

Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s

**Consultation on draft guideline - Stakeholder comments table
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Association for Respiratory Technology and Physiology	Guideline	007	002	Although ARTP appreciates why PAT has been grouped with polygraphy, we are concerned that the interpretation of this will be that PAT is of equal value to polygraphy. PAT does not measure respiratory signals. Termination of sleep disordered breathing events is associated with an increase in heart rate, blood pressure, and sympathetic activation. This increase in sympathetic activation results in peripheral vasoconstriction. PAT measures arterial pulse volume changes in the finger as a result of vasoconstriction and vasodilatation. The PAT signal is used to detect apnoea events, but the correlation against AHI from full polysomnography (the gold standard) is not optimal, and may be lower than that achieved using polygraphy, especially in the population where there is significant endothelial dysfunction, i.e., in patients with stiffer arteries.	Thank you for your comment. By PAT we assume you mean peripheral arterial tonometry. We did not include devices that use PAT alone without other respiratory channels in our evidence review. The recommendations we have made for respiratory polygraphy assume that any device used includes at least 4 channels such as oximetry, breathing rate, apnoeas and hypopnoeas, snoring and body position as detailed in the 'Terms used in this guideline' section.
Association for Respiratory Technology and Physiology	Guideline	007	006	ARTP has concerns regarding the quality and number of studies used to evidence the decision making for using nocturnal pulse oximetry in the detection of OSAHS. ARTP notes the very small number of studies in the evidence review for pulse oximetry and believes that this has resulted significant bias in sensitivity and specificity. ARTP recommends clinical judgement be included in the decision making for diagnostic selection.	<p>Thank-you for your comment. The committee acknowledges that the evidence for the relative effectiveness of oximetry is limited and of low quality and they discussed this in detail when making recommendations. Home respiratory polygraphy was more cost effective than both hospital (inpatient) respiratory polygraphy and home oximetry. The committee noted that respiratory polygraphy has the added benefit of aiding the diagnosis of other conditions such as central sleep apnoea and nocturnal hypoventilation and it is better than oximetry alone in identifying artefacts in the recordings. The sleep service will be presented with people with a suspected sleep disorder and not all of those will have clear symptoms of OSAHS.</p> <p>On reviewing all the stakeholder comments the committee agrees that oximetry has a role to play but respiratory polygraphy should be the first choice.</p> <p>The recommendations now state: 1.3.1 Offer home respiratory polygraphy as the first-choice test to people with suspected OSAHS.</p>

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					1.3.2 If access to respiratory polygraphy is limited consider home oximetry for people with suspected OSAHS. Take into account that oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung diseases.
Association for Respiratory Technology and Physiology	Guideline	014	020	ARTP considers that the monitoring of treatment efficacy should include direct questioning concerning sleepiness and driving.	Thank you for your comment. We have added this to the recommendation. The bullet point now reads as "OSAHS symptoms, including the Epworth sleepiness scale and vigilance, for example when driving"
Association for Respiratory Technology and Physiology	Guideline	015	014	<p>When supporting adherence to treatment, ARTP considers it important to recognise that the treatment does not yield a successful outcome for all patients. There comes a point in clinical practice where a decision to terminate the treatment with CPAP has to be made.</p> <p>The guideline currently contains no reference as to how long perseverance with CPAP should persist before that decision has to be made in both the interests of the patient and also the efficiency of the NHS service. ARTP believes that a period not exceeding 4 months from commencement is an appropriate period.</p> <p>If the guideline committee decides not to include such a recommendation, then ARTP would suggest that this is an area for further research.</p>	<p>Thank you for your comment.</p> <p>The committee did not make a recommendation on the withdrawal of treatment for CPAP. Other interventions (oral devices, positional modifiers and surgery) are recommended when CPAP is not working or poorly tolerated (which may be a reason for non-compliance). The committee also make recommendations to support adherence that can be tried if people are not managing to use their devices properly.</p> <p>The committee agreed it is difficult to define when treatment should be withdrawn. This was not an area included in the scope of the guideline and clinical judgement will need to be used to decide whether to stop treatment if none of the offered treatments seem to work, including for non-compliance.</p>
Association for Respiratory Technology and Physiology	Guideline	General	General	ARTP welcomes this guideline which is very clear and wishes to thank the guideline group members for their hard work.	Thank you for your comment.
Association for Respiratory Technology	Guideline	General	General	ARTP has concerns about the recommendation for fixed CPAP as first line treatment. The economic modelling on the use of fixed level devices will vary significantly across the NHS and the	Thank you for your comment. While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS

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and Physiology				<p>guideline group will not have been privy to the significant range of commercial variation between the price of Auto and Fixed pressure CPAP devices. Further the use of auto-titrating device can result in significant savings of human resources; that is beyond question.</p> <p>ARTP recommends that the use of auto-titrating and fixed level devices should be a clinical and service provision decision. ARTP concurs that one of these forms is recommended for the treatment of OSAHS.</p>	<p>treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agree that there might be local circumstances that favour auto-CPAP first-line and so the following bullet point has been added: 'where auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP'.</p>
Association of respiratory Nurse Specialists	Guideline	008	018	<p>For people with mild OSAHS offering Auto CPAP would have an advantage over fixed level CPAP. More adaptable pressure in auto set CPAP compared to fixed. This allows for less clinic follow as titration automatic rather than manual.</p>	<p>Thank you for your comment. The evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p>

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Association of respiratory Nurse Specialists	Guideline	009	001	Telemonitoring should be ongoing. This allows for patient to not need to have face to face appointments, reduces days off needed to visit a sleep clinic. Allows the clinic to see other patients face to face. Better quality for patients as clinicians can remotely access patient cpap data and report to the patient at anytime.	Thank you for your comment. The committee agree telemonitoring is useful beyond 12 months, however, they did not have the evidence to make a strong recommendation. Because of the associated costs of telemonitoring and lack of certainty that it would be cost-effective the committee have made a weaker 'consider' recommendation.
Association of respiratory Nurse Specialists	Guideline	009	020	Mandibular advancement splint moulding, production and fitting is not available as standard in many clinics and therefore resource will be required for this to be put in place.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. We have noted in the rationale and impact section for this recommendation that NHS provision of dental services producing mandibular advancement splints is currently limited.
Association of respiratory Nurse Specialists	Guideline	010	006	Auto CPAP would have an advantage over fixed level CPAP. More adaptable pressure in auto set CPAP compared to fixed. This allows for less clinic follow as titration automatic rather than manual.	<p>Thank you for your comment. The committee agreed auto-CPAP has some advantages over fixed-level CPAP. However, the evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower</p>

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					<p>purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee made a research recommendation to help inform future guidelines (see Appendix J).</p>
Association of respiratory Nurse Specialists	Guideline	010	009	Telemonitoring should be ongoing. This allows for patient to not need to have face to face appointments, reduces days off needed to visit a sleep clinic. Allows the clinic to see other patients face to face. Better quality for patients as clinicians can remotely access patient cpap data and report to the patient at anytime.	<p>Thank you for your comment. The committee agreed telemonitoring is useful beyond 12 months and was only likely to be needed where optimal control of symptoms and AHI or ODI has not been achieved, or to help with solving problems that people with OSAHS might experience. Because of the associated costs of telemonitoring and lack of certainty that it would be cost-effective the committee have made a weaker 'consider' recommendation.</p> <p>The committee did not make a research recommendation for long term use of telemonitoring as they believe telemonitoring is already becoming common practice and will remain so in the future. They agreed it is more convenient for CPAP users and clinicians. It also saves time as users do not need to download data and post or take it in to the sleep service.</p>
Association of respiratory Nurse Specialists	Guideline	010	011	Auto CPAP would be more beneficial as a first line therapy rather than fixed.	<p>Thank you for your comment. The evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p>

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					<p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee made a research recommendation to help inform future guidelines (see Appendix J).</p>
Association of respiratory Nurse Specialists	Guideline	011	004	Mandibular advancement splint moulding, production and fitting is not available as standard in many clinics and therefore resource will be required for this to be put in place.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. We have noted in the rationale and impact section for this recommendation that NHS provision of dental services producing mandibular advancement splints is currently limited.
Association of respiratory Nurse Specialists	Guideline	011	011	What are deemed as positional modifiers. Will there be recommended positional modifiers?	Thank you for your comment. We have expanded our definition in the section on "Terms used in this guideline" to give examples of positional modifiers. There was limited evidence for the type of modifier and both electronic and physical devices such as a tennis ball were included in the report. Therefore, the committee leave it to the clinician to decide on which type to use.
Association of respiratory Nurse Specialists	Guideline	013	021	It is unusual to re-review patients with a mandibular advancement splint in the sleep clinic. Reduction in symptoms are reported by the patient. A sleep study may confirm but generally fi the mandibular advancement splint works the patient does not return	Thank you for comment. The committee believe it is good practice to check that all is working. The committee do not think that GPs could deal with all the potential queries should patients be

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				for follow ups. Current mandibular advancement splints do not indicate hours of use or how successful.	discharged. The committee believe the sleep service is the best place for this to happen. The committee do not mandate annual follow up rather ask clinicians to consider it.
Association of respiratory Nurse Specialists	Guideline	014	006	Re-reviewing patients with positional modifiers is depend on report of symptom control. Repeated sleep studys are uncommon and will add in another test if the patient is symptom free.	Thank you for your comment. The committee agreed that once a positional modifier has been offered the clinician needs to assess if the person's symptoms and AHI are controlled. A sleep study may be the only way of doing this and the clinician will need to make a judgement as to whether that is the case. The committee also noted that some electronic positional modifiers will automatically record AHI and therefore a sleep study will not be needed. .
Association of respiratory Nurse Specialists	Guideline	046	027	Customised mandibular advancement splints are not available in all centres, this would add a cost element to centres who need to set this up or at least refer to a centre that does.	Thank you for your comment. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with sleep apnoea will receive the appropriate care. Your comments will also be considered by NICE where relevant support activity is being planned.
British Sleep Society (BSS)	Guideline Economic report Economic report	009 011 046 047 049 050 032	019 - 025 003 - 008 027- 031 001- 028 022- 030 001- 010	The inclusion of mandibular advancement splints (MAS) as a recommended option for mild and moderate OSAHS is a welcome, evidence-based step forward in OSA management. However in our view the basis for limiting this recommendation to bespoke MAS and not including semi-bespoke MAS is flawed. The committee's exclusion of semi-bespoke devices is stated to have a predominantly experiential rather than evidence basis. Given the current limited access to semi-bespoke MAS we are concerned that the collective available experience of using semi-bespoke MAS may have been too limited to allow robust conclusions to be drawn. The TOMADO study was a head to head crossover RCT comparing semi-bespoke devices with bespoke MAS (and with no treatment, and boil and bite) in OSAHS (ref 56 of economic report).	Thank you for your comment. We have revised the economic model base case so that the mean durability is 14 months for semi-customised MAS corresponding to the audit you report. Semi-customised MAS were found to be cost-effective compared to conservative management in the base case analysis. In one of the sensitivity analyses, they were more cost-effective than fully customised MAS. The committee considered the relative cost effectiveness of these two categories of MAS to be uncertain and therefore decided to recommend both. The committee agreed that ready-made and semi-customised devices may be inappropriate for people with generalised tonic-clonic seizures, due to the potential risk of dislodging during a seizure. The committee agreed that for semi-customised devices it specifically relates to the quality of the fit of the device. When

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		032 038-040	002 - 004	<p>The study was commissioned by the HTA specifically to compare clinical and cost effectiveness of various MAS against no treatment in mild-moderate disease (refs 56 and 63 of economic report). The semi-bespoke device used was the Sleep pro 2 (SP2), which is used in the current analysis (economic report page 32, table 26). The HTA TOMADO report also included a network meta-analysis and long term health economics analysis (ref 63).</p> <p>The cost effectiveness findings of the NICE analysis differ from those of the HTA report. Exploring the new analysis' assumptions, the SP2 device life span is assumed to be 6 months for the base case, when it is found not to be cost effective. There is no basis given for this critical durability estimate (p32, lines 2-4, economic report). When lifespan is extended to 12 months in the sensitivity analysis semi-bespoke devices become cost effective compared to conservative management (p38-40, table 34). In the TOMADO-HTA report the SP2 base case lifespan was 12 months according to device manufacturer estimates at the time. It was extended to 18 months in sensitivity analysis. At base case life span the SP2 semi-bespoke was cost effective against conservative management, so in fact consistent with the current NICE analysis. When extended to 18 months and factoring in ESS effects found in-trial for the SP2, MAS dominated CPAP in the long term economic meta-analysis (ref 63).</p> <p>The TOMADO study found the SP2 and a bespoke MAD to be equally effective in terms of AHI reduction, ESS improvements and adherence. Side effects were no different. The boil and bite device was not statistically significantly different in terms of AHI and ESS effects, but a non-significant trend may have been due to significantly lower adherence, and the device was unpopular with patients at trial exit. The NICE committee critique TOMADO and other MAS studies as being unblinded and lacking placebo control arms. However sleep study scoring in TOMADO was blinded. The AHI effects could not have been a placebo effect and validated the</p>	<p>patients take these impressions [moulds] themselves there is a great deal of variability in quality and therefore 'fit' of the device. They noted that there are no contraindications to a standard, well-fitted dental device of any type which requires a mould to be taken and a suitably qualified dentist to fit for any seizure type, including GTCS. The only potential contraindication in people GTCS is loose fitting dentures or a badly fitting boil and bite device not fitted by dentist.</p>

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				<p>closely associated ESS effects. In its briefing for the trial invitation, the HTA specifically asked for a comparison trial against no treatment in a mixed severity group of patients. There had already been several placebo MAS trials, which showed a positive effect of MAS therapy. A criticism of placebo MAS is that by having no positive effect on OSA but disturbing sleep, they may exaggerate the benefits of active treatment, hence TOMADO.</p> <p>Royal Papworth Hospital conducted the TOMADO study. Their sleep service translated the TOMADO findings into routine practice shortly after the report was published in 2014. They run a MAS clinic where they provide the SP2 device to eligible patients with sufficiently symptomatic mild OSAHS and to those with more severe disease if they don't want or can't tolerate CPAP. The TOMADO findings have been borne out by experience gained through the MAS clinic in general and the use of semi-bespoke devices in particular. A recent small audit (n=22) found that average SP2 lifespan was 13.6 months, median (IQR) was 12 (10-15) months. The earliest reported SP2 replacement was 7 months, in a single case. Of the remainder of SP2 lifespan datapoints under 12 months, in 2/3 of cases the SP2 device age was taken at the last follow-up, but the device had not needed replacing. Patients are usually provided with a replacement moulding kit at the near-12 month review, even when their device is not yet worn out, in order to cover the future need for a replacement at some point.</p> <p>Feedback from the device manufacturer is similar from a much larger database. They examined the intervals between SP2 replacement for 616 orders received over 48 months. Mean interval was 19 months. The manufacturer has offered to provide anonymised data for 3rd party analysis.</p>	

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				<p>We respectfully suggest that there is a stronger basis for taking the base case lifespan of the SP2 as 18 months, and extending sensitivity analysis further.</p> <p>The importance of this can't be overstated. It is excellent news for patients that bespoke MAS will now be recommended. However, it will take time for a widespread appropriately trained dental sleep network to be developed. Even then there are likely to be gaps that would risk a persisting postcode lottery of access to MAS therapy if semi-bespoke devices are excluded from the recommendation as an option (for example if bespoke MAS are locally unavailable, access is limited, or local costs significantly exceed those used in the economic report).</p> <p>Other MAS-related points:</p> <ol style="list-style-type: none"> 1. On what basis are semi-bespoke devices considered inappropriate for use in seizures but bespoke devices appropriate? 2. In the TOMADO HTA report, sensitivity analysis included relatively reduced CPAP adherence compared to MAS of 10%. This led to CPAP being dominated by MAS. We recommend this be explored in the NICE analysis. There is good evidence that MAS are better tolerated than CPAP (eg Phillips et al. Health Outcomes of Continuous Positive Airway Pressure versus Oral Appliance Treatment for Obstructive Sleep Apnea. Am J Respir Crit Care Med 2013;187:879-87), leading to equivalent symptom benefit. 	
British Sleep Society (BSS)	Guideline	014 015	020 - 023 001 - 005	<p>Recommendation 1.9.9 Monitoring OSAHS treatment efficacy: The recommendation to monitor AHI at review will be challenging in practice and probably difficult to implement without drawing resources away from diagnostics in overstretched services, including those who rely more on oximetry. We are not aware of good evidence to support this.</p>	<p>Thank you for your comment. We have modified this to monitor AHI or ODI. AHI will be available as downloaded or telemonitoring data from CPAP when this is used by people with OSAHS and therefore the committee do not anticipate there would be the need to repeat the sleep study.</p>

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British Sleep Society (BSS)	Guideline	018 019	015 - 022 001 - 002	Recommendations 2.3.4-6 advise against using oximetry in OHS. We would strongly challenge this, not least given the lack of evidence. In the end if CO2 is higher than eg 7 or 8kPa then most would try NIV first. While polygraphy might help refine pressure titration, what is the evidence it is more effective including with costs than oximetry, which is more accessible and cheaper, and a reliable tool in well trained hands? Again this would have major implementation implications and would reduce patient access to lifesaving treatment.	Thank you for your comment. It is important to distinguish between those with OHS alone and those with OHS plus OSAHS (the latter being the majority). It is true that in many Units current practice is to try NIV first whenever OHS is diagnosed, but the evidence (which is relatively new) shows that CPAP is as effective as NIV when OSAHS is also present, even when the OSAHS is severe. CPAP is also more cost-effective and easier to set up. It is therefore important to identify OSAHS in people with OHS, and oximetry alone is not as good as respiratory polygraphy at making this distinction. NIV is recommended for people with OHS without severe OSAHS.
British Sleep Society (BSS)	Guideline	019 020	016 - 020 001 - 008	Recommendation to use CPAP first in non-acute ventilatory failure and OHS-OSAHS. This is likely to be difficult to implement in practice and may miss the point. Shouldn't a CO2 threshold be used instead, arbitrary if needed in absence of evidence? Non-acute patients are still high risk unless watched closely for ineffectiveness of CPAP. We suggest a stronger recommendation for OHS without OSAHS – use NIV first line. This further negates the role of polygraphy over oximetry.	Thank you for your comment. In people with stable OHS-OSAHS, based on the evidence and their experience, the committee agreed that CPAP should be offered as a first line treatment because it is more cost-effective, simpler to set up and may be better tolerated than non-invasive ventilation. There was no evidence to support use of a CO2 threshold when deciding what treatment to instigate. If symptoms do not improve, hypercapnia persists, AHI is not sufficiently reduced or CPAP is poorly tolerated, the committee agreed that treatment should be changed to non-invasive ventilation to control nocturnal hypoventilation. This is detailed in the committee discussion section of the evidence report. The committee have recommended use of NIV for people with OHS without accompanying OSAHS as you suggest. This is phrased as a "Consider" recommendation because there was no evidence comparing CPAP and NIV in people with OHS in whom OSAHS had been excluded.
British Sleep Society (BSS)	Guideline	023	004 - 011	Monitoring of OHS treatment efficacy. What is the purpose of recommending polygraphy be done at review? Surely symptoms and SpO2/CO2 response are most	Thank you for your comment. The committee agree that symptoms and SpO2/CO2 are important. However, in order to know if the person's OSAHS has been controlled it is also beneficial to know

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				important? Not only will this cause access restrictions in many centres (similar to PG vs oximetry for OSAHS above) but as the clinical experts will know, PG analysis is confounded by NIV.	their AHI or ODI. The recommendations do not imply that polygraphy needs to be done. AHI measurements are also available via downloaded and telemonitoring data from CPAP and NIV.
British Sleep Society (BSS)	Guideline	025	013 - 018	Assessment scales and tests for suspected COPD–OSAHS overlap syndrome: All questionnaires recommended in this draft guideline refer only to OSA, not to COPD (despite good validation of COPD questionnaires, such as the CAT score). We propose that in assessing individuals with overlap syndrome, validated questionnaires for COPD should also be utilised.	Thank you for your comment. The guideline scope excludes the management of COPD in people with overlap syndrome. COPD management is dealt with in the NICE guideline “Chronic obstructive pulmonary disease in over 16s: diagnosis and management” available from https://www.nice.org.uk/guidance/ng115
British Sleep Society (BSS)	Guideline	027	001 - 012	Referring suspected OSA-COPD overlap. Recommendation 3.2.2. Suggest adding any available blood gas details (eg from acute episodes/home visits etc.)	Thank you for your comment. The committee agree and have added “oxygen saturation and blood gas values, if available” as a bullet point to the recommendation.
British Sleep Society (BSS)	Guideline	028	001 - 010	Diagnosing OSA/nocturnal hypoventilation, recommendations 3.3.3-5. The recommendation for respiratory polygraphy in COPD seems to be questionable in the context of hypercapnic respiratory failure, when one would conventionally monitor arterial blood gas analysis, transcutaneous capnography, or even pulse oximetry. Clinical practice is based on the tracking of blood gases in COPD, not respiratory polygraphy, particularly in patients with co-existing hypercapnic respiratory failure. Suggest refine this according to whether there is hypercapnia. If $Co_2 > 7$ /higher you would go for NIV only, which is the key thing you are considering here. If you recommend against oximetry you would make guidance more difficult to implement in practice and adversely impact resource use and patient access to care.	Thank you for your comment. These recommendations only relate to diagnosing OSAHS or nocturnal hypoventilation in people with COPD and they are aimed at confirming a diagnosis of COPD-OSAHS overlap syndrome. The committee agree that blood gas analysis is required for assessment of hypercapnic respiratory failure, as set out in the preceding recommendations 3.3.1 and 3.3.2.
British Sleep Society (BSS)	Guideline	029	001 - 003	NIV for COPD–OSA overlap. Recommendation 3.5.2. Agreed NIV rather than CPAP if $Co_2 > 7$ but this should also be applied to pp19-20, recommendations 2.51-3 (see 4 above).	Thank you for your comment and agreement with this recommendation. The recommendation to use CPAP for OHS is based on the evidence and committee consensus. We have responded in more detail to your comment to which you refer above.

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British Sleep Society (BSS)	Guideline	030 - 031	015 - 022 011	p.30 lines 15-22. Follow-up of CPAP/NIV in COPD-OSA Again we would question the need for repeating polygraphy. We suggest that overnight oximetry, symptoms and CO2 would be more appropriate, cheaper and more accessible.	Thank you for your comment. The committee agree that oximetry can be used as a means of assessing people during follow-up. We have amended the recommendation to state AHI or ODI.
British Sleep Society (BSS)	Guideline	035	014	Typo: "Split" should read "Splint"	Thank you for your comment. We have corrected the typo.
British Sleep Society (BSS)	Guideline	037	005	Recommendations for research – all recommendations, except for the oxygen therapy, are focused around established treatments of OSA with already existing sound evidence (e.g. CPAP/MAD). Should the guideline not recommend further research in areas with lower levels of evidence, such as non-CPAP therapies, that are largely omitted in the current draft? For example, bariatric surgery, hypoglossal nerve stimulation, medication.	Thank you for your comment. The committee agree bariatric surgery is an important area but is beyond the scope of this guideline. It was not prioritised as a review question and therefore no research recommendation can be made on this topic. Similarly, pharmacological interventions for OSAHS were not included as part of the scope therefore the guideline makes no statement in relation to these. We included Hypoglossal Nerve Stimulation in our literature search including all the relevant search terms for this review, however we did not identify any evidence that met the inclusion criteria as specified in our protocol. The committee therefore agreed to include a research recommendation for Hypoglossal Nerve Stimulation to inform future updates of this guideline (Evidence report J, Appendix J).
British Sleep Society (BSS)	Guideline	065	001 - 011	Re: oxygen therapy in OHS. The Committee recommends adding oxygen if nocturnal hypoxaemia persists despite CPAP or NIV. What evidence based SpO2 threshold would the committee recommend? We suggest that if there is significant hypoxaemia despite correction of hypoventilation and OSAH then further investigation for the cause should be considered.	Thank you for your comment. In the absence of evidence, the committee used consensus to recommend 'considering' supplemental oxygen therapy. They agreed that it is difficult to define at what level of hypoxaemia that oxygen should be given and that this recommendation follows standard practice. We have amended the recommendation adding the clause in bold at the end. It now reads: "3.5.5 Consider supplemental oxygen for people with COPD–OSAHS overlap syndrome if hypoxaemia persists once control of apnoea and nocturnal hypoventilation has been optimised by

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					CPAP or non-invasive ventilation and address any additional underlying causes of hypoxaemia where possible."
British Sleep Society (BSS)	Guideline	General 010 048 049 054 055	002-015 020-028 001-021 019-029 001-018	<p>Mod-severe OSAHS – choice of CPAP type and telemonitoring</p> <p>The committee recommends using fixed pressure CPAP in most cases with recourse to auto-CPAP in certain situations. One of these is if telemonitoring is unavailable. We recognise the significant utility of telemonitoring including facilitating remote care which has been invaluable to many sleep apnoea services during the Covid pandemic. However, the implication is that without telemonitoring fixed CPAP can't be used. This is not the reality in UK practice, where there are a variety of successful models being used. For example, some services use auto-CPAP to initially titrate pressure, before switching patients to fixed CPAP at their first review. Until there is a sufficient evidence base in favour, it cannot be assumed that remote management (+/- telemonitoring) of OSAHS is equal/superior in terms of clinical or cost effectiveness. The ways and means of using telemonitoring are numerous and have not yet been sufficiently researched to allow conclusive evidence based recommendations to be made. The telemonitoring costing model is undermined by real life variability. It is also likely to be vulnerable to inflation by commercial providers after publication of this guidance. This should be considered in any analysis and recommendations. It is not clear that costing has taken into account the staff time that is taken up with telemonitoring, which is also an area in need of further research. Finally, having suggested fixed pressure is the first choice, there is no mention of how the fixed pressure setting is to be decided on.</p>	<p>Thank you for your comment. Overall, the evidence showed fixed-level and auto CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The lowest cost strategies in the model were fixed-level CPAP with autotitration, and fixed-level CPAP with telemonitoring for the first year. Therefore, fixed-level CPAP was also shown to be cost-effective without telemonitoring. The committee agreed to recommend fixed-level CPAP and telemonitoring as the first-choice treatment. Telemonitoring was recommended as a tool for improving adherence and to reduce contact with patients that might lead to transmission of infectious disease.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>We didn't include an analysis of using auto-CPAP for initial titration so have not suggested this as a strategy.</p>

