New Standards and Guidelines for Drivers with Obstructive Sleep Apnoea syndrome

Report of the Obstructive Sleep Apnoea Working Group

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Legal notice

This document reflects the consensus of experts who gathered to discuss the difficult issues contained herein. Consensus is generally defined as the majority opinion or general agreement of the group. In that vein, it should be noted that consensus does not mean that all of the participants unanimously agreed on all of the findings and recommendations. This report is based on publicly available data and information. The report reflects the views of a panel of thoughtful people who understand the issues before them and who carefully discussed the available data on the issues.

Glossary

OSA: Obstructive Sleep Apnoea

MVAs: Motor Vehicles Accidents

AHI: Apnoea-Hypopnoea Index

EEG: Electroencephalography

PSG: Polysomnography

ODI: Oxygen Desaturation Index

CPAP: Continuous Positive Airway Pressure

ESS: Epworth Sleepiness Scale

BMI: Body Mass Index

MS: Member State

MSLT: Multiple Sleep Latency Test

MWT: Multiple Wakefulness Test

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Abstract

Obstructive Sleep Apnoea syndrome (OSAS) is a prevalent chronic sleep-related disease inducing among other consequences an increased risk of Motor Vehicle Accidents (MVAs). The disease has been well characterized in the last two decades, but the effects of the disease on road traffic accidents have only been thoroughly confirmed in recent years. OSAS has not been included up to now in the list of diseases linked to driving risks, as listed in the Annex III of the Directive 2006/126/EC. According to the growing evidence, the driving licence committee established in 2012 a Working Group on OSA. This group has developed three main aspects of the problem, with the aim of making it possible to introduce OSA in the Annex III in the near future.

The Working Group has identified the population at risk, and has proposed to address all applicants for a driving licence, at the start and at each renewal period. A screening strategy has been devised, composed of simply available objective data, mainly anthropometric, complemented by questions on the presence of recent MVAs, of symptoms and complaints frequently associated with OSAS, and a questionnaire assessment of daytime sleepiness. This provides a simple semi-quantitative analysis of the probability of the applicant being afflicted by OSAS, thus needing a complementary medical advice procedure before an unrestricted licence can be delivered.

A series of different decisions on the delivery of the driving licence has been proposed according to the individual situation of the applicant, whether a diagnosis of OSAS is established, or a simple suspicion that the disease might be present, whether a treatment is available and complied with, whether disabling symptoms are controlled or not. The proposal also includes recommendations on the appropriate diagnostic expertise and technology required to offer sound guidance to the administrative authorities.

The Working Group has identified present information and education gaps that should worth be filled in order to enhance the awareness on the relation between OSAS and MVAs, and contribute to the preventive efforts to reduce the rate of MVAs. These efforts should address professional drivers and their employers, as well as police officers in charge of filling in the official forms required in case of MVAs with property damage or personal injuries. The aim in this context is to better assess the possibility of accidents being due to the driver having fallen asleep at the wheel, in order to improve the statistical information on accidents and sleepiness.

- OSAS is a high risk factor for MVAs
- The present recommendations apply to both Group 1 and Group 2 drivers
- Screening for OSAS before receiving or renewing a driver licence is based on responses to questionnaires and a short list of anthropometric data
- If screening reveals a high suspicion of OSAS, a medical advice will be required

Introduction

Accidents are infrequent events arising generally through the concurrent occurrence of several different causes. Accidents are difficult to predict, because despite the conjunction of many causes, a real accident does not necessarily happen.

Although a single individual accident is a rare occurrence in any human activity, the exposure to the risk of an accident depends on the frequency of a particular activity, and increases with its prevalence. Driving a motor vehicle has become a most common human activity, exposing millions of individuals every day to the risks of a motor vehicle accident (MVA).

Although the prediction of the occurrence of an accident is difficult if not impossible, there are known events that increase the risk of having a MVA. The speed of the vehicle is one of such risk factors, that authorities try to reduce whenever they aim at reducing the rate of MVAs.

Human behavior may represent another risk factor. There are specific characteristics pertaining to the driver that increase the likelihood of having a MVA. People who drive after having consumed alcoholic beverages will incur more frequently a MVA than people who did not drink, whatever the baseline driving abilities and experience of the drivers.

Human diseases are another well-known risk factor. Several diseases are associated with a raised prevalence of MVAs when compared to the general population. Diabetes, cardiovascular diseases, cerebral-vascular diseases, psychiatric conditions, uncorrected visual defects, obesity are linked to a higher risk of having a MVA. This is not to say that a given individual driver suffering from any of the above ailments will necessarily have a MVA. It simply states an association between the fact of pertaining to the group of drivers suffering from the disease and observing more MVAs in this group of drivers than in fellows not having the disease, independently of the driving experience and skills of any individual member of the group.

It is based on these associations that the legal licensing authorities have decided to restrict partially or totally driving privileges of those potential drivers suffering from these known causes of an increased accident risk. Each country has elaborated its own list of diseases that may limit obtaining a normal unrestricted driving licence. If a driver declares to suffer from a disease included in the list, he/she may need to demonstrate that corrective measures were adopted, or that despite the disease his/her ability to drive is not jeopardized before an unrestricted driving licence is issued. Authorities may limit the validity of the licence, or its extension.

Inasmuch as driving allows rapid long-distance travel, involving easy crossing of Member States' boundaries, a driver with unrestricted driving licence may find himself driving in a Member State where he would receive a restricted driving licence, or even where he would not be allowed to drive at all.

To circumvent this potential problem in a large geographic area with many borders, the European Union has issued a basic document that constitutes a minimum set of rules that every Member State needs to abide by. A first Directive on driving licences was issued in 1980, including minimum requirements on fitness-to-drive. It was subsequently replaced in 1991 by the 2nd driving licence Directive, Directive 91/439/EEC and lastly in 2013 when the 3rd driving licence Directive, Directive 2006/126/EC, fully entered into force. Annex III of the Directive introduces the minimum requirement as regards medical conditions. However, Member States may introduce more stringent rules in their National Legislation. The updated Annex III includes a list of disabilities (see Annex 1) most of them already present in the 1991 version. Annex III defines two groups of drivers: group 1 comprises drivers of vehicles of motorcycles and cars (categories A and B) and group 2 includes mostly professional drivers, i.e. drivers of lorries and buses (categories C and D), but may also include, depending on national legislation, drivers of category B vehicles using their vehicles for professional purposes (e.g. taxis and ambulances).

Obstructive Sleep Apnoea syndrome and MVAs

Obstructive Sleep Apnoea syndrome (OSAS) is a disease characterized by repetitive episodes of upper airway (i.e. the throat) obstruction with breathing interruptions lasting more than 10 seconds in patients without upper airway defects. Apnoea in these patients only develops during sleep, because of the sleep-related loss in muscle tone that maintains the airway open during wakefulness. Apnoeas cause falls in blood oxygen saturation with a consecutive decrease in the normal tissue oxygenation; they are also associated with surges in blood pressure and heart rate, and disrupt the normal sleep continuity. As hundreds of apnoeas present each night day after day, week after week, and month after month, clinical consequences arise. These include arterial hypertension, insulin resistance favoring diabetes, arteriosclerosis, daytime sleepiness and memory and cognitive deficits. In the long term, these lead to myocardial infarctions, stroke and premature death.

The relationship between Obstructive Sleep Apnoea syndrome, a disease described in the 70's, and MVAs became evident by the turn of the century. Several studies from countries as dissimilar as Spain, Canada, USA, Germany, France, Switzerland, Japan, Australia, the UK, with different climates, driving cultures, traffic densities and geographical characteristics coincided in showing an increased risk for MVAs among patients with Obstructive Sleep Apnoea syndrome.

