



Implementation of European national driving regulations for obstructive sleep apnoea: challenges and recommendations

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National driving regulations for patients with obstructive sleep apnoea have been successfully introduced in most European countries, but concerns remain regarding their implementation and the ability to objectively evaluate excessive sleepiness <https://bit.ly/4ivaq5U>

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Abstract

Background Obstructive sleep apnoea (OSA) carries an increased risk of motor vehicle accidents, which resulted in the European Commission introducing a legal directive (2014/85/EU) restricting driving in patients with moderate/severe OSA and sleepiness, unless effectively treated. We assessed the implementation of the directive in European Union (EU) member and non-member states.

Methods National sleep societies and/or selected other sleep specialists in EU member states and selected other European countries completed a questionnaire on the local introduction of the EU Directive, or similar, the OSA severity to restrict driving, criteria to resume driving, and the validity period for different driving licences.

Results Data were obtained from 25 out of 27 EU member states and all eight non-member states included, representing a population of ~770 million. All EU members had introduced the Directive into national regulations, largely unchanged, although some countries applied stricter criteria such as mild OSA and a minimum treatment period before resuming driving. Only five non-member states had driving regulations for OSA. Problems with implementation of regulations were reported in most countries, including inadequate resources to diagnose/treat OSA patients, excessive restrictions regarding disease severity and certification to resume driving, and under-reporting of symptoms by patients fearing the loss of their licence, especially professional drivers.

Conclusions Driving regulations for OSA apply in most European countries, but excessively strict criteria for OSA severity, sleepiness and delayed permission to resume driving are questionable. Further research is needed on whether such regulations result in fewer accidents and on the objective identification of sleepiness.

Introduction

Obstructive sleep apnoea (OSA) is the most prevalent medical cause of excessive daytime sleepiness (EDS) [1], affecting up to a billion people globally [2]. Medical status is widely recognised as an important consideration for safe driving and there is extensive evidence that OSA is an important risk factor for motor vehicle accidents (MVAs) [3], probably as a consequence of EDS. Patients with OSA have a two-to-three times higher risk of MVAs [4–6], and there is considerable evidence that effective therapy with continuous positive airway pressure (CPAP) reduces this excess risk [5, 7–9], although not all reports indicate such a benefit [10]. Indirect evidence for CPAP benefit in reducing MVA risk is a report that one night's CPAP withdrawal in otherwise compliant OSA patients results in marked impairment in simulated



driving performance [11]. EDS appears to be the most important factor contributing to MVA risk in OSA patients [3], especially sleepiness while driving [12], and sleepy drivers with OSA typically adopt coping strategies while driving in an effort to limit MVA risk such as opening the windows, pulling over to rest and/or taking a caffeinated beverage [13]. Pharmacological therapy to counteract sleepiness is associated with improved on-the-road driving performance in OSA patients with associated EDS [14], but should only be considered in the context of residual sleepiness despite satisfactory CPAP compliance.

As for other chronic diseases affecting driving ability, the need for an official policy to regulate continued driving in symptomatic patients with OSA has long been recognised [15]. Arising from repeated lobbying of officials and politicians, the European Commission established an official working group in 2012 to examine this topic, which resulted in an official report that was accepted by the Transport and Mobility Directorate of the Commission [16]. This resulted in an official legal directive by the European Union (EU), implemented in 2015, that gives criteria for patients with symptomatic OSA to continue driving (box 1) [17]. Briefly, this directive specifies that patients with moderate or severe OSA, as measured by an apnoea–hypopnoea index (AHI) ≥ 15 events·h⁻¹ and associated sleepiness should be restricted from driving until the disorder is effectively treated. Since EU directives are mandatory for implementation in member states, it was anticipated that these criteria would serve as the minimum standard for national policies on driving regulations for patients with OSA. While the EU Directive does not specify a level of sleepiness to restrict driving, or specific treatment criteria to permit resumption of driving, national licensing authorities retained the authority to categorise sleepiness and to regulate driving resumption. The present report examines the implementation of national policies on driving regulations for patients with OSA in EU member states in addition to selected European non-member states, representing a total population of ~770 million. Relatively few countries worldwide have introduced national driving policies for patients with OSA, and the EU population of ~450 million represents the largest population to have introduced such regulations.

Methods

Lead members of individual national sleep societies were contacted by email from the first author seeking details of national implementation of the EU Directive in member states, or similar national policies in non-member countries. These societies have memberships that constitute the full range of sleep disorders in their countries, including respiratory sleep disorders. Each national sleep society is a member of the Assembly of National Sleep Societies (ANSS), which is an affiliated body of the European Sleep Research Society (ESRS) [18]. The ANSS has an executive committee, which nominates a representative who is a full member of the ESRS Board. Thus, the national sleep society in each country, be it an EU member state or a non-member state, was viewed as the most appropriate source of information for this study. In some countries, information was also sought from other sleep specialists, usually when the national sleep society failed to respond to the questionnaire despite repeated reminders.

The questions posed are listed in the supplementary material. Since the Directive represents the minimum standard for driving regulation, it was anticipated that some EU member states may have national regulations that are more restrictive than the EU Directive. Where no response was received from the first email, up to two reminders were sent by the first author, and in some cases, alternative contact sources were approached where no response was received from the national sleep society.

