Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16 May 2018 to 13 June 2018

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Acurable Ltd.	**1**	27	While many UK sources report a prevalence of 5% of adult population, the most recent European reports estimate that " ***Obstructive sleep apnoea (OSA) is probably the most common respiratory disorder, with recent data from the United States and Europe suggesting that between 14% and 49% of middle-aged men have clinically significant OSA."1*** Indeed, UK only studies confirm that: "Recent evidence suggests that 85% of people with OSA in the UK are undiagnosed and therefore untreated (NHS North of England Specialised Commissioning Group, 2012)." (Obstructive Sleep Apnoea Health Economics Report, Consulting report for the British Lung Foundation, 2014) Please note that this source is somewhat out of date. 1 Epidemiological aspects of obstructive sleep apnoea, John F. Garvey, 1 Department of Respiratory Medicine, Galway University Hospitals, Galway, Ireland	Thank you for your comment. We have used the estimate most commonly cited although we acknowledge there is uncertainty around the true figures for obstructive sleep apnoea. The purpose of this section is to briefly introduce the condition.
Acurable Ltd.	**2**	31	There is a bi-directional relationship between the co-morbidities listed in the draft document and OSA. There is evidence that some of these comorbidities could be caused by OSA. Additionally: "Sleep apnoea is a common comorbidity in patients with interstitial lung disease as recognised by recent idiopathic pulmonary fibrosis (IPF) guidelines" 2. Finally, in a 2017 large multicentric study, the European Sleep Apnea Database (ESADA) explored the relationship between OSA and Cancer. The study found that there was an association between OSA (AHI cutoff 5) and a prevalent cancer diagnosis but only in patients aged below 50 years. 3 2 Raghu G, Rochwerg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: treatment of idiopathic pulmonary fibrosis. An	Thank you for this information. We will consider this when we do the reviews on the identification of sleep apnoea. The purpose of this section is to briefly introduce the condition and is not necessarily exhaustive.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			Update of the 2011 Clinical Practice Guideline. Am J Respir Crit Care Med 2015; 192: e3–19. 3 OSA and cancer in Europe: the European Sleep Apnea Database (ESADA) experience, European Respiratory Journal 2017 50: OA3209; DOI: 10.1183/1393003.congress-2017.OA3209	
Acurable Ltd.	6-7	168-171	When evaluating the potential diagnosis strategies, both from a clinical and cost-effectiveness perspectives, we would like the NICE panel to review the evidence for Acurable's AcuPebble diagnosis tool. Acurable is currently in the process of gaining regulatory approval for CE marking. AcuPebble is planned to be commercially available as a medical device in 2019. AcuPebble is the first wearable device that can measure accurately (i.e. with positive Signal to Noise Ratio in all possible scenarios) respiratory acoustic signals. From those acoustic signals it identifies respiratory rates and apnoea events, and automatically calculates the AHI (Apnoea-Hypopnoea Index), which can consequently be used to diagnose sleep apnoea. AcuPebble consists of a reusable sensing device, of approximately the size of a 10p coin, which attaches to the neck with a disposable adhesive. The sensor is used in combination with a very attractive and easy to use mobile app. A pilot clinical study showed that AcuPebble achieved 90% automatic apnoea detection agreement with specialist sleep consultant (who would base the diagnosis using the gold standard PSG). In comparison, the	Thank you for this information. The list of tools in the scope is not intended necessarily to be exhaustive. The guideline committee will discuss any potential additional tools or criteria at the protocol setting stage.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			automatic software of the state-of-the art polysomnography system used only achieved 12% agreement. 4 A large clinical trial for CE marking is starting in June 2018. This "Clinical evaluation of a wearable sleep diagnosis technology", (IRAS ID: 225818) has already received Ethics Approval and MHRA approval. This is planned to start at the Royal Free NHS Hospital, under the supervision of the chief investigator, and respiratory physician Dr Swapna Mandal. **What are the potential implication for NICE guidelines and benefits to the NHS?** 1) Clinical benefits: The pilot study showed that AcuPebble is up to 7 times more accurate in automatic event interpretation than the software of commercially available, clinically used systems. We anticipate that the results of the large clinical study will further validate this conclusion. 2) Cost-effectiveness benefits: Because the device is non-invasive an extremely easy to use, it reduces the existing bottleneck of having a patient sleep in a sleep clinic and needing a sleep specialist to manually interpret the sleep study data. With AcuPebble, the patient can go home to do the sleep study and the sleep test does not require specialist assistance to interpret the signals collected, lowering the total cost of diagnosis. It also enables remote diagnosis, if the patient lives far away. Doctor can mail the sensor to the patient and remotely access all patient's metrics. Patient training is not required because the system has a mobile app that takes the patient step by step through the process of using the system. 3) Patient experience benefits: AcuPebble is the size of a 10p coin and very easy to use. Once applied to the neck, it is easily	

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			forgotten, which means the patient can sleep undisturbed, in their own bed. In addition, this test can potentially save multiple trips to the hospital, hence reducing the burden to the patients who live far from a specialist clinic. 4 A pilot study of a wearable apnoea detection device Rodriguez-Villegas E, Chen G, Radcliffe J, et al A pilot study of a wearable apnoea detection device BMJ Open 2014;4:e005299. doi: 10.1136/bmjopen-2014-005299	
Acurable Ltd.	General	General	Although AcuPebble is not yet commercially available, we would like NICE to review the clinical and economic evidence available in 2019. We would be happy to provide all the evidence we have to date. We believe that AcuPebble is a revolutionary technology that can save money to the NHS and improve patient experience, whilst solving one of the biggest challenge faced by NHS: the challenge of diagnosing OSA in the UK.	Thank you for this information. The list of tools in the scope is not intended necessarily to be exhaustive. The guideline committee will discuss any potential additional tools or criteria at the protocol setting stage. Any evidence considered would need to fit the review protocols and be publically available to be used as evidence in the guideline.
British Dental Association	2	45	The BDA welcomes the recognition of the importance of experienced clinical teams. However, we believe this should be explored further in the scope, which should include consideration of the clinical and cost effectiveness of managing patients within both a Managed Clinical Network (MCN) and a multidisciplinary team (MDT). Key areas covered in section 3.3 on page 4 should include how MCNs and MDTs function – members, training, audit, primary vs. secondary care setting. Not every patient would need to see every member of a MDT, but evidence for the most efficient and effective ways to diagnose and treat patients should be assessed.	Thank you for your comment. The scope aims to address the issues of care delivery in questions on how diagnosis should occur and how monitoring should occur. Recommendations from these reviews may determine where patient management would need to occur. However, how clinical networks and multi-disciplinary teams should function in terms of members, training and audit has not been prioritised for inclusion in the scope of this guideline.
British Dental Association	7	181	We note that the scope will consider the design and cost-effectiveness of mandibular advancement devices (MADs). As the provision of such a device requires a dental impression to be taken, it falls within the practice of dentistry. Although a few such devices are provided in hospital dental units, most are provided privately by dentists, with varying cost, design,	Thank you for this information. Resource implications will be considered by NICE if these devices are found to be cost effective.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			quality and level of training of the providers. We would caution that problems of capacity and funding will arise if MADs are found to be cost-effective for NHS provision, in addition to an issue with training of dentists at both undergraduate and postgraduate level; deaneries are reluctant to deliver training for a procedure which, at present, is largely provided privately in primary care	
British Dental Association	7	193	NICE should scope the evidence around auditing of outcomes of treatment, and provide advice on who should do this and how it should be funded.	Thank you for your comment. This is outside of the remit of the guideline. NICE will produce a quality standard which will cover some aspects of the recommendations.