Some studies found a threshold value of severity of the disease (generally measured as the Apnoea-Hypopnoea Index or number of breathing interruptions per hour of sleep) above which the risk increased. Other studies failed to find such a threshold. Very few studies established a dose effect relationship between symptoms (meaning more MVA's as the severity of the disease increases), especially daytime sleepiness or sleepiness at the wheel, and occurrence of MVAs. Some authors compared the risk of drivers with Obstructive Sleep Apnoea syndrome to that of a control group, others to the risk of the general population of a large geographic zone. Some studies took into account possible confounding factors, such as the frequency of driving (distance driven per year), the presence of visual defects, alcohol consumption, or of obesity. Some studies focused on prospective assessment of an epidemiologic sample, others on actual accidents detected at Emergency Rooms. Some authors relied on subjects declarations; others verified the occurrence of MVAs from Police registries.

Diagnosis and characterization of OSAS

The diagnosis of OSAS is based on the recordings during sleep of some signal of air flowing in and out of the nose and/or mouth (generally nasal pressure is recorded). If airflow stops for more than 10 seconds, an apnoea is identified. Recordings of respiratory movements of the thorax allow to classify apnoeas as central (there is no flow and no respiratory movements, i.e. the subject has stopped breathing) or obstructive (there is no flow but respiratory efforts persist, i.e. there is an obstruction between the nose/mouth and the lungs at the level of the throat or pharynx). Hypopneas are episodes of at least 10 seconds duration where some air still flows, but not enough to insure adequate renewal of lung fresh air. Both apnoeas and hipopneas will lead to a drop in the oxygen content of the lungs that will become unable to adequately transfer oxygen to the blood, with a consequent drop in oxygen blood content. The recording usually includes an oxygen sensor at the tip of a finger, reflecting the fact that during an apnoea all tissues of the body will be exposed to insufficient levels of oxygenation to grant normal cell functioning. Many diagnostic systems offer the assurance that the subject is sleeping, by recording the electrical activity of the brain, the electroencephalogram (EEG). This is called Polysomnography. The most complete polysomnography records also the heart rhythm, muscle tonus, eyes movements, snoring sounds and legs movements. Other simpler systems assume that a full night recording is performed while the

subject sleeps, without measuring sleep itself. Some very simple systems rely on just the recording of blood oxygen content, an oximetric recording. This allows the determination of the number of oxygen drops per hour of recording, termed the Oxygen Desaturation Index, or ODI. It is generally accepted in the medical field that the presence of more than 15 obstructive apnoeas or hypopnoeas per hour of sleep (this is termed the apnoea-hypopnoea index, AHI) every night for years will result in unfavorable health consequences including high blood pressure, myocardial infarction or stroke, in addition to complaints of unrefreshing and restless sleep, daytime sleepiness, loud habitual snoring.

All these studies came up with significant increased rates of MVAs in patients with Obstructive Sleep Apnoea syndrome. The increased risk could be observed for single or multiple accidents and near-missed accidents. The strength of the association between the disease and accidents was variable from one study to the next.

Two meta-analyses have been performed in recent years on this literature, concluding on a risk increase for MVAs of 2 to 3 times (200 to 300%) that of the general public. This is similar or higher than most other diseases included in Annex III. For example, in 2003, and within the scope of the « IMMORTAL » project funded by the European Commission, Truls Vaa performed a first meta-analysis of published studiers relating medical conditions and motor vehicle accidents. The relative risks of accident involvement in drivers with a medical condition were found as follows:

Vision Impairment confers a relative risk of 1.09 (meaning 9% more accidents than the general population)

Hearing impairment: 1.19

Arthritis/locomotor disability: 1.17

Cardiovascular Diseases: 1.23

Diabetes Mellitus: 1.56

Neurological Diseases: 1.75

Mental Disorders: 1.72

Alcoholism: 2.00

Drugs and Medicines: 1.58

Renal disorders: 0.87

All these Relative Risks were statistically significant, except for Renal Disorders.

The relative Risk for Sleep Apnoea/Narcolepsy was 3.71, and most of it was due to Sleep Apnoea.

Several authors have assessed the effect on MVA of the treatment of Obstructive Sleep Apnoea syndrome with an efficient therapy, generally Continuous Positive Airway Pressure (CPAP). These studies used a before-after comparison strategy, with some including a separate group of healthy controls. The treatment resulted in significant decreases, or even normalization, of the risk of MVAs in almost all studies.

The treatment of OSAS

The standard treatment for Obstructive Sleep Apnoea syndrome, the most common presentation of the disease, is to blow air into the nose at a slight positive pressure in order to push apart the walls of the throat, allowing breathing to proceed unimpeded. This is called Continuous Positive Airway Pressure, or CPAP. It is applied with a light-weight nasal mask kept in place with elastic straps and connected through a wide bore tube to a silent flow generator, a small turbine delivering air at positive pressure. The level of pressure needed by a particular patient can be determined during treatment trials by various methods, until the desired pressure is reached that suppresses all apnoeas and hipopnoeas and allows normalization of breathing and sleep.

In Annex 2 are mentioned the references of studies devoted to the relation between Obstructive Sleep Apnoea syndrome and MVA risk, as well as those assessing the effects of CPAP on the risk of MVA.

Obstructive Sleep Apnoea syndrome and Annex III of the Directive on Driving Licence

Given the findings of a significant risk for MVAs in drivers with Obstructive Sleep Apnoea syndrome, the Committee set up under Directive 2006/126/EC on driving licences agreed to gather a working group to propose adding Obstructive Sleep Apnoea syndrome to the Annex III. A specific questionnaire was designed and sent to all Member States (MS) to obtain a baseline picture of the national legislations on driving licence and Obstructive Sleep Apnoea syndrome in the different countries of the European Union.

Most MS responded. The full questionnaire and the summary of responses are included in Annex 3. The responses show that a sizeable minority of Member States have included OSAS into their national legislation, but that the majority still ignores this cause of motor vehicle accidents. Many MS consider that OSAS could be tackled through other headings, without

specifically referring to it. Rather inconsistently, many MS stated in their answers that OSAS constituted a limitation to driving licensing. Only four MS included questions referring to OSAS in their driving licence forms. The presence of hypertension was sought for by a majority of respondents in all driving licence applicants. In case of renewal, almost no MS made an inquiry into recent MVAs. Again, rather inconsistently with the absence of specific reference to OSAS in most MS, the treatment of the disease was said to condition the lifting of a restriction to drive. Most MS do not require medical practitioners to declare OSAS diagnosis to public authorities, and only one MS includes a questionnaire on sleepiness on its forms. Only 4 MS have put in place public campaigns on OSAS and the risk of MVA targeting both drivers and the medical profession. Five MS consider OSAS as a neurological disease whereas nine MS include it in the context of respiratory diseases. Some MS refer to OSAS as both a neurologic and a respiratory condition; others have a specific Sleep Disorders section, still one other includes OSAS as an otorhinolaryngological disorder.

Three main aspects have been developed by sections of the working group:

1.- Identification of the target population and screening strategy

2.- Driving Licence Issues

3.- Education, information, awareness

These are presented in the following chapters, with a brief background and several proposals that should allow the inclusion of Obstructive Sleep Apnoea syndrome in the Annex III of the Directive.

The Working Group members are well aware that our level of knowledge on OSAS is incomplete, that many issues are yet unsolved, that in a disease like Obstructive Sleep Apnoea syndrome (like in many others), the influence of the disease on MVAs will depend on many variables, not the less of them the compensatory physiologic mechanism that will enter into play, the presence or absence of comorbidities, the lifestyle and others. This will inevitably introduce uncertainty into the recommendations that can be formulated on the issue of driving in OSAS. Nevertheless, the increased risk for MVAs in drivers with OSAS cannot be ignored. The proposals here formulated constitute a trade-off between our knowledge and our ignorance.

