

# *Obstructive Sleep Apnoea: a treatable cause of driver fatigue*

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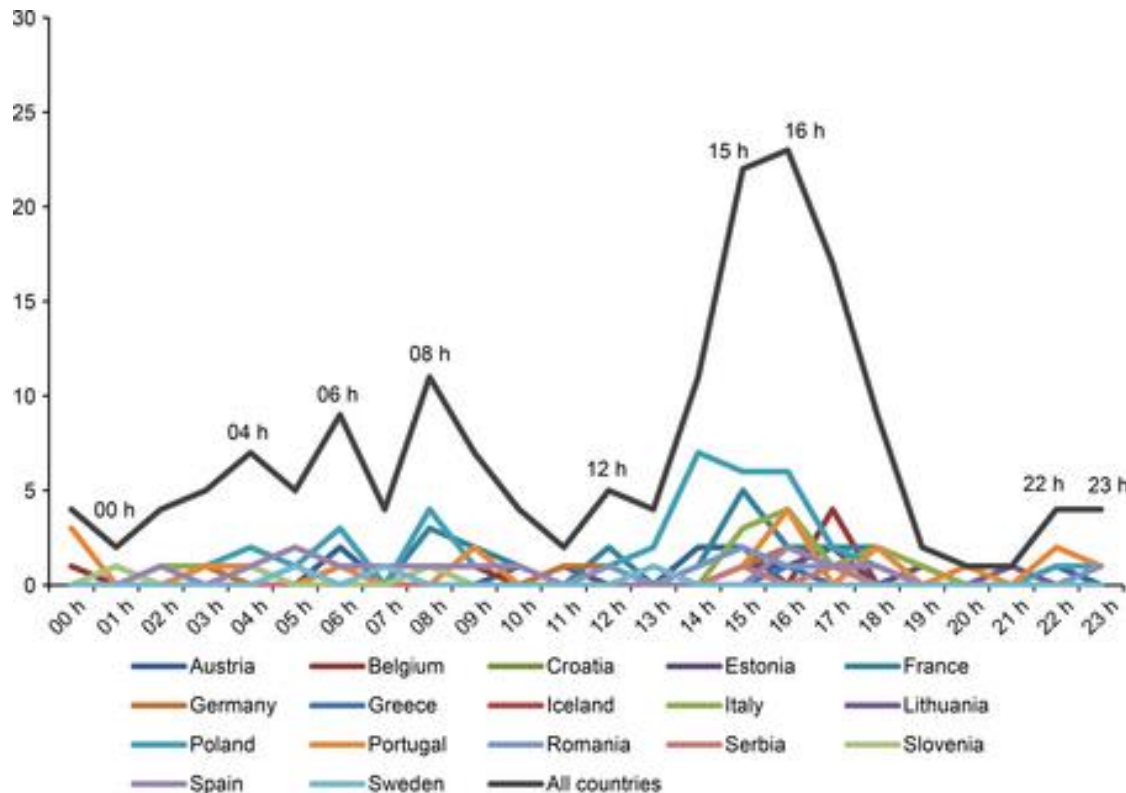
# Fatigue/Sleepiness and Driving

- ▶ 20-25% of major highway motor vehicle accidents can be attributed to fatigue/sleepiness
- ▶ Sleep apnoea is the most prevalent medical disorder associated with sleepiness

# Common Characteristics of Sleepiness-Related Crashes

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

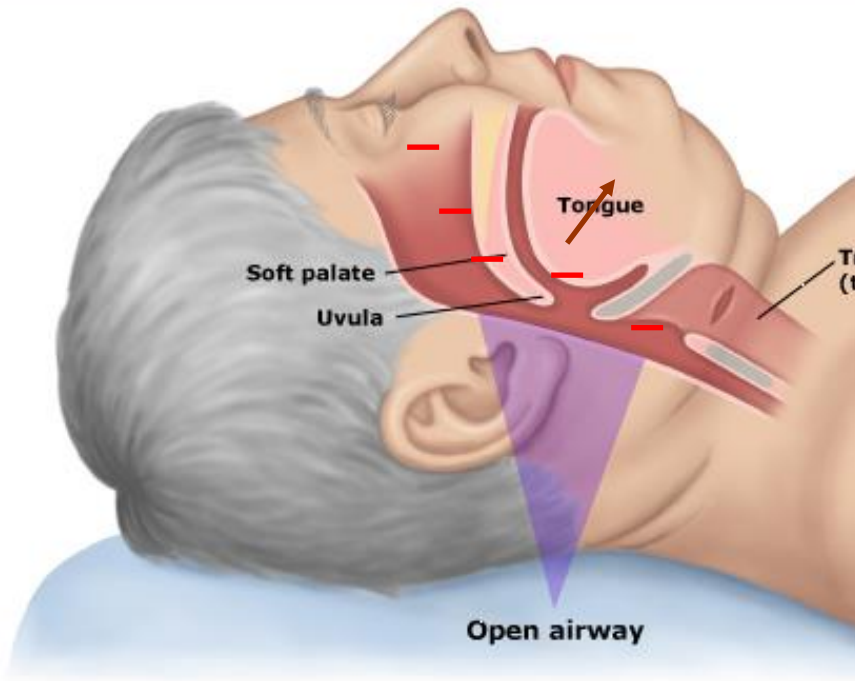
# Sleepiness at the wheel across Europe: a survey of 19 countries. *Goncalves J Sleep Res 2015.*