British Society for Heart Failure	6	160	"In whom should obstructive sleep apnoea/hypopnoea syndrome be suspected (based on symptoms or coexisting conditions)? Symptoms: Gender-related differences in symptoms of patients with suspected obstructive sleep apnoea hypopnoea syndrome should be given consideration. Women with obstructive sleep apnoea hypopnoea syndrome often present with more generalised symptoms, including depression, fatigue, lack of energy or insomnia. Less frequent reporting of common obstructive sleep apnoea hypopnoea syndrome symptoms such as snoring and sleepiness, and increased reporting of atypical symptoms, could therefore contribute to the under recognition of obstructive sleep apnoea hypopnoea syndrome in women and consequently lower referral rates to sleep disorder services. Consideration of these gender related differences in clinical presentation is likely to contribute to increased awareness and improved diagnosis, therefore ensuring equitable access to diagnosis and treatment.	Thank you for this information. The guideline committee will consider this when the review protocols are set.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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British Society for Heart Failure	6	160	"In whom should obstructive sleep apnoea/hypopnoea syndrome be suspected (based on symptoms or coexisting conditions)? Coexisting conditions: Patients with heart failure should be considered as high risk of comorbid obstructive sleep apnoea. Despite the high prevalence of obstructive sleep apnoea in patients with heart failure, identification of obstructive sleep apnoea is challenged by the fact that patients with heart failure may present with less typical symptoms of sleep apnoea, such as fatigue or insomnia, rather than sleepiness. In addition, an overlap of symptoms between chronic heart failure and obstructive sleep apnoea (for example fatigue and nocturia), may contribute to the presence of obstructive sleep apnoea being overlooked as symptoms of heart failure.	Thank you for this information. The guideline committee will consider this when the review protocols are set.
British Society for Heart Failure	6	161	"What assessment scales should be used if obstructive sleep apnoea/hypopnoea syndrome is suspected (for example, the Epworth sleepiness scale, STOP-Bang sleep apnoea questionnaire or Berlin questionnaire)? • Patients with heart failure and co-existing obstructive sleep apnoea are less sleepy than patients without heart failure. The use of the Epworth sleepiness scale as a single measure/tool will therefore not be effective in this high-risk sub population. • The STOP-Bang questionnaire is easy to use, high methodological quality and has been validated in a sleep clinic and surgical population. The questionnaire has proven useful in the surgical population, but from a general perspective, the sleep clinic population has a high pre-test probability, hence limiting	Thank you for this information. The guideline committee will consider this when the review protocols are set.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			the ability to determine the utility of the questionnaire in an unselected population.	
British Society for Heart Failure	General	General	A good, comprehensive scope addressing key clinical questions. Obstructive sleep apnoea is associated with cardiovascular events and due to the high prevalence in patients with heart failure, it is of specific relevance and interest to the heart failure community. Obstructive sleep apnoea remains significantly under diagnosed in this patient group often due to challenges around the initial identification of comorbid obstructive sleep apnoea in heart failure. Many patients with heart failure may present with atypical symptoms rather than sleepiness per se. If these patients are missed on initial identification, many patients that could benefit from assessment and treatment, would remain undiagnosed with further cost-implications for the NHS. It would therefore be helpful if the guidance could address this under presentation and initial identification.	Thank you for your comment. The guideline will consider in what groups of people OSAHS should be suspected. This may include populations with heart failure however, this level of detail will be agreed upon, based on the expertise of the guideline committee, at the protocol setting stage of development
British Society of Dental Sleep Medicine	General	General	*Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?* • Mandibular advancement appliances [acknowledged in draft consultation document] • Role of dentistry in aiding screening and identification of sleep disordered breathing • The role of mandibular advancement appliances in failed CPAP	Thank you for this information.
British Thoracic Society	4	96	We are surprised about the inclusion of rhinitis and emphasis on this, given this does not typically feature in clinical practice in most patients	Thank you for your comment. Taking into account all feedback on the scope document and at the workshop stage, it appears

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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				there is sufficient reason to include a question on rhinitis management.
British Thoracic Society	7	189	3.6 – Should health economic outcomes be listed here also?	Thank you for your comment. The guideline technical team routinely looks for health economic evidence for all questions.
British Thoracic Society	General	General	The British Thoracic Society is grateful for the opportunity to comment on the draft scope of this guideline. In general the scope is appropriate and we have no substantive comments. Minor points are mentioned below.	Thank you for your comment.
Dr Shaza Zackaria	6	157	This part focuses on Identification and Assessment of people with suspected obstructive sleep apnea/hypopnea. Whereas, when it comes to referral, there is no explanation on why and how will the suspected/identified cases will be referred and what are the tools of referral.	Thank you for your comment. The questions we have drafted in this section aim to address who is at risk and therefore who should be referred for assessment. The subsequent questions will aim to determine which treatments are effective in specific patient groups and that this in turn will give an indication of an individual's subsequent management.
Dr Shaza Zackaria	General	General	It seems to cover almost all aspects of sleep disordered breathing. A Great work is clearly done in this draft.	Thank you for your comment.
Dr Shaza Zackaria	General	General	Since the guideline is focused on several groups along with Health care professionals, i.e. the public and people using services and their families, there is no focus on the language that will be used to design this guideline .In my opinion the language used needs to be user friendly and free of medical jargon. This point might help the guideline to be well read and easily understood.	Thank you for your comment. NICE always endeavours to keep documents as digestible as possible. These principles will apply to the guideline and the recommendations.
ENT UK	1	21	Complete or partial obstruction may be due to obvious anatomical abnormality which can be identified by performing a formal and thorough assessment with a flexible endoscope. Thus input in diagnostic and management may necessitate referral to ENT	Thank you for your comment. The purpose of this section is to briefly introduce the condition and is not necessarily exhaustive.
ENT UK	2	48	CPAP is indeed very effective but CPAP failure constitutes a largish proportion of patients. CPAP failure may be due to obstructive upper	Thank you for this information. Surgery is included as a possible treatment option in the scope.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			airway and these patients may benefit from an ENT opinion. Surgery may be adjunctive or curative	
ENT UK	2	51	Mandibular advancement devices do work well but in some individuals who have difficulty breathing through the nose may find it difficult to tolerate. Again, some of these patients may benefit by seeing ENT surgeons to endoscopically evaluate the nasal passage.	Thank you for this information. We have added to this bullet point that surgical intervention may an option.
ENT UK	4	96	Treatment of rhinitis needs sub-division in medical and surgical	Thank you for your comment. Taking into account all feedback on the scope document and at the workshop stage, it appears there is sufficient reason to include a question on rhinitis management.
ENT UK	4	97	Upper airway surgery needs a somewhat broader division - broadly speaking soft tissue surgery needs to be distinguished from more aggressive skeletal framework surgery such as bilateral maxilla-mandibular advancement. Furthermore, minimally invasive radiofrequency surgery for milder sleep disordered breathing needs to be compared to more radical palatal surgery with various modifications. Trans-oral robotic surgery has allowed to address more challenging anatomical structures such as the base of tongue and epiglottis in patients who have failed CPAP. Similarly, Hypoglossal nerve stimulations has been shown to be effective in long-term.	Thank you for this information. The guideline committee will discuss and agree the precise interventions under consideration at the protocol setting stage of the relevant evidence reviews.
ENT UK	6	167	In terms of diagnostics, evaluation of upper airway is critical and especially so in patients who fail CPAP therapy or oral appliances so should be included. The ENT surgeon is well trained in utilising the rigid and flexible endoscopes and in evaluating the anatomical segment causing the upper airway obstruction	Thank you for your comment. The guideline committee will consider this when the review protocols are discussed.
ENT UK	10	243	The overview flowchart could be more comprehensive if the above comments are considered and the pathway the "failed CPAP and oral	Thank you for your comment. This is a diagrammatic overview of the guideline and not meant to represent a patient pathway.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			appliance patients" would follow may have an added arm of upper airway evaluation by ENT referral	An algorithm is usually created along with the guideline. The content of this will depend on the recommendations made.
ENT UK	General	General	Surgical Intervention for CPAP failures needs serious consideration and a two prong approach is suggested: firstly, upper airway surgery is conducted to improve airway dimensions and thus facilitate CPAP therapy perhaps by reducing the pressure requirement. Secondly, in carefully selected patients upper airway surgery may alleviate the need of CPAP therapy. Patient selection is crucial and in particular the evaluation of the obstructive upper airway during sleep is essential – this is performed using drug induced sleep endoscopy.	Thank you for this information. Upper airway surgical interventions will be considered in this guideline.