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					The committee anticipate that clinical judgement is used to decide on setting the pressure for fixed-level CPAP. A common way to do this is to start with lower pressure then you adjust according to symptom control, telemonitoring data or variation in AHI.
British Sleep Society (BSS)	Guideline Evidence review D / Economic report Economic report	General 007 042 - 043 General 176 010 / 027	001 - 029 007 - 009 008	<p>The evidence base for oximetry is limited to 4 studies, but as the committee acknowledges even these are of low quality. We respectfully suggest that the evidence and resulting analyses are too weak for the committee to recommend against oximetry in favour of polygraphy. The recommendation does not reflect wider UK consensus.</p> <p>Examples of the limitations of the included oximetry studies:</p> <ul style="list-style-type: none"> - The ODI cut-offs used are arbitrary - Three of 4 studies are over 20 years old and the oximeters used fall short of current requirements. The argument that similarly aged polygraphy/polysomnography studies balances this weakness is controversial and we would suggest doesn't justify including the studies. - The problem caused by the age of the studies is highlighted by the fact that the oximeter used by Wiltshire et al had a sampling and storage frequency of 12 seconds. The resulting negative impact on sensitivity would have been considerable and so the data from this study should not contribute to the crucially important analyses which led to the recommendation that oximetry be used only as a back-up in the event of polygraphy being unavailable, or the health economic analysis that finds oximetry to not be cost effective. <p>There are a number of other problems with the methodology used in the economic analysis that found in favour of home polygraphy (PG):</p> <ul style="list-style-type: none"> - The methods for determining costs of diagnostic tests are crucial to the output, but they are inconsistently applied 	<p>Thank you for your comments.</p> <p>Inclusion of oximetry accuracy studies The committee acknowledges that the evidence for the relative effectiveness of oximetry is limited and of low quality. However, this is not a compelling reason to give oximetry an equal weighting to respiratory polygraphy (RP) equal weighting in the recommendations.</p> <p>The oximetry accuracy evidence is particularly weak for the cut-off of AHI=5/ODI=5, which is based on only two studies. We have re-run the economic analysis taking out each of these studies in turn, but the cost effectiveness results are not sensitive to this as respiratory polygraphy is clearly more accurate at the higher threshold (AHI=15/ODI=15).</p> <p>Calculation of test costs in economic analysis In answer to your query, there was a typo on page 10 of the economic analysis report and the cost of respiratory polygraphy should have been £189, not £89. This has now been corrected in the report.</p> <p>We agree that the methods for calculating the cost of oximetry and RP were inconsistent but the consequence of this is if anything to bias the results against home respiratory polygraphy.</p> <p>We have now lowered the cost of oximetry in the economic analysis along the lines you propose:</p> <ul style="list-style-type: none"> - using a health care assistant - assuming only 15 minutes is required - assuming the device can be used 4-5 times a week

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	Evidence review D Economic report	029	004 -	<p>between tests. Home oximetry costs were calculated from assumed component costs (and were overestimated) but PG costs were obtained from NHS reference costs. Different costs for PG are quoted in table 3 on page 10 of the economic report (£89) and on page 27 (£189.28). Which one is used in the analysis?</p> <p>In any case, if for consistency one applied the method used for costing oximetry to PG, then PG costs would be around 3 to 4 times higher than oximetry depending on the banding of the physiologist scoring the study (suggest between 5 and 7).</p> <ul style="list-style-type: none"> - The base case assumption for oximetry costing includes a band 5 nurse or band 6 physiologist to give out, collect and interpret oximetry studies. This is not what happens in practice. UK centres delivering large numbers of oximetry studies employ band 2 Health Care Assistants in this role. If a band 5/6 nurse/physiologist <u>is</u> involved in the pathway then it is to interpret the oximetry <u>instead</u> of a Dr. However, the time taken for interpretation in the assumption is an overestimate. The major advantage of oximetry is that it can be interpreted so quickly (c.5 minutes maximum). Any additional time spent involves review of the case/consultation. If a Dr is due to interpret the study/consult then there is no need for a band 5/6 to do so as well. In contrast PG has a defined analysis time (estimate 30-60 minutes) that requires a band 5-7 physiologist to interpret, which is <u>in addition</u> to the consultation time/case review. 	<p>But this ad only a modest impact on the results.</p> <p>We also added a sensitivity analysis with a bottom-up cost for home RP but this only served to make home RP appear more cost effective.</p> <p>Re-testing threshold analysis in economic analysis You note that the results are potentially sensitive to the assumption that the more severe OSA patients will typically have correspondingly more symptoms and therefore are more likely to be re-tested. This was a somewhat arbitrary assumption, and therefore we conducted a threshold sensitivity analysis. However, this assumption was biasing in favour of oximetry. So, when this assumption is relaxed, it is not oximetry that is more cost effective but a screening strategy, which involves systematically re-testing patients that test negative, which is something you suggest is unnecessary.</p> <p>Oximetry accuracy in heart failure or chronic lung disease The included oximetry studies excluded people with heart failure, respiratory insufficiency, COPD and anaemia. The committee agreed that this was important because these are common conditions. The committee agree that normal oximetry is useful but abnormal oximetry is more difficult to interpret in conditions such as heart failure and chronic lung disease which can result in desaturation without the presence of OSAHS. Without evidence to refute this the committee agreed this is an important point to highlight in the guideline. However, the committee agreed that oximetry has a place in the diagnosis of OSAHS and have recommended it can be considered if access to respiratory polygraphy is limited then oximetry can be considered.</p>
	Evidence review D	030		<ul style="list-style-type: none"> - There are other assumptions in the oximetry screening model that we would like to challenge. The cost effectiveness model assumes that all patients with negative oximetry, who have underlying moderate to severe OSAHS, will require further testing with PG. This 	<p>Cardiovascular consequences of missing moderate/severe OSAH</p>

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	Evidence review D	036		<p>is based on the assumption that they will all be sufficiently symptomatic to lead to the clinical decision to retest/escalate. Some members of this stakeholder organisation run large sleep services which use home oximetry as the entry level test, with recourse to PG/PSG if needed. Their view, based on considerable experience of using oximetry to screen patients referred from primary and secondary care with possible OSAHS, is that this assumption is flawed. It is well known that (i) there is poor correlation between objective severity of OSAHS and symptom level and (ii) a substantial proportion of patients with mod-severe OSAHS have little or no sleepiness. This is the basis for the DVLA regulations regarding OSAHS and fitness to drive, that were revised following advice from some of the UK's leading sleep apnoea experts. Many patients present due to partners' concerns about snoring, witnessed apnoeas or other symptoms, but often don't suffer sufficient daytime sleepiness to merit further testing in the event of negative oximetry.</p> <ul style="list-style-type: none"> - Annuitised costs are based on the assumption that oximeters could be used 130x/year. Many sleep centres turn around oximeters within 24 hours, so they can be used 4-5 days a week. - We note on p36 of Evidence review D that, even when using the flawed costings and relying on the inadequate oximetry evidence, if the retesting threshold for oximetry-negative mod-severe OSAHS dropped to 68% then oximetry would become the most cost effective. Based on the above the proportion of patients who don't require retesting is probably more than 1/3 anyway. If the costs are adjusted along the lines suggested above, then we 	<p>The committee believe that the cardiovascular consequences of missing cases of sleep apnoea need to be noted. However, they note that in the economic analysis, the impact is small.</p> <p>REM sleep behaviour disorder and parasomnia Not all people suspected of OSAHS present with excessive daytime sleepiness. While a lot of people will be suspected of OSAHS at the point of diagnosis some will be suspected of a sleep disorder but it may not be clear which sleep disorder. The committee believe this is an important consideration for diagnosis and may help reduce the need to do another sleep study.</p> <p>Research recommendation The committee made a strong recommendation for diagnosis based on the evidence and the economic model and therefore they did not make any research recommendation for these tests.</p> <p>Practical implications The committee acknowledge the practical concerns with using RP and therefore have modified the recommendations to allow more use of oximetry where RP is not practical.</p>

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	Guideline	007	006 - 007	<p>anticipate the modelling would show oximetry to be most cost effective as the entry level test.</p> <p>Other points:</p> <ul style="list-style-type: none"> - The committee states that oximetry may be inaccurate for diagnosing OSAHS in heart failure or chronic lung disease. This is controversial as discussed above and below. An additional point is that normal oximetry is still clinically useful in this setting. It should also be remembered that in such cases both oximetry <u>and</u> PG should be interpreted alongside skilled clinical assessment and other investigations (imaging/lung function) as appropriate. - The concerns about cardiovascular consequences of missing mod-severe OSAH if oximetry is negative are misplaced. Oximetry parameters are known to be more reliable predictors of adverse cardiovascular outcomes than AHI (which is poor). High quality RCTs have failed to show a cardiovascular benefit of CPAP [SAVE (McEvoy et al. NEJM 2016; 375:919-931) and MOSAIC (Craig et al. J Clin Sleep Med 2015;11(9):967–973) beyond lowering blood pressure in refractory hypertension. If oximetry is normal or shows only mild OSAHS and symptoms are minimal/mild then the role of the Guidelines should be to educate and empower clinicians to manage patients according to the oximetry findings. - REM sleep behaviour disorder and parasomnia don't present with EDS <p>Based on all the above, we suggest that the guidance regarding the use of oximetry in OSAHS diagnostics be revised to better</p>	
	Evidence review D	049	025 - 028		

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	Evidence review D	047	003 - 005	<p>reflect the inadequate evidence base and the range of expert opinions:</p> <ul style="list-style-type: none"> - Either oximetry or PG could be used as entry level OSAHS diagnostic tests. - If oximetry is used there must be recourse to PG/PSG when oximetry is negative but symptoms are compelling. <p>Research: The Committee acknowledges that diagnostic practice varies between sleep centres, with the entry level test being either oximetry or polygraphy. They acknowledge the lack of evidence in this area. The committee recognises that their recommendations will mean some centres will have to reduce oximetry activity and increase PG activity. This is stated to be a good thing in reducing variation. No research recommendations are made for diagnostic testing.</p> <p>We would like to challenge these statements for the following reasons:</p> <ol style="list-style-type: none"> 1. We have highlighted the lack of expert consensus on this issue. 2. In the absence of consensus and evidence this is surely an area that should be prioritised for research, particularly given the new evidence that supports the extension of CPAP therapy to milder OSAHS. 3. We recognise the GIRFT policy to eliminate variation in practice, but surely this should only follow the evidence and not precede it. Until then variability allows research to be conducted in real life settings. <p>Practical implications: Replacement of home oximetry with respiratory polygraphy would have a major negative impact. It would be costly and difficult to implement in many centres which rely on oximetry screening. Costs would include extra</p>	
		047	007 - 013		

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				<p>equipment and hiring and training more staff. PG turnaround time is longer than oximetry. The reality in a resource limited NHS is that fewer patients would receive access to a timely diagnosis and therefore treatment because fewer studies would be performed in areas currently well served by centres using oximetry first. Varying reliance on oximetry and PG between current UK diagnostic service models may explain some of the wide range of waiting times identified in the recent GIRFT report. Patients with symptomatic moderate to severe OSA, most of whom would be readily diagnosed with oximetry, would probably be disproportionately affected by this recommendation. One way that some services or NHS purchasers might try to solve these new access restrictions would be to outsource polygraphy to private companies. This already happens in areas where NHS sleep service coverage is inadequate. The prices charged by many private providers are often significantly higher than the PG costings used here, and there would be a risk of inflation in a seller's market.</p> <p>PG does not reduce the risk of inappropriate management. There would be a greater risk of false positives and overtreatment. This could be harmful to patients and wasteful, as CPAP initiation would probably increase at the expense of adherence to treatment.</p>	
British Sleep Society (BSS)	Guideline Evidence reviews Economic report	General	General	<p>We applaud the Committee's considerable achievement in producing these draft guidelines in the face of the Covid pandemic. The OSA Alliance also agreed that those members who sat on the NICE Committee deserve our appreciation for the hard, and often difficult, work which has gone into the drafting of these guidelines. While there are notable positives, the focus of our feedback will be on those areas of the guidance which members of our Society feel are in particular need of revision, in order to better reflect the significant evidence gaps and wider range of opinions of clinical sleep specialists within the UK.</p>	Thank you for your comment. We have responded to each individual comment in turn.

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British Sleep Society (BSS)	Guideline	General	General	<p>The current draft recommendation document does not contain, mention or cross-reference to other relevant NICE references (both established and in development):</p> <ol style="list-style-type: none"> Bariatric surgery / weight loss surgery (e.g. CG189) Hypoglossal nerve stimulation (IPG598) Solriamfetol (ID1499) Pitolisant (ID1065) 	<p>Thank you for your comment.</p> <p>We have cross referred to relevant guidelines the obesity guideline CG189 (which includes recommendations for bariatric surgery) and other weight loss NICE guidance within the section on lifestyle advice.</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p> <p>Pharmacological interventions for OSAHS were not included as part of the scope therefore the guideline makes no statement in relation to these.</p>
British Society for Dental Sleep Medicine	Guideline	003		The BSDSM unequivocally agrees with the prescription of CPAP in this category of patients as 'first line treatment.	Thank you for your comment
British Society for Dental Sleep Medicine	Guideline	004		<p>Developing NICE guidelines: the manual. Process and methods. 15 October 2020. States:</p> <p><i>"Some recommendations are 'strong'. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. The 'strength' of a</i></p>	Thank you for your comment. The limited availability of evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the

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				<p><i>recommendation should be reflected in the consistent wording of recommendations within and across guidelines. In recommendations on interventions that should be offered, use directive language such as 'offer'. If there is a closer balance between benefits and harms, use 'consider'."</i></p> <p>The committee have clearly stated in the case of bespoke, dentally fitted MADs that there is good evidence, they are cost effective and there is no evidence of harm. There would be harm, however, if patients are left untreated due to the long list of comorbidities, RTAs, socioeconomic costs etc. Based on NICE's own guidelines and the committee's findings we strongly believe the "consider" should be replaced with "offer"</p>	<p>recommendations and explained in the committee discussion section of Evidence report G.</p> <p>The committee agree that not treating people who need treatment can be harmful. However, there also needs to be evidence of benefit for an intervention to be recommended. Here the recommendation is written as 'consider' rather than 'offer' because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.</p> <p>A consider recommendation does not prevent mandibular advancement splints being recommended. If a clinician believes a person will be harmed by not providing treatment and mandibular advancement splints are a suitable option then the committee anticipate that they will prescribe them.</p>
British Society for Dental Sleep Medicine	Guideline	004	010	<p>Consider specifying that all suitably qualified health care providers, including dentists, can screen for obstructive sleep apnoea. This may result in earlier diagnosis due to the primary care medical service being over-stretched with inadequate time for a thorough medical history and examination – particularly in OSA cases where a patient is likely to present with multiple morbidities. In the case of dentists, patients are more likely to visit their dentists and hygienists regularly where medical histories are updated every 3-24 months. This often includes a snoring history where they can be the signal diagnosticians for OSA. Dentists can easily observe signs of sleep disordered breathing and other associated conditions such as reflux and sleep bruxism. This additional information may assist the sleep clinician or GP in deciding an appropriate assessment and referral pathway. It also follows NHS principles of "making every contact count"</p>	<p>Thank you for your comment. NICE guidelines make recommendations on treatment and processes of care but do not generally specify who should carry them out. In practice this would be any healthcare professional with the appropriate qualifications and competencies.</p>
British Society for Dental	Guideline	005	006	<p>Dentists update medical history of every patient at regular intervals usually bi-annually. The presence of the conditions outlined in this draft, should be a red flag to further screen these patients for any</p>	<p>Thank you for your comment. The committee agree that dentists play an important role in documenting medical history. NICE guidelines make recommendations on treatment and processes of</p>

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Sleep Medicine				underlying SDB problems with appropriate screening questionnaires.	care but do not generally specify who should carry them out. In practice this could be any healthcare professional with the appropriate qualifications and competencies.
British Society for Dental Sleep Medicine	Guideline	007	001	It is not clear in the Guideline who should be offering these diagnostic tests for OSAHS? It is absolutely accepted that diagnosis lies with the medical experts but the use of ambulatory testing by trained dentists for screening for OSA has been accepted by ARTP. By engaging with trained dentists with onward referral to secondary care or GPs with the test results would reduce the burden further. The BSDSM has an established Protocol that all dentists are encouraged to follow to work within our scope of practice. www.bsdsd.org.uk	Thank you for your comment. NICE guidelines make recommendations on treatment and processes of care but do not generally specify who should carry them out. In practice this would be any healthcare professional with the appropriate qualifications and competencies
British Society for Dental Sleep Medicine	Guideline	007	014	Dentists are already providing advice on smoking cessation and lifestyle changes. Dentists and hygienists/therapists can further take on this role and consideration should be given to include them in this aspect of management protocol	Thank you for your comment. NICE guidelines make recommendations on treatment and processes of care but generally avoid specifying who should carry them out. In practice this would be any healthcare professional with the appropriate qualifications and competencies. We have added 'dentist' into the "Who it is for" section of the guideline.
British Society for Dental Sleep Medicine	Guideline	008	009	While these patients may not need treatment, we need to consider the effect of no treatment, (especially if snoring continues), on their bed partner's quality of sleep. Perhaps the committee could consider the newly emergent daytime NMES devices that shows promise in dealing with snorers and mild OSA?	Thank you for your comment. We did not include using NMES in the scope of the guideline and it was not prioritised as an intervention to review in the guideline. Consequently, we have not made any recommendations for or against its use.
British Society for Dental Sleep Medicine	Guideline	008	018	For those mild OSAHS patients, with co-existing Insomnia, should be offered Mandibular Advancement Therapy (MAD) as a first line treatment. It is well documented that CPAP although very efficacious, is poorly tolerated by insomniacs. Patient preference for MADs is well documented.	Thank you for your comment. CPAP was shown to be the most cost-effective first choice. For those unable to tolerate CPAP mandibular advancement splints can be considered. We didn't find evidence specifically related to insomnia and kept the recommendation more general. The committee anticipate the clinician will assess who cannot tolerate CPAP. Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee

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					made a research recommendation to help inform future guidelines (see Appendix J).
British Society for Dental Sleep Medicine	Guideline	009	020	<p>Developing NICE guidelines: the manual. Process and methods. 15 October 2020. States:</p> <p><i>“Some recommendations are 'strong'. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. The 'strength' of a recommendation should be reflected in the consistent wording of recommendations within and across guidelines. In recommendations on interventions that should be offered, use directive language such as 'offer'. If there is a closer balance between benefits and harms, use 'consider'.”</i></p> <p>The committee have clearly stated in the case of bespoke, dentally fitted MADs that there is good evidence, they are cost effective and there is no evidence of harm. There would be harm, however, if patients are left untreated due to the long list of comorbidities, RTAs, socioeconomic costs etc. Based on NICE's own guidelines and the committee's findings we strongly believe the word “offer” should be used rather than “consider</p>	<p>Thank you for your comment. The availability of limited evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G.</p> <p>Here the recommendation is written as ‘consider’ rather than ‘offer’ because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.</p>
British Society for Dental Sleep Medicine	Guideline	009	023	<p>The cut off point for eligibility may be higher for males who have been shown to continue to develop until the age of 20. As this development occurs predominantly in the mandible in a forwards and anterior direction, a MAD may impact on this growth pattern. There is no evidence of the impact of MADs on late stage developing jaw but the council may want to consider this. Prof Ama Johal, as an orthodontist, will be well placed to advise.</p>	<p>Thank you for your comment. On taking advice from the co-opted orthodontist the committee agreed that 18 is a suitable age for mandibular advancement splints to be considered. Clinicians may wish to exercise caution patients with a Class III occlusion but the dental changes that could take place are just as relevant in more ‘mature’ adult patients with this occlusion. This has been added to the committee discussion for the evidence report but the committee did not think this level of detail needed a recommendation. They anticipate the dentist assessing the person for a mandibular advancement splint would make a judgement on whether to prescribe it.</p>

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British Society for Dental Sleep Medicine	Guideline	009	024	What constitutes 'suitable dentition'? this is a rather loose term and needs clarification. There may have been historical limitations but with the advances made in manufacture of precision devices, most patients can be accommodated for treatment with an MAD. Development of MADs for edentulous or partially edentulous patients is now very much possible. ALL patients need to be treated and by putting this loose term in is subject to misinterpretation depending on the experience of the prescriber. If a patient cannot tolerate CPAP and is a priority patient do the council have guidelines over the risk to life vs risk of exacerbating a dental condition?	<p>Thank you for your comment. The text 'suitable dentition' has been edited to 'optimal dental and periodontal health.' This emphasises that MAS should not be made for patients with untreated dental decay or active periodontal disease. The latter is important in not only ensuring minimal unwanted tooth movement [as teeth with reduced bone support will move more readily which is not desirable] and more importantly could accelerate their loss, thereby compromising the long-term use of an MAS.</p> <p>Patients that are edentulous can be managed but require more experienced specialist care. This is detailed in the committee discussion section of Evidence report G.</p> <p>The guideline also has recommendations to consider positional modifiers or surgery for people with OSAHS who meet specific criteria and are unable to use CPAP or MAS.</p>
British Society for Dental Sleep Medicine	Guideline	009	024	<p>There are patients who present with periodontal disease who are deemed 'not suitable' for oral appliance therapy</p> <ol style="list-style-type: none"> 1. Suggestion of having a 'suitable dentition' BEFORE they can be offered a MAD is not in the best interest of the patient's wellbeing. Periodontal disease can take many months to treat. In the case of a CPAP non-compliant patient, it may be worth considering the risk of further dentition damage versus benefit of treating their OSAHS, needs to be considered 2. There is an association between periodontal disease and OSA. It is possible that managing a patient's OSA may help motivate these patients to get help to control their periodontal disease <p>It is also recognised that poor sleepers have poorer diets which may contribute towards development of dental decay. The BSDSM advocates that these patients should not be declined treatment but may need closer monitoring, in addition to enhanced diet and oral hygiene advice as they attempt to manage all conditions.</p>	<p>Thank you for your comment. The text 'suitable dentition' has been edited to 'optimal dental and periodontal health.' This emphasises that MAS should not be made for patients with untreated dental decay or active periodontal disease. The latter is important in not only ensuring minimal unwanted tooth movement [as teeth with reduced bone support will move more readily which is not desirable] and more importantly could accelerate their loss, thereby compromising the long-term use of an MAS. This is detailed in the committee discussion section of Evidence report G.</p> <p>The committee agree that managing OSAHS may help control a person's periodontal disease or other conditions should they have any. However, we did not review the evidence for this and have not made statements in this area.</p> <p>The committee agree that people should not be denied treatment. They anticipate the dentist assessing the person for a mandibular advancement splint will make a judgement on whether they have optimal dental and periodontal health to be able to use a splint..</p>

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British Society for Dental Sleep Medicine	Guideline	013	021	We believe with custom made precision devices, the need for face to face follow up is not always essential Video or phone consultations are adequate and work well.	Thank you for your comment. The committee decided to recommend face-to-face, video or telephone consultations and to leave it to the clinician to decide which is the most appropriate.
British Society for Dental Sleep Medicine	Guideline	014	001	A face-to-face follow-up is only required IF the patient has a problem with fit of the device. If well-constructed precision devices are provided, the patient very rarely returns with these problems.	Thank you for your comment. The committee decided to recommend face-to-face, video or telephone consultations and to leave it to the clinician to decide which is the most appropriate.
British Society for Dental Sleep Medicine	Guideline	014	002	Although patients <i>may</i> take as long as 3 months to optimise with their devices, this is not the norm IN OUR EXPERIENCE. Devices fitted in a starting protrusive position at 50-60% of range and then gradually titrated take much less time to optimise. This is the guideline from several national dental sleep societies across the world, as is with the BSDSM.	Thank you for your comment. The committee agreed that a follow-up at 3 months is needed to ensure therapeutic effectiveness along with adherence with a MAS, as it requires sufficient time for adaption and any adjustment with the use of device. The committee agree that any emergency need can be undertaken prior to the initial 3-month follow-up appointment as in current clinical practice.
British Society for Dental Sleep Medicine	Guideline	014	003 - 004	Subsequent follow up will be much sooner than three-month in our experience as patients will report subjective symptom relief sooner through follow up titration from an already protruded position. The objective reduction of AHI can be tested as soon as patient reports subjective symptom relief, snoring elimination, no further nocturia, no gasping or choking and waking refreshed with possible return of dreaming. We would request guidance in the case of high risk patients who are unable to tolerate CPAP and have symptom relief with a MAD. Should a dentist be referring back to the overseeing consultant to objectively confirm a clinical improvement?	Thank you for your comment. The committee agreed that a follow-up at 3 months is needed to ensure therapeutic effectiveness along with adherence with a MAS, as it requires sufficient time for adaption and any adjustment with the use of device. The committee agree that any emergency need can be undertaken prior to the initial 3-month follow-up appointment as in current clinical practice.
British Society for Dental Sleep Medicine	Guideline	034	021	This is well documented and compliment the committee on taking these points into consideration. There is a point to note that with the use of precision custom made mandibular advancement devices, the risk of tooth movement is minimised	Thank you for your comments. The committee were not aware of any evidence to support Jaw exercises as an intervention, and this was not reviewed in the guideline. Therefore, no recommendations have been made for this.

