PSG using a screening approach will fail to follow-up (see below and question 5 for more information).

Studies from other nations employing a census approach to administering PSG found a quarter to forty percent or more of commercial drivers testing positive.

Data are insufficient to put a point estimate on how many drivers may have at least mild OSA: however, it is not unreasonable to expect that the number of drivers with at least mild OSA is greater than one in five and perhaps as many as nine out of ten. This is consistent with the recent finding that more than two-thirds of CMV drivers are obese.[18]

There is strong evidence that at least one in ten CMV drivers will screen as at-risk for OSA according to Joint Task Force Criteria, and weak evidence that the number of drivers screening positive according to this criteria may be up to three times higher. Four recent studies found that 12-32% of all drivers screened according to the criteria were at high-risk of having OSA. **However, current screening guidelines may be insufficiently sensitive to detect all drivers with OSA.** See question 5 for more information.

[18] Sieber, W. K., Robinson, C. F., Birdsey, J., Chen, G. X., Hitchcock, E. M., Lincoln, J. E., Nakata, A. and Sweeney, M. H. (2014), "Obesity and other risk factors: The National Survey of U.S. Long-Haul Truck Driver Health and Injury." Am. J. Ind. Med.

Research Question 2

Question 2 asks: Based on studies of CMV crashes related to human factors, what is the relationship of those crashes to OSA risk factors such as high body mass index, neck circumference, snoring and excessive daytime sleepiness, and previous diagnosis of OSA?

Evidence Base for Question 2

The evidence base for Question 2 consists of n=5 studies, as shown in Figure 3.

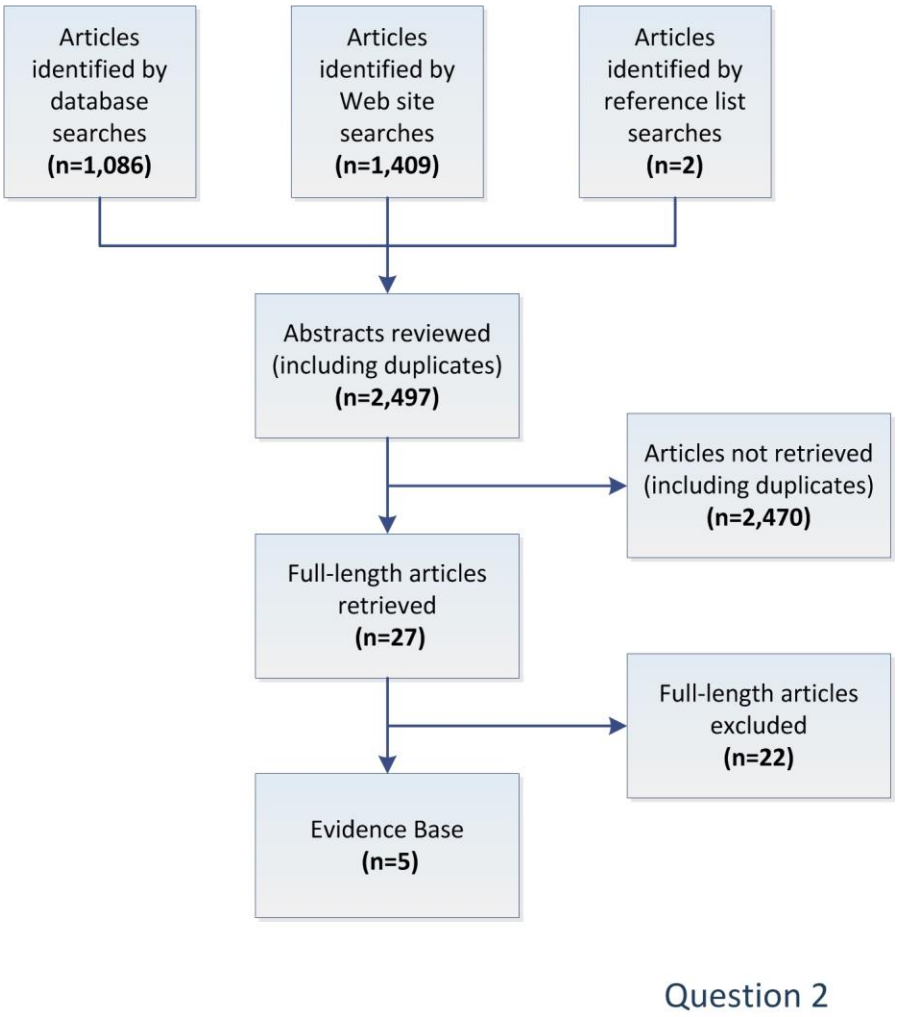
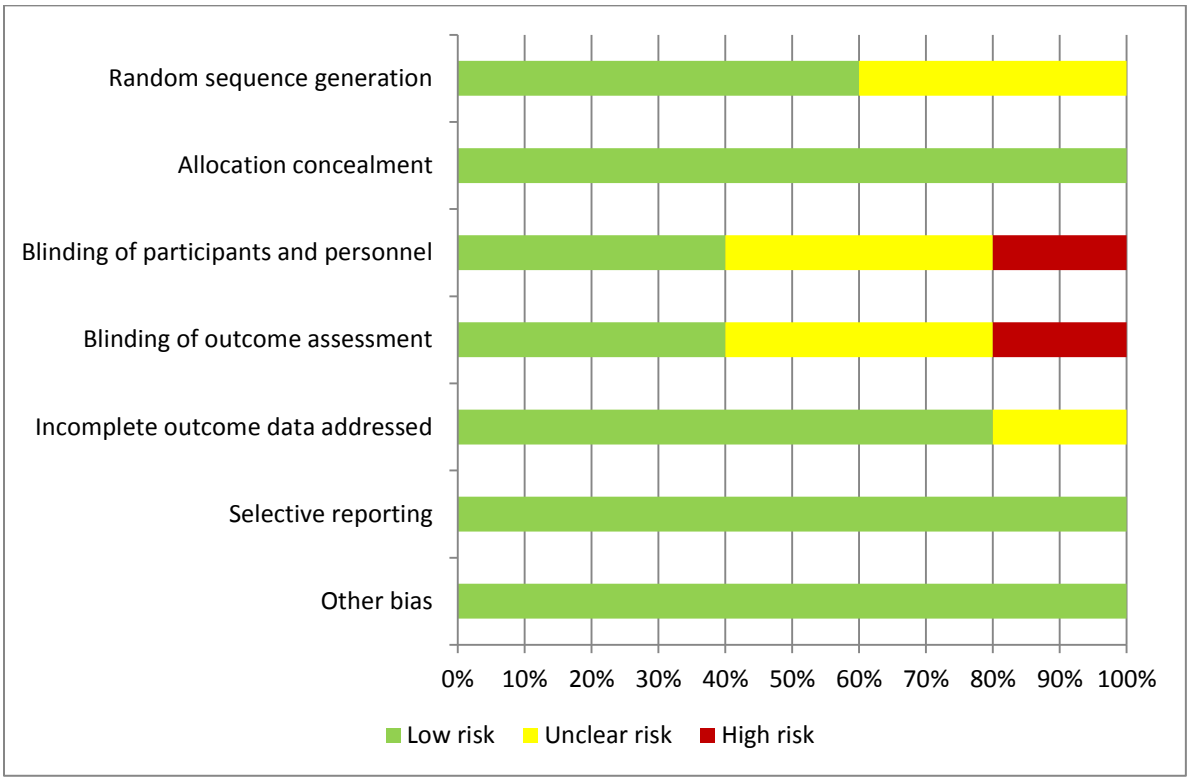


Figure 3: Evidence base, Question 2

Quality of Included Studies

Each identified item was ranked for quality using the categories described in the research methodology section. The ratings for the original research articles are presented in Table 8. The studies were generally of good quality.

Table 8: Study Quality for Q2 Research Article



Summaries of Included Studies

Original research articles that address Q2 are shown in the tables below. Table 9 shows information about the study design and conclusions. Table 10 shows detailed findings for each of the original research articles.

Table 9: Study Design and Conclusions for Original Articles that Address Q2

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Cantor et al. (2010) [16]	USA, Retrospective cohort study	Identify driver level factors that contribute to the increased likelihood of crash occurrence	Data on CMV drivers were extracted from FMCSA's Driver Information Resource database (age, gender, height, and weight; roadside inspection records over a 2 year period; crash records over a 5 year period). Data was also collected on reportable crashes between September 2007 and June 2008. Thus, all crashes occurred in the 10 month time window subsequent to the time period of the independent variables.	n=560,965 CMV drivers	Higher body mass index in commercial motor vehicle drivers is a predictor of future crashes
Akkoyunlu et al. (2013) [14]	Turkey, Cross-sectional study	Assess the prevalence of OSA in long-distance drivers located in the Zonguldak area of Turkey	Participants answered a questionnaire about demographic data, time driving, number of accidents, symptoms associated with OSA, snoring, Epworth Scale, and Berlin questionnaire. Annual accident rates were calculated by dividing the number of accidents by the number of years in occupation. Subjects suspected of OSA were offered PSG, conducted according to standard guidelines.	n=241 long-distance drivers (all male; mean age 42 ± 9.85; BMI 27.3 ± 4.2; neck circumference (cm) 39.7 ± 2.9; waist-neck ratio 0.93 ± 0.4)	AHI is positively correlated with accident risk
Catarino et al. (2013) [11]	Portugal, Cross-sectional study	Determine prevalence of sleep disorder symptoms among truck drivers and identify individual traits and work habits associated with sleepiness and accident risk	Forty-five companies were contacted about distributing questionnaires to their employees and eighteen participated. Respondents answered questions related to sociodemographic data, personal habits, previous accidents, Epworth, and the Berlin questionnaire. This data was used to determine the prevalence of various sleep disorders.	n=714 (all male, mean age 43.1±10.0, mean BMI 28.5±3.8, 47.1% overweight, 34.6% obese)	Berlin score, BMI, and neck circumference were all associated with increased risk

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Karimi et al. (2013) [12]	Sweden, Cohort study	Investigate the prevalence of sleep disorders among public transport operators and assess the interventional effects on hyper somnolence and neurocognitive function in those diagnosed with OSA	Overnight PSG and questionnaire data were collected from employees of a transportation company. Treatment was offered in cases with newly detected OSA. Daytime sleep episodes and neurocognitive function were assessed before and after intervention.	n=101 evenly split between bus and tram drivers (72% male, median age 48, BMI 27)	Public transit officers with OSA, excessive daytime sleepiness, and OSA with excessive daytime sleepiness had a higher self-reported risk of motor vehicle crash in the past five years
Wahida et al. (2013) [10]	Malaysia, Cross-sectional study	Identify the prevalence of OSA among truck drivers in Malaysia using the Berlin questionnaire and among express bus drivers using Berlin questionnaire and PSG	Commercial truck drivers were given the Berlin questionnaire to determine the prevalence of OSA. These drivers were not given a PSG because of budget constraints. Express bus drivers were given the Berlin questionnaire and completed PSG.	n=130 truck drivers (high risk for OSA: mean age 40.2, mean BMI 30.6, mean neck circumference 40.9; low risk of OSA: age 38.7, BMI 24.8, neck 40.9); n=292 bus drivers (OSA: age 45.4, BMI 29.4, neck 40.0; non-OSA: age 42.5, BMI 25.7, neck 37.4)	Truck drivers at high risk of OSA were not at significantly higher risk of accident, although this may be because the sample size was too small

Table 10: Detailed Findings for Original Articles that Address Q2

Author (Year)	Findings
Cantor et al. (2010) [16]	1. Poisson regression coefficient for BMI, predicting future crash involvement=0.01, p<0.01
Akkoyunlu et al. (2013) [14]	1. Relationship between the ratio of traffic accidents per year and AHI: r=0.571, p < 0.05
Catarino et al. (2013) [11]	1. Odds ratio of individuals with BMI>25 and <35 in an accident in the last 5 years: 1.10 (0.72–1.68) 2. Odds ratio of individuals with BMI>35 being in an accident in the last 5 years: 2.99 (1.35–6.64) 3. Increased risk of feeling sleepy while driving with each centimeter added to neck circumference: 1.38 (CI: 1.15–1.65) 4. Increased risk of having a near-miss accident for drivers with a high Berlin score: 2.05 (CI: 1.37–3.05) 5. Increased risk of having an accident for drivers with a high Berlin score: 1.44 (CI: 0.97–2.14)
Karimi et al. (2013) [12]	1. Relative risk of self-reported motor vehicle accidents among participants diagnosed with OSA vs. among those with no sleep disorder: 1.37 vs. 1.0 2. Relative risk of self-reported motor vehicle accidents among participants with OSA and excessive daytime sleepiness vs. those with no sleep disorder: 2.19 vs. 1.0 3. Rate of self-reported motor vehicle accident in last five years for subjects with no sleep disorder: 37% 4. Rate of self-reported motor vehicle accident in last five years for subjects with OSA without excessive daytime sleepiness: 50% 5. Rate of self-reported motor vehicle accident in last five years for subjects with excessive daytime sleepiness: 77% 6. Rate of self-reported motor vehicle accident in last five years for subjects with OSA and excessive daytime sleepiness: 80%
Wahida et al. (2013) [10]	1. Odds ratio of being in a motor vehicle accident in the past 3 years for commercial truck drivers who screened high risk on the Berlin questionnaire: 1.58 (CI: 0.52 - 4.72)

Findings

Findings are presented first for the one identified study conducted within the United States and then for the four identified studies conducted outside the United States.

United States

We only identified one study on OSA risk factors and CMV crash risk conducted within the United States. Cantor et al. [16] used FMCSA's databases to investigate driver information (including height and weight) and crashes. They calculated a regression equation predicting future crash involvement, and found that BMI is a significant predictor, with increased BMI associated with increased crash risk.

Outside the United States

Four studies looked at OSA risk factors and CMV drivers outside the United States.

In a study of Turkish drivers, Akkoyunlu et al. [14] found that there is a positive and significant relationship between traffic accidents per year and AHI.

Catarino et al. [11] gathered data from eighteen trucking companies in Portugal and found that drivers with a BMI>35 had significantly higher odds of having been in a traffic accident over the last five years (the odds were also elevated, but not significantly so, for drivers with BMIs between 25-35). The same study found that as neck circumference increased, so did self-reported driver sleepiness. In addition, near-miss accidents were significantly associated with high Berlin scores, and actual accidents were elevated (but not significantly so) among drivers with high Berlin scores.

A Swedish study of public transit drivers (busses and trams, but not trucks) found that self-reported traffic accidents increased among drivers with OSA [12]; the risk was even higher among those with self-reported daytime sleepiness and a sleep disorder. In general, self-reported accidents over the previous five years increased as subjects reported OSA and daytime sleepiness, with the highest rates reported for drivers who had either daytime sleepiness or OSA with daytime sleepiness, almost all of whom (77% and 80%) reported an accident in the past five years.

Finally, a study from Malaysia [10] found that commercial truck drivers with high Berlin scores had an elevated risk of being in a traffic accident in the past three years, but this increase was not significant.

Conclusions

There is moderate evidence that OSA risk factors including BMI, AHI, daytime sleepiness, and scores on the Berlin questionnaire are associated with increased crash risk for CMV drivers. Studies both within and outside the United States have found elevated risks for

those factors. There are insufficient data to quantify these risks, however, due to small number of available studies, and the different factors and investigative approaches used by these studies.

Research Question 3

Question 3 asks: What is the cost and diagnostic accuracy of various options for diagnosing OSA, including paper-based questionnaires, home studies and overnight sleep studies?

Evidence Base for Question 3

The evidence base for Question 3 consists of n=40 studies, as shown in Figure 4.

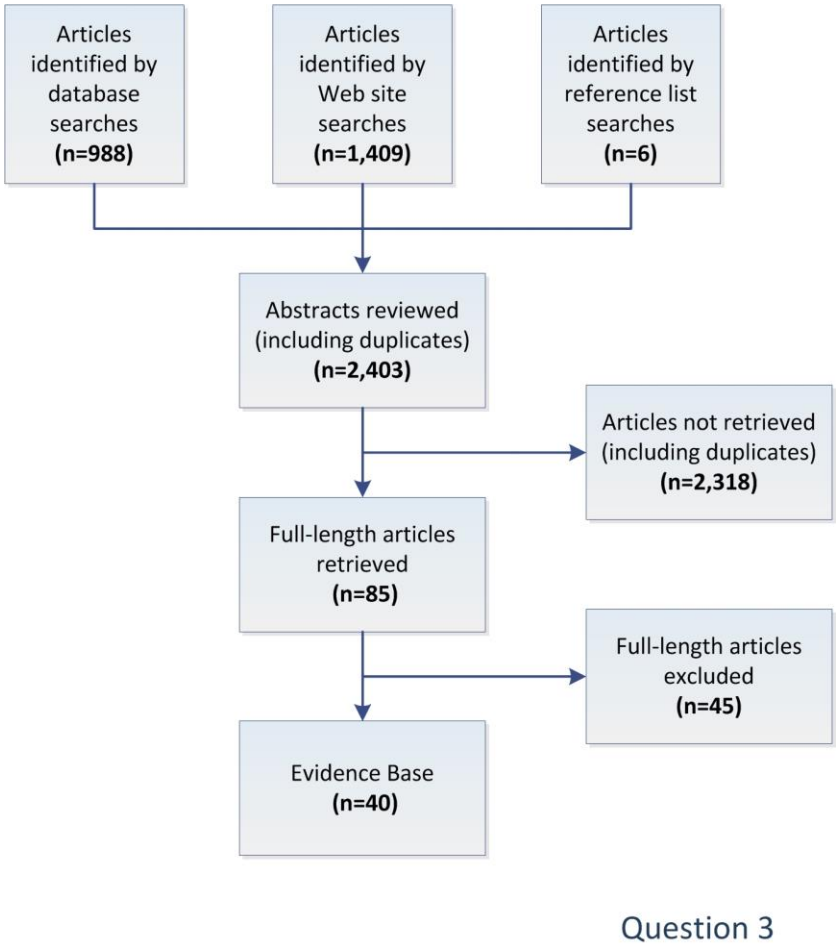
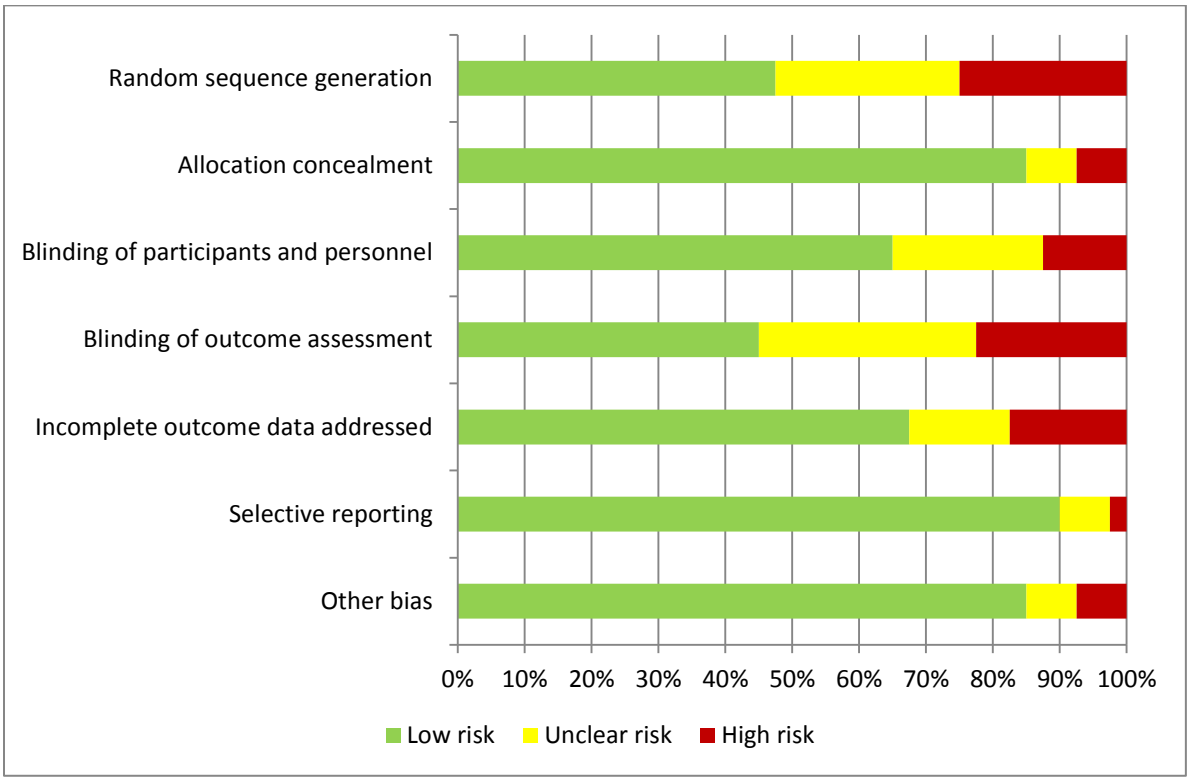


Figure 4: Evidence base, Question 3

Quality of Included Studies

Each identified item was ranked for quality using the categories described in the research methodology section. The ratings for the original research articles are presented in Table 11. The evidence quality is reasonably good.

Table 11: Study Quality for Q3 Research Article



Summaries of Included Studies and Findings from Meta-Analysis

Original research articles that address Q3 are shown in the tables below. Table 12 shows information about the study design and conclusions. Tables 13-17 show findings from the meta-analysis. Table 18 shows findings related to financial information for the n=6 studies that included cost information. Table 19 shows current Medicare Physician Fee Schedule Pricing for services related to OSA diagnosis.

