

Obstructive Sleep Apnoea and Driving

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Disclosures


Consultancy fees:
MSD and Jazz Pharmaceuticals

Objectives

- Accident Risk associated with OSA
- Impact of therapy
- European regulations
- Evaluation of driving suitability
- Future direction

Fatigue/Sleepiness and Driving

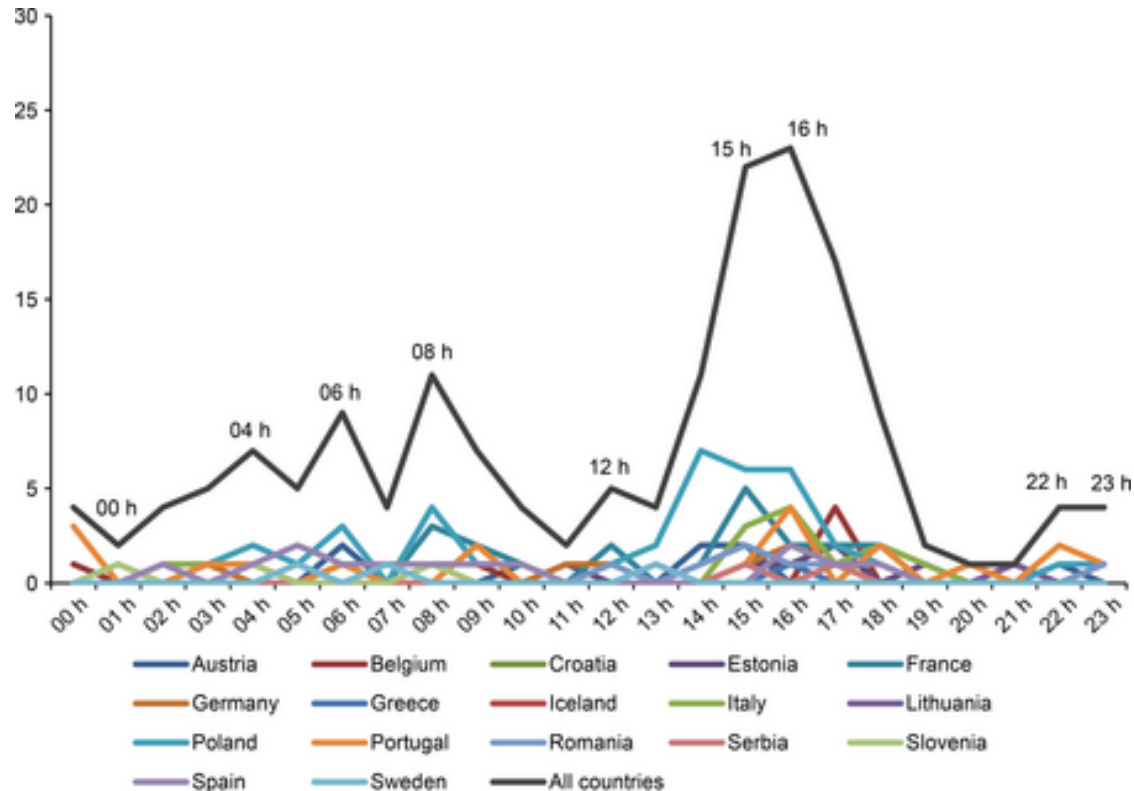
- 20-25% of highway motor vehicle accidents can be attributed to fatigue/sleepiness
- Sleep apnoea is the most prevalent medical disorder associated with sleepiness, affecting up to one billion adults worldwide



Common Characteristics of Sleepiness-Related Crashes

- Often associated with morbidity and mortality
- Most common after midnight and in mid-afternoon, corresponding with the 2 circadian periods of sleepiness and lowered performance
- Typically involve a single vehicle leaving the roadway
- Occur more often on high speed roads
- Sleepy drivers are less likely to take evasive action
- Sleepy drivers are usually alone in the vehicle

Sleepiness at the wheel across Europe: a survey of 19 countries. *Goncalves J Sleep Res 2015.*