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:  $P = 0.002$ )

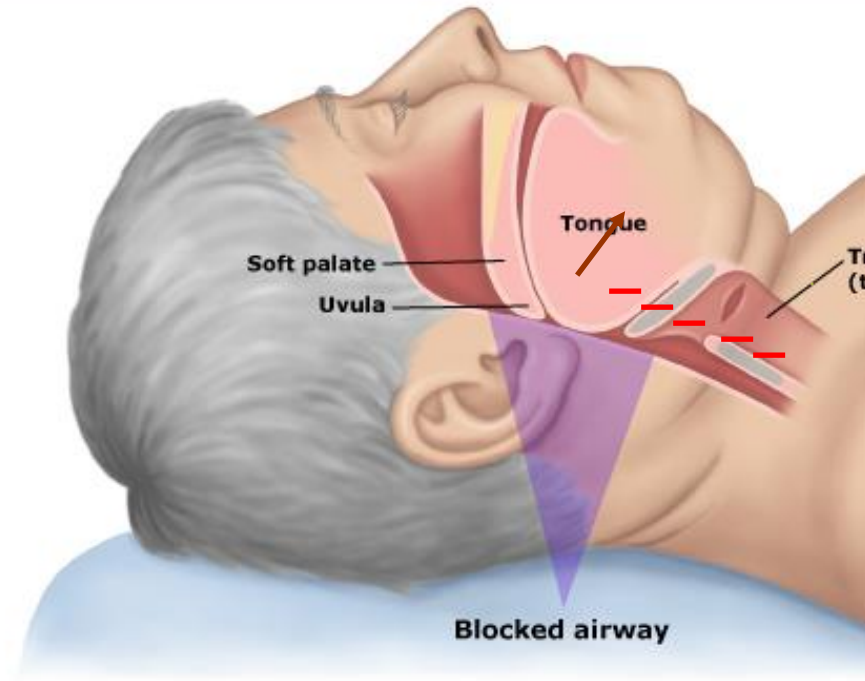
# Obstructive Sleep Apnoea - the most prevalent medical disorder associated with sleepiness

Normal airway during sleep



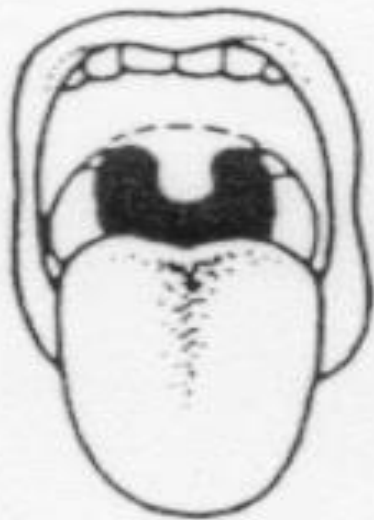
This figure shows how the tongue, uvula, and soft palate (with the upper airway) should normally look in a person who is sleeping.

Sleep apnea



This figure shows how the upper airway can become blocked in people with obstructive sleep apnea.

