NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Assessment Programme

Novel home-testing devices for diagnosing obstructive sleep apnoea/hypopnoea syndrome

Final scope

May 2023

1 Introduction

The topic selection oversight panel identified novel home-testing devices for diagnosing obstructive sleep apnoea/hypopnoea as suitable for evaluation by the Diagnostics Assessment Programme based on a topic briefing produced after clinical experts highlighted system interest in the topic.

The scope was informed by discussions at the scoping workshop on 5 April 2023 and the assessment sub-group meeting on 19 April 2023.

A glossary of terms is provided in appendix A.

2 Description of the technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and on information available in the public domain. NICE has not carried out an independent evaluation of this description.

Purpose of the medical technology

Home respiratory polygraphy systems currently widely used in the NHS for diagnosing Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS) include multiple wired components which require training to operate and can be uncomfortable to wear. Home pulse oximetry is also used as an alternative to home

respiratory polygraphy, however is not considered as sensitive a test for OSAHS diagnosis.

A person's sleep can be affected by their discomfort, which can shorten the length of time they are asleep leading to an invalid test result (due to insufficient recording time). If parts of the device apparatus become detached in the night this can also result in not enough information being collected to make a diagnosis. Both of these scenarios mean the home test may need to be repeated or the person may need an in-hospital sleep study. Patients highlighted discomfort associated with wearing nasal cannulas, which experts said may be particularly problematic for children. Home testing devices may also need to be picked up from and returned to the hospital, which requires arranging travel and potential time off work.

Newer diagnostic technologies that can be used by a person while they sleep at home may be easier to put on and operate and also be more comfortable to wear than currently used testing apparatus. This may:

- Require minimal to no assistance from a healthcare professional to help with understanding of wearing and operating the device.
- Improve detection of OSAHS if the device is more comfortable to wear which means a person would have less disturbances or chance of waking from sleep and so providing more representative data on the person's usual sleep.
- Reduce the number of invalid results being returned due to the person not being able to sleep long enough if the device is uncomfortable to wear or parts of the technology become detached in the night. This would mean fewer tests may need to be repeated. Invalid test results can delay a diagnosis being made, and take up NHS resources, potentially requiring a sleep study done in hospital.
- Reduce anxiety and stress for person having a sleep test if the technologies are simpler to use and more comfortable to wear. Time spent training to use the home-tests could also be reduced.

Clinical experts highlighted issues with waiting times for home testing, particularly following the COVID-19 pandemic. As a result of delayed diagnosis, treatment initiation is delayed. Any impact the newer technologies can have on improving access to home testing could reduce wating lists. Some of the newer devices can be directly sent through the post which could improve access. However, experts did highlight that current devices can be sent to patients using courier services.

Newer technologies may differ to current widely used technologies in how they detect physiological parameters related to OSAHS, or what exact parameters they detect. This could be to try and improve OSAHS diagnosis and/or to avoid the need for sensors that may be more intrusive (for example, a nasal cannula to measure air flow). The newer technologies may also differ in their capacity to do automated analysis of the data they collect and what they output (compared to each other or technologies currently widely used in the NHS), and potentially the length of time it takes healthcare professionals to use outputs to make a diagnosis. Any improvement in test accuracy or analytical capabilities that help a healthcare professional make a diagnosis may:

- Reduce the amount of time a clinician spends reviewing the test data, freeing up NHS resources. This could allow for increased number of tests conducted with the same resources or people who are on a waiting list being tested sooner, reducing time to a diagnosis and treatment.
- Improve detection of OSAHS when compared to current testing. The newer technologies may provide more information than current home respiratory polygraphy or oximetry systems to help a diagnosis be made or calculate the same outputs but in a different way.

Conversely, if the newer technologies don’t perform as well as tests currently widely used in the NHS to detect OSAHS this will have implications in terms of missing or over diagnosing OSAHS.

2.1 Product properties

The following technologies have been included in this assessment because they are less intrusive than devices currently widely used in the NHS, are easier to put on

and operate and may also be more comfortable to wear. This may offer benefits (described above) but also uncertainty about performance. Considerations on technologies to include were based on discussions with clinical experts and information submitted by companies.

At the scoping workshop, clinical experts and companies agreed that healthcare professionals make the final decision about diagnosis and further care, with outputs from the technologies being interpreted by healthcare professionals and used alongside additional information, such as patient symptoms. The technologies differ in the exact outputs they produce and stated intended use (described in the sections below) so could potentially be used differently by healthcare professionals in making decisions about care.

Experts also commented that the most appropriate way to assess use of the technologies was when used in place of home testing devices that are currently used in the NHS (see section 4).

The level of detail in the following descriptions depends on the extent of information provided by manufacturers during topic scoping.

Technologies will only be included in guidance if they are available to the NHS and have appropriate regulatory approval.

AcuPebble SA100 (Acurable)

The AcuPebble SA100 is a class IIa CE-marked device and is indicated for use in adults suspected of having sleep apnoea. The device has a wireless sensor, enclosed in a plastic case that is attached to a person using the provided double coated adhesive tape. It records sounds generated by a person's respiratory and cardiac functions. The intended use states that algorithms operating remotely use those signals to automatically extract parameters that are clinically relevant for the diagnosis of sleep apnoea. A compatible third-party oximeter can be added as an option.

The company offers a logistics service to post the device directly to the person and is returned in this way after use. Hospitals can also choose to manage the delivery and receiving of devices if this is more preferred.

The device needs to be worn for a minimum of 4 hours. The system also requires a wi-fi connection and a smartphone or tablet or computer that the company can provide, pre-installed with the application, if needed. The data are transferred wirelessly to a mobile device and are then uploaded to a cloud platform.

