NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

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

NHS England has asked NICE to develop a new guideline on sleep disordered breathing.

Following consultation with stakeholders it has been agreed that this guideline will focus on obstructive sleep apnoea/hypopnoea syndrome, including overlap with chronic obstructive pulmonary disease, and also obesity hypoventilation syndrome.

The guideline will be developed using the methods and processes outlined in developing NICE guidelines: the manual.

This guideline will also be used to develop the NICE quality standard for sleep disordered breathing.

1 Why the guideline is needed

Sleep disordered breathing is a generic term that includes obstructive sleep apnoea/hypopnoea syndrome, central sleep apnoea and nocturnal hypoventilation. There is an overlap between these conditions, but the underlying aetiology and pathogenesis is diverse, and prevalence, investigation and management differ. Obstructive sleep apnoea/hypopnoea syndrome is the most common form of sleep disordered breathing and therefore it is the main focus of the guideline. However, the guideline will also cover obesity hypoventilation syndrome and overlap syndrome (the coexistence of obstructive sleep apnoea/hypopnoea syndrome and chronic obstructive pulmonary disease).

Although obstructive sleep apnoea/hypopnoea syndrome is common, it is a frequently unrecognised cause of serious disability that has important health and social consequences. It is characterised by recurrent episodes of complete or partial upper airway obstruction during sleep resulting in dips in oxygen level, autonomic dysfunction and sleep fragmentation. The consequent excessive sleepiness can be profound, affecting social activities, work performance, the ability to drive safely and quality of life.

Key facts and figures

- It is estimated that 5% of adults in the UK have undiagnosed obstructive sleep apnoea/hypopnoea syndrome that is, over 2.5 million people.
- Although closely associated with obesity, one-quarter to one-third of people with obstructive sleep apnoea/hypopnoea syndrome are not obese.
- High-risk groups include those with cardiac disease, refractory hypertension, arrhythmias, cerebrovascular disease and type 2 diabetes.
 Obstructive sleep apnoea/hypopnoea syndrome can worsen these conditions.
- Obesity hypoventilation syndrome occurs in people with daytime alveolar hypoventilation and a BMI equal or greater than 30 kg/m². It is estimated to affect 0.3–0.4% of the general population, with prevalence likely to grow.
- People with obesity hypoventilation syndrome have reduced life expectancy compared to people without obesity, and often have cardiovascular complications and other comorbidities. It is usually associated with obstructive sleep apnoea/hypopnoea or sleep-related hypoventilation.
- Obstructive sleep apnoea/hypopnoea syndrome and chronic obstructive pulmonary disease (COPD) are common conditions that are estimated to coexist (known as 'overlap syndrome') in about 1% of adults. The combined effects of these disorders can result in a greater degree of hypoxaemia and increased comorbidity compared with either condition alone.

Current practice

- Clinical assessment and questionnaires are sometimes used to select patients for investigation.
- Diagnosis is made by monitoring breathing during sleep a sleep study. A
 range of sleep studies of varying complexity can be performed, some as an
 inpatient, or at home, depending on local arrangements and patient
 preference.
- The availability of appropriate services for investigation and management is patchy. Failure to treat the condition can result in increased use of services and may leave people with reduced quality of life.
- Recognition and optimal investigation and management need experienced clinical teams, usually working in respiratory medicine departments in secondary care.
- Highly effective treatment, in the form of continuous positive airway pressure (CPAP), is available, however approaches to personalising CPAP therapy differ.
- Non-invasive positive pressure ventilation (NIV) may be more suitable for treating alveolar hypoventilation, or significant nocturnal or daytime hypercapnia.
- Other forms of treatment, or adjuncts to treatment, include oral devices, advice on weight reduction and surgical intervention.
- Guidance is needed on when, and in whom, these treatments may be effective.
- In people who are severely obese, bariatric surgery may improve symptoms of obstructive sleep apnoea/hypopnoea syndrome in addition to its other recognised benefits.
- Clinics, telemonitoring and data downloads from CPAP and NIV devices may help with adherence to therapy, but their effectiveness is not clear.

