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Country Report

Developing policy regarding obstructive sleep apnea and driving among commercial drivers in the United States and Japan

Ronald FILOMENO[1, 2], Ai IKEDA[1] and Takeshi TANIGAWA[1]*

[1]Department of Public Health, Juntendo University School of Medicine, Japan
[2]Department of Public Health Sciences, Office of Public Health Studies, University of Hawai'i at Mānoa, USA

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Abstract: Obstructive Sleep Apnea Syndrome (OSAS) has emerged as a global public health problem. OSAS is largely recognized as a factor for increased risk of vehicular related accidents for those diagnosed and undiagnosed. This article serves as a country report that reviews current and potential policies regarding OSAS induced drowsy driving in both Japan and the United States of America. In addition to reviewing policies, various case finding techniques are also explored as methods to reduce accidents due to OSAS induced drowsy driving. Evaluation of the effectiveness of methods used in the United States of America and Japan for safe driving among commercial drivers is a key step to decreasing vehicular related accidents through stronger policy development and subsequent enforcement. Case finding has emerged as one of the most effective and realistic methods to detect OSAS in the driving population based on research done in the U.S. and Japan. Subsequently, case finding can lead to treatment to further prevent future accidents from occurring due to OSAS drowsy driving.

Key words: Obstructive Sleep Apnea Syndrome (OSAS), Sleep-disordered breathing (SDB), Case finding, Commercial Driving, Policy

Introduction (background)

Sleep-related disorders, such as obstructive sleep apnea syndrome (OSAS), are increasingly being recognized as major public health issues. OSAS, characterized by periodic complete or partial upper airway obstruction during sleep, causes intermittent cessations of breathing (apneas) or reductions in airflow (hypopneas) despite ongoing respiratory effort causing a decrease in overall sleep quality[1]. Overall poor sleep quality has been directly linked to motor vehicle accidents, industrial disasters, medical, and other occupational errors[2]. It has been established that sleep-disorders result in drowsy driving, fatigue, and excessive sleepiness throughout the day regardless of the amount of time spent in bed[3]. Commercial drivers with excessive sleepiness are an extremely serious public health issue that places the health of everyone on the road at risk. Patients with sleep-related disorders, particularly those afflicted with OSAS, are more likely to have major personal injuries from crashes and accidents than those on treatment or without OSAS[2]. With emphasis on the United States and Japan, this public health issue negatively affects drivers on the road in both respective nations[4].

In the United States, the Centers for Disease Control and Prevention (CDC) identifies commercial motor vehicle (CMV) drivers, shift workers, drivers with untreated sleep disorders such as OSAS, drivers using sedative medications, and drivers who do not have adequate sleep

*To whom correspondence should be addressed.
E-mail: tt9178tt9178@gmail.com

as populations most likely to drive drowsy[5]. The National Highway Traffic Safety Administration (NHTSA) estimates that 2.4% of fatal crashes and 2% of injury crashes involve drowsy driving in the United States[6]. However, according to data from Australia, England, Finland, and other European nations, all of which have much more consistent crash reporting procedures in place than the United States, drowsy driving represents 10–30% of all crashes; a markedly higher estimate than that from the National Highway Traffic Safety Administration[7]. The differences in crash reporting procedures can be seen from the ability of state governments within the United States to enact their own laws. There are States that use a unique crash report and separate data file system that differs from other States, which leads to overall decentralization of traffic safety reporting as a nation. An example of this decentralized procedure is the NHTSA's State Data System (SDS). The SDS obtains, from thirty-four of the fifty participating states, computer data files coded from police accident reports to provide a census of national traffic statistics. While the NHTSA aims to have all fifty U.S. states enrolled in SDS in the near future, the remaining sixteen states, which currently do not participate in SDS, have led to an incomplete and decentralized crash reporting procedure in the United States. In contrast, the crash reporting procedures in Australia, UK, Finland, and other European countries are more centralized. In Australia, the Department of Infrastructure and Regional Development functions as producers of national road safety statistics under the jurisdiction of the Government of the Commonwealth of Australia. In Europe, centralized national authorities, much like the Department of Infrastructure and Regional Development in Australia, direct the collection of road safety data, such as the Department for Transport in the U.K. and Statistics Finland and the Traffic Safety Committee of Insurance Companies in Finland[31, 32].

