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European Union directive 2014/85/EU on driver licensing in obstructive sleep apnoea: early experiences with its application in the UK

Obstructive sleep apnoea (OSA) is a prevalent condition, affecting up to 20% of the population in first world countries [1]. The obstructive sleep apnoea hypopnea syndrome (OSAHS) is diagnosed when symptoms of excessive daytime somnolence or cognitive impairment are present in the context of an elevated apnoea-hypopnoea index (AHI) per hour of sleep. The definitions vary according to the lower cut-off for the AHI, which can range from >5 to >15 events per hour [2]. However, as with any sleep disorder, it is important to establish whether the sleep disordered breathing (SDB) *per se* is the true cause of symptoms of daytime somnolence. As is apparent to everyone who practises in the area, a large number of other factors can intervene, such as shift work, sleep insufficiency, psychiatric disorders, metabolic disorders and nutritional deficiencies, which may be the true cause of the somnolence rather than the AHI as measured on polysomnography. Additionally, a true AHI cannot be reported on the basis of any respiratory measurements conducted during sleep, if no electroencephalogram is simultaneously recorded [2].

With respect to driving, it is sleepiness while driving that is the greatest risk factor for road traffic accidents (RTAs) [3]. The risk of having a crash with untreated moderate to severe OSAHS is superseded only by age and time of day as risk factors [4]. A recent meta-analysis examining nine observational studies reviewing crash risk of drivers with OSA *versus* post-continuous positive airway pressure (CPAP) found significant risk reduction following treatment (relative risk 0.278, 95% CI 0.22–0.35; $p < 0.001$) [4]. Although crash data were not available to assess the time course of change, daytime sleepiness improved significantly following a single night of treatment with CPAP and simulated driving performance improved significantly within 2–7 days of CPAP treatment [5].

On the basis of our knowledge in this area, Annex III of the European Union (EU) Directive on Driving Licences was revised in 2014 on the recommendations from a working group established by the Transport and Mobility Directorate of the European Commission in 2012 [6]. The new directive, which was made subject to mandatory

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OSA patients' risk of RTA should be assessed using detailed driving history with specific focus on "red flags" <http://ow.ly/mxPi305isni>



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implementation by all member states from December 31, 2015, is as follows.

- 1) "Applicants or drivers in whom a moderate or severe obstructive sleep apnea 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.
- 2) "Driving licences may be issued to applicants or drivers with moderate or severe obstructive sleep apnea syndrome who show adequate control of their condition and compliance with appropriate treatment and improvement of sleepiness, if any, confirmed by authorised medical opinion.
- 3) Applicants or drivers with moderate or severe obstructive sleep apnea syndrome under treatment shall be subject to a periodic medical review, at intervals not exceeding 3 years for drivers of group 1 (*i.e.* non-commercial drivers) and 1 year for drivers of group 2 (*i.e.* commercial drivers), with a view to establish the level of compliance with the treatment, the need for continuing the treatment and continued good vigilance."

Furthermore, the terms used in the amendment are defined as follows.

- 1) "... 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.
- 2) "Applicants or drivers in whom a moderate or severe obstructive sleep apnoea syndrome is suspected shall be referred for further authorised medical advice before a driving licence is issued or renewed. They may be advised not to drive until confirmation of the diagnosis.
- 3) "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.
- 4) "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 three years for drivers of group 1 and one year for drivers of group 2, with a view to establish the level of compliance with the treatment, the need for continuing the treatment and continued good vigilance."

In a clinical setting, the patient who presents with symptoms consistent with OSA (snoring,

choking arousals and witnessed apnoeas) will require assessment for excessive daytime sleepiness. This is generally undertaken by way of subjective questionnaires, such as the Epworth Sleepiness Scale (ESS) [7]. These methods of assessing sleepiness are susceptible to reporting bias, particularly by professional drivers who may seek to underestimate severity. Objective evaluation is expensive, time consuming and not well suited to being performed on a large scale [1]. Probably, the most commonly performed test for assessing treatment effectiveness is the maintenance of wakefulness test (MWT), which in no respect replicates real-life driving situations and is often restricted to large sleep centres. The test is time-consuming and expensive. Additionally, the correlation between the results of the MWT and accidents is very weak [8]. Driving simulators may not uniformly assess skills on the road and are likewise not in widespread clinical use [4, 5].