Healthcare professionals receive an automatically generated report within minutes which is accessible through the AcuPebble SA100 web application. The web application also displays the raw data of the recorded signals but does not offer manual scoring capability by default. Manual scoring can however be made available upon request.

The automated report includes an overall assessment (rated no OSA, mild OSA, moderate OSA or severe OSA) based on the Apnoea Hypopnoea Index (AHI) or Oxygen Desaturation Index (ODI). Clinicians may choose either the AHI (3% or 4% desaturation criteria) or the ODI (3% or 4% desaturation criteria) for OSAHS diagnosis. For each index, the AcuPebble system provides a severity score based on the classification described in section 3.2.1. Other outputs include: classification of apnoea events, heart rate, respiratory rate, snoring evaluation, acoustic derived airflow, acoustic derived relative desaturation, and activity. Graphical representations of these are also provided.

The packaging of the AcuPebble SA100 is made of recyclable aluminium and only the medical adhesive is non-reusable. The AcuPebble SA100 is composed of electronic components compliant with the Restriction of Hazardous Substances (RoHS) directive 2011/65/EU for the restriction of hazardous substances and the IEC 60601-1-9 standard on Environmentally Conscious Design. The rechargeable, battery-operated AcuPebble sensor is multi-use. The plastic sensor enclosure needs to be wiped with an alcohol wipe and the battery must be recharged between users.

The AcuPebble SA100 device may not be suitable for patients with sleep bruxism (unconsciously grinding or clenching jaw during sleep).

2.1.1 Brizzy (Nomics)

The Brizzy is a CE-marked class IIa device and is indicated for use in the screening and diagnostic evaluation of sleep breathing disorders in children and young people (over 3 years old) and adult patients. The intended use is as a portable sleep recorder for detecting sleep apnoea syndrome and for monitoring its treatment. The technology can be used at home and in sleep clinics. A report is produced for a healthcare professional that may aid in the diagnosis of sleep breathing disorders or for further clinical investigation. The device consists of a recording device hub to which electromagnetic sensors are connected. The sensors are fixed on the chin and forehead and measure jaw activity signal (referred to as "Jawac" by the company): mandibular movement, mouth opening, and nervous gnathic twitch. A pulse oximeter or an electrocardiogram (ECG) with 3 electrodes may also be added on optionally to be used with the device. The central device hub is attached to a fastening belt and is worn around the waist during sleep.

It is currently unclear how the device will be distributed to the users.

The company advise having at least 4 hours of recording. Once the device is returned, a physiologist uploads the study to the web portal (CERES software) using a wired USB connection to produce an automated report. Raw data from the recorded study can be accessed and manually scored by healthcare professionals if needed.

The Brizzy device measures an output called the respiratory events index JAWAC (REI_JAWAC). Other outputs measured by the device are total sleep time (TST), sleep fragmentation, respiratory effort, number and frequency of apnoea events (broken down by type: obstructive, central, or mixed), positional analysis (total sleep time in supine versus non-supine position, REI-JAWAC in supine versus non-supine position), and mandibular activity. If the healthcare professional chooses to add an oximeter or an ECG, the device can also measure heart rate, oxygen saturation (SpO_2), ODI, and an ECG graph.

The device provides an automated qualitative output of OSAHS severity based on the REI_JAWAC measure using the criteria described in section 3.2.1.

The device has a lithium polymer battery (rechargeable by USB), and the storage capacity and battery life allow for recording several nights if used without oximetry or ECG.

The company states that there are no known contraindications, and the technology can be used during pregnancy. The company advise caution when used for people with restless leg syndrome as the number of apnoea events automated can be overestimated in this group. For people with Parkinson's disease and temporomandibular disorders, the healthcare professional should assess whether the disorder could impact jaw movements and interpret results accordingly.

The central hub and JAWAC sensors are reusable, made of recyclable Acrylonitrile Butadiene Styrene plastic. The fastening belt may be machine-washed and reused. The central hub is both RoHS and Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) compliant.

NightOwl (ResMed)

The NightOwl software is a class IIa medical device and is used with the NightOwl sensor, a class I medical device. The NightOwl Software is intended for physiological signal retrieval, visualisation, report generation, analysis and interpretation for the area of direct diagnosis and monitoring of obstructive sleep apnoea. The technology requires a smartphone, and an accompanying app which connects with the sensor using Bluetooth.

The device contains a photoplethysmography (PPG) sensor and is worn on the fingertip or forehead using an adhesive. Data extracted from the PPG signal are changes in peripheral arterial tone (PAT), oximetry, and pulse rate. A probabilistic model determines a respiratory event from the co-occurrence of oxygen desaturation, vasoconstriction manifested as a PAT channel decrease, and a pulse rate increase.

The NightOwl software automatically scores sleep events and generates a diagnostic report with information on the AHI severity category on a colour-coded scale, pulse rate, SpO_2, ODI, TST and the presence or absence of a substantial

changes in PAT that may be caused by the presence of irregular heart rhythms. It also contains information on the location of desaturations and signal artifacts.

The system must be recording for at least 4 hours to obtain sufficient data. The device communicates with the companion app by Bluetooth, and at the end of the night, the results are automatically uploaded to the analytics platform by the internet connection (3G or 4G) of the smartphone. The raw data can be accessed on the analytics platform by a healthcare professional and be manually scored, if needed. The data is stored in the NightOwl database.