BOX 1 Official text of the European Union Directive on fitness to drive in patients with obstructive sleep apnoea: revision to annex III – European Union directive 2014/85/EU; June 2014

- 11.2. In the following paragraphs, a moderate obstructive sleep apnoea syndrome corresponds to a number of apnoeas and hypopnoeas per hour (Apnoea–Hypopnoea Index) between 15 and 29 and a severe obstructive sleep apnoea syndrome corresponds to an Apnoea–Hypopnoea Index of 30 or more, both associated with excessive daytime sleepiness.
- 11.3. Applicants or drivers in whom a moderate or severe obstructive sleep apnoea syndrome is suspected shall be referred to further authorised medical advice before a driving licence is issued or renewed. They may be advised not to drive until confirmation of the diagnosis.
- 11.4. Driving licences may be issued to applicants or drivers with moderate or severe obstructive sleep apnoea syndrome who show adequate control of their condition and compliance with appropriate treatment and improvement of sleepiness, if any, confirmed by authorised medical opinion.
- 11.5. Applicants or drivers with moderate or severe obstructive sleep apnoea syndrome under treatment shall be subject to a periodic medical review, at intervals not exceeding 3 years for drivers of group 1 and 1 year for drivers of group 2, with a view to establish the level of compliance with, the maintenance of good vigilance, and the need for continuing, the treatment.

Since the study involved national regulations and policy regarding driving in patients with OSA, and included no patient data, the study was considered to be exempt from a requirement for ethical approval.

Results

All 27 EU member states were contacted directly by the first author and detailed responses were obtained from 25 national representatives. In addition, ANSS members from countries that are not EU member states were contacted, and all eight such members responded. Details of national driving regulations are provided in table 1 and indicate that all 25 EU member states that responded have implemented the EU Directive, with 63% of member states having implemented the Directive largely unchanged both in terms of diagnostic OSA severity criteria and the criteria for resumption of driving after initiating effective treatment. Some member states have implemented more stringent regulations. Greece and Bulgaria specify an AHI threshold of 5 events·h⁻¹ together with sleepiness as the minimum criteria unless effectively treated, and Greece specifies an Epworth Sleepiness Score (ESS) score >14 in their regulations. All countries include sleepiness in the assessment of driver fitness, although Croatia refers to sleepiness in practice guidelines rather than the official regulation.

The Directive does not specify a level of sleepiness to restrict driving, but some member states have qualified this criterion. In Ireland and the Netherlands, the criterion is modified to sleepiness while driving. Other countries have specified a level of sleepiness based on a minimum ESS, most commonly a score ≥10 (Czech Republic, Estonia, Finland and Poland). Some other countries did not include sleepiness in their regulations, quantifying OSA severity based only on the AHI. Norway and the Netherlands did not initially include sleepiness in the regulations, but later revised them to do so. Lithuania does not specify sleepiness in the national policy, but feedback from the national ANSS representative indicates that sleepiness is included in the evaluation of OSA severity in clinical guidelines.

Regarding the resumption of driving after treatment, the EU Directive does not specify a time interval between the confirmation of effective treatment and the approval to resume driving. However, 37% of EU member states specify an interval ranging from 2 weeks to 2 months, but none of the non-member states indicate such a requirement (table 1). The criteria for approval to resume driving typically follow the Directive, requiring the combination of objective compliance, control of AHI and resolution of sleepiness. In France, a normal maintenance of wakefulness test (MWT) is also required after 1 month of effective treatment for both group 1 (cars and motorcycles) and group 2 (trucks and buses) drivers, to objectively demonstrate control of sleepiness in addition to treatment compliance and control of sleep disordered breathing. If sleepiness resolves and this is proved by MWT, a temporary driving licence is issued for a maximum of 3 years, which must be renewed after confirmation that treatment is still effective. A minority of countries (32% of those surveyed) specify a minimum compliance requirement of 4 h nightly in their assessment of treatment efficacy.

Some European countries that are members of the ANSS, but are not EU member states, have no official regulations (Russia, Serbia, Armenia), whereas others have implemented the EU Directive unchanged (Iceland). Other countries, such as Switzerland, have implemented driving regulations that are linked to the presence of sleepiness rather than specifically for OSA, although in this instance, OSA is specified as one cause of sleepiness. Norway initially introduced driving regulations for OSA that were linked to AHI without reference to sleepiness, but more recently, these regulations have been modified to specify the additional requirement of sleepiness to limit driving in patients with OSA. Finally, the United Kingdom has implemented driving regulations for OSA based on an AHI ≥5 events·h⁻¹ associated with sleepiness, and resumption of driving requires control of AHI and sleepiness.

The responsibility to inform the licensing authorities of the diagnosis of significant OSA varies between countries. In 32% of countries, there is no legal requirement to inform the authorities; in 25% of countries it is the patient's responsibility; in 32% of countries it is the doctor's responsibility; and in 10% the responsibility is placed on both patient and doctor to inform the licensing authorities. In the countries where there is a responsibility on the treating doctor to inform the authorities, no specific threshold is specified other than the clinician's opinion that continued driving poses a risk to traffic safety. In the surveyed countries, no difference was reported between public and private clinical pathways in the responsibility to report a diagnosis of OSA and its treatment. In a minority (15%) of countries, no private treatment option is available.