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				A possible addition to this list is the education of patients to perform some jaw exercises to help with possible occlusal changes. This can be in the form of a pre-printed leaflet given to patient when device is fitted.	
British Society for Dental Sleep Medicine	Guideline	045	008 - 009	Please note our comment regarding bed partner quality of sleep if patient asymptomatic not warranting treatment other than lifestyle changes which are not always feasible or taken on board	Thank you for your comment. We note in your previous comment related to bed partner you suggest NMES as an intervention. We did not include NMES using in the scope of the guideline and it was not prioritised as an intervention to review in the guideline. Consequently, we have not made any recommendations for or against its use.
British Society for Dental Sleep Medicine	Guideline	047	009	The term 'some' could be replaced with 'a significant number' of CPAP users find it unacceptable and MADs are a viable option as well documented.	Thank you for your comment. The committee agreed that while some people find CPAP unacceptable most users do not. They are not sure how to define what a significant number would mean and believe 'some' is the appropriate term to use in this sentence.
British Society for Dental Sleep Medicine	Guideline	047	011	The term 'offered' replaces 'consider' for reasons in comment 11. MADs have been shown to be a viable and cost-effective alternative to CPAP economically as well as through better compliance and mean disease alleviation.	Thank you for your comment. The recommendation referred to here is for people with mild OSAHS in whom we identified only one study of 6 weeks duration comparing MAS to placebo, and no studies of MAS vs CPAP. The committee do not interpret this as strong evidence and therefore believe the use of "consider" is appropriate for this recommendation.
British Society for Dental Sleep Medicine	Guideline	047	014 - 016	The evidence shows there is no one device better than the other generally. All MADs work well but no one device is suitable for every patient in our experience. The committee would be well placed to consider a range of custom devices be made available for the trained dentist to select from depending on each patient's physical characteristics and preference.	Thank you for your comment. We have amended the recommendation on mandibular advancement splints to include semi-customised devices. Due to lack of sufficient evidence the committee will not be able to comment on specific customised or semi-customised devices.
British Society for Dental Sleep Medicine	Guideline	049	026	The term 'offered' replaces 'consider' for reasons stated above in comment 11 and 20	Thank you for your comment. The availability of limited evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G. Here the recommendation and the text in the rationale is written as 'consider' rather than 'offer' because of the limited evidence of

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					varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.
British Society for Dental Sleep Medicine	Guideline	049	028	Could the council consider that in patients with severe disease who cannot tolerate CPAP that a MAD should be offered in order that they receive <i>some</i> treatment benefit versus none? This is outlined in the joint position statement of the AASM/AADSM 2015.	Thank you for your comment. The committee agree and have made a recommendation to consider mandibular advancement splints for people with severe OSAHS too.
British Society for Dental Sleep Medicine	Guideline	050	017	The NIHR funded TOMADO study is limited in that a non-titratable device was given as the custom-made device. As this does not allow for accurate titration, the clinical outcomes and subsequent cost-effectiveness analysis would have been impacted negatively against a titratable device. This should be taken into consideration.	Thank you for your comment. The committee were aware of the limitations of the TOMADO study and have included a research recommendation on mandibular advancement splints.
British Society for Dental Sleep Medicine	Guideline	056	001	We unequivocally agree with the committee's recommendations.	Thank you for your comment.
British Society for Dental Sleep Medicine	Guideline / Evidence review C	General	General	The BSDSM compliments the Committee on the extensive work that has been undertaken to prepare the guideline document with the exhaustive literature review. For this we are thankful. We, as a Society of predominantly dental practitioners, very much appreciate the inclusion of a dental expert. However, it is also worth considering that few dental schools include the dental management of OSAS in the dental curriculum and subsequently the standards in treatment can vary. It is worth bearing in mind that this guidance is also a suggested standard for treatment for dental clinicians and any increased detail on national evidence based recommendations would be welcomed by the profession.	Thank you for your comment. The committee recognise that training is an important issue but unfortunately this topic was not prioritised during the scoping process for this guideline.
British Thoracic Society	Evidence review D	007 176	001 - 029 008	Issues with the cost effectiveness models comparing different diagnostic strategies for OSAHS: - Quality of studies and acceptance of proxy values for the index test. There were only two small studies for home oximetry in all severities of OSAHS. They both used proxy cut-off	Thank you for your comments. Inclusion of oximetry accuracy studies The committee acknowledges that the evidence for the relative effectiveness of oximetry is limited and of low quality. The committee also accept that the sampling interval of modern oximeters are much shorter than older models. However, they

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	Economic model	027	003-015	<p>values to diagnose OSA: ODI ≥ 7 (Rofail 2010), ODI ≥ 10 (Wiltshire 2001). The study by Wiltshire also used a proxy for the reference standard (AHI ≥ 10). Using arbitrary cut-offs that are different to the current classification of OSA severity, particularly when the ODI threshold is higher than the reference AHI threshold, will have an obvious impact on the sensitivity and specificity of the screening test. Inclusion of such studies is controversial. Further, it must be noted that in the study by Wiltshire the oximeter used had a capacity to store data points only every 12 s. Such oximeter would have been regarded as inadequate for SDB diagnostics even 20 years ago when the study was performed. Modern oximeters are far more sensitive and have a sampling and recording frequency of 1-2s. This study should have not been included in the meta-analysis performed to calculate the estimated sensitivity of home oximetry. It appears that its inclusion brought down the pooled sensitivity for oximetry by approximately 10% which may have significantly impacted the cost effectiveness models.</p> <p>- Adherence to treatment.</p> <p>Estimates of CPAP adherence were sourced from a large study by Kohler (2010) who found that 4% ODI was the only independent predictor of long-term adherence to CPAP. For the purpose of the model these data were used to calculate the CPAP dropout rates in the mild, moderate and severe OSAHS groups. However, it should be noted that the study by Kohler used nocturnal oximetry to diagnose patients with OSA and therefore it is uncertain whether the same dropout rates would be observed for the OSA severity groups defined by AHI. This may not be true particularly for people with negative</p>	<p>agreed that a longer sampling time may not markedly affect the accuracy of diagnosis and this is not the sole determinant in the diagnosis of OSAHS. The points raised are relevant to oximeters used in respiratory polygraphy apparatus too. The committee agreed that none of these points provide a compelling reason to give oximetry an equal weighting to respiratory polygraphy (RP) in the recommendations.</p> <p>The oximetry accuracy evidence is particularly weak for the cut-off of AHI=5/ODI=5, which is based on only two studies. We have re-run the economic analysis taking out each of these studies in turn, but the cost effectiveness results are not sensitive to this as respiratory polygraphy is clearly more accurate at the higher threshold (AHI=15/ODI=15).</p> <p>Adherence to treatment The committee think it reasonable to assume that people with a higher AHI will be more likely to adhere to treatment. However, we have added a sensitivity analysis where the adherence to treatment is the same regardless of AHI level. Changing this assumption made very little difference to the relative cost effectiveness of the different tests.</p> <p>Calculation of test costs in economic analysis In answer to your query, there was a typo on page 10 of the economic analysis report and the cost of respiratory polygraphy should have been £189, not £89. This has now been corrected in the report.</p> <p>We agree that the methods for calculating the cost of oximetry and RP were inconsistent but the consequence of this is if anything to bias the results against home respiratory polygraphy.</p> <p>We have now lowered the cost of oximetry in the economic analysis along the lines you propose:</p>

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	Evidence review D Economic analysis	029 022		<p>oximetry who receive a diagnosis of OSA based on respiratory PG or PSG.</p> <p>- Diagnostic test costs. There are serious concerns about the methodology used to calculate the costs of home oximetry and home respiratory PG. The costs of home oximetry were directly calculated from all its component costs but the same methodology was not followed for respiratory PG. Instead, the costs of respiratory PG were obtained from NHS reference costs. Such approach is methodologically invalid and may have misinformed the cost-effectiveness models. In all these models the actual costs of the tests are essential input parameters.</p> <p>Further, the oximetry costs seem overestimated. We disagree with the Committee's advice that a band 5 nurse or band 6 physiologist are required to give out, collect and process oximetry recordings. In large centres which deliver over 100 oximetry studies a week this is successfully done by a band 2 Health Care Assistant. In the Economic analysis, different costs for respiratory PG are quoted in table 3 on page 10 (£89) and in paragraph 2.2.9 on page 27 (£189.28). It is unclear which figures were entered into the models. The authors reference the cost of respiratory PG to <i>National Schedule of NHS Costs 2018/19</i>. In this document, the DZ50Z currency code is described as <i>Respiratory Sleep Study</i> and attributed a <i>National Average Unit cost of £85</i>. In the 2020/21 National Tariff Payment System (NHS Improvement) a cost of £356 for an outpatient procedure is attributed to the DZ50Z HRG code. These inconsistencies should be addressed.</p>	<p>- using a health care assistant - assuming only 15 minutes is required - assuming the device can be used 4-5 times a week But this adds only a modest impact on the results.</p> <p>We also added a sensitivity analysis with a bottom-up cost for home RP but this only served to make home RP appear more cost effective.</p> <p>We have changed the cost of a polysomnography using a non-elective short stay sleep study cost from the NHS Reference costs (£938).</p> <p>Assumptions in screening strategy in economic analysis You note that the results are potentially sensitive to the assumption that the more severe OSAHS patients will typically have correspondingly more symptoms and therefore are more likely to be re-tested. This was a somewhat arbitrary assumption, and therefore we conducted a threshold sensitivity analysis. However, this assumption was biasing in favour of oximetry. So, when this assumption is relaxed, it is not oximetry that is more cost effective but a screening strategy, which involves systematically re-testing patients that test negative, which is something you suggest is not justifiable. You make the point that patients will not need re-testing if they are either not sufficiently symptomatic or else have other conditions. However, diagnosis and treatment of OSAHS might still yield quality of life improvement and prevent road traffic accidents and cardiovascular events in these patients.</p> <p>Research recommendation The committee made a strong recommendation for diagnosis based on the evidence and the economic model and therefore they did not make any research recommendation for these tests.</p>

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	Guideline Evidence review D	045 036	002-009	<p>Based on an analysis performed in a large sleep centre, if the same method of direct costs calculation is used for respiratory PG, its costs are 3.4 to 4.4 (depending on the seniority of the Healthcare Scientist performing the analysis) times higher than home oximetry.</p> <p>The cost of polysomnography is assumed to be the same as the cost of hospital RP. This is unlikely to be true. Full montage polysomnography is a more time-consuming test both in terms of its set up and the subsequent scoring which also requires higher level of expertise and therefore a higher band staff than processing respiratory PG. Thus, the cost of polysomnography should be expected to be higher than an inpatient respiratory PG.</p> <p>- Assumptions in the oximetry screening model.</p> <p>In the Guideline, the Committee acknowledges that many people with mild OSA will just require a lifestyle advice. Yet, the cost effectiveness model there is an assumption that all patients with negative oximetry will require further testing with respiratory PG. This assumption is not justifiable. Based on our clinical experience a substantial proportion of patients with negative oximetry do not have sufficient symptoms of OSA to warrant further investigation or treatment, or they symptoms are related to other sleep disorders and/or sleep hygiene and sleep scheduling issues. For those patient, lifestyle and sleep hygiene advise is often all that is required. The proportion of these patients is likely more than 1/3 but even if, following the 'intervention' model, it is assumed that 2/3 of patients with negative oximetry have sufficient symptoms to warrant CPAP or MAD and are therefore further investigated, oximetry screening as the first line test followed by respiratory PG when appropriate, would be the most cost-effective approach (extrapolating from the</p>	<p>Practical implications</p> <p>The committee acknowledge the practical concerns with using RP and therefore have modified the recommendations to allow more use of oximetry where RP is not practical. The recommendation takes into account your suggestion. It is "1.3.2 If access to respiratory polygraphy is limited consider home oximetry for people with suspected OSAHS. Take into account that oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung diseases."</p>

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	Evidence review D	047	007-011	<p>68% re-testing threshold calculated in a sensitivity analysis, Evidence review D, page 36)</p> <p>For all these reasons the validity of the cost-utility models is highly questionable and they should not be used to support the Committees' recommendations.</p> <p>Wider issues with diagnostic tests:</p> <ul style="list-style-type: none"> - The Committee acknowledges that the <i>current diagnostic practice is variable with some sleep centres offering oximetry as the first-line test others offering home respiratory polygraphy</i>. They further acknowledge that there is a lack of evidence for diagnostic tests for OSAHS. Yet, the Committee makes strong recommendations based on their experience and decides not to make any research recommendations for the diagnostic tests. Such statements and decisions fall short of NICE standards. There is a clear need for high quality research studies comparing home oximetry screening with respiratory PG. This should be endorsed by NICE and the current recommendation downgraded. Why is further research on this required? <ul style="list-style-type: none"> • Because there are no sufficient quality studies to determine the true sensitivity and specificity of home oximetry performed with modern devices which could inform the most cost-effective approaches. • Because it is uncertain whether 3% or 4% desaturation criterion should be used for home oximetry to achieve the optimal balance between sensitivity and specificity. • Because there is more evidence in support of CPAP as the first line treatment option for 	

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	Guideline	044	001-006	<p>people with mild OSA and therefore the current practice of treating OSA will change. Differentiating between mild and moderate OSA seems now less important.</p> <ul style="list-style-type: none"> • Because it is uncertain whether people diagnosed with moderate/severe OSA based on respiratory PG (AHI) have the same cardiovascular benefits from CPAP as those diagnosed with moderate/severe OSA based on oximetry (ODI). It is now recognised that AHI (determined based on the latest AASM respiratory events classification) is a poor predictor of cardiovascular outcomes and novel indices based on oximetry (such as hypoxia burden index) can better risk stratify OSA patients for cardiovascular and cerebrovascular risks and thus the potential benefits from CPAP therapy. • Because there is no consensus on the first line test for OSA. Experience and preferences vary across different centres. <p>- Practical implications The recommendation to replace home oximetry with respiratory polygraphy will be costly and very difficult to implement in many large centres which rely on oximetry screening. The Committee seems to have underestimated the impact of this recommendation. It is not just a matter of replacing equipment but employing and training additional personnel to score and process the studies. Some large centres carry out 100-200 oximetry studies a week. Performing the same number of respiratory polygraphy tests will not be possible without a large investment in infrastructure and personnel which may not be deliverable in resource-constrained settings. This recommendation may therefore have adverse</p>	

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				<p>consequences on timely accessibility to OSA assessment and result in delays in treatment which could particularly disadvantage patients with moderate to severe OSA who would have been diagnosed based on oximetry and who benefit most from the treatment. There is also a risk that diagnostic services will be outsourced to private companies who will control prices and this may lead to higher costs of OSA diagnostics in the future.</p> <p>During the COVID-19 pandemic some centres have introduced a postal oximetry service which is relatively cheap, convenient for patients and allows to reduce face-to-face contacts. The same will not be possible for respiratory polygraphy.</p> <p>Performing respiratory PG universally on all patients referred to OSA clinics will not per se improve the quality of care or remove the need for a good clinical judgement which is necessary at all steps of the diagnostic and treatment process. High quality training and good clinical judgement will remain central to the quality of care provided in sleep services irrespective of whether it is a about interpreting oximetry and making decisions if a patient with negative oximetry requires further investigation or, whether a patient with AHI of 6 requires treatment.</p> <p>Please consider modifying the diagnostic recommendations down the line of:</p> <p><i>Where access to respiratory PG is limited then consider offering oximetry first. Be aware that oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung diseases, but a negative test is still useful. If oximetry results are negative but significant OSAHS</i></p>	

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				<i>symptoms are present then consider escalating to respiratory PG or PSG.</i>	
British Thoracic Society	Guideline	004 - 005		The list of symptoms suggestive of OSAHS is helpful in guiding clinicians which patients should be assessed for OSAHS but this list should be accompanied by a definition of OSAHS to avoid misunderstanding that a presence of 2 of the listed symptoms (for instance a combination of snoring and witnessed apnoeas) in the context of a positive sleep test is sufficient to diagnose OSAHS. Such definition should be broad but focused on symptoms which affect sleep quality, quality of life, performance at work or driving, daily functioning rather than symptoms which may just be a nuisance to the bed partner (e.g. snoring and apnoeas).	Thank you for your comment. There is a definition for OSAHS immediately preceding the title for initial assessment and recommendation on when to suspect. The aim of this list is not to diagnose OSAHS but to alert clinicians to the possibility of its presence.
British Thoracic Society	Guideline	006	005 - 015	Prioritisation and fast tracking OSAHS assessment for patients to whom it is essential to start the treatment urgently is an important recommendation which should help to improve a timely access to sleep clinics for these patients. Driving safety is one of the main considerations. Inability to drive because of suspected OSAHS will have a significant impact not only on people who have a vocational driving jobs but others who depend on driving e.g. carers, people living in remote areas with no access to public transport, parents who rely on driving to do school runs etc. A consideration should be given to make this list more inclusive. Where recommendations for prioritisation are made on the basis of observational associations between OSA and co-morbidities or peri-operative outcomes rather than evidence that CPAP therapy makes any difference to such co-morbidities or outcomes this should be explicitly discussed. Otherwise, clinicians may feel obliged to recommend CPAP therapy for any degree of OSA severity and regardless of symptoms for patients on the priority list. Such practice would not be supported by the existing evidence and may result in unnecessary treatment.	Thank you for your comment. The committee discussed this in detail to ensure they came up with the right balance in the recommendation. The committee agree that it is important for all people to be assessed but could not prioritise everyone and focussed on the key groups. The recommendation does not preclude a clinician from prioritising a sleepy driver. The committee agreed that it was sensible for the sleep service to prioritise individuals in whom untreated OSAHS would be likely to impact on comorbidities and the other factors listed in the recommendation. They also agreed that these people should be offered CPAP if they are diagnosed with OSAHS and meet the criteria laid out in the recommendations. This would apply to all severities of OSAHS although those with mild OSAHS need to also have symptoms that affect their affect their quality of life and usual daytime activities. There is a more in-depth discussion about prioritisation factors in evidence report C.
British Thoracic Society	Guideline	008	005	The recommendation to consider auto-CPAP as an alternative to fixed-level CPAP in people who need high pressure only for certain times during sleep is puzzling. It is not clear how clinicians would know which patients require high pressure only for certain times	Thank you for your comment. The committee agreed this is difficult to define in a recommendation and is part of clinical judgement. The usual practice is for the clinician to make a decision on what pressure to start with and then adjust the pressure accordingly.

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				during sleep. This would require an inpatient CPAP titration under PSG and cannot be reliably determined from telemonitoring with fixed-level CPAP devices.	Telemonitoring will give CPAP data on AHI and the control of events which will help the clinician decide if the pressure needs adjusting. Previously, data had to be downloaded and sent to the sleep service.
British Thoracic Society	Guideline	009 011	019 - 025 003 - 008	The recommendation that mandibular advancement splints (MAS) should be offered as a treatment option for people with mild and moderate OSAHS is welcomed. However, the basis for limiting this recommendation to bespoke MAS and excluding semi-bespoke MAS seems flawed and is not consistent with the available evidence.	Thank you for your comment. We have revised the economic model base case so that the mean durability is 14 months for semi-customised MAS based on a small audit reported by a stakeholder organisation. Semi-customised MAS were found to be cost-effective compared to conservative management in the base case analysis. In one of the sensitivity analyses, they were more cost-effective than fully customised MAS. The committee considered the relative cost effectiveness of these two categories of MAS to be uncertain and therefore decided to recommend both.
	Guideline	046 – 047 049 - 050	027 - 031, 001 - 028 022 - 030, 001 - 010	<p>The Committee's exclusion of semi-bespoke devices is stated to have a predominantly experiential rather than evidence basis. Given the current limited access to bespoke MAS we are concerned that the collective anecdotal experience of using semi-bespoke MAS may have been too limited to allow robust conclusions to be drawn.</p> <p>There are studies which clearly support clinical effectiveness and cost-effectiveness of semi-bespoke MAS. For instance, TOMADO study, which was commissioned specifically to compare clinical and cost effectiveness of various MAS against no treatment in mild-moderate OSAHS found a semi-bespoke MAS and a bespoke MAS to be equally effective in terms of AHI reduction, ESS improvements and adherence. Side effects were no different. The HTA TOMADO long term health economics analysis was also favourable. The cost effectiveness findings of the current analysis differ from those of the HTA TOMADO study and this seems largely due to the fact that semi-bespoke MAS life span is taken as 6 months as appose to 12 months for the base case. Clinical experience and manufacturer guidance indicate that these devices last, on average, for 12-18 months and rarely need replacing before 12 months. The Committee has not given the basis for the 6 months' assumption.</p>	

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British Thoracic Society	Guideline	012	002 - 003	The Committee recommends consideration of tonsillectomy for people with OSAHS who have large obstructive tonsils and a BMI of less than 35 kg/m ² . We agree that people with high BMI are less likely to benefit from tonsillectomy than people with low BMI but when a very specific BMI threshold is recommended this should be born out of evidence and not based on a consensus opinion.	Thank you for your comment. The committee agree that there is no evidence to for the suggested BMI threshold but agreed that tonsillectomy is commonly accepted. Radiological studies have shown deposition of fat in tongue-base and pharyngeal spaces adversely impacting the patency of upper airway. The higher the BMI the worse the problem but the figure of 35 is commonly accepted.
British Thoracic Society	Guideline	013 054	013 020 - 023	As it is stated, CPAP adherence patterns are usually established in the first week of therapy. Therefore, an initial consultation for troubleshooting and supportive measures should ideally take place 7-14 days after CPAP initiation. This will be particularly important for patients started on a fixed-level CPAP with empirically set pressure level who may need re-titration. Could a more ambitious follow up target than <i>within 1 month</i> be recommended?	Thank you for your comment. The committee has also recommended telemonitoring to allow for titration before the follow up meeting. The recommendation is for follow up within 1 month rather than at 1 month. The treating clinician may decide to arrange a meeting sooner than 1 month but for some people a longer time period may be needed.
British Thoracic Society	Guideline	014 - 015	020 - 023, 001 - 005	Monitoring treatment efficacy. The recommendation to assess severity of OSAHS at review using AHI (respiratory PG) will be difficult to implement without drawing resources away from diagnostics in overstretched services and is unnecessary in the majority of patients. Assessment of symptomatic response to treatment, adherence data and data downloaded from the device or telemonitoring are sufficient to evaluate responsiveness to treatment. Oximetry or respiratory PG should be reserved for those patients in whom there are specific clinical concerns regarding OSAHS control. The same concerns pertain to using respiratory PG in monitoring people with OHS and overlap syndrome where symptomatic improvement, improvement in nocturnal oximetry and daytime blood gases are sufficient to assess for response to treatment.	Thank you for your comment. We have modified this to monitor AHI or ODI. AHI will be available as downloaded or telemonitoring data from CPAP when this is used and the committee do not anticipate there would be the need to repeat the sleep study.
British Thoracic Society	Guideline	018 - 019 063	017 - 022, 001- 002	The Committee's opinion that respiratory polygraphy should always be performed in people with suspected OHS is not widely shared and is not a standard practice in many NHS hospitals. Obesity hypoventilation is not diagnosed based on respiratory polygraphy. Nocturnal oximetry (including visual inspection of the oximetry trace by a sufficiently trained clinician) and, when	Thank you for your comment. It is important to distinguish between those with OHS alone and those with OHS plus OSAHS (the latter being the majority). It is true that in many Units current practice is to try NIV first whenever OHS is diagnosed, but the evidence (which is relatively new) shows that CPAP is as effective as NIV when OSAHS is also

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			006	appropriate, transcutaneous CO2 monitoring, in addition to daytime blood gases are sufficient to make the diagnosis of OHS (+/- OSA) and guide CPAP/NIV titration. Respiratory polygraphy adds little value to the management of OHS. This change to practice should only be recommended if the Committee presents supporting evidence.	<p>present, even when the OSAHS is severe. CPAP is also more cost-effective and easier to set up. It is therefore important to identify OSAHS in people with OHS, and oximetry alone is not as good as respiratory polygraphy at making this distinction.</p> <p>NIV is recommended for people with OHS without severe OSAHS.</p>
British Thoracic Society	Guideline	019 - 020	016 - 020, 001 - 008	We have some reservation about the recommendation to use CPAP as the first line treatment in people with OHS and severe OSAHS regardless of daytime CO2 levels. A CO2 threshold should be considered (same as it was for the overlap syndrome) as people with severe chronic hypercapnia are more likely to fail CPAP and benefit from NIV as the first line treatment.	<p>Thank you for your comment.</p> <p>In people with stable OHS-OSAHS, based on the evidence and their experience, the committee agreed that CPAP should be offered as a first line treatment because it is more cost-effective, simpler to set up and may be better tolerated than non-invasive ventilation. There was no evidence to support use of a CO2 threshold when deciding what treatment to instigate.</p> <p>If symptoms do not improve, hypercapnia persists, AHI is not sufficiently reduced or CPAP is poorly tolerated, the committee agreed that treatment should be changed to non-invasive ventilation to control nocturnal hypoventilation. This is detailed in the committee discussion section of the evidence report.</p> <p>The committee have recommended use of NIV for people with OHS without accompanying OSAHS as you suggest. This is phrased as a "Consider" recommendation because there was no evidence comparing CPAP and NIV in people with OHS in whom OSAHS had been excluded.</p>
British Thoracic Society	Guideline	065	001 - 011	Re: oxygen therapy in OHS. We are concerned that the Committee recommends adding oxygen if nocturnal hypoxaemia persists despite CPAP or NIV without recommending further investigations to the cause of hypoxaemia. Persistent hypoxaemia despite well controlled nocturnal hypoventilation always requires further investigation and this should be clearly stated as otherwise the guideline will appear to sanction poor practice. Also, the current practice, supported by knowledge and experience, is to switch	<p>Thank you for your comment. The committee recommend the addition of supplemental oxygen therapy to the CPAP or non-invasive ventilation during sleep to correct this hypoxia. We have amended the oxygen recommendation 2.5.8 to include the statement: "...and address any additional underlying causes of hypoxaemia, where possible".</p> <p>The committee also recommend offering non-invasive ventilation as an alternative to CPAP for people with OHS and severe</p>

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				CPAP to NIV if nocturnal hypoxaemia persists (and there is no other cause for it) before oxygen is added. It is not clear on what basis the Committee recommends adding oxygen to CPAP for OHS. Oxygen as a long-term treatment should only be added when nocturnal hypoxaemia persists despite a trial of NIV with appropriate IPAP and EPAP titration and when other causes of hypoxaemia are excluded/adequately treated. Also, the Committee should consider to recommend a saturation threshold for prescribing nocturnal oxygen or, if there is no sufficient evidence to guide this, make an appropriate research recommendation.	<p>OSAHS if symptoms do not improve, hypercapnia persists, apnoea-hypopnoea index (AHI) or oxygen desaturation index (ODI) are not sufficiently reduced or CPAP is poorly tolerated.</p> <p>The committee could not define a saturation threshold to pick and therefore could not define a research recommendation. The saturation threshold would depend on comorbidities and underlying lung disease.</p> <p>The committee has also added a recommendation in monitoring treatment efficacy which reads "For people with OHS having supplemental oxygen therapy, review whether this is still needed after treatment with non-invasive ventilation or CPAP has been optimised"</p>
Faculty of General Dental Practice (FGDP)	Evidence review G	001	011	Although perhaps self-explanatory, we suggest that the sentence could be clarified to read "...prevent pharyngeal collapse (during sleep)".	Thank you for your comment. The text has edited as suggested.
Faculty of General Dental Practice (FGDP)	Evidence review G	001	013	<p>The text implies a balance of advantages and disadvantages between over-the-counter self-use devices and custom-made appliances. However notwithstanding the unequivocal message from the evidence review, the main, if possibly sole, advantage of the out-of-the-box self-use devices bought over the internet or pharmacy counter is surely their low initial cost. However without educated support to assess suitability, and to fit devices correctly in the optimum location and in an effective manner without causing harm (usually by burning), these appliances have only that benefit of low initial cost to the user, and may potentially mask OSAHS - if used, as many members of the public do (for snoring symptoms), without insight into the potential medical impact of undiagnosed OSA.</p> <p>Perhaps a more considered narrative might be more appropriate?</p>	<p>Thank you for your comment. The introduction to the chapter is intended to give background to the review only, not as a means of rationalising the evidence.</p> <p>We address the benefits and harms of oral devices in the review. We have also included a recommendation in the section on Information for people with OSAHS, OHS or COPD–OSAHS overlap syndrome covering the information to give people using oral devices that includes providing information on how to use them and their benefits and harms.</p>

