

CONTEXT

OSA is very common in adults in the UK. OSA can be truly Patients must be given correct advice: generic statements asymptomatic, but can also be associated with excessive to "stop driving and notify the DVLA", without any sleepiness, which may have an adverse effect on driving informed assessment of sleepiness or OSA, have caused whilst OSA is untreated. These people are therefore at some patients to lose their livelihoods when they were not increased risk of motor vehicle collisions.

patients with OSA made it harder for health care tracked for diagnosis and treatment of symptomatic OSA professionals to advise their patients. In January 2016, a (within 4 weeks of referral), so that symptoms are rapidly European Commission Directive on Driving led to controlled, minimising time away from work. This will give extensive changes to the "Excessive Sleepiness including drivers the confidence to present with symptoms OSA" section of the DVLA "Assessing Fitness to Drive – a suggestive of OSA. guide for medical professionals" document of March 2016. Following consultations with professional and patient SCOPE bodies², the DVLA guidance was subsequently updated in This statement supports the current DVLA guidance for the October 2017, see appendix 1. This new guidance is much UK⁴. Although patients will initially present to primary clearer. A new British Thoracic Society (BTS) position care, BTS supports the view that specific advice about statement is therefore appropriate, to clarify and driving and sleep disorders should be part of the standardise the driving advice given to patients with OSA assessment made by the specialist team. General advice by sleep specialists and their teams.

driving and potential loss of licence and livelihood.

sleepy and did not have OSA on subsequent assessment.

In the last two years, changes to the driving rules for BTS strongly supports professional drivers being fast-

not to drive if sleepy applies to all drivers, and it is the driver's responsibility to ensure their fitness to drive. This It is crucial that patients are not deterred from seeking statement is not written for patients specifically. The Sleep advice and treatment for OSA because of concerns about Apnoea Trust website may be helpful to them with its Detailed DVLA Guidance for Drivers⁵.

WHEN IS SLEEPINESS EXCESSIVE AND LIKELY TO ADVERSELY AFFECT DRIVING?

-The ESS alone is unlikely to be adequate, as it is subjective

-The ATS Practice Guidelines offer useful guidance⁸. They emphasise the importance of the clinician identifying a high risk driver by direct questioning. They suggest a high risk driver is one who has moderate to severe daytime sleepiness (suggesting an ESS of >17/24) plus a recent motor vehicle collision (MVC) or a near-miss attributable to sleepiness, fatigue or inattention. They found no compelling evidence to restrict driving privileges in patients with OSA if there had not been a motor vehicle crash or equivalent event.

-People who experience head nodding, hitting the rumble strip, regularly using alerting manoeuvres such as keeping the windows open, stopping for a drink or to stretch, listening to loud music are more likely to have impaired driving due to sleepiness⁹.

-Some specialists impose restrictions on driving, suggesting "some people find they can avoid excessive sleepiness by driving short distances only, driving for less than an hour, driving at times of day when they recognise they are most alert and ensuring adequate night time sleep plus daytime naps".

-Specialist tests of alertness and driving simulation may help to inform these discussions, but do not have any legal standing, and there is no evidence that they predict the likelihood of MVCs. They are not routinely performed in most clinical practice but may have an occasional role in specific circumstances.



ROLES AND RESPONSIBILITIES

GP or other referring health care professional should:

- Recommend that a patient does not drive if excessive sleepiness is having or likely to have an • adverse effect on driving, whatever the cause.
- Arrange onwards referral for specialist review if indicated and ensure prioritisation of cases as urgent where patients report an impact on vigilant • critical activities such as driving, flying or operating dangerous machinery.

The sleep specialist team member (clinician, sleep nurse, sleep physiologist) should:

- Advise the patient that if they hold a driving licence they must follow the DVLA's guidance.
- Help the patient to assess the likely impact of their **The DVLA will:** symptoms on their safety to drive with a detailed . driving history including distances driven, episodes of drowsy driving, information from family members, identifying any crashes or near misses which could be attributed to sleepiness or inattention.
- Advise the patient whether they have just OSA (no DVLA GUIDANCE need to contact DVLA), or OSA plus sleepiness (need This can be viewed in Appendix 1. gives options for "Which condition have you been Appendix 2. diagnosed with?" including "Sleep Apnoea (with excessive sleepiness during normal waking hours) or • OSAS or other sleep condition". Record clearly the discussion and recommendations about driving, and whether the DVLA should be notifed, in the . patient's notes.