Chapter 1

Defining and Guidelines for the Screening of Populations at Risk of Obstructive Sleep Apnoea syndrome

Patients with Obstructive Sleep Apnoea syndrome have no particular physical trait that may allow identifying them as such. It affects males and females (admittedly more the former, but the latter are no rarity), young and elderly subjects (admittedly more the latter than the former, but young patients abound), obese as well as lean subjects (the relation of OSAS with body weight remains of course valid, but does not at all preclude the presence of the disease in a sizeable proportion of non-obese patients).

The assessment of obesity

The usual assessment of obesity relies not on the weight, but on the Body Mass Index (BMI), which takes into account both the weight and the height of the individual. It is calculated as the ratio between the weight (measured in kilograms) divided by the square of the height (measured in meters). Obesity is defined as a BMI equal or higher than 30 kg/m^2, overweight as a BMI between 25 and 29.9 kg/m^2, whereas the normality corresponds to a BMI between 20 and 24.9kg/m^2). A BMI of 35 kg/m^2 or higher defines morbid obesity.

The symptoms of OSAS are not specific of the disease. Loud frequent snoring, one of the most prevalent symptoms, is by far more frequently found in simple snorers than in patients with OSAS. Daytime sleepiness or fatigue, considered a usual symptom of OSAS, may be absent in a large proportion of patients whereas it can present in many people that do not suffer from OSAS. Hypertension, an associated disease that can be considered as a marker for OSAS, is very prevalent in the general population. Only resistant hypertension, a condition where more than two classes of drugs are needed to keep arterial pressure at or near normal values, seems to be particularly associated to OSAS.

The level of severity of the disease giving rise to an increased risk for MVAs is not well defined. The studies that found a threshold for the risk point to moderate or severe OSAS (meaning an apnoea-hypopnoea index greater than 15), but other studies have found neither a threshold nor a relationship between severity and risk.

The different degrees of severity of OSAS

Like any other disease, OSAS may be mild, moderate or severe. It is generally assumed that mild disease may give rise to complaints or symptoms (like loud habitual snoring) but will not lead to untoward health consequences. By contrast, moderately severe disease will affect health, even in the absence of symptoms, and this will be more prominent in severe disease. Mild disease is usually defined with an Apnoea-Hypopnoea Index between 10 and 15 events per hour. An AHI of 16 to 29 events per hour characterizes a moderate disease, whereas severe OSAS is defined by an AHI of 30 or more events per hour.

It may be relatively easy to define driving licence rules for drivers diagnosed with OSAS, but the problem is much more complicated when the diagnostic status of the driver is unknown. In other words, when the driver himself is not aware that he is afflicted by a disease that can impair his ability to safely drive. It is therefore desirable, in order to identify those applicants that might suffer from OSAS without being aware of this, to design a screening strategy with simple, robust and widely applicable methods. Unfortunately, such instruments are not easy to apply in large groups of subjects and the solutions that may circumvent the problem remain not fully satisfactory.

The administrative organization of the driving licence issuing offers, despite the above noted problems, repeated opportunities to detect a set of elements that may orient the identification of a candidate driver potentially cumulating several risk factors for OSAS, and alerting the candidate himself and the authorities to the need to clarify the diagnostic dilemma. Indeed, the driving licence needs periodical renewals, and each of these may serve to obtain objective (like body weight) and subjective (like sleepiness) data likely to pinpoint a candidate needing a more thorough assessment of his status regarding OSAS.

It may be feasible therefore to construct a minimal set of questions that candidate drivers should answer at each renewal and that would allow to class applicants in a “safe” category from the point of view of OSAS risk, and an “undetermined” category where a medical advice is worth obtaining before a decision on driving licence delivery is reached by the administrative authorities.

Defining the population at risk

The question refers to the best approach to adopt considering the large prevalence of OSAS, its chronic nature and the role attributed to daytime sleepiness as the link between the disease and MVAs.

Obstructive Sleep Apnoea syndrome affects about 2 to 4 % of the adult population. Severe OSAS (i.e. an AHI of 30 or more events per hour) may represent more than 1% of the adult population. The disease does not seem to spontaneously regress or improve, and the best available treatment (CPAP) is only symptomatic and does not cure the disease, so that once a patient is diagnosed, he will remain afflicted with the disease for long periods. Thus, the chances to find a candidate driver with severe OSAS are rather high. Most candidate drivers pertain to Category 1 drivers, i.e. private drivers whereas Category 2 drivers constitute a minority of candidates. Although the latter are much more individually exposed to MVAs than the former, because they drive much more kilometers per year, the numbers of private drivers makes them, as a group, the largest population at risk for an MVA. It has been shown that professional drivers have fewer accidents per kilometer than private drivers. Thus, their expertise more than compensates their excess exposure to the risk.

There are other sleep-related diseases beyond OSAS that lead also to an excess risk for MVAs. The best example is narcolepsy, a disease characterized by sudden irresistible sleep episodes with sleep starting in the paradoxical state or REM sleep, with loss of muscle tonus. However, narcolepsy is a rare disease, with prevalence in the 0.01% range, making it an exceptional finding in the line of driving licence candidates.

It seems therefore preferable to screen every candidate to the driving licence rather than restrict screening to a subcategory of candidates, this implying that there are categories where the chances of finding someone afflicted with OSAS would be small, a notion for which evidence is lacking.

Components of a screening strategy

A screening program should be based on objective data completed by the presence of symptoms or complaints frequently found in patients with OSAS. The easiness of obtaining these data is of the upmost importance since the screened population is vast, and the annoyance of the screening should be kept minimal. Five objective elements are easily obtained: the gender, age, weight and height, and the existence of recent MVAs involving injuries or property damage that needed Police reports. The complaints and symptoms to be assessed should concern the frequency and intensity of snoring, the

presence of breathing pauses as identified by bed partners or witnesses, the restorative quality of sleep, the presence of daytime sleepiness, especially if this happens while driving and the diagnosis of arterial hypertension. Most questions can adopt a YES/NO/DON'T KNOW approach whereas daytime sleepiness can be explored using the Epworth Sleepiness Score.

The evaluation of daytime sleepiness, the Epworth Sleepiness Scale

Assessing the presence of daytime sleepiness can be as easy as to ask someone whether he feels hard times staying alert during the day, or whether he feels somnolent during daytime to the point of interfering with daily life activities. Things become more complex if one tries to quantify how much somnolent a person is, and even more if one tries to compare the somnolence of two different persons. To try to standardize the evaluation of sleepiness, most specialists turn to one or another questionnaire with stereotyped questions and a small number of possible answers. This limits the richness of the qualitative description of the sensation, but insures a more easy way to classify the strength of the sensation among different persons and even at different times in a given person. Most physicians interested in OSAS have chosen the Epworth Sleepiness Scale or ESS to assess daytime somnolence. It is an 8 items questionnaire with 4 possible answers per question valued from 0 to 3. Thus a total of 24 points is the maximum sleepiness level. Normal subjects have a mean ESS of 10 and a value of 11 is considered as mild abnormal daytime sleepiness, whereas a score of 15 or higher is considered as severe somnolence.

Proposed questionnaire to screen for OSAS

1. Gender
2. Age
3. Weight
4. Height
5. Did it already happen to you to doze off while driving? YES NO DON'T KNOW
6. Did you have a serious accident (with personal injuries or property damage) due to sleepiness in the last 3 years? YES NO DON'T KNOW
7. Do you usually snore loudly almost every night? YES NO DON'T KNOW
8. Have you been told your breathing stops during your sleep? YES NO DON'T KNOW
9. Do you usually wake up refreshed after a full night sleep? YES NO DON'T KNOW
10. Do you suffer from, or are you being treated for, Arterial Hypertension? YES NO DON'T KNOW
11. Please complete the questionnaire on usual daytime sleepiness, called the Epworth Sleepiness Scale, on the next page

All questions have a YES/NO/DON'T KNOW type of answers.