In general, focus on OSAS induced drowsy driving has not been evaluated enough worldwide to advance policy development on case finding for sleep-related disorders. *A priori* on policy development focusing on drowsy driving has emphasized short sleep duration and not necessarily the potential causes for poor sleep. However, groundwork research and studies have led to identifying factors that directly affect sleep quality and its subsequent health related problems. Therefore, *a posteriori* justification for implementing more drowsy driving focused evaluations to help promote the benefits of OSAS case finding has emerged around the world, particularly in the United States and Japan.

From a policy standpoint, not enough is being done to curb the potential for high loss of life and/or property damage due to drowsy driving in both Japan and the United States. Japan and the United States currently do not have enforced regulation specifically utilizing case finding for identifying drowsy driving as a means to effectively identify commercial drivers potentially at risk, to ensure treatment compliance, and to prevent potential accidents caused by OSAS induced drowsy driving. The lack of enforced regulation on OSAS induced drowsy driving may stem from the overall low focus on evaluation for drowsy driving in general.

Major Risk Factors for OSAS Induced Drowsy Driving

Growing evidence of major risk factors for drowsy driving related to OSAS in the United States and Japan, has emphasized case finding and screening as primary focuses for identifying seemingly healthy commercial drivers potentially at risk.

BMI

Acknowledging the differences of each nation and their respective populations, such as those present in the United States and Japan, is necessary in order to develop policies regarding OSAS induced drowsy driving. Potential OSAS strategies must be relevant and applicable to the population. For example, for North American commercial drivers, the simplest and most effective objective potential strategies call for body mass index (BMI) cutoffs for obesity to merit OSAS testing[8]. However, using BMI as a primary focus for Asian populations such as the Japanese, would not work as effectively. The U.S. Department of Health and Human Services Office of Minority Health and the World Health Organization (WHO), have reported Asians to be less obese when compared with Caucasians and the rest of the world[7, 9]. Despite the differences in BMI and obesity in those populations, a systemic investigation on the risk of motor vehicle accidents among male Japanese drivers with OSAS was carried out in the Tokyo Metropolitan Area in 2009. Those with higher BMI showed greater severity of OSAS induced drowsy driving and increased risks of sleeping while driving[4]. The major findings of this study showed: the mean BMI was significantly higher in the OSAS group than in the control group, the proportion of subjects with motor vehicle accidents in the preceding five years was significantly higher in the OSAS group than in the control group, and dozing off at the wheel was also

significantly higher in the OSAS group compared with the control group[4].

In Japan, the prevalence of OSAS has been estimated at 9.0% for men and 2.8% for women in the general subset of the population[10]. In contrast, Kato *et al.* have found that the prevalence of OSAS in the United States is about 24% for men and 9% for women; however it should be noted that the U.S. estimate contains other sleep disorders as well[11]. In general, more than 85% of patients with clinically significant OSAS have never been diagnosed, which may explain the relatively high estimate on an emerging public health issue[11].

Furthermore, a study on Japanese commercial vehicle operators reinforced the notion of a positive correlation between BMI/weight and OSAS for the Japanese population[8]. The study found that weight gain of >=10 kg or an increase in BMI of >=5 kg/m^2 were associated with increased sleepiness and sleep disordered breathing, which potentially could lead to motor vehicle accidents[8]. It is important to note that Asian populations are not obese by international criteria, but increases in BMI have subsequently resulted in increases in OSAS prevalence; a common global risk identifier for OSAS[4, 7–9]. Despite increases in BMI, it is currently thought that the craniofacial features of Asians may predispose them to OSAS[11, 12]. One study found that regardless of the lower rates of obesity in Japan compared to that of the United States, the prevalence of sleep-disordered breathing was about 25% among commercial drivers[13].

While utilizing BMI as a sole identifier of OSAS has been shown to be insufficient, utilization of combined apnea-related symptoms and BMI with oximetry have shown otherwise and can potentially serve as a means to effectively identify and treat those at risk[14]. As such, the U.S. Joint Task Force BMI guidelines serve as a default standard in the U.S. and have shown to be generally effective in identifying commercial drivers with OSAS. The BMI threshold, when maintained around the U.S. Joint Task Force recommended screening criterion of 35 kg/m^2, captured about 36–46% of subjects with OSAS[8]. However, Xie *et al.* found that a lower BMI threshold of ≥30 kg/m^2 had a strong association with risk of OSA with an odds ratio of 26.86. That BMI threshold is much lower than the present U.S. Joint Task Force-recommended threshold of 35 or more, and may be the key to more effectively identifying and treating those at risk to decrease crash-related injuries and fatalities due to OSAS[15].