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Faculty of General Dental Practice (FGDP)	Evidence review G	001	020	Significant work similar to this project has been undertaken elsewhere by other professional bodies and we are mindful of the jurisdiction with the greatest exposure and longest experience in this field. Has the committee considered the Clinical Practice Guidelines for the Treatment of OSA and snoring with Oral Appliance Therapy published in J Clin Sleep Medicine 2015 July 15:11(7), 773-882 by the AASM, whose committee members include eminent clinicians from the Mayo Clinic and Walter Reed Hospitals amongst others?	<p>Thank you for your comment. The committee were aware of the resource highlighted. This guideline included an up-to-date systematic review which included a few studies published since the AASM guideline was published and compared oral devices with other CPAP, positional modifiers and surgery.</p> <p>NICE guidelines also consider cost-effectiveness from a UK perspective and in this guideline we included oral devices as part of an economic model..</p>
Faculty of General Dental Practice (FGDP)	Evidence review G	007	039	<p>The draft guidance states that “There was no evidence of tongue retaining devices”. However there is a reference in the bibliography to a paper by Deane et. al. which is an RCT of the efficacy of tongue-retaining devices which paints them in a comparable and not un-favourable light to custom-made adjustable splints/appliances. Is this an oversight?</p> <p>The significance of tongue retainers is that they may be fitted to edentulous users, and to those with compromised dentitions, therefore providing a treatment modality to people who may not be capable of tolerating CPAP or suitable for surgical intervention. Recent published work from China suggests that tongue stimulation related to tongue advancement materially improves pharyngeal airway volume independently of mandibular advancement per se. Furthermore while a healthy, cared-for and intact dentition is most helpful for MAS therapy, we are concerned about:</p> <ol style="list-style-type: none"> 1. The education of patients on the impact of oral biofilm associated with splint use, and the concomitant impact on the periodontal support to the very same teeth supporting the device. 2. That colleagues do not rule out MAS use if implants, or indeed favourable residual edentulous ridges, exist to support appliances capable of supporting suitable MAS or tongue retainers. Indeed in our experience both in hospital and dental practice limited 	<p>Thank you for your comment. Deane et al 2009 compared mandibular advancement splint with tongue stabilising device. This comparison was not one included as part of the protocol comparing different oral devices and therefore the study was excluded. The guideline review comparing different oral devices only looked at different types of mandibular advancement splints. It was added to the guideline when the committee realised there was evidence suggesting mandibular advancement splints were effective and that there was likely to be a difference in effectiveness between types.</p> <p>The recommendations for people using oral devices in the section on information for people with OSAHS, OHS or COPD–OSAHS overlap syndrome recommends people are informed of possible side effects, how to adjust the device, maintaining good health and who to contact if there are problems. This could include the point you mention in item 1. We have avoided going into all detail and leave that to the healthcare professional prescribing the device.</p> <p>We have amended our recommendations related to mandibular advancement splints to recommend that people have “optimal dental and periodontal health” rather than “suitable dentition”.</p>

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				numbers of implant fixtures have significant potential to support oral appliances most effectively.	
Faculty of General Dental Practice (FGDP)	Evidence review G	032	1.5.5 .2	<p>Regarding MAS costs, durability is “assumed” at 2y. Without supporting evidence this appears to be an arbitrary figure, and in view of the wide range of variables - including differing appliance designs and materials used in their fabrication, as well as patient factors such as age, dexterity, oral health, dental support, individual physical impact and care of the appliance - surely longevity is almost impossible to quantify without good retrospective study data?</p> <p>Many clinicians have cared for numerous users with stable, well-cared-for dentitions who have looked after and used a particular design of adjustable appliance for well over 5 years without problems, and others with the very same appliance discontinue its use within 6 months. Maybe some primary evidence for individual design types might be helpful, and we might again look to the US to help identify some of the more long-lasting and cost-effective designs. Similarly, a simple request to leading laboratories supplying custom appliances should provide indication of longevity and cost.</p>	<p>Thank you for your comment. We acknowledge that 2 years is an arbitrary figure. For this reason, we conducted a sensitivity analysis around this parameter in our economic modelling. The cost effectiveness of custom-made MAS is extremely sensitive to the durability.</p> <p>It would have been useful to have evidence regarding durability. However, this is not the only area of uncertainty about MAS. The committee have made a research recommendation for MAS. Even, if the committee had detailed information about durability, they would not have made a strong recommendation without stronger evidence of effectiveness.</p>
Faculty of General Dental Practice (FGDP)	Evidence review G	General	General	We would be grateful to be informed of the evidence behind the stated NHS reference cost of £113 for set-up and review of appliances and cannot see that in any NHS GDS payment narratives. Please could this be clarified for the many general dental practitioners who provide possibly the majority of oral appliances in the UK, and might be unaware – as we are - of any NHS funding to support the superintending of oral appliances in their practices.	<p>Thank you. In the evidence review we gave only an overview of our model methods – details are in the guideline model report. In our economic evaluations generally, we use NHS reference costs, which are not the same as payment tariffs.</p> <p>In the absence of specific information on customising mandibular advancement splints, we used the cost of a Consultant-led outpatient visit– for the Dental medicine specialty. This has now been added to the model report.</p> <p>The committee are not aware of the payment mechanisms for mandibular advancement splints. Commissioners might have to review this when implementing this guidance. It is anticipated that</p>

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					commissioners will review the guideline when deciding on what to fund and implement.
Faculty of General Dental Practice (FGDP)	General Guideline	020		<p>We do not consider that fixed three-month follow-up appointments are necessarily appropriate for patients fitted with MAS or indeed any appliances - especially if a patient develops some of the very common associated problems which are noted in many of the studies referenced; pain, mucosal ulceration due to pressure, tooth loosening, TMJ and muscle pain among others.</p> <p>We would suggest that a flexible review or open-door system allowing patients to return for urgent care, advice, reassurance and any necessary modification before lasting harm is caused (whether by inappropriate usage or appliance /mouth interface factors) would be more appropriate.</p> <p>We are confident in noting the ability of primary care practitioners to respond swiftly and efficiently to support patients in a way that secondary and tertiary care systems are not geared to do, and would ask the committee to consider the potential advantages of creating Clinical Pathway Networks for referral, treatment and management for healthcare users between General Medical Practitioners, General Dental Practitioners and secondary/tertiary care units, with suitable training and expertise to improve patient journeys and ideally make the care provision more responsive to patient needs, more cost-effective, and to deliver optimal quality of life outcomes to patient users.</p>	<p>Thank you for your comment. The committee do not exclusively state that patients cannot be seen sooner but agreed that a follow-up at 3 months is needed to ensure therapeutic effectiveness along with adherence with a MAS, as it requires sufficient time for adaption and any adjustment with the use of device. The committee agree that any emergency need can be undertaken prior to the initial 3 month follow-up appointment as in current clinical practice.</p>
Hope2Sleep Charity	Comments form	Question 2		<p>Despite our submitted comments, these proposed new NICE Guidelines are a big step forward and will be welcomed by patients too.</p> <p>Regarding overall cost implications, priority should be given to issue Auto CPAP (APAP) rather than a fixed CPAP pressure machine. (Perhaps manufacturers to help lower costs of APAP). Most patients gain better compliance and comfort when pressures remain lower and only raise for the breathing events. This is one of the biggest complaints we get at the Hope2Sleep Charity that</p>	<p>Thank you for your comment. The evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p>

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				<p>patients who are initially trialled on APAP and do well, then struggle when moved to a fixed pressure CPAP and even when not trialled on APAP they struggle with higher pressures all night. This results in lots of extra demands on the clinic for additional support and eventually, after lots of pleading, the patient is often then moved to APAP (or even purchase one themselves). When the 2nd machine (APAP) is then issued by clinics this means 2 machines have been given to the patient which is not cost effective. Issuing an APAP to all patients means one machine would only ever need to be issued which last for several years, and for the smaller percentage of patients where fixed pressures are better, the same APAP machine can be changed to CPAP mode. As we are now living in this COVID-19 pandemic, this also means it will cut down on the risk of cross contamination by machines used by different patients and would also mean less visits to the sleep clinic. For the extra one-off cost of APAP vs CPAP, this would result in overall cost savings and more compliant patients.</p>	<p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee made a research recommendation to help inform future guidelines (see Appendix J).</p>
Hope2Sleep Charity	Guideline	007	006 - 007	<p>From our experience in dealing with frustrated and tired patients who have had a sleep 'study' based on pulse oximetry only, many patients are missed a diagnosis of sleep disordered breathing – even those without heart failure or chronic lung disease. This is why we believe pulse oximetry should not be used for diagnosing patients with suspected sleep disordered breathing as not all breathing events cause an oxygen desaturation, but there is still pressure on the heart and interrupted sleep – thus undiagnosed untreated struggling people with daytime tiredness, meaning they are at risk of driving accidents, depression, anxiety and other linked medical conditions of untreated sleep disordered breathing.</p>	<p>Thank you for your comment. The committee agree that respiratory polygraphy is the better tool. They also agreed that oximetry can still be useful in certain circumstances. We have amended the recommendations so that oximetry is recommended where access to respiratory polygraphy is limited. The new recommendation is:</p> <p>“1.3.2 If access to respiratory polygraphy is limited consider home oximetry for people with suspected OSAHS. Take into account that oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung diseases. “</p>

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Hope2Sleep Charity	Guideline	008	011	Whilst appreciating lifestyle changes can help mild OSAHS, to state that 'treatment is not usually needed' would be upsetting for the patient, as unless they are struggling with symptoms of mild OSAHS, they'd hardly have reached the point of a referral and sleep study. These patients should be offered a further appointment after any lifestyle changes have been addressed, or if none relevant they should be offered some form of treatment.	Thank you for your comment. The committee agree it is important to follow up people who have symptoms. There is also a recommendation in this guideline that follow up should be tailored to individual needs and the clinician can decide the most appropriate way to follow up patients on a case-by-case basis.
Hope2Sleep Charity	Guideline	008	019	Fixed level CPAP regularly fails many patients, including those with mild OSAHS and especially as they often suffer from UARS (upper airways resistance syndrome) and due to nasal stuffiness they often need higher pressures on different nights, depending on their severity of nasal congestion which varies. For the one-off extra cost of Auto CPAP (APAP), this would also cut down on further appointments and demands on the time of the busy clinics when patients struggle with one fixed pressure.	<p>Thank you for your comment.</p> <p>There was no sufficient evidence to suggest that tolerability outcomes such as nasal blockage, dry mouth, tolerance of treatment pressure and mask leak are different in auto CPAP and fixed CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p>
Hope2Sleep Charity	Guideline	009	003	Auto CPAP (APAP) would be better given at the start as most patients, regardless of severity of OSAHS need different pressures based on sleep position, nasal stuffiness, medications etc. This would also cut down on patients needing to change from fixed CPAP to Auto CPAP (APAP) and they would not need a different machine which is especially important during this COVID-19 pandemic.	<p>Thank you for your comment. The committee understand that many patients prefer auto-CPAP but evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-</p>

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					<p>CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee made a research recommendation to help inform future guidelines (see Appendix J).</p>
Hope2Sleep Charity	Guideline	009	008	Bearing in mind a lot of patients with mild OSAHS suffer from nasal congestion and rhinitis (even when not CPAP-induced), when some clinics decide to hold off from issuing humidification initially, it is important patients are told a humidifier can be supplied at a later date, as many patients are unaware of this and some even give up on CPAP – little realising there is a solution that can help dry mouth and rhinitis etc. Furthermore, we would stress the importance of avoiding dry mouth which leads to gum disease and tooth decay.	Thank you for your comment. We have added a point to the recommendations on Information for people with OSAHS, OHS or COPD–OSAHS overlap syndrome advising that people starting treatment on CPAP are given information on humidification.
Hope2Sleep Charity	Guideline	010	006	Fixed level CPAP regularly fails many patients, including those with moderate or severe OSAHS as many patients require different pressures (lower as well as higher) as no 2 nights are the same, which is evidenced when viewing the same patient on different nights of sleep studies. There are many reasons different pressures are required in all ranges of OSAHS, such as nasal congestion, sleeping position, sedating medications needed, alcohol (even in small quantities) body temperature etc. Therefore, the one-off extra cost of Auto CPAP (APAP), would also cut down on further appointments and demands on the time of the busy clinics when patients struggle with one fixed pressure.	<p>Thank you for your comment. The evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP.</p> <p>While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that</p>

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					<p>with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee made a research recommendation to help inform future guidelines (see Appendix J).</p>
Hope2Sleep Charity	Guideline	011	004	<p>The biggest concern patients have with a mandibular advancement splints is that they have no evidence as to whether they are successfully treating their OSAHS (unlike most CPAP machines can confirm) and have to rely on how they 'feel.' Therefore, a repeat sleep study should be offered with the mandibular advancement in place, which would also help the dentist know whether further adjustment is necessary. A cease in snoring does not always mean there are no breathing events happening which would be putting pressure on the heart and most often causing oxygen desaturations.</p>	<p>Thank you for your comment. The committee agree that symptomatic mild-moderate-severe patients, intolerant or 'fail' CPAP, offered MAS therapy should be considered for a limited follow-up sleep study as it is generally regarded to be good clinical practice. This is reflected in recommendation 1.9.5 "... subsequent follow-up according to the person's needs and until optimal control of symptoms and AHI or ODI is achieved".</p>
Hope2Sleep Charity	Guideline	011	009	<p>Whilst it is a positive step forward that further treatments have been suggested (namely positional modifiers, some surgery and mandibular advancement splints) it is disappointing to see other proven treatments not mentioned or considered in these guidelines, such as bariatric</p>	<p>Thank you for your comment. Pharmacological interventions for OSAHS were not included as part of the scope therefore the guideline makes no statement in relation to these.</p>

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				surgery or the 'Inspire' upper airways stimulation which frustratingly is hard to access in the UK, despite it being a successful treatment for several years in the USA and is FDA approved. A lot of time and expense has also been spent on the the non-invasive electrical stimulation (TESLA) therapy at Guy's & St Thomas for which studies have also been very positive, so again this is disappointing for it not to be included. There are also none of the approved medication mentioned (such as Sunos and Pitolisant, amongst others) for residual excessive sleepiness. The eXciteOSA has also been given FDA approval and is the first daytime therapy in the world so should be considered.	<p>The committee agree bariatric surgery is an important area but it is beyond the scope of this guideline.</p> <p>We included Hypoglossal Nerve Stimulation in our literature search including all the relevant search terms for this review, however we did not identify any evidence that met the inclusion criteria as specified in our protocol. The committee therefore agreed to include a research recommendation for Hypoglossal Nerve Stimulation to inform future updates of this guideline (Evidence report J, Appendix J).</p> <p>The committee were also aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p>
Hope2Sleep Charity	Guideline	011	011	It is good to see positional modifiers being offered, but it would also be beneficial for a further sleep study when the patient has been trained to stay off their back to check the OSAHS is being treated by body position alone, so that they can decide whether to also introduce a combination treatment, such as mandibular advancement splints, or even the new eXciteOSA daytime therapy or other...	Thank you for your comment. The committee recommends people are followed up once they are started on treatment. They anticipate the treating clinician will decide whether to do a sleep study. Combinations of treatments were not assessed in this guideline and therefore the committee have not made recommended them.
Hope2Sleep Charity	Guideline	012	002	It is important to have a further sleep study when healing has settled after tonsillectomy, as at the charity we have experienced many patients who have had a tonsillectomy and it has been assumed rather than prove, this has cured the OSAHS – only to	Thank you for your comment. We have recommended an initial follow-up consultation with respiratory polygraphy within 3 months of any operation.

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				discover later that it has not been successful in curing the OSAHS and in most cases only improved it. In fact this comment applies to all surgery undertaken.	
Hope2Sleep Charity	Guideline	012	004	As with all surgery, it is important to have a further sleep study to check the OSAHS has improved dramatically or been cured.	Thank you for your comment. We have recommended an initial follow-up consultation with respiratory polygraphy within 3 months of any operation.
Hope2Sleep Charity	Guideline	024	004	Also give patients information of the registered charitable patient organisations for non-medical support, ie our own organisation, Hope2Sleep Charity and SATA who have evidence that ongoing patient support, which clinics don't usually have time for, is the key to compliance. In our own recent survey at Hope2Sleep, of CPAP-treated patients, out of 567 patients, 526 confirmed they use their CPAP every night, 39 stated they use it regularly but not every night and only 2 patients never use it. This proves that with good support, compliance is far higher than the quoted lower compliance figures.	Thank you for your comment. NICE provides links to relevant patient support organisations on its website via the guideline web pages.
Inspire Medical Systems, Inc.	Evidence review J	006	024	<p>[...] although at present this treatment option is not widely available.</p> <p>Comments: This statement is incorrect – Hypoglossal Nerve Stimulation (HNS) is widely available although not yet widely utilized in the UK:</p> <ul style="list-style-type: none"> • In 2019 NHS England added HNS technology to the High Cost Drug and Device exclusion list • In 2017 IPG assessed HNS therapy and recommended its use with special arrangements (IPG598) • HNS therapy is the broadly utilized standard of care across Europe and the US for this patient population <p>The outcomes with Hypoglossal Nerve Stimulation (HNS) therapy are clinically relevant and provide substantial improvement in health-related quality of life and constant reductions in OSA severity in patients with PAP intolerance or PAP failure. Adverse events are in the range of 3-5% and surgical procedure for implantation of a hypoglossal nerve stimulation system is well and</p>	<p>Thank you for your comment and for your suggested evidence.</p> <p>The statement in the introduction section has now been amended to state that at present hypoglossal nerve stimulation treatment option is not widely used in the UK.</p> <p>All the references you cite have all been checked for their relevance to the review protocol. When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For this review it was agreed to restrict it to RCT evidence, as the highest quality evidence. Non- randomised/observational studies were agreed as not sufficient quality for this question. Offering surgery for treatment of OSAHS is not currently common practice. To demonstrate it could be cost-effective to warrant a change in practice identifying RCT evidence was considered important.</p> <p>None of the following studies referred are RCTs and therefore do not meet inclusion criteria for the guideline review: Heiser C et al.</p>

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				<p>has a low technical learning curve (Heiser C et al. 2016, Heiser C et al. 2017, Murphey AW et al. 2015, Larsen C et al. 2020). Based on >150 peer-reviewed publications, HNS therapy is recommended in different treatment guidelines as alternative treatment for patients with OSA and intolerance of CPAP therapy.</p> <p>Germany German Society for Sleep Research and Sleep Medicine (DGSM) The German Society for Sleep Research and Sleep Medicine (DGSM) states in their S3 Guideline Sleep-Related Breathing Disorders in Adults that Hypoglossal Nerve Stimulation (HNS) should be considered in patients with CPAP intolerance or ineffectiveness with an AHI 15-65/h and a BMI up to 35 kg/m² and in the absence of anatomic abnormalities and moderate to severe OSA. The recommendation refers to evidence level 1b with recommendation grade B (page 30, highlighted). Furthermore a positioning paper of the Sleep Medicine Working Group of the DGHNO-KHC (German Society of Oto-Rhino-Laryngology, Head and Neck Surgery) on HNS as treatment option of OSA has been published recently (Steffen et al. 2020).</p> <p>Switzerland Swiss Society of Sleep Medicine (SSSC) The Swiss Society of Sleep Medicine (SSSC) recently updated their treatment recommendations for obstructive sleep apnea and included Hypoglossal Nerve Stimulation as an evidence-based alternative treatment after failure or intolerance of CPAP therapy (page 7).</p> <p>The Netherlands Dutch Guidelines for Treatment of Obstructive Sleep Apnea Recommendation: Consider treating a patient with OSAH with AHI between ≥15 and ≤65 who is CPAP intolerant with hypoglossus nerve stimulation. If there is insufficient effect of CPAP (therapy efficacy failure), the diagnosis must be reconsidered. After</p>	<p>2016 is a before after study and did not have a control group ; Heiser C et al. 2017 is a narrative article and it doesn't reference any evidence that would meet the criteria for this review protocol; Murphey AW et al. 2015 is a retrospective review; Larsen C et al. 2020 was not included as it is a retrospective review of registry data; Steffen et al 2020 is not in English, non-English studies were excluded in the protocol. The abstract suggests that it is not a randomised study.</p> <p>We included Hypoglossal Nerve Stimulation in our literature search for this review, however we did not identify any evidence that met the inclusion criteria as specified in our protocol and therefore did not find anything to show that hypoglossal nerve stimulation therapy is cost-effective. The committee therefore agreed to include a research recommendation for Hypoglossal Nerve Stimulation to inform future updates of this guideline (Evidence report J, Appendix J).</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p> <p>The methods followed in the development of the guideline are consistent with those detailed in Developing NICE Guidelines: The Manual, and detailed further in the methods chapter for this guideline. The search strategies for each review question are</p>

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				<p>polysomnography and DISE, it is preferable to discuss other treatment options for the patient concerned in a multidisciplinary consultation. Alternative treatment options such as an MRA, position training or upper airway surgery should be evaluated. Do not treat a patient with hypoglossus nerve stimulation if there is a BMI > 32, a complete concentric collapse at the level of the volume (with DISE), or more than 25% central apnea.</p> <p>U.K. National Institute for Health and Care Excellence (NICE) In November 2017, the UK National Institute for Health and Care Excellence (NICE) published Interventional Procedures guidance on 'Hypoglossal nerve stimulation for moderate-to-severe obstructive sleep apnoea' (nice.org.uk/guidance/ipg598). This guidance is the result of a health technology assessment for multiple neural stimulation technologies, where all devices stimulate the hypoglossal nerve to cause contraction of the genioglossus muscle which controls tongue movement. All provide therapeutic treatment for OSAH. Of the technologies reviewed, two devices have received CE Mark allowing for commercialization in Europe and the UK, however, only one device (the Inspire® UAS System) has FDA approval for commercialization in the US.</p> <p>The recommendation from the NICE assessment is that, although current evidence of hypoglossal nerve stimulation for moderate to severe OSAH is limited, physicians interested in performing the procedure may do so by making 'special arrangements' for clinical governance, consent and audit, or research NICE has also requested that further research, including registry data, should provide information on patient selection, long-term outcomes, and the position of the procedure in the treatment pathway.</p> <p>In addition, different institutions across North America and Europe carried out Health Technology Assessments to evaluate the therapeutic benefits with HNS therapy:</p>	<p>detailed in appendix B of the relevant chapters. The protocols for each review (in appendix A) detail the study design that is appropriate to answer each review question.</p> <p>NICE takes into account cost effectiveness as well as clinical effectiveness. It is key to decision making on a national level that treatments recommended are based on evidence of cost effectiveness as well as clinical effectiveness, as the NHS has a limited budget, and the opportunity cost of investment has to be considered. Although clinical excellence is of course the aim, there are not unlimited resources available to be able to support this, and the best balance between costs and benefits underpins NICE recommendations.</p>

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				<p>AETS – ISCIII (Institute Carlos III, Spain) Within the scope of the “Early detection of new and emerging RedETS health technologies” program a technical report entitled “Hypoglossal nerve stimulation systems for treatment of obstructive sleep apnea” was published in 2018. This report examined intermittent stimulation (synchronized with breathing) technologies: Inspire and HGNSTM (Apnex), as well as continuous stimulation technologies: Aura6000TM (ImThera) and GenioTM System (Nyxoah). These technologies were indicated for the treatment of selected patients with moderate or severe OSA and with inadequate adherence or rejection of usual treatment consisting of CPAP. The report found these technologies to be therapeutic alternatives for moderate OSA with inadequate adherence to CPAP avoiding the need for soft tissue resection through surgery. Though the analysis was carried out technically correct, we feel that the report did not account for immanent differences of the mechanisms of action of the respective HNS platforms investigated. In addition, the comparator was not adequate given the treatment journey of OSA patients, who regularly receive surgical interventions after PAP failure, even though the outcomes of these procedures are of questionable efficacy and they carry a high rate of acute and longterm complications.</p> <p>Blue Cross Blue Shield Evidence Street® (United States) The most thorough HTA of Inspire’s body of evidence was performed in 2018 by Blue Cross Blue Shield Association’s Evidence Street team. This assessment took nearly a year and included a rigorous review of published evidence with significant input from the American Academy of Otolaryngology. On January 7th, 2019 Evidence Street issued a positive assessment of Hypoglossal Nerve Stimulation (HNS) finding:</p>	

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				<p><i>"For individuals who have OSAH who receive hypoglossal nerve stimulation, the evidence includes two nonrandomized studies with historical controls and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, body mass index, and favorable pattern of palatal collapse. These results were maintained out to five years in the pivotal single arm study. Clinical input supplements and informs the interpretation of the published evidence. Clinical input indicates that [Hypoglossal Nerve Stimulation] HGNS leads to a meaningful improvement in health outcomes in appropriately selected adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HGNS. The improvement in AHI with HGNS, as shown in the STAR trial, is similar to the improvement in AHI following MMA. Clinical input also supports that HGNS results in a meaningful improvement in health outcomes in appropriately selected adolescents with OSAH and Down's syndrome who have difficulty in using CPA".</i></p> <p>Finally, in the opinion of BCBSA the therapy is appropriate in patients with:</p> <ul style="list-style-type: none"> - age ≥ 22 years in adults, or adolescents with Down's syndrome (age 10 to 21 years); and - diagnosed moderate to severe OSAH (with less than 25% central apneas); and - CPAP failure or inability to tolerate CPAP; and - body mass index ≤ 35 kg/m² in adults; and - favourable pattern of palatal collapse 	

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				<p>“The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome for patients meeting the following selection criteria which are based on information from clinical study populations and clinical expert opinion”.</p> <p>(Source: Surgical Treatment of snoring and Obstructive Sleep Apnea Syndrome: Blue Cross Blue Shield Association Evidence Street® Assessment; 2019)</p> <p>eviCore healthcare Clinical Guidelines (United States) In February 2019, eviCore healthcare released their Clinical Guidelines for Sleep Apnea and Treatment version 1.01.2019. They concluded that implantation of hypoglossal nerve stimulation can be considered if all of the following are met:</p> <ul style="list-style-type: none"> - Age ≥ 22 - Moderate to severe obstructive sleep apnea, with apnea hypopnea index on polysomnography between 15 and 65 with less than 25% central apneas - Failure of alternative therapies for the treatment of obstructive sleep apnea due - to both: <ul style="list-style-type: none"> • Inability or unwillingness to use CPAP and/or bilevel PAP after a minimum of a one-month trial, as demonstrated by documentation of subjective (i.e. side effects or device-related problems) and/or objective (i.e. titration study results and/or downloaded data reports) assessment of response to PAP and Failure of other non-invasive treatments for obstructive sleep apnea, or documentation that alternative treatments were considered and deemed inappropriate, including oral appliance therapy - BMI ≤ 32 - Absence of complete concentric collapse on drug induced endoscopy 	