The company offers a logistics service (called ReSupply) to send the device apparatus to the person directly. Sleep centres also have the option to do this themselves if preferred. If the healthcare professional specifically requests, the person can also collect the device in person, however this is not the preferred method.

The device can be used by adults and children aged 13 or over without requiring direct supervision by a healthcare professional. The device should not be used on patients with known severe ventricular extrasystole as this is likely to lead to insufficient clean data segments and therefore a failed test. The performance of the device could be adversely impacted if a person has changes in their sympathetic response or has reduced blood flow to the fingers. This may be caused in people using drugs that affect the autonomic system (for example, alpha-adrenergic antagonists), or people with peripheral vascular disease (for example, secondary Raynaud's disease).

The company have indicated that the NightOwl device to be commercialised in the UK has a built-in battery that allows for 10 nights of recording. The device is not rechargeable, and after use, it is to be discarded by ideally any existing recycling program for electronic waste.

2.1.2 Sunrise system (Hello Sunrise)

The Sunrise device is a class IIa CE-marked system that comprises a wireless sensor placed on the chin and worn overnight. The device measures mandibular movement to estimate interruptions and breathing during sleep. The intended use is

as an aid for the detection of sleep-related breathing disorders in adults with suspicions of sleep disorders, and in children (from 3 to 18 years) with suspicions of obstructive sleep apnoea or habitual snoring. It is also intended to assist healthcare professionals in their diagnosis and prescription decision making, or in referral to further diagnostic assessment when required.

The company offers logistics services to handle shipping the device directly to the person. The sleep service may also keep stocks of the devices and handle the shipping or have the person pick up the device during their consultation appointment. A person is given a kit containing the sensor, a quick start guide, a measuring tape, adhesive bandages, and a user manual. A prepaid and self-addressed envelope is also provided to send the device back to the manufacturer. The plastic body of the device is recycled while the electronic part is repurposed.

The system requires a wireless internet connection (wi-fi or 3G/4G) and a smart phone. Recorded data by the sensor is transferred by Bluetooth to a smartphone application. Upon completion of the test, the recorded data is transferred by wireless connection for automated analysis and storage in cloud-based software. The software uses an algorithm to analyse the data and generates an automated sleep study report for the clinician to review. The online web portal also allows the clinician to access the raw data for manual scoring.

The report consists of the following parameters: OSA severity scoring (non-OSA, mild, moderate, or severe), sleep/wake states (TST), sleep stages, respiratory events (AHI, RDI, OAHI, central AHI [cAHI], obstructive respiratory disturbance index [ORDI], RERA index, respiratory effort), awakenings and arousal index, oxygen saturation, heart rate, position changes index and sleep bruxism (extent of teeth grinding during sleep). The company states the device diagnoses OSAHS using AHI and/or ORDI, and the severity is determined by the criteria described in section 3.2.1.

The sensor is for a single use. A multi-night version device is expected to be launched by end of 2023 which allows the user to use each device for three nights. The company state that the returned devices are disposed of in accordance with the European Union’s Waste Electrical and Electronic Equipment (WEEE) directive. The

company is also compliant with the EU's RoHS directive and follows the IEC 60601-1-9 requirements for Environmentally Conscious Design (ECD).

Sunrise advises against using the device with a pacemaker or similar implanted devices as it could impair its functioning. The device should not be used for people with conditions affecting the rotation of the condyle in temporo-mandibular joint (part of the jawbone).

2.1.3 WatchPAT 300/WatchPAT ONE (Zoll/Itamar)

The WatchPAT 300 (WP300) device is a class IIa CE-marked system intended for use as a diagnostic aid for the detection of sleep related breathing disorders for people with suspected sleep related breathing disorders. The WP300 device attaches to the chest, wrist, and forefinger. It measures a proprietary PAT signal, heart rate, oximetry, actigraphy (movement tracking), body position, snoring and chest motion.

Following the sleep study, the device is returned for the recorded data to be analysed by the zzzPAT software. The zzzPAT algorithm calculates the AHI, cAHI, respiratory disturbance index (RDI), ODI, wake/sleep states, sleep stages, body position, snoring, heart rate, chest movement, oxygen saturation, and actigraphy. The generated sleep report provides interpretation of the data. The AHI and ODI (below 3% or 4% desaturation) are used for the diagnosis of OSAHS, and the AHI severity (no apnoea, mild, moderate or severe apnoea) displayed on a colour-scale, is determined using the criteria described in section 3.2.1.

The finger-mounted probe, bracelet and the adhesive sticker on the chest sensor are single-use only. Other parts of the device can be wiped clean with 70% alcohol before reuse.

The manufacturer states that the WP300 is not indicated for use in people unable to wear a finger probe on any of their eight fingers. The central AHI (AHIc) is not clinically assessed for use at high altitudes or for people using opioids. The device should not be used in people on medication including alpha blockers or short acting nitrates (taken less than 3 hours before the study), or for people with a pacemaker, or people with sustained non-sinus cardiac arrythmias. Additional precautions are

stated for people aged 12 to 17 years of age. WatchPAT is suitable for people 12 years old and above.

The company mentions 2 modes of delivery for the WP300 device:

- If the WP300 belongs to the NHS trust, it involves delivery back and forth to the clinical setting. A healthcare professional downloads the recorded study and results are analysed by the zzzPAT software
- The WatchPAT Direct service provides delivery services directly from and return to the manufacturer, who sends the results to the sleep service

The WatchPAT ONE (WP1) is a fully disposable version of the WatchPAT 300, comprising the same sensory attachments and software for automated data analyses. The WP1 uses an additional smartphone application and so requires access to a smartphone and internet connection. After the sleep study is completed, the data are automatically uploaded to a web server, from which data can be downloaded and analysed using the zzzPAT software. The raw data can also be accessed by healthcare professionals and manually score the recorded data, if needed.