Table 12: Study Design and Conclusions for Original Articles that Address Q3

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Chen et al. (2011) [17]	Biometrics + Questionnaire	China, Retrospective cohort study	Develop a two-tiered prediction algorithm using quality-of-life measures and pulse oximetry to prioritize sleep-disordered breathing patients for PSG	Chinese version of the ESS and snore outcomes scores were compared against respiratory disturbance index. In the first-tier screening, receiver-operating characteristics were calculated with an initial strategy of choosing optimal prediction sensitivity. The second-tier strategy investigated the association between pulse oximetry data against RDI to optimize prediction specificity.	n=355 (312 males, age 44.7±11.3, BMI 27.4±4.1)	Quality-of-life and pulse oximetry information can help clinicians to identify patients who need early PSG diagnosis
Gurubhagavatula et al. (2008) [2]	Biometrics + Questionnaire	USA, Case control study	Investigate whether screening is cost-effective using (a) in-laboratory PSG on all drivers or (b) selective PSG; also identify the minimum rate of treatment acceptance for screening programs to be cost-effective	CMV drivers answered a questionnaire to screen them for OSA risk and to calculate costs and effectiveness of screening for OSA.	n=247 high-risk drivers; n=159 low-risk drivers; average age=45.4±11.0, BMI 29.9±5.2 kg/m2; 28.1% had AHI≥5 h−1, 32.6% had Epworth score > 10; 8.7% of the sample had OSA; AHI=6.0±11.5 and Epworth=8.8±4.4, with 32.6% (95% CI 28.2–36.9%) having scores in above 10.	Selective PSG is cost-effective; using a combination of BMI, age and gender to determine who should undergo PSG and then treating identified cases is considerably less expensive if combined with oximetry; oximetry used in conjunction with BMI, age and gender is only marginally more expensive offers one advantage: it requires fewer in-laboratory studies

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Gurubhagavatula et al. (2013) [18]	Biometrics + Questionnaire	USA, Prospective crossover study	Validate a two-stage strategy to screen for severe OSA syndrome among hypertensive outpatients, with PSG as the gold standard	All patients were given questionnaires which included demographic information as well as Epworth. Patients were then given a PSG and an at home monitoring system. A multivariable apnea prediction score, combined symptoms, BMI, age, and sex were used to compute OSA risk. Risk was also calculated using facial morphometrics and neck circumference.	n=250 (mean age 52.6, 200 males, mean BMI 32.1, mean neck circumference 42.2cm, 28.8% current smokers, 33.2% ever smokers)	Home sleep studies combined with clinical data can be useful in identifying severe OSA in hypertensive outpatients, without incurring greater cost and patient burden associated with in-laboratory PSG
Bruyneel et al. (2011) [19]	In-home	Belgium, Prospective, crossover, single-blind study	Comparing home-PSG with laboratory PSG	All patients underwent both attended in-hospital PSG and unattended home-based PSG within 2 weeks, performed by the same sleep technician.	n=66 (39 males, mean age 49 ± 13 years, mean BMI 30 ± 7)	Full-night unattended home-based PSG is associated with increased sleep efficiency in a high-risk OSA population and thus should be considered as a good alternative to sleep laboratory PSG

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Campbell & Neill (2011) [20]	In-home	New Zealand, Prospective cohort study	Determine technical reliability and diagnostic accuracy of unattended, home set-up vs. attended laboratory-based PSG in patients with suspected OSA	Patients underwent three separate nights of study within a 2-week period. After completing informed consent, patients were randomized to an initial lab-based PSG followed by a home set-up PSG and lab-based PSG. Techniques were standardized, and studies were scored by a blinded technologist according to guidelines. Patients were asked which study-type they preferred at the end of the study.	n=30 (24 male, age 49.1 ± 13.8; BMI 31.0 ± 6.1; ESS 10.8 ± 4.9)	Unattended home set-up PSG is technically reliable and achieves excellent diagnostic utility; signal loss was higher at home but mitigated by multi-channel redundancy
Andreu et al. (2012) [21]	In-home	Spain, Randomized prospective cohort study	Evaluate the efficacy of a home-based program on clinical response, CPAP compliance, and cost in a population with high pre-test probability of OSA	Patients were randomized into the following three groups: home respiratory polygraphy and home follow-up; hospital PSG and hospital follow- up; and home respiratory and hospital follow-up. Evaluation during 6 months included Epworth scale, Functional Outcomes Sleep Questionnaire, and daily activity and symptom questionnaires.	n=66 (83% male, age 52 ± 10 yrs, BMI 34 ± 7kgm^{-2}, AHI 43 ± 20 h^{-1}, CPAP pressure 8 ± 2 cm H_2O)	Patients with a high initial probability of having OSA can be diagnosed and treated in a home setting, with a high level of CPAP compliance and lower cost than using either a hospital-based approach or home RP/hospital follow-up
Masa et al. (2013) [22]	In-home	Spain, Randomized, blinded crossover study	Determine the agreement between home respiratory polygraphy and PSG, and between simultaneous respiratory polygraphy and PSG	All patients performed at-home and hospital protocols in a random order. PSG and respiratory polygraphy scorings were completed separately and technicians and physicians were blinded to any identifying patient information and any previous results.	n=342 (75.1% male, mean age 48.7, mean BMI 31.0, 24.4% smokers, mean neck circumference 40.9 cm)	AHI from home respiratory polygraphy scorings (with and without surrogate arousal) had similar agreement with PSG

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Rosen et al. (2012) [23]	In-home	USA, Randomized controlled trial	Test the utility of an integrated clinical pathway for OSA diagnosis and CPAP treatment using portable monitoring devices.	Home-based level 3 testing followed by one week of autoPAP with fixed pressure, compared with attended, in-laboratory studies.	n=136 (completed both visits: 61=LAB, 75=HOME)	A home-based strategy for diagnosis and treatment compared with in-laboratory PSG was not inferior in terms of acceptance, adherence, time to treatment, and functional improvements
Chai-Coetzer et al. (2011) [24]	In-home, Questionnaire	Australia, Non-randomized controlled trial	Develop and validate a simplified two-stage method for identifying moderate to severe OSA in primary care via screening questionnaire and home sleep apnea monitoring	Patients were asked to complete a general health questionnaire, Epworth Scale, and Berlin questionnaire. Four "high-risk" patients to every "low-risk patient" (according to Berlin questionnaire results) underwent simultaneous home PSG and monitoring with a two-channel portable device. Patients were visited at home by a trained sleep nurse who took anthropometric measurements and attached sleep recording devices.	n=157 (developmental group: n=79, age 55, age range 45-62, 53% male, BMI 31.7, neck 40.3 ± 4.2, waist 106.7 ± 13.9, ESS 8, total AHI 20.9, AHI range 13.1-41.3; validation group: n=78, age 50, age range 40-58, 44% male, BMI 29.3, neck 38.6 ± 4.1, waist 101.3 ±15.8, ESS 7, AHI 16.5, AHI range 9.6-28.2)	A two-stage model of screening questionnaire followed by home oximetry can accurately identify patients with OSA in a primary care setting and has the potential to expedite care for patients

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Nigro et al. (2011) [25]	Lab	Argentina, Cohort study	Compare the performance of automated detection vs. manual scoring from the ApneaLink™ device to diagnose OSA	Patients underwent overnight PSG. Sleep stages, arousals, and analysis of apneas, hypopneas, and respiratory effort related arousals were identified. Subjects wore an ApneaLink device during overnight study. ApneaLink data was scored automatically by software and again manually, corrected by physician following automatic scoring.	n=90 patients (69 male, age 49.6 ± 15.1, BMI 29.3 (25.2-32.5), RDI ≥ 30 28.9%)	The manual scoring of an ApneaLink recording applied in the sleep laboratory was a reliable procedure indicated by the good interobserver agreement and better than automatic scoring; almost 90% of the patients were correctly classified
Nigro et al. (2013) [26]	Lab	Argentina, Non-randomized controlled study	Validate the automatic and manual analysis of ApneaLink Ox™ in patients with suspected OSA	All the patients underwent overnight PSG with a computerized PSG system. Subjects also were monitored with ApneaLink Ox™ and the diagnoses were compared.	n=55 (38 male, mean age 48.2, median RDI 15.1, median BMI 30 Kg/m2)	The AHI obtained automatically from the ApneaLink Ox™ had a good performance to diagnose OSA; manual scoring from ApneaLink Ox™was better than automatic scoring to discriminate patients with OSA

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Maury et al. (2013) [27]	Lab	Belgium, Cohort study	Compare attended PSG with two other methods, with or without mandible movement automated analysis, provided by a distance-meter and added to airflow and oxygen saturation analysis	All subjects underwent attended PSG and JawSens recording. The results of each recording were compared.	n=570 (mean age 50 ± 14 years, BMI 29 ± 7 kg m^{-2})	The correlation between PSG and the method with mandible movement automated analysis was excellent; mandible movement automated analysis significantly improves the respiratory index calculation accuracy compared with an airflow and oxygen saturation analysis; this is an attractive method for the screening of OSA
Oliveira et al. (2012) [28]	Lab	Brazil, Prospective randomized cohort study	Evaluate the accuracy of a portable monitoring device (Stardust -STD) in the detection of OSA in patients with chronic obstructive pulmonary disease (COPD)	Prior to PSG, Berlin questionnaire and Epworth were applied; BMI, cervical circumference, and blood pressure were evaluated. All patients underwent two sleep assessments: one at home and one in lab. PSG was scored by a trained technician according to accepted standards. Patients were given instructions for use at home. Only patients who presented more than 60% of recording with good technical quality on all channels were considered for analysis.	n=26 (13 male, age 62.8 ± 8.5, BMI 31.0 ± 5.6, ESS 10.5 ± 4.1)	Despite the agreement found in a small number of patients between AHI, a large number of failures in the recording limits the use of this portable device (Stardust -STD) for the diagnosis of OSA in patients with chronic obstructive pulmonary disease

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Montazeri et al. (2011) [29]	Lab	Canada, Cohort study	Investigate differences between the breathing sounds of people with different degrees of OSA during wakefulness, and offer a simple method to identify degrees of OSA severity during wakefulness	Researchers recorded tracheal breath sounds of 17 non-apneic individuals and 35 people with various degrees of severity of OSA in supine and upright sitting positions during both nose and mouth breathing at medium flow rate.	n=52 (37 males)	Results show a good separability between the groups with different degrees of severity of OSA; may pave the way for a simple, non-invasive, and inexpensive screening tool for the people suspected of OSA, as well as predicting the degree of severity of the OSA during wakefulness
Jianling et al. (2011) [30]	Lab	China, Case control study	Evaluate the feasibility of screening OSA patients by ambulatory electrocardiogram monitoring using two different analytic approaches: time-domain analysis and frequency-domain analysis	Patients were subjected to an overnight sleep study simultaneously using PSG and ambulatory electrocardiogram monitoring. Two ECG analyzers independently gave the diagnosis as positive or negative without the knowledge of clinical data or PSG results.	n=95 (n=48 patients (34 male): age 52.15 ± 15.35, BMI 28.73 ± 3.99; n=47 controls (25 male): age 37.23 ± 16.73, BMI 23.21 ± 3.61)	The time-domain and frequency-domain analyses of heart rate variability can be used as two useful analytical approaches for screening of individuals with OSA whereas the frequency-domain analysis was found to be more sensitive than the time-domain analysis

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Zaffaroni et al. (2013) [31]	Lab	Ireland, Prospective cohort study	Assess the utility of a bio-motion sensor in the diagnosis of OSA	Patients underwent an overnight PSG. Sleepminder was plugged into the PSG monitor. Following completion of the sleep study, proprietary software was used to process overnight data from SleepMinder, allowing measurement of sleep/wake status and respiration.	n=74 (80% male, 55.4% obese, mean age 49.9)	In an unselected clinical population undergoing investigation for suspected OSA, SleepMinder measurement of sleep-disordered breathing correlates significantly with PSG
Kobayashi et al. (2012) [32]	Lab	Japan, Non-randomized controlled study	Investigate whether the accuracy of the SD-101 for OSA screening is improved by measuring percutaneous oxygen saturation (SpO2)	Subjects gave researchers their medical information and then took part in a sleep lab study.	n=60 (53 male, age 50.0±13.5 years, BMI 25.5±3.3 kg/m2)	AHI determined from PSG and the respiratory disturbance index determined from SD-101 measurements significantly correlated; this modality appears to offer high sensitivity and specificity for detecting even moderately severe OSA

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Watkins et al. (2009) [7]	Lab	USA, Consecutive case series	Compare the accuracy of portable monitoring for OSA with PSG in commercial drivers	Drivers screening positive on history and physical exam by the Consensus Criteria scheduled for a PSG. PSG results were interpreted as positive if AHI ≥ 10, or if sleep specialist recommended treatment due to severe nocturnal hypoxia, regardless of AHI. Drivers screening positive were requested to use a single-channel portable apnea monitor device for one night (RUSleeping) to compare the accuracy of portable monitoring screening to formal PSG.	n=346 newly hired drivers undergoing medical exams	A quarter of drivers who were originally scheduled to have a PSG terminated their employment and were thus lost to follow-up; the portable monitoring device demonstrated specificity > 0.70 in all AHI ranges >10; there is moderately high correlation between the results of the portable monitoring device and the standard procedure PSG, although this screening device is unable to completely rule out those that do not have OSA
Berry et al. (2012) [33]	Lab	USA, Non-randomized controlled study	Compare automatic event detection of respiratory events using a positive airway pressure (PAP) device with manual scoring of PSG during PAP treatment of OSA	A PSG was performed initially and at 6 months. The PAP device was modified to produce square wave outputs of different voltage and duration that identified when an apnea, hypopnea, or snoring event was detected. An automatic event detection algorithm was used to determine apnea events and then was compared to PSG results.	n=115 (mean age 49.5 ± 11.3, mean BMI 36.2 ± 7.6, 73% male)	Automatic event detection tended to overestimate the AHI when the manually scored AHI was low and underestimate the AHI when the manually scored AHI was high; detection had a high specificity but only modest sensitivity

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Polese et al. (2013) [34]	Lab, In-home	Brazil, Prospective randomized cohort study	Evaluate the diagnostic effectiveness of at-home portable monitoring in elderly patients	Patients were evaluated for BMI, neck circumference, and blood pressure. Berlin questionnaire and Epworth were applied. Patients underwent two sleep assessments: one performed with portable monitoring at home without technical supervision, and one performed simultaneously with PSG in the lab. After undergoing PMhome, patients were asked to complete an analog scale assessing difficulty of setting up and operating equipment, and comfort while in use.	n=43 total (44% male, age 70.0 ± 5.0, BMI 30.3 ± 6.0, neck circumference (cm) 38.9 ± 3.4, ESS 9.1 ± 6.1)	The Stardust II, a type 3 portable monitor, provided effective and good diagnostic agreement with attended PSG in an elderly population and could provide an affordable and comfortable alternative to in-laboratory PSG
Pietzsch et al. (2011) [35]	Lab, In-home	USA, Markov model	Evaluate the cost-effectiveness of three commonly used diagnostic strategies (full-night PSG, split-night PSG, unattended portable home-monitoring) in conjunction with CPAP therapy in patients with moderate-to-severe OSA	Baseline computations were performed for a hypothetical average cohort of 50-year-old males with a 50% pretest probability of having moderate-to-severe OSA (AHI≥ 15 events per hour). A Markov model was created to compare cost and effectiveness of different diagnostic and therapeutic strategies over a ten year interval and the expected lifetime of the patient.	Based on a model of 50 year old male; 50% pretest probability of OSA	Full-night PSG is cost-effective and is the preferred diagnostic strategy for adults expected to have moderate to severe OSA when all diagnostic options are available; split-night PSG and unattended home monitoring can be considered cost-effective alternatives when full-night PSG is not available

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Oktay et al. (2011) [36]	Lab, In-home	USA, Prospective cohort study	Validate the ApneaLINK as an accurate tool for determining the presence of OSA in an at-risk sleep clinic population in a home test environment	Consecutive participants referred with the suspicion of OSA were evaluated in the home with a portable monitor (AL Home), followed by simultaneous data collection with diagnostic PSG and the portable monitor in a sleep lab.	n=53 (45% male; mean age 45.1 ±11.3 years; BMI 35.9 ± 9.1 kg/m^2)	The AL home test is an accurate alternative to PSG in sleep clinic populations at risk for moderate and severe OSA
Simpson et al. (2013) [37]	Questionnaire	Australia, Case control study	Estimate undiagnosed moderate to severe OSA in a general population sample and determine the ability of questions from the Berlin questionnaire to identify subjects with OSA	Subjects underwent overnight single-channel nasal airflow studies. The Berlin questionnaire was coded in two different ways: by categories (snoring, daytime symptoms, and comorbidities) and by examining the screening properties of the constituent questions by themselves.	n=793 subjects (48% male, 48% smokers, 15% with moderate or severe OSA (AHI ≥ 15), 97% European ancestry, BMI 27.5 ± 4.7, waist circumference (cm) 92.1 ± 13.1)	The Berlin questionnaire has sub-optimal screening properties for OSA within a general population; snoring frequency and hypertension are associated with a higher post-test probability of AHI < 15 than the complete Berlin questionnaire
Sharwood et al. (2012) [9]	Questionnaire	Australia, Cross-sectional study	Determine the relationship between subjective and objective assessments of OSA in CMV drivers	Drivers were interviewed regarding their driving experience, personal health, shift schedules, payments, and various questions on sleep and tiredness in order to describe their sleep health across a range of variables. In addition, home recordings using a flow monitor were used during one night of sleep.	n=517 (recruited; 50% obese); n=325 (completed data and flow monitoring)	Sleep apnea remains a significant and unrecognized problem in CMV drivers; objective testing for this sleep disorder needs to be considered, as symptom reports and self-identification appear insufficient to accurately identify those at risk

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Chung et al. (2013) [38]	Questionnaire	Canada, Non-randomized controlled study	Determine the predictive performance of the STOP-Bang questionnaire in obese and morbidly obese patients	Patients underwent an initial PSG and then additional PSGs throughout the study (2 years). The scores on these studies were compared with STOP-Bang questionnaire scores.	n=450 (n=310 obese patients: 41% male, mean age 57.4±11, mean BMI 35.7±5, mean neck circumference 39.8±4 cm; n=140 morbidly obese patients: 26% male, mean age 56.4±11, mean BMI 40.1±5, neck 40.7±4 cm)	A STOP-Bang score of 4 as the cutoff gives a good discrimination in the obese and morbidly obese patients for identifying OSA, especially severe OSA, since the predicted probability for severe OSA was twofold higher in the obese patients with a score of ≥4 than a score of <4
Zou et al. (2013) [39]	Questionnaire	China, Retrospective cohort study	Develop a simple and efficient model for identifying OSA in Chinese adult population	All participants were asked to complete a uniform questionnaire regarding histories of current and previous illnesses and medical treatments. The Epworth questionnaire was completed before a subject underwent overnight PSG. The questionnaire and PSG data were collected and analyzed by two independent investigators.	n=2,816 (n=2,032 (test cohort; unrelated consecutive subjects suspected as having OSA); n=784 (independent validation cohort))	A practical screening model comprising minimum SaO_2 and other parameters could efficiently identify undiagnosed OSA from the high-risk patients; additionally, a sex-specific difference should be considered if the Epworth alone is used

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Pecotic et al. (2012) [40]	Questionnaire	Croatia, Case control study	Evaluate Croatian Epworth and STOP as screening instruments for OSA	Patients and controls were both given Epworth questionnaire (Croatian translation) and a STOP questionnaire. Patients were then given a PSG.	n=425 (217 patients referred to sleep lab, 208 healthy controls) (patient: 167 males, mean BMI 30.1±4.7, median age 55; controls: 125 male, mean BMI 29.3±4.9, median age 55)	Both ESS and STOP successfully distinguished healthy subjects from subjects with OSA; STOP had better probability to correctly predict high-risk patients compared to ESS
Bouloukaki et al. (2013) [41]	Questionnaire	Greece, Non-randomized controlled study	Explore whether the Greek Berlin questionnaire could be used to help identify primary care patients at greater risk of having OSA	Patients were given a translated version of the Berlin questionnaire. Results were then compared to a PSG test and ESS scores.	n=189 (mean age 47 ± 13, 61.9% male, mean BMI 35.0 ± 25.1)	For different AHI cutoff points, Berlin questionnaire showed a moderate to high sensitivity and a specificity that was low to moderate; in primary care patients, the Berlin questionnaire can be helpful in detecting a high risk of having OSA, especially if the OSA is moderate or severe

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Amra et al. (2013) [42]	Questionnaire	Iran, Cross-sectional linguistic validation study	Assess the reliability and diagnostic accuracy of the Persian version of the Berlin questionnaire in diagnosis of OSA in Iranian sleep clinic patients	Patients completed a Persian translation of the Berlin questionnaire and then participated in an overnight PSG study at the clinic.	n=157 (55.4% male, mean age 52.3 ± 13.6 years)	According to high sensitivity and PPV of the test, the Persian Berlin questionnaire is useful as a screening test for diagnosing OSA in patients with sleep complaints; however, the test has very low specificity
Jauhar et al. (2012) [43]	Questionnaire	Scotland, Non-randomized controlled study	Test the validity of the Kushida Index for screening for sleep apnea	Researchers met with patients and took measurements to input into the Kushida Index. Participants then all had limited sleep studies (respiratory PSG) carried out using the Somnoscreen system (S-Med,UK) and manually analyzed by a sleep technician.	n=85 (63 males, mean age 47.6, BMI 33.7, neck circumference 42 cm)	The sensitivity and specificity of the Kushida Index for the prediction of OSA were found to be rather lower in this present study compared to Kushida's original results
Kang et al. (2013) [44]	Questionnaire	South Korea, Non-randomized controlled study	Develop the Korean version of the Berlin questionnaire and evaluate its usefulness in identifying patients with OSA in the general population	Door-to-door surveys were conducted. These surveys included a Korean version of the Berlin questionnaire as well as demographic questions. Some participants then took part in an overnight sleep study.	n=1,305 survey participants (mean age 52.78 ± 16.55, 47.7% male, mean BMI 22.81±4.86 g/m2); n=101 sleep study participants (77 male)	The Korean Berlin Questionnaire showed relatively good internal consistency and excellent test–retest reliability; the AHI derived from the PSG was significantly correlated with the scores with a sensitivity of 69% and specificity of 83%

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Firat et al. (2012) [15]	Questionnaire	Turkey, Cohort study	Assess the usefulness of four standardized questionnaires (Berlin, STOP, STOP-BANG, and OSA50) in identifying high-risk bus drivers for OSA	Four questionnaires for predicting OSA were translated and adapted to Turkish and completed by subjects with the help of a physician prior to PSG. Subjects completed a 5 hour PSG after working a full night shift. Blood pressure, blood count, liver and renal function tests, spirometry, lipid panel, and thyroid function tests were obtained. National Cholesterol Education Program Adult Treatment Panel III criteria were used for the metabolic syndrome definition.	n=85 bus drivers; all male (n=23 < 45 years of age: BMI 27.7 ± 2.9, neck circumference 40.1 ± 2.5, waist circumference 94.7 ± 8.3, AHI 14.4 ± 11.6; OSA (AHI > 15) 30.4%, metabolic syndrome 8.7%; n=62 ≥ 45 years of age: BMI 29.7 ± 4.0; neck 41.5 ± 2.9; waist 101.4; AHI 23.6 ± 18.5; OSA 62.9%; metabolic syndrome 33.9%)	Objective parameters such as BMI, neck circumference, waist circumference, or presence/absence of hypertension, and gender are used in different tests in different combinations; STOP-BANG had the highest sensitivity; STOP test had the lowest values

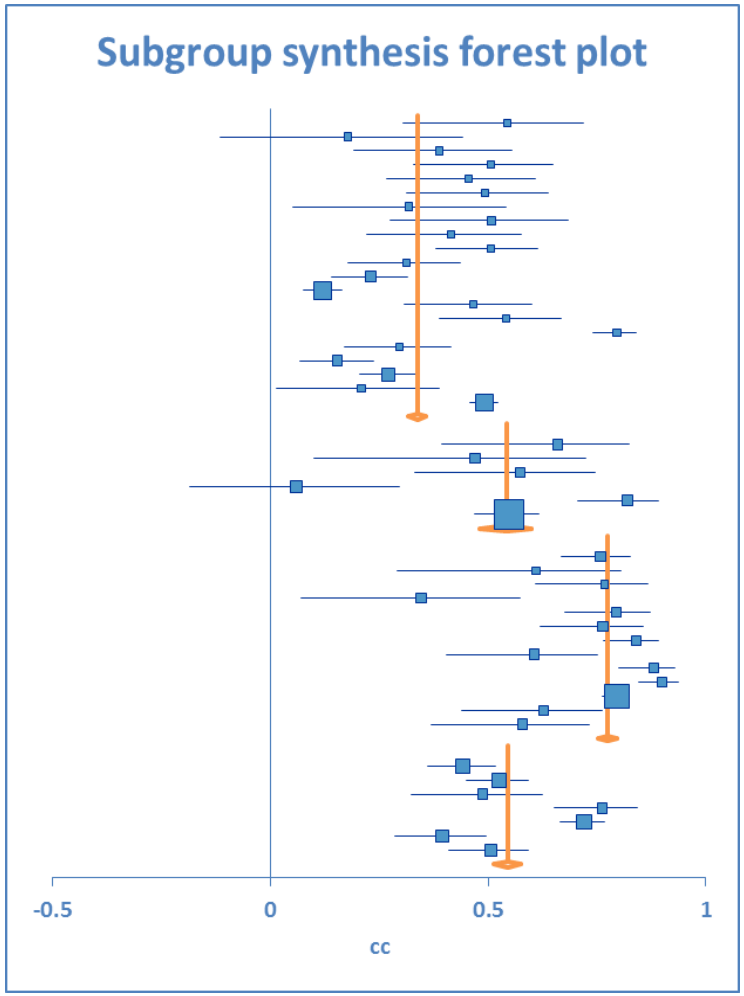
Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Ugur et al. (2011) [45]	Questionnaire	Turkey, Cohort study	Investigate the impact of two different application methods (self or nurse administered) on Epworth scores and compare the scores according to the correlations between PSG findings	Patients completed the self-administered Turkish version of the Epworth following examination. During a second visit 7 days later, patients completed the Epworth again. Diagnostic PSG was also performed. Staging was performed according to the guidelines of Rechtschaffen, Kales and the American Sleep Academy Association 2007 criteria. Respiratory events were scored as apneas or hypopneas. Apnea was defined as a 90% reduction in airflow for a duration of at least 10 s. Hypopnea was defined as a 30% or greater decrease in flow lasting at least 10 s and associated with a 4% or greater oxyhemoglobin desaturation.	n=101 patients (n=71 male, age 45 ± 12, BMI 30 ± 6, AHI 30 ± 28, 17.8% simple snorers, 19.8% mild OSA, 22.8% moderate OSA, 39.6% severe OSA)	The scores of the nurse-administered Epworth were clinically significantly correlated with the AHI; in routine clinical practice, the ESS can be performed using the nurse-administered method which is more comprehensible
Sil & Barr (2012) [46]	Questionnaire	UK, Retrospective cohort study	Assess the association between the Epworth Sleepiness Scale and OSA	A literature review was conducted on articles that demonstrated a direct association between Epworth and OSA. The effect size of the Epworth score in relation to the AHI was computed, and a partial meta-analysis was done on all studies that met the criteria. Second study: data was taken from consecutive patients at a sleep lab between 1998 and 2008. Epworth and presence or absence of OSA was recorded for each patient.	n=343 (patients); n=16 (past studies on ESS and OSA)	The Epworth Scale is only marginally useful in predicting the occurrence of OSA

