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

The widespread recognition that obstructive sleep apnea (OSA) represents an important risk factor for motor vehicle accidents, 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. This directive was the result of recommendations from a Working Group established by the Transport and Mobility Directorate of the European Commission in 2012 (McNicholas, 2013). The new Directive, which is subject to mandatory implementation by all Member States from 31 December 2015, states:

- '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.
- 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.
- 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.'

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 have to face several problems. First, practical application of the Directive is demanded from governments of Member States. Because rules for medical assessment before obtaining a driving licence differ among European States (Alonderis *et al.*, 2008), a standardized approach to implementation of the EU Directive would be highly desirable. Secondly, patients with diagnosed OSA represent the tip of the iceberg of a large population with unrecognized and untreated sleep-disordered breathing, and the new requirements established by the EU Directive can considerably increase the requests for specialist evaluation and lengthen waiting-lists. Affordable medical evaluation, and an acceptable time-frame to obtain the new or renewed driving licence, appear to be reasonable targets, but screening for OSA on a large scale will strain the Health Systems considerably throughout Europe. Thirdly, 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 a common problem (Gonçalves *et al.*, 2015). Sleepiness at the wheel was associated with poor sleep, younger age, male gender, driving exposure, daytime sleepiness and high risk of OSA (Gonçalves *et al.*, 2015).

Although OSA increases the risk of traffic accidents (Strohl *et al.*, 2013), the disorder is associated with excessive daytime sleepiness (EDS) in only approximately 50% of patients. While reports differ, the majority of evidence supports the view that driving risk in OSA is related more closely to the degree of daytime sleepiness than the objective severity of sleep-disordered breathing as measured by the frequency of apneas and hypopneas per hour of sleep [Apnea–Hypopnea Index (AHI)] (McNicholas and Rodenstein, 2015). However, other factors can contribute to sleepiness in patients with OSA, which include inadequate sleep time, time of day (early morning and afternoon), shiftwork, sedative medications, poor sleep hygiene, other sleep disorders and alcohol intake (Di Milia *et al.*, 2011), and these additional factors may be particularly important in commercial drivers. Furthermore, these factors, which are not related directly to OSA severity, may contribute to some of the variability in reported sleepiness in patients with differing levels of disease severity based on the AHI and, of course, may also be present in patients without OSA, thus contributing to accident risk. Effective OSA treatment, usually with CPAP, resolves both apnea and EDS rapidly in the large majority of affected patients (Sassani *et al.*, 2004; Tregear *et al.*, 2010).

A possible way to deal with the problem of driving in OSA patients was proposed by the British Thoracic Society (BTS) in 2014. The BTS statement on driving licence regulation focused pragmatically on the evaluation and treatment of sleepy patients only. 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 manages the assessment directly, if necessary together with the GP or a specialist (BTS Statement, 2014). Such an approach would be hardly applicable in most EU Member States, where the GP or a specialist have 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 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 (Dwarakanath *et al.*, 2015).

Because of the major impact the Directive might have on sleep and pulmonary specialists, the European Respiratory Society and the European Sleep Research Society 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 will also be involved, by providing the important points of view of patients with OSA. Patient involvement is particularly important in order to minimize the risk of encouraging OSA patients to avoid seeking medical attention and treatment because of the understandable concern that such a diagnosis would compromise the ability to continue driving. This risk is particularly concerning for commercial drivers, who depend upon 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 is required on this topic.

Questions to be adressed by the group include:

- 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?
- Based on which tests or investigations should continued good vigilance be certified?

As well as this document, planned for early 2016, further initiatives will be set to obtain additional information over time, and update/adjust recommendations.

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