Gender and age

In the United States, the Morbidity and Mortality Weekly Report (MMWR) of March 4, 2011, was the first in the United States to present estimates of the prevalence of unhealthy sleep-related behaviors including nodding off or falling asleep while driving. The MMWR's estimates were based on responses to questions added to the Behavioral Risk Factor Surveillance System (BRFSS) survey in 2009 and include nationwide surveillance data through 12 states (California, Georgia, Hawai'i, Illinois, Kansas, Louisiana, Maryland, Minnesota, Nebraska, New York, Texas, and Wyoming). According to the findings, the prevalence of falling asleep while driving ranged from 2.0% among those aged ≥65 years to 7.2% among persons aged 25–34. Those findings are similar to those of Bixler *et al.*, who noted the prevalence of OSAS increasing in younger to middle aged groups (20–64 years) then decreasing in the older age group (≥65 years)[13].

In Japan, a study evaluated excessive daytime sleepiness among the general Japanese population through a self-administered questionnaire in 2000[16]. The questionnaire targeted a randomly selected population from 300 communities throughout Japan and focused on sleep habits and sleep problems. The results from the study found that males had a higher prevalence of excessive daytime sleepiness compared to females (male=2.8% and female=2.2% with overall prevalence at 2.5%). The Japanese participants in the study aged 20–49 for both sexes, reported to have the highest percentages of insufficient sleep as well as excessive daytime sleepiness when compared to any other age range, similar to the results from the U.S. BRFSS survey.

It should be noted that commercial drivers are predominantly male, and the use of these surveys and questionnaires have recognized disadvantages including hesitation or unwillingness to share sensitive personal information. Also, the estimates were self-reported rather than through physiological measures of sleep behaviors with actigraphy or polysomnography[17]. Use of physiologic methodologies to measure sleep behaviors lead to loss of autonomy and potential financial burdening dependent on insurance and work.

Shift duration

The distance driven and the shift duration of the driver are frequently referenced factors for OSAS related drowsy driving accidents. Using real world instances and the data presented, it is apparent that the numbers for those dozing/nodding off or falling asleep are unacceptable and need to

be moderated in an concerned effort to protect the population. The bus crash in Gunma prefecture on April 28, 2012 in Japan that left seven dead and 39 injured, is a key example of both major factors playing a role in this instance[18]. The bus driver mentioned and lamented over the fact that "he was overworked, and that he shouldn't have been driving that night because he suffers from sleep apnea."[19] Furthermore, the distance that he drove that night was a major factor, as the company he worked for argued that a relief driver was only necessary if the journey was over 670 kilometers; the stated distance of the trip to Tokyo Disneyland was 540 kilometers[18].

On June 10, 2014 in the United States, a big-rig truck accident killed a man and critically injured comedian Tracy Morgan[20]. In the United States, it has been concluded that drowsy driving is the cause for approximately 1.9 million crashes each year and that 20% of all serious motor vehicle accidents — one out of every five — involve sleepy drivers[6]. The big-rig truck driver had been awake for 24 hours prior to the accident and it is not known why he had not rested prior to starting his shift[20]. Federal law requires long-haul truck drivers to work no more than 14 hours for any shift, with 11 hours of driving. Federal law also requires long-haul truckers to not drive without first taking 10 hours off-duty, and to not drive if their alertness is dangerously impaired through fatigue, illness, or any other cause[20].

Policies Regarding OSAS and Drowsy Driving in the US and Japan

In the United States alone, drowsy driving causes about $12.5 billion in monetary losses yearly according to the NHTSA[7]. Data estimates, such as that provided by the NHTSA, are glaring and highlights the importance of shifting the focus of policy makers at all levels to identifying and subsequently treating those afflicted. At the federal level in the United States, President Barack Obama signed into law a bill that requires the Department of Transportation's Federal Motor Carrier Safety Administration (FMCSA) to use a formal rulemaking process instead of guidance if it wishes to require sleep apnea testing for commercial truck drivers on October 2013[21, 22]. Guidance can be issued without public comment and completely bypasses the formal rulemaking process, which permits public comment before setting guidelines.

However, given the size of the United States and autonomy of each individual state, the limitation on direct federal government intervention regarding OSAS and commercial driving does not prevent each state from generating policies of their own. Currently there are only seven states with laws, resolutions, guidelines, or policies pertaining to drowsy driving in the United States. The states of Arkansas, California, Florida, New Jersey, Pennsylvania, Texas, and Utah have various laws and resolutions in place that stand as blueprints for further development on drowsy driving[9].