Application of European Union Directive 2014/85/EU in the UK

In the UK, the Driver and Vehicle Licensing Agency (DVLA) have recently changed their advice regarding who should not drive and who needs to notify them (table 1) [9]. The DVLA seems to have interpreted the EU directive in a way that has caused some consternation amongst both patients and clinicians (multiple personal communications). The DVLA have moved away from the idea of being informed only when there is sufficient sleepiness to impair driving to a combination of the former along with generalised sleepiness and severity of SDB based on AHI. The guidance has also become more confusing with the introduction of "obstructive sleep apnoea syndrome" (OSAS) as a diagnosis for which they are to be notified even without a degree of sleepiness that might impair driving. If somebody has "excessive sleepiness" but has mild OSAS (AHI 5-15), they must stop driving until sleepiness has been controlled but they do not have to inform the DVLA unless they are a bus or heavy goods vehicle (HGV) driver. However, the same patient with an AHI of >15 would have to inform the DVLA. To complicate matters, the latter patient must inform the DVLA and stop driving when this diagnosis is suspected, rather than after confirmation. On this basis, if a clinician suspects that their patient has moderate or severe OSAS (but not mild) they should be advised to stop driving and inform the DVLA. If a patient is diagnosed with moderate or severe OSA but does not have sleepiness they also should not drive until "associated symptoms" like "poor concentration" are controlled. However, they do not have to inform the DVLA even if they are HGV drivers.

The evidence base of such advice is limited. While there is no dearth of evidence supporting

Table 1 Excessive sleepiness, including obstructive sleep apnoea syndrome

	Group 1: car and motorcycle	Group 2: bus and lorry
Excessive sleepiness including due to mild obstructive sleep apnoea syndrome AHI <15 (mild) on the or equivalent sleep study measure	Must not drive but may not need to notify the DVLA Driving may resume only after satisfactory symptom control	Must not drive and must notify the DVLA Driving may be licensed again once control of symptoms is satisfactory The DVLA will require a specialist's confirmation of ongoing adherence to treatment Licensing is subject to review, usually annually
Obstructive sleep apnoea syndrome, moderate and severe apnoeas with sleepiness AHI 15–29 (moderate) or ≥30 (severe) or equivalent sleep study measure	Must not drive and must notify the DVLA This requirement also applies for a suspected diagnosis yet to be confirmed Subsequent licensing will require control of condition sleepiness improved treatment adherence The DVLA will need medical confirmation of the above, and the driver must confirm review to be undertaken every annually at the minimum	Must not drive and must notify the DVLA This requirement also applies for a suspected diagnosis yet to be confirmed Subsequent licensing will require control of condition sleepiness improved treatment adherence The DVLA will need medical confirmation of the above, and the driver must confirm review to be undertaken every 3 years at the minimum
Obstructive sleep apnoea, moderate and severe apnoeas without sleepiness AHI 15–29 (moderate) or ≥30 (severe) or equivalent sleep study measure	Must not drive but need not notify the DVLA Driving may resume once associated symptoms such as poor concentration have been brought under control	Must not drive but need not notify the DVLA Driving may resume once associated symptoms such as poor concentration have been brought under control

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that, on average, OSA sufferers are more likely to be involved in RTAs, there is conflicting evidence in terms of the association between RTA and generalised sleepiness due to OSA as assessed by the ESS [4, 10–12]. Similarly, none of the studies have shown any definite relationship between an increased incidence of RTAs with more severe SDB [12, 13]. There have been some data to suggest that assessing sleepiness while driving might be more useful in assessing the risk of RTA [14]. The American Thoracic Society and the British Thoracic Society have based their fitness to drive advice on this aspect [15, 16].