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				<p>- Surgical consultation indicating absence of other anatomical findings that would interfere with performance or evaluation of the device (Source: eviCore Healthcare: Clinical Guidelines – Sleep Apnea and Treatment; version 1.0.2019)</p> <p>Medicare Inspire UAS Assessment (United States) Medicare is a health insurance system managed by the United States federal government for the benefit of people over 65 or meeting certain criteria, such as disabled status determined by the Social Security Administration, insufficient end-stage renal disease or amyotrophic lateral sclerosis. In 2018, according to the 2019 Medicare Trustees report, Medicare provides health insurance to more than 59.9 million people in the United States (including 52 million people aged 65 and over).</p> <p>2019 Proposed Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (DL38385) The strengths of the STAR study are:</p> <ul style="list-style-type: none"> - Prospective nature: gold standard of epidemiological studies. - Measurement of the primary and secondary endpoints at inclusion and at 12 months; - Randomization of patient subgroups of this study: the patients were randomized into two subgroups, for one subgroup the therapy was switched off for 7 days, and for the other subgroup the therapy was maintained. Polysomnography was performed after the randomization period to measure the effects of stopping treatment compared to continued use. <p>Thus, stimulation of the hypoglossal nerve has been shown to improve patient outcomes when used in a group of properly selected patients. In patients meeting the criteria for inclusion of IHA, BMI and a favorable anatomical profile (collapse of the</p>	

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				<p>palate), approximately two thirds of them were responders (cf. STAR study).</p> <p>The results observed during follow-up after 12 months were maintained at 3 years. The results at 48 months showed that the treated patients maintained a sustained benefit in terms of ESS drowsiness score and quality of life (questionnaire on functional sleep and snoring results). The conclusions concerning the results at 5 years are as follows: stimulation of the upper airways is a surgical treatment that does not modify the patient's anatomy and has long-term benefits for people with moderate to severe OSAH who have failed to maintain CPAP therapy. Safety and effectiveness have been assessed using multiple outcome measures.</p> <p>Treatment with hypoglossal nerve stimulation in patients with OSAH has sufficient data to determine that the therapy results in significant improvement in patient health when used as described in this technology assessment.</p>	
Inspire Medical Systems, Inc.	Evidence review J	006	General	<p>1.2 Introduction</p> <p>Broadly speaking, surgery can be divided into three categories: (new) a. Minimally invasive and reversible non-anatomic correction surgery, implantation of Hypoglossal Nerve Stimulator (HNS)</p> <p>(new, before a) b. Soft tissue surgery (nasal surgery, tonsillectomy, palatal surgery, (tonsillectomy and palatal surgery known as oropharyngeal surgery), tongue-base surgery)</p> <p>(new, before b) c. Skeletal framework surgery (e.g. bilateral maxilla-mandibular advancement, mandibular osteotomy).</p>	Thank you for your comment. The surgery categories in the introduction have been amended to include a third category. This includes other surgeries and hypoglossal nerve stimulation has been given as an example.
Inspire Medical Systems, Inc.	Evidence review J	007	General	<p>A review of PICO listed interventions does include upper airway stimulation, however, this treatment is also known as hypoglossal nerve stimulation, stimulation of the upper airway etc. Relevant</p>	Thank you for your comment. We included Hypoglossal Nerve Stimulation in our literature search including all the relevant search terms for this review, however we did not identify any evidence

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				studies/ data might not have been included within review when using limited keywords.	<p>that met the inclusion criteria as specified in our protocol. The committee therefore agreed to include a research recommendation for Hypoglossal Nerve Stimulation to inform future updates of this guideline (Evidence report J, Appendix J).</p> <p>The methods followed in the development of the guideline are consistent with those detailed in Developing NICE Guidelines: The Manual, and detailed further in the methods chapter for this guideline. The search strategies for each review question are detailed in appendix B of the relevant chapters. The protocols for each review (in appendix A) detail the study design that is appropriate to answer each review question.</p>
Inspire Medical Systems, Inc.	Evidence review J	149	General	<p>Stollo et al. 2014 has been excluded due to inappropriate study design of this cohort study.</p> <p>Comments: Identification of a comparator was a key consideration in the design of this trial. Deficits in the "standards of care" at the time of study planning were a major challenge. For example, adequate adherence to CPAP and missing standardized follow-up protocols in clinical practice are a significant limitation. Further, HNS is only indicated in those who have failed a trial of CPAP, so a randomized study comparing CPAP and HNS is illogical. Due to the significant subjective and objective improvements in the feasibility trials with the Inspire™ UAS system (Van de Heyning PH et. al, 2012), a randomization including a group of patients with an implanted device that is switched off or to sham-stimulation to serve as control, was considered unethical by the study investigators as well as the competent authority.</p> <p>The use of surgery as a comparator has been rejected, given the low degree of procedural standardization. In addition, as published by Sher and colleagues in a meta-analysis of UPPP, surgery has a very low quality of evidence, only ~40% responder rate, with degrading results over time, and a high incidence of serious</p>	<p>Thank you for your comment. All the references you cite have all been checked for their relevance to the review protocol. When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For this review it was agreed to restrict it to RCT evidence, as the highest quality evidence. Non- randomised/observational studies were agreed as not sufficient quality for this question. Offering surgery for treatment of OSAHS is not currently common practice. To demonstrate it could be cost-effective to warrant a change in practice identifying RCT evidence was considered important.</p> <p>The references you provide have been checked for their inclusion. None of them meeting the inclusion criteria in that they are not RCTs or they address a different question to that in the protocol criteria: In Stollo et al 2014 everyone had surgery where as our review looked at comparing surgery to no surgery. Friedman et. al 2002 is a retrospective review; Van de Heyning PH et. al, 2012 is a single arm study.</p> <p>The recommendations are based on reviews of the available evidence, and only recommend those demonstrated to be clinically and cost effective. Oropharyngeal surgery was found to be</p>

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				<p>adverse events. Friedman et. al, (2002) published a 31.3% response rate for UPPP. Emerging research also underlined the importance of genioglossus muscle activation to maintain airway patency, which cannot be addressed by conventional tissue-removing surgical interventions.</p> <p>Given this, a randomized-controlled withdrawal phase, with patients serving as their own control, as conducted in the STAR trial (Strollo et al. 2014), was considered most adequate for proper hypothesis testing as well as protecting individuals participating in the trial from the risks of untreated OSA. This trial design, specifically therapy withdrawal, has been used in other neuromodulation therapies to validate treatment effectiveness and is accepted by healthcare stakeholders around the globe, in cases where comparison to no-treatment or standard of care is impossible or ethically questionable.</p>	<p>effective in people with moderate or severe OSAHS who are unable to tolerate or adhere to CPAP and mandibular advancement splints. There were some adverse effects associated with surgery, but the committee agreed that they were not clinically significant. The quality of the evidence was taken into account in the interpretation of the evidence. This is detailed in the committee's discussion of the evidence in the evidence review.</p> <p>The methods followed in the development of the guideline are consistent with those detailed in Developing NICE Guidelines: The Manual, and detailed further in the methods chapter for this guideline. The search strategies for each review question are detailed in appendix B of the relevant chapters. The protocols for each review (in appendix A) detail the study design that is appropriate to answer each review question.</p>
Inspire Medical Systems, Inc.	Evidence review J	151	General	<p>The following publications were not reviewed and therefore available data not included within this review.</p> <p>The committee should review Hypoglossal Nerve Stimulation (HNS) again and include recommendations for this treatment option within the NICE guideline for <i>Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s</i>.</p> <p>1. Huntley C, Boon M, Tschopp S, Tschopp K, Jenks CM, Thaler E, Baptista Jardin P, Shah J, Kominsky A, Kezirian EJ, Heiser C, Waxman J, Lin HS. Comparison of Traditional Upper Airway Surgery and Upper Airway Stimulation for Obstructive Sleep Apnea. <i>Ann Otol Rhinol Laryngol</i>. 2021 Apr;130(4):370-376. doi: 10.1177/0003489420953178. Epub 2020 Aug 29. PMID: 32862654.</p> <p>2. Mehra R, Steffen A, Heiser C, Hofauer B, Withrow K, Doghramji K, Boon M, Huntley C, Soose RJ, Stevens S, Larsen C, Maurer JT, Waters T, Walia HK, Kominsky AH, Trask D, Schwab RJ, Thaler</p>	<p>Thank you for your comment. When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For this review it was agreed to restrict it to RCT evidence, as the highest quality evidence. Non-randomised/observational studies were agreed as not sufficient quality for this question. Offering surgery for treatment of OSAHS is not currently common practice. To demonstrate it could be cost-effective to warrant a change in practice identifying RCT evidence was considered important.</p> <p>All of the references you provided have been checked for their inclusion. None of them are RCTs and therefore do not meet the study design inclusion criteria for the guideline review: Huntley 2021 is a case control study; Mehra 2020 is a non-randomised experimental study; Thaler 2020 is a cohort study, Steffen 2019 is a single arm study; Huntley 2018 is a case control, retrospective review; Boon 2018 is an observational study based on registry data; Heiser 2019 is an observational study based on registry data; Huntley 2018 is a retrospective review; Shah 2018 is</p>

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				<p>ER, Strollo PJ. Upper Airway Stimulation versus Untreated Comparators in Positive Airway Pressure Treatment-Refractory Obstructive Sleep Apnea. <i>Ann Am Thorac Soc</i>. 2020 Dec;17(12):1610-1619. doi: 10.1513/AnnalsATS.202001-015OC. PMID: 32663043.</p> <p>3. Thaler E, Schwab R, Maurer J, Soose R, Larsen C, Stevens S, Stevens D, Boon M, Huntley C, Doghramji K, Waters T, Kominsky A, Steffen A, Kezirian E, Hofauer B, Sommer U, Withrow K, Strohl K, Heiser C. Results of the ADHERE upper airway stimulation registry and predictors of therapy efficacy. <i>Laryngoscope</i>. 2020 May;130(5):1333-1338. doi: 10.1002/lary.28286. Epub 2019 Sep 14. PMID: 31520484; PMCID: PMC7217178</p> <p>4. Steffen A, Sommer UJ, Maurer JT, Abrams N, Hofauer B, Heiser C. Long-term follow-up of the German post-market study for upper airway stimulation for obstructive sleep apnea. <i>Sleep Breath</i>. 2020 Sep;24(3):979-984. doi: 10.1007/s11325-019-01933-0. Epub 2019 Sep 4. PMID: 31485853.</p> <p>5. Huntley C, Steffen A, Doghramji K, Hofauer B, Heiser C, Boon M. Upper Airway Stimulation in Patients with Obstructive Sleep Apnea and an Elevated Body Mass Index: A Multi-institutional Review. <i>Laryngoscope</i>. 2018;128(10):2425-8. Epub 2018/08/10. doi: 10.1002/lary.27426. PubMed PMID: 30098035.</p> <p>6. Boon M, Huntley C, Steffen A, Maurer JT, Sommer JU, Schwab R, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Results from the ADHERE Registry. <i>Otolaryngol Head Neck Surg</i>. 2018;194599818764896. Epub 2018/03/01. doi: 10.1177/0194599818764896. PubMed PMID: 29557280.</p> <p>7. Heiser C, Steffen A, Boon M, Hofauer B, Doghramji K, Maurer JT, et al. Post-approval upper airway stimulation predictors of treatment effectiveness in the ADHERE registry. <i>Eur Respir J</i>.</p>	<p>retrospective case series; Woodson 2018 is a prospective cohort study; and Woodson 2014 is a single group cohort study followed by a randomised, therapy-withdrawal trial that included only participants who had had a response to therapy i.e. therapy maintenance group vs therapy withdrawal group - this was not the comparison we included in the protocol.</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p>

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				<p>2019;53(1). Epub 2019/01/03. doi: 10.1183/13993003.01405-2018. PubMed PMID: 30487205; PubMed Central PMCID: PMC6319796.</p> <p>8. Huntley C, Chou DW, Doghramji K, Boon M. Comparing Upper Airway Stimulation to Expansion Sphincter Pharyngoplasty: A Single University Experience. Ann Otol Rhinol Laryngol. 2018;3489418771395. Epub 2018/04/01. doi: 10.1177/0003489418771395. PubMed PMID: 29707958.</p> <p>9. Shah J, Russell JO, Waters T, Kominsky AH, Trask D. Uvulopalatopharyngoplasty vs CN XII stimulation for treatment of obstructive sleep apnea: A single institution experience. Am J Otolaryngol. 2018. Epub 2018/03/02. doi: 10.1016/j.amjoto.2018.03.003. PubMed PMID: 29540289.</p> <p>10. Woodson BT, Gillespie MB, Soose RJ, Maurer JT, de Vries N, Steward DL, et al. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. Otolaryngol Head Neck Surg. 2014;151(5):880-7. Epub 2014/09/09. doi: 10.1177/0194599814544445. PubMed PMID: 25205641.</p> <p>11. Woodson BT, Strohl KP, Soose RJ, Gillespie MB, Maurer JT, de Vries N, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. Otolaryngol Head Neck Surg. 2018;194599818762383. Epub 2018/03/01. doi: 10.1177/0194599818762383. PubMed PMID: 29582703.</p>	
Inspire Medical Systems, Inc.	Guideline	012	General	<p>1.7.3 (new)</p> <p>Hypoglossal Nerve Stimulation (HNS) for people with moderate to severe obstructive sleep apnoea (OSA) with continuous positive airway pressure (CPAP) intolerance or ineffectiveness, absence of complete concentric collapse at the level of the soft palate, and</p>	<p>Thank you for your comment and for your suggested evidence.</p> <p>We included Hypoglossal Nerve Stimulation in our literature search for this review, however we did not identify any evidence that met the inclusion criteria as specified in our protocol. The committee therefore agreed to include a research recommendation for</p>

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				<p>less than 25% central apneas. (Follow Interventional procedures guidance (IPG598)).</p> <p>1.7.4 (new, before 1.7.3) Consider tonsillectomy for people with OSAHS who have large obstructive 2 tonsils and a BMI of less than 35 kg/m2.</p> <p>1.7.5 (new, before 1.7.4) Consider referral for assessment for oropharyngeal surgery in people with severe OSAHS who have been unable to tolerate CPAP and a customised mandibular advancement splint despite medically supervised attempts.</p> <p>Explanation: We suggest inclusion of Hypoglossal Nerve Stimulation (HNS) therapy in this guideline to align with the NICE assessment performed in 2017 where the IPG group evaluated this important new standard of care (IPG598). The IPG published by NICE allows patients to be treated by clinicians with special expertise in management of OSA under special arrangements, such as information of clinical governance leads, written informed consent and audit and review of clinical outcomes. Since NICE assessment in 2017, substantial new evidence has been published, which underlines the clinical benefits of HGNS therapy, in selected patients with OSA who cannot adhere to CPAP or in whom this treatment does not provide sufficient symptom relief. Based on different clinical evaluations, predictors of therapy success with HNS have been defined, which are:</p> <ul style="list-style-type: none"> • Moderate to severe OSA • Have failed or are intolerant of CPAP • Absence of concentric collapse at soft palate • < 25% central or mixed apneas <p>HNS represents a valid treatment option that should be available to patients with OSA who meet the indications above. Research</p>	<p>Hypoglossal Nerve Stimulation to inform future updates of this guideline (Evidence report J, Appendix J).</p> <p>The methods followed in the development of the guideline are consistent with those detailed in Developing NICE Guidelines: The Manual, and detailed further in the methods chapter for this guideline. The search strategies for each review question are detailed in appendix B of the relevant chapters. The protocols for each review (in appendix A) detail the study design that is appropriate to answer each review question.</p> <p>When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For this review it was agreed to restrict it to RCT evidence, as the highest quality evidence. Non- randomised/observational studies were agreed as not sufficient quality for this question. To demonstrate it could be cost-effective to warrant a change in practice identifying RCT evidence was considered important.</p> <p>None of the suggested references are RCTs and therefore do not meet inclusion criteria for the guideline review: Campbell 2015 is a survey; Strollo 2014 is a uncontrolled cohort study; Woodson 2018 is a prospective cohort study; Thaler 2019 is a cohort study; Steffen et al 2020 is not in English, the abstracts suggests it is a follow up study for a case series; and Friedman 2002 is a retrospective review.</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain</p>

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				<p>from the UK of patient preferences shows that up to one fifth of OSA patients would prefer HNS as a treatment (Campbell T et al. 2015).</p> <p>HNS is a minimally invasive procedure with very positive, long-term published outcomes (Strollo et. al, 2014; Woodson et. al, 2018; Thaler et. al, 2019; Steffen et. al, 2019) and is the standard of care in other countries including Germany, Netherlands, United States, etc. Other surgical alternatives for treating this patient population, including Uvulopalatopharyngoplasty (UPPP) and its variants have extremely poor published outcomes and a high risk of severe surgical complications (Friedman et. al, 2002).</p>	<p>criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p>
Inspire Medical Systems, Inc.	Guideline	014	General	<p>1.9.7 Offer people with OSA who have had Hypoglossal Nerve Stimulation (HNS) surgery:</p> <ul style="list-style-type: none"> • an initial activation visit of the fully implanted device (Implantable Pulse Generator) after approx. 4 weeks post-implantation followed by a titration visit (after 3 months of activation visit) with polysomnography (PSG) or • an initial follow-up consultation with respiratory polygraphy within 3 months of the operation and • subsequent follow-up according to the person's needs. <p>Explanation: When utilizing Hypoglossal Nerve Stimulation (HNS) for people who suffer from moderate to severe OSA, a visit for device activation approx. 4 weeks post-surgery must be added in the follow-up section, as well as a titration visit 3 months post activation. The titration process for HNS is very similar to CPAP, but instead of adjusting pressure levels, amplitudes of stimulation-current will be titrated to patients' individual levels to ensure optimal treatment efficacy.</p>	<p>Thank you for your comment. We did not find the evidence to recommend hypoglossal nerve stimulation and have therefore made a research recommendation to inform future updates of this guideline (Evidence report J, Appendix J). Because we did not recommend it as an intervention, we have not made a recommendation related to follow up appointments for hypoglossal nerve stimulation either.</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p>
Inspire Medical Systems, Inc.	Guideline	014	General	<p>1.9.9 Assess the effectiveness of treatment with CPAP, mandibular advancement splints, positional modifiers, and Hypoglossal Nerve</p>	<p>Thank you for your comment. We did not find the evidence to recommend hypoglossal nerve stimulation and have therefore made a research recommendation to inform future updates of this</p>

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				<p>Stimulation (HNS) in people with OSAHS by reviewing the following:</p> <p>Comment: Add "and Hypoglossal Nerve Stimulation (HNS)" like shown above.</p>	<p>guideline (Evidence report J, Appendix J). Because we did not recommend it as an intervention, we have not made a recommendation related to monitoring treatment efficacy for hypoglossal nerve stimulation either.</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p>
Inspire Medical Systems, Inc.	Guideline	015	General	<p>1.9.9</p> <ul style="list-style-type: none"> OSAHS symptoms, including the Epworth sleepiness scale severity of OSAHS, using AHI adherence to therapy telemonitoring data or download information from the device (if available) device check with battery status and lead/ sensor check (if available) <p>Comment: Add bullet point "device check with battery status and lead/ sensor check (if available)" like shown above.</p>	<p>Thank you for your comment. The committee recommend using telemonitoring with CPAP and they agreed that when this is used there is no need to see the machine. The readings obtained from the downloaded or telemonitoring data will indicate if there is a problem with the device. Device check is already covered in the last bullet point of rec 1.9.10 "cleaning and maintenance of equipment".</p>
Inspire Medical Systems, Inc.	Guideline	038	General	<p>What is the clinical and cost effectiveness of upper airway surgical interventions for people with OSAHS who are unable to tolerate or adhere to CPAP?</p> <p>Comment:</p>	<p>Thank you for your comment and suggested evidence.</p> <p>When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For this review it was agreed to restrict it to RCT evidence,</p>

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				<p>In context of the health economic analysis of the Hypoglossal Nerve Stimulation (HNS) two peer-reviewed publications from Pietzsch et al. 2015 and 2019 in European settings are available. Pietzsch et. al, 2019 summarizes that UAS adds meaningful benefit to the health of OSA patients who cannot adhere to CPAP therapy and is a cost-effective treatment strategy. Additionally, a U.K. cost effectiveness model has been developed and recently accepted at PharmacoEconomics entitled "Breathing synchronized Hypoglossal Nerve Stimulation (HNS) with Inspire for Untreated Severe Obstructive Sleep Apnoea / Hypopnoea Syndrome (OSAHS): A simulated Cost-Utility Analysis from an NHS Perspective" (Blissett et. al, 2021).</p>	<p>as the highest quality evidence. Non- randomised/observational studies were agreed as not sufficient quality for this question. Offering surgery for treatment of OSAHS is not currently common practice. To demonstrate it could be cost-effective to warrant a change in practice identifying RCT evidence was considered important.</p> <p>The references you provided have been checked for their inclusion: Pietzsch et al. 2015 and Pietzsch et. al, 2019 are single arm studies, therefore do not meet inclusion criteria for this guideline review.</p> <p>There are no economic evaluations based on randomised evidence and therefore it is not possible to assess properly the cost effectiveness. This is particularly important given the high cost of this intervention.</p>
Inspire Medical Systems, Inc.	Guideline	051	General	<p>Surgery, like Uvulopharyngopalatoplasty [UPPP] or other types of oropharyngeal surgery may be offered to patients who have failed a trial of PAP. This family of surgeries attempts to provide an anatomic solution by removal of "unnecessary" palatal or oropharyngeal tissue to open the airway. Maxillofacial realignment may also be considered in a smaller subset of patients. (Kezirian, et. al, 2011).</p> <p>However, all these surgical techniques have the objective of changing existing anatomy by removing tissue and/ or manipulating skeletal framework. These techniques are irreversible, impacting physical, psychological, and cosmetic characteristics (due to change of face, mimic, voice, etc.), which impacts a patient's wellbeing. Therefore, less invasive, and potentially reversible surgery should come first. This includes neurostimulator implantation such as Hypoglossal Nerve Stimulation (HNS), which has an existing positive interventional procedure guidance from NICE (IPG598).</p>	<p>Thank you for your comment.</p> <p>The recommendations are based on reviews of the available evidence, and only recommend those demonstrated to be clinically and cost effective. Oropharyngeal surgery was recommended as it was found to be clinically and cost effective in people with severe OSAHS. The quality of the evidence was taken into account in the interpretation of the evidence. This is reflected in the committee's discussion of the evidence in the evidence review.</p> <p>We included Hypoglossal Nerve Stimulation in our literature search including all the relevant search terms for this review, however we did not identify any evidence that met the inclusion criteria as specified in our protocol. The committee therefore agreed to include a research recommendation for Hypoglossal Nerve</p>

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				<p>Furthermore, for some of these invasive surgery techniques, like for UPPP, the enthusiasm has waned over the years due to its modest success, surgical morbidities, and also an improved understanding of the underlying pathophysiology. For example, OSA is characterized by a reduction in drive to the upper-airway muscles, and upper-airway patency is strongly correlated with the activation of the genioglossus muscle. Therefore, HNS has been investigated as a physiologic alternative to the anatomic approach of UPPP. In addition, as published by Sher and colleagues in a meta-analysis of UPPP, surgery has a very low quality of evidence, only ~40% responder rate, with degrading results over time, and a high incidence of serious adverse events. Friedman (2002) published a 31.3% response rate for UPPP. Emerging research also underlined the importance of genioglossus muscle activation to maintain airway patency, which cannot be addressed by conventional tissue-removing surgical interventions.</p>	<p>Stimulation to inform future updates of this guideline (Evidence report J, Appendix J). We have checked the references you cite and neither met the inclusion criteria for the protocol: Kezirian, et. al, 2011 is a cross-sectional study; and Friedman 2002 is a retrospective review. For this review it was agreed to restrict it to RCT evidence, as the highest quality evidence. Non-randomised/observational studies were agreed as not sufficient quality for this question. Offering surgery for treatment of OSAHS is not currently common practice. To demonstrate it could be cost-effective to warrant a change in practice identifying RCT evidence was considered important.</p> <p>The committee were aware of the NICE interventional procedures (IP) guidance on Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. (IPG598). IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.) IPG598 makes recommendations with 'special' arrangements which means certain criteria detailed in the guidance should be met before the intervention is used in practice. We don't cross refer to IP guidance with 'special' arrangements but a link to it will be added to the NICE pathway that is published with this guideline.</p>
Jazz Pharmaceuticals UK Ltd	Guideline	013	016	<p>We are concerned that the use of the term “optimised” with respect to CPAP therapy is not clearly defined.</p> <p>There is evidence that symptoms such as excessive daytime sleepiness (EDS) persist despite adherence to CPAP and normalisation of Apnoea-Hypopnoea Index (AHI) scores (Fong, 2009; Pepin, 2009; Budhiraja, 2017; Marklund, 2015; Gasa, 2013). Without a definition for “optimal” it could create a cycle of continual manipulation of CPAP, creating an unwarranted resource utilisation, when therapies licensed for use in this population could be of benefit to a patient's symptoms.</p>	<p>Thank you for your comment. Optimised is defined in the preceding recommendation as “control of symptoms and apnoea–hypopnoea index (AHI) or oxygen desaturation index (ODI)”.</p> <p>Excessive daytime sleepiness (EDS) was not the outcome specified in our protocol, instead Epworth sleepiness score (ESS) was used to measure sleepiness in all reviews and the committee have used this information while interpreting the evidence.</p> <p>All of the references you provide have been checked for their inclusion. None of the following met the inclusion criteria for the</p>

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				<p>Fong SY-y, et al. Sleep and Biological Rhythms. 2009;7(3):193-200.</p> <p>Pepin JL, et al. Eur Respir J. 2009;33(5):1062-7.</p> <p>Budhiraja R, et al. Eur Respir J. 2017;50(5).</p> <p>Marklund M, et al. JAMA Intern Med. 2015;175(8):1278-85.</p> <p>Gasa M, et al. J Sleep Res. 2013;22(4):389-97.</p>	<p>protocol and were therefore not included in the review: Fong, 2009 is a non-randomised study (before and after); Pepin, 2009 is a non-randomised study (cross-sectional); Budhiraja, 2017 included people with severe OSAHS at baseline, this was not included in the review for CPAP in mild OSAHS as it was not correct population, and not included in the PA variants review its comparison was not part of the protocol (sham vs CPAP); Gasa, 2013 is a cohort study.</p> <p>Marklund, 2015 was included in oral devices review.</p>
Jazz Pharmaceuticals UK Ltd	Guideline	General	General	<p>We are concerned that the use of OSAHS as a blanket term could cause confusion.</p> <p>We suggest inclusion of the accepted diagnostic criteria from the International Classification of Sleep Disorders (2014) of "Obstructive Sleep Apnoea (OSA)" and the clear definition from the NICE Clinical Knowledge Summary (March 2021) "Obstructive Sleep Apnoea Syndrome (OSAS)" where symptoms such as excessive daytime sleepiness (EDS) are being caused by the underlying diagnosis. These are important to ensure consistent recognition and recording of important ongoing symptoms such as EDS.</p>	<p>Thank you for your comment. The committee have used the term OSAHS which would include all the conditions you describe. They wanted to use an overarching term to ensure all conditions are covered by our recommendations for OSAHS.</p> <p>We have not made specific reference to excessive sleepiness in our definition. In the past excessive sleepiness was seen as the main symptom for OSAHS. The committee were aware that recent data suggests it is not just excessive sleepiness that suggests a presence of OSAHS and other factors listed in recommendation 1.1.1 on when to suspect are also important.</p>
Jazz Pharmaceuticals UK Ltd	Guideline	General	General	<p>We suggest consideration of these research recommendations:</p> <ul style="list-style-type: none"> - The effect of pharmacologic wake-promoting agents on quality of life measures and partner utilities when used as an adjunct to CPAP. In the economic report, reference is made to the McDaid (2009) method to map Epworth Sleepiness Scores to EQ-5D values. While McDaid (2009) is a robust method, complimentary and contemporary methods would be valuable in the economic assessment of emerging therapies in OSAHS. <p>Interventions to improve CPAP adherence should take into account whether or not persistence of symptoms (EDS) play a role in low adherence rates.</p>	<p>Thank you for your comment. Pharmacological interventions for OSAHS were not included as part of the scope therefore the guideline makes no statement in relation to these.</p>

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Jazz Pharmaceuticals UK Ltd	Guideline and Algorithm	General	General	<p>The algorithm and guideline seem to imply that there is no role for pharmacotherapy in the management of OSAHS.</p> <p>There are two groups of patients in which EDS persists despite the availability of CPAP and other primary therapies. The first group comprises people compliant on CPAP (or other primary therapies) who have residual EDS. The second group comprises people who are intolerant to CPAP (or other primary therapies) and have persistent EDS. For these groups of people, pharmacotherapy is an option.</p> <ul style="list-style-type: none"> - Solriamfetol is indicated to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP). Solriamfetol is currently being appraised by NICE (ID1499). <p>Pitolisant is undergoing assessment for marketing authorisation for the treatment of EDS caused by OSA and is currently being appraised by NICE (ID1065).</p>	Thank you for your comment. Pharmacotherapy was not prioritised during the scoping process for this guideline. Therefore, we have not made any recommendations in this area.
Medtronic UK	Guideline	012	004	Section 1.7 - Specific to section 1.7.4 - Consider referral for assessment for bariatric surgery based on an accepted manuscript c/o academic in confidence (AIC) status. Evidence derived from National Bariatric Surgery Registry (NBSR)	Thank you for your comment. The committee agree bariatric surgery is an important intervention but it is beyond the scope of this guideline.
NHS England and NHS Improvement	General	General	General	A well written and appears quite a sensible guideline. It appears follows present practice and will have little impact on primary care as is being pitched predominately at secondary care services(PC)	Thank you for your comment.
NHS England and NHS Improvement	Guideline	017	006	This part of the guideline is confusing, the previous section mentions who to suspect and assessment scales to use, this will be easy to complete in primary care. The next section talks about how to prioritise people for rapid assessment. Line 9 talks about if 'thy have severe hypercapnia (PaCo2 over 7 kPa), I am unsure as to how primary care would be able to supply this information to secondary care as this is not an available test to primary care. This information will only be available if they have had an admission	Thank you for your comment. The committee anticipate that not everyone suspected of OSAHS will be identified in primary care. Some will be identified in secondary care where blood gas measurement is possible. We have changed the order of the recommendations in the prioritisation section to make it clearer. The recommendation for referral now comes first and the recommendation on prioritisation follows it.