# Oropharyngeal narrowing in OSAS



Class 1



Class 2

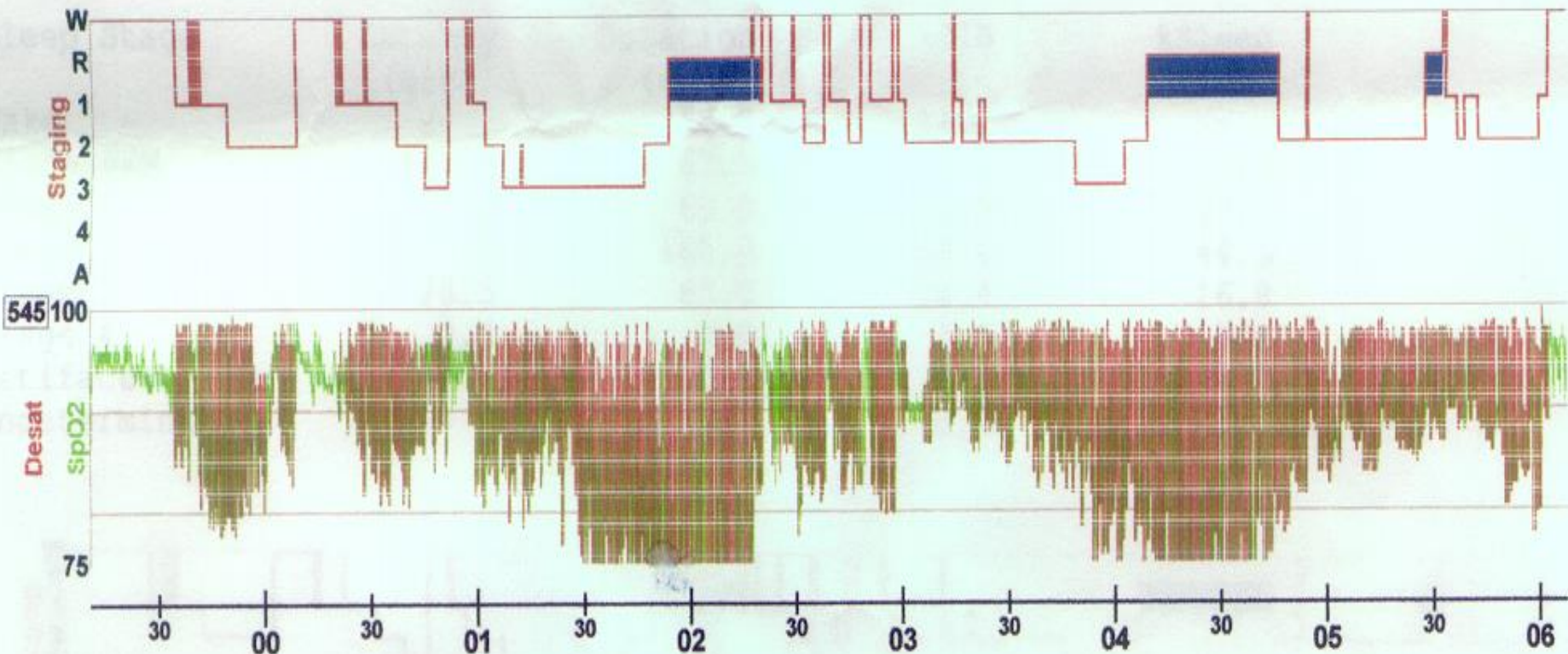


Class 3

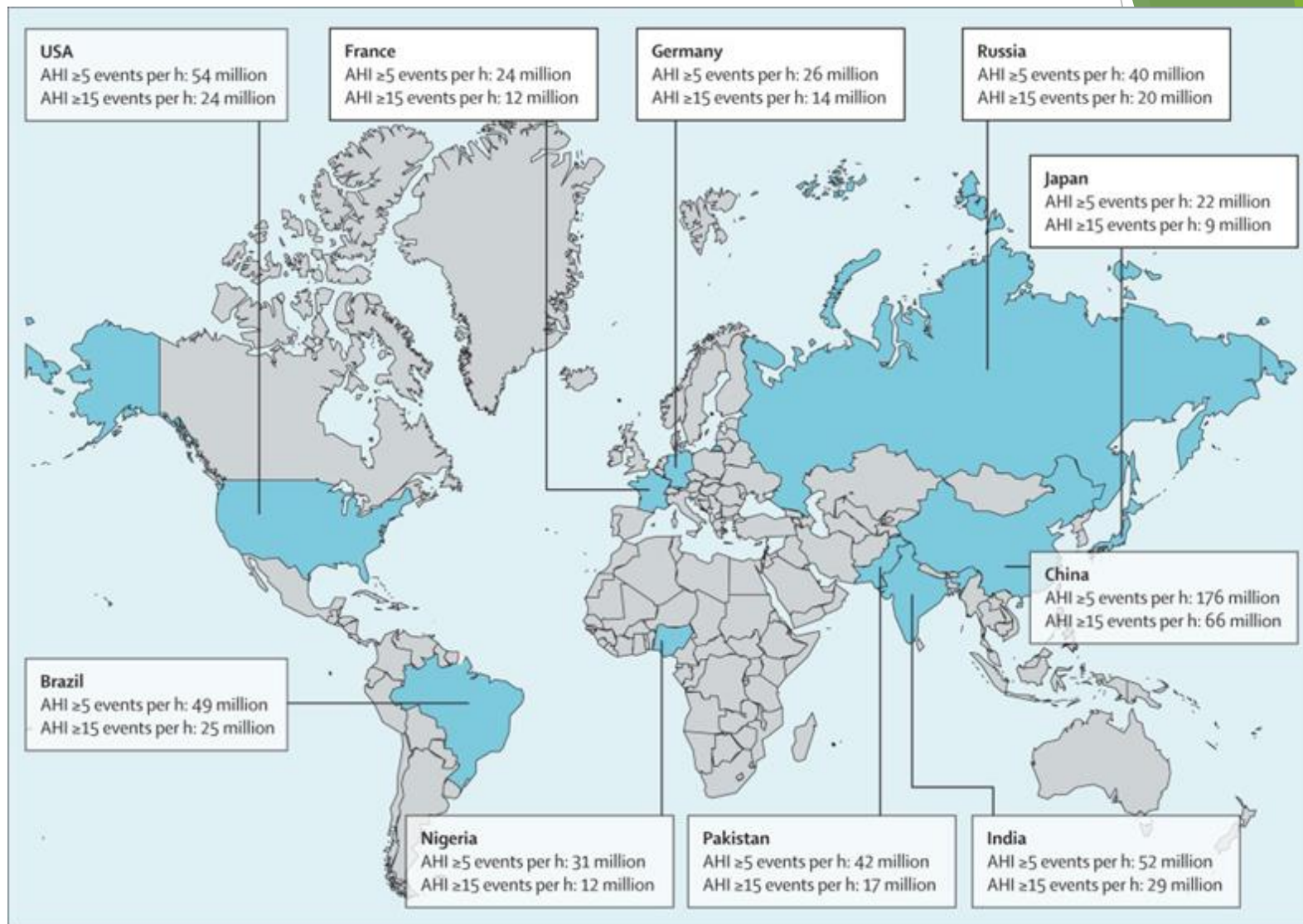


Class 4