ENT UK	General	General	The role of ENT surgeons in evaluating and rectifying the obstructive upper airway is useful and therefore they should be included and involved more substantially in order to apply a truly multi-disciplinary approach to sleep disordered breathing.	Thank you for your comment. Surgery is included as an intervention in the scope.
Faculty of General Dental Practice	2	51	In the health systems of many other developed countries - often with more numerous and more integrated diagnostic and care pathways than the NHS - oral appliance therapy is used as both a diagnostic tool and as a primary and secondary management strategy. This is especially the case for patients where OSA is mild, or those with simple OSA where continuous positive airway pressure (CPAP) is poorly tolerated. As above, an example can be seen in the Dutch national guideline on managing OSA, which emphasises the use of oral appliances, and can be accessed at: https://www.ncbi.nlm.nih.gov/pubmed/20446552. Also as above, the American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine produce a clinical guideline on the treatment of OSA with oral appliances. The full guideline can be viewed at	Thank you for this information. The guideline committee will consider evidence from all settings that are applicable and relevant to the NHS.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			https://aasm.org/resources/clinicalguidelines/oral_appliance-osa.pdf, and a summary https://aasm.org/aasm-and-aadsm-issue-new-joint-clinical-practice-guideline-for-oral-appliance-therapy/. The AASM and AADSM have also developed a highly pertinent position statement providing detailed clarification on the respective roles of dentists and physicians in the diagnosis and treatment of OSA using oral appliances, available at https://aasm.org/resources/pdf/aadsmjointosapolicy.pdf. We would also encourage the guideline development group to consider the pathways and evidence in relation to Belgium, Germany and the Scandinavian countries.	
Faculty of General Dental Practice	2-3	35-62	In the 'Current Practice' section, no mention is made of the increasing number of patients who self-diagnose, or are persuaded by their partners to seek help – in many cases from their dentist. GDPs also receive referrals from General Medical Practitioners (GMPs), ENT surgeons, respiratory physicians and other healthcare practitioners to help manage a patient's snoring, which is a common symptom of OSA. In view of the public's growing ability to access information and increasing willingness to seek answers to health queries from all healthcare providers, and in line with the intention that all settings in which NHS-commissioned care is provided will be covered by the guidance (page 4, line 87), we would urge the guideline development group to consider GDPs when developing guidance on making referrals for the treatment of OSA.	Thank you for this information. The scope outlines initial assessment and referral as areas the guideline committee will seek to address. We have added to section 2 that the guideline may also be relevant to non-NHS healthcare professionals making a referral to NHS commissioned services. Thank you for your reference, the scope outlines adherence as a question for consideration (draft question 3.7).

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			In order to ensure that patients with suspected OSA are referred correctly, GDPs will need to be advised to whom they should make referrals, and the type of information which it may be helpful to supply to the receiving healthcare practitioner. To enable better patient identification, it may also be helpful to make GDPs and other healthcare practitioners aware of the symptoms which patients with OSA may present with (even when snoring is not proactively mentioned by the patient). The guideline development group should also be aware of the growing number of GDPs and orthodontists trained to treat and manage OSA through the use of oral appliance therapy. The group may also be interested in this study of non-clinical factors affecting the use of oral appliance therapy in the treatment of OSA: Espeland, A, 2016, Impediments and facilitators for cooperation between dentists and medical specialists in obstructive sleep apnoea treatment: a qualitative study (available at: https://www.duo.uio.no/handle/10852/52668).	
Faculty of General Dental Practice	3	65	Many GDPs (and indeed GMPs) do not provide NHS services, or provide limited NHS services, but they are still able to make referrals to NHS services where necessary, and their patients will still access NHS services in other healthcare settings. Where these GDPs have patients who require or request management of OSA, it may be appropriate for GDPs to make a referral to NHS services, and they should be encouraged to follow national guidelines in so doing.	Thank you for your comment. We have added "Non-NHS healthcare professionals making a referral to NHS commissioned services" as a bullet point to this section.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			We would therefore recommend that line 65 be amended to read "Healthcare professionals providing **or making a referral to** NHS-commissioned services."	
Faculty of General Dental Practice	4	87	As per comment 6, many GDPs do not provide NHS services, or provide limited NHS services, but they are still able to make referrals to NHS services where necessary, and their patients will still access NHS services in other healthcare settings. Where these GDPs have patients who require or request management of obstructive sleep apnoea, it may be appropriate for them to make a referral to NHS services, and they should be encouraged to follow national guidelines in so doing. We would therefore recommend that line 87 be extended to read "All settings in which NHS commissioned care is provided**, or from which referral to NHS services may be required**."	Thank you for your comment. NICE guidelines are written for NHS services. We have added that it may also be relevant for "Non-NHS healthcare professionals making a referral to NHS commissioned services" under the section on 'who the guideline is for'.
Faculty of General Dental Practice	4	99	While we are pleased to see the inclusion within the draft scope of mandibular advancement devices, they are not the only form of effective or appropriate oral appliances or devices that can be used. Due to anatomical or other reasons, a small number of patients may better tolerate, or otherwise derive greater benefit from, tongue-retaining or palatal positioning devices. We would recommend that such devices be included within the scope, and that the reference to mandibular advancement devices be amended to read "mandibular advancement devices **and other therapeutic oral appliances and devices**".	Thank you for your comment. This has been amended to oral devices.
Faculty of General	6	147	We would urge the development group, in its consideration of economic aspects, to consider the economic models in European health systems,	Thank you for this information. The guideline committee will consider the international evidence with regard to both

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Dental Practice			and in particular the evidence relating to the wider use of home monitoring and oral appliances both as diagnostic tools and in active management of OSA. The value of simple polygraphic monitoring as an adjunct to in-hospital polysomnography has recently been highlighted in the European Respiratory Review (Vol 26, Issue 143: Verbraecken, J, Hedner, J, Penzel, T, 2017, Pre-operative screening for obstructive sleep apnoea. Available at: http://err.ersjournals.com/content/26/143/160012).	monitoring and management, should it meet the agreed review protocols.
Faculty of General Dental Practice	6	167	We would encourage the development group, in its consideration of diagnostic strategies and monitoring proposals, to look at the home recording systems, used abroad and in the UK as an adjunct and support to current hospital-based polysomnography services, which combine oximetry, digital noise sampling and respiratory effort. As above, the value of simple polygraphic monitoring as an adjunct to in-hospital polysomnography has recently been highlighted in the European Respiratory Review (Vol 26, Issue 143: Verbraecken, J, Hedner, J, Penzel, T, 2017, Pre-operative screening for obstructive sleep apnoea. Available at: http://err.ersjournals.com/content/26/143/160012).	Thank you for your comment. The guideline committee will consider this when the review protocols are set.
Faculty of General Dental Practice	General	General	The Faculty of General Dental Practice (UK) is the only professional membership body in the UK specifically for general dental practice. Based at the Royal College of Surgeons of England, our mission is to positively influence oral health through education of the dental profession and the provision of evidence-based guidance.	Thank you for your comment.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Faculty of General Dental Practice	General	General	We welcome the development of this guidance, its recognition of the importance of the conditions covered to a patient's wider health, and the opportunity to comment.	Thank you for your comment.
Faculty of General Dental Practice	General	General	We would like to make the guideline development group aware that guidance on the management of obstructive sleep apnoea (OSA) is already provided for general dental practitioners (GDPs) by the British Society of Dental Sleep Medicine (https://bsdsm.org.uk) and the European Academy for Dental Sleep Medicine (https://www.eadsm.eu/). This guidance is currently under review in conjunction with standard-setting bodies within the UK dental profession. We would also like to highlight the Dutch national guidance (see https://www.ncbi.nlm.nih.gov/pubmed/20446552), as well as that developed by the American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine (see https://aasm.org/resources/clinicalguidelines/oral_appliance-osa.pdf). A summary of the AASM-AADSM guideline is available at https://aasm.org/aasm-and-aadsm-issue-new-joint-clinical-practice-guideline-for-oral-appliance-therapy/. The AASM and AADSM have also developed a highly pertinent position statement providing detailed clarification on the respective roles of dentists and physicians in the diagnosis and treatment of OSA using oral appliances, available at https://aasm.org/resources/pdf/aadsmjointosapolicy.pdf.	Thank you for your suggestions. We will look at these guidelines.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Hope2Sleep	2	38	States "diagnosis is made by monitoring breathing during sleep" However, there are clinics that rely on pulse oximetry only, and many people miss being diagnosed.	Thank you for this information. The scope includes questions aimed at addressing this variability.