Interpretation:

The questions are attributed a value, reflecting the strength of the association between a given answer and the risk of MVAs or the possibility of suffering from OSAS, as well as the level of uncertainty concerning this strength. This is based on a consensus minimal agreement among the members of the working group.

Q. 1: Female =1; Male =2

Q. 2: Age below 30 yo= 2; Age 31 yo or above= 1

Q. 3-4: A BMI below 30 kg/m²= 1, 31-35 kg/m²= 2; 36 kg/m² or higher= 3

Q. 5: A positive answer= 3; negative answer= 0; don't know= 2

Q. 6: A positive answer= 4; negative answer= 0; don't know= 3

Q. 7: A positive answer= 2; negative answer= 0; don't know= 1

Q. 8: A positive answer= 1; negative answer= 0; don't know= 0

Q. 9: A negative answer= 2; positive answer= 0; don't know 1

Q. 10: A positive answer = 2; negative answer = 0; don't know = 1

ESS: From 11 to 14= 2; 15 or higher: 4

The maximal possible value for this *sui generis* questionnaire is 24. A male middle-aged obese male has already a value of 5 or 6 (depending on the level of obesity) from the start. If he has 3 characteristics linked to OSAS (questions 7, 8, 9 and 10), he will score 10 points. If he has previous MVAs or probable sleep episodes at the wheel, he will score 8 or 9 points, and if he is mildly sleepy or has some evidence of sleep apnoea syndrome, he will also reach the 10 points value.

If the result is **10 or higher**, screening is defined as positive and a medical advice should be required before a decision is reached on the driving licence to be delivered, as specified in Chapter 2.

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Note: These recommendations are based on the work of Section 1 of the Working Group..

Chapter 2

Driving Licence Issues

A driver afflicted by Obstructive Sleep Apnoea syndrome has an increased risk of motor vehicle accidents, especially if the disease is moderate to severe. When associated with relevant daytime symptoms, particularly excessive sleepiness, an AHI between 15 and 29[1] defines a moderate disease, whereas an AHI of 30 or more[2] defines a severe disease[3]. The notion of severity refers to a compound of symptoms and clinical consequences, including comorbidities (arterial hypertension, obesity, diabetes, myocardial infarction or stroke) and MVAs. Severe disease results also in a decreased survival.

The relation of this clinical evidence with driving risks may adopt different aspects: the attitude to be taken with a candidate driver with untreated moderate to severe OSAS is not necessarily the same as with a candidate driver with mild OSAS. If the candidate driver is following a treatment, the attitude could depend on the type of treatment.

The matter is complex, and the rules should not disregard the fact that for the same degree of severity of the disease, the symptoms (such as excessive sleepiness, to which most of the MVAs risk is attributed) may differ from one person to the next. For instance, the conjunction of OSAS and chronic sleep restriction or shift work, a common occurrence in the modern society, may give rise to a heightened level of excessive sleepiness and lead to a further increase risk of MVAs.

Patients with OSAS may be offered several types of treatment with different degrees of efficacy that may fully or only partially restore a normal level of vigilance, and normalize the risk for MVAs. Even if a treatment is theoretically capable of abolishing the increased risk of MVAs, the patient needs to comply with the treatment in order to obtain its benefits. The attitudes to be defined once a driver with untreated OSAS is treated should take these issues into account.

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[1] i.e. between 15 and 29 apnoeas/hypopnoeas per hour of sleep.

[2] i.e 30 apnoeas/hypopnoeas or above per hour of sleep.

[3] Flemons, WW; Buysse, D;Redline, S; Pack, A; Strohl, K; Wheatley, J; Young, T; Douglas, N; Levy, P; McNicholas, W; Fleetham, J; White, D; Schmidt-Nowarra, W); Carley, D; Romaniuk, J. Sleep-related breathing disorders in adults: Recommendations for syndrome definition and measurement techniques in clinical research. *Sleep* 1999; 22:667-689.

A different situation arises when a candidate driver has not received a diagnosis of OSAS, but he presents some or several risk factors for a diagnosis of OSAS, as recalled in Chapter 1. What kind of decision should be taken while the medical situation is clarified?

The group dealing with these issues has performed a thorough critical analysis of the evidence found in the literature and of the foreign experience in countries that have already dealt with OSAS in relation to motor vehicles driving, and has come up with a series of proposals that are detailed below.

Specific Standards for driving licence delivery in OSAS

Specific recommendations for Driving Licence and medical advice

1. For driver candidates who have been identified as **positive in the screening questionnaire** to obtain or renew the driving licence:

1.A - A medical advice is required that will either exclude or confirm the presence of moderate to severe OSAS

1.B - A driver candidate suspected of being affected by OSAS may receive a conditional driving licence for a limited time until a definite diagnosis is established

2. For driver candidates who have been **diagnosed with OSAS** and want to obtain or renew the driving licence

2.A - A driver candidate with a diagnosis of OSAS needing treatment in the opinion of his physician and who, for any reason, is not treated, should not receive an unconditional driving licence.

2.B - A driver candidate with a diagnosis of OSAS needing treatment in the opinion of his physician and who is effectively treated according to usual medical standards should receive a driving licence as long as treatment is necessary and complied with.

2.C - The need for, and compliance with, treatment should be subject to medical review at intervals not exceeding 2 years for drivers of Group 1, and 1 year for drivers of Group 2.

In all cases the criteria for diagnosis and treatment as well as the recommendations for fitness in driving vehicles will be made preferably by an accredited sleep laboratory or a certified sleep specialist

The responsibility for determining fitness to drive a vehicle (including a conditional licence) depends ultimately on the competent administrative authority in each Member State with decisions supported by medical reports and recommendations of specialized physicians or structures.

Patients will receive verbal and written information on their situation with regards to their control of the disease and they will be invited to report such information to the authorities competent for driving licence delivery.

Commercial vehicle drivers who are diagnosed with OSAS and require treatment are advised to have annual review by a sleep specialist whereas for non-commercial vehicle drivers the review will be every 2 years.

Annex 4 summarizes recommendations that may help medical practitioners assess and advise driver candidates concerning their status as far as OSAS is considered.

Note: These recommendations are based on the work of Section 2 of the Working Group..

Chapter 3

Complementary Measures, centered on Education and Information addressed to specific groups of interest.

Although the specialized medical realm is nowadays generally aware of the existence and health implications of OSAS, there are sectors of the public that are concerned with OSAS, especially in relation with MVAs, and lack appropriate information. A group that would benefit from gaining information on issues relevant to driving and vigilance is the group of professional drivers. They could receive information on OSAS and MVAs, but also on general notions on vigilance and sleep, the consequences of sleep restriction and of chronic sleep debt on alertness, as well as the effects of medications (such as pain killers or antihistamines) and alcohol on driving ability. According to Directive 2003/59/EC, professional drivers are required to follow a program of continuous education that could be enriched with a chapter on OSAS and sleep.

In order to improve and facilitate the access of professional drivers to this kind of information, their employers should also be offered the possibility to access this type of education program. The implications in terms of accidents, repairs and insurance costs are so huge that owners and administrators of transport companies, both of persons and goods, should be made aware of this.

Similarly, physicians not well acquainted with the notions of sleep medicine could be offered a structured program allowing them to close the gap usually existing between daytime medicine and sleep medicine.