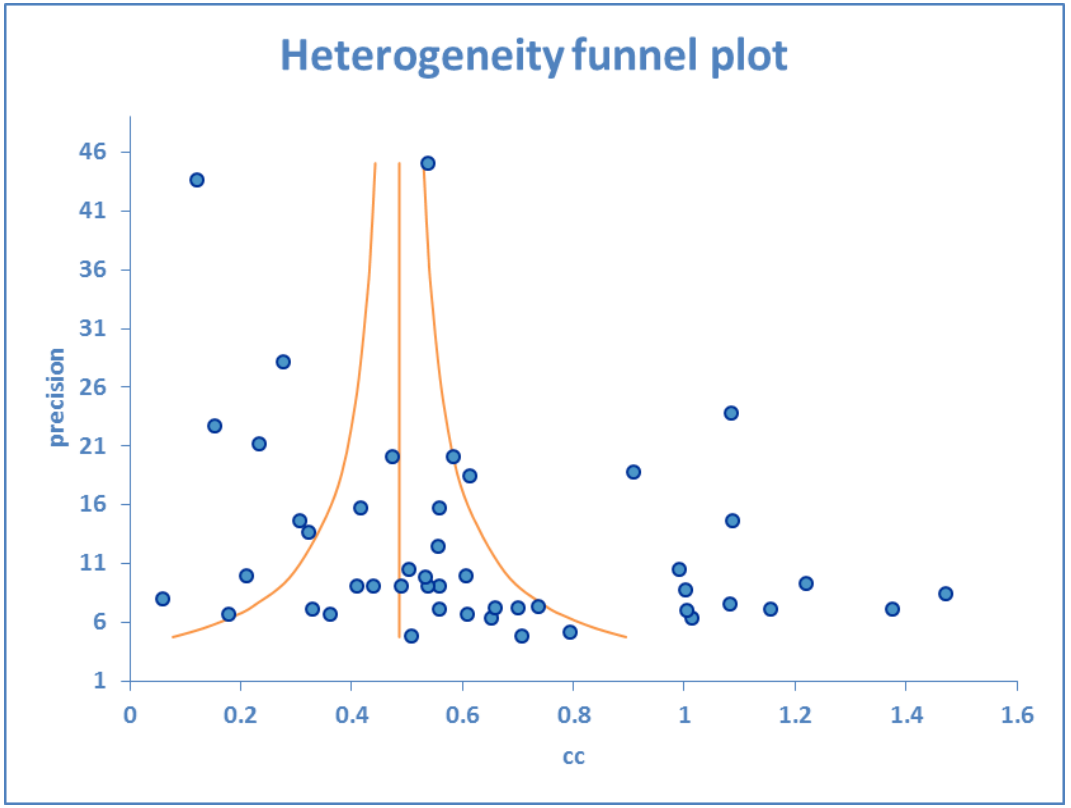
Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Enciso & Clark (2011) [47]	Questionnaire	USA, Case control study	Compare the sensitivity and specificity of two questionnaires to identify patients with OSA	OSA status was made using standard medical classification (RDI ≥ 15/hr) and based on ambulatory somnographic assessment by a physician; subjects were interviewed and answered the Berlin and ARES questionnaires.	n=53 moderate to severe OSA patients (45 male); age (years): 58.4 ± 10.34; neck circumference (in): 16.3 ± 1.50; BMI 27.6 ± 3.74; RDI (events/hr) 33.9 ± 16.30; apnea index (events/hr) 14.2 ± 15.5. n=31 controls (20 male); age 49.0 ± 12.63; neck 14.8 ± 1.25; BMI 24.9 ± 3.28; RDI 8.0 ± 3.65; apnea index 1.2 ± 1.43	A subject having a high risk ARES questionnaire was more likely to have OSA; ARES performs better than the Berlin questionnaire as a screening for OSA patients except in its ability to identify correctly individuals who truly do not have the disease
Ishii et al. (2011) [48]	Questionnaire	USA, Non-randomized controlled study	Explore the association between the NOSE score and the Epworth score for screening patients at risk for OSA.	Patients were given three separate questionnaires (NOSE, ESS, and SOS). Then statistical analysis was used to see if a correlation could be detected.	n=112 (44 males, male mean age 54.5, female mean age 43.9)	In patients who snore and have a deviated septum, there is an association between elevated NOSE scores and elevated Epworth scores; patients with elevated Epworth scores should have further evaluation by a sleep specialist and should possibly undergo PSG

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Vana et al. (2013) [49]	Questionnaire	USA, Non-randomized controlled study	Compare the predictive abilities of the STOP-Bang and Epworth scale for screening sleep clinic patients for OSA	Patients completed the STOP-Bang questionnaire and Epworth scale. Several measurements (blood pressure, weight, neck circumference) were also taken to complete the STOP-BANG assessment. After these assessments patients were given a PSG.	n=47 (16 male, mean age 46.4, mean BMI 36.3, mean neck circumference 15.0)	The SB30 had a higher sensitivity and identified more patients with OSA than the Epworth or SB35 in this sleep clinic population
Hesselbacher et al. (2012) [50]	Questionnaire	USA, Retrospective cohort study	Examine differences in Epworth scores between various demographic groups of patients referred for PSG and the relationship of these scores to sleep-disordered breathing	Prior to undergoing PSG, subjects completed questionnaires reporting demographics and general sleep health. Overnight comprehensive PSG was performed in the sleep laboratory. Data were scored manually.	n=1,900 patients referred for PSG (1092 males: 54% Caucasian, 43% Hispanic, age 53 ± 15, height (cm) 177 ± 8, weight (kg) 73 ± 8, BMI 35 ± 8, neck circumference (cm) 17 ± 2; 805 females: 50% Caucasian, 48% Hispanic, age 55 ± 14, height 161 ± 9, weight 63 ± 17, BMI 36 ± 9, neck 15 ± 3)	While the Epworth is well-validated to detect sleepiness, it is probably influenced by other factors; its sensitivity to detect clinically important OSA is insufficient to be used as a screening tool in the absence of other clinical data

Author (Year)	Approach	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Xie et al. (2011) [8]	Questionnaire, Biometrics + Questionnaire	USA, Cross-sectional, retrospective, case-control design	Identify factors associated with OSA risk during commercial driver medical examinations	Each driver completed the health history section of the federal CDME form. Each driver's blood pressure, height (inches), weight (pounds), and neck circumference (inches) were measured. The examining physician determined whether the driver met the consensus criteria for PSG. Drivers with suspected OSA were issued a 3-month medical certification and referred for PSG evaluation in a sleep laboratory.	n=1,890 (91.6% male, average age 43.7 ±11.52 years, average BMI 30.5 ±6.6)	Medical examiners' use of objectively measurable risk factors, such as obesity, history of hypertension, and/or diabetes, rather than symptoms, may be more effective in identifying undiagnosed OSA in commercial drivers during the commercial driver medical examinations
Platt et al. (2013) [4]	Questionnaire, Biometrics + Questionnaire	USA, Prospective cohort study	Evaluate Joint Task Force criteria-based screening for severe OSA in commercial drivers	Subjects self-reported demographics, apnea symptoms, tobacco and alcohol use, and Epworth scores. A pre-employment physical exam was simulated to determine fitness for duty, using the US DOT's Medical Examination Report for Commercial Driver Fitness Determination. Physician measured BMI, blood pressure, and neck circumference. PSG was conducted in-home. Primary analyses considered severe OSA as AHI of 30 or more per hour. An alternate threshold of 20 or more was considered for secondary analyses.	n=100 drivers with active commercial driver's licenses (94% male, mean age 44.0 ± 8.6, BMI 34.3 ± 8.0, neck circumference (cm) 43.2 ± 4.0, Epworth 6.6 ± 4.0; AHI 26.6 ± 22.6)	Our findings indicate that one third to one fifth of cases of severe OSA may be missed by existing Joint Task Force guidelines; examination-based criteria missed 20% of severe OSA cases; combining examination with confidentially reported symptoms improved sensitivity but required confirmatory PSG in 86% of cases, supporting universal screening of all drivers

Table 13: Overall Meta-Analysis Findings for Q3





Type	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value
Questionnaire	0.34	0.32	0.36	30.18	0.00
Home Device	0.54	0.48	0.60	14.16	0.00
Lab Device	0.78	0.75	0.80	35.16	0.00
Biometrics + Questionnaire	0.57	0.54	0.61	24.52	0.00

Table 14: Meta-Analysis Findings for Questionnaires

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Vana et al.	0.54	0.30	0.72	4.04	0.00	0.60%
Vana et al.	0.18	-0.12	0.44	1.19	0.23	0.60%
Firat et al.	0.39	0.19	0.56	3.71	0.00	1.12%
Firat et al.	0.51	0.33	0.65	5.07	0.00	1.12%
Firat et al.	0.45	0.27	0.61	4.44	0.00	1.12%
Firat et al.	0.49	0.31	0.64	4.88	0.00	1.12%
Enciso & Clark	0.32	0.05	0.54	2.33	0.02	0.68%
Enciso & Clark	0.51	0.28	0.68	3.96	0.00	0.68%
Jauhar et al.	0.41	0.22	0.58	3.99	0.00	1.12%
Amra et al.	0.51	0.38	0.61	6.93	0.00	2.10%
Bouloukaki et al.	0.31	0.18	0.44	4.42	0.00	2.53%
Chung et al.	0.23	0.14	0.32	4.96	0.00	6.08%
Hesselbacher et al.	0.12	0.08	0.17	5.31	0.00	25.82%
Ishii et al.	0.47	0.31	0.60	5.27	0.00	1.48%
Kang et al.	0.54	0.39	0.67	6.01	0.00	1.33%
Pecotic et al.	0.80	0.74	0.84	15.92	0.00	2.91%
Pecotic et al.	0.30	0.17	0.41	4.48	0.00	2.91%
Sharwood et al.	0.15	0.07	0.24	3.52	0.00	7.00%
Simpson et al.	0.27	0.21	0.33	7.81	0.00	10.75%
Ugur et al.	0.21	0.01	0.39	2.10	0.04	1.33%
Zou et al.	0.49	0.46	0.52	24.25	0.00	27.61%
Synthesis	**0.34**	**0.32**	**0.36**	**30.18**	**0.00**	**100%**

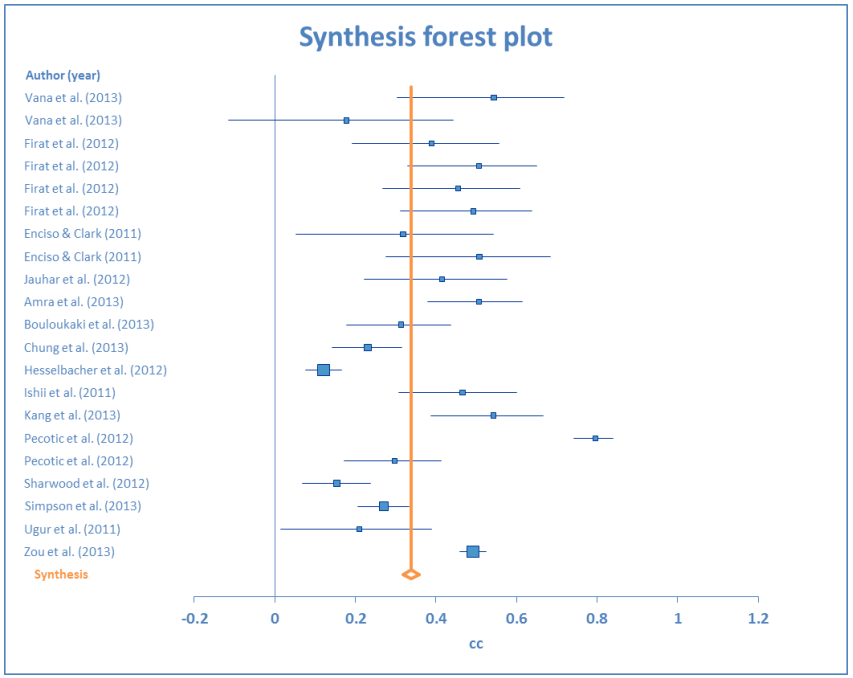


Table 15: Meta-Analysis Findings for Home Devices

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Campbell & Neill	0.66	0.39	0.82	4.13	0.00	4.98%
Oliveira et al.	0.47	0.10	0.73	2.45	0.01	4.24%
Polese et al.	0.57	0.33	0.75	4.13	0.00	7.38%
Bruyneel et al.	0.06	-0.18	0.30	0.48	0.63	11.62%
Oktay et al.	0.82	0.71	0.89	8.18	0.00	9.23%
Masa et al.	0.55	0.47	0.62	11.33	0.00	62.55%
Synthesis	**0.54**	**0.48**	**0.60**	**14.16**	**0.00**	**100%**

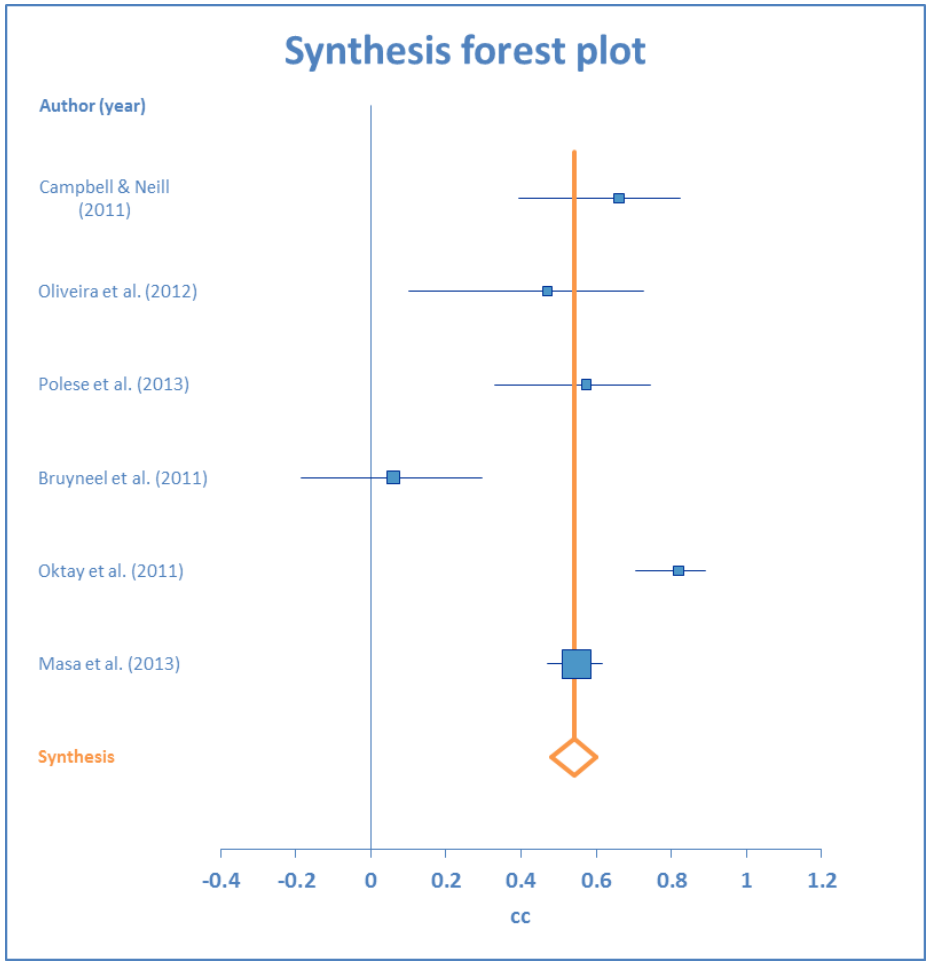


Table 16: Meta-Analysis Findings for Lab Devices

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Oliveira et al.	0.61	0.29	0.81	3.40	0.00	2.01%
Polese et al.	0.77	0.61	0.87	6.42	0.00	3.49%
Jianling et al.	0.35	0.07	0.57	2.43	0.02	3.92%
Kobayashi et al.	0.79	0.68	0.87	8.17	0.00	4.97%
Montazeri et al.	0.76	0.62	0.86	7.04	0.00	4.27%
Nigro et al.	0.58	0.37	0.73	4.77	0.00	4.53%
Nigro et al.	0.84	0.77	0.89	11.39	0.00	7.59%
Nigro et al.	0.61	0.41	0.75	5.06	0.00	4.53%
Oktay et al.	0.88	0.80	0.93	9.73	0.00	4.36%
Zaffaroni et al.	0.90	0.85	0.94	12.41	0.00	6.19%
Maury et al.	0.80	0.76	0.82	25.88	0.00	49.43%
Watkins et al.	0.63	0.44	0.76	5.42	0.00	4.71%
Synthesis	**0.78**	**0.75**	**0.80**	**35.16**	**0.00**	**100%**

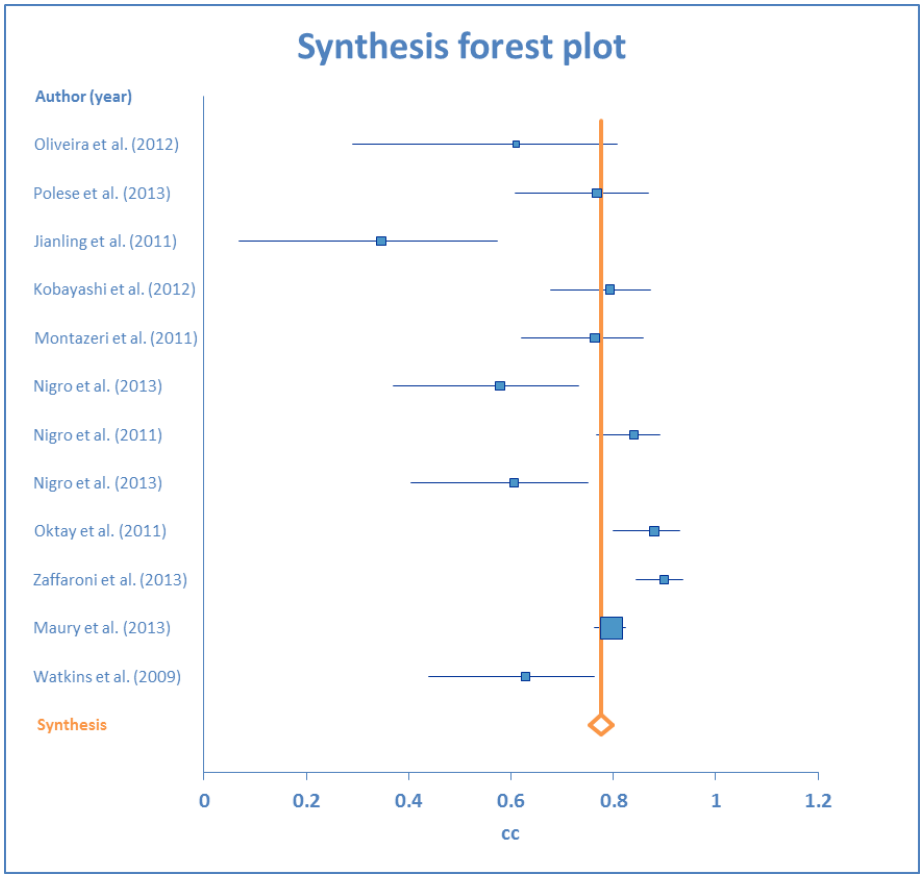


Table 17: Meta-Analysis Findings for Biometrics Plus Questionnaire

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Gurubhagavatula et al.	0.53	0.45	0.59	11.71	0.00	28.34%
Platt et al.	0.49	0.32	0.62	5.26	0.00	6.82%
Chai-Coetzer et al.	0.76	0.65	0.84	8.74	0.00	5.34%
Chen et al.	0.72	0.67	0.77	17.06	0.00	24.75%
Gurubhagavatula et al.	0.39	0.28	0.49	6.56	0.00	17.37%
Gurubhagavatula et al.	0.51	0.41	0.59	8.79	0.00	17.37%
Synthesis	**0.57**	**0.54**	**0.61**	**24.52**	**0.00**	**100%**