The company have stated that they are currently setting up a recycling service where users can return the product to the manufacturer free-of-charge.

3 Target conditions

3.1 Obstructive sleep apnoea/hypopnoea syndrome

Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) is a respiratory condition in which the upper airway becomes blocked repeatedly during sleep, reducing or completely stopping airflow. The term 'obstructive' distinguishes OSA from rarer forms of sleep apnoea, such as central sleep apnoea (CSA), which is caused by the brain not sending signals to the breathing muscles during sleep. Symptoms of sleep apnoea include breathing stopping and starting, making gasping, snorting or choking noises, waking up a lot and loud snoring. Hypopnoeas are events during sleep where airflow is reduced, rather than intermittently stopped as with apnoeas. The symptoms of hypopnoea are like those of sleep apnoea. Many people with OSA

experience episodes of both apnoea and hypopnoea, which is referred to as OSAHS. Symptoms of OSAHS may also occur during waking hours, including drowsiness, mood swings and headaches. Sleep interruptions and excessive sleepiness can reduce quality of life, cognitive function, and mental health. Daytime sleepiness in children may occur but is uncommon in young children. OSAHS in children is associated with neurocognitive impairment, behavioural problems, failure to thrive, hypertension, cardiac dysfunction, and systemic inflammation.

Amongst people in the UK aged between 30 and 69 years old, Benjafield et al. (2019) estimated that 25% (9 million people) have either mild, moderate or severe OSA (see section 3.2.1 for definitions): 20% have mild OSA, and 5% have moderate or severe OSA. About 85% of people with OSA in the UK are undiagnosed and therefore untreated (British Lung Foundation, 2014). If left untreated, OSA increases the risk of cardiovascular and cerebrovascular complications such as myocardial ischaemia, stroke and arrhythmias (Sharma and Culebras, 2016) and can shorten life expectancy.

The prevalence of OSA in children is between 1 to 3% of children, and most commonly caused by adenotonsillar hypertrophy (enlarged tonsils or adenoids) obstructing the airway during sleep (GOSH NHS Foundation Trust, 2015). OSA is much more common (up to 25%) in children with conditions such as obesity, sickle cell disease or Down's syndrome. It causes a range of problems including sleep disruption, educational and cognitive impairment, and behavioural problems. For children with underlying conditions, OSA may also cause recurrent respiratory illness, hospital admissions and death (BTS Guideline, 2022).

COPD–OSAHS overlap syndrome occurs in people who have both chronic obstructive pulmonary disease (COPD) and OSAHS. The combined effect of these conditions on ventilatory load, gas exchange, comorbidities and quality of life is greater than either condition alone.

3.2 Diagnostic and care pathway

3.2.1 Diagnosing OSAHS in people over 16 years old

Clinicians highlight that the American Academy of Sleep Medicine (AASM) is highly regarded and generally used alongside the UK NG202 guidelines.

The NG202 guideline for OSAHS describes the initial assessment for OSAHS in people over 16 years old. A person is referred to a sleep service if they have sleep history and symptoms indicating OSAHS. If OSAHS is suspected, a detailed referral is sent to a sleep service to perform further diagnostic testing.

NG202 recommends that a home respiratory polygraphy is first offered to a person suspected to have OSAHS. This is defined as including at least 4 channels such as oximetry, breathing rate, apnoeas and hypopnoeas, snoring and body position. For an accurate assessment, patients need to sleep with the equipment on for at least 4 hours. Standard cardiorespiratory polygraphy devices widely used in the NHS perform automated analysis of the recorded data to help make a diagnosis, however raw data can be accessed for review and manual scoring by a healthcare professional. Manually scoring cardiorespiratory polygraphy signals has been suggested to take up to between 1 to 2 hours per patient (Devani et al. 2021). Experts said this would be done by sleep physiologists (typically band 5 level or higher).

NG202 recommends that if access to home respiratory polygraphy is limited, home oximetry should be considered for people with suspected OSAHS. However clinical experts advise that oximetry alone is not considered a sensitive test for OSAHS as it cannot detect apnoeas or hypopnoeas, but only changes in oxygen levels which may be caused by movement, medications, or conditions such as chronic obstructive pulmonary disease (COPD). Oximetry is described in the guidance as measuring arterial oxygen saturation and heart rate.

NG202 recommends considering respiratory polygraphy or polysomnography if oximetry results are negative but the person has significant symptoms. If home respiratory polygraphy and home oximetry are impractical or additional monitoring is needed, NG202 recommends hospital respiratory polygraphy for people with

suspected OSAHS. NG202 further recommends that polysomnography should be considered if respiratory polygraphy results are negative, but symptoms continue.

However, clinical experts commented that in practice, not all services can provide inpatient testing and may only offer home-based testing (home respiratory polygraphy and home oximetry). If the first home sleep study fails, the test is repeated at home. In cases where the home testing cannot provide information for a diagnosis, experts commented that the person is offered treatment on clinical grounds.

Following a positive OSAHS diagnosis, a hospital appointment is offered to discuss treatment options.

NG202 recommends using the results of the sleep study to diagnose OSAHS and determine the severity of OSAHS (mild, moderate or severe) determined by the AHI, (the number of apnoea and hypopnoea events per hour of sleep divided by the total sleep time). Clinical experts advise that ODI (how many times per hour, on average, blood oxygen levels fall below normal for 10 seconds or longer, divided by the total sleep time) is also used. The following severity criteria is used for both AHI and ODI:

- Mild OSAHS: 5 or more to less than 15 events per hour
- Moderate OSAHS: 15 or more to less than 30 events per hour
- Severe OSAHS: 30 or more events per hour.