Hope2Sleep	2	42	Agree the management can be patchy in certain areas. As a sleep disordered breathing charity we come across many people who have had to fight for CPAP therapy with an AHI below 15, who have experienced positive changes to their lives once on CPAP.	Thank you for this information.
Hope2Sleep	2	51	Often when oral mandibular advancement devices are recommended, they are not supplied on the NHS. Also, we hear too often that people are told to lose weight when appropriate. It is not possible in most cases to prove whether losing weight will cure sleep apnoea as there are many people who started out as slim snorers and the untreated sleep apnoea caused or exacerbated their weight gain. Furthermore, it is very difficult for people with untreated sleep apnoea to lose weight due to a slow metabolism and sheer exhaustion. However, once on CPAP therapy, losing weight usually becomes much easier.	Thank you for this information. We will consider these points when discussing potential recommendations related to treatments.
Hope2Sleep	2	55	Before bariatric surgery is considered, it would be advisable to offer CPAP therapy, as in many instances huge weight loss can be achieved when patients are treated for sleep apnoea. A combination of CPAP and weight management would be ideal. This is also important, due to the higher risks with anaesthetic.	Thank you for your comment. We will consider this when discussing potential recommendations in this area.
Hope2Sleep	2	58	Efficacy data when revealed to the patient definitely encourages compliance, as well as flagging up improvements patients can work towards, such as mask leaks and usage hours. Our experience in our support work indicates patients are more motivated in their own treatment with clinics who encourage this data. The only negative is that certain anxious patients may contact their clinics unnecessarily, which is why it's important to also encourage patients to join support groups provided by recognised reputable charities for sensible non-medical advice when	Thank you for this information. The scope outlines monitoring, adherence and information and support as areas for review.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			occasionally they may see a higher AHI which can happen for different reasons and are often easy to determine why, such as alcohol use, hot nights, allergies etc. Where it states effectiveness is not clear regarding data downloads and telemonitoring, it would be worth looking at the studies already carried out by at least 2 of the manufacturers, namely Philips Respironics and Resmed.	
Hope2Sleep	4	104	To improve adherence, it should be encouraged to join reputable support groups run by registered charities. Some clinics do offer walk-in patient support clinics, but these are few and far between. Although clinicians' intervention is required at times, most often the comfort aspects of CPAP is improved through conversations, tips and support from existing sufferers. It should also be noted that some clinics do not explain the importance to patients' health of why adherence is so important. Whilst the scaremongering of the DVLA rules have spurred people on to remain compliant with therapy, the more recent updates by the DVLA, whilst positive in some ways, will work against clinics encouraging compliancy.	Thank you for your comment. The guideline committee intends to address information and support needs of patients.
Hope2Sleep	4	105	Strongly agree more information and support should be offered to patients, their families and carers as to the seriousness of untreated sleep apnoea and signposting to reputable charities' support groups as previously mentioned.	Thank you for your comment.
Hope2Sleep	4	96	It is a good suggestion for an ENT consultation to examine the upper airways to see if the cause for obstructive sleep apnoea can be found, and in certain cases even resolved with treatment and/or surgery.	Thank you for your comment.
Hope2Sleep	4	98	Whilst it is perceived that CPAP is the gold standard treatment for sleep apnoea, other options should be explored as some people have simple positional sleep apnoea, mandibular devices can help with milder cases and other treatments could be explored such as the newer non-invasive electrical stimulation recently trialled by Guy's & St Thomas' Hospital.	Thank you for your comment. Interventions other than CPAP are to be covered in the guideline, as outlined in the scope.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Hope2Sleep	4-5	114	Sad to see management of central sleep apnoea and other disorders such as hypoventilation will not be included, bearing in mind both CPAP and non-invasive ventilation therapy are so similar and produce the same problems, especially regarding comfort.	Thank you for your comment. The scope was focused to obstructive sleep apnoea as this is the most common disordered breathing condition. We have expanded the scope to include obesity hypoventilation and overlap syndrome (i.e. obstructive sleep apnoea and COPD overlap). Other types of sleep apnoea would need different, separate guidelines.
Hope2Sleep	6	159	BOTH existing symptoms AND co-existing conditions should warrant investigations for sleep disordered breathing.	Thank you for your comment. The aim is to cover both in the review question.
Hope2Sleep	6	161	All the relevant screening questionnaires have flaws that cause diagnoses to be missed, so if questionnaires are necessary then they should all be used, but ideally a simple cheap home screening kit, measuring both breathing and oxygen levels, could be issued - perhaps even by a GP	Thank you for this information. The guideline committee will consider this when the review protocols are set.
Hope2Sleep	6	165	Drivers of public transport and pilots should be prioritised - as should patients who have already suffered a heart attack or stroke and ideally anyone suffering severely from mental/emotional problems, which we know sleep deprivation exacerbates.	Thank you for your comment. The review aims to address this question.
Hope2Sleep	6	168	Pulse oximetry can almost prove if a person has sleep apnoea, but it cannot disprove that a patient is not having breathing events with their bodies working hard to maintain their oxygen levels. This would have the same negative consequences on the heart and other organs, so is, therefore, an unreliable form of diagnosing and lets many patients down. Home sleep studies would be more cost-effective and give a better assessment of a 'normal' night's sleep in a patient's own bed, with hospital sleep studies being reserved for more complicated cases or insufficient data from a home study.	Thank you for your comment. The guideline committee will consider this when the review protocols are set.
Hope2Sleep	6-7	173-183	The clinical effectiveness of all the suggestions would be worth pursuing when applicable, in an effort to both improve the severity of sleep apnoea and also in most of the points suggested to ease the comfort aspects of	Thank you for your comment. The guideline committee will consider all interventions listed in the scope and make recommendations where evidence allows.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			therapy. This would have a knock-on effect on the cost effectiveness as compliance would be higher and some people may be cured.	
Hope2Sleep	7	184	It would make sense for clinics to have the resources to be able to offer variable pressure CPAP to all patients as it is a known fact (from our angle of supporting patients) that a high percentage of patients fare better on variable pressures which is why their CPAP trial is often more successful than their long-term therapy (in patients who are swapped to fixed pressure CPAP). For the smaller percentage of patients that are treated successfully with fixed pressure, then the issued machine could simply have the settings changed to fixed. All variable pressure machines also store efficacy data which would help clinics monitor patients more easily and would encourage patients themselves to work hard at maintaining or improving their therapy. This in turn would help with costs as patients struggling on higher fixed pressures are more likely to be compliant. Pressure should be put on manufacturers to lower the prices of variable pressure machines, or perhaps this would be a natural course if hospitals were purchasing them in greater supply and production could even cease of fixed pressure machines.	Thank you for this information. This will be considered by the guideline committee when we discuss the evidence.
Hope2Sleep	7	189	Humidification should be offered far more than it is, as often patients are unaware humidifiers are available, and most patients greatly benefit from this addition.	Thank you for your comment. This review question seeks to address the effectiveness of this intervention.
Hope2Sleep	7	192	Without a doubt, patients who are signposted to or 'stumble across' reputable support groups gain improved adherence. Sleep disordered breathing patients can feel isolated currently, due to the fact that most people remain undiagnosed, so being in the midst of other sufferers, supporting each other, raises motivation for adherence.	Thank you for your comment. The guideline committee will review the evidence and make recommendations as appropriate.
Hope2Sleep	**7**	194	In most cases, efficacy is adequate via variable pressure CPAP, but the important thing is that titration IS carried out and guessed pressures, relying on symptoms only, should not be continued, which is happening in	Thank you for this information. The guideline committee will consider this when they review the evidence in this area.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			some clinics who struggle more with resources. This very often involves patients suffering unnecessarily, despite CPAP usage and also warrants further appointments with their hospitals.	