Discussion

The present report indicates that all responding EU member states have applied the EU Directive in national policy, mostly without significant alteration. Some countries apply a stricter threshold for AHI of

TABLE 1 Details of national driving regulations for patients with obstructive sleep apnoea (OSA) in European countries

	National regulation	Specified AHI events·h ⁻¹	EDS	Time interval on treatment	Criteria to resume driving	Licence validity Group 1	Licence validity Group 2
EU countries							
Austria	Yes	≥15	Yes: unquantified	4 weeks (clinical guideline)	AHI control and no EDS by medical opinion	3 years	1 year
Belgium	Yes	Moderate/severe OSA	Pathological sleepiness	1 month	Successful treatment: unspecified	2 years, then open	1 year, then 5 years
Bulgaria	Yes	≥5	Yes: unquantified	Not specified	AHI and EDS	3 years	1 year
Croatia	Yes	≥15	Guidelines only	Not specified	AHI control	3 years	1 year
Cyprus	NA						
Czech Republic	Yes	>15	Yes: ESS ≥10	1 month	AHI control and compliance	3 years	1 year
Denmark	Yes	≥15	Yes: fatigue or sleepiness	Not specified	AHI control and disorder control	3 years	1 year
Estonia	Yes	≥15	Yes: ESS >10	Not specified	Disorder control with treatment	3 years	1 year
Finland	Yes	≥15	Yes: ESS >10 plus objective testing	Not specified	Disorder control with treatment	3 years	1 year
France	Yes	≥15	Yes: unquantified	4 weeks	Disorder control with treatment and MWT	3 years	1 year
Germany	Yes	≥15	Yes	Clinical guidelines: 6 weeks	Disorder control with treatment by specialist report	3 years	1 year
Greece	Yes	≥5	ESS >14	Not specified	Disorder control with treatment	2 years, then 15 years	1 year, then 5 years
Hungary	Yes	≥15	Yes: unquantified	Not specified	AHI control and no EDS	3 years	1 year
Ireland	Yes	≥15	Sleepiness while driving	Not specified	AHI control and compliance	3 years	1 year
Italy	Yes	≥15	Yes: unquantified	Not specified	AHI and symptom control	3 years	1 year
Latvia	Yes	≥15	Yes: unquantified	Not specified	AHI and symptom control	3 years	1 year
Lithuania	Yes	≥15	Not specified in regulation	Not specified	Disorder control with treatment	3 years	1 year
Luxembourg	NA						
Malta	Yes	≥15	Yes: unquantified	Not specified	Disorder control	3 years	1 year
The Netherlands	Yes	≥15	Sleepiness while driving: as guideline	2 months Group 1; 3 months Group 2	AHI and sleepiness	1 year, then 3 years	1 year
Poland	Yes	≥15	ESS >10	1 month	Disorder control	3 years	1 year
Portugal	Yes	Moderate/severe OSA	Yes: unquantified	Not specified	AHI and sleepiness	3 years	1 year
Romania	Yes	≥15	Yes: limit driving until diagnosis	Not specified	Disorder control	3 years	1 year
Slovakia	Yes	≥15	Yes: unquantified	Not specified	Disorder control	3 years	1 year
Slovenia	Yes	≥15	Yes: ESS >10	2–4 weeks	AHI and sleepiness; MWT if EDS	3 years	1 year
Spain	Yes	≥15	Yes: moderate/severe	4–6 weeks	AHI and sleepiness	3 years	1 year
Sweden	Yes	≥ 15	Yes: limit driving until diagnosis	At first CPAP follow-up	AHI and sleepiness	3 years	1 year

Continued

TABLE 1 Continued

	National regulation	Specified AHI events·h ⁻¹	EDS	Time interval on treatment	Criteria to resume driving	Licence validity Group 1	Licence validity Group 2
Non-EU countries							
Armenia	No						
Iceland	Yes	Moderate or severe OSA	Yes: unquantified	Not specified	AHI and sleepiness	Not implemented	Not implemented
Norway	Yes	≥15	Yes: intrusive	Not specified	Disorder control	3 years	1 year
Russia	No						
Serbia	No						
Switzerland	Yes	≥15 only as one cause of EDS	Yes: focus of regulation	Not specified	Disease control	Not specified	Not specified
Turkey	Yes	≥15	Yes	Not specified	AHI and sleepiness (three-person committee)	Not specified	Not specified
United Kingdom	Yes	≥5	Yes: unquantified	Not specified	AHI and sleepiness	Not specified	Not specified

AHI: apnoea–hypopnoea index; EDS: excessive daytime sleepiness; Group 1: Group 1 driving licence holders (cars and motorcycles); Group 2: Group 2 licence holders (trucks and buses); EU: European Union; NA: not applicable; ESS: Epworth Sleepiness Scale; MWT: maintenance of wakefulness test; CPAP: continuous positive airway pressure.

5 events·h⁻¹ associated with sleepiness, which raises the possibility that sleepiness in this context may be a result of other factors than OSA, since an AHI ≥5 events·h⁻¹ may be present in up to half the general population [19]. Thus, licence restriction in this context could be viewed as a more general restriction on patients with excessive sleepiness, and the reference to OSA in the licence restriction is of questionable relevance.

Furthermore, many countries apply a stricter requirement to resume driving than required by the EU Directive, such as a time duration of effective therapy prior to certification to resume driving, or the objective demonstration of effective control of sleepiness.

Non-EU member states were highly variable in regulations for drivers with OSA, with no regulations applying in several states. Of note, both France and Switzerland focus on excessive sleepiness in their driving licence regulation, with OSA as just one clinical example of a disorder associated with sleepiness. Iceland has implemented the EU Directive without modification, but drivers in this country are given an open-ended licence, which limits the ability to identify clinical disorders potentially affecting driving safety such as OSA.