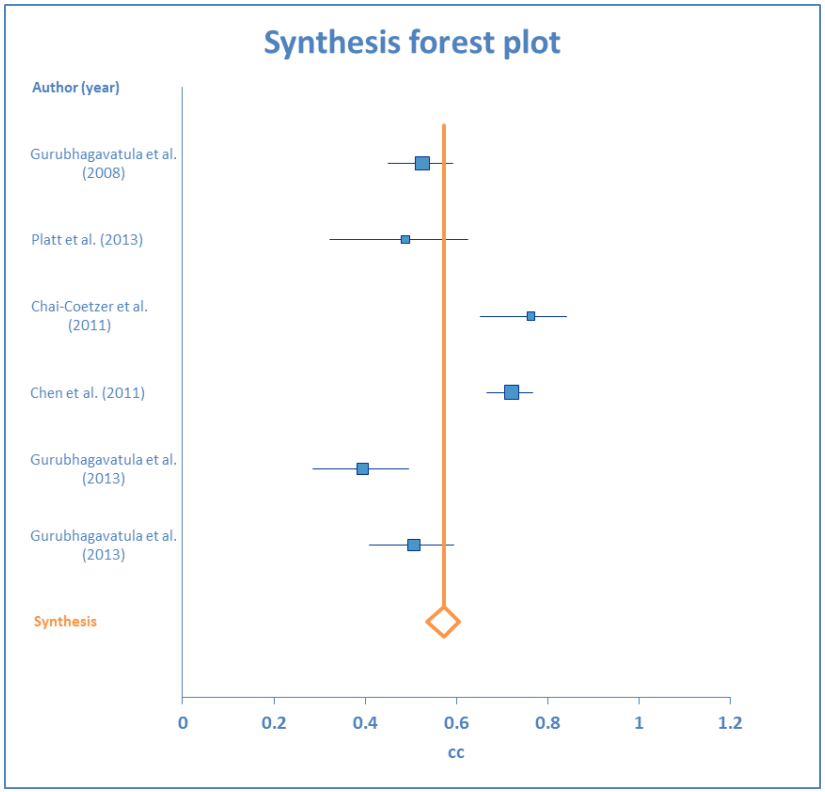


Table 18: Findings Related to Financial Information for Articles that Address Q3

Author (Year)	Financial Conclusions	Findings Related to Cost of Treatment
Gurubhagavatula et al. (2008) [2]	Selective PSG is cost-effective; using a combination of BMI, age and gender to screen for PSG and then treating identified cases is less expensive if combined with oximetry; oximetry in conjunction with BMI, age and gender is only marginally more expensive and requires fewer in-laboratory studies	1. Cost of driver PSG screening program: $920 per driver ($768 for testing + $152 cost of treatment) 2. Cost of one-stage screening program: $358 per driver ($252 for testing + $107 cost of treatment) 3. Cost of two-stage screening program: $372 per driver ($268 for testing + $104 cost of treatment) 4. Cost of missed case for not screening to be most cost-effective: $6,100 5. Cost of missed case for one-stage screening to be most cost-effective: $6,100-$22,700 6. Cost of missed case for two-stage screening to be most cost-effective: $6,500-$21,000 7. Cost of missed case for PSG screening to most cost-effective: More than $22,700 8. Treatment acceptance rate for one-stage screening to be cost-effective: 73.5% 9. Treatment acceptance rate for two-stage screening to be cost-effective: 78.5%
Campbell & Neill (2011) [20]	Home PSG costs about 75% the cost of lab-based PSG, even taking into account the need to repeat PSGs due to failures	1. Failure rate of home PSG (out of 100): 6.7 2. Home PSG cost vs. lab PSG cost: 70% 3. Home PSG cost vs. lab PSG cost (taking into account failure rate): 75%
Andreu et al. (2012) [21]	Home-based PSG and follow-up costs substantially less than hospital-based PSG and follow-up, and somewhat less than home-based PSG and hospital follow-up	1. Cost per patient (including tests, visits, and calls) for home respiratory polygraphy and home follow-up group: € 590 ± 43 2. Cost per patient (including tests, visits, and calls) for hospital PSG and hospital follow-up group: € 894 ± 11 3. Cost per patient (including tests, visits, and calls) for home respiratory polygraphy and hospital follow-up group: € 644 ± 93
Rosen et al. (2012) [23]	Home PSG costs about 70% the cost of lab-based PSG	1. Initial home PSG cost vs. lab PSG cost (including patient visits, PSG, and titration): 75%
Pietzsch et al. (2011) [35]	Full-night PSG is cost-effective and the preferred diagnostic strategy for adults expected to have moderate to severe OSA; split-night PSG and unattended home monitoring can be considered cost-effective alternatives when full-night PSG is not available	Note: All based on modeled scenario for 50-year-old male with moderate to severe OSA, findings are in 2008 $. 1. Incremental cost effectiveness ratio for full-night PSG in conjunction with CPAP therapy (for a population with 50% prevalence of OSA): $17,131 per-QALY gained (quality adjusted life year, takes into account years and health of those years)
Vana et al. (2013) [49]	Questionnaires are affordable to administer	1. Per-patient cost of administering the SB30 (direct and indirect costs, 2010 $): $7.47 2. Per-patient cost of administering the Epworth (direct and indirect costs, 2010 $): $8.65

Table 19: Medicare Physician Fee Schedule for Services Related to OSA Diagnosis, 2014 Costs

HCPCS Code	Description	Cost (at a facility)
95810	Full-night PSG	$621.17
95811	Split-night PSG	$651.62
95806	Unattended home monitoring	$173.02
95801	Home oximetry	$95.29

Source: http://www.cms.gov/apps/physician-fee-schedule/overview.aspx, Accessed March 2, 2014

Findings

Findings are presented first for the meta-analysis and then for the financial information.

Meta-analysis

In order to obtain an effect size for all diagnostic studies, the sensitivity and specificity of each approach to diagnosis OSA were converted to a diagnostic odds ratio, which was then transformed to Pearson's r correlation, and standardized using Fisher's z. The correlation reported for each study is an indicator of how well each diagnostic strategy is related to PSG, which is viewed as the gold standard of diagnosing OSA. Higher correlations indicate stronger associations to PSG (or better diagnostic approaches), whereas lower correlations indicate weaker associations to PSG.

Group differences are shown in a subgroup synthesis forest plot in Table 13. The horizontal axis of this plot shows the range of effect size, with the vertical axis being a correlation of zero. Squares on the forest plot represent the effect size for each study, with the lines extending from each square representing confidence intervals. The orange horizontal lines represent the confidence interval for each subgroup, while the orange vertical lines mark the articles included in each subgroup.

Diagnostic approaches were categorized into questionnaire, home device, lab device, and biometrics plus questionnaire. These groups appear in the subgroup synthesis forest plot from top to bottom, respectively. A subgroup analysis showed all diagnostic groups to be significantly different from a correlation of zero. In other words, all approaches were at least somewhat successful in diagnosing OSA.

The forest plot indicates that subgroup 3, lab devices, had a significantly stronger correlation to lab PSG than the other diagnostic strategies. In addition, subgroup 1, questionnaires, has a significantly weaker correlation to lab PSG compared to other diagnostic strategies. Subgroups 2 and 4, home devices and biometrics plus questionnaire, show a weaker correlation to lab PSG compared to Subgroup 3, and a stronger correlation to lab PSG compared to Subgroup 1; however, Subgroups 2 and 4 were not significantly different from each other. This indicates that home devices and biometrics plus questionnaires are similar in their ability to diagnose OSA.

The heterogeneity funnel plot for all studies included in the overall meta-analysis is reported in Table 13. The funnel plot indicates that nearly half of the studies included in the overall analysis have significant variation in effect size.

Meta-analyses were performed on each individual category of diagnostic approach. One of the 21 studies included in this group had an effect size that did not differ from zero, but the

overall correlation coefficient for questionnaires is 0.34, p<.01. Analysis of heterogeneity statistics indicate a significant Q statistic (Q= 350.57, p<0 .05). This finding indicates that the effect sizes may have potential moderators- other variables influencing the effect size. A dissemination bias test on these studies did not show significant biases in the studies included in this analysis.

A meta-analysis conducted on the home device group (n=6) indicates an overall significant difference in effect size from a zero correlation. The correlation coefficient for home devices is 0.54, p<0.01. However, one study out of the six included in this analysis reported an effect size not significantly different from a zero correlation. The forest plot of all studies included in the home device analysis is shown in Table 15. The reported Q statistic for heterogeneity was significant (Q= 35.23, p<0.05). However, a dissemination bias test conducted on these studies reported a non-significant p-value, indicating no bias among these studies.

Analysis run on the lab device group (n=12) indicates a significant group difference from a correlation of zero, with all studies differing from a zero correlation individually. The correlation coefficient is 0.78, p<0.01. The group forest plot is shown in Table 16. The heterogeneity statistic Q was significant (Q= 64.73, p<0.05). Begg's test was conducted on these data to investigate any biases in the included studies. The test for biases was non-significant, which indicates no bias among studies included in this analysis.

A meta-analysis performed on the biometrics plus questionnaire group (n=6) reported a significant difference in mean effect size for the group compared to a zero correlation, with all studies included significantly differing from the zero correlation. The correlation coefficient is 0.57, p<0.01. The forest plot produced for this group analysis is shown in Table 17. The test of heterogeneity reported a significant Q statistic (Q= 51.62, p<0 .05). Begg's test of dissemination biases reported no significant bias among the studies included in this analysis.

Financial information related to cost of diagnosis

The studies included limited information related to costs, with only n=6 studies providing financial information. To supplement the information identified in the studies, we also report the current Medicare Physician Fee Schedules for lab-based PSG and home studies (see Table 19).

As seen in the 2014 Medicare Physician Fee Schedules, home-based PSG testing has a substantially reduced initial cost compared to lab-based testing, with a cost difference of almost $450. However, that initial difference does not reflect the true cost disparity, which needs to take into account re-screenings because of failures, titration, and associated doctor visits (which are required regardless of screening method). Several studies have investigated the true cost difference between lab-based PSG and home-based PSG [20,21,23], which

includes these other costs, and these studies have established that home-based PSG costs 65-75% of lab-based PSG. Even with this cost difference, Pietzsch et al. [35] recently found that lab-based monitoring is more cost effective for patients with suspected moderate to severe OSA. This is because other diagnostic strategies result in more false-positives. However, the authors note that other screening methods are also cost-effective when lab-based screening is not available.

At least one study has also investigated the question of whether having all CMV drivers undergo PSG, whether one-stage screening followed by selective PSG, two-stage screening followed by selective PSG, or no screening is more cost-effective. Gurubhagavatula et al.'s study [2] used one-stage screening based on BMI, age, and gender; and two-stage screening based on BMI, age, gender and oximetry. The result was heavily dependent on the cost of a missed case, with no screening being more cost effective when missed cases have a low cost (under $6,100) and universal PSG being most cost effective when missed cases have a high cost (over $22,700). One- and two-stage screening is most cost effective when missed cases have an intermediate cost. However, these authors defined OSA as a combination of both high AHI scores and a high Epworth score; their calculations would vary substantially had they used AHI scores alone; they identified a much higher percentage of drivers based on AHI alone (28%) vs. AHI in combination with Epworth (9%).

The final cost study we identified looked at the cost of administering two questionnaires (SB30 and Epworth) to screen for OSA risk. For both cases, the cost of administering a questionnaire to screen for OSA was quite low (<$9) [49].

Conclusions

There is strong evidence that lab-based diagnostic approaches are the most sensitive and specific way to diagnosis OSA. Other diagnostic approaches, including home-based studies and questionnaires plus biometric data, are acceptable approaches when a lab-based option is not available. Questionnaires are a less sensitive and specific way to diagnosis OSA, although some questionnaires perform better than others (see question 5 for additional discussion)**.** These findings are based on a meta-analysis of recent research findings.

There is strong evidence that a screening program to identify drivers at-risk for OSA, followed by selective PSG, is more cost-efficient related to immediate short-term costs. Screening programs allow for the identification of drivers who are likely to be at higher risk for OSA, and reduce the number of PSGs performed, thus reducing immediate costs. **However, there is insufficiently weak evidence to identify whether screening is more cost-effective than universal PSG in the long-term, especially for a population like CMV drivers that is highly at-risk for OSA.** This is because long-term cost savings are highly

dependent on the cost of missed cases. Only one study has investigated this relationship, and it was based on a definition of OSA that includes Epworth scores as well in addition to AHI.

There is strong evidence that home-based PSG is more cost-efficient related to immediate short-term costs than lab-based PSG. Home-based PSG appears to cost 65-75% of lab-based PSG. However, one study suggests that lab-based monitoring may be more cost effective in the long-term, especially among audiences likely to have moderate to severe OSA. Additional research is required to investigate this topic.

Research Question 4

Question 4 asks: What is the cost and effectiveness of current treatment options for individuals diagnosed with OSA?

Evidence Base for Question 4

The evidence base for Question 4 consists of n=40 studies, as shown in Figure 4.

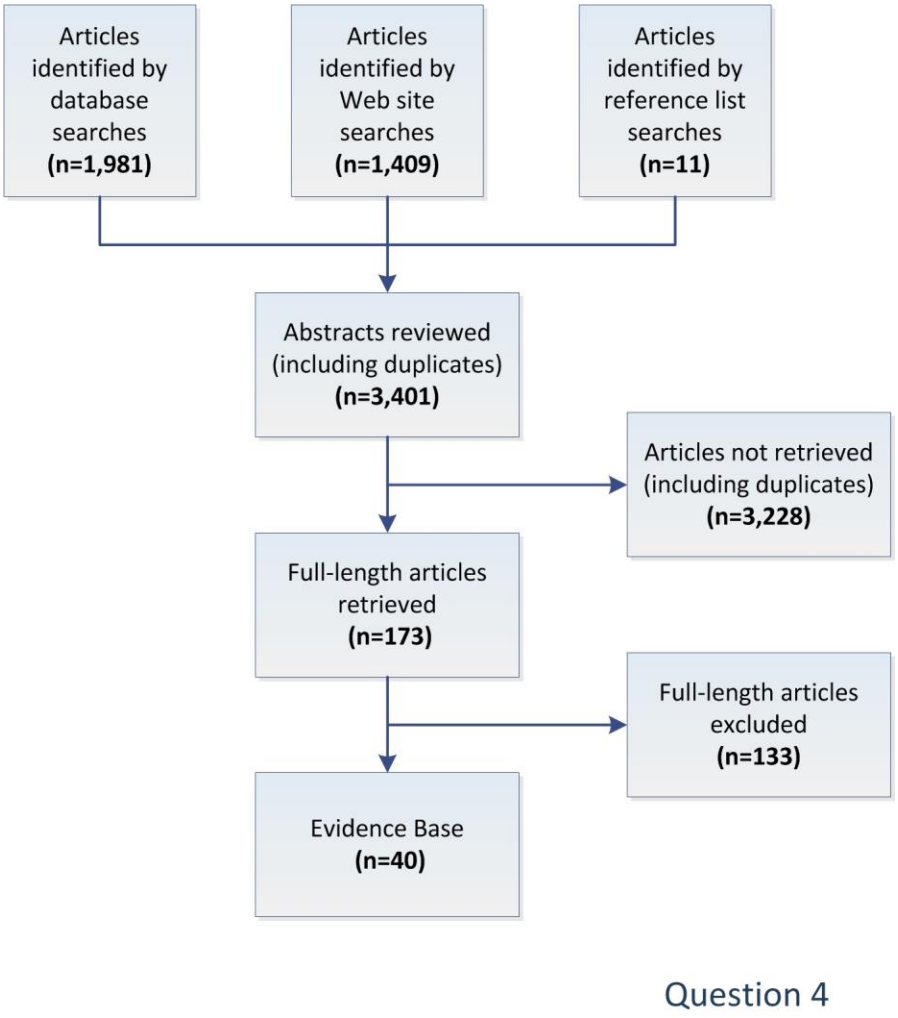
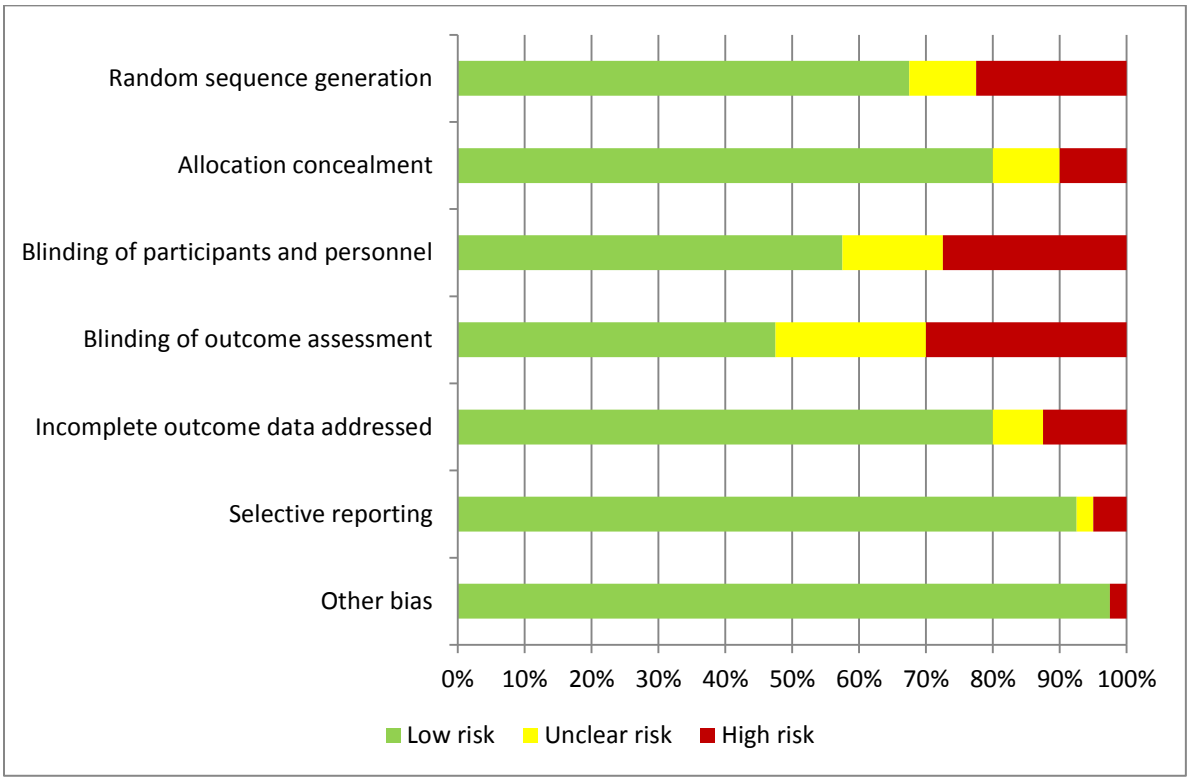


Figure 5: Evidence base, Question 4

Quality of Included Studies

Each identified item was ranked for quality using the categories described in the research methodology section. The ratings for the original research articles are presented in Table 20. The studies are of acceptable quality.

Table 20: Study Quality for Q4 Research Articles



Summaries of Included Studies and Findings from Meta-Analysis

Original research articles that address Q4 are shown in the tables below. Table 21 shows information about the study design and conclusions. Tables 22-28 shows findings from the meta-analysis. Table 29 shows findings related to financial information for the n=3 studies that included cost information.

Table 21: Study Design and Conclusions for Original Articles that Address Q4

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Blau et al. (2011) [51]	Germany, Randomized controlled trial	Air pressure	Evaluate the efficacy and compliance of ABPR-PAP compared with CPAP in OSA patients	Patients were randomized into the CPAP or the ABPR-PAP treatment group. AHI was determined using PSG before and after treatment.	n=35 (34 male; age 54.2± 11.7 years; mean BMI 30.9±5.7 kg/m^2)	ABPR-PAP is a promising new ventilation mode that enables effective treatment of OSA patients
Damiani et al. (2013) [52]	Italy, Randomized controlled study	Air pressure	Compare the titration effectiveness of two A-CPAP devices using different flow-based algorithms in patients with OSA	Each patient was observed on four different nights to assess the effects of two different A-CPAP devices. Each participant used both devices on alternating days.	n=79 (60 male, age 55.31± 10.93, BMI 35.01±5.54, neck circumference 43.35±3.51)	Two A-CPAP devices using different algorithms are equally effective in initial titration of CPAP (based on two nights' data collection)
Ebben et al. (2012) [53]	USA, Randomized controlled study	Air pressure	Compare the efficacy of three different masks, nasal pillows, nasal masks and full face (or nasal) masks, during a single night of titration with CPAP	Patients were given a PSG to assess the severity of their OSA; they were then given one of three different masks for CPAP therapy. The effectiveness of these masks was then compared.	n=55 (33 male) (nasal mask: age 58.5±14.7, BMI 31.1 ±6.6) (nasal pillows: age 57.5 ±14.9, BMI 35.6 ±7.9) (oronasal: age 51.75 ±13.5, BMI 32.10 ±6.7)	CPAP applied through either a nasal mask or nasal pillow is equally effective in treating patients with mild, moderate, and severe sleep apnea; however, oronasal masks with considerably higher final pressures were needed to treat patients with moderate and severe sleep apnea

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Farid-Moayer et al. (2013) [54]	USA, Non-randomized controlled study	Air pressure	Examine the initial-use safety and effectiveness of a noninvasive oral pressure therapy system developed to treat OSA	Participants were given a baseline PSG and then used oral pressure therapy for one night. A second PSG was done while patient were using the ORT device.	n=76 (56 mean, mean age 50.8 ± 12.0, mean BMI 32.5 ± 5.8)	While oral pressure therapy would not be appropriate for treating all patients, a subset of strong responders can be identified with PSG; evaluation can be safely and rapidly performed without the need to customize equipment or limiting options
Kushida et al. (2011) [55]	USA and Germany, Randomized, double-blinded, 3-arm, multicenter trial	Air pressure	Determine the efficacy of APAP with a comfort feature (A-Flex) in participants with moderate to severe OSA and determine the relative difference between APAP with A-Flex, CPAP, and CPAP/APAP on long-term changes in functional outcomes	All patients were given a PSG at the start of the study to establish a baseline. Patients were then randomized and given one of the three treatment options. Follow-up was conducted after a week, 2 weeks, 1 month, 3 months, and 6 months to assess the efficiency of the treatment and patient adherence.	n=164 (A-flex: mean age 49.1 ± 11.6, 75.9% male, mean BMI 33.0 ± 6.60, mean neck circumference 16.5 ± 1.7in; CPAPapap: mean age 48.3 ± 10.0, 75.5% male, mean BMI 35.6 ± 8.3, neck 17.1 ± 3.9; CPAP: mean age 48.8 ± 12.0, 75.4% male, mean BMI 34.9 ± 8.0, neck 16.6 ± 2.3in)	Indices of sleep disordered breathing were significantly worse for A-Flex compared to CPAP at baseline; however, after 180 days, there were no significant differences between A-Flex and CPAP on these measures

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Pietzsch et al. (2011) [35]	USA, Markov model	Air pressure	Evaluate the cost-effectiveness of three commonly used diagnostic strategies (full-night PSG, split-night PSG, unattended portable home-monitoring) in conjunction with CPAP therapy in patients with moderate-to-severe OSA	Baseline computations were performed for a hypothetical average cohort of 50-year-old males with a 50% pretest probability of having moderate-to-severe OSA (AHI≥ 15 events per hour). A Markov model was created to compare cost and effectiveness of different diagnostic and therapeutic strategies over a ten year interval and the expected lifetime of the patient.	Based on a model of 50 year old male; 50% pretest probability of OSA	CPAP therapy increases life expectancy and quality-adjusted life expectancy, and reduces the rate of fatal and non-fatal motor vehicle collision, myocardial infarction, and stroke; CPAP therapy is cost-effective for men and women at all ages considered (30-70 years) who have already been diagnosed with moderate-to-severe OSA, and is a good value
Ryan et al. (2011) [56]	Ireland, Randomized crossover study	Air pressure	Investigate the benefits and effectiveness of nasal pillow devices	Subjects were assigned to a four-week period of nasal pillows and a nasal mask in a randomized, crossover design. Each patient underwent in-lab CPAP auto titration and, following review of the study, CPAP treatment was prescribed. After four and eight weeks patients were evaluated for side effects and compliance.	n=21 (19 males; age 49 ± 10 years)	Nasal pillows are equally effective in CPAP therapy, but do not generally lead to improved compliance

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Stuck et al. (2012) [57]	Germany, Retrospective cohort study	Air pressure	Investigate the effectiveness of CPAP with regard to the reduction of AHI	The electronic database of a hospital sleep center was analyzed for regular follow-up visits of patients receiving CPAP (regular or automatic) for OSA. The following information was extracted: AHI at diagnosis, AHI with CPAP, duration of therapy, hours of CPAP use, and subjective hours of sleep.	n=82 (mean age 61.7± 11 years; 19 females, 63 males)	CPAP cannot eliminate respiratory events due to limited adherence; adherence needs to be taken into account when comparing the effects of CPAP with alternative treatment, especially those with 100% adherence (e.g., surgery)
Tarasiuk et al. (2012) [58]	Israel, Longitudinal interventional study	Air pressure	Identify whether financial incentives have a role in OSA patients' decisions to purchase a CPAP device in a healthcare system that requires cost sharing	Patients completed a variety of questionnaires. A survey was conducted one year following CPAP treatment initiation: self-reported CPAP use, Epworth score, CPAP side effects score, reasons for using or declining CPAP, and social support. Patients in the control group were required to pay the full co-payment for the CPAP treatment ($330-660). The financial incentive group was offered CPAP at a subsidized cost ($55). In cases where auto-titrating CPAP was purchased, patients were required to pay the difference.	n=258 (control group: 50.9±10.3 years, AHI 39.9±22; financially incentivized group: n=137, 50.8±10.6 years, AHI 38.7±19.9)	Cost sharing increases CPAP acceptance and reduces a major barrier among low income patients