One of the most frustrating issues on MVAs related to OSAS is the lack of information on the characteristics of the accident scene, that might indicate that sleepiness played a causal factor in MVAs. Indeed, throughout the European Union, whenever an accident with injuries or deaths occurs, Police reports are established describing the scene and circumstances of the accident, as far as they can be established. However, in many Member States, sleepiness is not identified as a source of the accidents in the police report and form and most Police officers are not aware of this disease, and even if they were, there is no possibility to collect data around it as it is not yet foreseen in the report format. The European Union, via the Directorate for Mobility and Transport could propose a periodic education program for Police officers and staff involved in accidents reporting which would achieve

a better and more complete collection of statistics on sleepiness as a causal factor in MVAs.

Suspecting sleepiness as a causal factor in the scene of a MVA

- Direct report from the driver
- Absence of brake marks
- Single vehicle accident
- Rear-end or head-on collision
- MVA during the height of sleepiness hours (13-15 and night hours)
- MVA with injuries or fatalities

Taking all these issues into account, the group dealing with this chapter has put forward a series of recommendations that are detailed below. The full text of recommendations is to be found in Annex 3

Recommendations for actions complementary to the screening of OSAS in candidate drivers and subsequent possible driving restrictions

The primary goal is to disseminate adequate information on OSAS and its relation to MVA to the different groups of interest, namely professional drivers and their employers, medical professionals involved in the assessment of medical conditions in relation to driving licence and Road Police Departments and Police personnel.

The information should be centered on the characteristics and risks of sleep apnoea and the association between OSAS and an increased risk for motor vehicle accidents. In should also include the impact and characteristics of sleepiness during driving as well as the available countermeasures.

The information for professional drivers could take advantage of the periodic training specifically addressed to them (35 hours continuing education every

5 years), by including in the curriculum a section on OSAS, physiology of sleep and vigilance, and sleepiness at the wheel.

Employers of professional drivers could also be included in a program of dissemination of information concerning the physiology of sleep, the influence of circadian rhythms on sleep and vigilance, the effects of chronic sleep restriction on daytime sleepiness, the effects of shift work and night work on sleep and the biological clock. The economic consequences of MVAs in terms of damage to property, repairs and insurance costs should be underlined.

Medical professionals, including general practitioners that might be involved in assessing or counselling a driver candidate in relation to OSAS should find accessible and accurate information on OSAS in particular, but also on the physiology of sleep, sleep disorders in general, their diagnosis and treatment, and the effects of medications on sleep and vigilance.

Police personnel involved in MVA reporting should receive information on sleepiness and falling asleep at the wheel as a potential cause of a MVA, and should be able to assess and inform on this possibility in the official forms to be filled in case of MVA.

Note: These recommendations are based on the work of Section 3 of the Working Group. A complete list of educational contents is shown on Annex 5.

Concluding Remarks

This document justifies the inclusion of Obstructive Sleep Apnoea syndrome among the medical conditions listed in the Annex III to the Directive 2006/126/EC, concerning driving licensing issues. It summarizes the information needed to specify the concerned applicants, the means to close up on the applicants at risk and confirm or exclude the presence of the disease. It suggests the possible actions from the licensing authorities before the diagnosis is made and after that time, to protect the applicant himself and the public by implementing the best adapted decision to the situation of the applicant. It proposes a specific program for professional drivers and their employers. Finally, it enlarges the field of MVA information by proposing to incorporate the notion of sleepy driving in the police reporting.

The document should help the translation of scientific knowledge into legal regulations to be applied throughout the geography of the European Union with the aim of decreasing the number of accidents and of injuries and deaths on the road.

Annex 1

Diseases Included in the Annex III of the Driving Licence Directive

- Diseases affecting Eyesight
- Diseases affecting Hearing
- Locomotor Disability
- Cardiovascular Diseases
- Diabetes Mellitus
- Neurological Diseases
- Epilepsy
- Mental Disorders
- Drugs or Medicinal products abuse
- Renal Disorders
- Organ Transplantation
- Any other disorder affecting safety at the wheel

Annex 2

Main scientific literature on Obstructive Sleep Apnoea syndrome and motor Vehicle Accidents

Casel W, Ploch T, Becker D, Dugnus D, Peter JH, von Wichert P. Risk of traffic accidents in patients with sleep-disordered breathing: reduction with nasal CPAP. Eur Respir J 1996; 9: 2606-2611

Engleman EM, Asgari-Jirhandeh N, McLeof AL, Ramsay CF, Deary IJ, Douglas NJ. Self-reported use of CPAP and benefits of CPAP therapy. Chest 1996; 109: 470-476

Krieger J, Meslier N, Lebrun T, Levy P, Phillip-Joet F, Sailly JC, Racineux JL. Accidents in obstructive sleep apnea patients treated with nasal continuous positive airway pressure. Chest 1997; 112: 1561-1566

Young T, Blustein J, Finn L, Palta M. Sleep-disordered breathing and motor vehicle accidents in a population-based sample of employed adults. Sleep 1997; 20: 608-613

Barbe F, Pericas J, Muñoz A, Findley L, Anto JM, Agusti AGN. Automobile accidents in patients with sleep apnea syndrome. Am J respire Crit Care Med 1998; 158: 18-22

Teran-Santos J, Jimenez-Gomez A, Cordero-Guevara J. The association between slep apnea and the risk of traffic accidents. N Eng J Med 1999; 340: 847-851

Findley L, Smith C, Hooper J, Dineen M, Suratt PM. Treatment with nasal CPAP decreases automobile accidents in patients with sleep apnea. Am J Respir Crit Care Med 2000; 161: 857-859

Horstmann S, Hess CW, Bassetti C, Gugger M, Mathis J. Sleepiness-related accidents in sleep apnea patients. Sleep 2000; 23: 383-389

Masa JF, Rubio M, Findley LJ. Habitually sleepy drivers have a high frequency of automobile crashes associated with respiratory disorders during sleep. Am J Respir Crit Care Med 2000; 1562: 1407-1412

Yamamoto H, Akashiba T, Kosaka N, Ito D, Horie T. ong-term effects of nasal continuous positive airway pressure on daytime sleepiness, mood ansd traffic accidents in patients with obstructive sleep apnoea. Respire Med 2000; 94: 87-90

Mulgrew AT, Nasvadi G, Butt A, Cheema R, Fox N, Fleetham JA, Ryan CF, Cooper P, Ayas NT. Risk and severity of motor vehicle crashes in patients with obstructive sleep apnoea/hypopnoea. Thorax 2008; 63: 536-541

George CFP, Smiley A. Sleep Apnea & Automobile crashes. Sleep 1999; 22: 790-795

Vaa T. Impairments, diseases, age and their relative risks of accident involvement: Results from a meta-analysis. Institute of Transport Economics, Oslo, Norway, 2003.