Clinical experts advise that they often use ODI and AHI alongside each other to determine the severity of OSAHS, because ODI cannot differentiate between OSAHS and other conditions that may present with low oxygen levels (for example, heart failure or chronic lung disease), while AHI on its own cannot distinguish between a clinically significant or insignificant apnoea event (significant to cause desaturation and consequently needing treatment). Clinicians noted having greater confidence in results when both measures are used.

NG202 also has recommendations on assessment and treatment of OSAHS in people with COPD. For diagnosing OSAHS in people with suspected COPD–OSAHS overlap syndrome, the guidance recommends offering respiratory

polygraphy, either in hospital or at home. It further states to not use oximetry alone to diagnose OSAHS in people with suspected COPD–OSAHS overlap syndrome.

3.2.2 Diagnosing OSAHS in children

Clinical experts commented that a child is often brought to a GP by their parents due to loud snoring, witnessed apnoea events, restless sleep, and mouth breathing. The GP may refer the child to a sleep specialist if they find adenotonsillar hypertrophy upon physical examination. The sleep specialist takes a careful history and examination before a sleep study. In majority of the cases the first-line treatment is an adenotonsillectomy (surgical removal of adenoids or tonsils) if OSAHS is detected.

Other children may have underlying comorbidities such as neuromuscular disorders, nerve conduction disorders, neurodevelopmental and metabolic disease, craniofacial and skeletal disorders, which may predispose them to OSAHS. These children present with less obvious symptoms (such as poor growth, disturbed sleep, delayed development) and are also referred to a sleep specialist for further assessment.

In addition to diagnosing OSAHS, a sleep study also helps with surgical stratification (assessing level of risk associated with anaesthesia and surgery) to determine whether they will need high dependency or intensive monitoring after surgery or if they can be sent home on the same day. A higher OSAHS severity score, coexisting medical conditions and young age are all high-risk factors when considering surgery.

Draft British Thoracic Society (BTS) guidance (described below) states severity criteria for children (below 16 years old), with the corresponding obstructive AHI (OAHI) cut-off values defined as:

- Mild OSAHS: OAHI 1 or more to less than 5
- Moderate OSAHS: OAHI 5 or more to less than 10
- Severe OSAHS: OAHI 10 or more

The Guideline Development Group (GDG) of the BTS noted in the draft BTS guidelines that evidence linking AHI values in children to functional outcomes is

sparse, especially in children with underlying conditions, and caution healthcare professionals from using the AHI alone to guide decision making.

Currently, there are no finalised UK guidelines for the diagnosis and management of paediatric OSAHS. However, clinical experts highlighted that the following guidelines are currently used in the UK:

- European Respiratory Society (ERS) taskforce statements for diagnosis and treatment of paediatric sleep disordered breathing for children aged 1 to 23 months and 2 to 18 years.

- The Australian Sleep Society's guidance on Overnight Oximetry for evaluating Paediatric Obstructive Sleep Apnoea. Provides technical specifications and interpretation guidelines for pulse oximetry.

- The British Thoracic Society (BTS) is currently in the process of developing guidelines for the diagnosis of sleep disordered breathing in paediatrics, which is expected to be published in 2023 but are unavailable at the time of publishing this scope. The draft guidelines are currently available until the final version is published.

All guidelines recommend overnight, attended, in-hospital polysomnography for children as the gold standard test for the diagnosis of OSAHS and assessing its severity. Experts mention in some cases ambulatory polysomnography (with CO_2 monitoring) may be considered instead of inpatient polysomnography if the parent felt a home sleep study would give more representative data.

Polysomnography may not always be possible due to limited availability and NHS resources, in which case, the BTS draft guidelines recommend using one or more alternative tests, such as:

- Pulse oximetry
- Respiratory polygraphy (with CO_2 monitoring)
- Paediatric sleep questionnaire

Clinical experts commented there is variation in how these tests are done. Some centres across the UK lack in-patient facilities and may do more home studies. In cases where home testing isn't considered appropriate, inpatient respiratory

polygraphy is performed at the tertiary care level as it is not commonly available through secondary care. Some clinicians may prefer in-hospital testing for children so that if a child is struggling, the clinician can troubleshoot with device sensors and help with repositioning. Quite often the study fails because of choosing the wrong environment for the child. In these situations, experts may choose home testing devices as they are able to collect more representative data with the child being able to sleep better at home.

3.2.2.1 Diagnosing OSAHS in children over 2 years old

The BTS draft guidance recommends pulse oximetry as a first-line diagnostic test, if the child:

- has no comorbidities, and;
- mild OSAHS is suspected

The draft guidance also recommends pulse oximetry if the child:

- has comorbidities, and;
- mild-to-moderate sleep disordered breathing is suspected

The GDG advise caution with interpreting the oximetry results as desaturations are non-specific. If oximetry results are negative and the child is highly symptomatic, the specialist would repeat the test or follow it with a respiratory polygraphy test (with CO_2 monitoring). Either test may be done as a home study if the person and carer are suitable for a home sleep study. If results from respiratory polygraphy are negative and the child is still symptomatic, a polysomnography test is recommended.
The BTS draft guidelines recommend respiratory polygraphy (with CO_2 monitoring) as the first-line test if:

- The child is over 2 years old and;
- has comorbidities

This is because they require a more detailed study than can be provided by oximetry. This may be a home respiratory polygraphy test if the child and carer are better suited for a home sleep study. If respiratory polygraphy is not available,

oximetry would be the next option. If results are negative and child is symptomatic, a polysomnography test is recommended.