Hope2Sleep	**7**	196	We would assume it is more cost-effective to monitor patients via SD card downloads or telemonitoring, and it is possible this service could even be outsourced. There is scope for telephone consultations when necessary (if issues are flagged up on the compliance and efficacy data). Patients would then only need to visit the clinics for replacement supplies, or for any complications that arise.	Thank you for your comment. This review aims to address this question.
Hope2Sleep	**7**	202	It is crucial people are provided with information with a full explanation of what sleep disordered breathing is, and the consequences of not being treated. Many people require ongoing support, hence the 12K+ sufferers our charity already support and, therefore, it would benefit most patients if they were signposted to a reputable charity for support. This would also ease the pressure on the hospitals.	Thank you for your comment. The guideline is intending to cover information and support. .
Hope2Sleep	7	204	Patients, carers and families need information and support on the issues regarding driving (DVLA), managing their CPAP therapy and the comfort aspects, which is the biggest reason people will not remain compliant. Our charity work hard helping and supporting patients to be compliant with their therapy, and when people are aware of the true consequences of no treatment and are willing to be helped, we would estimate success in more than 94% of patients, and even those with multiple health issues whereby they occasionally don't even 'feel' the daytime benefits, but know they are protecting themselves from more damage!	Thank you for your comment. The guideline is intending to cover information and support, including advice on driving and treatment. We have also included a draft review question on what support improves adherence to CPAP or other interventions (draft question 3.7).
Hope2Sleep	General	General	We feel that CPAP and non-invasive ventilator Masks should be considered, as the correct mask is as important as the machine. There are many different masks available from all the manufacturers, and bearing in mind our faces are very individual, the correct mask is crucial.	Thank you for your comment. The questions outlined in the scope are drafts and the precise wording will be agreed upon with the guideline committee. The issue of masks as a component of CPAP efficacy will be discussed at the protocol setting stage and pending committee consensus and

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			Occasionally some clinics give out nasal masks, assuming it's possible for everyone to revert to nose breathing only, and likewise some clinics give out only full face masks, even to nose breathers. However, this is not always physically possible for some patients to nose breathe, even though nose breathing is healthier. Some clinics struggle with resources and have to limit patients to just one choice of mask from their selection, depending on whether they nose breathe or mouth breath. However, just like with shoes which will not give the same comfort to everyone's feet, not every mask will suit a person's face, and can also cause pressure sores, ugly deep lines which don't disappear and pain. This is one of the biggest causes of non-compliance as when sleeping with a mask for 7-9 hours it has to be as comfortable as possible. Furthermore, it is important that patients are measured and fitted for masks, and ideally whilst laid down and with the machine blowing air. A lot of NHS money is wasted when the wrong mask is issued, and people are having to resort to purchasing masks, which are extensive and not affordable to all.	prioritisation, may be addressed as part of the evidence reviews on CPAP.
Hope2Sleep	General	General	*Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?* Issue of a correct mask (as below). More patients diagnosed which would save money on the related medical conditions untreated sleep apnoea exacerbates or causes.	Thank you for your comment. The questions outlined in the scope are drafts and the precise wording will be agreed upon with the guideline committee. The issue of masks as a component of CPAP efficacy will be discussed at the protocol setting stage and pending committee consensus and prioritisation, may be addressed as part of the evidence reviews on CPAP.
Itamar Medical Ltd.	6	157	We would like to suggest that certain cardiac conditions would be included in any assessment scale.	Thank you for your comment. The guideline committee will discuss the exact outcomes for each review at the protocol

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			Epworth Sleepiness Scale (which is commonly used in the NHS), does not include medical comorbidities, and while other questionnaires (such as Berlin questionnaire) include hypertension; no assessment scale includes Atrial Fibrillation (AF) at all. There is growing evidence that Sleep Apnoea treatment improves AF outcome, and effectively reduces the risk of AF reoccurrence. The cost of AF treatment, mostly ablation procedures, is significantly higher than the cost of diagnosing and treating sleep Apnoea. Furthermore, the European Society of Cardiology (ESC) published new guidelines for management of Atrial Fibrillation in 2016 that include management of Sleep Apnoea in chapter seven therein – Detection and management of risk factors and concomitant cardiovascular diseases. Therefore, we suggest that Hypertension and Atrial Fibrillation will be included as independent risk factors in any assessment tool that is chosen. For reference please see: 1. European Society of Cardiology Guidelines for Management of Atrial Fibrillation 2016 (https://academic.oup.com/eurheartj/article/37/38/2893/2334964) (go to section 7.6 – Obstructive Sleep Apnoea) 2. Larry Chinitz et el JACEP Feb 2015 – Meta Analysis - Effect of Obstructive Sleep Apnea Treatment on Atrial Fibrillation Recurrence (http://electrophysiology.onlinejacc.org/content/1/1-2/41) 3. Anter et al, Circ Arrhythm Electrophysiol. 2017 - Atrial Substrate and Triggers of Paroxysmal Atrial Fibrillation in Patients With Obstructive Sleep Apnea (https://www.ncbi.nlm.nih.gov/pubmed/29133380)	setting stage but the impact of OSAHS and its treatment on co-existing conditions is a topic that will be discussed.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			4. Marin et al, JAMA 2012 – Association between treated and untreated Obstructive Sleep Apnea and Risk of Hypertension (https://www.ncbi.nlm.nih.gov/pubmed/22618924)	
Itamar Medical Ltd.	6	167	We would like to suggest the inclusion of Peripheral Arterial Tonometry (PAT) technology for diagnosis of Sleep Apnoea. PAT technology is well validated and accredited in the American Academy of Sleep Medicine (AASM) 2017 guidelines for Diagnoses of Sleep Apnoea. PAT based device is simpler to operate and use than most other ambulatory sleep study devices, yet offers a much more comprehensive output, such as Total Sleep Time and full Hypnogram. A major advantage of the PAT technology, is that it can be easily operated in primary care (i.e GP clinics), and thus save the need to refer patients to sleep centres for diagnosis of Sleep Apnoea. For reference please see: 1. Yalamanchali et al, JAMA Otolaryngol Head Neck Surg, 2013 – Diagnosis of Obstructive Sleep Apnea by Peripheral Arterial Tonometry: Meta Analysis (https://www.ncbi.nlm.nih.gov/pubmed/24158564) American Academy of Sleep Medicine Clinical Practice Guidelines – (https://aasm.org/resources/clinicalguidelines/diagnostic-testing-osa.pdf) (search "Peripheral" in page 487).	Thank you for your comment. The list of tools in the scope is not intended necessarily to be exhaustive. The guideline committee will discuss any potential additional tools or criteria at the protocol setting stage.
Lincoln Medical Ltd.	General	General	We would request that NICE considers the role and potential launches of pharmacological products (eg Pitolisant) for the treatment of OSA, where CPAP / MAD are not suitable, or have not benefited the patient and as such the patient is still experiencing Excessive Daytime Sleepiness (EDS) to impact on the patient's Quality of Life. These products are planned for launch before August 2020. Since this issue was discussed in full at the recent scoping meeting as one of the Top 3 priorities for consideration, we are disappointed not to see any reference to this in the consultation	Thank you for your comment. The overall feedback during the scope development was that, given the current stage of development of pharmacological products used for OSAHS, it would be better to leave this for consideration in future updates of this guideline.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			document. Not including these new therapies, would risk missing new cost effective interventions that improve patient outcomes not addressed by current therapies.	