The sleep specialist is not responsible for notifying the DVLA, or preventing the patient from driving, or monitoring their compliance with any advice that they should stop driving. If the patient does not accept the opinion of the diagnosis and driving advice, they are entitled to a second opinion. If the specialist becomes • aware that a patient with excessive sleepiness, likely to adversely affect driving, is continuing to drive against medical advice, new strengthened guidance from the GMC⁶ emphasises the doctor's duty to notify the DVLA. It • is acknowledged that this would be a last resort, if efforts to encourage the patient to act responsibly have failed. The doctor does not need the patient's consent. BTS • supports the GMC advice that the patient should be informed of this intention in writing first.

The patient should:

- Report their symptoms honestly to their clinicians.
- Notify the DVLA regarding a diagnosed medical condition when required to do so, including: OSA which affects their ability to drive safely, OSA syndrome
- Comply with the instructions of the DVLA:
 - -The DVLA website A-Z page provides a link to the form that needs to be completed = SL1 or SL1V'.
 - On receipt of this, DVLA opens enquiries with an SL2 (for car/ motorcycle license holders) and SL2V (for lorry and bus licence holders), which are sent to the patient's GP/ hospital consultant as necessary.

Decide whether the patient is fit to drive and whether they can hold a driving licence (acting on information from the patient, and potentially from the GP and/or sleep specialist if this is requested).

to contact the DVLA). The DVLA's new SL1 and SL1V Examples of real life driving scenarios are provided in

- Anyone with excessive sleepiness having or likely to have an adverse affect on driving, whatever the cause, must not drive.
- The updated guidance is absolutely clear that it is only OSA with 'excessive sleepiness having, or likely to have, an adverse effect on driving' that concerns the DVLA. The guidance therefore does not apply to people who do not have excessive sleepiness affecting driving, thus recognising the widespread phenomenon of asymptomatic, or minimally symptomatic, OSA.
- It is called OSA syndrome in the initial section to distinguish it from symptomless OSA and in recognition that in reality even mild OSA (AHI<15 or equivalent test) may adversely affect driving.
- There is now no longer the suggestion that symptomless patients with OSA need to be treated before they can drive.
- The DVLA only needs notifying when the diagnosis has been made, including an informed assessment and a sleep study showing moderate or severe OSA.



- Those with <u>diagnosed</u> moderate or severe OSA and sleepiness affecting driving must not drive and must notify the DVLA. Their continuing licensing requires control of the condition, improved sleepiness and treatment adherence. There is also a requirement for a three yearly review of these factors although the details of this are not yet known.
- Furthermore, there is no need for a patient to notify the DVLA when there is only a suspicion that they might have OSA with sleepiness adversely affecting driving (but they must of course stop driving). This applies to people and awaiting sleep studies assessment. Such sleepiness may turn out to be something different, such as nights disturbed by pain or depression or sedative medication, the • symptoms of which should resolve within three months to allow safe driving again. Even if due to mild OSA with AHI <15 then this too may be relatively easily treated within three months, with • changes in life style for example. The three month rule brings sleepiness in line with other medical conditions which may resolve within three months.

Whilst the differentiation between those patients with mild OSA and moderate to severe OSA is arbitrary, and based on sleep study definitions, the importance of control of condition with improved sleepiness is emphasised for both categories. At present, this symptom control is more likely to be achieved with CPAP for those people with moderate and severe OSA and thus be delivered via the Sleep clinic, and for mild OSA it is more likely to be achieved with non-CPAP therapies such as weight loss, sleeping position, and dental devices for mandibular positioning reality, significant In sleepiness (particularly if adversely affecting driving) in people with mild OSA is likely to prompt a trial of CPAP if first line therapies fail.

- This guidance is applicable to both Group 1 and Group 2 drivers. For Group 2 drivers, compliance with treatment and ongoing symptom control must be assessed on an annual basis.
- The Sleep Apnoea Trust Association recommends patients write to the DVLA rather than communicating by phone or online, to ensure a consistent assessment.

