



New rules on driver licensing for patients with obstructive sleep apnoea: EU Directive 2014/85/EU

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Joint ERS/ESRS working group on the EU directive on issuing driving licences in obstructive sleep apnoea patients <http://ow.ly/UNchD>

The widespread recognition that obstructive sleep apnoea (OSA) represents an important risk factor for motor vehicle accidents (MVA), which is reversed by successful therapy with continuous positive airway pressure (CPAP), has led to a revision of annex III of the European Union (EU) directive on driving licences that is subject to mandatory implementation by all member states from December 31, 2015 [1]. This directive was the result of recommendations from a working group established by the Transport and Mobility Directorate of the European Commission in 2012 [2]. The directive states [1]:

- 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.
- 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.
- 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 [noncommercial drivers] and one year for drivers of group 2 [commercial drivers], with a view to establish the level of compliance with the treatment, the need for continuing the treatment and continued good vigilance.

While the recognition of OSA and its potential consequences on driving represents a major step towards increased safety on the road, European pulmonologists and sleep specialists face several problems. First, practical application of the directive is demanded from governments of member states. Since rules for medical assessment before obtaining a driving licence differ among European states [3], a standardised approach to implementation of the EU directive would be highly desirable. Second, patients with diagnosed OSA represent the tip of the iceberg of a large population with unrecognised and untreated sleep disordered breathing, and the new requirements established by the EU directive could considerably

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increase the number of requests for specialist evaluation, and lengthen waiting lists. Affordable medical evaluations, and an acceptable timeframe to obtain the new or renewed driving licence, appear reasonable targets, but screening for OSA on a large scale will put considerable strain on health systems throughout Europe. Third, episodes of sleepiness at the wheel in the previous 2 years were reported by 17% of European drivers in a recent survey, underlining that it is quite a common problem [4]. Sleepiness at the wheel was associated with poor sleep, younger age, male sex, driving exposure, daytime sleepiness and a high risk of OSA [4].

Although OSA increases the risk of traffic accidents [5], the disorder is associated with excessive daytime sleepiness (EDS) in only ~50% of patients. While reports differ, the majority of evidence supports the view that driving risk in OSA is more closely related to the degree of daytime sleepiness than the objective severity of sleep disordered breathing as measured by the frequency of apnoeas and hypopnoeas per hour of sleep (apnoea-hypopnoea index) [6]. However, other factors can contribute to sleepiness in patients with OSA, which include inadequate sleep time, time of day (early morning and afternoon), shift work, sedative medications, poor sleep hygiene, other sleep disorders, and alcohol intake [7]. These additional factors may be particularly important in commercial drivers. Furthermore, these factors, which are not directly related to OSA severity, may contribute to some of the variability in reported sleepiness in patients with differing levels of disease severity based on apnoea-hypopnoea index, and of course may also be present in patients without OSA, thus contributing to accident risk. Effective OSA treatment, usually with CPAP, rapidly resolves both apnoea and EDS in the large majority of affected patients [8, 9].

A possible way to deal with the problem of driving in OSA patients was proposed by the British Thoracic Society (BTS) in 2014 [10]. The BTS statement on driving licence regulation pragmatically focused on the evaluation and treatment of sleepy patients only [10]. However, UK subjects requesting a driving licence receive detailed information about OSA symptoms, and have to report symptoms of sleepiness to their general practitioner (GP). Moreover, the Driver and Vehicle Licensing Agency directly manages the assessment, together with the GP or a specialist, if necessary [10]. Such a model is hardly applicable in most EU member states, where the GP or specialist has to issue a medical certificate.

Subjective EDS in OSA patients is usually assessed by questionnaires, which are subjective and thus susceptible to reporting bias by a driver who seeks to underestimate severity, whereas objective evaluation is expensive, time consuming, and not well suited to being performed on a large scale. It is likely that the EU directive will foster research to develop new tools to assess fitness to drive. Such tools are currently lacking, and this is a major problem to face in the near future.

This lack of tools is particularly evident in the context of the assessment of sleepiness. The need for practical guidelines for clinicians is particularly evident in a recent report demonstrating a lack of consensus in clinicians' judgement of fitness to drive in both untreated and CPAP-treated patients with OSA [11].

Because of the major impact the directive might have on sleep and pulmonary specialists, the European Respiratory Society (ERS) and the European Sleep Research Society (ESRS) will jointly appoint a group of experts to develop practical recommendations to cope with the problems raised by the new EU directive on issuing driving licences in Europe. The European Lung Foundation (ELF) will also be involved, providing the important point of view of patients with OSA. Patient involvement is particularly important in order to minimise the risk of encouraging OSA patients to avoid seeking medical attention and treatment because of the understandable concern that such a diagnosis would compromise their ability to continue driving. This risk is particularly concerning for commercial drivers who depend on retention of a valid driving licence for their livelihood and also represent the group where failure to diagnose and treat OSA carries the greatest risk to public safety. In this context, a "carrot and stick" approach is required with the principal emphasis being on the carrot, and a detailed campaign to educate patients, employers and other relevant stakeholders about this topic is required.

Questions to be addressed by the group include the following. How should the suspicion of moderate or severe OSA be justified? Are there simple and readily available tools to assess OSA and sleepiness in the population? What is the consensus on a minimal medical expert standard to establish good compliance to, and effectiveness of, treatment? Which tests or investigations should be used to certify continued good vigilance? In addition to this document, planned for early 2016, further initiatives will be set up to obtain additional information over time, and update/adjust recommendations.

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