This guideline aims to provide evidence-based recommendations for the investigation and management of obstructive sleep apnoea/hypopnoea syndrome, overlap syndrome and obesity hypoventilation syndrome in adults and young people (16 and older).

2 Who the guideline is for

This guideline is for:

- Healthcare professionals providing NHS-commissioned services.
- Commissioners of health and social care services.
- People using services, their families and carers, and the public.

It may also be relevant for:

- Driver and Vehicle Licensing Agency (DVLA).
- Non-NHS healthcare professionals making a referral to NHS-commissioned services.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the <u>Welsh Government</u>, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out <u>an equality impact assessment</u> during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

3 What the guideline will cover

3.1 Who is the focus?

Groups that will be covered

Adults and young people (16 and older) with suspected or confirmed:

- obstructive sleep apnoea/hypopnoea syndrome
- obesity hypoventilation syndrome
- overlap syndrome (coexisting obstructive sleep apnoea/hypopnoea syndrome and COPD).

No specific subgroups of people have been identified as needing specific consideration.

3.2 Settings

Settings that will be covered

All settings in which NHS-commissioned care is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

- Initial identification, assessment and referral of people with suspected obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome or overlap syndrome.
- 2 Diagnosis of obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome.
- 3 Management of obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome:
 - treatment of rhinitis
 - upper airway surgical interventions
 - interventions to modify sleeping position
 - oral devices
 - use of positive airway pressure devices
 - oxygen therapy
 - how to improve adherence.
- 4 Monitoring of obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome:
 - determining efficacy of treatment
 - how to monitor.
- Information and support for people with obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome or overlap syndrome, and their families or carers.

Areas that will not be covered

- Clinical and cost effectiveness of CPAP as a treatment option for adults with obstructive sleep apnoea/hypopnoea syndrome (this guideline will cross refer to 'Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome' NICE technology appraisal guidance 139).
- 2 Lifestyle interventions including those for obesity (this guideline will cross refer to other appropriate NICE guidelines).
- 3 Assessment and management of central sleep apnoea.
- 4 Management of COPD in people with overlap syndrome.

Related NICE guidance

Published

- Stop smoking interventions and services (2018) NICE guideline NG92
- Hypoglossal nerve stimulation for moderate to severe obstructive sleep
 apnoea (2017) NICE interventional procedures guidance 598
- Cerebral palsy in under 25s: assessment and management (2017) NICE guideline NG62
- Transition from children's to adults' services for young people using health or social care services (2016) NICE guideline NG43
- Obesity: identification, assessment and management (2014) NICE guideline CG189
- Physical activity: exercise referral schemes (2014) NICE guideline PH54
- Weight management: lifestyle services for overweight or obese adults
 (2014) NICE guideline PH53
- Smoking: harm reduction (2013) NICE guideline PH45
- Chronic obstructive pulmonary disease in over 16s: diagnosis and management (2010) NICE guideline CG101
- Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (2008) NICE technology appraisal guidance 139
- Soft-palate implants for obstructive sleep apnoea (2007) NICE interventional procedures guidance 241

Obesity prevention (2006) NICE guideline CG43

In development

- <u>Cerebral palsy in adults</u>. NICE guideline. Publication expected January 2019.
- <u>Suspected neurological conditions</u>. NICE guideline. Publication date to be confirmed.
- <u>Thyroid disease: assessment and management</u>. NICE guideline.
 Publication expected November 2019.

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to the investigation and management of obstructive sleep apnoea/hypopnoea syndrome:

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76

3.4 Economic aspects

We will take economics into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether the area should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using a NHS and personal social services (PSS) perspective. In sensitivity analyses, we will seek to include broader public sector costs, if applicable.

3.5 Key issues and draft questions

While writing this scope, we have identified the following key issues and draft questions related to them:

1 Initial identification, assessment and referral:

- 1.1 In whom should obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome or overlap syndrome be suspected (for example, based on symptoms or coexisting conditions)?
- 1.2 What assessment scales should be used if obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome or overlap syndrome is suspected (for example, the Epworth sleepiness scale, STOP-Bang sleep apnoea questionnaire or Berlin questionnaire)?
- 1.3 Which people with suspected obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome or overlap syndrome should be prioritised for further assessment?