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Tomfohr et al. (2011) [59]	USA, Randomized controlled trial	Air pressure	Investigate the effect of CPAP therapy on fatigue and energy in patients diagnosed with OSA	Men and women with OSA were randomly assigned to therapeutic or placebo CPAP in a double-blind fashion for a 3-week intervention period. Four outcome measures were assessed: (1) fatigue/vigor measured with the Multidimensional Fatigue Symptom Inventory—Short Form, the (2) fatigue and (3) vigor subscales of the Profile of Mood States—Short Form, and (4) the Epworth Sleepiness Scale.	n=59 (BMI range 20-50 kg/m^2; age range 29-50 years)	Three weeks of therapeutic CPAP significantly reduced fatigue and increased energy in patients with OSA
Walsh et al. (2011) [60]	USA, Prospective cohort study	Air pressure	Evaluate tolerability, efficacy, and short-term adherence of expiratory-PAP device in a sample of OSA patients who have either refused or reported minimal adherence with CPAP treatment	Patients were single-blindedly supplied with home EPAP devices having two different expiratory resistances. Patients recorded hours of device use and sleep duration. Patients meeting a criterion for device use of at least 70% of sleep time underwent a screening/baseline PSG (PSG1) without EPAP to obtain baseline data. Patients underwent a second PSG (PSG2) within 10 days to assess initial efficacy. Patients meeting efficacy criteria continued using EPAP for 5–6 weeks until PSG3. Epworth and Functional Outcomes of Sleep Questionnaire were administered at the end.	n=59	Improvements in AHI and ESS, combined with the high degree of treatment adherence, suggest that EPAP may be a useful addition to current therapeutic options

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Weaver et al. (2012) [61]	USA, Randomized double-blind clinical trial	Air pressure	Evaluate the efficacy of CPAP to improve the functional status in sleepy patients with mild and moderate OSA	Diagnostic and CPAP titration PSGs were performed. Participants were then randomized to eight weeks of either active or sham CPAP. Participants completed the assessment battery again after 8 weeks of intervention, and were informed of their assigned intervention. Those assigned to sham were crossed over to the active study protocol.	n=239 (active group: age 49.5 ± 10.9, 54.5% male, BMI 33.2 ± 6.3, weight 212.9 ± 44.3, AHI 12.8 ± 6.4, ESS 15.21 ± 3.37; placebo group: age 51.7 ± 11.9; 62.7% male; BMI 34.2 ± 7.8, weight 223.5 ± 22.2, AHI 12.5 ± 6.5, ESS 14.66 ± 3.05)	Sleepy patients with mild and moderately severe OSA had greater functional improvement after eight weeks of CPAP therapy compared with sham CPAP; it remains unclear whether those with milder OSA who do not report daytime sleepiness would experience similar benefits
Diaferia et al. (2013) [62]	Brazil, Randomized controlled trial	Air pressure, Behavior modification	Assess the effect of speech therapy alone or combined with CPAP on quality of life in patients with OSA using three different questionnaires	Men with OSA were randomly allocated to four treatment groups: sham speech therapy; speech therapy; CPAP; and CPAP plus speech therapy. All patients were treated for three months. Participants were assessed before and after treatment and after three weeks of a washout period using Functional Outcomes of Sleep Questionnaire, World Health Organization Quality of Life, and Medical Outcomes Study 36-Item Short-Form Health Survey. Additional testing measures included Epworth, PSG, and speech therapy assessment.	n=100 (males age 48.1 ± 11.2, BMI 27.4 ± 4.9 kg/m2, ESS 12.7 ± 3.0, AHI 30.9 ± 20.6)	Speech therapy alone as well as in association with CPAP might be an alternative treatment for the improvement of quality of life in patients with OSA

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Chai-Coetzer et al. (2013) [63]	Australia, Randomized, controlled, non-inferiority study	Air pressure, Behavior modification, Dental appliance, Medication, Surgery	Compare clinical efficacy and within-trial costs of a simplified model of diagnosis and care for OSA	Patients were randomized to receive treatment through either their primary care physician or a sleep center. Physicians were given training on various aspects of CPAP therapy. Follow up on both branches of the study was used to calculate efficiency and cost. Multiple imputation was used to generate missing data.	n=155 (primary care: 81 participants, 69 males, mean BMI 33.1, mean age 57.2, mean waist circumference 111.2 cm) (sleep center: 74 patients, 57 male, mean age 54.5, mean BMI 33.7, waist 113.1 cm)	Clinically significant improvements in daytime sleepiness were observed following treatment in both settings; outcomes for patients managed in primary care were not inferior to those treated in a specialist center; no differences were found in secondary outcomes
Aarab et al. (2011a) [64]	Netherlands, Randomized, placebo-controlled trial	Air pressure, Dental appliance	Compare the treatment effects of a titrated mandibular advancement device with those of nasal-CPAP and an intraoral placebo device	Participants were randomized into three different groups. Each participant then received a baseline PSG. They were then given an objectively titrated Mandibular Advancement Device, nCPAP, or a placebo device. They were given a second PSG after 6 months to establish the efficiency of each device.	n=57 (MAD group: n=20, mean age 50.3, 16 males, mean BMI 27.1, mean neck circumference 41.7; nCPAP: n=18, mean age 55.4, 12 males, mean BMI 30.7, neck 43.6; placebo n=19, mean age 51.3, 14 males, mean BMI 31.1, neck 42.6)	Found no significant difference between mandibular advancement device and nCPAP in the improvement of AHI

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Aarab et al. (2011b) [65]	Netherlands, Non-randomized controlled study	Air pressure, Dental appliance	Compare treatment aspects between mandibular advancement device and nasal CPAP in a 1-year follow-up	Participants were randomly assigned to two parallel groups: Mandibular Advancement Device and nCPAP. Four PSG recordings were obtained: one before treatment, one for the short-term evaluation, and two recordings 6 and 12 months after the short-term evaluation. Excessive daytime sleepiness was also evaluated.	n=71 (mild-moderate OSA patients on MAD or nCPAP: n=43, 52.2 ± 9.6 years; patients who completed follow up: n=28)	The absence of significant long-term differences in EDS improvements between the mandibular advancement device and the nCPAP groups with mild/moderate OSA may indicate that the larger improvements in AHI values in the nCPAP group are not clinically relevant; moreover, nCPAP patients may show more problems in accepting their treatment
Phillips et al. (2013) [66]	Australia, Randomized crossover open label study	Air pressure, Dental appliance	Compare health effects after one month of optimal CPAP and mandibular advancement device therapy in OSA	Treatment efficacy was established by PSG at the end of each treatment period under intention-to-treat conditions with devise use under patient control. Patients were randomized to both treatment acclimatization and treatment arm orders, resulting in four randomized sequences. Outcomes were assessed on three occasions: at baseline and at the end of each 1-month treatment. After completing trial but before knowledge of their results, patients reported their treatment preference (CPAP, Mandibular Advancement Device, either, or neither).	n=126 (n=23 mild OSA, n=69 moderate OSA, n=34 severe OSA; n=102 male; age 49.5 ± 11.2; BMI 29.5 ± 5.5; neck circumference 40.5 ± 3.8; AHI 25.6 ± 12.3)	Important health outcomes were similar after one month of mandibular advancement device and CPAP treatment in patients with moderate-severe OSA; the results may be explained by greater efficacy of CPAP being offset by inferior compliance relative, resulting in similar effectiveness

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Sufioglu et al. (2012) [67]	Turkey, Prospective case series	Air pressure, Surgery	Investigate the effects of surgical intervention for nasal pathologies on OSA and CPAP titrations in patients with OSA	Patients received an initial assessment and PSG. Patients with >50% nasal obstruction received surgery; all patients received CPAP.	n=31 (26 males, mean age 53 ± 9.6, mean BMI 30.3 ± 4.1)	AHI and mean oxygen saturation values did not significantly improve, but subjective complaints were improved after nasal surgery alone; surgery should not be offered as the primary treatment for OSA
Kline et al. (2012) [68]	USA, Retrospective analysis of a randomized controlled trial	Behavior modification	Explore the utility of exercise training for improving daytime functioning in adults with OSA	Patients were randomized to 12 weeks of moderate-intensity aerobic and resistance exercise training or low-intensity stretching control treatment. Sleepiness, functional impairment due to sleepiness, depressive symptoms, mood, and quality of life were evaluated with validated questionnaires, and cognitive function was assessed with a neurobehavioral performance battery. OSA severity was measured with one night of laboratory PSG before and after the intervention.	n=43	Exercise training may be helpful for improving aspects of daytime functioning of adults with OSA
Dungan et al. (2011) [69]	Australia, Randomized crossover trial	Dental appliance	Study the acute effect of SensAwake CPAP modality (reducing pressure on awakenings) on wake after sleep onset and other PSG measures in patients with OSA	Trial comparing an AutoCPAP with and without SensAwake on sleep architecture. CPAP naïve patients received each therapy for a single night in the laboratory with at least 1-week washout. Both patients' and technicians' subjective satisfaction was assessed. Pressure data measured and stored by the device were also analyzed.	n=42	SensAwake provides similar control of AHI to standard AutoCPAP but does so at lower mean pressures; however, no measure of sleep architecture was significantly improved by the SensAwake mode during this initial acute exposure

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Giannasi et al. (2013) [70]	Brazil, Prospective cohort study	Dental appliance	Validate the use of a mandibular repositioner appliance to treat OSA and primary snoring, comparing PSG and Epworth score data prior to and during treatment	Patients with different degrees of OSA severity or primary snoring were fitted to mandibular advancement splint (PM Positioner). Diagnosis was established by a PSG prior to treatment and after 6 months to verify the efficacy of therapy. Epworth scores were taken before and after treatment.	n=63 (mean age 48 ± 11, BMI 26.7 ± 3.6, neck circumference cm 40.6 ± 3)	The findings validate the efficacy of the adjustable PM positioner for the safe treatment of OSA
Lee et al. (2013) [71]	South Korea, Retrospective cohort study	Dental appliance	Compare the efficacy and compliance between mono-bloc and bi-bloc mandibular advancement devices in the treatment of OSA	Response to mandibular advancement device treatment was defined as AHI decreased by more than 50% from baseline. Patients were considered to be compliant if they used the device more than 4 hours/day for five or more days/week. Both mono-bloc and bi-bloc devices were designed to hold the mandible fixed at 60% of maximal protrusion. Follow-up PSG with MAD was performed within 3 months of use, and compliance of use was evaluated after 1 year.	n=153 consecutive visiting patients (treated with mono-bloc MAD: n=43 mild to moderate, n=50 severe, 83 male, age 50.6 ± 10.9; BMI 25.6 ± 2.9; baseline AHI without MAD 34.7 ± 14.7; Bi-bloc group: n=27 mild to moderate, n=33 severe, 55 male, age 51.8 ± 10.7, BMI 25.0 ± 2.3; baseline AHI 30.9 ± 15.3)	Although the mono-bloc mandibular advancement device was superior to the bi-bloc mandibular advancement device in efficacy, the bi-bloc device was superior in compliance; thus, efficacy and compliance should be considered at the same time for OSA patients

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Lettieri et al. (2011) [72]	USA, Retrospective cohort study	Dental appliance	Compare the efficacy of adjustable and fixed oral appliances for the treatment of OSA	Patients received education on OSA, therapy, and proper use of the device. After receiving the device, patients conducted an at-home adjustment prior to titration PSG. Patients maintained a comprehensive sleep diary. Optimal mandibular advancement was determined based on highest level of subjective sleep quality. Successful treatment was defined as a decrease in the AHI to < 5 events/hour. Failures were defined as intolerance to the device or incomplete resolution of events. Reduction of AHI to < 10 with Epworth < 10 served as a secondary endpoint.	n=805 patients (treated with an adjustable oral appliance: n=602, 86.4% male, age 41.3 ± 9.0, BMI 28.7 ± 4.4, ESS score 13.2 ± 5.1, Mallampati score 2.9 ± 0.9, AHI 29.7 ± 24.1, 30.9% mild OSA, 28.2% moderate, and 40.9% severe; treated with a fixed oral appliance: n=203, 86.0% male, age 42.9 ± 9.6, BMI 29.3 ± 4.7; ESS 14.3 ± 4.5; Mallampati 3.1 ± 0.9; AHI 30.1 ± 24.4, 35.1% mild OSA, 30.2% moderate, and 34.7% severe)	Adjustable appliances are superior to fixed in their ability to reduce AHI; although fixed devices were frequently successful in patients with mild disease, adjustable devices performed better across all severities of OSA

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Ma et al. (2013) [73]	Australia, Prospective cohort study	Dental appliance	Determine whether resting masticatory muscle activity influences the response to mandibular advancement splint treatment in patients with OSA	Baseline electromyographic activities of the right anterior and posterior temporalis, masseter, and submandibular muscles were recorded with surface electrodes while the patients were awake, in the upright and supine positions, with the jaw in the postural position, and with and without a mandibular advancement splint. Muscle activity of the patients with OSA was compared between responders (AHI change>50%, and AHI<10) and non-responders (AHI change<50%).	n=38 (68% male, age 52.55 ± 10.7, BMI kg/m² 27.73 ± 4.36, neck circumference 39.63 ± 3.98)	Inherent baseline differences in muscle activity between responders and non-responders were observed; there might be a correlation between responsiveness with mandibular advancement splint treatment and baseline muscle activity
Milano et al. (2013) [74]	Italy, Non-randomized controlled study	Dental appliance	Assess the impact of mandibular advancing device therapy in patients with OSA	All patients received a PSG at the start of the study. They were then given an oral device and instructions on usage and management. Interviews were conducted after 1 week, 1 month, and 3 months. After 6 months, patients were given a second PSG to assess the effect of the device.	n=42 (38 males, mean age 53.2 ± 11.1)	The efficacy of Somnodent® (an oral device) was demonstrated at reducing AHI

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Sutherland et al. (2011) [75]	Australia, Cohort study	Dental appliance	Assess and compare the effects of mandibular advancement splint and tongue stabilizing device appliances on upper airway structure	Patients were provided with a mandibular advancement device. Magnetic resonance imaging (MRI) was performed while patients were awake, supine, and positioned with the Frankfort plane perpendicular to horizontal. Scans of each patient were acquired with and without each of the appliances. Contiguous T1-weighted spin-echo images were acquired through the mid-siggital plane and axial plane. MRI data were assessed by the segmentation of upper airway lumen and soft tissue structures and identification of cephalometric landmarks. All patients underwent PSG to determine treatment outcome.	n=39 patients (64% male, age 50 ± 10.7, BMI 29.2 ± 5.5, neck circumference 39.3 ± 4.2)	Results indicate that both mandibular advancement splint and tongue stabilizing device increase upper airway dimensions but that there are differences in their effects on upper airway structure; tongue stabilizing device had a greater effect on upper airway size
Tihacek-Sojic et al. (2012) [76]	Serbia, Non-randomized controlled study	Dental appliance, Medication	Examine the effectiveness of mild or moderate OSA treatment with mandibular advance oral appliance in older lorazepam users compared with the age-matched lorazepam-free patients	Patients were separated into a control group (not using lorazepam) and an experimental group (using lorazepam).Patients then received an initial assessment and a custom mandibular device was made for each patient. Patients then completed subjective assessment forms every 3 months for a year and were given a PSG at the end of treatment.	n=40 (23 male, all not overweight, mean age 69)	Mandibular advancement oral appliances are capable of complete control of the OSA in one third of cases; in patients using lorazepam, mild and moderate OSA can be successfully and safely controlled with oral appliances

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Sukys-Claudino et al. (2012) [77]	Brazil, Randomized, double-blind, placebo-controlled study	Medication	Evaluate the effects of donepezil on OSA in non-Alzheimer's disease patients	Patients were submitted to a one-night PSG for habituation, and again for baseline, prior to beginning treatment. Donepezil and placebo were administered in a single dose at bedtime, with one tablet/day (5mg) for the first two weeks, and two tablets/day (10mg) for the last two weeks. A second PSG was recorded after the one month treatment period.	n=21 males (35-65 years of age, BMI < 35 kg/m2, neck circumference placebo group 40.5 ± 3.0, neck circumference donepezil group 40.7 ± 2.1)	Donepezil treatment improved OSA index, oxygen saturation, and sleepiness in parallel with a reduction in sleep efficiency; findings support the concept that cholinergic transmission may influence breathing regulation in OSA patients
Balsevičius et al. (2013) [78]	Lithuania, Randomized controlled trial	Surgery	Assess the efficacy of radiofrequency treatment of the soft palate and combined radiofrequency-assisted uvulopalatoplasty in the treatment of snoring and mild to moderate OSA	Patients underwent upper airway exam and a baseline PSG. They also completed a clinical test battery twice: at baseline and 2-3 months after treatment. Patients were randomized into two groups. Group I underwent two sessions of radio frequency treatment of the soft palate. Group II underwent 2 sessions of radio frequency treatment and radiofrequency-assisted uvulopalatoplasty. Final exam was carried out 2-3 months after completed treatment.	n=32 patients (RFT group: age 42.96 ± 10.43, BMI 30.18 ± 2.08, AHI 8.94 ± 6.76, ESS 8.23 ± 3.66; RF-UPP group: age 46.0 ± 5.75, BMI 28.84 ± 4.68, AHI 12.51 ± 7.66, ESS 9.37 ± 2.99)	Combined radio frequency treatment and radiofrequency-assisted uvulopalatoplasty was effective in the treatment of mild to moderate OSA, outperforming radio frequency treatment alone

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Browaldh et al. (2013) [79]	Sweden, Prospective controlled trial with two parallel arms and stratified randomization	Surgery	Assess the 6-month efficacy of uvulopalato-pharyngoplasty compared with expectancy in selected patients with OSA	Patients were randomized to receive either UPPP within 1 month or no treatment at all for 7 months. After the second evaluation with PSG the patients in the control group also had surgical treatment. All patients were instructed to maintain their weight, to avoid new medicines, and were restricted from other treatments during the study.	n=65 (intervention group: mean age 41.5, mean BMI 28.2, mean tonsil size 2.5; control: mean age 42.9, mean BMI 27.7, mean tonsil size 2.3)	Greater mean reduction of AHI in the uvulopalato-pharyngoplasty group compared with controls; furthermore UPPP significantly reduced the mean AHI after 6 months in the intervention group by 60% compared with 11% in the control group
Choi et al. (2011a) [80]	Korea, Prospective cohort study	Surgery	Investigate the clinical efficacy of single-staged modified uvulopalato-pharyngoplasty with nasal surgery and the relationship between surgical outcomes and an anatomy-based staging system in patients with OSA with nasal obstruction	The investigators compared subjective symptoms and PSG data before and after surgery and investigated objective surgical outcomes according to the anatomy-based (Friedman) staging system and postoperative complications.	n=41 (all males; mean age 40.1 ± 7.3)	Single-staged modified uvulopalato-pharyngoplasty with nasal surgery is a relatively safe surgical approach in OSA patients with nasal obstruction; to achieve the best possible surgical outcomes, it is important to select appropriate patients using the anatomy-based staging system

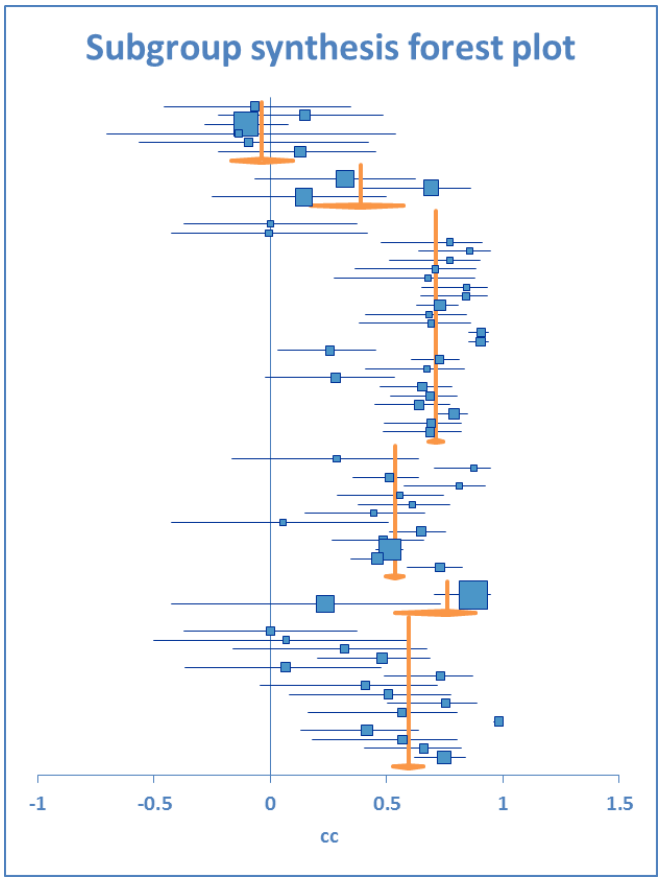
Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Choi et al. (2011b) [81]	Korea, Prospective cohort study	Surgery	Investigate the efficacy of nasal surgery on sleep quality, architecture, and position, as measured by PSG in patients with OSA and nasal obstruction	All participants underwent a standard PSG evaluation. All participants with OSA and nasal obstruction were treated with nasal surgery. Comparisons between pre-op and post-op variables were conducted.	n=22 (consecutive male patients; mean age 41.3 ± 10.9 years)	Nasal surgery alone was partially effective in improving sleep quality, architecture, and snoring, but it had no effect on the change of the distribution of sleep positions and OSA in patients with OSA and nasal obstruction
Eastwood et al. (2011) [82]	Australia, Single-arm, open-label study	Surgery	Examine safety and efficacy of a novel Hypoglossal Nerve Stimulation	Consenting patients underwent surgical implantation of a HGNS system. Therapy was initiated at approximately 30 days post-implant. Daytime and overnight studies were used to determine the stimulation settings considered effective. Sleep studies were repeated at 1, 3, and 6 months after implant.	n=21 (14 male, age 53.6 ± 9.2, BMI 32.7± 3.6, waist circumference 107.5±11.9, neck circumference 41.4±4.9)	Treatment of OSA with implantable HGNS system is a safe and effective way to treat individuals with moderate to severe OSA; when assessed at 3 and 6 months post-implant, there were decreases in the severity of OSA and daytime sleepiness; therapy usage was high
Friedman et al. (2012) [83]	USA, Retrospective analysis of a cohort study	Surgery	Assess the feasibility of performing robotically assisted partial glossectomy without tracheotomy and assess efficacy by comparing outcomes with those of established techniques	Patients underwent transoral robotic surgery. Data from patients who underwent concomitant z-palatoplasty with 6-month follow-up were compared with those of two matched cohorts of patients who underwent either radiofrequency base-of-tongue reduction or submucosal minimally invasive lingual excision reduction of the tongue base and z-palatoplasty.	n=40	Robotically assisted partial glossectomy can be performed without the need for tracheotomy; this technique resulted in greater AHI reduction but increased morbidity compared with the other techniques studied