The states of Arkansas and New Jersey are the only states that have laws that have a direct impact on drowsy driving by classifying drowsy driving to be on par as a Class-A misdemeanor or as an intoxicated driver. In the United States, a Class-A misdemeanor is the most serious classification of misdemeanor charges. A misdemeanor is an offense that is punishable with jail time of up to a year maximum. Class-A misdemeanors carry fines raging from $500 to $5,000, a year in jail, and potential mandatory rehabilitation programs or community service per judge discretion[23].

An overview of policies and laws in the U.S. and in Japan can be found on Table 1. The states of California, Florida, Pennsylvania, Texas, and Utah have resolutions and or concurrent state commissioned studies that focus on educating the population about the dangers of drowsy driving and the potential causes and treatments available. Overall, there are no federal laws or resolutions that directly identify OSAS and provide a governmentally enforced stringent guideline or policy to reduce potential motor vehicle accidents caused by drowsy driving. The lack of focus on OSAS induced drowsy driving is made apparent in Table 1, as only seven out of the fifty U.S. states have related laws or resolutions; with only two states having laws and five states having some form of resolution or ongoing studies. As Kato *et al.* have estimated the prevalence of OSAS and other sleep disorders at a 24% prevalence in the United States, causing up to 6,000 fatal accidents each year, it is extremely concerning that there are no distinguishable enforced federal laws in place[5, 11].

It should be noted that FMCSA Federal Code 49 CFR 391.41 (b)(5), under the guidance section of regulations, stipulates that the driver; "has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with his ability to control and rive a motor vehicle safely."[33] As OSAS can develop after becoming a qualified driver through lifestyle changes, there may be no established medical history or clinical diagnosis of respiratory dysfunction to prevent them from qualifying to become drivers in the first place. Furthermore, the FMCSA commercial driver fitness application form has the same disadvantages surveys and questionnaires possess. Surveys

Table 1. Acts/Resolutions/Guidelines/Policies regarding OSAS and driving in the U.S.A. and Japan

	Acts/Resolutions/Guidelines/Policies	Summary
U.S. Federal Government	H.R. 3095	To ensure that any new or revised requirement providing for the screening, testing, or treatment of individuals operating commercial motor vehicles for sleep disorders is adopted pursuant to a rulemaking proceeding, and for other purposes[30].
Arkansas	S.B. 874	Classifies "fatigued driving" as an offense under negligent homicide punishable by a Class-A misdemeanor when the driver is involved in a fatal accident has been without sleep for 24 consecutive hours or is in a state of sleep after being without sleep for 24 hours[2].
California	S.C.R. 27	April 6 – Drowsy Driver Awareness Day. Promote awareness of drowsy driving[9].
Florida	Ronshay Dugans Act	First week of September – "Drowsy Driving Prevention Week." Department of Highway Safety and Motor Vehicles and the Department of Transportation focuses on educating the law enforcement community and the public about the relationship between fatigue and driving performance[9].
New Jersey	§2C:11–5	Considers a driver that has been without sleep for 24 hours to be driving recklessly, in the same class as an intoxicated driver[9].
Pennsylvania	H.R. 664	Month of April – "Distracted Driving Awareness Month"[9].
Texas	H.R. 1389	November 6 – 12 – "Drowsy Driving Prevention Week." Educate the motoring public about the dangers of drowsy driving and offer preventative methods to avoid drowsy driving[9].
Utah	State commissioned study	Installation of road signs that warn against drowsy driving and provide information on where drivers can pull over to rest[9].
Japan	Article 3, Article 20 of Truck Transport Safety Regulations. Article 21, Article 48 of Passenger Transportation Vehicle Regulation	Company must check if employee (commercial driving) has any signs or symptoms of illness that may affect their driving ability. Subsequently, the company must decide if employee is able to maintain current position or change to a new one (i.e. decrease hours/driving distance). Company must also perform a pre-departure examination for each shift[24, 25].

and questionnaires often pose questions that could possibly be detrimental to ones potential work opportunities and livelihood. Subsequently, if a question is asked that may disqualify someone from a job opportunity, it will most likely be answered with a lie. This is further insinuated on the actual application form on the "Medical Examination Report For Commercial Driver Fitness Determination" page, where the Medical Examiner's Comments on Health History section notes, "The medical examiner must review and discuss with the driver any "yes" answers and potential hazards of medications, including over-the-counter medications, while driving. This discussion must be documented below." It is mandatory by the report to elaborate on any "yes" answers but not for "no" answers[34].