# Oxygen desaturation patterns in OSAS



# Global prevalence and burden of OSA





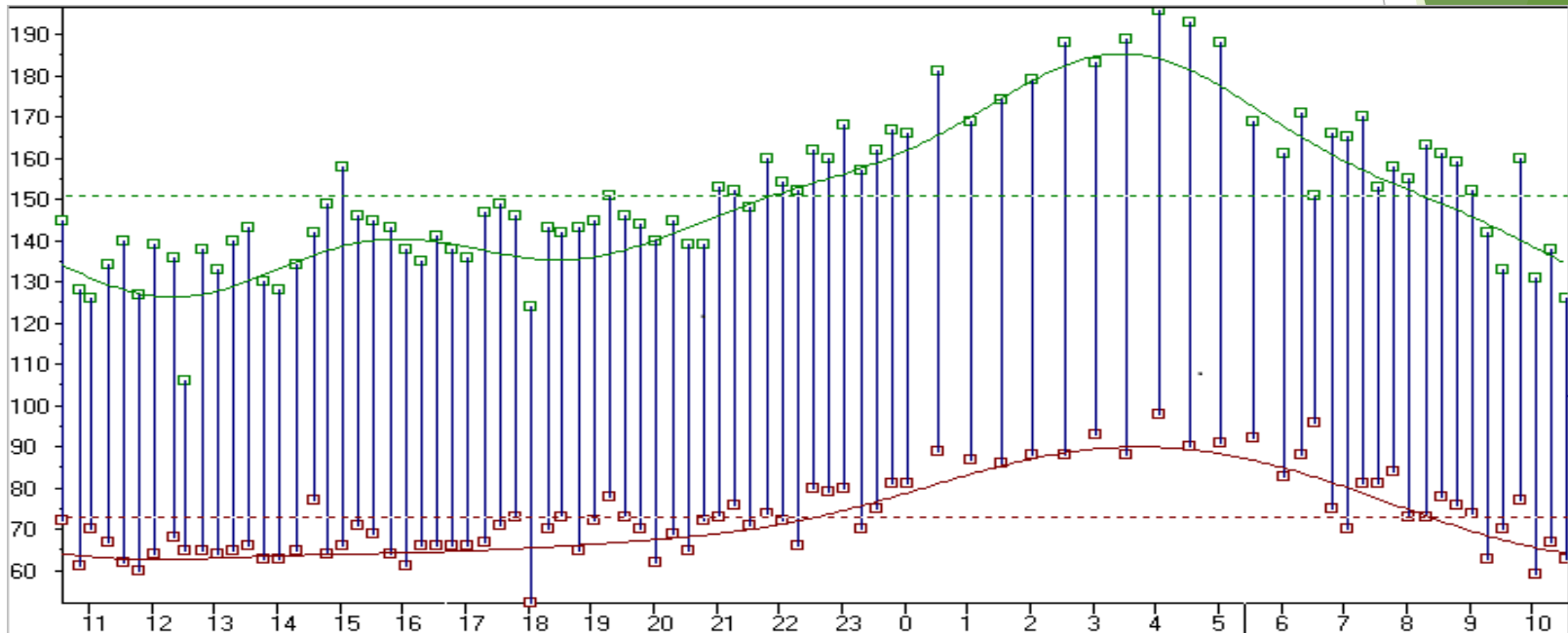
# Sleep Fragmentation from OSA leads to daytime sleepiness