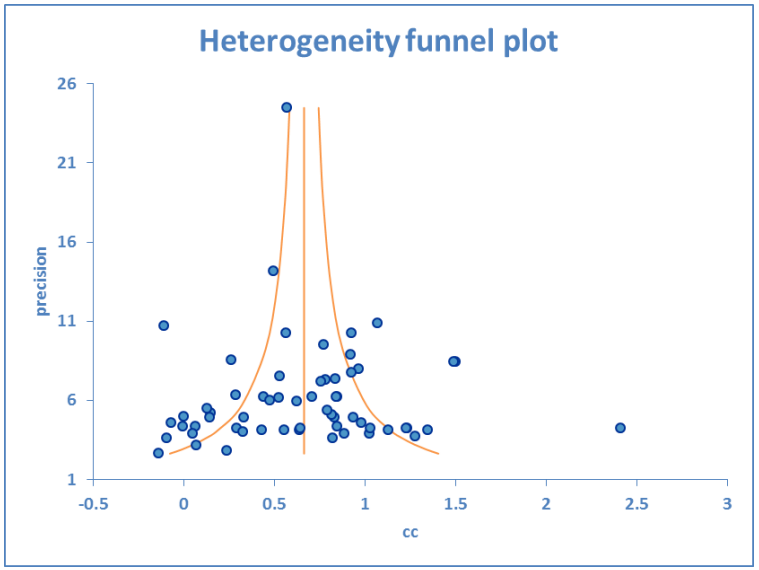
Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Hou et al. (2012) [84]	China, Prospective non-randomized case control study	Surgery	Determine the safety and efficacy of tongue coblation via the ventral approach in the treatment of hypopharyngeal obstruction for patients with OSA	Tongue coblation was performed under local anesthesia in patients diagnosed with OSA with predominant hypopharyngeal obstruction after failed uvulopalatopharyngoplasty. In the ventral approach, only one puncture point was applied at the center of lingual frenulum, and 12 radiofrequency volumetric tissue reduction lesions were implanted in the tongue. In the dorsal approach, eight RFVTR lesions were distributed on the tongue. Using portable PSG and the Epworth scale, followed patients for one year after operation. Good outcome defined as AHI <20 or reduction >50%.	n=40	Tongue coblation via the ventral approach is an effective and safe technique to treat hypopharyngeal obstruction in OSAHS surgery
Komada et al. (2012) [85]	USA, Prospective cohort study	Surgery	Evaluate objective and subjective improvement after applying a surgical technique, two-piece palatopharyngoplasty, to the treatment of OSA	PSG was performed and Epworth score was determined before and three months after surgery. Patients then underwent Two-P4 surgery. Some patients underwent 3D–CT from skull base to larynx before and 3 months after surgery.	n=24 (patients with mild to moderate OSA, 23 males, mean age 40.8 ±13.6, mean BMI 27.4± 4.0)	The success rate for Two-P4 is very high; some patients show an almost 50% reduction in AHI after surgery

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Lee et al. (2012) [86]	USA, Non-randomized controlled study	Surgery	Assess the use of transoral robot-assisted lingual tonsillectomy and uvulopalato-pharyngoplasty for the surgical management of tongue base obstruction in patients with OSA	Patients were brought in for an initial assessment and PSG. Patients then received a Robot-Assisted Lingual Tonsillectomy and Uvulopalatopharyngoplasty. Three months after the surgery researchers followed up with these patients.	n=20 (70% male, mean age 45.7 years, mean BMI 32.6)	Transoral robot-assisted lingual tonsillectomy with uvulopalato-pharyngoplasty can be used to achieve a significant reduction in AHI, a significant improvement in minimum arterial oxygen saturation, and a significant improvement in daytime somnolence as measured by Epworth
Li & Shi (2013) [87]	China, Prospective cohort study	Surgery	Evaluate the efficacy and safety profile of midline partial glossectomy guided by lingual artery computed tomographic angiography for the treatment of OSA due to tongue hypertrophy	Patients underwent uvulopalatopharyngoplasty in combination with midline partial glossectomy. The operation zone was determined according to the anatomic measurement obtained from lingual artery computed tomographic angiography and the resected region was much larger than with conventional midline partial glossectomy. Postoperative complications were closely monitored and sleep condition was followed up for more than six months and re-evaluated by PSG.	n=67 (all males; mean age 38, mean BMI 28.9)	Midline partial glossectomy guided by lingual artery computed tomographic angiography demonstrated a satisfactory safety profile and therapeutic effect for patients with OSA due to tongue hypertrophy

Author (Year)	Location and Design of Study	Intervention Type	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Mora et al. (2012) [88]	Italy, Non-randomized controlled study	Surgery	Verify the efficacy and applicability of uvulopalato-pharyngoplasty with harmonic scalpel in the treatment of patients affected by OSA and users of CPAP	All participants underwent an initial PSG. Patients then underwent uvulopalatopharyngoplasty with harmonic scalpel. Patients were reevaluated after 6 months.	n=21 (14 males, median age 47, median BMI 31)	Significant improvement of AHI observed 6 months after the surgical treatment; when compared with preoperative values, surgery did improve some important outcomes (ODI4, ESS, SL)
Ugur et al. (2013) [89]	Turkey, Prospective cohort study	Surgery	Evaluate the long-term efficacy anterior palatoplasty technique in treatment of patients with mild to moderate OSA	Patients were evaluated with one night PSG before the surgery and 24 months after surgery. All patients underwent otorhinolaryngological physical examination, flexible nasopharyngolaryngoscopy. Patients completed Epworth scale and snoring visual analog scale before and 24 months after the surgery.	n=42 (mean age 39.2± 7.6)	Anterior palatoplasty is an effective, inexpensive technique for mild and moderate OSA patients

Table 22: Overall Meta-Analysis Findings for Q4





Type	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value
Control (n=6)	-0.04	-0.17	0.10	-0.54	0.59
Behavioral Mod. (n=3)	0.39	0.17	0.57	3.38	0.00
Air Pressure (n=22)	0.71	0.68	0.74	28.52	0.00
Dental (n=13)	0.54	0.50	0.57	21.49	0.00
Medication (n=2)	0.76	0.54	0.88	4.97	0.00
Surgery (n=15)	0.60	0.53	0.66	13.24	0.00

Table 23: Meta-Analysis Findings for Control Studies (Placebo, No Treatment, or Sham Treatment)

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Diaferia et al.	-0.07	-0.46	0.35	-0.30	0.76	9.86%
Tomfohr et al.	0.15	-0.22	0.48	0.78	0.44	12.68%
Weaver et al.	-0.11	-0.28	0.08	-1.14	0.25	53.99%
Sukys-Claudino et al.	-0.14	-0.71	0.54	-0.36	0.72	3.29%
Kline et al.	-0.09	-0.56	0.42	-0.34	0.74	6.10%
Browaldh et al.	0.13	-0.22	0.45	0.71	0.48	14.08%
Synthesis	**-0.04**	**-0.17**	**0.10**	**-0.54**	**0.59**	**100%**

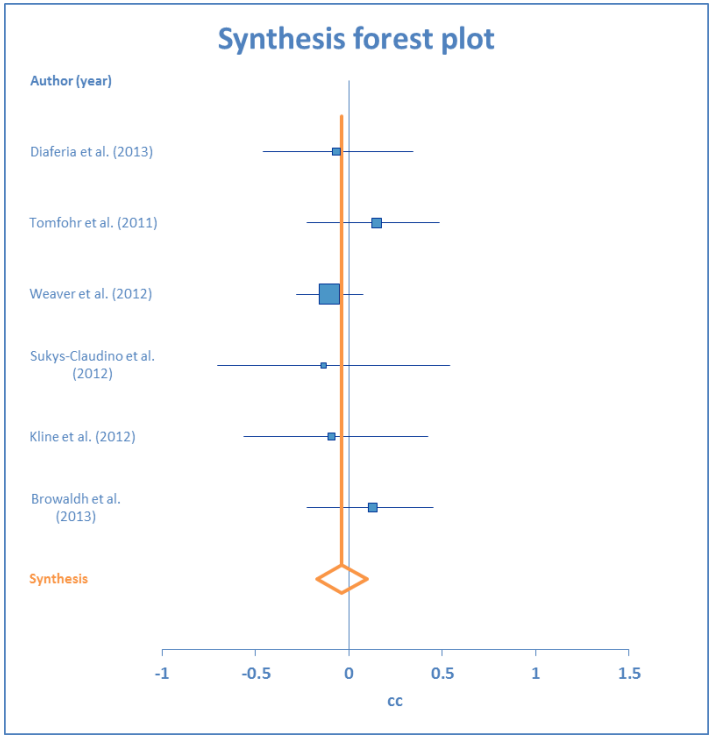


Table 24: Meta-Analysis Findings for Behavioral Interventions

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Diaferia et al.	0.32	-0.07	0.63	1.64	0.10	35.82%
Diaferia et al.	0.69	0.38	0.86	3.70	0.00	28.36%
Kline et al.	0.14	-0.25	0.50	0.71	0.48	35.82%
Synthesis	**0.39**	**0.17**	**0.57**	**3.38**	**0.00**	**100%**

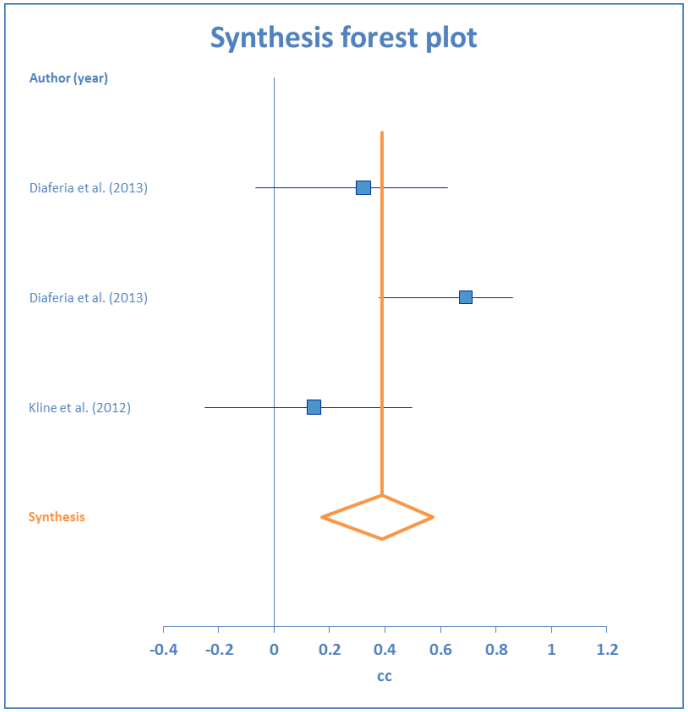


Table 25: Meta-Analysis Findings for Air Pressure Treatment

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Sufioglu et al.	0.00	-0.37	0.37	0.01	0.99	2.46%
Aarab et al.	-0.01	-0.43	0.42	-0.02	0.98	1.87%
Blau et al.	0.77	0.48	0.91	3.97	0.00	1.47%
Blau et al.	0.86	0.64	0.95	4.79	0.00	1.38%
Ebben et al.	0.77	0.51	0.90	4.37	0.00	1.77%
Ebben et al.	0.71	0.36	0.88	3.43	0.00	1.47%
Ebben et al.	0.68	0.27	0.88	2.97	0.00	1.28%
Ryan et al.	0.84	0.65	0.94	5.24	0.00	1.77%
Ryan et al.	0.84	0.64	0.93	5.21	0.00	1.77%
Phillips et al.	0.73	0.63	0.81	9.52	0.00	10.31%
Diaferia et al.	0.68	0.41	0.84	4.09	0.00	2.36%
Diaferia et al.	0.69	0.38	0.86	3.70	0.00	1.87%
Damiani et al.	0.91	0.85	0.94	12.67	0.00	6.97%
Damiani et al.	0.90	0.85	0.94	12.59	0.00	6.97%
Farid-Moayer et al.	0.26	0.03	0.46	2.24	0.03	7.17%
Stuck et al.	0.73	0.60	0.81	8.18	0.00	7.76%
Tomfohr et al.	0.67	0.41	0.83	4.17	0.00	2.55%
Walsh et al.	0.28	-0.02	0.54	1.82	0.07	3.93%
Kushida et al.	0.65	0.47	0.78	5.69	0.00	5.21%
Kushida et al.	0.69	0.52	0.80	6.18	0.00	5.30%
Kushida et al.	0.64	0.45	0.77	5.46	0.00	5.11%
Weaver et al.	0.79	0.71	0.85	11.64	0.00	11.59%
Dungan et al.	0.69	0.49	0.82	5.30	0.00	3.83%
Dungan et al.	0.69	0.49	0.82	5.27	0.00	3.83%
Synthesis	**0.71**	**0.68**	**0.74**	**28.52**	**0.00**	**100%**

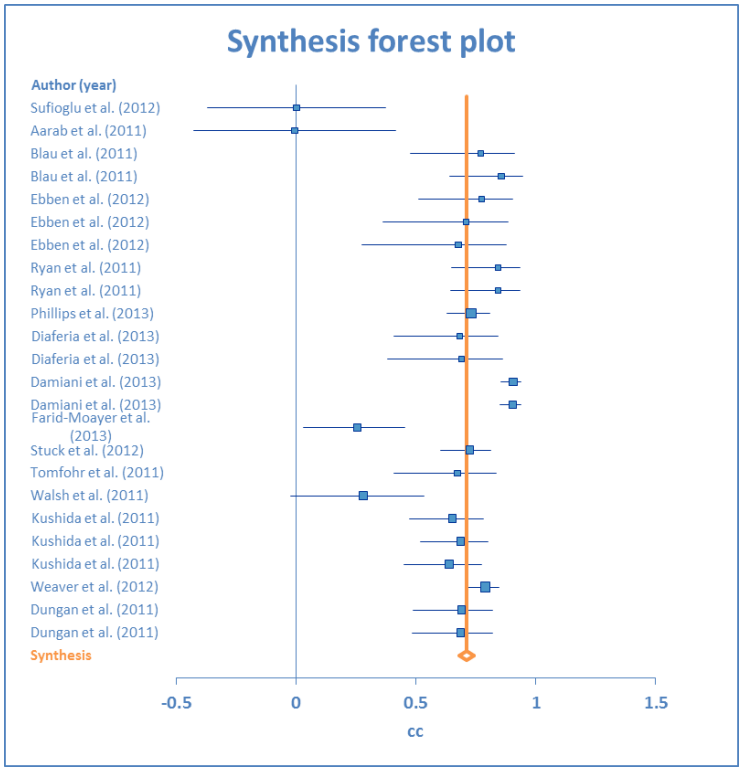


Table 26: Meta-Analysis Findings for Dental Appliances

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Aarab et al.	0.29	-0.17	0.64	1.24	0.21	1.40%
Tihacek-Sojic et al.	0.87	0.70	0.95	5.57	0.00	1.32%
Phillips et al.	0.51	0.36	0.64	5.78	0.00	8.15%
Tihacek-Sojic et al.	0.81	0.58	0.92	4.67	0.00	1.32%
Ma et al.	0.56	0.29	0.74	3.71	0.00	2.72%
Milano et al.	0.61	0.38	0.77	4.45	0.00	3.03%
Sutherland et al.	0.44	0.15	0.67	2.87	0.00	2.80%
Sutherland et al.	0.05	-0.42	0.51	0.21	0.84	1.16%
Lee et al.	0.65	0.51	0.75	7.33	0.00	6.99%
Lee et al.	0.49	0.27	0.66	4.01	0.00	4.43%
Lettieri et al.	0.52	0.45	0.57	13.95	0.00	46.51%
Lettieri et al.	0.46	0.35	0.56	7.05	0.00	15.53%
Giannasi et al.	0.73	0.59	0.83	7.20	0.00	4.66%
Synthesis	**0.54**	**0.50**	**0.57**	**21.49**	**0.00**	**100%**

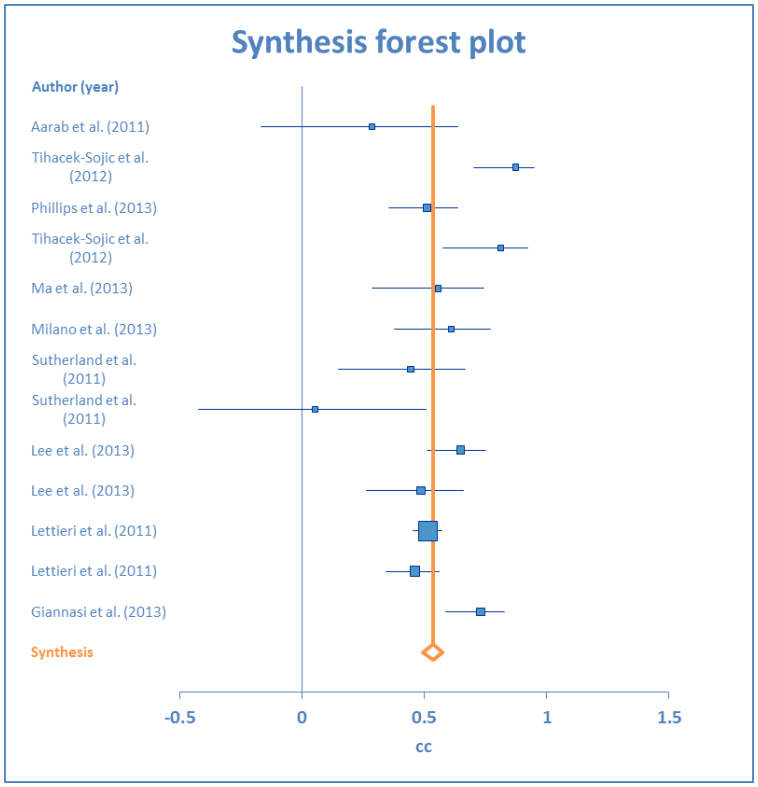


Table 27: Meta-Analysis Findings for Medication

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Tihacek-Sojic et al.	0.87	0.70	0.95	5.57	0.00	68.00%
Sukys-Claudino et al.	0.23	-0.42	0.73	0.68	0.50	32.00%
Synthesis	**0.76**	**0.54**	**0.88**	**4.97**	**0.00**	**100%**

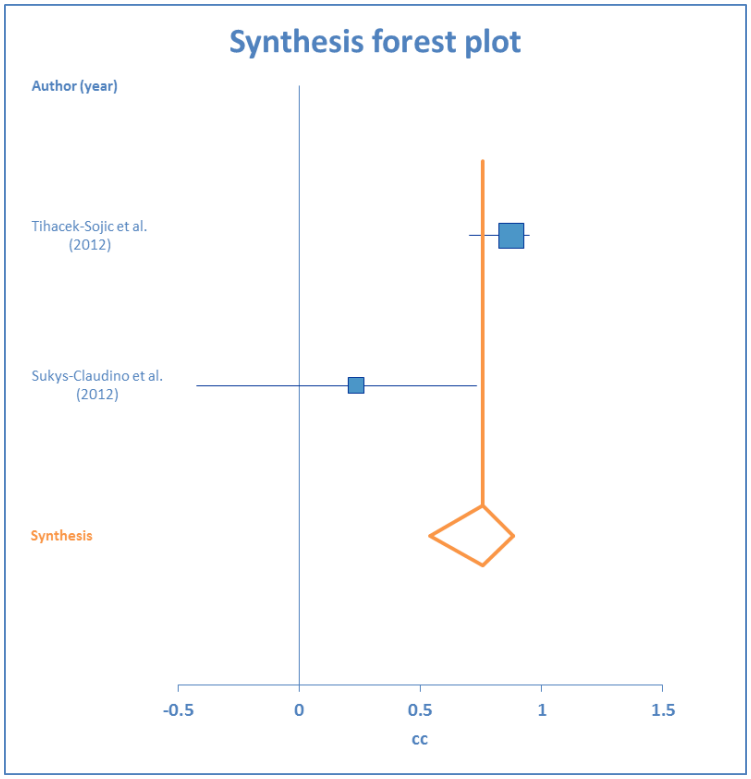


Table 28: Meta-Analysis Findings for Surgery

Author	Correlation Coefficient	Lower Limit	Upper Limit	Z-Value	P-Value	Weight
Sufioglu et al.	0.00	-0.37	0.37	0.01	0.99	6.72%
Balsevičius et al.	0.07	-0.50	0.60	0.22	0.83	2.69%
Balsevičius et al.	0.32	-0.16	0.67	1.32	0.19	4.30%
Choi et al.	0.48	0.20	0.69	3.24	0.00	10.22%
Choi et al.	0.07	-0.37	0.47	0.29	0.77	5.11%
Friedman et al.	0.73	0.49	0.87	4.58	0.00	6.45%
Hou et al.	0.41	-0.04	0.72	1.79	0.07	4.57%
Hou et al.	0.51	0.08	0.78	2.30	0.02	4.57%
Komada et al.	0.75	0.50	0.89	4.51	0.00	5.65%
Lee et al.	0.56	0.16	0.81	2.64	0.01	4.57%
Mora et al.	0.98	0.96	0.99	10.24	0.00	4.84%
Ugur et al.	0.42	0.13	0.64	2.77	0.01	10.48%
Eastwood et al.	0.57	0.18	0.80	2.73	0.01	4.84%
Browaldh et al.	0.66	0.41	0.82	4.28	0.00	7.80%
Li & Shi	0.75	0.62	0.84	7.74	0.00	17.20%
Synthesis	**0.60**	**0.53**	**0.66**	**13.24**	**0.00**	**100%**

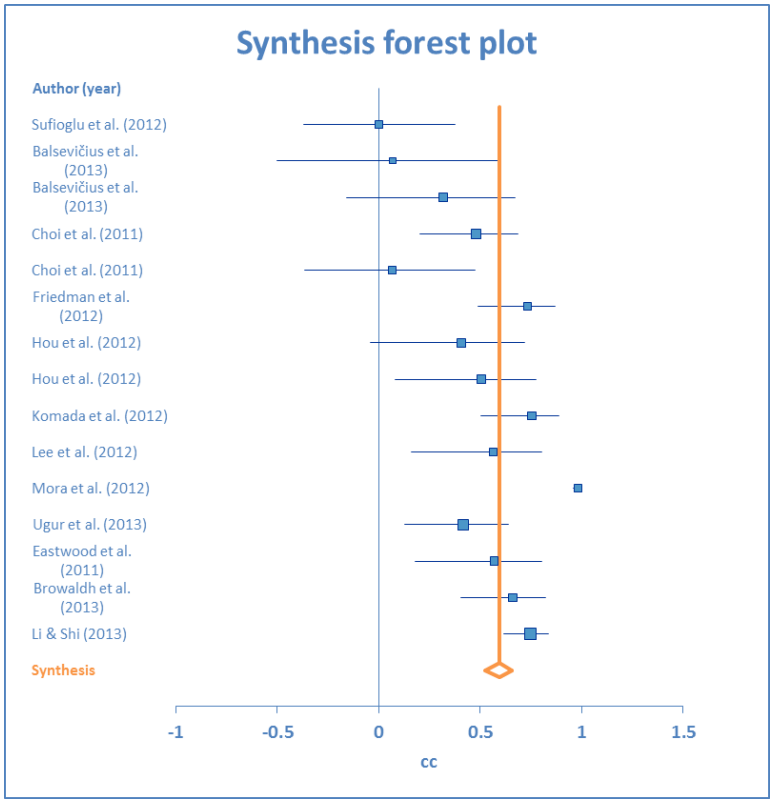


Table 29: Findings Related to Financial Information for Articles that Address Q4

Author (Year)	Conclusions	Findings Related to Cost of Treatment
Pietzsch et al. (2011) [35]	CPAP therapy increases life expectancy and quality-adjusted life expectancy, and reduces the rate of fatal and non-fatal motor vehicle collision, myocardial infarction, and stroke; CPAP therapy is cost-effective for men and women at all ages considered (30-70 years) who have already been diagnosed with moderate-to-severe OSA, and is a good value	Note: All based on modeled scenario for 50-year-old male with moderate to severe OSA; findings are in 2008 US$ 1. Incremental cost effectiveness ratio for CPAP treatment vs. no treatment: $24,222 per life year gained 2. Incremental cost effectiveness ratio for CPAP treatment vs. no treatment: $15,915 per QALY gained (quality adjusted life year, takes into account years and health of those years)
Tarasiuk et al. (2012) [58]	Cost sharing increases CPAP acceptance and reduces a major barrier among low income patients	1. CPAP acceptance rate (incentive vs. control): 47.4% vs. 33.1% (p=0.02) 2. CPAP acceptance rate among low income (incentive vs. control): 46.7% vs. 40.5% (p=0.16) 3. Regression predicting CPAP acceptance among low-income participants (significant variables controlling for age, gender, BMI, living with partner, tobacco smoking): financial incentive 3.43 (1.09–10.85), age (each additional year) 1.1 (1.03–1.17), AHI (>30) 4.87 (1.56–15.2), and family/friends having positive experience with CPAP (y/n) 4.27 (1.05–17.51)
Chai-Coetzer et al. (2013) [63]	Clinically significant improvements in daytime sleepiness (Epworth) were observed following treatment in both settings; outcomes for patients managed in primary care were not inferior to those treated in a specialist center; no differences were found in secondary outcomes; treatment consisted of PAP, mandibular splints, or conservative measures	1. Average cost of care (includes diagnostic study, physician consultation, etc.) for primary care vs. specialist: US $1,819.44 vs. US $3,067.86 (based on 2011 Medicare Physician Fees)

Findings

Findings are presented first for the meta-analysis and then for the financial information.