Barbe F, Sunyer J, de la Peña A, Pericas J, Mayoralas LR, Anto JM, Agusti AG. Effect of continuous positive airway pressure on the risk of road accidents in sleep apnea patients. Respiration 2007; 74: 15-16

Horne JA, Reyner LA. Sleep related vehicle accidents. BMJ 1995; 310: 565-567

Tregear S, Reston J, Schoelles K, Phillips B. Obstructive Sleep Apnea and Risk of Motor Vehicle Crash: Systematic Review and Meta-Analysis. Journal Clin Sleep Med 2009; 5: 573-581

Tregear S, Reston J, Schoelles K, Phillips B. Continuous Positive Airway Pressure Reduces Risk of Motor Vehicle Crash among Drivers with Obstructive Sleep Apnea: Systematic Review and Meta-Analysis. Sleep 2010; 33: 1373-1380

Annex 3

Questionnaire addressed to all Member States on the present status of Obstructive Sleep Apnoea in National Driving Licence Legislation

Q #	Question	Answer	TOTAL/27
1	Is Obstructive Sleep Apnoea (OSA) mentioned in your national legislation on medical conditions for the issuing of driving licences?	NO YES	16 9
1.2.	If OSA is not considered in your National Legislation as such, is there any other section where it could be referred to (such as Sleepiness, Vigilance lapses…) and what is the exact wording?		10
2	In your national legislation is OSA considered as: A neurological disorder, a respiratory disorder or other (please identify…) □	ND RD Other	5 9 12
3	Does the presence of OSA constitute a limitation to driving licensing? NO ? YES? If yes, please describe shortly, if appropriate for each category of driver or vehicle, which restrictions are in place, e.g. prohibition of driving, temporary licence, etc:	NO YES	5 19
4	Is there any questionnaire listing symptoms (for instance loud snoring, witnessed breathing pauses, obesity, and daytime sleepiness) to be filled by the applicant? If such guidance or questionnaire is available, please send a copy or a link to the Commission.	NO YES	20 4
5	Are body weight (kg) and body height (m) recorded on the administrative application form for a driving licence?	NO YES	19 4
5.2.	Does your official documents include a question on diagnosis or treatment of hypertension?	NO YES	10 13
5.3	If the answer is yes, does it concern all applicants or just Group 2 ones?	all applicants group 2 only	13 3

6	For renewal applications, does the administrative questionnaire request the applicant to indicate the occurrence of recent motor vehicle accidents or near-accidents possibly due to drowsiness?	NO YES	20 3
6.2	Does a positive answer to the previous question require a new examination by a medical expert?	NO YES	 2
7	Is the treatment of OSA taken into account as a pre-condition for the issuing, the renewal of a driving licence or before the lifting of a restriction or a prohibition to drive?	NO YES	7 17
7.2	Is there an obligation for a medical practitioner to declare a diagnosis of OSA to the Driving Licensing Authorities?	NO YES	18 5
8	Are private and professional drivers considered alike as far as OSA is concerned in your driving licence legislation? If Yes, please describe the differences.	NO YES	13 6
9	Is a sleepiness questionnaire (for instance the Epworth Sleepiness Scale) included in the administrative application form for a driving licence with a view to measure the level of daytime sleepiness of the applicant? If Yes, please send the copy of the questionnaire.	NO YES	23 1
10	Please indicate if other actions aimed at increasing awareness on OSA, sleepiness or vigilance and driving have been put in place at national level, e.g. incorporation into the national training curriculum for professional driver, information targeting drivers or doctors (information campaigns, leaflets or brochures), etc. If YES (Please send a copy of brochures, leaflets etc.)	NO YES	17 4

* Responses received from: Austria, Belgium, Croatia, Czech republic, Germany, Denmark, Estonia, Spain, Finland, Aland island (Finland), France, Ireland, Lithuania, Latvia, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, United Kingdom, Northern Ireland (United Kingdom) and Gibraltar (United Kingdom).

Annex 4

General Recommendations Regarding OSAS

1. OSAS diagnosis precludes unconditional certification.

2. A driver with an OSAS diagnosis may be authorized to drive if the following conditions are met:

   2A. The driver has untreated mild OSAS with an apnoea-hypopnoea index (AHI) of less than or equal to 15 (mild-moderate OSA), and

   2B. The driver does not admit to experiencing invalidating excess sleepiness during the major wake period (ESS < 15); denies motor vehicle accidents; does not suffer from hypertension requiring two or more agents to control it and BMI is less than 35 kg/m^2)

3. The driver's OSAS is being effectively treated

   3A. A driver with a moderate to severe OSAS diagnosis may be authorized to drive, based on demonstrating compliance with treatment. Minimally acceptable compliance with Positive Airway Pressure (PAP) treatment consists of at least 4 hours per day on 70% of days. The need for, and the compliance with, treatment should be subject to periodic medical review. The periodicity may differ in drivers from Group 1 and Group 2.

4. Drivers with an OSAS diagnosis should be disqualified immediately or denied certification if any of the following conditions are met:

   4A. The driver admits experiencing invalidating excessive sleepiness during the major wake period while driving (Epworth Sleepiness Scale ≥ 15)

   4B. Has had a Motor vehicle accident likely related to somnolence at the wheel.

   4C. Previously diagnosed OSAS not compliant with treatment and non-recent medical follow-up

5. A driver with a diagnosis of OSAS may receive a conditional certification, pending a medical evaluation, in the following cases:

    5A. The driver has been previously diagnosed with OSAS and he declares to be compliant with therapy, but there is no recent medical report

5B. The driver does not have invalidating sleepiness (ESS < 15), he has had no recent motor vehicle accident and his BMI is not greater than 35 kg/m^2

6. Recovery of Driving Licence after treatment

    6A. Adequate positive airway pressure should be established preferably in an accredited sleep laboratory or by certified sleep specialist, through one of the following methods:

        6A1. Titration study with polysomnography

        6A2. Auto-titration system

    6B. A driver who has been disqualified may return to drive if the three following conditions are all met:

        6B1. The driver is successfully treated for 2- 4 weeks, and

        6B2. The driver can demonstrate at least minimal compliance (i.e., 4 hours use per night on 70% of days), and

        6B3. The driver does not report invalidating excessive sleepiness during the major wake period.

7. In professional drivers, the recording on treatment (manual titration or autoCPAP) should lead to a residual AHI of less than10 and to the disappearance of excessive daytime sleepiness.

8. With other treatments like mandibular advancement devices, treatment with surgery or weight loss a sleep study should demonstrate a residual AHI of less than 10 and the disappearance of excessive daytime sleepiness

In some cases with presence of symptoms and always at the discretion of the sleep specialist it may be necessary to perform objective specialized tests measuring sleepiness or restored alertness after treatments (Multiple Sleep Latency Test, Maintenance of Wakefulness Test, Osler Test

Assessment of Sleepiness

Objective assessment of sleepiness is usually performed with the Multiple Sleep Latency Test (MSLT), where a subject is repeatedly asked to nap in a sleep-favoring environment during daytime and the latency to sleep (time necessary to fall asleep since lights are turned off) is repeatedly measured. The ability to stay awake is assessed using the Multiple Wakefulness Test (MWT), where the subject is asked to remain awake while he is exposed repeatedly to a sleep-favoring environment, and the sleep latency is repeatedly measured). These tests are technically difficult, and the simpler Osler Test has also been proposed but with less scientific evidence. It consists on a repetitive boring behavioral task (pushing a button in response to a light flashing) that increases sleep propensity while the subject is asked to remain awake throughout the test.

Annex 5

Information/Education, drivers training, police reporting

Proposal

Recommendations for actions complementary to the screening of OSAS in drivers and subsequent driving restrictions

Primary goals:
- Disseminate adequate information on the OSAS problem to the different populations involved;
- Stimulate the scientific insight and fostering research into the problem of OSAS in drivers;
- Increase the access to adequate diagnosis and treatment of OSAS;
- Proposal of interventions at the level of the infrastructure.

1. **Awareness: promote the awareness in drivers of the association between OSAS and an increased risk for motor vehicle accidents**

   - *Professional drivers and their employers*

     - Subject: the impact and characteristics of sleepiness during driving, characteristics and risks of sleep apnoea

     - Framework: the periodic training of Group 2 (professional drivers; 35 hrs in total every 5 years, with a focus on the awareness of the importance of medical fitness)

     - First proposed action: Include a lecture on risks associated with sleep apnoea in the professional drivers continuing education program *(see **Table 1a**)*

     - Second proposed action: guidelines towards employers of professional drivers (*see **Table 1b**)*

   - *General public*: objective screening for OSAS in all private drivers is not feasible at this time, stressing the need to encourage the awareness of the risks and available treatments of OSAS in the general public

     - Goal: stress the personal responsibility of drivers regarding ones physical and mental condition in the context of OSAS

- Potential strategies: the construction and promotion of a forum providing information on OSAS for private and professional drivers, public campaigns.