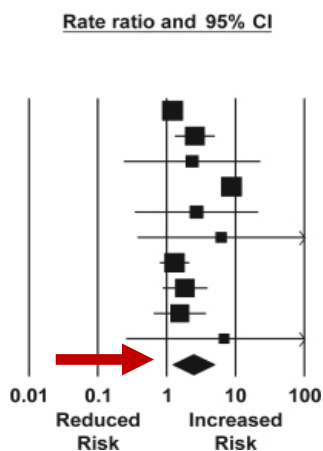
Distribution of the absolute number of accidents by time of day (n = 167 accidents in 17 countries except Turkey and Netherlands where no accidents were reported, chi squared test, compared to random distribution: P = 0.002

OSA and risk of motor vehicle crash.

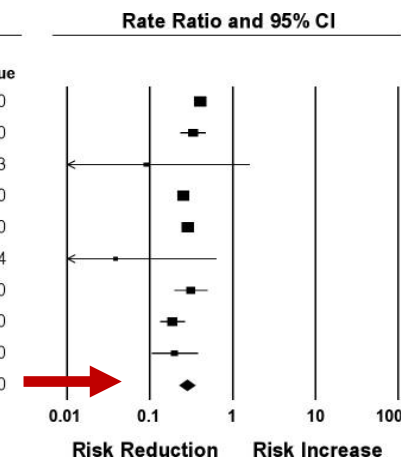
Tregear, J Clin Sleep Med 2009.

CPAP reduces risk of motor vehicle crash among drivers with OSA. *Tregear Sleep. 2010*

Study name	Statistics for each study				
	Rate ratio	Lower limit	Upper limit	Z-Value	p-Value
Mulgrew	1.220	0.920	1.618	1.381	0.167
Barbe	2.570	1.304	5.065	2.727	0.006
Shiomi	2.342	0.237	23.151	0.728	0.467
Horstmann	8.719	6.179	12.303	12.326	0.000
Lloberes	2.720	0.342	21.645	0.946	0.344
Findley 2000	6.195	0.373	102.896	1.272	0.203
George	1.306	0.791	2.157	1.043	0.297
Stoohs	1.848	0.865	3.948	1.586	0.113
Haraldsson	1.551	0.641	3.754	0.973	0.331
Findley 1988	6.833	0.257	181.683	1.148	0.251
	2.427	1.205	4.890	2.480	0.013



Study Name	Statistics for Each Study				
	Rate Ratio	Lower Limit	Upper Limit	Z-Value	P-Value
Barbe	0.407	0.370	0.447	-18.566	0.000
George	0.333	0.231	0.482	-5.850	0.000
Findley	0.090	0.005	1.631	-1.629	0.103
Horstmann	0.255	0.232	0.279	-29.279	0.000
Scharf	0.286	0.250	0.327	-18.292	0.000
Yamamoto	0.039	0.002	0.649	-2.260	0.024
Krieger	0.313	0.194	0.503	-4.797	0.000
Cassel	0.188	0.131	0.267	-9.246	0.000
Engleman (injury)	0.200	0.104	0.385	-4.811	0.000
	0.278	0.223	0.348	-11.214	0.000