Japan is very similar to the United States, as it also lacks any real enforced law or policy that highlights OSAS and drowsy driving. The regulations active in Japan are focused primarily on companies taking the charge for enforcement rather than the government itself. To enlighten the transportation industry, the Ministry of Land, Infrastructure and Transport distributed a Sleep Apnea Syndrome (SAS) manual along with an official notice to relevant bodies all over Japan in March 2003[24]. The regulations focus on company vigilance in the checking of employee driving fitness and finding potential alternatives for the employee should the need arise[25, 26].

Polysomnography (PSG) is recognized to be the gold standard for case finding and identifying various sleep disorders such as OSAS, but in Japan much more cost-effective and feasible case finding methods that have proven to be effective in identifying OSAS in research studies, such as pulse-oximetry and flow sensor[27, 28]. Due to the vast majority of the Japanese population not classified by international BMI standards to be obese, the flow sensor method in particular has shown to be an effective case finding method in Japan; due to its ability to better estimate respiratory disturbance events during sleep in non-obese persons than pulse-oximetry. Additionally, flow sensor usage has shown to be feasible as well due to its easy applicability, high reproducibility, and relatively high agreement with polysomnography results[27]. Due to the largely underestimated focus on OSAS induced drowsy driving and drowsy driving overall among commercial drivers, diagnostic methods such as PSG, are not heavily focused upon throughout this article.

Discussion

The varying factors referenced throughout the article focuses on the lack of regulations in evaluating and subsequently treating OSAS. Case finding as a primary means to identifying those at an increased risk for potentially having

OSAS would most likely decrease motor vehicle related fatalities, injuries, and property damage. With obesity being widely recognized as major risk factors for OSAS, it has been highlighted that BMI or weight alone are not enough in identifying those at increased risk. More case finding utilities and guidelines that supplement BMI readings must be enforced as well. The noticeable increase in sensitivity when supplementary BMI assessment is used to detecting OSAS, such as neck and abdominal measurements, reinforces the importance of the readings overall. While at the same time, utilizing universal guidelines such as the international BMI criteria causes specificity to decrease; furthermore supporting the shortcomings of relying on BMI as a sole means of testing for OSAS.

The differences in ethnicity also play a factor as BMI and obesity levels are far below international standards in Asia. The severe OSAS occurrences in Asians due to the differences in craniofacial anatomy is definitely something of interest but not something that can be necessarily changed through policy. Therefore, case finding that utilizes a multitude of factors, such as neck circumference and blood pressure elevation assessments, can much better identify those at higher risk of having OSAS and serve as a more realistic method in controlling the rise in damages and loss of life due to motor vehicle accidents.

Furthermore, while not statistically significant, findings have established that males (5.8%) have a higher prevalence of falling asleep or nodding off while driving than females (3.5%). Seeing as males are the predominant sex in commercial driving occupations, it is not too surprising that males are more commonly associated with having OSAS and drowsy driving[2, 29]. More studies need to be done on female commercial drivers in order to get a clearer picture of the spread of OSAS on the commercial driving population as a whole. Also, those aged between 25 and 45 had the highest percentage of nodding off or falling asleep while driving in the past month than any other age range should be noted. That age range may highlight risk factors such as increased alcohol intake, shorter sleep duration due to longer night activity, overall drive duration, or tobacco usage as factors worth researching in regards to OSAS.

As studies and research continue to come through regarding OSAS and drowsy driving, it becomes increasingly important to note the severity of this issue. When real world accidents such as the disastrous Gunma prefecture night bus trip in Japan take place, the lack of policy regarding OSAS and drowsy driving demonstrate the significance of policies/guidelines on sleep disorders. Government entities and companies should be working with a concerned effort to better prevent instances like that from happening again or ever happening in the first place. Emulating what is being done in the European Union (EU), patients with untreated sleep apnea are considered unfit to drive but are able recover their driving capacity after physician's consent. The EU system is based on symptom control and compliance with treatment, which is something that potentially can be implemented for commercial drivers in the U.S. and in Japan. However, keep in mind that this physician based clearance method is utilized in only seven of the current twenty-eight member EU[30].

Sleep hygiene as well as the distance and duration of commercial drivers shift should always be taken into consideration. Recognizing the work schedule of employees and not basing company policy on distance alone is just as important as not utilizing BMI as sole indicator for OSAS. OSAS is identified by the presence of multiple criteria that include BMI. Identifying various factors that may affect driving performance by their employees should be the focus when creating company policy. Enforced regulation and a focus on case finding as a primary means to identifying, evaluating, and subsequently treating OSAS is paramount to preventing OSAS related vehicular accidents.

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