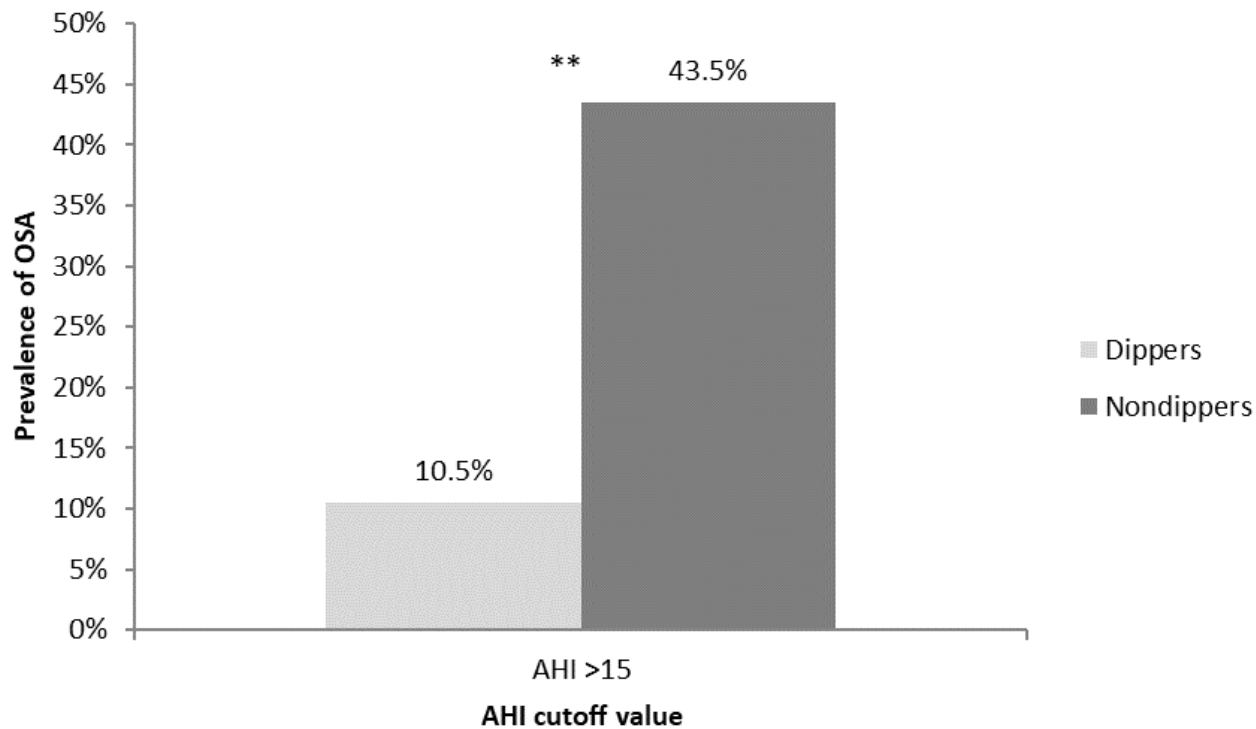
# Truck Drivers represent a special risk group