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British Thoracic Society 30 April 2018

Appendix 3 added 1 May 2019

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Appendix 1: Excessive sleepiness—including obstructive sleep apnoea syndrome

Assessing fitness to drive – a guide for medical professionals DVLA Longview Road Morriston Swansea SA6 7JL www.gov.uk/dvla/fitnesstodrive

2018

Chapter 08: Miscellaneous conditions

Excessive sleepiness

- including obstructive sleep apnoea syndrome

'Excessive sleepiness' having, or likely to have, an adverse effect on driving includes:

- obstructive sleep apnoea syndrome of any severity
- any other condition or medication that may cause excessive sleepiness
- see also guidance on Primary/central hypersomnias, including narcolepsy

Legislation states that objective sleep study measurements for driving assessment purposes should use the apnoea-hypopnoea index (AHI). Recognising that not all sleep services use AHI, the DVLA will accept results of equivalent objective tests.

The 'Tiredness can kill' leaflet (INF159) is for drivers concerned about excessive sleepiness.

	Group 1 car and motorcycle	Group 2 bus and lorry
Excessive sleepiness due to a medical condition (see relevant chapter) including mild obstructive sleep apnoea syndrome (AHI below 15) or medication.	Must not drive. Driving may resume only after satisfactory symptom control. If symptom control cannot be achieved in three months the DVLA must be notified.	Must not drive. Driving may resume only after satisfactory symptom control. If symptom control cannot be achieved in three months the DVLA must be notified.
Excessive sleepiness due to obstructive sleep apnoea syndrome – moderate and severe: AHI 15 to 29 (moderate) AHI 30 or more (severe) on the apnoea-hypopnoea index or equivalent sleep study measure.	Must not drive and must notify the DVLA. Subsequent licensing will require: control of condition sleepiness improved treatment adherence. The DVLA will need medical control of the above, and the driver must confirm review to be undertaken every three years at the minimum.	Must not drive and must notify the DVLA. 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 annually at the minimum.
Excessive sleepiness due to suspected obstructive sleep apnoea syndrome.	Must not drive. Driving may resume only after satisfactory symptom control. If symptom control cannot be achieved in three months the DVLA must be notified. See above when diagnosis is confirmed.	Must not drive. Driving may resume only after satisfactory symptom control. If symptom control cannot be achieved in three months the DVLA must be notified. See above when diagnosis is confirmed.
105 ₩ Driver & Vehicle Licensing Agency		

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Appendix 2: BTS Position Statement on Driving and Obstructive Sleep Apnoea (OSA) 2018

REAL LIFE SCENARIOS

These questions and answers are based on interactions with clinicians, patients and the DVLA and provide some further guidance on the enactment of the new DVLA guidelines.

They are not exhaustive and not every person with OSA will fit the scenarios. We would be pleased to hear of other scenarios that are causing problems.

1. Whose responsibility is it to assess whether a patient has excessive sleepiness, such that it is "having or likely to have an adverse effect on driving"?

condition that might affect driving, such as Parkinson's at night for example. disease. It is also the patient's responsibility to notify the DVLA, not the clinician's.

can strongly advise the patient to stop driving. In this therefore be interested in this. situation it would be unwise for the patient to ignore this be prosecuted for dangerous driving.

The GMC has guidelines on the process a doctor has to same. go through if they want to notify the DVLA directly, when they think the patient is a danger to society by continuing to drive.

2. Is there a difference between OSA, OSA syndrome and OSA with sleepiness?

Most clinicians regard OSA as something found on a It is the patient's responsibility to decide if they are safe sleep study that may or may not be producing any to drive, but they may consult a professional to help symptoms. Many people have a degree of OSA without them make this decision, and also to decide whether significant symptoms. OSA syndrome suggests a systemic they need to notify the DVLA. The professional may effect of the OSA found on a sleep study, usually daytime suggest talking to others who know the patient to inform sleepiness, but technically could be other symptoms this decision. This is no different to any other medical caused by OSA, such as sweating at night or gastric reflux

For the purposes of the DVLA however there is either OSA without excessive sleepiness adversely affecting If the patient appears not to understand the implications driving, or OSA with excessive sleepiness adversely of their sleepiness on driving, and the doctor is affecting driving. There might be some sleepiness that is concerned they are a potential danger, then the doctor not adversely affecting driving, but the DVLA should not

advice; should there be a subsequent, apparently sleep- The DVLA's new SL1 and SL1V gives options for "Which related accident, such a driver would be more likely to condition have you been diagnosed with?" which include: "Sleep Apnoea (with excessive sleepiness during normal waking hours) or OSAS", which are basically the

3. If a patient is on CPAP does this automatically mean they should notify the DVLA?

If the CPAP was prescribed in the presence of excessive sleepiness, "having or likely to have an adverse effect on driving" then yes. For most patients prepared to use CPAP this is probably true. However some patients may be using CPAP for other reasons (very loud snoring for example) and they would not in theory have to notify the DVLA. However it would probably be wise to do so, safe in the knowledge that, because there is/was no sleepiness, there should be no restrictions on licensing.