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				AND PaCO ₂ has been recorded – one would assume that if they had been admitted with hypercapnia then they would be assessed in secondary care either as an inpatient or upon rapid discharge) All the other recommendations in this section are more achievable. (PC)	
NHS England and NHS Improvement	Guideline	026	015	Same as above for the section on COPD-OSAHS, this is not practical (PC)	Thank you for your comment. The committee anticipate that not everyone suspected of OSAHS will be identified in primary care. Some will be identified in secondary care where blood gas measurement is possible. The recommendations are written so that they apply to any healthcare professional assessing a person with suspected OSAHS regardless of their role or setting. <i>[NGC note for NICE: we believe this is a copy of ID160 so have used the same response] – delete this comment after QA</i>
NHS England and NHS Improvement	Guideline	060 071		On these pages the guidelines concedes that this is not an evidence based as no evidence is available (PC)	Thank you for your comment. In the absence of evidence the committee used their experience to make consensus recommendations in accordance with the Developing NICE guidelines: The Manual . They agreed it was important to make strong recommendations, rather than a research recommendation, to ensure there is little delay in receiving treatment for those who need it most.
Obesity Group of the British Dietetic Association	Guideline	005	008 - 009	Part of the risk for OSHAS is obesity, diagnosed at BMI at or above 30kg/m ² . However, increased risks for some co-morbidities of obesity are recognised to occur at lower cut-off points in those from some ethnic minority groups groups (e.g. BMI 23kg/m ² increased risk & BMI 27.5kg/m ² high risk). This possibility is not recognised within this guideline; it may need to be highlighted as a research priority.	Thank you for your comment. We have a cross reference in the guideline to the NICE obesity guideline CG189 which provides details about BMI cut-off. The obesity guideline recommends caution when interpreting BMI for some groups and provides a cross reference to the NICE guideline on “BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups”, https://www.nice.org.uk/guidance/ph46 which documents these differences.
Obesity Group of the British	Guideline	006	008 - 015	We agree that some groups should be prioritised for rapid assessment. However, given the potential impact on learning in	Thank you for your comment. Children were excluded from the scope for this guideline.

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Dietetic Association				children with possible OSHAS, we would recommend that they are also considered for prioritisation.	
Obesity Group of the British Dietetic Association	Guideline	007	013 - 016	We agree that lifestyle change including weight management and physical activity as well as sleep hygiene should be discussed with all those with OSHAS. Such discussions should be carried out by those with appropriate skills, knowledge and time in a non-judgemental way, with the offer of referral on to appropriate local services. However, many weight management services may now be online due to Covid-19 and we do not yet have long-term data on their effectiveness. We see this as an important area needing research data.	Thank you for your comment. A review of the evidence related lifestyle advice, including weight management and obesity, was not included in this guideline because existing NICE guidance covers this. This is why the guideline only cross refers to other relevant NICE guidelines related to lifestyle advice, including those with weight management advice and does not make separate recommendations in this guideline.
Obesity Group of the British Dietetic Association	Guideline	017	024	We agree that BMI should be reported to facilitate rapid assessment; however, given that different cut-off points for BMI may reflect differential health risks in different ethnic groups, in our view ethnicity should be reported along with BMI.	Thank you for your comment. We have a cross reference in the guideline to the NICE obesity guideline CG189 which provides details about BMI cut-off. The obesity guideline recommends caution when interpreting BMI for some groups and provides a a cross reference to the NICE guideline on BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups https://www.nice.org.uk/guidance/ph46 .
OSA Partnership Group	General	General	General	In general, these guidelines are excellent and those involved deserve congratulations for what must have been a major exercise. The dilemma in such guidelines is the tension between aspirations to best practice, and what the NHS is prepared to provide. Thus, best practice should be the aspiration, but allowance for alternatives where appropriate should be made.	Thank you for your comment
OSA Partnership Group	Guideline	005	001	Excessive sleepiness as a symptom is far more common than tiredness or fatigue, and this point would be worth making. Perhaps 'unexplained excessive sleepiness, and less commonly tiredness or fatigue'.	Thank you for your comment. In the past excessive sleepiness was seen as the main symptom for OSAHS. The committee were aware that recent data suggests it is not just excessive sleepiness that suggests a presence of OSAHS. The aim of this recommendation is to highlight this fact.
OSA Partnership Group	Guideline	005	006 - 007	Hypothyroidism has been left off the list as a condition in which there is also a higher prevalence of OSA.	Thank you for your comment. The committee agree and hypothyroidism has now been added to the recommendation.

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OSA Partnership Group	Guideline	006	003 - 004	<p>This sentence could perhaps be usefully expanded to read – ‘Do not use the Epworth Sleepiness scale (ESS) alone to determine if referral is needed, because not all people with <i>OSAH</i> have excessive sleepiness, and not all people with a high ESS have <i>OSAH</i>’.</p> <p>In the original it was inappropriate to put <i>OSAHS</i> in the first part of this sentence, because excessive sleepiness essentially defines the final S in <i>OSAHS</i> and thus without sleepiness, using <i>OSAH</i> is more appropriate. This sentence occurs subsequently too.</p>	Thank you for your comment. In the past excessive sleepiness was seen as the main symptom for <i>OSAHS</i> . The committee were aware that recent data suggests it is not just excessive sleepiness that suggests a presence of <i>OSAHS</i> . The aim of this recommendation is to highlight this fact.
OSA Partnership Group	Guideline	006	005	Another reason for rapid assessment would be evidence of OHS in addition to <i>OSAH</i> . For example, a low awake saturation less than 94%.	Thank you for your comment. This is covered in the recommendations for when to suspect OHS.
OSA Partnership Group	Guideline	006	014	There is no evidence that identifying and treating <i>OSA</i> pre-operatively influences outcomes. Diagnosis may help the anaesthetist, but pre-op treatment has no evidence base.	<p>Thank you for your comment. The committee agree there is no evidence for this. The committee consensus was that in those with a high probability of <i>OSAHS</i> in who need major surgery, fast track provision of sleep study and treatment should be provided. Once treatment such as CPAP is shown to control symptoms and AHI surgery can proceed.</p> <p>This guideline was developed in accordance with the Developing NICE guidelines: The Manual. The manual explains how consensus methods can be used where there is no evidence or limited evidence.</p>
OSA Partnership Group	Guideline	006	016 - 018	Particularly following COVID, many GPs now have oximeters. It is recommended that the referral information includes a resting SaO ₂ value when available. A figure below 94 or so, and certainly below 91, would suggest ventilatory failure and rapid assessment would be advisable. This therefore helps triaging referrals to the sleep unit.	Thank you for your comment. The committee agree and have added “oxygen saturation and blood gas values, if available” as a bullet point to the recommendation.
OSA Partnership Group	Guideline	006 / 017 / 026	General	We are particularly delighted with the decision to include prioritisation for rapid assessment for those who have a vocational driving job. The OSA Partnership represents members of the transport industry within its membership structure, and it is our experience that in the past drivers have not come forward for	Thank you for your comment. The committee believe that groups prioritised for assessment are likely to be prioritised for treatment sooner as well. Although not all people in those groups may need treatment.

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				treatment because of concern about losing their driving licence. This step will go some way to alleviating their concerns, although we strongly recommend that the prioritisation should extend to treatment as well as assessment. This is relevant to all condition categories addressed in these guidelines.	
OSA Partnership Group	Guideline	007	006 - 007	<p>The implication in the guidelines is that PSG should be offered 1st in preference to oximetry alone. We agree with this in principle, but many sleep services cannot afford this aspiration (lack of both kit and people to report the studies) and, if they follow this guideline, they will have to do fewer studies and treat fewer patients. We appreciate this is a dilemma, but in expert hands oximetry alone can be useful. The costing models used in these guidelines must have enormous confidence intervals given that local circumstances vary considerably. Therefore, we would recommend that 1.3.3 becomes: <i>'Be aware that oximetry alone may be inaccurate for diagnosing OSAHS in people with heart failure or chronic lung disease and requires expert interpretation if used as the sole diagnostic test'</i>.</p> <p>We would also add that although oximetry alone (without expert interpretation and integration with the history and examination) is not adequate for a robust diagnosis, however it is adequate for follow up of patients where OSA has already been diagnosed; for example, to see if someone who has lost weight still needs CPAP, and has stopped it for a trial period (usually 1 to 2 weeks) prior to testing. Satisfactory control of OSA on CPAP can be followed from telemonitoring of modern CPAP machines but where this facility is not available, oximetry alone is acceptable.</p>	<p>Thank you for your comment. The committee agree with your statement and have added the following recommendation:</p> <p>"1.3.2 If access to respiratory polygraphy is limited, consider home oximetry for people with suspected OSAHS. Take into account that oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung diseases. "</p>
OSA Partnership Group	Guideline	009 / 010	003 - 004 / 011 - 012	<p>The suggestion is to offer fixed pressure CPAP first, rather than auto CPAP. We agree with this on usual cost grounds, but there are certain services that have worked out that for them using auto CPAP machines routinely is more cost effective; for example, this may be because they have negotiated local deals and thus the costing model used by NICE in these guidelines is inappropriate; furthermore, the model has made a number of assumptions that</p>	<p>Thank you. We agree that there might be circumstances that favour auto-CPAP and so the following bullet point has been added to consider auto-CPAP "where auto-CPAP is available at the same or lower purchase and administration cost than fixed-level CPAP".</p>

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				<p>are not universally applicable. It would be wrong to suggest that auto CPAP should never be a routine first choice. So, page 10, 1.6.3 could have a fourth bullet point, '<i>where specific local circumstances favour them as the cost-effective first choice</i>'.</p> <p>In addition, having suggested fixed pressure is the first choice, there is no mention of how the fixed pressure is to be decided on. There are a few ways, usually by an algorithm based on obesity and OSA severity, or following a period on auto CPAP, for example (PMID 14971879, 14971878, 16254055).</p>	<p>The committee anticipate that clinical judgement is used to decide on setting the pressure for fixed-level CPAP. A common way to do this is to start with lower pressure then you adjust according to symptom control, telemonitoring data or variation in AHI. Algorithms are not generally used nowadays.</p>
OSA Partnership Group	Guideline	013	013	<p>There is considerable evidence that patterns of CPAP use, including giving up entirely, are set very early on following initial use (Pubmed ID 31587046, 32974833, 17425228, 26904268 for example). Thus, when possible, most sleep units would want to follow up their patients sooner than a month, if administratively possible, in an attempt to problem-solve early on, and avoid rejection of CPAP if at all possible. Every patient who fails to stay on CPAP represents a total waste of money and the cost-per-qaly is heavily dependent on long term adherence rates (PMID 18408048). Thus, in our view this line should read 'an initial follow-up consultation as early as possible, but certainly within a month'.</p>	<p>Thank you for your comment. The recommendation is to follow up people within a month. Clinicians may choose to do this sooner. Telemonitoring is also recommended with CPAP which will enable clinicians to see patterns of use and any problems with pressure settings. These can be addressed as soon as they arise.</p>
OSA Partnership Group	Guideline	015	002	<p>Given that ODI closely correlates with AHI and is actually a more robust derivative of polygraphy, and better predictor of symptoms and CPAP response (particularly when computer analysed, PMID 9731004), ODI should be an alternative numerical index of severity. Some polygraphy systems do not generate a conventional AHI, but do calculate an ODI. ODI is mentioned elsewhere in the guideline and we appreciate that the use of oximetry alone is not supported for initial diagnosis, but oximetry plus other derivatives can define obstructive versus central events. Wherever AHI is used in the guideline we would change to AHI/ODI. It is interesting that in the DVLA guidelines, to which you refer, this interchangeability is accepted.</p>	<p>Thank you for your comment. The committee agree and have amended the recommendation to include either ODI or AHI to assess severity of OSAHS.</p>

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OSA Partnership Group	Guideline	021 / 029	003 – 007 / 019 - 022	Although it is suggested that O ₂ therapy can be added to CPAP or NIV, there is no evidence for the benefit of this. If there are strong reasons to suggest this then there ought to be clearer guidelines on when to add it (ie how low the oxygen saturations remain despite NIV) and how much higher one is aiming for. In addition, it would be worth highlighting that O ₂ ALONE is dangerous and produces adverse consequences in these patient groups.	<p>Thank you for your comment. In the absence of evidence, the committee used consensus to recommend 'considering' supplemental oxygen therapy. They agreed that it is difficult to define at what level of hypoxaemia that oxygen should be given and that this recommendation follows standard practice.</p> <p>We have amended the recommendation adding the clause in bold at the end. It now reads: "Consider supplemental oxygen therapy with CPAP or non-invasive ventilation for people with OHS who remain hypoxaemic despite optimal control of nocturnal hypoventilation and AHI on CPAP or non-invasive ventilation and address any additional underlying causes of hypoxaemia where possible."</p>
Philips Respironics	Evidence review H	021		<p>Reason to treat Sabil et al. have conducted a study in the largest cohort where both clinical and polygraphic characteristics were analyzed to provide a complete report on the prevalence as well as on PAP treatment adherence of POSA and e-POSA in a clinic population. They found that POSA and e-POSA are associated with a significantly lower likelihood of PAP treatment adherence at 6 months compared to Non POSA. Despite a higher likelihood of PAP treatment response POSA was negatively associated with PAP treatment success <i>(A. Sabil et al. J Clin Sleep Med. 2020; 16(12):2037–2046)</i></p>	<p>Thank you for your comment and suggested reference.</p> <p>When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For intervention reviews of effectiveness this is widely agreed to be RCTs or systematic reviews of RCTs. Non randomised/observational studies were agreed as not sufficient quality for this question.</p> <p>Sabil 2020 was not included as it is not an RCT and therefore did not meet the inclusion criteria as specified in the review protocol. Seven RCTs were included in this review.</p>
Philips Respironics	Evidence review H	021	007	<p>Efficacy on AHI Berry et al. showed a decrease in AHI both in the Positional therapy and PAP groups.</p>	<p>Thank you for your comment. We have now included the study Berry 2019 in the Positional modifiers review in our guideline. The results of the Berry 2019 study have now been evaluated as part of the meta-analysis of all the studies included in the Positional modifiers review. Its inclusion does not change the overall results and does not affect the recommendations.</p>
Philips Respironics	Evidence review H	021	009	<p>We think this statement will make the therapy decision more complicated both for the patient and the caregiver and may be more expensive. Indeed, Sabil et al (2020). showed that Patients</p>	<p>Thank you for your comment. The committee carefully considered the evidence when making the recommendation for positional modifiers and this statement reiterates the recommendation. CPAP</p>

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				with POSA and e-POSA have lower PAP therapy adherence, and this choice of treatment may not be optimal. Thus, there is a need to offer these patients an alternative therapy	<p>remains the first-choice treatment followed by oral devices. The committee believe positional modifiers can provide benefit and therefore made a recommendation to consider their use if other treatments are unsuitable or not tolerated.</p> <p>When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For intervention reviews of effectiveness this is widely agreed to be RCTs or systematic reviews of RCTs. Non randomised studies were agreed as not sufficient quality for this question. Sabil 2020 was not included as it is not an RCT and therefore did not meet the inclusion criteria as specified in the review protocol.</p>
Philips Respironics	Evidence review H	073	Table 19 - second table	<p>Exclusion of the Berry et al paper (2019) The Berry 2019 publication was excluded from the assessment for not having a washout period- a requirement that was not listed in the PICO. In addition, the co-primary outcomes in the POSA trial are the residual AHI and adherence, for which a washout period was deemed unnecessary (please refer to the rationale below).</p> <ul style="list-style-type: none"> • A washout period is required in a cross over clinical trial when there is reason to believe that there may be a carry-over effect; that is, if the residual effect of the therapy applied in the first arm of the study would impede the ability to interpret the second arm of the study. • In the POSA trial the co-primary endpoints were AHI and adherence, for which a washout period was deemed unnecessary. <ul style="list-style-type: none"> ○ <u>AHI endpoint</u>: In the POSA trial, the AHI endpoint was simply the difference in the AHI between the PSGs conducted at the end of the NightBalance and PAP arms. The baseline value was not taken into account in this analysis. Thus, there was no need to allow the AHI to return to baseline level prior to initiating the 	<p>Thank you for your comments. We have now included the study Berry et al 2019 in our review and the evidence report has been updated accordingly. Its inclusion does not change the overall results and does not affect the recommendations.</p>

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				<p>second arm of the study. PAP withdrawal studies have demonstrated that the AHI 'rebounds' very soon after withdrawal of therapy (within one week; see Schwartz <i>et al.</i> (2018) <i>J Thorac Dis</i>). Given that each arm of the POSAive study was three months in duration, there is no physiological reason to suspect that the application of therapy in the first arm of the study would impact the residual AHI measured three months later in the second arm of the study.</p> <ul style="list-style-type: none"> ○ <u>Adherence endpoint</u>: A washout period is not applicable for the adherence endpoint, as this data can only be collected during periods in which the participant/patient is treated. <p>Therefore, the above points support the inclusion of Berry (2019) as evidence for positional modifiers.</p>	
ProSomnus Sleep Technologies	General	General	General	ProSomnus thanks the Committee for the considerable efforts made to ensure that this document provides evidence-based guidance on the most effective management of patients suffering from Obstructive Sleep Apnea and related maladies. ProSomnus also appreciates the collaborative approach to developing this guideline, specifically the inclusion of a dental sleep medicine expert.	Thank you for your comment
ProSomnus Sleep Technologies	Guideline	004	010	Consider identifying and including dentists, and other relevant health professionals, who are in a position to screen patients for OSA and refer them for proper diagnosis. Many patients regularly visit dentists. Moreover dentists are trained in the anatomy of the airway, and can be utilized to identify patients at risk of OSA.	Thank you for your comment. NICE guidelines make recommendations on treatment and processes of care but do not generally specify who should carry them out. In practice this would be any healthcare professional with the appropriate qualifications and competencies
ProSomnus Sleep Technologies	Guideline	008	013	Studies report the progression, worsening, of OSA over time. Thus healthcare providers may wish to advice asymptomatic OSA patients to continue to monitor their condition.	Thank you for your comment. The committee anticipate that if a person's condition worsens, they will present to the GP for advice.

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ProSomnus Sleep Technologies	Guideline	008	018	Consider OAT as frontline, or co-frontline, therapy for patients with mild OSA. Numerous studies, such as a RCT by Phillips in 2013, report similar, non-inferior, health outcomes between Oral Appliances and CPAP. Accordingly, numerous papers report that patients prefer Oral Appliances to CPAP, such as White 2013, Ferguson 1996 and Tan 2002.	<p>Thank you for your comment. The studies cited are in moderate or severe OSAHS.</p> <p>The recommendation referred to here is for people with mild OSAHS in whom we identified only one study of 6 weeks duration comparing MAS to placebo, and no studies of MAS vs CPAP. This is not strong evidence and the committee believe the use of “consider” is appropriate for this recommendation.</p>
ProSomnus Sleep Technologies	Guideline	008	018	Consider OAT as frontline therapy for patients presenting with mild OSA and complicating factors such as insomnia or PTSD. It is well documented that patients with such complications cannot tolerate CPAP. The burden should not be placed upon the patient with complications to first refuse CPAP, particularly if their OSA is mild.	<p>Thank you for your comment. No evidence was identified for people with insomnia or PTSD. The committee discussed whether mandibular advancement splints may be preferable in those people with mild OSAHS and BMI of less than 35 kg/m2 with predominant insomnia, difficulty initiating sleep, sleep disturbance and sleep fragmentation. However, they agreed there is no evidence to enable them to recommend mandibular advancement splints as a first-choice treatment in these groups.</p> <p>The committee are not aware of any evidence for PTSD being a factor that would make people unable to tolerate CPAP.</p>
ProSomnus Sleep Technologies	Guideline	009	020	It may be appropriate to change this statement from “Consider a customized” to “Offer a customized...” per NICE guidelines manual. Oral appliances have demonstrated equivalent health outcomes, cost effectiveness, and minimal evidence of side effects that result in discontinuation of therapy.	<p>Thank you for your comment. The availability of limited evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G.</p> <p>Here the recommendation is written as ‘consider’ rather than ‘offer’ because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.</p>
ProSomnus Sleep Technologies	Guideline	009	024	Consider removing the, “Suitable Dentition,” statement. This statement is no longer applicable. Modern Oral Appliances are currently and routinely utilized to treat fully edentulous patients, for example. Oral Appliances can be made over edentulous ridges,	<p>Thank you for your comment. The text ‘suitable dentition’ has been edited to state ‘teeth present should be of optimal dental and periodontal health.’ This emphasises that MAS should not be made for patients with untreated dental decay or active periodontal</p>

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				over dentures or even implant borne. Moreover, this claim is general and subjective, and not supported by any rigorous scientific evidence.	<p>disease. The latter is important in not only ensuring minimal unwanted tooth movement [as teeth with reduced bone support will move more readily which is not desirable] and more importantly could accelerate their loss, thereby compromising the long-term use of an MAS.</p> <p>Patients that are edentulous can be managed but require more experienced specialist care. This is detailed in the committee discussion section of Evidence report G.</p> <p>While there is no evidence to support this statement the committee agreed that it is an important point to make. They noted that if the devices do not fit properly then they are unlikely to work well.</p>
ProSomnus Sleep Technologies	Guideline	011	003	Currently the guideline does not instruct practitioners to consider Oral Appliances for the treatment of Severe OSA. The evidence establishes that for patients who refuse or cannot tolerate CPAP, treatment with Oral Appliances is better than no treatment.	Thank you for your comment. The committee agree and have made a recommendation to consider mandibular advancement splints for people with severe OSAHS.
ProSomnus Sleep Technologies	Guideline	011	004	It may be appropriate to change this statement from "Consider a customized" to "Offer a customized..." per NICE guidelines manual. Oral appliances have demonstrated equivalent health outcomes, cost effectiveness, and minimal evidence of side effects that result in discontinuation of therapy.	<p>Thank you for your comment. The limited availability of evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G.</p> <p>Here the recommendation is written as 'consider' rather than 'offer' because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.</p>
ProSomnus Sleep Technologies	Guideline	034	025	It is clearly good practice to inform patients of potential side effects. Having said this, it is unusual to advise on dental side effects without advising on potential side effects for CPAP. Studies report that the probability of side effects resulting in discontinuation of therapy, pain, infection and craniofacial changes are all	Thank you for your comment. The committee agree and have now amended the third bullet point of the recommendation to include side effects with the use of CPAP. We have also added the first two bullet points from the CPAP recommendation to the MAS rec to make these look more balanced.

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				significantly higher with CPAP than Oral Appliances. Either advise for both, or neither.	
ProSomnus Sleep Technologies	Guideline	047	009	The term "some" should be replaced with "many" or "a significant number" or "a majority" of CPAP users are unable to tolerate it.	Thank you for your comment. The committee agreed that while some people find CPAP unacceptable most users do not. They are not sure how to define what a significant number would mean and believe 'some' is an appropriate term to use in this sentence.
ProSomnus Sleep Technologies	Guideline	047	011	Per NICE development guidelines, replace the term "consider" with the word "offer".	Thank you for your comment. The recommendation referred to here is for people with mild OSAHS in whom we identified only one study of 6 weeks duration comparing MAS to placebo, and no studies of MAS vs CPAP. The committee do not interpret this as strong evidence and therefore believe the use of "consider" is appropriate for this recommendation.
ProSomnus Sleep Technologies	Guideline	047	014	Evidence indicates that dual block (two arch style) Oral Appliances perform better than Monoblock style Oral Appliances. Dual block Oral Appliances perform better than Tongue Retaining style Oral Appliances. Titratable Oral Appliances perform better than non-titratable Oral Appliances. Customised Oral Appliances perform better than non-customised Oral Appliances. And it is worth noting that non-metal Oral Appliances should be considered over Oral Appliances with metal components to avoid allergic reactions.	Thank you for your comment. We have amended the recommendation on mandibular advancement splints to include semi-customised devices. Due to lack of sufficient evidence the committee will not be able to comment on specific customised or semi-customised devices.
ProSomnus Sleep Technologies	Guideline	049	026	Evidence may support the use of the term "offer" as opposed to "consider".	Thank you for your comment. The availability of limited evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G. Here the recommendation and the text in the rationale is written as 'consider' rather than 'offer' because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.