Assessing individual driving risk is difficult. Traditional objective tests of excessive daytime sleepiness like the MWT or OSLER do not represent a complex task like driving. Similarly, tests using simple driving simulators do not reliably replicate real driving and are insufficiently sensitive to identify individual “at-risk” drivers [17, 18]. More recently, using advanced office-based driving simulators with more realistic graphics and controls it has been shown that it is possible to identify a subgroup of OSA sufferers with a higher degree of accuracy who would perform worse than others (area under the receiver operating characteristic curve 0.93) [19–21]. However, no simulation can fully replicate real life. Real-life accidents occur due to a multitude of causes, not just sleepiness. Hence, like everything else in medicine, an individual risk assessment

remains a combination of detailed history and certain investigations.

In practise, a detailed history should include a thorough assessment of a patient's perception of any problems with driving. Patients should be asked about any sleepiness while driving in different driving situations (*e.g.* on motorways or urban roads, and at different times of day). Any history of nodding off at the wheel should be explored and the circumstances of such an incident probed. Patients should be specifically asked about how long they can drive on a motorway without a break. Any history of accidents should be explored, focussing on the circumstances leading up to it. A patient's insight into these problems has to be assessed; for example, a patient might say they do feel sleepy at times and they would routinely pull over for a rest while another patient might admit to feeling sleepy in the afternoons but prefer to finish the drive in one go. The type of driving is also important; for example, somebody who commutes short distances on urban roads might be at lower risk than someone who drives regularly on the motorway. This information has to be combined with other methods of assessing OSA like the ESS and objective measurement of the severity of SDB. While it is possible that some patients might not be as forthcoming with any problems while driving due to worries about losing their licence, assessing the risk from multiple angles should increase the

Table 2 Parameters to assess the risk of road traffic accidents in patients suspected of having obstructive sleep apnoea/hypopnoea syndrome**Driving-related parameters**

- Taking a break at <1 h during long journeys
- Likelihood of feeling sleepy while driving
- Nodded off whilst driving in the last year
- Any accidents in the last 3 years related to sleepiness

Clinical parameters

- Epworth Sleepiness Scale and history of tiredness and sleepiness
- Objective testing: apnoea-hypopnoea index, apnoeas and hypopnoeas/ time in bed, oxygen desaturation index

chance of picking up an issue. A recent study has shown that a subject is much more likely to fail a simulated driving test if they have admitted to nodding off at the wheel ($p=0.014$), feeling highly sleepy while driving ($p=0.006$) or taking a break at less than an hour of driving ($p<0.001$) suggesting some correlation between real life and simulated performance [22]. There was correlation with higher ESS ($p=0.04$) but the correlation with severity of OSA ($p=0.08$) and real-life accidents ($p=0.09$) stopped short of statistical significance.

In conclusion, an OSA patient's risk of having a RTA should be assessed using detailed driving history with a specific focus on the "red flags" (table 2). The driving regulatory authorities should take this

into account while issuing their guidance. While allowing a driver who is not safe to drive can have potentially disastrous consequences, preventing a person who is as safe as anybody else in the community can have significant consequences in terms of their employment and quality of life. It also risks driving the problem underground with people not coming forward with suspected OSA for fear of losing their licence. Finally, it is important to note that one clinician's comprehensive risk assessment of driving may lead to a different conclusion from that of another. This is unavoidable, but if there are large discrepancies this may lead to significant dissatisfaction from patients [23].

Currently, the British Sleep Society and the British Thoracic Society are attempting to negotiate with the DVLA regarding the guidance issued in response to the EU directive. Driving risk has been based purely on the severity of SDB without defining excessive daytime sleepiness. Failure to include a specialist in the area of SDB on the DVLA panel when revising the advice or to consult with clinicians working in this area has led to confusing and contradictory guidelines, and throws into question the concept of "authorised medical advice". The European Respiratory Society has established a task force in the area of driving and OSA to develop guidance and help ensure that any adoption of EU directive 2014/85/EU is undertaken in a reasoned, sustainable and fair manner in line with each country's legislative procedures and economic resources [24, 25].

Conflict of interest

Disclosures can be found alongside this article at breathe.ersjournals.com

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