2. <u>Stimulating the visibility and scientific insight into the problem</u>

- Explicitly including sleepiness as a causal factor of motor vehicle accidents in police reports
    - Add a section addressing the potential role of sleepiness in motor vehicle accidents to police forms
    - List of details relating to somnolence as a possible cause of motor vehicle accidents (***Table 2***)
- Funding of research projects on the topic

3. <u>Access to diagnosis and treatment of OSAS for drivers</u>

- Include sleep and sleep disorders, especially those disorders negatively affecting driving ability, such as narcolepsy and OSAS, in the educational program of medical doctors
    - Basis in the general medical training
    - Specialist training
        - Proposal of lecture content for medical professionals involved in sleep apnoea diagnosis and treatment ***(Table 3a)***
    - Offer a platform with information on OSAS and the ability to drive to health professionals in general
        - Suggested content
            - Information on sleep apnoea and the associated driving risks
            - Information on the assessment of the ability to drive
            - Information on the legal responsibilities
        - Summary for medical and paramedical practitioners on sleep apnoea and driving risks - cfr Australia, GB (***Table 3b***

- Support the installation and/or the maintenance of sufficient clinical sleep laboratories for diagnosis and treatment of OSAS
    - Staffed with personnel having relevant expertise (see previous paragraph)
    - Goal: minimum 1 clinical sleep laboratory per 100.000 inhabitants
- In relation to professional drivers, promote the development of referral lines from occupational physicians to medical doctors qualified in sleep medicine

4. Interventions at the level of infrastructure

- *Types of countermeasures*
    - Rumble strips
    - Rest areas
    - Visual warnings at the road side reminding the danger of drowsy driving
        - The countermeasures listed have been shown to lead to a substantial crash reduction with high (rumble strips) to moderate (rest areas and visual warnings) confidence (Austroads research report, 2011).
- *Guidelines*
    - Priority for high risk situations, e.g. roads frequently used for long, monotonous drives
    - Based on scientific knowledge in the domain, for instance in cooperation with universities

Table 1a

Contents of a lecture on risks associated with sleep apnoea for professional drivers continuing education program

- **The basics of sleep:**
    - How sleep evolves throughout the night in cycles
        - Each cycle of +/-90 minutes starts with light sleep, goes to deep sleep, returns to light sleep and ends with dream sleep
        - First two cycles: more deep sleep; next cycles: more dream sleep
    - Difference between sleeping during day and night time
        - Sleeping during the night: more deep sleep; sleeping during the day: more dream sleep and more interrupted, less recuperative sleep
    - Effect of a lack of sleep
        - Irritated and negative mood, attention problems, specifically problems in staying alert for new signals in a monotonous situation, short sleep attacks of which one is not always aware
- **Clinical symptoms, characteristics and consequences of obstructive sleep apnoea syndrome**
    - Definition of Obstructive Sleep Apnoea Syndrome (OSAS)
        - As a result of an obstruction of the upper airways during sleep, the air flow to the lungs is blocked, although breathing effort is present. These so-called apnoeas appear five times or more per hour of sleep.
    - Clinical symptoms
        - Main symptoms: excessive sleepiness during daytime, loud snoring and breathing stops during nighttime or unrefreshing sleep
        - Other symptoms
            - During the night: nightmares, frequent toilet visits (polyuria), restless sleep, frequent awakenings and insomnia, transpiration
            - During the day: unrefreshed feeling upon awakening, feelings of exhaustion, sleepiness during driving, cognitive problems (short term memory and attention), mood

disturbances (irritable and depressed mood), morning headache, sexual problems

- Epidemiology
  - More prevalent in men (4-10%) than in women (2-5%)
  - Increased prevalence with aging

- **Drowsy driving**
  - Accidents related to drowsy driving: prevalence and causes of drowsiness
    - Increased risk for people with OSAS (2-4 fold risk), people that snore, people sleeping less than 6hrs daily, people frequently suffering from insufficient sleep
    - Further increase in danger when combining different risk factors: OSAS, lack of sleep, night driving, long distance driving, use of sedating medications
  - Warning signs of drowsy driving
    - Yawning and blinking
    - Impression of driving automatically: difficulty remembering the past few miles driven
    - Missing exits
    - Difficulty in maintaining a steady road position – drifting from one's lane –hitting a rumble strip
    - Difficulty in maintaining a constant speed
    - Nodding
  - Efficacy of different countermeasures
    - Fresh air and music have only very short lasting effects
    - Prevention and proper preparation is the best way to avoid drowsy driving accidents:
      - attention for symptoms of OSAS and seeking treatment if necessary
      - ensure sufficient sleep before the journey
    - In case of sleepiness at the wheel
      - Recognize the warning signs

- Take a break including a short nap of 15-20 minutes to keep you fit for maximum 2hrs
- Look for a place to spent the night and sleep until no longer drowsy
- Change drivers when possible

Table 1b

Guide to employers of professional drivers

- **Sleepiness is involved in about 5-7% of all motor vehicle accidents, with higher prevalence rates around 17% in accidents involving fatalities.**
    - Conditions leading to an increased risk of drowsy driving
        - Commercial driving
        - Working at night
        - Long distance driving
        - Insufficient sleep
        - Presence of an untreated sleep disorder
            - People suffering from OSAS have a 2-4 fold risk for getting involved in a motor vehicle accident.
            - In the general population the average prevalence of the Obstructive Sleep Apnoea Syndrome (OSAS) is about 5%. In the group of professional drivers it is even more prevalent, with estimates ranging from 5 to 50% depending on the severity criteria used (e.g. Tregear et al., 2009).
        - Lack of frequent breaks during driving, including short naps
        - Use of sedating medications
    - A further increase in danger is observed when combining different risk factors: OSAS, lack of sleep, night driving, long distance driving, use of sedating medications
- **Necessary conditions to allow adequate countermeasures to drowsiness, possibly related to OSAS, in professional drivers**
    - Awareness of the problem of drowsiness and driving
        - Both in the drivers as their employers
        - Knowledge of the warning signs for drowsiness by the drivers
    - Having the opportunity to apply adequate countermeasures in the working context (see next paragraph)
    - Employers are advised to address these issues, with a specific focus on OSAS, in the periodic training of professional drivers (see attachment 1a)

- **Efficacy of countermeasures for drowsy driving**
    - Fresh air and music have only very short lasting effects
    - Prevention and proper preparation is the best way to avoid drowsy driving accidents:
        - attention for symptoms of OSAS and seeking treatment if necessary
        - ensure sufficient sleep before the journey
    - In case of sleepiness at the wheel
        - Recognize the warning signs
        - Take a break including a short nap of 15-20 minutes to keep you fit for maximum 2hrs
        - Look for a place to spent the night and sleep until no longer drowsy
        - Change drivers when possible

Table 2

List of details relating to somnolence as a possible cause

of motor vehicle accidents

- **Defining characteristics of sleepiness related accidents**
    - Falling asleep at the wheel as reported by the driver involved
    - No brake marks
    - Single-vehicle crash
        - After in-depth analysis, an estimate of 10% of all single vehicle accidents appears to be related to fatigue (Report of the DaCoTa Project, European Commission, Directorate-General for Mobility and Transport)
    - Rear-end or head-on collision
- **Other characteristics of sleepiness related accidents**
    - Frequency of sleepiness related accidents is higher during the night and in the afternoon
    - Sleepiness related accidents are more likely to result in injuries and fatalities

Based on these characteristics, **it is recommended that police reports include the information below** (based on the Austroads research report, entitled "Innovative Road Safety Measures to Address Fatigue: Review of Research and Results from a Treatment Trial").
In combination with information on, among other aspects, the blood alcohol concentration of the driver, this enables the identification of drowsiness related accidents and distinguishing them from non-drowsiness related crashes.