Several aspects of driving regulations for patients with OSA warrant detailed consideration.

Does regulation of driving in patients with OSA result in reduced accident risk?

Although there are no randomised controlled trials on this question, many epidemiological reports have indicated reduced accident risk in OSA patients who are effectively treated with CPAP [7]. GEORGE [5] reported that patients with OSA effectively treated with CPAP had an accident risk equivalent to the general driving population in Ontario, Canada, whereas the risk was three-fold higher before therapy. KARIMI *et al.* [8], using data from a Swedish traffic accident registry, reported an increased MVA risk ratio of 2.45 in OSA patients compared with controls, which reduced to control levels in CPAP-compliant patients. A recent French report supports this finding, and especially demonstrates the importance of sleepiness at the wheel as an important risk factor for MVA, and the benefit of CPAP compliance in risk reduction [20]. However, an observational study from Finland reported no reduction in MVA rates in CPAP-compliant OSA patients comparing the years prior to commencing CPAP therapy with subsequent years [10]. While these epidemiological data are important, they do not necessarily imply that official regulations regarding fitness to drive in patients with OSA result in a reduced MVA risk, and further research is required to demonstrate benefit. However, a Swedish study comparing OSA patients treated with CPAP undergoing certification of fitness to drive with a general population of CPAP-treated OSA patients reported a higher compliance and greater reduction in subjective sleepiness [21], suggesting an incentive to comply with treatment in order to retain driving certification [22].

The MVA risk in OSA is especially important in commercial drivers [23, 24] and in this context the report of BURKS *et al.* [25] from the USA indicated that truck drivers with OSA who adhered to CPAP therapy had an MVA risk equivalent to a general driving population, whereas nonadherent patients had a five-fold higher accident rate. The topic of enhancing public health and safety by diagnosing and treating OSA in the transportation industry has been the subject of a recent position statement by the American Academy of Sleep Medicine [26]. The authors urged key stakeholders, including clinicians and patients, to engage in a collaborative approach by following previous guidelines issued by a medical review board of the US Federal Motor Carrier Safety Administration that were not officially implemented, and that current standards of care demand action to mitigate the serious health and safety risks of OSA in commercial drivers. The available evidence clearly demonstrates the potential benefits to driving safety from engagement with the trucking industry regarding the diagnosis of OSA and its treatment and supports the need for a more broad-based education programme targeting the transportation industry. Although data are limited in the African subcontinent, a recent report indicated that commercial vehicle drivers in Zambia with a high risk of OSA had a significantly higher rate of MVAs [27]. Factors other than OSA, especially sleep debt, may contribute to MVA risk in commercial vehicle operators [28].

An overall strategy to reduce MVA risk in private and professional drivers is proposed in figure 1.

Does the presence of national driving regulations for OSA imply that such regulations are effectively implemented?

Most respondents to the present survey reported problems with the local implementation of national regulations. Many countries seek information on specified medical conditions such as OSA at the time of driving licence renewal, which has limitations where the period of validity of a driving licence is lengthy, such as 10 years in many countries, and Iceland has a lifelong period of validity once the licence has been initially awarded. Thus, there is a need to proactively consider the implications for driving safety and certification at the time of initial diagnosis, while at the same time avoiding a scenario where patient referrals for diagnosis and treatment are inhibited by a concern that such a diagnosis would lead to disqualification from driving. This aspect emphasises the importance of education of patients, clinicians, and where relevant, employers.

What threshold of AHI is appropriate?

The general population prevalence of $AHI \geq 15$ events·h⁻¹, which is the conventional threshold for moderate OSA, is very high, with an estimated global prevalence of 425 million adults [2]. Thus, consideration of additional criteria such as sleepiness is required to avoid unrealistic regulations.

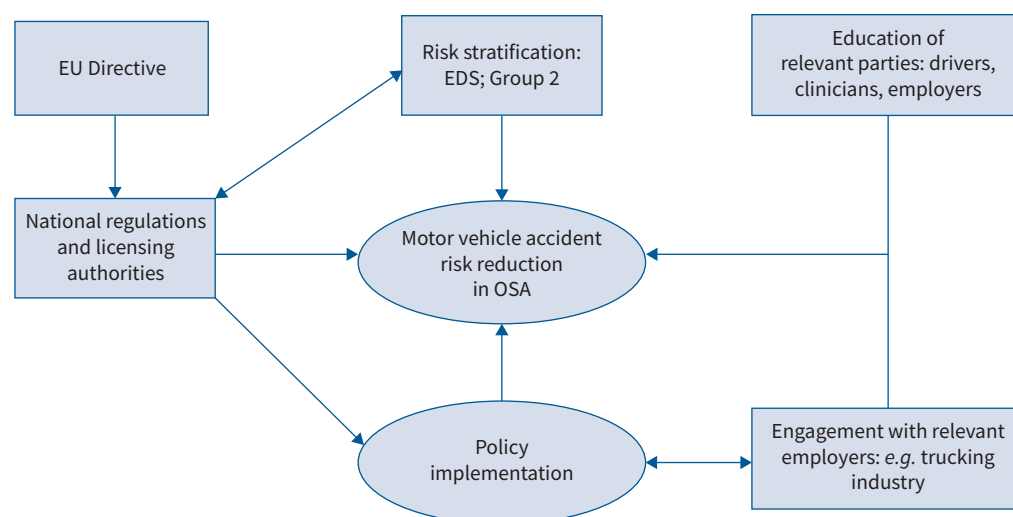


FIGURE 1 Strategies towards motor vehicle accident risk reduction in patients with symptomatic obstructive sleep apnoea (OSA) indicating the interacting importance of education of relevant stakeholders, engagement with relevant employers such as the trucking industry, official policies and regulations, and implementation. EU: European Union; EDS: excessive daytime sleepiness; Group 2: Group 2 licenced drivers (applicable to trucks and buses).