Meta-analysis

Pearson's r correlation was computed for each study using pre- and post- AHI levels. All correlation coefficients were standardized by converting correlation coefficients into Fisher's z scores. A meta-analysis was conducted on effect sizes across all groups. The fixed effects model indicated significant variation in effect size.

A subgroup analysis showed all intervention groups to be significantly different from the control group. These group differences are shown in a subgroup synthesis forest plot in Table 22. The horizontal axis of this plot shows the range of effect size, with the vertical axis representing a correlation of zero. Squares on the forest plot represent the effect size for each study, with the lines extending from each square representing confidence intervals. The orange horizontal lines represent the confidence interval for each subgroup, while the orange vertical lines mark the articles included in each subgroup.

Studies were categorized into six different types, representing a control group and five different categories of treatment: control (including placebo and sham studies or no treatment), behavior modifications, air pressure treatment, dental appliance, medication, and surgery. These groups appear in the subgroup synthesis forest plot from to top to bottom, respectively.

In addition, the heterogeneity funnel plot in Table 22 indicates that several studies may have other factors contributing to the reported effect size. Dissemination biases using Begg's test conducted across all studies showed no significant publication bias.

Results for each sub-group analysis are presented, followed by some overall discussion.

Table 23 shows a meta-analysis conducted only on the control group (n=6). The results from this meta-analysis showed no significant effect sizes in the included studies. Analysis of heterogeneity produced a non-significant Q statistic ($Q= 2.47$, $p > .05$). Therefore, the results indicate that effect sizes in the control group did not vary significantly across studies, and that the controls are not significantly different from an effect size of zero. A forest plot for the studies included in the control group analysis is also reported.

Table 24 shows a meta-analysis conducted on the behavioral modification group (n=3). The results showed a significant difference in effect sizes within the included studies. The correlation coefficient for Behavioral Modification studies was 0.39, $p<0.01$. The p- values for two out of the three studies included were significantly different from a correlation of zero.

Heterogeneity statistics produced a non-significant Q-statistic (Q= 5.50, p > .05). A forest plot for studies included in the Behavioral Modifications group analysis is reported.

Table 25 shows the results for the meta-analysis conducted on the air pressure group (n=22). The results showed a significant difference in effect size. The correlation coefficient for air pressure studies was 0.71, p<.01. P=values for 19 of the 22 studies were significantly different from zero. Analysis of heterogeneity produced a significant Q statistic (Q=144.03, p < .05), indicating significant variance in effect sizes. This variability among studies may be due to potential moderating variables that influence effect sizes. A forest plot for studies included in the air pressure group analysis is reported.

Table 26 shows reported results from a meta-analysis computed on the dental appliances group (n=13). Results from this analysis show a significant difference in effect size. The correlation coefficient for dental appliance studies was 0.54, p < .01. P-values for 11 of the 13 studies were significantly different from zero. Heterogeneity statistics indicated a significant Q statistic (Q= 33.80, p < .05).

Table 27 report results from a meta-analysis computed on the medication group (n=2). Results indicate a significant difference in effect size. Furthermore, one of the two studies included in this group were not significantly different from zero. The correlation coefficient for medication studies was 0.76, p < .01. Heterogeneity analysis indicated a significant Q statistic, which indicates a variation in reported effect sizes for studies included in this group analysis. However, due to the low sample size of studies included in this analysis, it is possible that the significant Q statistic could be a reflection of the small sample (Q= 6.71, p< .05). A forest plot showing reported effect sizes for the included studies is shown.

Results from a meta-analysis conducted on the surgery group are reported in Table 28. Results indicate a significant difference in effect size. However, five of the fifteen included studies produced non-significant p-values. Analysis of heterogeneity statistics returned a significant Q statistic (Q= 92.00, p < .05), indicating significant variation in effect sizes within studies included in the surgery group. A forest plot of the reported effect sizes for each study included in this analysis is shown.

The correlation coefficients for all treatment types except control were significant, indicating that all the treatments lead to some improvement in pre- to post-AHI scores. Comparisons between each intervention type are done by comparing the mean correlation coefficient for each group to the range for all other groups. The results show the air pressure treatments and medication performed the best, although medication has a wide confidence range (likely due to the small number of identified studies). Behavioral studies performed the worst, being outperformed by all other categories of treatments, although still superior to no-treatment.

	Superior to	Possibly Superior	Possibly Inferior	Inferior to
Behavioral (B)			D	AP, M, S
Air pressure (AP)	B, D, S		M	
Dental (D)		B	M, S	AP
Medication (M)	B	AP, D, S		
Surgery (S)	B	D	M	AP

Financial information related to cost of treatment

The studies included limited information related to costs, with only n=3 studies providing financial information. The few studies that were identified tended to focus on CPAP treatment, as this is one of the most common treatments for OSA.

Pietzch et al. [35] conducted a modeling study looking at a 50-year old male with moderate to severe OSA. Their finding is that CPAP therapy can be considered highly cost-effective, with an incremental cost effectiveness ratio of $15,915 per quality adjusted life year gained (this takes into account years of life and health of those years). Thus, the cost of treatment more than pays for itself in terms of improved health outcomes in addition to reduced costs related to fatal and non-fatal motor vehicle collisions. The cost/benefit of CPAP treatment in individuals with moderate to severe OSA was also found to compare favorably to accepted costs of treatment for other health conditions in the U.S.

Another study identified the role of cost-sharing in CPAP acceptance rates. Tarasiuk et al. [58] found that cost-sharing increased CPAP acceptance rates, especially among low-income individuals.

The final study looked at the effects of OSA treatment taking place in a primary care setting vs. a sleep specialist setting. The outcome measure used was changes in Epworth scores over the study period. Chai-Coetzer et al. [63] found that treatment in the primary care setting was not inferior, and, moreover, that treatment was significantly more affordable in the primary care setting. The average cost of care including diagnostic study, physician consultation, and treatment-related costs was $1,819.44 vs. $3,067.86 over the six month study period.

Conclusions

There is strong evidence that air pressure treatment is an effective way to treat OSA. This is based on the results of a meta-analysis of recent studies.

There is moderate evidence that medicine is an effective way to treat OSA. While medicine had a large effect size in the meta-analysis, there were fewer studies looking at the effects of medicine, and the confidence interval on this finding is large.

There is moderate evidence that surgery and dental appliances can be an effective way to treat OSA, although they appear to be not as effective as air pressure treatment or medicine. However, these treatment approaches may offer the advantage of permanence (in the case of surgery) and possibly higher adherence rates (in the case of dental appliances). Further study is required.

There is strong evidence that behavioral interventions approaches were the least effective approach to treat OSA.

There is weak evidence that CPAP treatment is cost effective. One study found that such treatment has a positive effect, but further research is needed. A major factor affecting the cost-effectiveness of CPAP is adherence rate, as CPAP is not an effective treatment if patients do not comply with treatment. **There is weak evidence that cost of treatment may be a barrier to CPAP adherence, based on the results of one study.**

There is weak evidence that OSA treatment can be conducted effectively in a primary care setting. One study found treatment was non-inferior and substantially more affordable in a primary care setting; however, this study used only Epworth scores as its outcome metric, and further research is required.

Research Question 5

Question 5 asks: Looking specifically at CMV drivers: Which diagnostic strategies have been tested with a population of CMV drivers? Which treatment options have been tested with a population of CMV drivers? How can treatments be tracked to ensure CMV driver compliance?

Evidence Base for Question 5

The evidence base for Question 5 consists of n=12 studies, as shown in Figure 6.

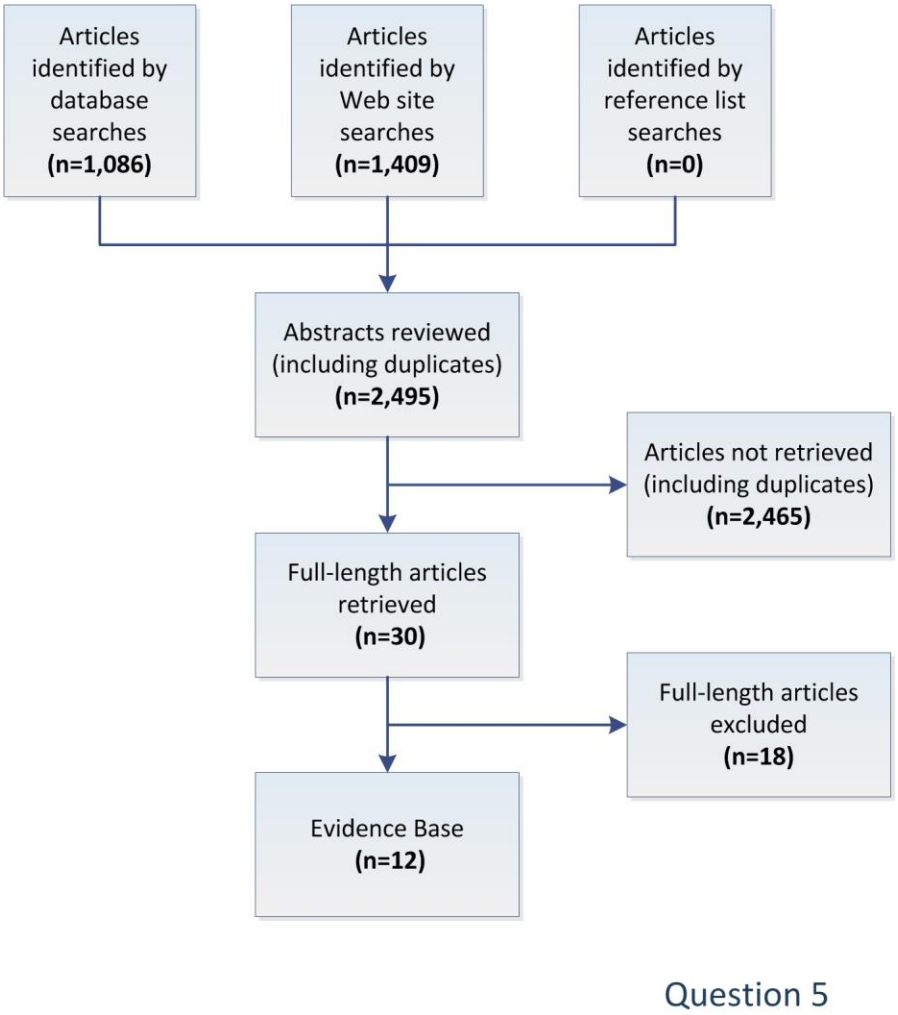
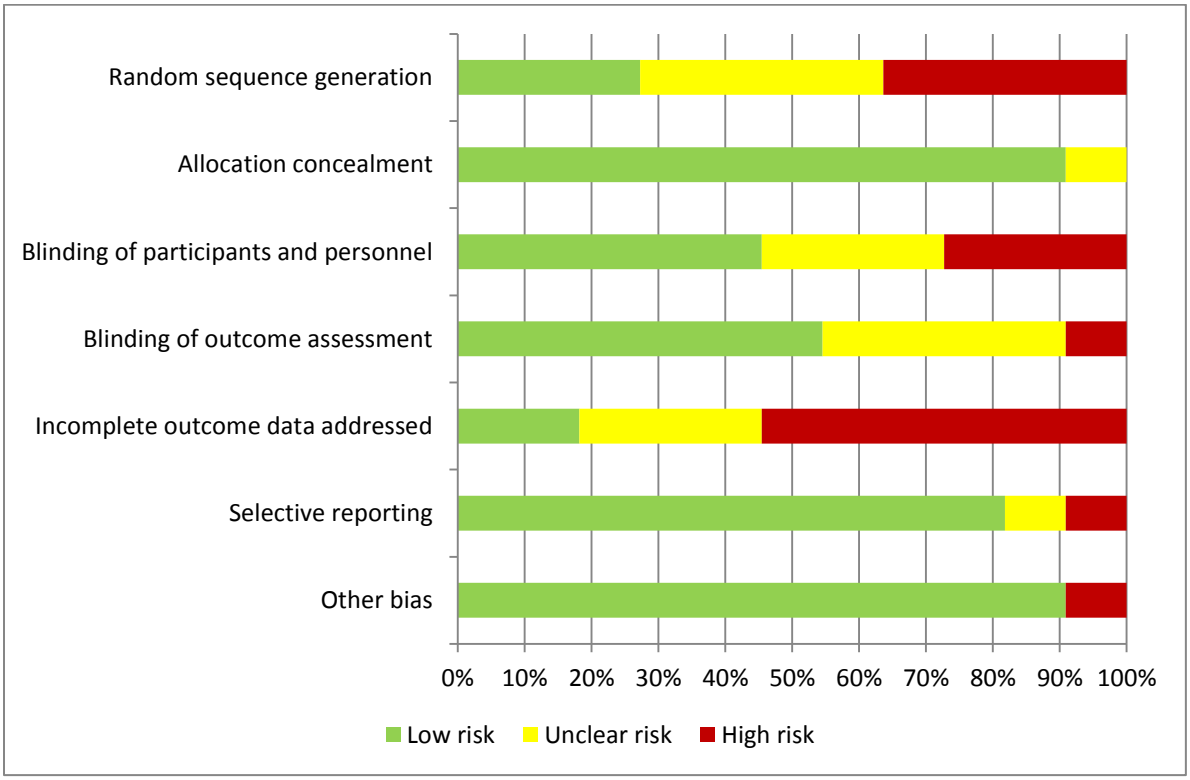


Figure 6: Evidence base, Question 1

Quality of Included Studies

Each identified item was ranked for quality using the categories described in the research methodology section. The ratings for the original research articles are presented in Table 30. The studies are of moderate quality, and of low quality pertaining to incomplete outcome data. As was the case for study quality for question 1, many of these studies experienced high attrition rates as drivers refused PSG.

Table 30: Study Quality for Q5 Research Articles



Summaries of Included Studies

Original research articles that address Q5 are shown in the tables below. Table 31 shows information about the study design and conclusions. Table 32 shows detailed findings for each of the original research articles.

Table 31: Study Design and Conclusions for Original Articles that Address Q5

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Berger et al. (2012) [1]	USA, Survey; retrospective analysis	Investigate the prevalence of OSA among CMV drivers	Commercial drivers were screened for OSA with an online questionnaire through employer mandates. Questionnaire and PSG results were analyzed retrospectively.	n=19,371 (male: 91.1%, age 41.2 ± 11.2, BMI 30.9 ± 6.6, neck size 17 ± 1.6; female: 7.6%, age 41.2 ± 9.7, BMI 31.0 ± 7.4)	Somni-Sage® is an online screening questionnaire to screen drivers for OSA; self-report, categorizes individuals as high or low risk
Gurubhagavatula et al. (2008) [2]	USA, Case control study	Investigate the cost effectiveness of different approaches to screening for OSA and the minimum treatment adherence rate necessary to make treatment cost effective	CMV drivers answered a questionnaire to screen for OSA risk; they also completed PSG.	n=247 high-risk drivers; n=159 low-risk drivers (average age 45.4±11.0 years, BMI 29.9±5.2 kg/m2)	Screening using BMI, age and gender alone or with oximetry is a viable strategy to detect OSA in commercial drivers, and lowers the need for in-laboratory PSG studies; despite missing some cases, this strategy requires lower rates of treatment acceptance than routine PSG in order to be cost-effective, given the high cost of crashes
Hoffman et al. (2010) [90]	USA, Retrospective, pre/post claims-based comparison analysis	Assess the impact on health plan and disability costs associated with continuous positive airway pressure or bi-level positive airway pressure treatment of OSA in a commercial driver population	This study compared the costs of treatment of OSA with non-treatment in a control group.	n=244 (control: mean age 44.4, 95.7% male; study: mean age 44.7, 99.4% male)	Drivers who were treated for OSA with either a CPAP or BiPAP device exhibited lower total health plan costs and fewer missed workdays because of short-term disability during the 24 months after the initiation of the treatment, resulting in $6,341 in total health plan and disability cost savings per treated driver

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Parks et al. (2009) [3]	USA, Questionnaire-based cross-sectional study	Evaluate Joint Task Force criteria for screening commercial drivers for OSA	All drivers received a commercial driver medical examination. Patients that presented a high likelihood according to the Joint Task Force OSA screening criteria were instructed to receive a PSG to determine whether or not they had OSA.	n=456 (mean age 39.22, mean BMI 29.07, mean neck circumference 16.36)	Study found high positive predictive value of the consensus guidelines but low follow-up rates
Platt et al. (2013) [4]	USA, Prospective cohort study	Evaluate Joint Task Force criteria-based screening for severe OSA in commercial drivers	Subjects self-reported demographics, apnea symptoms, tobacco and alcohol use, and Epworth. A pre-employment physical exam was simulated to determine fitness for duty, using DOT's Medical Examination Report for Commercial Driver Fitness Determination. PSG was conducted in-home, set up and scored by registered technologists for all participants. Primary analyses considered severe OSA as AHI of 30 or more per hour.	n=100 drivers with active commercial driver's licenses (94% male, mean age 44.0 ± 8.6, BMI 34.3 ± 8.0, neck circumference (cm) 43.2 ± 4.0)	One third to one fifth of cases of severe OSA may be missed by existing JTF guidelines, which are based on a threshold BMI of 35 kg/m2 or more; these data support the need to consider a lower BMI threshold for screening; subjective data, when provided in a confidential and non-punitive environment, add discriminatory value to BMI; findings also support the consideration of universal testing

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Rizzo et al. (2013) [91]	USA, Case control study	Identify and evaluate cognitive and behavioral indices that are sensitive to sleep deprivation and may help identify CMV drivers who are at-risk for driving in a sleep deprived state	Participants were observed driving their own vehicles using an instrumented vehicle data acquisition system containing 3 devices: an internal camera cluster, a GPS, and a central processing unit obtaining data from OBD-II and accelerometers. There were 2 periods of observation: a) a two week period prior to beginning PAP and b) a period of 3 months after beginning PAP. Participants wore actigraphy watches that collected objective measures of daily sleep quality during the 3.5 month period. Video samples were coded for indicators of sleepiness.	n=44 drivers diagnosed with OSA; n=22 matched controls	Video-based measures of driver sleepiness and scored sleepiness did not distinguish participants with OSA from matched controls, did not differ as a result of PAP treatment, did not predict total sleep; found no scientific evidence to support the inference that driver physiognomy provides a valid measure of sleep deprivation
Talmage et al. (2008) [6]	USA, Consecutive case series	Validate the recently published consensus criteria for screening commercial drivers for OSA	Federal Commercial Driver Medical Examinations were administered; each driver completed the history section of the form, a questionnaire about factors that would suggest sleep apnea might be present, and Epworth. A physical exam included blood pressure, BMI, and neck circumference. If the drivers met the examined criteria they were informed they would have a limited 3-month certification and would be required to have a PSG.	n=134 completed PSG (no OSA: BMI 35.9, mean neck circumference 17.0; Mild OSA: BMI 39.7, neck 17.7; Moderate OSA: BMI 40.1, neck 17.9; Severe OSA: BMI 41.6, neck 18.1)	The consensus criteria detect drivers with a high probability of having OSA; ESS is inversely associated, suggesting potential denial or deception; testing decisions require objective criteria, not subjective admission of symptoms

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Watkins et al. (2009) [7]		Compare the accuracy of portable monitoring for OSA with PSG in commercial drivers	Newly hired drivers underwent commercial driver certification exams; drivers screening positive on history and physical exam by the consensus criteria were scheduled for PSG. PSG results were interpreted as positive if the AHI was ≥ 10, or if sleep specialist recommended treatment with CPAP due to severe nocturnal hypoxia, regardless of AHI. Drivers screening positive were requested to use a single-channel portable apnea monitor device for one night (RUSleeping) to compare the accuracy of portable monitoring screening to the formal PSG scheduled 3 months later.	n=346 drivers	A portable monitoring device (RUSleeping RTS) was compared to standard PSG among a population of truck drivers who tested as likely to have OSA; there is moderately high correlation between the results of the portable monitoring device and the standard procedure PSG, although this screening device is unable to completely rule out those that do not have sleep apnea
Xie et al. (2011) [8]	USA, Cross-sectional, retrospective, case-control design	Identify factors associated with OSA risk during commercial driver medical examinations	Each driver completed the health history section of the federal CDME form. Blood pressure, height, weight, and neck circumference were measured. The examining physician determined whether the driver met the consensus criteria for PSG. Drivers with suspected OSA were issued a 3-month medical certification and referred for PSG evaluation. The AHI or respiratory disturbance index and lowest recorded oxygen saturation were used to indicate the presence and severity of OSA.	n=1,890 (91.6% male, average age 43.7 ±11.52 years, average BMI 30.5 (±6.6))	Medical examiners' use of objectively measurable risk factors, such as obesity, history of hypertension, and/or diabetes, rather than symptoms, may be more effective in identifying undiagnosed OSA in commercial drivers during the commercial driver medical examinations

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Sharwood et al. (2012) [9]	Australia, Cross-sectional study	Determine the relationship between subjective and objective assessments of OSA in CMV drivers	Drivers were interviewed regarding their driving experience, personal health, shift schedules, and various questions on sleep and tiredness in order to describe their sleep health across a range of variables. In addition, home recordings using a flow monitor were used during one night of sleep for all participants.	n=517 recruited (50% obese); n=325 completed data and flow monitoring	Significant differences between subjective and objective assessments for OSA and related sleepiness in a representative sample of long-distance CMV drivers; identified a high rate (41%) of previously undiagnosed OSA via a portable testing device, while only 12% of drivers reported excessive daytime sleepiness
Firat et al. (2012) [15]	Turkey, Cohort study	Assess the usefulness of four standardized questionnaires (Berlin, STOP, STOP-BANG, and OSA50) in identifying bus drivers at high risk for OSA	Questionnaires for predicting OSA were translated and adapted to Turkish and completed by subjects with the help of a physician. Subjects completed a 5 hour PSG after working a full night shift.	n=85 bus drivers (all male; < 45 years of age: BMI 27.7 ± 2.9; neck circumference (cm) 40.1 ± 2.5; AHI 14.4 ± 11.6; ≥ 45 years of age: BMI 29.7 ± 4.0; neck circumference 41.5 ± 2.9; AHI 23.6 ± 18.5)	Different tests showed different sensitivity and specificity, with STOP-BANG being most sensitive and STOP having the lowest values; objective parameters such as BMI, neck circumference, waist circumference, presence/absence of hypertension, and gender influence the presence of OSA and are used in different tests in different combinations