# Diurnal Blood Pressure Pattern in OSA – loss of normal nocturnal dipping

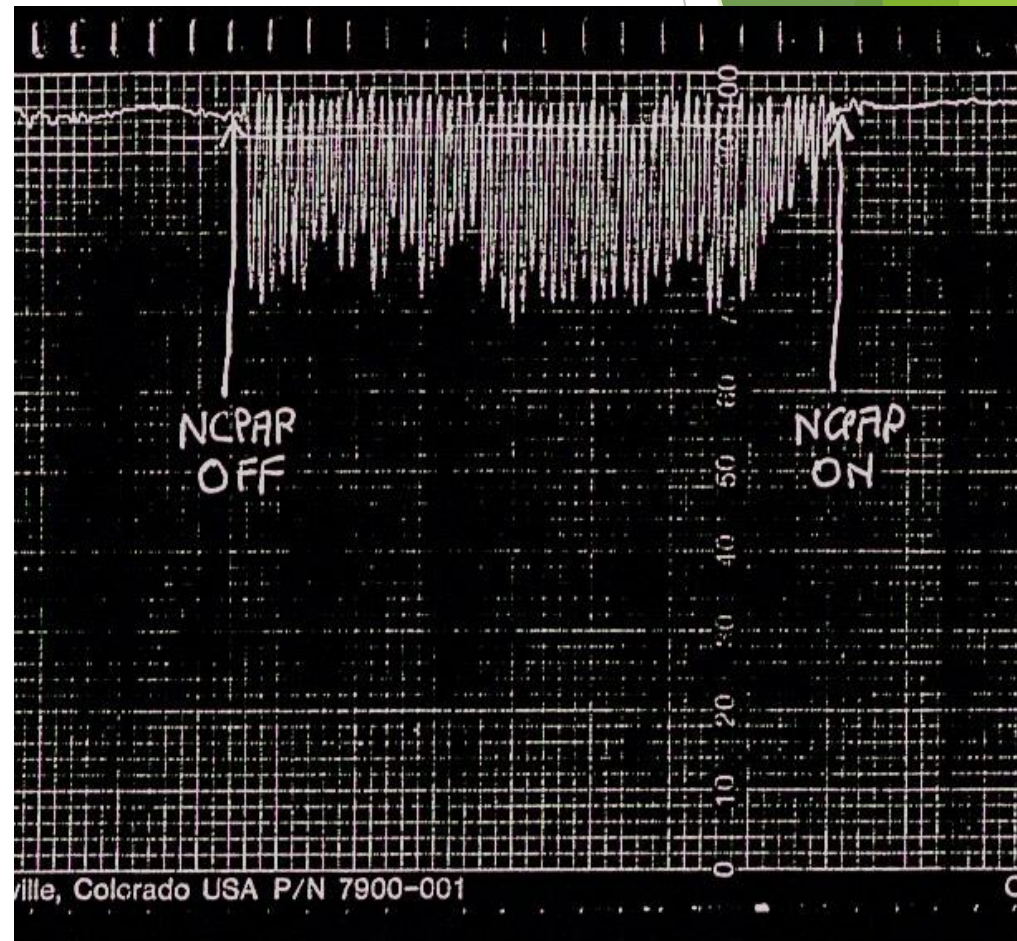


# Prevalence of OSA in Hypertension: Dipper v non-dipper



*Crinion, McNicholas et al. J Clin Sleep Med 2019*

# Effect of Continuous Positive Airway Pressure (CPAP) on Oxygen levels (1989)



# OSA and risk of motor vehicle crash. *Tregear, J Clin Sleep Med 2009.*

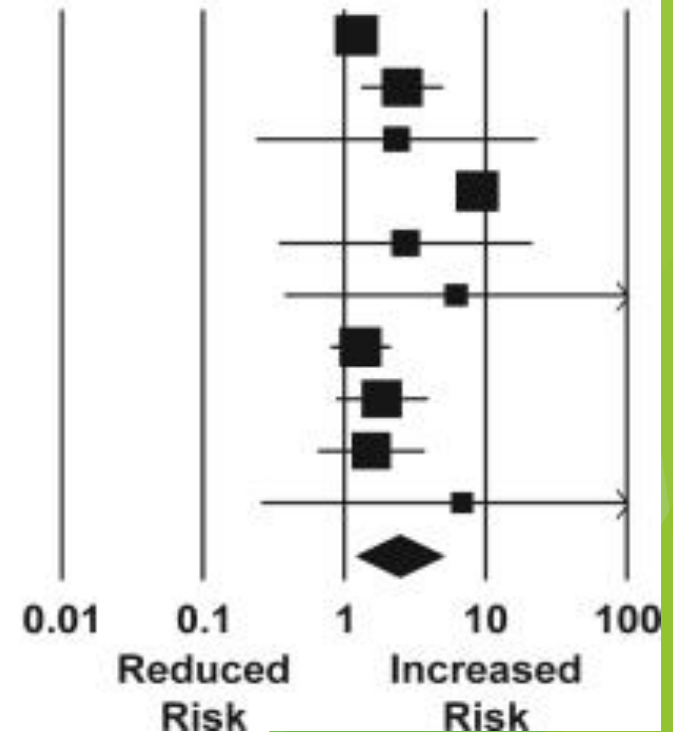


## Study name

## 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

## Rate ratio and 95% CI

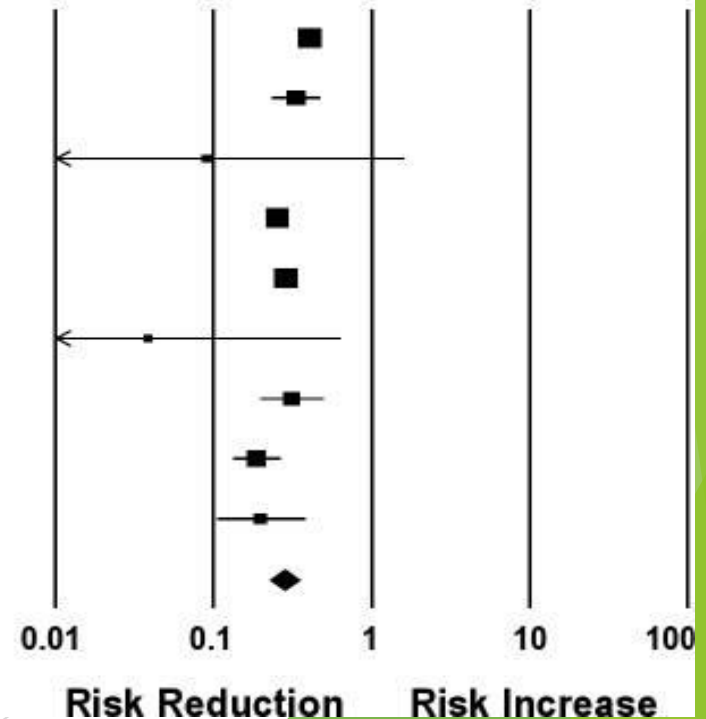


# CPAP reduces risk of motor vehicle crash among drivers with OSA. *Tregear Sleep. 2010*



Study Name	Statistics for Each Study				
	Rate Ratio	Lower Limit	Upper Limit	Z-Value	P-Value
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	0.200	0.104	0.385	-4.811	0.000
(injury)	0.278	0.223	0.348	-11.214	0.000