The BTS draft guidelines recommend an OSAHS sleep questionnaire if:

- The child is over 2 years old;
- has no comorbidities, and;
- moderate-to-severe sleep disordered breathing is suspected

If the results are negative and the child is symptomatic, pulse oximetry is recommended and the same pathway for oximetry is considered.

The AASM have published a position paper that recommends against the use of home sleep apnoea testing devices for children as they do not offer CO_2 monitoring, a standard required measure across paediatric testing. The lack of CO_2 monitoring may lead to underestimating the presence and severity of OSAHS. The draft BTS guidance recommends the use of CO_2 monitoring as part of respiratory polygraphy for diagnosis of OSAHS. Clinical experts explained that home transcutaneous CO_2 monitoring is done alongside home testing devices where clinicians send a transcutaneous CO_2 monitor with the home testing device to get the required data.

Experts highlighted that, similar to respiratory polygraphy devices currently used in the NHS, newer technologies do not have integrated CO_2 monitoring. A third-party transcutaneous CO_2 monitor will therefore be required when this functionality is needed.

Home monitoring

The draft BTS guidance also has guidance on home sleep studies. It recommends that where a patients or carers are deemed appropriate for implementing a home sleep study, home respiratory polygraphy sleep studies can be considered for diagnosing sleep disordered breathing in children without comorbidities. If a test result is inconsistent with the clinical picture a repeat study should be offered and consideration should be given as to whether this should be undertaken as an inpatient. The guidance also says that (under good practice points) home respiratory polygraphy can be also considered for children with comorbidities and home pulse

oximetry can be considered for children with, or without comorbidities if the patient and carer are deemed appropriate for home sleep studies. A flowchart of the home monitoring pathway is set out in section 9.6 of the draft BTS guidance.

3.2.2.2 Diagnosing OSAHS in children under 2 years old

Clinical experts stated that respiratory polygraphy would be a first-line test if a child is less than 2 years old and OSAHS is suspected. This is because infants are predisposed to central sleep apnoea (CSA) and oximetry is unable to differentiate between OSA and CSA.

3.2.3 Treatment options for people over 16 years

NICE NG202 recommends that personal treatment plans are tailored to the patient following an OSAHS diagnosis. Non-pharmacological treatments based on appropriate lifestyle changes should be discussed with all people with OSAHS.

Recommendations for treatment based on severity of OSAHS and monitoring and support are provided in NG202. Treatment can be stopped if OSAHS is considered to have resolved. If symptoms return, the person may be re-evaluated and offered a sleep study.

3.2.4 Treatment options for children and young people

3.2.4.1 Treatment for children over 2 years old

Adenotonsillar hypertrophy and obesity are the predominant cause for OSAHS in children above 2 years of age. The ERS task force statements recommend a stepwise treatment approach for this group. Children with obesity are advised weight loss as an effective treatment for OSAHS. Nasal corticosteroids or montelukast are recommended for children with mild-moderate severity OSAHS. Adenotonsillectomy is indicated in children with OSAHS and adenotonsillar hypertrophy. Rapid maxillary expansion and orthodontic appliances are recommended in some cases. CPAP is advised for OSAHS after adenotonsillectomy, OSAHS related to obesity, craniofacial abnormalities or neuromuscular disorders. If nocturnal hypoventilation occurs, NPPV is preferred. In children with syndromic craniofacial abnormalities, craniofacial surgery should be offered. If the child has severe OSAHS and all other interventions have failed or are contraindicated, tracheostomy (a small surgical opening made

through the front of the neck into the windpipe) is recommended in the ESR statements.

3.3 Patient issues and preferences

Some of the technologies may require patients to have access to a home internet connection, a smartphone or both, which could be a barrier to using the technology for some people. In 2020, the Office of National Statistics reported 20% of households with one adult aged 65 and over did not have internet connection.

Technologies that require user input or setup (for example, to use smartphone apps) may not be suitable for people with severe cognitive impairment (such as people with dementia or autism) or people with impulse disorders, as it may cause stress and anxiety. Clinical experts also highlighted that people who are less familiar with technologies needed to use some of the devices may have difficulty setting up testing or require help to do this. Some people may also struggle to wear and operate technologies if they are frail or have motor, visual, or hearing impairments. Patient usability is an important consideration to make sure the devices can be correctly used at home.

There may be potential issues with people having difficulty collecting and returning devices, particularly those with mobility issues. Some may have limited access to transportation and are unable to get to the hospital to collect and return the device. This group may benefit from having the device sent to them by post. Reducing travel costs, including parking, and time off work or school needed to collect or return equipment would also be beneficial.

Using the devices as intended can be challenging for children as they may resist a caregiver's effort to put on the device or may pull it off during sleep. This may especially be pronounced in children with neurocognitive disorders, anxiety, or other behavioural problems.

Clinical experts expressed concerns over the potential of choking hazards for some of the smaller sized devices. Infants, young children, and children with cognitive impairment could be especially prone to this hazard.

Concerns were raised at the scoping workshop with some people facing difficulties in affording costs associated with recharging the technologies at home.

4 Comparators

A comparator for this assessment for people over 16 years is home respiratory polygraphy. An alternative comparator, where access to respiratory polygraphy is limited (as described in section 3.2.1 above), is home oximetry.

For people with COPD (suspected COPD–OSAHS overlap syndrome), oximetry alone is not recommended (see section 3.2.1).