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ProSomnus Sleep Technologies	Guideline	049	028	Also, reconsider the inclusion of Oral Appliances for the treatment of Severe OSA. Oral Appliances have been shown to improve OSA in severe patients who refuse or fail CPAP.	Thank you for your comment. The committee agree and have made a recommendation to consider mandibular advancement splints for people with severe OSAHS too.
ProSomnus Sleep Technologies	Guideline	050	017	Modern precision Oral Appliances currently offer a 3-to-5-year warranty, commensurate with the expected reasonable useful life of the device. However, devices that include metal components or soft-liner components generally carry a 1-year warranty and should therefore be considered only for patients with certain dental conditions that require those specific type of componentry.	Thank you for your comment. We had a figure of 2 years in the draft guideline and acknowledge that this is an arbitrary figure. For this reason, we conducted a sensitivity analysis around this parameter in our economic modelling. The cost effectiveness of custom-made MAS is extremely sensitive to the durability. It would have been useful to have evidence regarding durability. However, this is not the only area of uncertainty about MAS. The committee have made a research recommendation for MAS. Even, if the committee had detailed information about durability, they would not have made a strong recommendation without stronger evidence of effectiveness. There was not evidence that would allow the committee to recommend some devices over others.
ProSomnus Sleep Technologies	Guideline	054	019	Multiple studies demonstrate that the side effects associated with CPAP are more severe and more likely to result in the discontinuation of therapy than other therapies such as Oral Appliances. As such it may be advisable to add language to the follow up section advising healthcare providers to monitor and manage side effects.	Thank you for your comment. We have amended the third bullet point to include side effects related to CPAP. We have detailed the side effects in the committee discussion section of the evidence report.
ProSomnus Sleep Technologies	Guideline	075	022	Poor dentition is no longer a clinical concern with modern, precision, Oral Appliances. Granted, this was a concern with many of the antiquated Oral Appliances featured in some of the papers from decades ago. However in current practice, precision, modern, Oral Appliances are routinely fabricated for patients with edentulism, mixed dentition and overall poor dentition.	Thank you for your comment. We have amended the bullet point of the recommendation and rationale to state the person should have "optimal dental and periodontal health". We agree that people who are edentulous can use mandibular advancement splints but they require more experienced specialist care.
ResMed (UK) Ltd	Evidence review F	065	007	The table 15: 'Lifetime mean cost (£) per patient of each strategy'; also shows a marginal cost variation across the different CPAP devices.	Thank you for your comment. The difference in cost might seem small at £600 per patient but when multiplied across the many thousands of people that might benefit from CPAP, this represents a significant cost to the NHS.
ResMed (UK) Ltd	Evidence review F	068	045	Patient preference for auto CPAP is important to improve adherence and compliance ["there was a numerically superior	Thank you for your comment. The committee agree that patient preference is important. They take this into account along with the

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				<p>preference for auto-CPAP"] – this has also been expressed by OSA Partnership Group</p>	<p>whole body of available evidence from the review and cost-effectiveness of an intervention.</p> <p>The evidence showed that there was also no clinically important difference between auto CPAP and fixed-level CPAP for patient preference. However, the results from the studies indicated wide variation between users of CPAP in terms of how they respond to the different modes of pressure delivery. In eight of the 14 studies reporting this outcome, there was a numerically superior preference for auto-CPAP over either fixed-level CPAP, or neither treatment. However, in 6 studies the preference was in the opposite direction. There was no obvious explanation for this apparent discrepancy in terms of study design and technology of active interventions.</p> <p>Overall, the evidence showed fixed-level and auto CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP. While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved.</p> <p>The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances.</p> <p>The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower</p>

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					purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.
ResMed (UK) Ltd	Guideline	008	019	Having liaised with the OSA Partnership Group and our discussions with UK Respiratory Physicians - we are concerned that the recommendation is restrictive, we believe that healthcare professionals should be able to choose the most appropriate CPAP device, tailored to the need of their patients.	Thank you for your comment. NICE makes recommendations on the basis of cost-effectiveness, and these should be applicable in most circumstances. If there are reasons for an individual person with OSAHS to have different treatment these can be documented and the appropriate therapy used. In relation to the choice between auto or fixed-level CPAP, fixed-level is recommended as first choice based on cost-effectiveness, but potential exceptions have been included in the recommendation.
ResMed (UK) Ltd	Guideline	010	006	CPAP for moderate and severe OSAHS: we believe HCPs should be able choose the most appropriate CPAP device, based on the needs of their patients. This opinion is based on our discussions with OSA Partnership Group and UK Respiratory Physicians.	Thank you for your comment. The evidence showed fixed-level CPAP and auto-CPAP to be equally effective. The committee noted the evidence was mostly of low or very low quality. Although they were not completely confident in the findings the committee were limited in what they could recommend by the available evidence and the difference in costs between auto and fixed-level CPAP. While there might be some extra staff time involved with fixed-level CPAP, the included economic evaluation, Bloch 2018, showed that with auto-CPAP OSAHS treatment costs were higher overall and quality-adjusted life-years were not improved. The committee agreed to recommend fixed-level CPAP as the first-choice treatment. The committee also recommend that auto-CPAP can be considered as an alternative to fixed-level CPAP in certain circumstances. The committee were aware that some hospitals get significant discounts on auto-CPAP devices, which might make them more cost effective. Following stakeholder consultation, the committee agreed that if auto-CPAP is available at the same or lower

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					<p>purchase and administration cost than fixed-level CPAP, auto-CPAP could be considered. This has been added to the recommendation.</p> <p>Given the low quality evidence and uncertainty about the cost-effectiveness between auto and fixed-level CPAP the committee made a research recommendation to help inform future guidelines (see Appendix J).</p>
ResMed (UK) Ltd	Guideline	037	008	'1 Interventions to improve CPAP adherence': ResMed would be happy to support academia to evaluate this research /evidence gap.	Thank you for your support.
ResMed (UK) Ltd	Guideline	038	007	'5 Treatment for people with COPD–OSAHS overlap syndrome': ResMed would be happy to support academia to evaluate this research /evidence gap.	Thank you for your support.
Restorative Dentistry UK (RD-UK)	Evidence review G	066 - 075	General	<p>We are pleased that the review of literature has been undertaken and that there is general support for Mandibular Advancement Splints MAS, made and fitted by a suitably trained dentist.</p> <p>We highlight that such a device requires fabrication by a suitably trained dental technician, working closely with the suitably trained dentist, who will make the impressions (moulds) and record the patient's bite relationship in the advanced position.</p> <p>We agree that there is merit in a sleep medicine service working in collaboration with local general dental practitioners and primary care groups. We recommend dental technicians to be added to this collaboration, to support the GDP.</p> <p>We highlight that there is currently no NHS funding within the primary care GDP contact to provide MAS and such a service would need to either be locally commissioned (potentially as a pilot, prior to national roll-out) or provided under a self-funded, private contract.</p> <p>In addition to the recommendations for further studies, we recommend that a study examining the cost-effectiveness of funding GDP dental involvement in a collaboration with sleep medicine services would be worthwhile.</p>	<p>Thank you for your comments. We agree that many local services will have to adapt and sleep and dental services liaise in order to provide readier access to MAS. It is anticipated that commissioners will review the guideline when deciding on what to fund and implement. The committee hope that by making the recommendation these will be funded on the NHS.</p> <p>The configuration and delivery of services is outside the scope of this guideline and would need to be determined locally. Because it is not covered in the guideline, we have not made a statement or research recommendation about who should be involved when mandibular advancement splints are used in practice.</p>

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Royal College of Nursing	General	General	General	Thank you for the opportunity to contribute to this guideline. We do not have any comments to add on this occasion.	Thank you for your comment
Royal College of Paediatrics and Child Health	Guideline	General	General	The reviewer noted that this is a very comprehensive guideline.	Thank you for your comment
Royal College of Paediatrics and Child Health	Guideline	General	General	The practice of Telemedicine should aim to promote a case model in which patients, sleep specialists, primary care providers and health care team aim to improve the value of health care delivery in a coordinated way (American academy of sleep medicine 2021). Telemedicine is a potentially effective alternative for early identification and intervention, and should be considered to prevent inadequate OSA treatment. Telemedicine has the potential to deliver effective and convenient care that can improve compliance and patient satisfaction and reduce absenteeism to attend specialist sleep centres.	Thank you for your comment. The committee agree that telemedicine offers the potential to improve care for people with OSAHS and telemonitoring with CPAP has been recommended.
Royal College of Paediatrics and Child Health	Guideline	General	General	Obtaining adequate compliance to CPAP is the greatest challenge related to OSA. In addition, as the prevalence of OSA is growing and the aging population is increasing, OSA is associated with increased health care costs which could be streamlined by the application of Telemedicine which could offer cost effective management options. Multiple modalities such as telediagnosics, teleconsultation, teletherapy and telemonitoring can be successfully employed. If effectively used Telemedicine leads to decreased nursing workload, early identification of problematic patients and better treatment adherence.	Thank you for your comment. The committee agree that telemedicine offers the potential to improve care for people with OSAHS and telemonitoring with CPAP has been recommended.
Royal College of Paediatrics and Child Health	Guideline	General	General	Home CPAP titration and controlling by polygraphy is a valuable alternative to in-lab attended titration and results in similar clinical outcomes in terms of adherence, sleepiness improvement and quality of life. As it is possible to remotely change the settings of the device this leads to further improvement in treatment. After treatment initiation telemonitoring can be used to rapidly identify two categories of patients, those who quickly adopt well and those with problems (acceptance, leaks, adherence, mask discomfort, nasal/mouth dryness) who need more support and intervention.	Thank you for your comment. The committee agree that telemedicine offers the potential to improve care for people with OSAHS and telemonitoring with CPAP has been recommended.

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Royal College of Paediatrics and Child Health	Guideline	General	General	Studies have shown patient acceptance of telemonitoring and satisfaction was also high. It would be necessary to explore newer diagnosis and treatment pathways for these patients including use of disposable diagnostic tools and non-contact sleep surveillance. Thus, both Telemedicine and associated CPAP monitoring can be cost effective alternative to conventional medicine.	Thank you for your comment. The committee agree that telemedicine offers the potential to improve care for people with OSAHS and telemonitoring with CPAP has been recommended.
Royal College of Paediatrics and Child Health	Guideline	General	General	However, telemedicine carries an inherent risk of reliance on technology and dehumanisation. Social interaction domain is significantly higher in the HR and Telemedicine cannot be a substitute to HR.	Thank you for your comment. The committee agree that while telemedicine is a useful tool and has been recommended with CPAP human interaction is also important.
Royal College of Paediatrics and Child Health	Guideline	General	General	The COVID-19 Pandemic has disrupted the lives of people with OSA (and those being at risk of OSA) undermining sleep, psychological and physical health. The greatest impact of this has been on patients who have other co-morbidities, those who have contracted the disease itself or those experiencing the consequences of lifestyle restriction imposed to reduce the risk of infection. Introducing behavioural interventions and mitigation strategies should be considered.	Thank you for your comment. Recommendations on behaviour interventions and mitigation strategies are beyond the remit of the guideline.
Royal College of Physicians	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Thoracic Society (BTS).	Thank you for your comment. We have responded to each BTS comment in turn.
Royal College of Surgeons of England - Faculty of Dental Surgery	Guideline	007	015	I feel this might be worth mentioning the negative impact of Caffeinated Drink/foodstuffs before sleep.	Thank you for your comment. The impact of caffeine and food is covered in the recommendation by the broader term 'sleep hygiene'. We expand on this in the rationale and committee discussion.
Royal College of Surgeons of England - Faculty of Dental Surgery	Guideline	009	024	In our trust we have found active periodontal disease a common factor in delaying or contraindicating a Mandibular Advancement Device. We would recommend thorough dental and periodontal assessment prior to referral and repeated assessment and monitoring throughout treatment. This can be under the care of the patient's General Dental Practitioner. We also advise patients of	Thank you for your comment. The committee agree that MAS should not be made for patients with untreated dental decay or active periodontal disease. The latter is important in not only ensuring minimal unwanted tooth movement [as teeth with reduced bone support will move more readily which is not desirable] and more importantly could accelerate their loss,

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				<p>the risks to periodontal health with use of a Mandibular Advancement Device. We also advise the patient of possible short and long term effects on the Temporomandibular Joint with use of Mandibular Advancement Devices. This is partially covered in 4.1.5 page 34</p>	<p>thereby compromising the long-term use of an MAS. This is detailed in the committee discussion section of Evidence report G.</p> <p>We have updated the text in the recommendation from 'suitable dentition' to state 'teeth present should be of optimal dental and periodontal health.'</p> <p>The committee did not comment on the service delivery as this was not reviewed as part of the guideline and will be determined locally considering local circumstances.</p>
Royal College of Surgeons of England - Faculty of Dental Surgery	Guideline	012	004	<p>For cases refractory to CPAP or Mandibular Advancement Devices, there are other surgical options for the management of OSAHS which can be discussed with the patient. The risk surgery and General Anaesthesia needs to be balanced against any potential benefit. OSA elective surgery for patients with high BMI (suggest >30kg/m²) is often viewed as contraindicated and a course of weight loss treatment is recommended. Soft tissue procedures such as Uvulopalatopharyngoplasty, Septoplasty or Tongue base reduction surgery with use of Trans Oral laser that can be offered. (this maybe covered by an ENT Specialist contributing to these guidelines) Bimaxillary or Mandibular Advancement Osteotomy (Orthognathic Surgery) can be offered. This can be combined with Orthodontic treatment but this needs assessing on a patient to patient basis. The ideal is for patient management via an MDT combining airway, skeletal form and oral health assessment. Follow for these patients undergoing Orthognathic Surgery should be for a minimum of 2 years post operatively to assess for relapse. (page 56 line 10).</p>	<p>Thank you for your comment. The recommendations are based on reviews of the available evidence, and only recommend those demonstrated to be clinically and cost effective. We found evidence for the surgery types you mention but did not have sufficient evidence to make recommendations for specific types of surgeries. Oropharyngeal surgery was found to be effective in people with moderate or severe OSAHS who are unable to tolerate or adhere to CPAP and mandibular advancement splints. There were some adverse effects associated with surgery, but the committee agreed that they were not clinically significant. The committee agreed to leave it to the surgeon to decide which type of oropharyngeal surgery to use.</p> <p>There was no evidence available for other types of surgery and therefore the committee did not make any recommendations for these. A research recommendation has been made to inform future updates of this guideline.</p>
Royal College of Surgeons of England - Faculty of	Guideline	023	002	<p>With respect to DVLA regulations about driving and OHS, CPAP machines can be scrutinised to prove usage and compliance with treatment whereas the use of a Mandibular Advancement Device is uncheckable. This may have implications on DVLA report writing.</p>	<p>Thank you for your comment. Mandibular advancement splints are not recommended for people with OHS. Was your comment</p>

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Dental Surgery					intended for people with OSAHS using mandibular advancement splints? The committee anticipate where data is not available from a machine that clinicians will ask the person directly about their use of MAS and assess how well symptoms are controlled.
Sleep Apnoea Trust Association (SATA)	Guideline	General	General	<p>The definition of OSAHS in Section 1 of the Guidelines is a simplified version of the definition of OSAHS contained in the Summary section of the NICE Clinical Knowledge System (CKS) topic on Obstructive sleep apnoea syndrome. The Definition section of this CKS topic repeats the definition of OSAHS, defines Obstructive Sleep Apnoea/Hypopnoea (OSAH) and includes the British Thoracic Society (BTS) definitions of Obstructive Sleep Apnoea Syndrome (OSAS) and Obstructive Sleep Apnoea (OSA). The Definition section concludes with the statement that the topic “will use the term “obstructive sleep apnoea syndrome” when referring to OSAHS”. However these Guidelines do not refer to Obstructive Sleep Apnoea Syndrome or Obstructive Sleep Apnoea, nor to OSAS or OSA, anywhere in the document.</p> <p>The omission of these additional definitions of OSAS and OSA creates a mismatch between the draft Guidelines and the everyday terminology sleep apnoea patients encounter in discussions with their sleep clinics, where OSAS and OSA, as defined by the BTS, is in common usage. It also creates a mismatch with the Driver and Vehicle Licensing Agency (DVLA) guidance on excessive sleepiness and driving and the DVLA advice to medical professionals (Miscellaneous conditions: assessing fitness to drive – Excessive sleepiness - including obstructive sleep apnoea syndrome). Both of these DVLA documents use OSAS and OSA, and do not refer to OSAHS or OSAH at all.</p> <p>In the absence of any reference to OSA in the Guidelines SATA considers that a strict reading could lead to their interpretation as applying only to Obstructive Sleep Apnoea where excessive</p>	<p>Thank you for your comment. The committee have used the term OSAHS which would include all the conditions you describe. They wanted to use an overarching term to ensure all conditions are covered by our recommendations for OSAHS.</p> <p>We have not made specific reference to excessive sleepiness in our definition. In the past excessive sleepiness was seen as the main symptom for OSAHS. The committee were aware that recent data suggests it is not just excessive sleepiness that suggests a presence of OSAHS and other factors listed in recommendation 1.1.1 on when to suspect are also important.</p>

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				<p>sleepiness during waking hours is involved, and not to OSA without such symptoms. It is not beyond the realms of possibility that a CCG which is desperate to make best use of scarce resources could mount a legal defence of its decision to not provide CPAP or MAD therapy for sleep apnoea patients with no excessive sleepiness during waking hours on the grounds that the Guidelines do not explicitly require them to do so.</p> <p>In order to overcome these concerns SATA proposes that at the beginning of Section 1 of the Guidelines an additional sentence is added, along the following lines;</p> <p>“Throughout this document reference to Obstructive Sleep Apnoea/Hypopnea Syndrome (OSAHS) and Obstructive Sleep Apnoea/Hypopnoea (OSAH) includes, wherever appropriate, reference to Obstructive Sleep Apnoea Syndrome (OSAS) and Obstructive Sleep Apnoea (OSA).”</p>	
Sleep Apnoea Trust Association (SATA)	Guideline	General	General	<p>In Section 1.2 it would be helpful to indicate what is expected by “Prioritising people for rapid assessment by a sleep service”. If a sleep clinic service in pre-Covid times habitually took several months between referral, diagnosis and compliant provision of CPAP therapy, “rapid assessment” might mean a three-month process rather than their normal 6 months. Some sort of target, for example “a normal maximum of four weeks between referral and provision of CPAP or MAD therapy” would be helpful.</p>	<p>Thank you for your comment. The aim of this section is to alert the sleep service to people with suspected OSAHS considered to be a priority who should be prioritised for assessment ahead of other people. The committee did not seek to define a time limit on when to assess someone.</p>
Sleep Apnoea Trust Association (SATA)	Guideline	General	General	<p>No mention is made in the guidelines in respect of mask selection. With current rates of CPAP non-compliance SATA believes that it is essential that Sleep Clinics are quite clear that they are required to provide the most appropriate mask for each patient when the CPAP is first issued, and that they are required to change the type of mask if the mask originally supplied proves to be unsuitable for that patient in daily use. This requirement should include an obligation on sleep clinics to provide masks from manufacturers</p>	<p>Thank you for your comment. We have amended the recommendations related to monitoring treatment efficacy for OSAHS, OHS and COPD-OSAHS overlap syndrome to include mask type and fit. In the recommendations on Information for people with OSAHS, OHS or COPD-OSAHS overlap syndrome we also recommend that patients are told where to seek help should they have problems.</p>

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				other than the manufacturer of the CPAP in standard use in that clinic. For example, only one manufacturer at present offers a fabric mask, and the design of nasal pillow-type masks differs between manufacturers.	
Slimming World	Guideline	007	012	<p>We're pleased to see the advice is that all people with OSAHS should be offered support and information on losing weight if appropriate. While the guideline refers to the relevant weight management guidelines we'd suggest that it could be made clear that these patients would be a priority for providing a referral into a weight management service given weight reduction is likely to have a significant impact on their condition and quality of life. In a recent survey (conducted in 2020) we identified that over 1 in 10 of our membership report having sleep apnoea.</p> <p>In a previous study we worked in partnership with a chest clinic where patients were offered 12 weeks at a Slimming World group. Significant weight loss was achieved over the 12 weeks along with improvements in Epworth Sleepiness Scores. The study concluded that partnership between Slimming World and a secondary care provider proved successful in supporting this specific patient group with a chronic condition to lose weight, thus improving their medical status.</p> <p><i>Ref: Lavin, J.H., Avery, A., Eveleigh, M. and Newham, J. (2005). An innovative partnership to support weight loss in patients with obstructive sleep apnoea. Presented at NICE Annual Conference, Birmingham ICC</i></p>	<p>Thank you for your comment. A review of the evidence related lifestyle advice, including weight management and obesity, was not included in this guideline because existing NICE guidance covers this. This is why the guideline only cross refers to other relevant NICE guidelines related to lifestyle advice, including those with weight management advice and does not make separate recommendations in this guideline.</p>
SomnoMed UK	Evidence review G	072	024	<p>Linking Sleep, Dental and Primary care for these patients is possible with Intra Oral Scanning (IOS). A Dentist or Dental Tech/Nurse could easily fit into a service in a GP practice or Community Hospital. Treating "locally" is better for the environment, reduces Infection control issues and is quick and convenient for patients.</p>	<p>Thank you for your comment. The configuration and delivery of services is not covered by this guideline and would need to be determined locally.</p>

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SomnoMed UK	Evidence review G	073	008	As stated, the NHS provision of dental services producing mandibular advancement splints is limited. However, by utilising a private dentist with IOS in a once a fortnight/once a month Sleep/GP clinic this would become more efficient and cost effective, with a marked reduction in waiting times and an increase in the number of patients being treated. This is already working very effectively in some NHS Trusts where MADs have been recognised as an essential part of the treatment protocol for mild to moderate OSA	Thank you for your comment. The configuration and delivery of services is not covered by this guideline and would need to be determined locally
SomnoMed UK	Evidence review G	073	009	Mandibular Advancement Splints only need replacing at regular intervals if they are made from inferior materials. When treating a medical condition, the treatment should be of medical grade, with ISO certification a must. Device life expectancy should be a minimum of 3-5yrs and should be offered with a manufacturers warranty of up to 5 years.	Thank you for your comment. Assuring quality of devices not within the scope of this guideline and would usually be done by CE marking..
SomnoMed UK	Evidence review N	082	001 - 004	<p>Rotenberg et al 2016 concluded – “The rate of CPAP adherence remains persistently low over twenty years’ worth of reported data (82 papers included). No clinically significant improvement in CPAP adherence was seen even in recent years despite efforts toward behavioural intervention and patient coaching. This low rate of adherence is problematic, and calls into question the concept of CPAP as gold-standard of therapy for OSA.”</p> <p>Evidence shows the milder the disease, the lower the compliance rate to CPAP - Chang 2019, Baratta, 2018, Madbouly et al 2016, Kreiger 1996</p> <p>The evidence demonstrates that compliance and patient satisfaction is higher in mild to moderate OSA with MAD treatment than with CPAP - Chen et. al 2020, Dieltjens et. Al 2013, Barnes et al 2004, Ferguson et al 1997 therefore additional costly interventions are unlikely to be required for MAD compliance.</p> <p>This calls into question whether the extra expense of staff training/time to learn and administer additional interventions in an</p>	<p>Thank you for your comment and suggested references.</p> <p>All of the references you provided have been checked to see if they met the review protocol and could be included in the guideline. The committee agreed that RCT evidence was the most appropriate study design to inform the review question. High quality evidence was thought to be most appropriate to be able to recommend an intervention such as oral devices that are not widely used in current practice. Non- randomised/observational studies were agreed as not sufficient quality for this question.</p> <p>The following references were not included as they did not meet the inclusion criteria for study design and comparisons as specified in the protocol: Rotenberg et al 2016 is a systematic review and included studies with comparisons not included in the protocol (CPAP vs sham CPAP, CPAP vs placebo, CPAP vs conservative or no therapy, cpap vs oral appliance, CPAP vs postural therapy and CPAP alone assessing different means to modify adherence); Chang 2019 is a cohort study; Baratta, 2018 is a cohort study;</p>

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				<p>attempt to increase CPAP usage will have any benefit or rather further reduce its cost effectiveness. MAD is available as a cost effective, efficacious alternative with high rates of patient acceptance.</p>	<p>Kreiger 1996 is a cohort study; Chen et. al 2020 is a cohort study; Dieltjens et. Al 2013 is a cohort study.</p> <p>Madbouly et al 2016 could not be assessed as we do not have the full reference.</p> <p>Studies Barnes et al 2004 and Ferguson et al 1997 have been reviewed in the oral devices review.</p> <p>The NICE technology appraisal guidance TA139 on continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome recommends CPAP as a treatment option for moderate and severe OSAHS. The committee agreed that CPAP is an effective treatment for OSAHS and that the recommendation within the technology appraisal is still valid. In line with this, they agreed that CPAP should be a first-line treatment choice for people with moderate and severe OSAHS. While evidence was identified that oral devices are cost-effective compared to no treatment there was not sufficient evidence to recommend them ahead of, or on an equal level to CPAP.</p> <p>For people with symptomatic mild OSAHS whose symptoms affect their usual daytime activities, the evidence suggested that CPAP was more clinically and cost effective than conservative management, including lifestyle changes and sleep hygiene. There was very little evidence for oral devices in people with mild OSAHS. One study showed little benefit of mandibular advancement splints compared with no treatment in people with mild symptomatic OSAHS, but the committee agreed that the duration of the study was not sufficient for the true benefit to be assessed.</p> <p>As CPAP is recommended for all severities of OSAHS the committee believe it should be properly tried before changing interventions and encouraging adherence is part of this.</p>

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					<p>An economic analysis showed that CPAP was slightly more cost effective than customised mandibular advancement splints. Based on this the committee recommended CPAP as the first choice for people with mild symptomatic OSAHS and oral devices should be considered as a treatment for people with mild OSAHS who have symptoms that affect their usual daytime activities if they are unable to tolerate or decline to try CPAP. The sensitivity analyses conducted suggested uncertainty around the relative cost effectiveness of MADs and therefore the committee recommended further research.</p> <p>The committee recognise that training is an important issue. This topic was not prioritised during the scoping process for this guideline.</p>
SomnoMed UK	Guideline	009	020	<p>Developing NICE guidelines: the manual. Process and methods. 15 October 2020. States:</p> <p>“Some recommendations are 'strong'. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. The 'strength' of a recommendation should be reflected in the consistent wording of recommendations within and across guidelines. In recommendations on interventions that should be offered, use directive language such as 'offer'. If there is a closer balance between benefits and harms, use 'consider'.”</p> <p>The committee have clearly stated in the case of bespoke, dentally fitted MADs that there is good evidence, they are cost effective and there is no evidence of harm. There would be harm, however, if patients are left untreated due to the long list of comorbidities, RTAs, socioeconomic costs etc. Based on NICE's own guidelines</p>	<p>Thank you for your comment. The availability of limited evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G.</p> <p>Here the recommendation is written as 'consider' rather than 'offer' because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.</p>