Rate Ratio and 95% CI

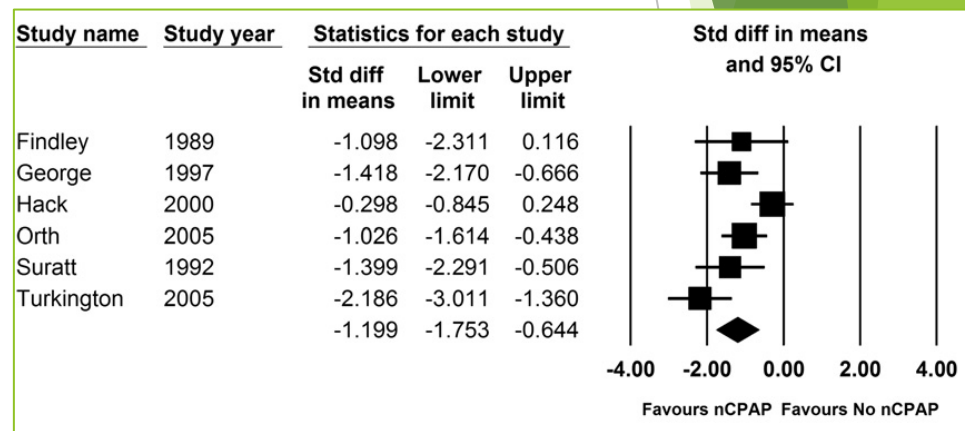
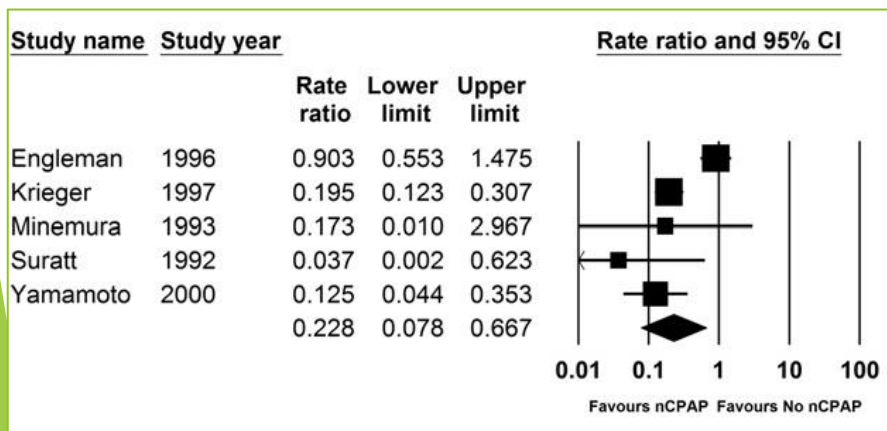


# Nasal CPAP: road traffic accidents and driving simulator performance.

Antonopoulos, Sleep Med Rev 2011

## Near-missed accidents

## Simulated driving





# 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.**

# European Commission

- ▶ EC Transport Directorate established a Working Group on “Driving and Sleep Apnoea” in 2012.
- ▶ Report completed: May 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 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 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

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

- ▶ Define the population: Sleepy patients with moderate/severe OSAS defined by standard criteria (AHI >15)
- ▶ 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 with 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](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](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.*

*Ireland has adopted the Directive largely unchanged*

# Practical Difficulties with Implementation of the Directive

- ▶ How to assess significant sleepiness?
  - ▶ Patient's own report is all that the Directive requires but simple objective screening tools needed
- ▶ Who should be responsible for patient certification to drive?
  - ▶ Ideally, should come from sleep specialist but patient volumes make this unfeasible
  - ▶ Technology of CPAP devices help considerably
    - ▶ *Data on compliance and efficacy*
  - ▶ Ultimate responsibility to issue licence remains with Licensing authority

# Practical Difficulties with Implementation of the Directive

- ▶ How to assess significant sleepiness?
  - ▶ Patient's own report is all that the Directive requires but simple objective screening tools needed
- ▶ Who should be responsible for patient certification to drive?