For people 16 or under, the comparators are home respiratory polygraphy or home pulse oximetry. CO_2 monitoring may be used alongside these technologies (see section 3.2.2).

Comparators should reflect established NHS practice in England (and not include the technologies being assessed, as listed as interventions in table 1 of this scope).

Various technologies are currently used across the NHS. During scoping, experts highlighted several technologies they are currently using (but noted this is not an exhaustive list of technologies used in the NHS):

- Alice NightOne (Philips)
- ApneaLink Air (ResMed)
- Embletta MPR PG (Stowood)
- NoxT3s (ResMed)
- Somnotouch (Somnomedics)
- Konica Pulse Ox 300i (Stowood)
- Viatom CheckMe O2 (Stowood)
- WristOx 2 (Nonin)

4.1 Reference standard

The reference standard used in the evidence review for NICE guidance on OSAHS (NG202) was hospital polysomnography (see review question in table 1 of Evidence review D). Clinical experts highlighted during scoping that polysomnography done

outside hospital or respiratory polygraphy done in a healthcare setting (rather than at home) may be acceptable reference standards.

5 Scope of the assessment

Table 1: Scope of the assessment

Decision question	Do novel home-testing devices for OSAHS represent a clinically and cost-effective use of NHS resources?
Populations	People with suspected OSAHS (who are considered suitable for a home sleep study). The population is separated by age groups: • People over 16 • Children and young people aged 16 and under* Where data permits, the following subgroups may be considered: • People with COPD • People who have neuromuscular disorders • People from black, Asian and minority ethnic backgrounds • For children and young people aged 16 and under, with and without comorbidities (as defined in the BTS's guidelines for the diagnosis of sleep disordered breathing in paediatrics) • Pregnant women and pregnant people *Some technologies included for assessment are not indicated for use in children or young people, or not for all ages in this group. No devices included are indicated for use for people under 2 (see section 2.1 for further details of included technologies)
Interventions	• AccuPebble SA100 (Acurable) • Brizzy (Nomics) • NightOwl (ResMed) • Sunrise (Hello Sunrise) • WatchPAT 300 (Zoll/Itamar) • WatchPAT ONE (Zoll/Itamar) For children and young people, use of the interventions may be alongside CO_2 monitoring (see section 3.2).
Comparator	• For people over 16: Home respiratory polygraphy or home oximetry*

	• For children and young people aged 16 and under: Home respiratory polygraphy or home oximetry. CO_2 monitoring may be used alongside these technologies (see section 3.2). * For people with suspected COPD–OSAHS overlap syndrome, oximetry alone is not recommended.
Healthcare setting	Testing is to be done at home. Experts highlighted the importance of ensuring that a diagnosis is made by people with appropriate training and experience, for example in sleep services. However, they highlighted ongoing work on testing in Community Diagnostics Hubs, and for community-based pathways that maintain specialist input from hospital teams (see for example Devani et al. 2020).
Outcomes: intermediate measures	Intermediate measures for consideration may include: • Measures of performance to detect OSAHS and assess severity • Measures of concordance or agreement between intervention technologies, or between intervention technologies and comparators • Impact on clinical decision-making • Time to interpret device outputs and reach a diagnosis • Time to diagnosis or starting treatment • Number of repeat sleep studies done (at home or in hospital) • Use of healthcare resources (such as number and length of hospital admissions, use of pharmacological and non-pharmacological interventions for management of OSAHS) • Test failure rate (including incidences where data recorded can't be analysed or a person doesn't sleep long enough to generate enough data for assessment)
Outcomes: clinical	Clinical outcomes for consideration may include: • Morbidity • Mortality
Outcomes: patient-reported	Patient- and carer-reported outcomes for consideration may include: • Health-related quality of life • Ease of use and acceptability for patients and carers • Patient and carer experience
Outcomes: costs	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Costs of devices (including any additional software or hardware)

	• Costs related to using the interventions (including any time analysing and storing data, communicating results, and arranging for use of the technology) • Cost of maintenance of testing equipment • Cost of sending testing equipment to people's homes • Cost of follow-up appointments • Cost of further tests • Cost of treatment
Measuring cost-effectiveness	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.
Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

6 Other issues for consideration

6.1 Software updates

Software or algorithms used by the technologies may have been periodically updated, which may have had an impact on performance. This means that evidence based on earlier versions of the software may not accurately reflect the effectiveness of the current versions.

6.2 Environmental considerations

The NHS has set Net Zero goals for 2040. It is working towards reducing its reliance on disposable products and substituting these for low-carbon alternatives where they are available. The long-term sustainability of these devices should be considered in this assessment where possible. Detail on what aspects of technologies can be reused or recycled is included in technologies descriptions in section 2. Any reduction in the need to travel to healthcare centres to collect, and return, equipment may have benefits in terms of reducing carbon dioxide emissions.

6.3 Assessment done for NICE guidance on OSAHS in over 16s (NG202)

Evidence reviews for NICE guidance on OSAHS in over 16s included a literature review for data on test accuracy for home oximetry, home respiratory polygraphy and hospital respiratory polygraphy (among others; see Evidence review D for

further details and results). An economic analysis was also done for this guidance, which included a decision-analytic model of testing and treatment (see the economic analysis report that accompanied the guidance for details).

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with particular protected characteristics and others.

NG202 states OSAHS is more prevalent in people who are overweight or obese, people with COPD, older people, and more common in men than women. It is also more prevalent in pregnant women and pregnant people, and during obesity or overweight in pregnancy. Pregnancy and maternity are protected characteristics in the Equality Act (2010).

