Healthcare Improvement Scotland | SHTG Advice on health technologies

Innovative Medical Technology Overview | June 2026

Wearable home-testing devices for diagnosing obstructive sleep apnoea hypopnoea syndrome (OSAHS)

Key messages

- Wearable home-testing devices for diagnosing obstructive sleep apnoea hypopnoea syndrome (OSAHS) can offer a viable alternative to traditional in-hospital polysomnography (PSG) and home respiratory polygraphy for adults with suspected OSAHS.
- The National Institute for Health and Care Excellence (NICE) recommends the use of four wearable home-testing devices (AcuPebble SA100, Sunrise, WatchPAT 300 and WatchPAT ONE) as options to diagnose and assess the severity of OSAHS in people aged 16 and above.
- Published after the NICE recommendations, a well-conducted Cochrane review showed that level III wearable home-testing devices are clinical effective compared with in-hospital PSG for diagnosing OSAHS in adults aged 18 years and above.
- No evidence evaluating safety measures associated with the wearable home-testing devices was identified. The devices may produce false-positive or false-negative results, which can lead to inappropriate treatment decisions and potentially poorer clinical outcomes.
- Patients generally reported high acceptability with using the wearable home-testing devices; citing comfort, ease of use and convenience compared with in-hospital sleep studies. The devices may help reduce the requirement for travel to and from clinics, which may be particularly beneficial for people with mobility limitations, those living in rural areas, and individuals with limited work flexibility.
- Service providers should be aware than digital access barriers may affect users (access to smartphone or internet is required). Skin tone and physiological differences may affect diagnostic accuracy. Choice of device placement should accommodate individual physical features, religious or cultural practices and skin conditions.

- An economic model used to inform the NICE recommendations found that wearable home-testing devices are cost effective for the diagnosis of OSAHS. The analysis does not take into account the impact of the devices on the access to treatment.
- An indicative budget impact for the National Health Service (NHS) in Scotland found that introducing the new devices would cost between £901,200 and £1,425,486 depending on the device.

Definitions

Obstructive sleep apnoea hypopnoea syndrome (OSAHS) or obstructive sleep apnoea (OSA): a common sleep disorder where the soft tissues in walls of the throat relax and narrow or close the upper airway during sleep.[1]

Apnoea: total blockage of the airway for 10 seconds or more.[1]

Hypopnoea: a partial blockage of the airway, which causes airflow to reduce by more than 50% for 10 seconds or more.[1]

Background

OSAHS, also known as OSA, is a breathing disorder in which the upper airway becomes repeatedly blocked during sleep.[2] These interruptions in breathing can lead to a total blockage of the airway for 10 seconds or more (apnoea) or partial blockage of the airway, causing airflow to reduce by more than 50% for 10 seconds or more (hypopnea).[1] People with OSAHS can have both hypopnoea and apnoea throughout the night, with episodes occurring around once every 1 or 2 minutes in severe cases.[1, 2]

During an OSAHS episode, the temporary reduction in oxygen levels signals the brain to disrupt deep sleep, briefly awakening the person or shifting them into a lighter stage of sleep. This arousal allows the airway muscles to reopen and normal breathing to resume. These repeated cycles of airway obstruction and arousal throughout the night cause fragmented and poor-quality sleep, reduced oxygen levels and disrupted sleep patterns.[1] As a result, people with OSAHS often experience pronounced daytime tiredness, sleepiness, poor concentration, low energy and other symptoms such as loud snoring, choking, gasping or paused breathing. These symptoms can reduce daily functioning, overall quality of life, cognitive function and affect mental health.[1-3] OSAHS is linked to certain risk factors such as sex, age, obesity and neck circumference. It is also associated to a number of health conditions, including obesity, high blood pressure, type 2 diabetes, and cardiovascular diseases like arrhythmias and stroke.[2-4]

In the United Kingdom (UK), around 2.5 million people are living with OSAHS.[5] Data indicate that up to 85% of these patients are either undiagnosed or experience long delays in obtaining a diagnosis.[6] The estimated global prevalence of OSAHS among adults aged 30–69 years rose from 9.8 million in 2015 to 1.05 billion in 2019, with projections indicating it may reach around 1.15 billion by 2024. Moderate to severe sleep-disordered breathing affects around 10% of

men and 3% of women aged 30–49 years, rising to 17% of men and 9% of women in people aged 50–79 years.[4]

This report is focused on assessing the clinical effectiveness, cost effectiveness, safety and patient views of wearable home-testing devices for diagnosing OSAHS in people aged 16 years and above, compared with PSG and home respiratory polygraphy.