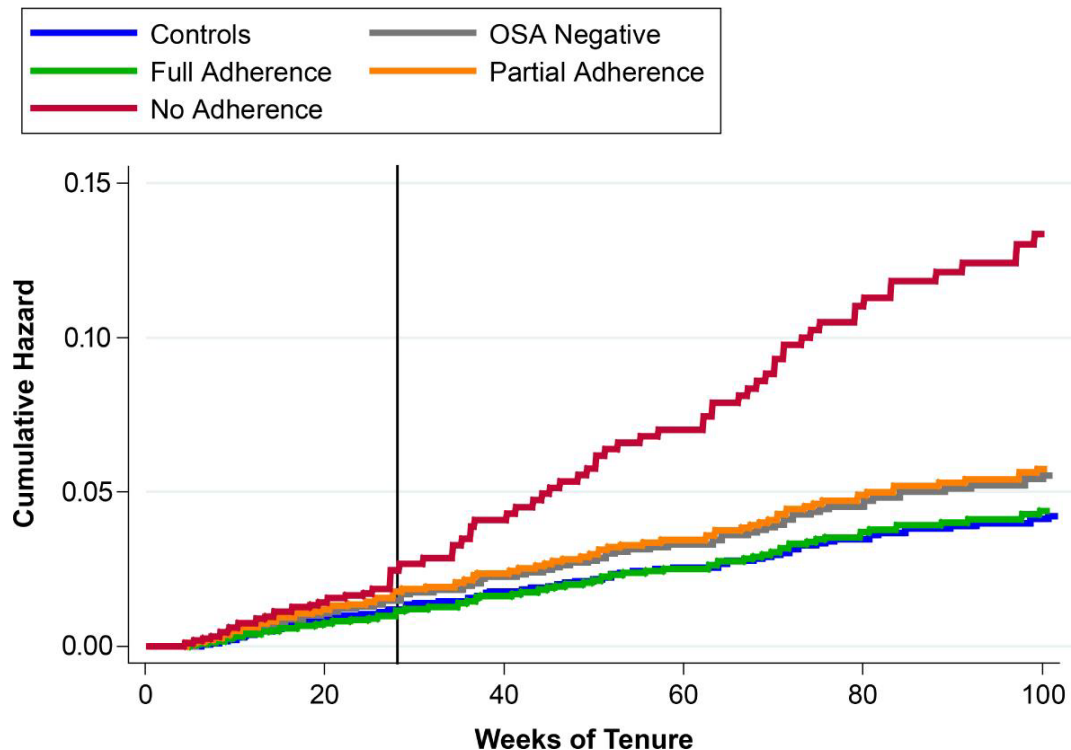
MVA Risk of Sleep Apnoea vs other Disorders

IMMORTAL Project, 2003 (Impaired Motorists, Methods Of Roadside Testing and Assessment for Licensing): Funded under EC Transport RTD Programme of the 5th Framework Programme.

- 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
- **The relative Risk of MVA for Sleep Apnoea/Narcolepsy was 3.71, and most of this was due to Sleep Apnoea.**

Non-adherence with Employer-Mandated OSA Treatment and Risk of Serious Truck Crashes

- US trucking industry study comparing OSA+ and OSA- patients from PSG studies with matched control drivers.
- DOT-reportable crashes/100,000 miles compared between groups with CPAP treatment stratified by adherence.



Conclusions:

- Untreated OSA is a substantial risk factor for MVA in truck drivers
- CPAP compliant drivers have same accident risk as controls

European Commission

- Working Group on “Driving and Sleep Apnoea” established in 2012 by the EC Transport Directorate.
- Report completed: May 2013 – presented to the Transport Directorate Driving Licence Committee, June 2013
 - McNicholas WT et al. New Standards and Guidelines for Drivers with Obstructive Sleep Apnoea. European Commission 2013.
- EU Directive on Licencing for Drivers with OSA.
 - Mandatory since December 2015

Revision to Annex III – EU Directive, June 2014

Mandatory Implementation by Member States - Dec 2015

- 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 with moderate or severe obstructive sleep apnoea syndrome should be advised to seek medical advice. They may be advised to seek medical advice if they are surprised by their excessive daytime sleepiness. They may be advised to seek medical advice if they are surprised by their excessive daytime sleepiness.
- 11.4.** Drivers with moderate or severe obstructive sleep apnoea syndrome should not drive until 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 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 maintain of good vigilance, and the need for continuing, the treatment

Patients with moderate or severe OSA associated with significant sleepiness should not drive until effective treatment is demonstrated

Revision to Annex III of Directive 2006/126/EC (2014) - OSA

- Define the population: Sleepy patients with moderate/severe OSAS defined by standard criteria
- Allow patients with adequately treated OSAS to resume or continue driving
- OSAS patients on treatment require periodic medical follow-up, with stricter requirements for Group 2 drivers.
- *Carrot and Stick* approach - emphasis on carrot

EU/EC Links to Documents

- Addition to Annex III:
 - http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.194.01.0010.01.ENG
- Working Group report:
 - http://ec.europa.eu/transport/road_safety/topics/behaviour/fitness_to_drive/index_en.htm

Individual Countries free to develop own regulations with EU Directive as the minimum requirement – many countries have adopted stricter criteria.