- ▶ Identify patient

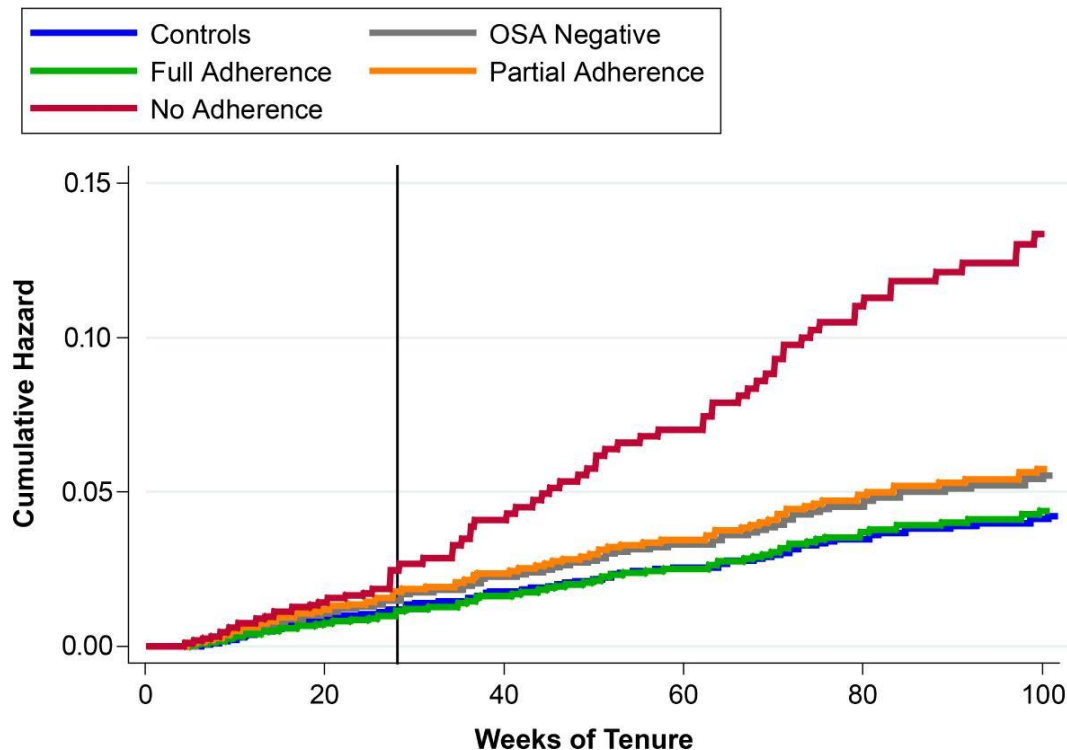
**Educate, Educate, Educate**

*Drivers, Clinicians, Industry*

- ▶ Ultimate responsibility remains with Licensing authority

# 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.

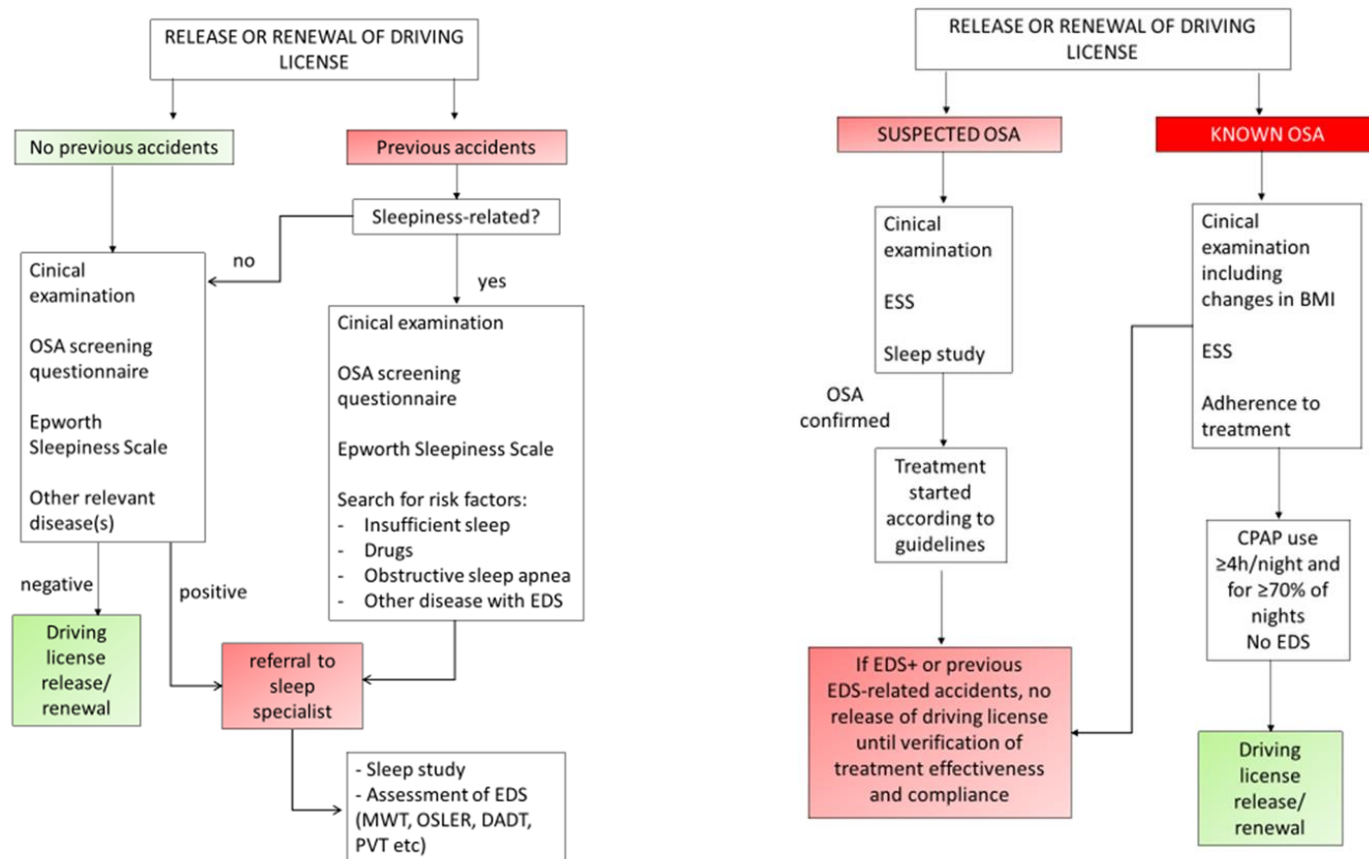


## Conclusions:

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



# European Respiratory Society Statement on Sleep Apnoea, Sleepiness and Driving Risk. Bonsignore Maria R, Randerath Winfried, Schiza Sofia, Verbraecken Johan, Elliott Mark W, .....McNicholas Walter T. Eur Resp J (IN PRESS)



# 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