Livanova PLC	2	48	Whilst continuous positive airway pressure (CPAP) is considered as a highly effective treatment, it should be noted that 30-40% (Weaver et al. 'Adherence to continuous positive airway pressure treatment for obstructive sleep apnoea: implications for future interventions', Indian J Med Res. 2010;131:245–58; Weaver et al 'Adherence to continuous positive airway pressure therapy: the challenge to effective treatment', Proc Am Thorac Soc. 2008;5(2):173–8.) of patients who, despite advances in CPAP technology and other techniques such as behavioural intervention, remain unable to adhere to this therapy (Rotenberg et al. 'Trends in CPAP adherence over twenty years of data collection: a flattened curve' Journal of Otolaryngology - Head and Neck Surgery (2016) 45:43). We estimate that the number of patients receiving CPAP therapy in England and Wales to be around 650,000 (based on an extrapolation from French and German population data) meaning that between 195,000 – 260,000 patients may be non-compliant with their therapy. Poorly managed or untreated moderate to severe obstructive sleep apnea (OSA) is a risk factor for resistant hypertension, fatal and non-fatal cardiovascular disease, neurological disease, and all-cause mortality (Young et al. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med. 2002; 165(9):1217–39.) We would welcome NICE's view on recent evidence that may support the use of innovative technology such as hypoglossal nerve stimulation in a sub group of patients who have failed CPAP and other treatment	Thank you for your comment. We will consider including adherence as an outcome to our review questions. We have also included a draft review question on what support improves adherence to CPAP or other interventions (draft question 3.7). NICE guidelines do not include reviews of technologies that are under special arrangement**s**. The NICE IPG on hypoglossal nerve stimulation has been added to the related guidance list. We have included reviews related to other treatment modalities in the guideline.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			modalities such as mandibular advancement devices or behavioural intervention.	
Livanova PLC	3	83	We would like see that this guideline consider the management of a sub-group of patients with moderate to severe OSA who are unable to adhere to CPAP or have failed other interventions early in the treatment pathway.	Thank you for your comment. The guideline committee will consider the impact of disease severity, in terms of treatment response, on a review by review basis.
Livanova PLC	4	95	We would welcome NICE's consideration of how to manage patients with moderate to severe OSA who do not respond to the treatments listed on lines 96-99.	Thank you for your comment. The guideline committee will consider the impact of disease severity in terms of treatment response, on a review by review basis.
Livanova PLC	5	117	Whilst later referred to on page, 9, under 'Related NICE Guidance' IPG598 'Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea' 2017, is not listed. Whilst under special arrangements' we believe it should be noted given the challenge and health risks associated with treating a sub-group of patients who are currently poorly managed. Further since NICE's IPG598 was published in 2017, there have been 29 publications of 23 unique studies concerning the clinical safety and efficacy of hypoglossal nerve stimulation. Of particular note is the long term follow up to the STAR study (Gillespie 2017, Woodson 2018) and publications related to the German post-marketing study (Hofauer 2017, Heiser 2017, Steffen 2018) and the ADHERE registry (Boon 2018, Zhu 2017).	Thank you for your comment. NICE guidelines to not include reviews of technologies that are under special arrangements. The NICE IPG on this technology has been added to the related guidance list.
Livanova PLC	6	165	We would welcome NICE's clinical guidance on how to address the management of a sub-population of moderate to severe OSA patients who have failed early interventions such as	Thank you for your comment. The guideline will seek to make recommendations on treatment sequences where the evidence allows. The guideline committee will consider during the protocol setting stage how best to approach the evidence for second-line options.
Livanova PLC	7	194	We would welcome the inclusion of quality of life measures such as SAQLI as a measure of efficacy.	Thank you for this information. Quality of life is a standard outcome for most reviews in NICE guidelines. SAQLI will be

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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				considered as a measure of this when we set the review protocols.
Livanova PLC	8	209	It would be worth considering adherence to treatment as a therapeutic outcome	Thank you for your comment. The guideline committee will discuss the exact outcomes for each review at the protocol setting stage. Adherence will be considered as an outcome to include. This list is an overview of the main outcomes and not meant to be exhaustive.
Livanova PLC	8	217	It would be of value to consider sleep specific QoL scales in addition to EuroQoL	Thank you for your comment. This list is not meant to be exhaustive. The guideline committee will discuss the exact outcomes for each review at the protocol setting stage. Sleep specific QoL scales will be considered.
NHS England	6-8	154-208	Should hypoglossal stimulation be in scope?	Thank you for your comment. NICE guidelines to not include reviews of technologies that are under special arrangements. The NICE IPG on this technology has been added to the related guidance list.
NHS England	General	General	NHS England warmly welcomes the development of these guidelines	Thank you for your comment.
NHS England	General	General	The guidelines cover adults and young people but not children. There are a significant number of children with OSA who will be excluded	The age limit of 16 is chosen because those aged 16 years and over would be managed in the same way as an adult, and usually on an adult ward. The management of the conditions covered by this guideline in people under 16 years is different to that of adults and would therefore need different guidance.
NHS England	General	General	The title of the guideline is sleep disordered breathing but only covers OSA. Hypoventilation, CSA and Cheyne-Stokes respiration, for example, seem to be excluded. Should the title just be OSA or the scope expanded?	Thank you for your comment. We have amended the title to "Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s" to reflect the main content of the scope. The guideline scope has been expanded to also cover the related conditions of obesity hypoventilation syndrome (OHS), and overlap syndrome (the co-existence of

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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				obstructive sleep apnoea/hypopnoea syndrome and chronic obstructive pulmonary disease).
OSA Partnership Group	4	96	We are uncertain about the relevance of rhinitis to the treatment of OSA as this is rarely a solution, however it may be an issue when CPAP therapy is started.	Thank you for your comment. Taking into account all feedback on the scope document and at the workshop stage, it appears there is sufficient reason to include a question on rhinitis management.
OSA Partnership Group	6	165	We believe that this needs to be clearer, perhaps with the addition of an example such as vocational drivers who depend on their licence for their livelihood, and for whom uncertainty over waiting times is, we know from experience, a barrier to coming forward for treatment. Furthermore, while we know that fast-tracked treatment is being adopted in many sleep centres in the UK, we would like the review to address a consistent national scheme that will provide vocational drivers with the reassurance and incentive they need to come forward. By doing this we believe that there will be cost savings within this group in both reduced healthcare utilisation for health issues associated with untreated OSA and in reduced road traffic accidents.	Thank you for this information. The aim of this question is to assess the evidence for anyone who should be prioritised. We have not added examples as this would be pre-empting the recommendation. One aim of NICE guidance is to create criteria, where evidence permits, that can be adopted widely, therefore reducing the variability you reference. The exact triggers for quicker referral will be agreed upon by the guideline committee following review of the relevant evidence.
OSA Partnership Group	General	General	The scope currently excludes reference to the significance of updating and maintaining consistent tariffs across UK sleep services. We feel this is important because the current system encourages a perverse incentive for centres to increase the number of appointments that patients attend. This is not only negative for NHS budgets but we know from experience that for those patients who need to take time off work, additional appointments can be a potential barrier to complying with treatment. Also with the advent of tele-monitoring the current tariffs are not appropriate and hold back connected care and other future advancements in treatment.	Thank you for your comment. NICE does not directly control tariffs. The guideline will seek to make recommendations about appropriate ways of delivering care and telemonitoring may be considered under monitoring strategies.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Primary Care Respiratory Society UK	3	68	Current wording: 'It may also be relevant for: Driver and Vehicle Licensing Agency (DVLA)' The scope document needs to be strengthened throughout so that there is appropriate coverage of the guidance people are given about driving from the time of suspected OSA through to ongoing treatment. Unclear guidance from DVLA has resulted in considerable difficulties for drivers under investigation for OSA, and it is essential that the guideline is clear about the importance of consistent advice to people on driving throughout the diagnostic and treatment processes. The guideline needs to be relevant for DVLA, to minimise the negative impact this area has been having on patient experience. We publicised the revised guidance to clinicians from the DVLA to our members in January 2018 as follows - https://www.pcrs-uk.org/news/new-dvla-guidance-assessing-fitness-drive-patients-sleep-apnoea The DVLA clarification: https://www.gov.uk/guidance/miscellaneous-conditions-assessing-fitness-to-drive#excessive-sleepiness--including-obstructive-sleep-apnoea-syndrome So guidance on driving should be incorporated into 'Key areas that will be covered' at line 89, and 'key issues and draft questions' at line 154. As per your Q2 above - Questions for inclusion could be: What advice should be given about driving to people who are suspected of having OSA? And	Thank you for your comment. Driving advice will be considered as part of the question on information and support needs.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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			What advice should be given about driving to people who have a firm diagnosis of OSA?	