Furthermore, there is a poor relationship between AHI alone and MVA risk [29–31], which further limits the relevance of AHI as the principal marker of OSA severity and accident prediction, especially in the mild category. There is also a growing trend to move beyond the AHI as the optimum objective measure of OSA severity [32] and alternative measures have been proposed that are better suited to ambulatory measurement and automated analysis. This topic is rapidly developing and is the subject of the ongoing EU Horizon 2020-funded research project Sleep Revolution [33].

In some countries with limited resources, overnight oximetry may be used as a screening tool for OSA. While there is reasonable concordance between AHI and oxygen desaturation index [34], the reliance on overnight oximetry alone to diagnose OSA is not recommended in international guidelines [35] and could be viewed as an overly simple assessment in the decision to restrict an individual's ability to continue driving, especially a professional driver. However, in a setting where the local resources are not available to perform conventional sleep studies, overnight oximetry together with a special focus on sleepiness, especially sleepiness at the wheel [36] may be a reasonable approach.

How best to categorise sleepiness?

While the EU Directive does not specify a level of sleepiness to preclude driving, there is limited evidence that a mild elevation of ESS score [11–15] is associated with a significant increased MVA risk, although many reports do not identify a specific ESS threshold in this context [3, 37]. However, there is evidence to support higher ESS scores being associated with a significant MVA risk, although the specific threshold associated with this increased risk varies between reports. One report involving commercial drivers indicated an ESS threshold of 18 for a significant increased risk of MVA compared to high normal scores [23], whereas another report involving the full spectrum of drivers identified a threshold of ≥ 16 as independently associated with increased MVA risk [8]. Sleepiness at the wheel is also a recognised risk factor for MVA [20, 36]. As there is a poor association between sleepiness at the wheel and the ESS score [29, 38], the ESS score alone is inadequate, and direct questions about sleepiness at the wheel are essential.

Some countries, such as Ireland and the Netherlands, specify sleepiness at the wheel, which is the most pertinent aspect of sleepiness relevant to driving safety. Sleepiness at the wheel is not always associated with EDS in general and is also influenced by annual mileage, habitual sleep duration and concurrent depressive symptoms [38]. New screening measures to specifically measure sleepiness at the wheel such as the Bordeaux Sleepiness Scale (BOSS), which combines annual driving distance with subjective measures of different situational sleepiness associated with driving [39], represent a significant development in this aspect. The BOSS is reported to have superior sensitivity/specificity characteristics to the ESS in identifying sleep-related driving near-misses or accidents [39], but further studies are required to confirm these findings. Pending such confirmatory studies, a suitable traditional threshold for sleepiness associated with significant MVA risk would be an ESS score >15 and/or a report of sleepiness at the wheel, while bearing in mind the possibility of under-reporting the severity of symptoms by the affected driver. Sleepiness at the wheel is especially relevant in commercial drivers who often drive long distances on high-speed motorways and thus would be especially prone to sleepiness and its consequences in this context.

Self-reported sleepiness has the potential for under-reporting, especially if financial or medicolegal issues are involved, especially in professional drivers. Where uncertainty is present regarding the validity of a patient's self-reported sleepiness, additional input from the partner, if applicable, should be sought. In addition, markers of high-risk MVA such as sleepiness at the wheel, exposure to the risk (distance (km) driven per year), and a history of previous MVA should be assessed. Some countries specify a level of ESS score ≥ 10 to determine significant sleepiness in the context of driving certification. A score of 10 is the recognised threshold for significant sleepiness and can be found in up to 33% of the general population [1], but may not be associated with sleepiness at the wheel, which has questionable validity.

Objective tests such as the MWT are significant predictors of MVA risk [40], although other reports have questioned the ability of the MWT to predict real-life driving ability [41]. Because of its complexity, the MWT appears most suited to commercial drivers. A recent report indicated that misjudgement in self-perceived sleep during MWT may improve accident risk prediction [42]. A simpler variant of the MWT is the Oxford Sleep Resistance test [43]. Objective surrogates of sleepiness at the wheel such as eye blinking and lane deviation correlate well with conventional measures of sleepiness, which is relevant to in-vehicle technology to detect drowsy driving [44]. While in-vehicle technology may play a role in assessing sleepiness in patients with disorders such as OSA in the future, further research is required to determine their relationship to crash risk and cut-offs for abnormality. The need for further such research is emphasised by a recent report in truck drivers that while advanced emergency braking systems are effective in mitigating nondrowsy driving-related collisions, they are less effective in drowsy driving-related collisions [45].

Driving simulators represent an additional objective test of potential sleepiness at the wheel, but may not replicate real-time driving [3]. Additional factors to AHI and sleepiness in OSA, such as obesity and cognitive effects, should also be considered in the clinical evaluation, as these may adversely affect driving ability and contribute to increased MVA risk.