Practical Difficulties with Implementation

- **How to assess significant sleepiness?**
 - Patient's own report is all that the Directive requires but open to subjective bias
 - Objective evaluation more complicated but driving simulator performance helpful in predicting accident risk
- **Who should be responsible for patient certification to drive?**
 - Ideally should come from sleep specialist but patient volumes make this very difficult
 - Technology of CPAP devices help considerably
 - Education of GP and non-sleep specialists
 - Ultimate responsibility to issue licence remains with Licensing authority

Variability in clinicians' opinions regarding fitness to drive in patients with OSA.

Dwarakanath et al, Thorax 2015;70:495-497

- Marked lack of consensus in clinicians' judgement of fitness to drive in both untreated and CPAP-treated OSAS patients.

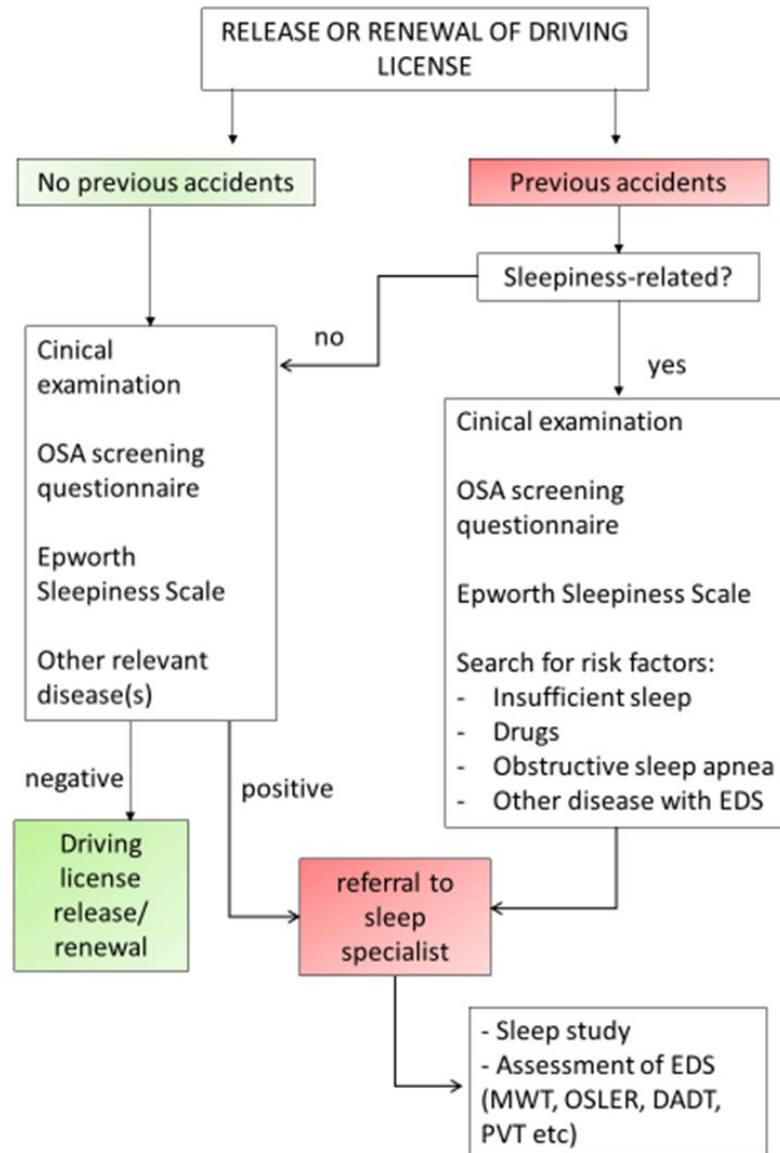
ERS Task Force on Sleep Apnoea, Sleepiness and Driving Risk.