4. If a patient has been diagnosed with OSA with If they then feel better with resolution of the sleepiness, excessive sleepiness, such that it is "having or likely to and hopefully a fall in ESS, then they would need to have an adverse effect on driving", has written to the notify the DVLA as the response to CPAP confirms the DVLA, and is awaiting arrival of SL1 or SL1V to diagnosis. complete, but has in the meantime responded to CPAP There are plenty of people who fall asleep in front of the (or other treatment) with resolution of sleepiness, can TV, and at meetings, who drive perfectly satisfactorily. If they drive immediately without awaiting the DVLA we unnecessarily stop people driving, we will frighten response to the completed SL1 or SL1V?

the patient has responded to the treatment with out patients who may choose to be untruthful about resolution of sleepiness, and is continuing to use the their sleepiness. It is generally believed that the vast CPAP (or other treatment), then they can be told they majority of patients know whether they are excessively responsibility not to drive if sleepiness returns for any affecting their driving. reason. When the SL1 or SL1V arrives, the patient will be able to fill it in and tick "Yes, the condition is under control" (which means that they are free of excessive 6. If a patient is suspected of having OSA with effect on driving) thus safe in the knowledge that does the DVLA need to be notified? because there is no longer any sleepiness, there should there should be no restrictions on licensing.

5. A patient with OSA admits to falling asleep in driving), is likely to be due to OSA, rather than meetings and in front of the television, but says they something else. Of course the patient should already are not sleepy when driving; should they stop driving have stopped driving, as is the case with anyone who has and does the DVLA need to be notified?

No, not necessarily. An attempt needs to be made technically they do not have to stop driving or tell the the SL1 or SL1V. DVLA. They should be advised in no uncertain terms that if they experience any sleepiness that might impair driving, they should stop driving and present for a trial of CPAP or alternative therapy.

away drivers from presenting, which would be the worst of both worlds. We have to take a pragmatic view, and The DVLA has agreed that if the clinician is satisfied that remember clinicians are not policemen trying to catch can drive, remembering that it still remains the patient's sleepy or not and whether it is likely to be adversely

daytime sleepiness having or likely to have an adverse sleepiness having an adverse effect on driving, when

The DVLA need to be notified by the patient when a diagnosis is proven, which usually involves a sleep study that indicates that the excessive sleepiness (affecting excessive sleepiness having or likely to have an adverse effect on driving, for whatever reason.

however (by both patient and clinician) to be satisfied If it is not clear from both the history and the sleep study that there is not any excessive sleepiness having or likely that the excessive sleepiness can definitely be to have an adverse effect on driving, by questioning a attributable to OSA, then the formal diagnosis may need partner for example and being sure there are no sleep- to await the results of a CPAP diagnostic trial, i.e. if CPAP related accidents or near misses. If it seems clear that helps then they have the DVLA notifiable condition, if there are no problems with driving, then the patient not, they presumably don't (unless an alternative need not stop driving and neither do they have to notify notifiable condition has been found of course, e.g. the DVLA. A high ESS however and a previous nodding narcolepsy). If a trial of CPAP is used in this diagnostic off event for example, might lead you to class them as a way, then the patient does not have to notify the DVLA high risk driver, although their other statements do not until they have responded to treatment, and can then support that driving is affected by sleepiness. Therefore say that their condition is under control when filling in



7. If a patient, initially suspected of having OSA, has 9. Does the driver or the sleep unit need to confirm the symptoms having an adverse effect on driving which new annual (class 2) or three year (class 1) review? And are subsequently controlled by treatment other than what does this review entail? CPAP, does the patient need to notify the DVLA and at what point?