Given the high prevalence of OSA in the general population and the logistical difficulties of MWT, an overall approach to the assessment of subjective sleepiness could be to rely on measures such as the ESS or BOSS score in private drivers, and to reserve objective testing such as the MWT for patients where there is a strong suspicion by the treating doctor that the level of sleepiness is under-reported. In commercial drivers, the threshold for performing MWT should be lower, although the availability of this test may be limited in many countries. The increasing sophistication of in-vehicle technology represents a potentially useful additional method to assess sleepiness in the future, which is particularly applicable to commercial drivers.

When to advise cessation of driving?

The appropriate time to cease driving for a patient with suspected OSA could vary depending on the severity of the clinical presentation. Where severe sleepiness (ESS >15 or sleepiness at the wheel) is disclosed, then it would be appropriate to restrict driving in advance of the diagnostic sleep study. However, for lesser degrees of sleepiness, it may be appropriate at the clinician's discretion to await the diagnostic study to decide on possible driving restriction until effective treatment is demonstrated.

How best to determine fitness to drive after treatment initiation?

Fitness to drive depends on the resolution of sleepiness at the wheel. As this may be difficult to measure objectively without MWT, CPAP-derived data on compliance and AHI control may be a surrogate marker. In patients treated with mandibular advancement devices (MAD), compliance and effectiveness data are not widely available. However, MAD is not a first-line treatment for moderate or severe OSA associated with EDS, although may be indicated in CPAP noncompliant patients. The requirement for MWT in sleepy OSA drivers could be focused on specific categories of drivers such as long-haul truck drivers. In France, the text regarding MWT applies only to sleepy OSA drivers, which is <50% of the whole sample of the apnoeic population, and the MWT requirement is applied in practice for professional drivers is stricter than for private drivers.

While the EU Directive does not specify a threshold for compliance, some countries (32% of those surveyed) have specified minimum criteria for compliance, typically a minimum of 4 h per night for $\geq 70\%$ of nights. Stricter requirements are appropriate for professional drivers when treatment is suboptimal, and objective testing of sleepiness by MWT could be appropriate in these circumstances as a matter of routine, depending on the availability of resources. The demonstration of acceptable resolution of sleepiness, especially sleepiness at the wheel, may be difficult, as in most circumstances this is based on the patient's own subjective report. Where uncertainty is present as to the validity of the patient's own report, additional information could be sought from the partner, if any. If doubt persists, additional testing would be appropriate such as MWT, especially in professional drivers.

Is a minimum treatment period justified before resumption of driving?

The EU regulation does not specify a minimum treatment period before resumption of driving, but many countries have included such a period in their national regulations ranging from 2 weeks to 2 months. Such a requirement is questionable, as sleepiness is typically reduced after starting CPAP therapy within a matter of days. As adjustment to an effective CPAP treatment (>4 h per night) may require some time; however, a period of 2–4 weeks seems reasonable before re-evaluation of fitness to drive.

Should stricter requirements be in place for patients with OSA who are commercial drivers?

While the EU regulations apply the same diagnostic criteria regarding AHI and EDS for private and commercial drivers, stricter requirements are specified for OSA patients who are commercial drivers regarding treatment and follow-up. Additional categorisation of sleepiness would be appropriate in commercial drivers, especially sleepiness at the wheel, which would be especially relevant in such drivers whose work frequently involves long periods of driving on high-speed motorways. In this regard, the BOSS provides a more specific focus on driving risk that is especially relevant to commercial drivers [39]. Commercial drivers may also be exposed to additional driving situations that predispose to increased sleepiness and MVA risk, such as shift work, sleep restriction and night driving. At present, the only difference in the EU Directive between private and commercial drivers is the duration of licence validity. As commercial drivers represent a special risk group because of the high mileage and motorway driving, with the added factor of the extra mass of an articulated truck, consideration could be given to special

restrictions in this group, such as a greater reliance on MWT. Restriction of night-time driving in this group may also be a consideration.

Strengths and limitations of the present report

A strength of the present report includes the large population involved in the study (EU population of 450 million and eight non-EU countries with a total population of ~320 million). Furthermore, information was obtained directly from national representatives in each country who have knowledge of the Directive or other similar regulation as it applies in their individual country, and, as somnologists, are aware of the practical difficulties with local implementation. A potential weakness is that the accuracy of data is reliant for some countries on the information supplied by the national ANSS representative rather than obtained directly from the regulatory authority.

Comparison with other geographic regions

Several other international jurisdictions have introduced driving regulations and/or guidelines for patients with OSA. While a detailed comparison with other international regions is beyond the scope of the present article, several aspects merit comment. While there are no federal regulations for drivers with OSA in the USA, some states have implemented their own regulations, which vary considerably. For example, New York state refers to sleep disorders in their medical certification form, which requires the clinician to specify the type and treatment, in addition to certifying that the patient is fit to drive. Conversely, Texas refers to severe OSA, which is based on an AHI >20 events·h⁻¹, and there is no specific mention of sleepiness in this context. Driving is precluded until effective treatment is demonstrated. In Canada, licensing requirements are within the jurisdiction of each province, although national guidance is provided by the Canadian Council of Motor Transport Administrators. As an example, Ontario specifies untreated OSA with an AHI >30 events·h⁻¹ and associated sleepiness in the medical report form to preclude driving. In contrast, Australia specifies OSA without an AHI threshold associated with moderate or severe EDS to preclude driving unless effectively treated. Brazil has no official driving regulation for patients with OSA, which also appears to be the case for other South American countries. Japan, China and India also have no specific official driving regulations for patients with OSA. Thus, these international variations emphasise the desirability of a global initiative on this topic to develop a common standard of OSA severity and treatment requirement to regulate driving for both commercial and private drivers, especially given the high global prevalence of the disorder and associated MVA risk.