2 Diagnosis:

2.1 What are the most clinically and cost effective diagnostic strategies for obstructive sleep apnoea/hypopnea syndrome, obesity hypoventilation syndrome and overlap syndrome, including home- and hospital-based studies, and investigations such as oximetry, capnography, respiratory polygraphy and polysomnography?

3 Management:

- 3.1 What is the clinical and cost effectiveness of treatment of rhinitis to improve symptoms of obstructive sleep apnoea/hypopnoea syndrome?

 3.2 What is the clinical and cost effectiveness of upper airway surgical interventions for people with obstructive sleep apnoea/hypopnoea syndrome?
- 3.3 What is the clinical and cost effectiveness of interventions to modify sleeping position for people with obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome or overlap syndrome?
- 3.4 What is the clinical and cost effectiveness of different types of oral devices for managing obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome?
- 3.5 What is the comparative clinical and cost effectiveness of different types of positive airway pressure devices (for example, fixed-pressure CPAP, variable-pressure CPAP, bi-level positive airway pressure or other modes of non-invasive ventilation) for managing obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome?

- 3.6 What is the clinical and cost effectiveness of oxygen therapy for managing obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome?
- 3.7 What is the clinical and cost effectiveness of the addition of humidification to positive airway pressure therapy for managing obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome?
- 3.8 What support improves adherence to CPAP or other interventions?

4 Monitoring:

- 4.1 How should efficacy of treatment be demonstrated (for example, variable positive pressure titration device, oximetry, capnography or polysomnography titration)?
- 4.2 What is the most clinically and cost effective strategy for monitoring obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome (for example, based on outpatient visits, download of data from devices or telemonitoring)?
- 4.3 What is the optimum frequency of monitoring of obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and overlap syndrome?
- 5 Information and support:
 - 5.1 What information and support do people and their families or carers need (for example, advice on lifestyle, driving and occupation, and their treatment)?

The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

3.6 Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

- 1 Health-related quality of life (for example, EQ-5D, SF-36).
- 2 Subjective and objective sleepiness scores (for example, the Epworth sleepiness scale).
- 3 Apnoea–Hypopnea Index (AHI).

- 4 Oxygenation indices and PCO₂ control (for example, oxygen desaturation index [ODI], arterial oxygen saturation [SaO₂] nadir, time SaO₂ < 90%, PCO₂).
- 5 Adverse effects of treatment.
- Impact on, or development of, coexisting conditions (for example, hypertension, ischaemic heart disease or heart failure).

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

NICE quality standards that will use this guideline as an evidence source when they are being developed:

 Sleep disordered breathing. NICE quality standard. Publication date to be confirmed.

4.2 NICE Pathways

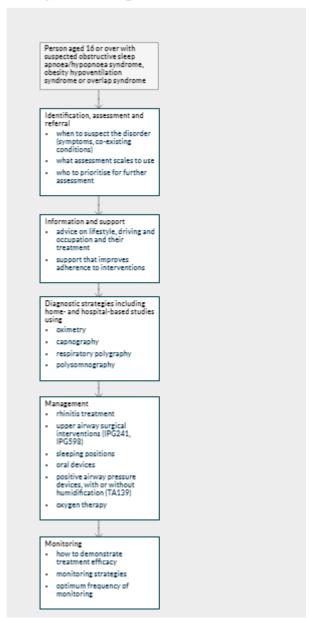
NICE Pathways bring together everything we have said on a topic in an interactive flowchart. When this guideline is published, the recommendations will be included in the NICE Pathway on sleep breathing disorders (in development).

Other relevant guidance will also be added, including:

- Hypoglossal nerve stimulation for moderate to severe obstructive sleep
 apnoea (2017) NICE interventional procedures guidance 598
- Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome (2008) NICE technology appraisal guidance 139
- <u>Soft-palate implants for obstructive sleep apnoea</u> (2007) NICE interventional procedures guidance 241

An outline based on this scope is included below. It will be adapted and more detail added as the recommendations are written during guideline development. Links will be added to relevant NICE Pathways.

Sleep breathing disorders overview



5 Further information

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in August 2020.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.

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