- Established in 2016 in co-operation with ESRS.
- Oxford Criteria for Evidence-based Medicine Levels of Evidence. Evidence base not sufficiently strong to produce Guidelines or Recommendations
- **European Respiratory Society Statement on Sleep Apnoea, Sleepiness and Driving Risk.** Bonsignore Maria R, Randerath Winfried, Schiza Sofia, McNicholas Walter T. Eur Resp J 2021 Feb 25;57(2):2001272

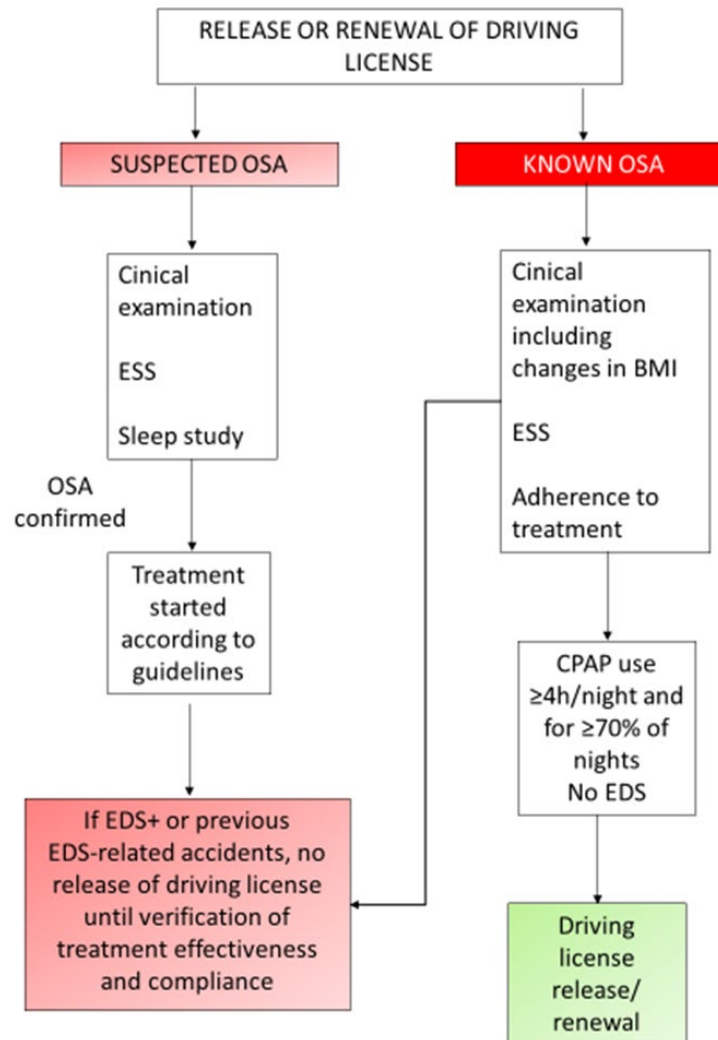
Statements for Clinicians Advising on Fitness to Drive in OSA Patients

- OSA severity assessed as AHI alone does not predict fitness to drive in OSA patients
- Excessive sleepiness is a major factor in determining accident risk in OSA, but does not relate to AHI and may be partly due to other non-OSA factors
- Where doubt exists regarding the validity of self-reported sleepiness, further investigation, such as MWT, is warranted, especially in professional drivers
- Effective and compliant treatment of OSA with CPAP largely reverses the increased accident risk and driving can resume once demonstrated