Quality Team	General	General	Recommendation 1.14.2 in NICE guideline NG62 Cerebral palsy in the under 25s mentions recognising common sleep disturbances in this population including sleep-induced breathing disorders. This is not included in the published QS162 Cerebral Palsy but we have highlighted it as the guideline is not referenced in the scope as a related guidance. Please note that published QS71 Transient loss of consciousness ('blackouts') contains a statement on driving advice which may be significant to this topic in terms of DVLA advice and driving safety. The draft scope exclusions are not likely to limit the quality standard on sleep disordered breathing or other future QS topics.	Thank you for your comment. We have added a link to NICE guideline NG62 in the scope as related guidance. Thank you for pointing out the overlap with QS71. We will take this into account when making recommendations related to driving.
RCGP	2	36	In many areas, a completed Epworth questionnaire must be sent with the referral otherwise it will not be accepted (Peterborough, Bristol))	Thank you for this information.
RCGP	2	42	The scope should not only be financial "increased healthcare utilisation" but must look at the patient's viewpoint "increased multi-morbidity" if few words are required.	Thank you for your comment. We have amended this point to state "Failure to treat the condition can result in increased use of services and may leave people with reduced quality of life". We will look at a range of outcomes in our reviews.
RCGP	2	46	Not only respiratory medicine but also Ear Nose and Throat Surgery is often needed.	Thank you for this information.
RCGP	General	General	Addressing obesity: The draft mentions bariatric surgery but it should be extended to cover other obesity interventions such as Low energy liquid drinks (LELD) and support through Tier 3 obesity services.	Thank you for your comment. The management of obesity is covered in NICE guideline CG189, "Obesity: identification, assessment and management" (https://www.nice.org.uk/guidance/cg189). We will cross refer to this where appropriate in the sleep apnoea guideline. CG189 has also been added this to the list of related NICE guidance in the scope.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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RCGP	General	General	This draft scope does not consider mastery or social support in potentially improving sleep disordered breathing. Mastery refers to the extent to which patients see themselves as being in control of the forces that affect their lives. It may play an important role in perceived health status and well-being. Social support and mastery are important aspects in the treatment of chronic diseases, however their role in connection with Obstructive Sleep Apnoea (OSA) remains unclear. A study by Timkova et el (2018) examined the associations between social support, mastery, sleep-related problems and functional status in untreated OSA patients. All patients in this cross-sectional study completed the Multidimensional Scale of Perceived Social Support, the Pearlin Mastery Scale, the Pittsburgh Sleep Quality Index, the Epworth Sleepiness Scale and the Functional Outcomes of Sleep Questionnaire. Multiple linear regression and mediation analyses were used to analyse the data. Participants were 150 newly diagnosed OSA patients (Apnoea-Hypopnoea Index–AHI≥5; 68% male; mean age 48.9 ± 9.5years). Compared with social support, mastery was more strongly associated with functional status. The indirect effects of sleep-related problems on functional status via mastery varied between 17.7% and 23.3%.Supporting OSA patients' sense of mastery may significantly contribute to better disease management. https://www.heartandlung.org/action/showFullTextImages?pii=S0147-9563%2817%2930363-1 https://doi.org/10.1016/j.hrtlng.2018.04.006	Thank you for this information. The guideline committee will consider information and support needs, and social support will be considered in this section. The types of information and support that the guideline committee recommend will be dependent on the evidence identified in the relevant reviews on adherence, information and support.
RCGP	General	General	The draft scope does not address the potential risks of alcohol consumption. A systematic review in 2017 identified 21 studies from which estimates of relative risk could be obtained. Meta-analysis of these estimates demonstrated that higher levels of alcohol consumption increased the risk of sleep apnoea by 25% (RR 1.25, 95%CI 1.13–1.38, I2 = 82%, p < 0.0001). This estimate's differences were robust in alcohol consumption and sleep apnoea definitions, study design, and quality but	Thank you for this information. The guideline committee will consider information and support needs, including advice on lifestyle.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			was greater in Low and Middle Income Country locations. https://doi.org/10.1016/j.sleep.2017.12.005	
RCGP	General	General	In 2017 the FDA has approved an upper airway simulation device for the treatment of moderate-to-severe obstructive sleep apnoea in those who have not been able to adhere to the usage of CPAP.	Thank you for this information.
RCP	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the responses submitted by the British Thoracic Society (BTS) and the British Society for Heart Failure (BSH). I would be grateful if you could confirm receipt.	Thank you for your comment.
ResMed (UK) Ltd.	2	35	The NICE TA139 cost effectiveness is based upon patients continuing to use therapy long-term, failure to keep patients compliant will incur increased healthcare costs.	Thank you for this information. We will consider including adherence as an outcome to our review questions. We have also included a draft review question on what support improves adherence to CPAP or other interventions (draft question 3.7).
ResMed (UK) Ltd.	2	45	To date, clinical management has been through respiratory medicine departments in Secondary Care.	Thank you for this information.
ResMed (UK) Ltd.	2	58	Clinical evidence shows early intervention is the best predictor of long-term compliance and with telemonitoring may drive positive adherence outcomes. However, which is the best pathway (combination of clinics, telemonitoring, data downloads) is unclear	Thank you for your comment. We have included a question to try and address this issue.
ResMed (UK) Ltd.	6	153	Define Cost-effectiveness. This should include a combination of equipment, national tariff, time and number of appointments (specify face to face, virtual, telephone consultation)	Thank you. The methods of economic evaluation that we will follow are outlined in Chapter 7 of Developing Guidelines:

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview "In general, interventions with an ICER [incremental cost-effectiveness ratio] of less than £20,000 per QALY [quality-adjusted life-year] gained are considered to be cost effective" We agree that this should include all relevant NHS costs including services, equipment and staff both in hospital and in primary care.
ResMed (UK) Ltd.	6	171	Is the most clinical and cost effective diagnostics strategies for obstructive sleep apnoea handled in primary, secondary or tertiary care?	Thank you for your comment. The guideline committee will consider the impact of settings of diagnostic tests when setting the protocol. Depending on what is decided and what evidence is found it may make recommendations related to the setting.
ResMed (UK) Ltd.	7	195	Or Polygraphy	Thank you for your comment. The guideline committee will define the questions more fully when setting the protocols.
ResMed (UK) Ltd.	8	215	/ Respiratory Related Arousals	Thank you for your comment. The guideline committee will discuss the exact outcomes for each review at the protocol setting stage. Respiratory related arousals will be considered as an outcome to include. This list is an overview of the main outcomes and not meant to be exhaustive.
Royal College of Nursing	2	51	Positional therapy in some cases may be a treatment option. This would be a cost saving option.	Thank you for this information. These interventions are outlined as the focus of potential review questions later in the scope.
Royal College of Nursing	5	115	Although the scope advises that nocturnal hypoventilation will not be covered, there should be an element of assessment conjunction with standard sleep apnoea to determine the risk factors for this. In patients with obesity hypoventilation and obstructive sleep apnoea (OSA), Continuous Positive Airway Pressure (CPAP) may be an option however in some cases non-invasive ventilation may be more suitable. Checking a venous bicarbonate may be an easy test to determine whether to proceed	Thank you for your comment. The scope was focused to obstructive sleep apnoea as this is the most common disordered breathing condition. We have expanded the scope to include obesity hypoventilation and overlap syndrome (i.e. obstructive sleep apnoea and COPD overlap). Other types of sleep apnoea would need different, separate guidelines.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			to a full capillary or arterial blood gas and would make a difference in management of sleep disordered breathing in this group of patients.	
Royal College of Nursing	5	118	Suggest cross reference to - NICE PH24 Alcohol – use disorders: prevention. Alcohol features in many cases of patients with OSA and tackling alcohol use should be seen as part of the treatment strategy in this group of patients.	Thank you for your suggestion. PH24 is a public health guideline and makes recommendations related to alcohol pricing, availability, marketing and licencing. It has a different focus to this clinical guideline. With this in mind we have not added it to the list of related guidelines.