Conclusion

While the EU Directive has been introduced successfully into national regulations, there is an urgent need for more accurate and reliable subjective and objective measures of sleepiness that are predictive of driving risk and suitable for implementation in large populations. Reliance on subjective scales is prone to potential individual bias, but is consistent at a populational level. Educational campaigns should be linked to developments in vehicle technology designed to detect impaired vigilance at the wheel, such as lane drift and eyelid blinking [44] to improve understanding and quantification of the associated accident risk. Further studies are required to assess the efficacy of the EU Directive in reducing MVA among effectively treated patients with OSA. EU member states with national databases of patient clinical data and MVA statistics that could be linked may allow comparison of MVA rates among OSA patients in the years prior to the EU Directive with rates during subsequent years.

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References

- 1 Pérez-Carbonell L, Mignot E, Leschziner G, *et al.* Understanding and approaching excessive daytime sleepiness. *Lancet* 2022; 400: 1033–1046.
- 2 Benjafield AV, Ayas NT, Eastwood PR, *et al.* Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. *Lancet Respir Med* 2019; 7: 687–698.
- 3 Bonsignore MR, Randerath W, Schiza S, *et al.* European Respiratory Society statement on sleep apnoea, sleepiness and driving risk. *Eur Respir J* 2021; 57: 2001272.
- 4 Pocobelli G, Akosile MA, Hansen RN, *et al.* Obstructive sleep apnea and risk of motor vehicle accident. *Sleep Med* 2021; 85: 196–203.
- 5 George CF. Reduction in motor vehicle collisions following treatment of sleep apnoea with nasal CPAP. *Thorax* 2001; 56: 508–512.
- 6 Tregear S, Reston J, Schoelles K, *et al.* Obstructive sleep apnea and risk of motor vehicle crash: systematic review and meta-analysis. *J Clin Sleep Med* 2009; 5: 573–581.
- 7 Tregear S, Reston J, Schoelles K, *et al.* 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.
- 8 Karimi M, Hedner J, Häbel H, *et al.* Sleep apnea-related risk of motor vehicle accidents is reduced by continuous positive airway pressure: Swedish Traffic Accident Registry data. *Sleep* 2015; 38: 341–349.