If the OSA originally showed an AHI/ODI >15 then yes, are under control, or a GP, a sleep nurse/physiologist, or notify the DVLA, but the patient will honestly be able to the sleep consultant. Once the DVLA agrees what this fill in SL1 or SL1V and be able to say they are not sleepy, will entail, we will communicate this through the OSA and their condition is under control, which will thus not Alliance Group membership (made up of the OSA lead to losing their license. If the AHI/ODI is <15 then Partnership Group, BTS, SATA, ARTP, BSS). technically the DVLA do not need to be notified. This is was the case before these recent changes.

8. The AHI is still included in the guidelines. If a patient has an AHI somewhere between 15 and 30 (or equivalent) who is not sleepy, does the DVLA need to be notified?

No. The DVLA do not need notifying because the patient does not have excessive sleepiness having an adverse effect on driving. In fact, even if the AHI or ODI are above 30, if there is truly no sleepiness having an adverse effect on driving, then there is no need to stop driving and notify the DVLA. Thus the only differentiation based on AHI is that if the AHI is <15 with sleepiness adversely affecting driving then, although driving must cease until the sleepiness resolves, the DVLA only needs to be notified if there is no resolution of sleepiness within three months. This is in accord with other medical events affecting driving that are likely to temporarily affect driving, such as a broken ankle. It is assumed that such mild OSA with symptoms may be improved by simple lifestyle measures, such as weight loss or decreased alcohol consumption.

This is not clear yet. We do not know if the patient may have to self-certify that their condition and symptoms

not entirely logical, given the poor correlation between The original EU report on OSA and driving was designed AHI/ODI and symptoms; however the DVLA felt the EU to harmonise different rules across the EU, which ranged Directive insisted on this differentiation. But at least this from no guidelines at all, to countries that do not allow is the right way around, and the DVLA are no longer OSA patients to drive, even when treated. The suggesting symptomless patients must notify them, as conversion of this into an EU directive, and then its translation into the previous 2016 DVLA guidelines, was what led to problems of interpretation.



Appendix 3: DVLA regulations regarding follow-up of people with OSA on CPAP

The law requires patients who have a diagnosis of moderate or severe obstructive sleep apnoea syndrome (OSA with excessive sleepiness having, or likely to have, an adverse effect on driving), and who are on treatment, to undergo regular review; every year in the case of Group 2 drivers (bus and lorry), and every three years in the case of Group 1 drivers (car and motorcycle). These follow-up appointments are as much for the protection of the patients as they are to satisfy the DVLA of continuing fitness to drive.

In order to subsequently qualify for an unrestricted license, patients who have declared their OSAS may sign a DVLA form (SL1 or SL1V) that, amongst other things, states that they will undergo these follow-up assessments, and it is the responsibility of the patient to organise these with either their GP or their sleep unit. When the DVLA have responded to the SL1 or SLV1 from a patient (saying that they do not have excessive sleepiness having, or likely to have, an adverse effect on driving, such that they do not lose their license) they will send a letter to the patient. It is advised that this is submitted to the sleep unit that treated them, or to their GP, indicating the 1 or 3 year process to be followed. The letter specifies that at the 1 or 3 year regular review, the sleep specialist should check adequate control of the OSAS (a clinical assessment), adequate compliance with treatment, and resolution of the excessive sleepiness. These reviews can be performed either by a doctor or an appropriately qualified sleep trained professional (such as a respiratory physiologist or respiratory specialist nurse).

The DVLA do not send out reminders, nor do they have a system to monitor if these checks are happening but, in the unfortunate event of an accident, it would help the driver to have shown compliance with these conditions. In addition, non-compliance might affect the validity of the vehicle insurance. There is no requirement to inform the DVLA of the results of this review (although of course if the patient no longer meets the medical standards of fitness to drive -e.g. due to excessive sleepiness- they do have a legal obligation to notify DVLA) and the patient should keep documentation (a clinic letter for example). If the review reveals the return of sleepiness sufficient to impair driving, which persists despite corrective advice and management, and the patient refuses to stop driving and notify DVLA, then a process laid down by the GMC needs to be followed before the DVLA can be informed of this issue by the health professional.

Statement agreed by Dr Nick Jenkins, Senior DVLA Doctor, Dr Nerys Lewis and Dr Amanda Edgeworth, DVLA Panel secretaries and DVLA Policy Department with Professor John Stradling and Gillian Gibbons, OSA Partnership Group: April 2019