Royal College of Nursing	5	118	Suggest cross reference to NICE CG91 and CG90 Depression in adults with a chronic physical health problem: recognition and management (2009). Many patients are assessed for OSA who have been started on anti- depressants by their General Practitioner (GP). In some cases medication has been started due to a patient's symptoms of anxiety or depression related directly to un-diagnosed OSA. Treating the OSA may change the symptoms and therefore the requirement for management of depression symptoms.	Thank you for your suggestion. If during development, our reviews indicate a link between OSA and depression then we will cross refer to relevant guidelines.
Royal College of Nursing	General	General	The Royal College of Nursing (RCN) and Association of Respiratory Nurse Specialists (ARNS) welcome proposals to develop guidelines for managing sleep disordered breathing. We invited comments nurses who care for people with this condition to review the draft scope on our behalf. The comments below reflect the views of our reviewers.	Thank you for your comment. We have responded to these where they appear below.
Royal College of Nursing	General	General	The draft scope seems comprehensive.	Thank you for your comment.
Royal National Throat,	2	51	Surgical options are also employed throughout the country including tonsillectomy, septoplasty, turbinate reduction, UPPP, tongue base reduction and pharyngoplasty	Thank you for this information. We have added to this bullet point that surgical intervention may an option.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Nose & Ear Hospital				
Royal National Throat, Nose & Ear Hospital	3	83	In the scoping meeting we discussed professional vehicle drivers, and those with resistance hypertension and other OSA related morbidity	Thank you for your comment. All the groups mentioned are equally as important as other groups and their treatment would be the same. Therefore we have not made a mention of them here. We have drafted a review question on who should be prioritised for further assessment (draft review question 1.3).
Royal National Throat, Nose & Ear Hospital	4	104	Adherence is only relevant to MAD and CPAP.	Thank you for your comment. Adherence may also be relevant to other areas of management.
Royal National Throat, Nose & Ear Hospital	4	95	Bariatric therapies should be included	Thank you for your comment. Bariatric surgery is covered in NICE guideline CG189, "Obesity: identification, assessment and management". We have added this to the list of relevant NICE guidance in the scope. We will also consider cross referring to this within this guideline.
Royal National Throat, Nose & Ear Hospital	6	154	New draft question – what treatment options should be considered if first line treatment options are not tolerated	Thank you for your comment. The guideline will seek to make recommendations on treatment sequences where the evidence allows. The guideline committee will consider during the protocol setting stage how best to approach the evidence for second-line options.
Sleep Apnoea Trust	**1**	24	"daytime sleepiness" should be "excessive sleepiness" or "excessive sleepiness during waking hours" as many people who do shift work, night work (especially truck drivers) sleep during daytime	Thank you for your comment. This has been amended.
Sleep Apnoea Trust	**1**	27	These figures are not correct. Using Dr Peppard's paper "Increased Prevalence of Sleep Disordered Breathing in Adults" (American Journal of Epidemiology {Oxford Journals} 01/05/2013) estimates that, in the USA, due to the rapid escalation of obesity, 13% of adult (30-70) men and 6% of adult (30-70) women have moderate or severe sleep disordered	Thank you for your comment. We have used the estimate most commonly cited although we acknowledge there is uncertainty around the true figures for obstructive sleep apnoea. The purpose of this section is to briefly introduce the condition.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			breathing. The UK is 5 to 7 years behind the USA in obesity levels, so using the 2015 census figures for the UK, there is a total UK adult (30-70) population of 33.2m, of which 16.3m are men and 16.8m are women. Applying Peppard's estimates it gives us 2.1m men and 1m women with moderate /severe OSAHS. The combined total of 3.1m represents 9.4% of the UK 30-70 group population, of which we estimate 700,000 have been diagnosed, bringing the figure down to 2.4m, which represents 7.2% of the adult (30-70) population, undiagnosed. As we also need to include those age 20-30 who are now presenting of obesity related OSAHS, this represents 3.9m adults (20-70) with OSAHS, of which 700,000 are diagnosed, yielding a figure of 3.2m undiagnosed, 7.6% of the 20-70 population. These estimates are also confirmed by Consultant Anaesthetists as their real life perioperative.	
Sleep Apnoea Trust	4-6	29	As obesity driven OSA is rising so quickly and no obese OSA is not, this figure of one-quarter to one third is out of date. In a paper published by Gray, McKenzie & Eckert (J Clin Sleep Med. 2017 Jan 15; 13(1): 81–88. Published online 2017 Jan 15. doi: 10.5664/jcsm.6394) the indication is thatt up to 20% of adult OSA patients are non-obese related.	Thank you for your comment. The numbers in the scope are the most accurate available for the UK, although we acknowledge there is uncertainty around these figures.
Sleep Apnoea Trust	General	154	Can there be far improved liaison between, Respiratory Depts, ENT, NHS Dental Support in providing a more flexible treatment pathway for all OSAHS patients, especially those intolerant to CPAP and those requiring an non CPAP solution eg, MAD)	Thank you for your comment. The scope aims to address the issues of care delivery in questions on how diagnosis should occur and how monitoring should occur.
Sleep Apnoea Trust	General	89	Mild OSAHS should be treated in the same was as moderate and severe OSAHS. The Assessment of the Effect of PAP on Energy and Vitality in Mild OSA Patients: The Merge Study, being conducted by Prof Mary Morrell, Imperial College, London (ClinicalTrials.gov Identifier: NCT02699463) will report during this review	Thank you for this information. All severities of OSAHS will be covered in the guideline. The guideline committee will consider the available evidence and decide whether similar recommendations can be made across all severities of OSAHS.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Sleep Apnoea Trust	General	89-146	Section 3.3 does not specifically cover the new step of first having a diagnosis appointment, then getting the patient back for a putting onto CPAP appointment. This current NICE TA139. "implies" diagnosis and commencement of CPAP therapy as one appointment, but this is increasingly rare. It adds cost, inconvenience and hardship for the clinic and patients, and, in some cases, can costs jobs, relationships and homes when the delay is months. So, SATA wishes that the pathway to treatment be defined and that diagnosis and CPAP commencement is a mandatory at the same appointment. This is based on real life experience from our Helpline and we assist, by getting the patient e-referred to a sleep clinic, such as GWH Swindon, which provides a drop in service every Wednesday	Thank you for your comment. The guideline will aim to address the best strategies for diagnosis and treatment. If the evidence permits, the guideline committee will also make a statement on the start time for treatments.
SomnoMed UK	1	27	The number of undiagnosed obstructive sleep apnoea patients is nearer 4 million	Thank you for your comment. We have used the estimate most commonly cited although we acknowledge there is uncertainty around the true figures for obstructive sleep apnoea. The purpose of this section is to briefly introduce the condition.
SomnoMed UK	2	31	If Obstructive Sleep Apnoea was prevented these conditions would be less likely to occur.	Thank you for your comment.
SomnoMed UK	2	42	Utilising General Practitioners and Dentists to assess patients before sending for further tests would be more efficient.	Thank you for your comment.
SomnoMed UK	2	51	Guidance is available in other countries such as the European Society of Dental Sleep Medicine, the British Society of Dental Sleep Medicine and the American Society of Dental Sleep Medicine we should review all of these to formulate a protocol.	Thank you for this information. These guidelines will be reviewed and considered when developing this NICE guideline.
SomnoMed UK	4	99	The evidence in both cost-effectiveness and health benefits are available, comparable to Continuous Positive Airway Pressure. All devices considered should have at least 3 independent research studies.	Thank you for your comment. The guideline committee will consider clinical and cost effectiveness evidence as it is identified.

Sleep Disordered Breathing

Consultation on draft scope
Stakeholder comments table

16/05/18 to 13/06/18

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
SomnoMed UK	7	181	Cost effectiveness is proven with dentally fitted, hardwearing, good lifespan, titratable devices with high patient compliance. It is paramount to prevent both dental and TMJ complications and provide a device that will not need replacing every 18 months to keep the costs down. Devices made by ISO certified production and warranty on the full device not only parts should only be considered when treating a medical condition.	Thank you for this information. The guideline committee will consider this when discussing the clinical and cost-effectiveness evidence for oral devices.