NG202 further states higher prevalence of OSAHS in people with any of the following conditions: treatment-resistant hypertension, type 2 diabetes, cardiac arrythmia, particularly atrial fibrillation, stroke or transient ischaemic attach, chronic heart failure, moderate or severe asthma, polycystic ovary syndrome, Down's syndrome, non-arteritic anterior ischaemic optic neuropathy, hypothyroidism, and acromegaly.

People with underlying conditions, for example, genetic disorders, neurodevelopmental and neuromuscular disorders, metabolic disease, craniofacial and skeletal disorders, can have a higher risk of developing OSAHS. Many people with OSAHS may be protected under the disability provision of the Equality Act because their condition could have long-term adverse effects on their ability to do normal day-to-day activities.

People who are frail or have cognitive impairment or both may struggle to use technologies that require more user-input by themselves. Technologies that are easier to use could offer additional benefit to these users.

Technologies that use light-based assessment, such as photoplethysmography (PPG) sensors and/or pulse oximetry, may overestimate levels of oxygen in the

blood for people with darker pigmentation and skin tones. The NHS Race and Health Observatory published a rapid review (2021) highlighting the limitations of using pulse oximetry for people from black, Asian and minority ethnic backgrounds.

Some technologies may be contraindicated for people with pacemakers or other implantable devices, people with known or suspected arrhythmias, people with significant cardiopulmonary or neurological disorders, or people with a known allergy to acrylate. Technologies that have adhesive sensors may not be suitable for people with physical features that impair adhesion (for example, skin growths or scars).

Access to the technology may be restricted in different populations due to wi-fi or smart phone requirements. Practices in rural or socioeconomically deprived areas may be less able to adopt these devices if the populations they serve have less access to a home wi-fi connection or a smartphone.

Clinical experts also highlighted that some people may be less familiar with, or confident, using technologies required to use the newer tests, for example smartphones, and may need more assistance to set up the overnight test.

Clear instructions on how to use the technologies will be particularly important as they are intended for use outside a healthcare setting. These instructions will need to consider any different needs for people with hearing loss or hearing impairment, who are blind or have visual impairment, or for whom English is not their first language. This also applies to currently used technologies.

The Sleep Apnoea Trust highlighted that the diagnostic pathway and access to more advanced diagnostic technologies currently varies in practice, and that this has resulted in a postcode lottery.

8 Potential implementation issues

A clinical expert mentioned issues with using the devices for children in the home setting. Some of the devices are small and easily detachable from the body, which creates a choking hazard for infants, young children and children with cognitive impairments. This may be less of an issue in the hospital setting because of monitoring by staff.

A clinical expert highlighted that there is a lack of access to CPAP machines and sleep services are currently understaffed. Any increase in people diagnosed with OSAHS is likely to increase demand for treatment and NHS resources (for example for monitoring and follow-up appointments for people with OSAHS).

Some technologies may require more training than others, particularly those that require greater user input to setup or operate the device.

When the software use cloud-based servers for the data analysis, there may be concerns about adequate protection of patient data.

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Appendix A Glossary of terms

Adenotonsillar hypertrophy

Adenotonsillar hypertrophy is the unusual growth (hypertrophy) of the adenoids and tonsils located in the back of the throat. This usually occurs in children and leads to snoring and obstructive breathing during sleep.

Adenotonsillectomy

An adenotonsillectomy is an operation to remove both the adenoids and tonsils when they are enlarged and cause obstructive breathing during sleep.

Apnoea

A complete pause in breathing, defined as lasting 10 seconds or more on a sleep study. An obstructive apnoea is caused by blockage of the upper airway, whereas a central apnoea occurs when there is no respiratory effort.

Apnoea-hypopnoea index

The number of apnoeas and hypopnoeas per hour, measured during a multi-channel sleep study. It is used to diagnose and estimate the severity of obstructive sleep apnoea/hypopnoea syndrome.

Continuous positive airway pressure

Continuous positive airway pressure (CPAP) is a form ventilation that delivers a constant level of pressure to the upper respiratory tract of a person, by a mask or nosepiece while they sleep.

Hypopnoea

A reduction in breathing, defined as lasting for 10 seconds or more on a sleep study. An obstructive hypopnoea is caused by partial obstruction of the upper airway.

Obstructive sleep apnoea

A respiratory condition where the walls of the throat relax and narrow during sleep, interrupting normal breathing.

Oxygen desaturation index

The oxygen desaturation index is defined as the number of episodes of oxygen desaturation per hour of sleep.

Polysomnography

Polysomnography (PSG) is a type of sleep study. It measures several parameters of sleep to diagnose different conditions. Polysomnography testing is done overnight in a hospital and includes respiratory polygraphy measures combined with assessment of sleep quality and duration using brain activity, eye movement, and muscle tone signals.

Pulse oximetry

Oximetry involves using a pulse oximeter, a small monitor clipped to the finger, to measure the blood oxygen level and heart rate of the patient. The device is worn overnight, and data is recorded continuously during sleep. An oximeter provides an oxygen saturation index (ODI) alongside oximetry values (minimum, maximum and average SpO_2) and heart rate.

Respiratory polygraphy

Respiratory polygraphy is a test that can diagnose different types of breathing difficulties and assess the severity of the condition. The test requires the person to wear equipment to record oxygen levels, breathing, breathing movements, snoring and body position. The system involves straps tightened around the torso and chest, an oximetry probe placed on a finger and a nasal cannula attached to a recording monitor with tubes. Tubes are secured to the body with tape to prevent them becoming unattached during sleep.

Appendix B References

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