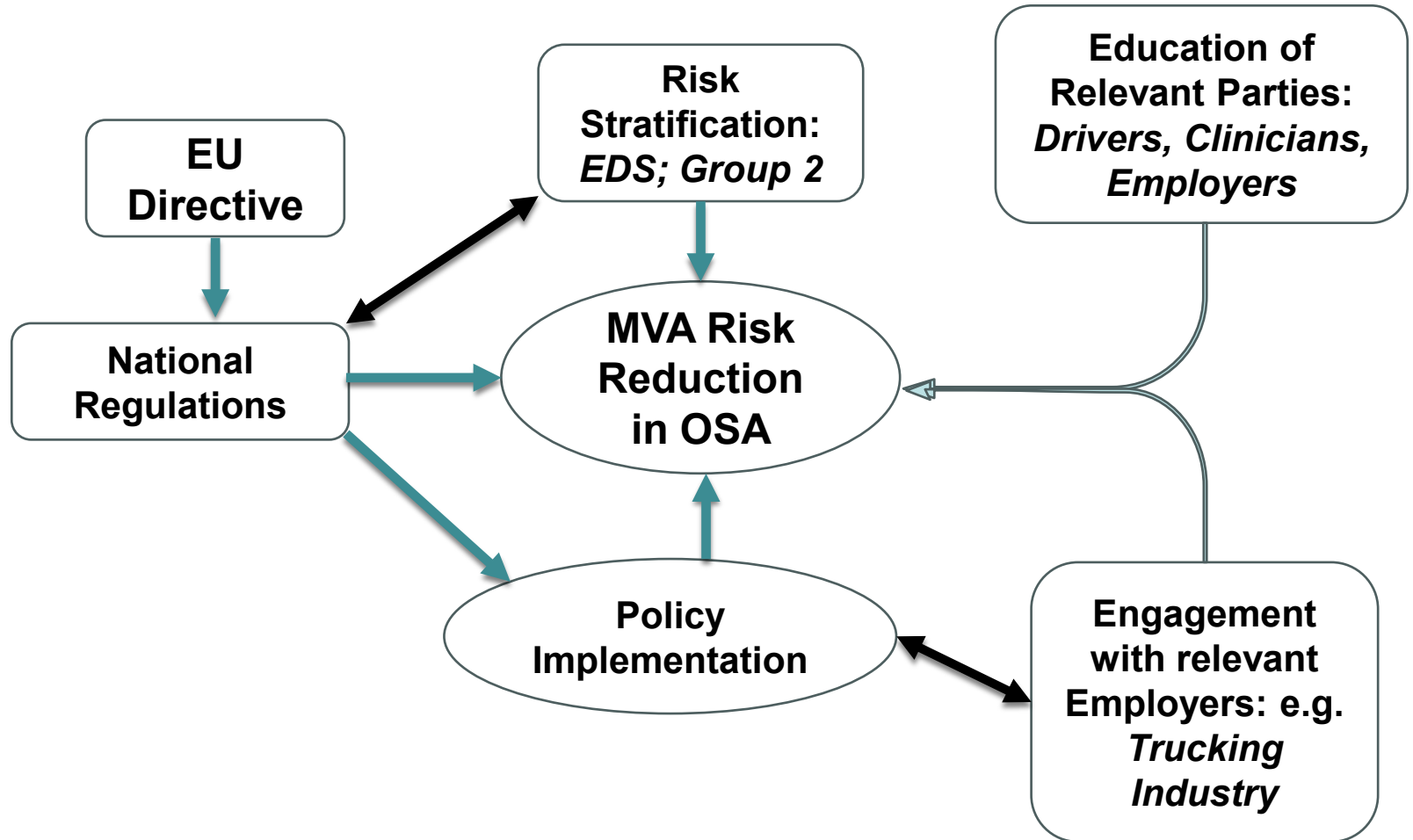
Evaluation of Drivers suspected of OSA



Evaluation of OSA Drivers for Licensing



Strategies towards MVA risk reduction in patients with OSA.



Vehicle Adaptations to minimise accident risk

- Drowsy driving detection – eyelid droop, lane drift
- Advanced emergency braking system reduces the risk of motor vehicle collisions caused by falling asleep while driving in patients with untreated OSA. *Arita A et al. J Sleep Res: Aug 2022*

Could this be a solution?



**Google
driverless
car**

- Current technology of driverless cars not sufficiently reliable
- Still need an alert “driver” in the vehicle
- Other in-vehicle technology to detect driver fatigue a better option for now

Conclusions

- OSA-associated EDS increases the risk for driving accidents, which is normalized by CPAP use
- The EU Directive specifies OSA as a risk factor for accidents and restricting driving licenses
- EU Countries have differently addressed the problem, and we still do not know the outcomes of the EU Directive.
- Technology, together with heightened medical awareness, will hopefully improve safety while driving