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				and the committee's findings we strongly believe the word "offer" should be used rather than "consider"	
SomnoMed UK	Guideline	009	024	With regard to suitable dentition, Clinicians need to be made aware that Edentulous type devices are now available which require a minimal number of teeth and, if made correctly, these devices will also support the remaining teeth without causing further damage. There also needs to be some clarity regarding priority of treating OSA and the resulting comorbidities versus concerns re health of teeth.	<p>Thank you for your comment. The text 'suitable dentition' has been edited to 'optimal dental and periodontal health.' This emphasises that MAS should not be made for patients with untreated dental decay or active periodontal disease. The latter is important in not only ensuring minimal unwanted tooth movement [as teeth with reduced bone support will move more readily which is not desirable] and more importantly could accelerate their loss, thereby compromising the long-term use of an MAS.</p> <p>Patients that are edentulous can be managed but require more experienced specialist care. This is detailed in the committee discussion section of Evidence report G.</p>
SomnoMed UK	Guideline	011	004	<p>Developing NICE guidelines: the manual. Process and methods. 15 October 2020. States:</p> <p>"Some recommendations are 'strong'. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. The 'strength' of a recommendation should be reflected in the consistent wording of recommendations within and across guidelines. In recommendations on interventions that should be offered, use directive language such as 'offer'. If there is a closer balance between benefits and harms, use 'consider'."</p> <p>The committee have clearly stated in the case of bespoke, dentally fitted MADs that there is good evidence, they are cost effective and there is no evidence of harm. There would be harm, however, if patients are left untreated due to the long list of comorbidities, RTAs, socioeconomic costs etc. Based on NICE's own guidelines and the committee's findings we strongly believe the word "offer" should be used rather than "consider"</p>	<p>Thank you for your comment. The limited availability of evidence and quality of the evidence for MAS did influence the strength of the recommendation and this is reflected in the wording of the recommendations and explained in the committee discussion section of Evidence report G.</p> <p>Here the recommendation is written as 'consider' rather than 'offer' because of the limited evidence of varying quality, the longest follow up for the MAS data was 6 weeks and the results from the economic model showed CPAP to be the most cost-effective option.</p>

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SomnoMed UK	Guideline	011	007	With regard to suitable dentition, Clinicians need to be made aware that Edentulous type devices are now available which require a minimal number of teeth and, if made correctly, these devices will also support the remaining teeth without causing further damage. There also needs to be some clarity regarding priority of treating OSA and the resulting comorbidities versus concerns re health of teeth.	<p>Thank you for your comment. The text 'suitable dentition' has been edited to state 'teeth present should be of optimal dental and periodontal health.'</p> <p>This emphasises that MAS should not be made for patients with untreated dental decay or active periodontal disease. The latter is important in not only ensuring minimal unwanted tooth movement [as teeth with reduced bone support will move more readily which is not desirable] and more importantly could accelerate their loss, thereby compromising the long-term use of an MAS.</p> <p>Patients that are edentulous can be managed but require more experienced specialist care. This is detailed in the committee discussion section of Evidence report G.</p>
SomnoMed UK	Guideline	047	006	An assumption has been made in the economic model that a mandibular advancement splint has a lifespan of 2 years. This is correct for some cheaper bespoke devices but SomnoMed devices have a regulatory lifespan of 5 years (we offer a manufacturer's materials warranty to reflect this). Due to the high quality, patented materials used they will also remain stain and odour free for this time period (if cared for correctly). This has a significant effect on the cost effectiveness of SomnoMed MADs versus "other" bespoke MADs and also versus CPAP. If the economic model input for MAD lifespan is changed to 5 years, you will note that rather than finding that "CPAP was slightly more cost effective than customised mandibular advancement splints", MAD becomes the more cost-effective treatment compared to CPAP. Cost effectiveness is a very important factor in the NICE guidance so it is important that the economic model does not create a disadvantage to better quality MADs by grouping all bespoke, dentally fitted MADs together under a 2 year lifespan.	<p>Thank you. We acknowledge that 2 years is an arbitrary figure. For this reason, we conducted a sensitivity analysis around this parameter in our economic modelling. The cost effectiveness of custom-made MAS is extremely sensitive to the durability.</p> <p>It would have been useful to have evidence regarding durability. However, this is not the only area of uncertainty about MAS. The committee have made a research recommendation for MAS. Even, if the committee had detailed information about durability, they would not have made a strong recommendation without stronger evidence of effectiveness. There was not evidence that would allow the committee to recommend some devices over others.</p>
SomnoMed UK	Guideline	048	010	With regards to Resource Recommendations for the provision of custom-made mandibular advancement splints, will there be a preferred supplier list for the NHSSC as there is with other medical and surgical devices? This ensures that there are clear guidelines to aid the choice of a good quality, cost effective device.	<p>Thank you for your comment. We do not know whether there will be a preferred supplier list; it is for NHS commissioners to determine how to procure devices.</p>

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SomnoMed UK	Guideline	050	016	As above	Thank you for your comment. Please see response to your comment above.
Sunrise Sleep	Evidence review D	005	019	I do not agree with the sentence “the simple diagnostic test is overnight oximetry”. Other single channel tests, like Sunrise are a least as simple both for the patient and the healthcare professional and provide robust information and diagnostic performances https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2759126	Thank you for your comment. We have amended the text to state “A simple diagnostic test is overnight oximetry”. Mandibular movement monitoring devices were not included as a diagnostic test to review in the guideline as they are not commonly used to diagnose OSAHS.
Sunrise Sleep	Guideline	036	019	I do not agree with the sentence “to diagnose sleep disorders by recording multiple channels”. I would like to draw the committee attention on the emergence of others devices deriving the same level of information for the clinician from a single channel using a new biosignal. For instance the mandibular movements as mentioned in this JAMA article https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2759126 or the references 293 and 294 by Martinot et al mentioned p 71 from Evidence review D – Diagnostic tests review	Thank you for your comment. Mandibular movement was not included as a technique for diagnosis in the review protocol as it is not commonly used in practice. This is why the studies you mention appear in the excluded studies list of the evidence review.
Total Diet & Meal Replacements (TDMR) Europe	Guideline	005	006 008 011	TDMR Europe is glad to see that the guideline acknowledges that there is a higher prevalence of OSAHS in people with a series of conditions, which include obesity and overweight, and type 2 diabetes (a disease itself linked to obesity).	Thank you for your comment
Total Diet & Meal Replacements (TDMR) Europe	Guideline	012	014	The guideline points to weight loss as part of the lifestyle changes that should be advised for all severities of OSAHS, and then points to NICE guidelines on obesity (recommendation 1.4.1) for more specific advice. However, no direct weight management recommendations are given in the sleep apnoea guideline nor revised lifestyle advice. This should be addressed.	Thank you for your comment. Thank you for your comment. A review of the evidence related lifestyle advice, including weight management and obesity, was not included in this guideline because existing NICE guidance covers this. This is why the guideline only cross refers to other relevant NICE guidelines related to lifestyle advice, including those with weight management advice and does not make separate recommendations in this guideline.
Total Diet & Meal Replacements	Guideline	General	General	Total Diet & Meal Replacements (TDMR) Europe is the European trade body for manufacturers and distributors of total diet replacements (TDRs) and meal replacements (MRPs), which	Thank you for your comment. A review of the evidence related lifestyle advice, including weight management and obesity, was not included in this guideline because existing NICE guidance covers this. This is why the guideline only cross refers to other

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(TDMR) Europe				<p>provide weight loss and weight management programmes for the overweight and obese.</p> <p>TDRs, which include very low-calorie diets (VLCDs) and low calorie diets (LCDs), are specifically formulated programmes that are based around formula foods that aim to replace the whole of the daily diet. These formula foods are nutritionally balanced with key vitamins, minerals, high quality protein, essential fats, fibre and other nutrients, and are designed to replace conventional foods for a period to facilitate optimal weight loss. Meal replacements are products presented as a replacement for one or more meals of the daily diet. They are used alongside conventional food, as part of an energy restricted diet, to facilitate and maintain weight loss.</p> <p>TDMR Europe fully supports the proposal to develop guideline “<i>GID-NG10098 on Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s</i>”.</p> <p>We are deeply concerned, however, by NICE’s decision not to review the evidence on lifestyle recommendations and not to include weight management advice as part of the development of the guidelines. TDMR Europe believes that the exclusion of weight management advice, and particularly dietary advice, is a missed opportunity in light of the strong link between obesity and overweight and sleep apnoea, and new scientific evidence pointing to the usefulness of TDRs for weight loss.</p>	relevant NICE guidelines related to lifestyle advice, including those with weight management advice and does not make separate recommendations in this guideline.
Total Diet & Meal Replacements (TDMR) Europe	Guideline	General	General	<p>TDMR Europe urges NICE to reconsider its decision not to include weight management advice within this guideline, and then to consider the evidence for inclusion of TDRs in the weight management recommendations for the treatment of OSA in adults.</p> <p>Guidelines from the American Thoracic Society of 2018 recommend that weight management strategies be incorporated into routine treatment of adults with OSA who are overweight and obese [Hudgel DW, Patel SR, Ahasic AM, Bartlett SJ, Bessesen</p>	Thank you for your comment. A review of the evidence related lifestyle advice, including weight management and obesity, was not included in this guideline because existing NICE guidance covers this. This is why the guideline only cross refers to other relevant NICE guidelines related to lifestyle advice, including those with weight management advice and does not make separate recommendations in this guideline.

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				<p>DH, Coaker MA, Fiander PM, Grunstein RR, Gurubhagavatula I, Kapur VK, Lettieri CJ, Naughton MT, Owens RL, Pepin JL, Tuomilehto H, Wilson KC; American Thoracic Society Assembly on Sleep and Respiratory Neurobiology. The Role of Weight Management in the Treatment of Adult Obstructive Sleep Apnea. An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med. 2018 Sep 15;198(6):e70-e87. doi: 10.1164/rccm.201807-1326ST. PMID: 30215551].</p> <p>The Scottish Intercollegiate Guidelines Network, meanwhile, already advocated in 2003 that weight loss should be encouraged as an adjunct to CPAP [SIGN (2003) Management of obstructive sleep apnoea/hypopnoea syndrome in adults: a national clinical guideline. Scottish Intercollegiate Guidelines Network. http://www.sign.ac.uk].</p> <p>If the current evidence for weight management in the treatment of OSA is not considered at this guidance development point, NICE guidance may well be significantly behind the advice given by other organisations.</p>	
Total Diet & Meal Replacements (TDMR) Europe	Rational and impact	044	013	<p>The reason given for not reviewing evidence for lifestyle advice is that this advice is covered by other NICE Guidelines. This is problematic because some of these NICE guidelines are outdated and do not include the latest scientific research on weight loss and weight management.</p> <p>NICE Guideline CG189 on “obesity: identification, assessment and management” was last updated in November 2014, over six years ago. Since then, a number of studies have shown the effectiveness of TDRs in tackling overweight and obesity, and the effect of weight loss in improving OSAHS.</p> <p>Public Health authorities are becoming increasingly aware of the effectiveness of TDRs for weight loss and the management of related diseases such as type 2 diabetes. NHS Scotland and NHS</p>	Thank you for your comment. A review of the evidence related lifestyle advice, including weight management and obesity, was not included in this guideline because existing NICE guidance covers this. This is why the guideline only cross refers to other relevant NICE guidelines related to lifestyle advice, including those with weight management advice and does not make separate recommendations in this guideline.

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				<p>England have launched a programme supporting TDRs for obese people with type 2 diabetes. These pilots build on the approaches of the Diabetes Remission Clinical Trial (DiRECT), and the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) trial, reflecting the evidence bases developed for both of these trials.</p> <p>The DiRECT trial showed that a high proportion of people would engage with a total diet replacement weight loss programme for up to 20 weeks and that a good proportion maintained their weight loss and diabetes remission. [Lean MEJ, Leslie WS, Barnes AC, Brosnahan N, Thom G, McCombie L, et al. Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster randomised trial. The Lancet. December 2017. https://doi.org/10.1016/S0140-6736(17)33102-1] [Lean MEJ, Leslie WS, Barnes AC, Brosnahan N, Thom G, McCombie L, et al. Durability of primary care-led weight-management intervention for remission of type 2 diabetes: 2 year results of the DiRECT open-label, cluster-randomised trial. The Lancet Diabetes & Endocrinology. March 2019. https://doi.org/10.1016/S2213-8587(19)30068-3]</p> <p>The results of DROPLET showed that GP referrals to a commercial provider offering a weight loss and maintenance programme, based on TDR with individual behavioural support, led to an average weight loss of 10.7 kg after 1 year (7.2kg more than usual weight-loss programmes offered in primary care). This was associated with significant reductions in CVD risk. [Astbury NM, Aveyard P, Nickless A, Hood K, Corfield K, Lowe R, Jebb SA. Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET): pragmatic randomised controlled trial. Nuffield Department of Primary Care Health Sciences, University of Oxford, UK. August 2018. http://dx.doi.org/10.1136/bmj.k3760]</p>	

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				<p>The Obesity Unit at the Karolinska Unit in Stockholm produced papers showing that the type of diet currently being rolled out for diabetes remission by NHS Scotland and NHS England (TDRs) could deliver large weight losses in a short period of time with large improvement in measures of sleep apnoea and that these changes were sustainable for one year. [Johansson K, Neovius M, Lagerros YT, Harlid R, RÅfssner S, Granath F et al. Effect of a very low energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial <i>BMJ</i> 2009; 339 :b4609 doi:10.1136/bmj.b4609]</p> <p>There are other recent studies showing TDRs potential to help people manage their weight. The Prevention of diabetes through lifestyle Intervention and population studies in Europe and around the World (PREVIEW) research team has presented results on weight maintenance over three years in over two thousand overweight people with pre-diabetes who begin their risk-reduction with an 800kcal/d total diet replacement (TDR) diet given with a behaviour change intervention. The overall mean weight loss after 8 weeks was 10.7 + 0.4kg (10.8% of body weight). After the initial weight loss period those who achieved 8% weight loss were entered into a randomised trial of higher and lower dietary protein intake, higher and lower dietary glycaemic index levels and higher and lower physical exercise activity intensity levels for three years. The results of the three year maintenance outcomes showed that both diets and both exercise strategies were equally effective for weight-loss maintenance. [Christensen P, Larsen TM, Westerterp-Plantenga M, Macdonald I, Alfredo Martinez J, Handjiev S, Poppitt S, et al. Men and women respond differently to rapid weight loss: Metabolic outcomes of multi-centre intervention study after a low-energy diet in 2500 overweight, individuals with pre-diabetes (PREVIEW). <i>Diabetes, Obesity and Metabolism, A Journal of Pharmacology and Therapeutics</i>. August 2018. https://doi.org/10.1111/dom/13466]</p>	

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University Hospitals Birmingham NHS Foundation Trust	General	General	General	We consider that the pandemic is likely to have accelerated a shift to tele-monitoring and tele-conferencing in the delivery of sleep healthcare. We welcome the committee's support for this.	Thank you for your comment.
University Hospitals Birmingham NHS Foundation Trust	General	General	General	We would welcome a statement from the committee concerning shift work and its interaction with OSA	Thank you for your comment. The committee wrote the recommendations with the idea they would apply to all people with OSAHS, OHS or COPD-OSAHS regardless of their work pattern. They discussed the implication of wording for shift workers and for the most part avoided using the words day or night where possible and used expressions such as 'when awake' or 'when asleep'. Usual 'daytime activities' has been used as it was in the TA and the committee thought that most people would understand to whom this applies.
University Hospitals Birmingham NHS Foundation Trust	General	General	General	The guideline is inconsistent in its recommendations. Bi-maxillary surgery is not recommended because of a "lack of sufficient evidence" but positional therapy, treatment of rhinitis and follow-up durations are all recommended despite explicit acceptance of a lack of sufficient evidence. We consider the guidelines need to be consistent in its approach.	Thank-you for your comment. In the absence of definitive evidence, the committee can make recommendations based on its experience providing there are no safety concerns, and the relevant interventions are not costly. Compared to the other examples you offer, bi-maxillary surgery is not widely practised, more costly, and has greater potential to cause adverse events.
University Hospitals Birmingham NHS Foundation Trust	Guideline	005	008	We think that untreated hypothyroidism should be added to this list.	Thank-you for your comment. The committee agree and hypothyroidism has been added to the recommendation.
University Hospitals Birmingham NHS Foundation Trust	Guideline	006	003	We agree that the Epworth score should not be used in isolation to determine if a patient should be investigated for OSA. However, the second half of the sentence – "not all people with OSAHS have excessive sleepiness" implies that our primary intention is to normalise the physiology. We are not aware of any evidence that treating asymptomatic OSA is beneficial. We would suggest "not	Thank you for your comment. In the past excessive sleepiness was seen as the main symptom for OSAHS. The committee were aware that recent data suggests it is not just excessive sleepiness that suggests a presence of OSAHS. The aim of this recommendation is to highlight this fact.

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				all people with OSA with pathological daytime somnolence score highly on the Epworth Scale.”	
University Hospitals Birmingham NHS Foundation Trust	Guideline	006	008	Our opinion on this is divided. Some consider prioritising patients for non-medical reasons to be unethical, since patient and public safety can be assured by ceasing driving. Those who do not/cannot afford to/do not wish to drive would be disadvantaged. However, others consider this is justified by the social good.	Thank you for your comment. The committee note that this is a difficult recommendation to get right. They discussed this in detail and believe they have the right balance for the recommendation. When deciding on those to be prioritised the committee discussed the effect of OSAHS on work performance and safety and how it could increase the risk of work accidents in safety-sensitive occupations. For those who have a vocational driving job a loss of income could have a negative outcome on their quality of life. What the committee recommend is what they would do in practice.
University Hospitals Birmingham NHS Foundation Trust	Guideline	006	009	Our opinion on this is divided. Some consider prioritising patients for non-medical reasons to be unethical, since patient and public safety can be assured by ceasing working and prioritising them would allow them to jump the queue over others who do not have safety critical jobs. Others consider this is justified by the social good.	Thank you for your comment. The committee note that this is a difficult recommendation to get right. They discussed this in detail and believe they have the right balance for the recommendation. When deciding on those to be prioritised the committee discussed the effect of OSAHS on work performance and safety and how it could increase the risk of work accidents in safety-sensitive occupations. For those who have a job where vigilance is critical to safety a loss of income could have a negative outcome on their quality of life. What the committee recommend is what they would do in practice. This does not preclude a clinician prioritising other people where they think it appropriate.
University Hospitals Birmingham NHS Foundation Trust	Guideline	006	013	We are not aware of evidence that pregnancy per se increases the risk posed by OSA.	Thank you for your comment. The committee from their experience agreed that risk of OSAHS can cause problems in pregnancy with an increased risk of adverse maternal and foetal outcomes. The also agreed that the prevalence increases across trimesters.
University Hospitals Birmingham NHS Foundation Trust	Guideline	007	006	We consider that oximetry is insufficiently accurate to be used in the diagnosis of OSA and that multi-channel studies should be the default first line test. Minority report: one of our team considers that it still has a useful role to play.	Thank you for your comment. The committee agree that multi-channel studies are the better first line test. However, on reviewing all the stakeholder comments about the quality of the evidence for oximetry and the big change to practice using home RP would be for come trusts the committee has recommended considering oximetry where access to home respiratory polygraphy is limited.

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					The recommendations now state: 1.3.1 Offer home respiratory polygraphy as the first-choice test to people with suspected OSAHS. 1.3.2 If access to respiratory polygraphy is limited consider home oximetry for people with suspected OSAHS. Take into account that oximetry alone may be inaccurate for differentiating between OSAHS and other causes of hypoxaemia in people with heart failure or chronic lung diseases.
University Hospitals Birmingham NHS Foundation Trust	Guideline	007	008	We think that "Consider polysomnography in people with suspected OSAHS who have a negative respiratory polygraphy result but continue to have symptoms" is insufficiently strong. We understand that polysomnography is not widely available. However if the patient is still sleepy and the test suggests OSA is not present then either further investigation or onward referral would be the most appropriate action.	Thank you for your comment. The word "consider" is used here to indicate a recommendation not backed by strong evidence, as described in "Developing NICE guidance: the Manual". The expectation is that the sleep service will carry out the diagnosis so the individual will be at the best place for assessment and no onward referral would be necessary.
University Hospitals Birmingham NHS Foundation Trust	Guideline	008	018	We agree that symptomatic patients with mild OSA should be offered treatment.	Thank you for your comment
University Hospitals Birmingham NHS Foundation Trust	Guideline	008	025	We do not think it is necessary to monitor patients for 12 months to determine whether or not they are compliant. We agree that patterns of compliance are established early. We suggest "12 months" be changed to "4-6 weeks". This decision should not be influenced by the committee's experience that tele-monitoring for 12 months is included in the price of the machine.	Thank you for your comment. The recommendation is to use telemonitoring for up to 12 months. The committee agreed that while a lot of people will be satisfactorily established in CPAP in a short time there will be others that need to be monitored for longer. The sleep service may decide to stop telemonitoring sooner when this is the case.
University Hospitals Birmingham NHS Foundation Trust	Guideline	009	020	We welcome the committee's advice to consider customised mandibular advancement splints as a treatment option for mild and moderate OSA patients. These are generally not provided by the NHS and we are concerned that the cost of private purchase will influence patient treatment choice. Does the committee have a view on NHS funding for MADs?	Thank you for your comment. The committee are not aware of the payment mechanisms for mandibular advancement splints. Commissioners might have to review this when implementing this guidance. It is anticipated that commissioners will review the guideline when deciding on what to fund and implement. The committee hope that by making the recommendation these will be funded on the NHS.

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University Hospitals Birmingham NHS Foundation Trust	Guideline	011	011	The committee has recommended consideration of positional modifiers despite the evidence for their use being scanty and the cost falling directly on the patient. If there is good evidence to support their use then they should be recommended and the treatment should be offered on the NHS. If there is not then we do not feel the treatment should be recommended.	<p>Thank you for your comment. The committee agree there was limited evidence. However, there was some evidence of a reduction of OSAHS severity in supine sleep and an associated fall in the number of apnoeas compared with no treatment, with no evidence of adverse effects. With this in mind and using their experience the committee agreed that they could be an option if other treatments were unsuccessful or not tolerated.</p> <p>It is anticipated that commissioners will review the guideline when deciding on what to fund and implement. The committee hope that by making the recommendation these will be funded on the NHS.</p>
University Hospitals Birmingham NHS Foundation Trust	Guideline	012	002	The committee has recommended consideration of tonsillectomy. Given that tonsillar oedema in untreated OSA is common and can be marked, should consideration of tonsillectomy occur only after the establishment of successful non-surgical treatment of OSA?	<p>Thank you for your comment. The committee discussed that all people eligible for tonsillectomy be individually judged based on patient anatomy. This is because tonsillar hypertrophy may interfere with CPAP compliance and adherence as pressure requirements may be much higher in some of these people where the oropharynx is compromised.</p>
University Hospitals Birmingham NHS Foundation Trust	Guideline	012	004	Oropharyngeal surgery for OSA is widely available but seems to have limited surgical success rates. Bi-maxillary advancement surgery is less widely available but seems to have a higher surgical success rate. Why did the committee recommend the former but not the latter?	<p>The recommendations are based on reviews of the available evidence, and only recommend those demonstrated to be clinically and cost effective. Oropharyngeal surgery was found to be effective in people with moderate or severe OSAHS who are unable to tolerate or adhere to CPAP and mandibular advancement splints. There were some adverse effects associated with surgery, but the committee agreed that they were not clinically significant. The quality of the evidence was taken into account in the interpretation of the evidence. This is detailed in the committee's discussion of the evidence in the evidence review.</p> <p>There was no evidence available for other types of surgery including bi-maxillary/maxillo-mandibular advancement surgery and therefore the committee did not make any recommendations for these. A research recommendation has been made to inform future updates of this guideline.</p>

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University Hospitals Birmingham NHS Foundation Trust	Guideline	013	010	There is little mention of treatment limitation or treatment withdrawal in the guideline. We consider there should be explicit guidance on when to withdraw treatment, especially in the light of non-compliance.	<p>Thank you for your comment. We have added a recommendation stating: 1.9.11 Consider stopping treatment if OSAHS may have resolved, for example with significant weight loss. After stopping treatment, re-evaluate any return of symptoms and consider a sleep study after at least 2 weeks without treatment.</p> <p>The committee did not make a recommendation on the withdrawal of treatment for CPAP. Other interventions (oral devices, positional modifiers and surgery) are recommended when CPAP is not working or poorly tolerated (which may be a reason for non-compliance). The committee also make recommendations to support adherence that can be tried if people are not managing to use their devices properly.</p> <p>The committee agreed it is difficult to define when treatment should be withdrawn. This was not an area included in the scope of the guideline and clinical judgement will need to be used to decide whether to stop treatment if none of the offered treatments seem to work, including for non-compliance.</p>
University Hospitals Birmingham NHS Foundation Trust	Guideline	013	016	We do not think there is any medical value in annual follow-up. We consider that all patients should be discharged from the service once stable and treated or once it becomes apparent that treatment has failed/not been tolerated.	<p>Thank you for comment. The committee believe it is good practice to check that all is working. The committee do not think that GPs could deal with all the potential queries should patients be discharged. The treatment may need some adaptation to the mask, filters or machines and the committee believe the sleep service is the best place for this to happen.</p> <p>The committee do not mandate annual follow up rather ask clinicians to consider it.</p>
University Hospitals Birmingham NHS Foundation Trust	Guideline	013	021	Given the follow-up recommendations for OSA patients treated with MADs, does the committee have any views on the integration or co-location of medical and dental sleep services?	<p>Thank you for your comment. The committee have not been asked to comment on service delivery within the guideline so have not considered this point.</p>

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University Hospitals Birmingham NHS Foundation Trust	Guideline	014	018	The DVLA requires follow-up of patients at annual/3yrly intervals, depending on licence class. We consider that adequately treated patients no longer have a medical need for follow-up. In addition there simply is not the capacity for it. The DVLA's requirement is a matter of occupational health and is not the proper concern of the NHS. We consider that spending public money on this, especially given the current strains on the NHS, is not justifiable.	<p>Thank you for comment. The committee believe it is good practice to check that all is working. The committee do not think that GPs could deal with all the potential queries should patients be discharged. The treatment may need some adaptation to the mask, filters or machines and the committee believe the sleep service is the best place for this to happen.</p> <p>The committee do not mandate annual follow up rather ask clinicians to consider it.</p>