- Does the driver report having fallen asleep at the wheel at the time of the accident? Yes/no/not possible to interview the driver
- Presence of brake marks: Yes/no
- Other evidence of an attempt to prevent the crash: Yes/no
- Single-vehicle crash: Yes/no
- Rear-end or head-on collision: Yes/no
- Time of day of the accident:
    - morning - noon (6:00 – 13:00)

        - afternoon (13:00 – 16:00)
        - evening (16:00 – 24:00)
        - night (24:00 – 6:00)
    - Injuries: Yes/no
    - Fatalities: Yes/no

Table 3a

Minimal lecture content for medical professionals

involved in sleep apnoea

- **Overview of sleep disorders**
    - Classification
    - Insomnia
    - *Sleep related breathing disorders (further parapraphs)*
    - Hypersomnia – central type, e.g. narcolepsia
    - Circadian rhythm disorders
    - Parasomnia, e.g. somnambulism
    - Sleep related movement disorders, e.g. periodic leg movement disorder
    - Isolated symptoms, e.g. long and short sleepers, snoring
- **Physiology and anatomy of sleep and breathing**
    - Neuroanatomy and neurobiology
    - Breathing during sleep and wakefulness
    - Homeostatic regulation during sleep
- **Pathophysiology of the upper airway in obstructive sleep apnoea syndrome (OSAS)**
- **Clinical symptoms and observations of OSAS**
- **Co-morbidity of OSAS**
    - Obesity
    - Diabetes
    - Cardiovascular diseases
- **Other sleep related breathing disorders**
    - Central sleep apnoea
        - Epidemiology and risk factors
        - Pathophysiology

        - Clinical aspects
        - Consequences
    - Hypoventilation syndromes
    - Comorbid respiratory disorders
    - Comorbid nonrespiratory disorders
- **Clinical assessment**
    - Sleep history
    - Differential diagnosis of hypersomnolence, tiredness, sleepiness, fatigue
    - Diagnostic algorithms
    - Sleep questionnaires
    - Surgical and anaesthesia risks
    - Predisposing factors
    - Comorbidity assessment
- **Diagnostic techniques**
    - Polysomnography
    - Assessment of daytime sleepiness
    - Cardiorespiratory monitoring during sleep
    - Actigraphy
    - Capnography
- **Treatment of OSAS: indications, efficacy and application**
    - Patient education including life style modification, sleep hygiene, PAP use
    - Weight loss
    - Positive Airway Pressure (PAP)
    - Mandibular devices
    - Surgical interventions
    - Pharmacological treatments
    - Follow-up and compliance
- **Medicolegal aspects of sleep disorders**

Table 3b

Summary for medical and paramedical practitioners

on sleep apnoea and driving risks

Characteristics and epidemiology

In the Obstructive Sleep Apnoea Syndrome (OSAS), the air flow to the lungs is frequently blocked during sleep, while breathing effort remains present, as a result of a repetitive obstruction of the upper airway, The cessation (apnoea) or reduction (hypopnea) of breathing appears five times or more per hour of sleep and is caused by relaxation of the dilator muscles of the pharynx and tongue and/or narrowing of the upper airway.

Following symptoms and clinical observations can be outlined:

- Main symptoms: excessive sleepiness during daytime(not always reported by respondent), loud snoring and breathing stops during nighttime or unrefreshing sleep

- Additional symptoms during the night: nightmares, nocturnal polyuria, restless sleep, frequent awakenings and insomnia, transpiration

- Additional symptoms during the day: feelings of exhaustion, sleepiness during driving, cognitive problems (short term memory and attention), mood disturbances (irritable and depressed mood), morning headache, sexual problems

- Clinical observations: obesity(BMI>35), neck circumference above 41 cm (women) - 42 cm (men), large uvula, long soft palate, nasal congestion, nasal polyposis, hypertrophy of tonsils, large tongue, small chin,

In the general population the average prevalence of the Obstructive Sleep Apnoea Syndrome (OSAS) is about 5%. In the group of professional drivers it is even more prevalent, with estimates ranging from 5 to 50% depending on the severity criteria used (e.g. Tregear et al., 2009).

On the one hand, OSAS is associated with a decrease in the recuperative potential of sleep, as it interferes with normal sleep architecture during the night. On the other hand, OSAS can result in hypoxemia during sleep. The first aspect results in important attention problems, the second is associated with an increased risk for cardiovascular disorders and diabetes.

Impact on driving safety

Excessive sleepiness during the day, a key symptom of OSAS, refers to the tendency to doze off or fall asleep in inappropriate situations, like during driving. It should be distinguished from fatigue, a complaint of weariness that is present in many chronic medical conditions, but is not associated with unintentionally falling asleep.

Studies show that excessive sleepiness is involved as a contributing factor in about 5-7% of all motor vehicle accidents, with higher estimates around 17% in accidents involving fatalities (e.g. Philip et al., 2010 and Tefft 2012). Accordingly, driving simulator research shows that the performance impairment in drivers suffering from OSAS is comparable to the impairment as a consequence of illegal alcohol consumption or sleep deprivation.

Other conditions that can lead to excessive sleepiness are a lack of sleep, time of day (early morning and afternoon), shift work, sedative medications, poor sleep hygiene habits, alcohol use and other sleep disorders. Sufferers from OSAS should be warned for the combination of several of these risk factors, in that way further increasing the risk of a drowsiness accident.

Assessment of OSAS

People at increased risk of OSAS can be identified by screening for the following characteristics (Chung, 2008):

- Loud snoring
- Tiredness or excessive daytime sleepiness, e.g. an Epworth Sleepiness Scale score of above 10 (associated with a significant sleep disorder) and above16 (associated with an increased risk for a motor vehicle accident)
- Apnoeas observed by the bed partner
- Increased blood pressure
- Body mass index above 35
- Age above 50 years
- Neck circumference above 42 cm
- Male

In case three or more of these characteristics are present, people should be referred to a sleep disorder specialist for further assessment, including overnight polysomnography and treatment when necessary. In addition, people suffering from unexplained sleepiness while driving or having been involved as a driver in a sleepiness related accident, should be referred to a sleep disorder specialist.

⇨ To be further specified based on the result of the other workpackages

In specialized clinical sleep laboratories objective assessment of excessive sleepiness can be performed using the maintenance of wakefulness test (MWT) or behavioural variants, that have been related to impaired driving performance.

Treatment and advice to patients

Treatment of OSAS with continuous positive airway pressure (CPAP) has been shown to bring the accident risk in patients back to normal levels. This has been confirmed by accident statistics as well as driving simulator studies (evidence level I, II, level of recommendation – standard).

In patients suspected of OSAS, in addition to referral to a sleep disorder specialist, following advice should be given:

- Avoid driving when sleepy
    - Being aware of one's own sleepiness level and taking into account the advice of a passenger (see critical warning signs below)
    - Avoid driving during nighttime, especially between 1 and 5 am
    - Avoid driving in the afternoon between 2 and 4 pm
    - Avoid driving in case of a lack of sleep
- Minimize unnecessary driving
- Avoid the combination with other risk factors
    - Alcohol and sedative medication
    - Long distance driving

Finally, high-risk people should be informed specifically of critical warning signs of drowsy driving:

- Yawning and blinking
- Impression of driving automatically: difficulty remembering the past few miles driven
- Missing exits
- Difficulty in maintaining a steady road position – drifting from one's lane –hitting a rumble strip
- Difficulty in maintaining a constant speed
- Nodding

In case one is confronted with these warning signs, it is the responsibility of the driver to stop driving or change drivers.

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