Author (Year)	Location and Design of Study	Study Objective	Procedures/Protocol	Sample Size and Demographics	Conclusions
Karimi et al. (2013) [12]	Sweden, Cohort study	Investigate the prevalence of sleep disorders among public transport operators (PTOs) and assess the interventional effects on hyper somnolence and neurocognitive function in those diagnosed with OSA	Overnight PSG and questionnaire data were collected from employees of a transportation company. Treatment was offered in cases with newly detected OSA. Daytime sleep episodes and neurocognitive function were assessed before and after intervention.	n=101 evenly split between bus and tram drivers (72% male, median age 48, BMI 27)	Elimination of OSA led to significant subjective and objective improvements in daytime function; OSA treatment improved drivers' capacity to maintain wakefulness and performance in standardized situations of monotonous tasks

Table 32: Detailed Findings for Original Articles that Address Q5

Author (Year)	Findings
Berger et al. (2012) [1]	1. Positive predictive value for definitive OSA (AHI>10) among those deemed higher risk by the OSA screening instrument (Somni-Sage®): 68% 2. Positive predictive value for OSA (AHI>5) among those deemed higher risk by the OSA screening instrument: 80% 3. Higher-risk drivers who had not received diagnostic confirmatory testing by the end of the study period: 64%
Gurubhagavatula et al. (2008) [2]	1. Specificity based on demographic information alone: 71% 2. Specificity with demographic information plus oximetry: 81%; Adding oximetry costs an additional $14/driver but requires fewer in-laboratory studies 3. Missed cases for one-stage strategies: 2.5%; Missed cases for two-stage strategies : 2.6%
Hoffman et al. (2010) [90]	1. Savings as a result of total health plan costs, fewer missed workdays and lower use of short-term disability for drivers treated with either a CPAP or BiPAP device in 24 months after treatment: $6,341/driver 2. Savings as a result of total health plan costs, fewer missed workdays and lower use of short-term disability for drivers diagnosed but not treated (controls) in 24 months after treatment: $1,206/driver 3. Days missed due to short-term disability after one year for treated group: 71.7% fewer 4. Days missed due to short-term disability after one year for control group: 38.0% fewer 5. Days missed due to short-term disability after two years for treated group: 40.6% fewer 6. Days missed due to short-term disability after one year for control group: 33.6% more

Author (Year)	Findings
Parks et al. (2009) [3]	1. Drivers screening positive by Joint Task Force consensus criteria: 17% 2. Drivers answering yes to screening question on FMCSA form: 3% 3. Drivers correctly referred for PSG based on Joint Task Force criteria: 67% (in remaining cases, examiners discounted or missed symptoms identified retroactively) 4. Positive predictive value of Joint Task Force consensus criteria: 100% 5. Compliance rate with PSG referrals and CPAP treatment: 37.7% 6. Drivers demonstrating treatment compliance after OSA diagnosis: 1 of 20 (5%)
Platt et al. (2013) [4]	1. Subjects with severe OSA (AHI>30) captured by BMI ≥35 kg/m2 alone (sensitivity): 63% (CI: 44-80); Diagnostic specificity: 71% (CI: 59-83) 2. Subjects with severe OSA (AHI>30) captured by BMI ≥30 kg/m2 alone (sensitivity): 90% (CI: 74-98); Diagnostic specificity: 37% (CI: 25-50) 3. Subjects with severe OSA (AHI>30) captured by any examination findings at BMI ≥35 kg/m2 (sensitivity): 80% (CI: 61-92); Diagnostic specificity: 41% (CI: 30-54) 4. Subjects with severe OSA (AHI>30) captured by any examination findings at BMI ≥30 kg/m2 (sensitivity): 90% (CI: 74-99); Diagnostic specificity: 24% (CI: 15-56) 5. Subjects with severe OSA (AHI>30) captured by complete JTF criteria (exam, history, BMI>35) (sensitivity): 97% (CI: 83-100); Diagnostic specificity: 19% (CI: 10-30) 6. Subjects lost to follow-up: 24% [all were provided with confidentiality certificates]
Rizzo et al. (2013) [91]	1. Quality of sleep (participants with OSA vs. matched controls): sleep efficiency (74 vs. 82); minutes slept (362 vs. 385 minutes) 2. Sleep data post PAP (pre vs. post): sleep efficiency (74 vs. 76); total sleep time (363 vs. 367); number awakenings (34 vs. 31) 3. Fixed gaze (based on video observations) as an indicator of sleepiness (OSA vs. matched control): 4% vs. 5% 4. Sleepiness indicators following PAP treatment (pre vs. post): fixed gaze (0.03 vs. 0.06) and low energy body movements (0.06 vs. 0.09) 5. Variance in indicators of sleepiness as a function of total sleep: did not vary
Talmage et al. (2008) [6]	1. Drivers with OSA who would have been tested or discovered based solely on the "yes" or "no" question on the federal CDME examination form: 0 2. Drivers who were referred for PSG who preferred to resign and seek employment elsewhere rather than undergo testing: 29.5% (cost of testing and lack of insurance are key related factors) 3. Trend test between increasing severity of OSA and higher BMI: $p<0.01$ 4. Trend test between increasing severity of OSA and larger neck circumference: $p<0.001$ 5. Trend test between increasing severity of OSA and Epworth score: $p<-0.05$ (suggests potential denial or deception) 6. Trend test between increasing severity of OSA and lower minimum O2 saturation: $p<0.001$

Author (Year)	Findings
Watkins et al. (2009) [7]	1. Respironics RUSleeping™ device sensitivity using AHI >15: 70%; Specificity: 83% 2. Drivers noncompliant with physician recommendations who did not complete both portable monitoring and PSG testing: 49%
Xie et al. (2011) [8]	1. Drivers reporting they suffer from sleep disorder, pauses in breathing while asleep, day time sleepiness, or loud snoring on CDME form: 2.6% (confirmed prevalence of OSA was 6.1%, and likely higher, due to substantial loss to follow-up) 2. Drivers with OSA reporting a sleep history suggestive of OSA: 36.1% 3. Drivers screening positive according to Joint Task Force Guidelines lost to follow-up: 66.1% 4. Positive predictive value of Joint Task Force Guidelines: 78.5% 5. Odds ratio for drivers with BMI ≥30 having OSA: 26.86 (CI: 10.85–66.48) 6. OSA prevalence among drivers with and without diabetes: 16.2% vs. 4.86% 7. OSA prevalence among drivers with and without hypertension: 12.5% vs. 3.8%
Sharwood et al. (2012) [9]	1. Relationship between Epworth score and difficulty staying awake while driving: positive and significant, $\chi 2 = 14.7$, $p < 0.001$ 2. Relationship between OSA diagnosis (AHI ≥18) and Epworth score: not significant, p=0.75 3. Relationship between OSA diagnosis (AHI ≥18) and self-reported insufficient sleep: not significant, p=0.70 4. Performance of multivariable apnea prediction index, based on self-reported measures for predicting OSA: sensitivity=0.56, specificity=0.58
Firat et al. (2012) [15]	1. Sensitivity of the Berlin questionnaire: 45.6% (CI: 31.2-60); Specificity of Berlin questionnaire: 84.6% (CI: 73.2-95.9) 2. Sensitivity of STOP questionnaire: 41.3% (CI: 27-55.5); Specificity of STOP questionnaire: 92.3% (CI: 83.9-100) 3. Sensitivity of STOP-BANG questionnaire: 87% (CI: 77.7-96.6); Specificity of STOP-BANG questionnaire: 48.7% (CI: 33.3-64.4) 4. Sensitivity of OSA50 questionnaire: 63% (CI: 49-76.9); Specificity of OSA 50 questionnaire: 82% (CI: 72-94)
Karimi et al. (2013) [12]	1. Mean Epworth Sleepiness Scores for those using CPAP or a mandibular device: 9.5 (pre) to 7.0 (post) 2. Current sleepiness scores, as measured by the Karolinska Sleepiness Scale, for those using CPAP or a mandibular device: 5.0 (pre) to 3.5 (post) 3. General fatigue, as measure by the Functional Impact of Sleepiness scale, for those using CPAP or a mandibular device: 33 (pre) to 2 (post) ($p < 0.04$)

Findings

Findings are presented according to the following categories: diagnostic strategies, treatment options, and tracking of compliance.

Diagnostic Strategies

OSA can be diagnosed in many ways, and a variety of diagnostic approaches have been tested with populations of CMV drivers. Questionnaire based-approaches include the FMCSA Commercial Driver Fitness Form and the Epworth Sleepiness Scale, among others. Other approaches include physical criteria such as BMI, combinations of physical criteria with questionnaires (such as the Joint Task Force consensus guidelines), and universal screening of all drivers using either lab-based or home PSG.

FMCSA's current Commercial Driver Fitness Form asks one question related to OSA risk. Talmage et al. [6] found none of the drivers they identified as having OSA (n=190) would have screened at-risk according to the form. Xie et al. [8] likewise found that only a small number of drivers (2.6%) would screen at-risk on the FMCSA form, even though at least 6.1% of all drivers in the study had OSA (and the actual number is likely higher because two-thirds of drivers referred for PSG were lost to follow-up). Xie et al. also found that sleep history is not highly predictive of OSA, with only a third (36%) of drivers with OSA reporting a sleep history suggestive of OSA.

The Epworth scale in one study was found to be negatively predictive of OSA: Talmage et al. [6] found inverse correlations between Epworth scores and OSA. The authors interpreted this to mean that drivers may intentionally lie when answering these questions. Sharwood et al. [9] likewise found no relationship between OSA diagnosis (AHI>18) and Epworth score, even though Epworth was associated with difficulty staying awake while driving.

Rizzo et al. [91] found that air pressure treatment did not reduce observed signs of sleepiness, nor did these measures correlate with total sleep. This suggests that physical measures of sleepiness are not a good indicator of OSA risk.

Firat et al. [15] looked at the sensitivity and specificity of several different questionnaires used to assess CMV drivers. They found wide variations in the results for each questionnaire:

Questionnaire	Sensitivity	Specificity
Berlin questionnaire	45.6%	84.6%
STOP questionnaire	41.3%	92.3%
STOP-BANG questionnaire	87%	48.7%
OSA50 questionnaire	63%	82%

Sharwood et al. [9] tested a multivariable apnea prediction index, based on self-reported measures, and compared it to PSG. They found it had a relatively low sensitivity (56%) and a low specificity (58%).

Yet another self-assessment is completed via Somni-Sage®, an online screening program. Truck drivers are asked to complete an assessment, and those at higher-risk for OSA are asked to complete PSG for further analysis. Among those who screened at high-risk and completed PSG, 80% of CMV drivers had AHI>5 and 68% had AHI>10 [1].

In addition to these questionnaire-based approaches, physical screening criteria can also be used to identify drivers at-risk. Platt et al. [4] looked at how often severe OSA (AHI>30) was captured by BMI alone at two levels. At BMI ≥35 kg/m2, the sensitivity/specificity was 63%/71%. At BMI ≥30 kg/m2, the levels were 90%/37%.

Physical criteria can also be combined with questionnaires to identify drivers at-risk for OSA. The most common such approach is the Joint Task Force consensus guidelines. Studies of the Joint Task Force consensus guidelines have generally found that these guidelines are highly sensitive, although perhaps not very specific. For example, Parks et al. [3] found 100% of drivers screening at-risk by the criteria had OSA. Xie et al. [8] found the positive predictive value of the guidelines was 78.5%. Platt et al. [4] looked at how severe OSA (AHI>30) was captured by the guidelines. They found that the guidelines were highly sensitive (97%) but with a low specificity (19%).

Other approaches using physical data and questionnaires have been tested with CMV drivers. Gurubhagavatula et al. [2] evaluated the effect of one-stage vs. two-stage screening for CMV drivers to determine if they had OSA. Their criteria for OSA included both an elevated AHI score (>5) and an elevated Epworth score (>10). They found that screening based on demographic information alone had a specificity of 71%, while using demographic information plus oximetry increased the specificity to 81%. Both approaches missed a similar number of cases (>3%).

Watkins et al. [7] tested a portable home monitor for PSG on CMV drivers. They found that the Respironics RUSleeping™ device had a sensitivity of 70% and a specificity of 83% using AHI >15 as the criteria for OSA.

Treatment Options

Only one study looked at how CMV drivers have been treated for OSA. Karimi et al. [12] investigated how drivers did after six months of treatment using CPAP or a mandibular advance device (based on the guidance of their physician). The study found that pre- to post-scores improved in several areas, including lower Epworth scores, lower current sleepiness

scores (using the Karolinska Sleepiness Scale), and lower general fatigue. Thus, OSA treatment improved several measures of sleepiness.

Tracking of Treatment Compliance

Seven studies looked at how CMV drivers comply with requests for follow-up PSG and with treatment for OSA.

Studies show a high attrition rate when drivers screen at-risk for OSA; many drivers are lost to follow-up when PSG is requested by a referring physician or suggested as a result of screening:

- Xie et al. [8] found a very high number of drivers (66%) screening as at-risk for OSA were lost to follow-up and did not complete PSG.
- Berger et al. [1] found that over half of all drivers (64%) who screened at-risk based on an online questionnaire failed to complete PSG by the end of the study period.
- Parks et al. [3] found 62% of drivers referred for PSG did not complete follow-up.
- Watkins et al. [7] found that 49% of drivers screening at risk for OSA did not comply with physician instructions to complete a PSG evaluation.
- Talmage et al. [6] found that 30% of drivers referred for PSG screening preferred to resign (seeking employment elsewhere) rather than be screened.
- Platt et al. [4] found only 24% of drivers were lost to follow-up; however, the authors had provided all participants with a certificate of confidentiality to resist court-ordered release of confidential health information and subjects were paid to participate in the study.

Very few studies have looked at treatment compliance. Parks et al. [3] found only one driver (5%) could demonstrate compliance with treatment, with the rest refusing to provide evidence or providing evidence of non-compliance. Hoffman et al. [90] found that treated drivers had substantially lower medical costs and costs due to missed work days due to disability over a two-year period from the start of treatment. This suggests that a number of drivers are complying with treatment, but treatment adherence rates were not known in the study.

Conclusions

There is strong evidence that FMCSA's Commercial Driver Fitness Form (used on its own) will underestimate cases of OSA among CMV drivers compared to other methods. Very few drivers screen as at-risk using the question on the current form, and several studies show that the actual rate of OSA among the CMV driver populations is much higher than that identified by the current form.

There is weak evidence that questionnaires can be used to identify OSA among a population of CMV drivers; however, the sensitivity and specificity of each instrument

varies considerably. Many of the instruments have only been tested in one study with CMV drivers; additional research is required to validate their use for this purpose.

There is weak evidence that BMI on its own may be a useful criteria to identify drivers at-risk for OSA. One study looked at the sensitivity and specificity of using BMI≥30 and BMI≥35 as criteria for OSA screening. It found that BMI (especially BMI≥35) has moderate sensitivity and specificity. Additional research is required.

There is strong evidence that the Joint Task Force Criteria are highly sensitive, and that most drivers screening at-risk according to these criteria will be confirmed by PSG to have OSA. There is weak evidence that these guidelines may not be very specific (based on the results of one study).

There is insufficiently weak evidence to identify preferred OSA treatment among CMV drivers. Only one study discussed treatment approaches, and only two types of approaches were discussed. Further study is needed to better understand how CMV drivers will respond to OSA treatment.

There is strong evidence that many drivers will not voluntarily complete requested PSG follow-up. Six studies found drop-out rates from 24-66%, with most studies averaging an attrition rate of over half of all drivers identified as at-risk. High loss to follow-up may significantly impact the identified rate of OSA among CMV drivers.

There is insufficiently weak evidence related to CMV driver compliance with treatment. Only one study directly addressed this question (and found low compliance); another study indirectly suggested compliance was high enough to reduce medical claims among drivers undergoing treatment.

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Appendixes

A. Search Summaries

A unique set of keyword combinations was used for each search topic to identify potential studies of interest. These keyword combinations varied slightly for each database, to reflect its organizational structure.

The search terms used for PubMed are provided here for reference:

- **For Q1/Q2/Q5:** ("obstructive sleep apnea" OR "obstructive sleep apnoea" OR "sleep disordered breathing") and ("truck driver" OR "trucking" OR "commercial motor vehicle" OR "CMV" OR "commercial driving" OR "commercial driver")
- **For Q3:** ("obstructive sleep apnea" OR "obstructive sleep apnoea" OR "sleep disordered breathing") and ("diagnosis" OR "screening" OR "guideline" OR "evaluation" OR "polysomnography" OR "home sleep" OR "anthropometric" OR "cephalometry" OR "oximetry" OR "Epworth" OR "Apnea Clinical" OR "Berlin" OR "Apnea Detector" OR "Functional Outcomes of Sleep")
- **For Q4:** ("obstructive sleep apnea" OR "obstructive sleep apnoea" OR "sleep disordered breathing") and ("treatment" OR "adherence" OR "compliance" OR "health outcome" OR "health outcomes" OR "noncompliance" OR "non-adherence" OR "nonadherence" OR "tracking" OR "SleepWatch" OR "Copilot" OR "SafeTRAC") and ("cost" OR "effectiveness" OR "efficacy")

B. Retrieval Criteria

These searches produced large numbers of search results. A member of our research team reviewed the title and abstract of each returned article. This information was reviewed against a set retrieval criteria that were defined a priori. If the article matched the criteria, it was entered into a reference database with a notation about which question it apparently applied to. Each article was obtained in full text (typically as a PDF file), and attached to the bibliographic information in the database.

The retrieval criteria were:

Retrieval Criteria for Key Question 1

- Article must be published in the English language.
- Article must be full-length and not a letter, editorial, news, comment, case report, review, note, abstract, or conference paper.
- Article must describe a study that enrolled 100 or more subjects over the age of 18 who are commercial motor vehicle drivers.
- Article must describe a study that attempted to determine the frequency or prevalence of OSA among a population of commercial motor vehicle drivers.
- Studies that evaluate both OSA and other sleep disorders are acceptable as long as data for OSA can be analyzed separately.
- Study must be published after January 1, 2007.

Retrieval Criteria for Key Question 2

- Article must be published in the English language.
- Article must be full-length and not a letter, editorial, news, comment, case report, review, note, abstract, or conference paper.
- Article must describe a study that enrolled 20 or more subjects over the age of 18 who are commercial motor vehicle drivers.
- Article must describe a study that looked at CMV crashes related to human factors and OSA risk factors and contain data on the relationship between these factors and crash risk.
- Studies that evaluate both OSA and other sleep disorders are acceptable as long as data for OSA can be analyzed separately.
- Study must be published after January 1, 2007.

Retrieval Criteria for Key Question 3

- Article must be published in the English language.
- Article must be full-length and not a letter, editorial, news, comment, case report, review, note, abstract, or conference paper.
- Article must describe a study that enrolled 20 or more subjects over the age of 18.

- Article must describe a study that identified diagnostic criteria.
- Article must include data on the efficacy of the diagnosis, including both sensitivity and specificity (that is, data on both false positives and false negatives), or on the cost to diagnose.
- Studies that evaluate both OSA and other sleep disorders are acceptable as long as data for OSA can be analyzed separately.
- Study must be published after January 1, 2011.

Retrieval Criteria for Key Question 4

- Article must be published in the English language.
- Article must be full-length and not a letter, editorial, news, comment, case report, review, note, abstract, or conference paper.
- Article must describe a study that enrolled 20 or more subjects over the age of 18.
- Article must describe a study discussing treatment options for OSA in one of the following five categories: behavior modifications, air pressure treatments, dental appliances, medication, or surgery.
- Article must describe a study that contains information on either the cost or effectiveness of treatment. Effectiveness must be measured using pre-test and post-test measures for either AHI or oximetry, or using an experimental design that randomly assigns patients to treatment condition.
- Studies that evaluate both OSA and other sleep disorders are acceptable as long as data for OSA can be analyzed separately.
- Study must be published after January 1, 2011.

Retrieval Criteria for Key Question 5

- Article must be published in the English language.
- Article must be full-length and not a letter, editorial, news, comment, case report, review, note, abstract, or conference paper.
- Article must describe a study that enrolled 20 or more subjects over the age of 18 who are commercial motor vehicle drivers.
- Article must describe a study discussing diagnostic or treatment options for OSA among a population of CMV driver.
- Article must describe a study that contains information on the efficacy of diagnosis, the cost to diagnose, or the effectiveness of treatment.
- Studies that evaluate both OSA and other sleep disorders are acceptable as long as data for OSA can be analyzed separately.
- Study must be published after January 1, 2007.

C. Inclusion Criteria

Once all sources had been searched, the reference database was searched to eliminate duplicate articles. A researcher then reviewed each article, again against a set of exclusion and inclusion criteria. These *a priori* criteria, below, largely mirror the retrieval criteria, but this time the decision was made based on a review of the full-text of the article as opposed to the abstract only.

Inclusion Criteria for all Questions

- Article must be published in the English language.
- Article must be full-length and not a letter, editorial, news, comment, case report, review, note, abstract, or conference paper
- Studies that evaluate both OSA and other sleep disorders are acceptable as long as data for OSA can be analyzed separately
- Study must be original research that meets our criteria
- If the same study is reported in multiple publications, the most complete publication will be the primary reference – full-length studies will not be double counted.

In addition to these criteria, there are criteria specific to each research question.

Inclusion Criteria for Key Question 1

- Article must describe a study that enrolled 100 or more subjects over the age of 18 who are commercial motor vehicle drivers.
- Article must describe a study that attempted to determine the frequency or prevalence of OSA among a population of commercial motor vehicle drivers (or have separable results from a larger study that includes a sufficient sample of CMV drivers).
- Study must be published after January 1, 2007.

Inclusion Criteria for Key Question 2

- Article must describe a study that enrolled 20 or more subjects over the age of 18 who are commercial motor vehicle drivers.
- Article must describe a study that looked at CMV crashes related to human factors and OSA risk factors and contain data on the relationship between these factors and crash risk.
- Study must be published after January 1, 2007.

Inclusion Criteria for Key Question 3

- Article must describe a study that enrolled 20 or more subjects over the age of 18.
- Article must describe a study that identified diagnostic criteria.
- Article must include data on the efficacy of the diagnosis, including both sensitivity and specificity (that is, data on both false positives and false negatives), or on the cost to diagnose.

- Study must be published after January 1, 2011.
- Data in study must be presented in such a way to enable meta-analysis.

Inclusion Criteria for Key Question 4

- Article must describe a study that enrolled 20 or more subjects over the age of 18.
- Article must describe a study discussing treatment options for OSA in one of the following five categories: behavior modifications, air pressure treatments, dental appliances, medication, or surgery.
- Article must describe a study that contains information on either the cost or effectiveness of treatment. Effectiveness must be measured using pre-test and post-test measures for either AHI or oximetry, or using an experimental design that randomly assigns patients to treatment condition.
- Study must be published after January 1, 2011.
- Data in study must be presented in such a way to enable meta-analysis.

Inclusion Criteria for Key Question 5

- Article must describe a study that enrolled 20 or more subjects over the age of 18 who are commercial motor vehicle drivers.
- Article must describe a study discussing diagnostic or treatment options for OSA among a population of CMV drivers.
- Article must describe a study that contains information on the efficacy of diagnosis, the cost to diagnose, or the effectiveness of treatment.
- Study must be published after January 1, 2007.