- 9 Walia HK, Thompson NR, Pascoe M, *et al.* Effect of positive airway pressure therapy on drowsy driving in a large clinic-based obstructive sleep apnea cohort. *J Clin Sleep Med* 2019; 15: 1613–1620.
- 10 Myllylä M, Anttalainen U, Saaresranta T, *et al.* Motor vehicle accidents in CPAP-compliant obstructive sleep apnea patients – a long-term observational study. *Sleep Breath* 2020; 24: 1089–1095.
- 11 Filtiness AJ, Reyner LA, Horne JA. One night's CPAP withdrawal in otherwise compliant OSA patients: marked driving impairment but good awareness of increased sleepiness. *Sleep Breath* 2012; 16: 865–871.
- 12 Philip P. Excessive daytime sleepiness *versus* sleepiness at the wheel, the need to differentiate global from situational sleepiness to better predict sleep-related accidents. *Sleep* 2023; 46: zsad231.
- 13 Dwarakanath A, Palissery V, Ghosh D, *et al.* An exploratory study evaluating the use of coping strategies while driving in obstructive sleep apnoea syndrome patients and controls. *ERJ Open Res* 2024; 10: 00638-2023.
- 14 Vinckenbosch F, Asin J, de Vries N, *et al.* Effects of solriamfetol on on-the-road driving performance in participants with excessive daytime sleepiness associated with obstructive sleep apnoea. *Hum Psychopharmacol* 2022; 37: e2845.
- 15 Krieger J, McNicholas WT, Levy P, *et al.* Public health and medicolegal implications of sleep apnoea. *Eur Respir J* 2002; 20: 1594–1609.
- 16 McNicholas WT, ed. New Standards and Guidelines for Drivers with Obstructive Sleep Apnoea Syndrome – Report of the Obstructive Sleep Apnoea Working Group. European Commission, 2013. <http://hdl.handle.net/10197/6809>.
- 17 Bonsignore MR, Randerath W, Riha R, *et al.* New rules on driver licensing for patients with obstructive sleep apnea: European Union Directive 2014/85/EU. *J Sleep Res* 2016; 25: 3–4.
- 18 van der Werf YD, Korostovtseva L, Khachatryan SG, *et al.* The history and role of the Assembly of National Sleep Societies (ANSS) within the European Sleep Research Society (ESRS). *J Sleep Res* 2022; 31: e13663.
- 19 Heinzer R, Vat S, Marques-Vidal P, *et al.* Prevalence of sleep-disordered breathing in the general population: the HypnoLaus study. *Lancet Respir Med* 2015; 3: 310–318.
- 20 Coelho J, Bailly S, Baillieu S, *et al.* Predictors of driving risk in patients with obstructive sleep apnea syndrome treated by continuous positive airway pressure: a French multicenter prospective cohort. *Sleep* 2024; 47: zsae211.
- 21 Grote L, Svedmyr S, Hedner J. Certification of fitness to drive in sleep apnea patients: are we doing the right thing? *J Sleep Res* 2018; 27: e12719.
- 22 McNicholas WT. Identifying and treating obstructive sleep apnea in sleepy drivers: everybody wins. *J Sleep Res* 2018; 27: e12787.
- 23 Howard ME, Desai AV, Grunstein RR, *et al.* Sleepiness, sleep-disordered breathing, and accident risk factors in commercial vehicle drivers. *Am J Respir Crit Care Med* 2004; 170: 1014–1021.
- 24 Gurubhagavatula I, Tan M, Jobanputra AM. OSA in professional transport operations: safety, regulatory, and economic impact. *Chest* 2020; 158: 2172–2183.
- 25 Burks SV, Anderson JE, Bombyk M, *et al.* Nonadherence with employer-mandated sleep apnea treatment and increased risk of serious truck crashes. *Sleep* 2016; 39: 967–975.
- 26 Das AM, Chang JL, Berneking M, *et al.* Obstructive sleep apnea screening, diagnosis, and treatment in the transportation industry. *J Clin Sleep Med* 2022; 18: 2471–2479.
- 27 Simpamba K, May JL, Waghat A, *et al.* Obstructive sleep apnea and excessive daytime sleepiness among commercial motor vehicle drivers in Lusaka, Zambia. *J Clin Sleep Med* 2023; 19: 1191–1198.
- 28 Garbarino S, Durando P, Guglielmi O, *et al.* Sleep apnea, sleep debt and daytime sleepiness are independently associated with road accidents. A cross-sectional study on truck drivers. *PLoS One* 2016; 11: e0166262.
- 29 Philip P, Bailly S, Benmerad M, *et al.* Self-reported sleepiness and not the apnoea hypopnoea index is the best predictor of sleepiness-related accidents in obstructive sleep apnoea. *Sci Rep* 2020; 10: 16267.
- 30 Mulgrew AT, Nasvadi G, Butt A, *et al.* Risk and severity of motor vehicle crashes in patients with obstructive sleep apnoea/hypopnoea. *Thorax* 2008; 63: 536–541.
- 31 Matsui K, Sasai-Sakuma T, Ishigooka J, *et al.* Insufficient sleep rather than the apnea-hypopnea index can be associated with sleepiness-related driving problems of Japanese obstructive sleep apnea syndrome patients residing in metropolitan areas. *Sleep Med* 2017; 33: 19–22.
- 32 Pevernagie DA, Gnidovec-Strazisar B, Grote L, *et al.* On the rise and fall of the apnea-hypopnea index: a historical review and critical appraisal. *J Sleep Res* 2020; 29: e13066.
- 33 Arnardottir ES, Islind AS, Óskarsdóttir M, *et al.* The Sleep Revolution project: the concept and objectives. *J Sleep Res* 2022; 31: e13630.
- 34 Sharma P, Thakur S, Rai DK, *et al.* Connecting the dots: analysing the relationship between AHI and ODI in obstructive sleep apnea. *Sleep Sci Pract* 2024; 8: 9.
- 35 Kapur VK, Auckley DH, Chowdhuri S, *et al.* Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med* 2017; 13: 479–504.
- 36 Bioulac S, Micolaud Franchi JA, Arnaud M, *et al.* Risk of motor vehicle accidents related to sleepiness at the wheel: a systematic review and meta-analysis. *Sleep* 2017; 40: zsx134.

- 37 Garbarino S. Excessive daytime sleepiness in obstructive sleep apnea: implications for driving licenses. *Sleep Breath* 2020; 24: 37–47.
- 38 Fanfulla F, Pinna GD, Marrone O, *et al.* Determinants of sleepiness at wheel and missing accidents in patients with obstructive sleep apnea. *Front Neurosci* 2021; 15: 656203.
- 39 Philip P, Micoulaud-Franchi JA, Taillard J, *et al.* The Bordeaux Sleepiness Scale (BOSS): a new questionnaire to measure sleep-related driving risk. *J Clin Sleep Med* 2023; 19: 957–965.
- 40 Philip P, Guichard K, Strauss M, *et al.* Maintenance of wakefulness test: how does it predict accident risk in patients with sleep disorders? *Sleep Med* 2021; 77: 249–255.
- 41 Virtanen I, Järvinen J, Anttalainen U. Can real-life driving ability be predicted by the Maintenance of Wakefulness Test? *Traffic Inj Prev* 2019; 20: 601–606.
- 42 Sagaspe P, Micoulaud-Franchi J-A, Bioulac S, *et al.* Self-perceived sleep during the Maintenance of Wakefulness Test: how does it predict accidental risk in patients with sleep disorders? *Sleep* 2021; 44: zsab159.
- 43 Bennett LS, Stradling JR, Davies RJ. A behavioural test to assess daytime sleepiness in obstructive sleep apnoea. *J Sleep Res* 1997; 6: 142–145.
- 44 Howard ME, Cori JM, Horrey WJ. Vehicle and highway adaptations to compensate for sleepy drivers. *Sleep Med Clin* 2019; 14: 479–489.
- 45 Kawaguchi K, Kumagai H, Sawatari H, *et al.* Evaluation of advanced emergency braking systems in drowsy driving-related real-world truck collisions. *Sleep* 2025; 48: zsae196.