Diagnostic tests for OSAHS

The main diagnostic test for OSAHS in Scotland is the home respiratory polygraphy. These tests are carried out in the patient's home. Patients travel to the hospital or sleep centre to collect the home polygraphy test kits for overnight sleep testing. Upon completion, patients return the test kit to the sleep centre where the data is uploaded for analysis.

PSG is reserved as second line test for complex patients or where additional monitoring is required.[3] PSG is usually conducted overnight in a specialised sleep centre, where trained staff observe and record physiological data during sleep. PSG records multiple physiological signals to monitor sleep stages and breathing patterns.[3]

PSG measurements typically include:

- electroencephalography (EEG) to record brain activity
- electro-oculography (EOG) to track eye movements
- electromyography (EMG) to measure muscle activity
- electrocardiography (ECG) to monitor heart rhythm
- additional sensors to measure airflow, chest and abdominal movement, snoring, body position and blood oxygen levels.[3]

PSG is resource intensive as it requires specialised equipment, trained staff and overnight observation. Less complex and resource intensive diagnostic sleep tests, referred to as limited channel sleep studies, have been developed. They offer a more practical alternative to full PSG, particularly for initial screening or diagnosis in patients with suspected OSAHS. These tests record fewer physiological signals (or channels) and can often be carried out in the patient's home.[3]

Sleep tests can be classified into the following levels based on the number and type of measurements taken. Only level I tests are carried out in a sleep clinic or hospital setting. Levels II, III and IV tests (limited channel sleep studies) are carried out in the home setting:

- level I: captures all the physiological parameters and is fully supervised in a sleep laboratory clinic setting
- level II: records the same physiological signals as level I but without direct supervision, and can be performed at home. This is the current standard diagnostic test in Scotland

- level III: measure two respiratory variables such as breathing effort and airflow, along with oxygen saturation and a cardiac parameter (for example, ECG or heart rate). It does not measure EEG
- level IV: record only one or two respiratory parameters, typically heart rate and oxygen saturation or in some cases, airflow alone.[3]

NICE clinical guidance (NG202) recommends the use of home respiratory polygraphy (level II) as the first-line diagnostic test for OSAHS in people over 16.[7] Hospital respiratory polygraphy or PSG (level I) can also be used, where additional monitoring or a higher-fidelity reference is required.[2]

Determining OSAHS severity

The severity of OSAHS is classified according to the number of breathing interruptions that occur per hour of sleep. These events are quantified using the apnoea hypopnoea index (AHI), which reflects the combined frequency of apnoea and hypoapnoea.[1] Severity is typically defined as follows:

- Mild: 5–14 breathing events per hour
- Moderate: 15–30 breathing events per hour
- Severe: more than 30 breathing events per hour.[1]

The technology and its use

Wearable home-testing devices for diagnosing OSAHS are portable electronic sleep-monitoring devices worn directly on the body to monitor sleep in real time.[4]

The wearable devices differ across their intended indications, contraindications, physiological parameters recorded, lifespan (single-use or reusable) and whether they require an internet connection or smartphone for setup and data transfer. Some devices can be used without internet access during the data recording period, but many require connectivity for setup, upload or automated scoring.[2]

The wearable home-testing devices also differ in terms of where their sensors are attached to the body. Devices such as NightOwl, WatchPAT 300 and WatchPAT ONE are placed on the finger. AcuPebble SA100 is attached to the neck, the Sunrise device is attached under the chin and the Brizzy device uses sensors on both the chin and forehead.[2]

What is innovative about the technology?

Wearable home-testing devices offer a more a practical and scalable alternative to traditional in-hospital PSG and home respiratory polygraphy.

They offer a more simplified self-administered test in the home environment. Compared with in-hospital PSG, these devices allow overnight testing in a person's usual sleep setting rather

than a hospital laboratory. Home respiratory polygraphy devices can be uncomfortable to wear and they include wired components that need instructions before people can operate them. Wearable home-testing devices have a reduced number of wires and sensors that are attached to the body compared with traditional sleep devices. This helps to facilitate a more natural and comfortable sleep.[2]

Compared with traditional sleep devices, wearable devices use fewer channels and incorporate wireless connectivity and disposable components, which reduces the need for technician setup and monitoring.[2, 3] The devices can also be mailed directly to the patient's home and returned by post after completing the test. This potentially enables faster turnaround times and improved access for patients in remote or underserved settings.[2]

The combination of an easier home-use application, a more simplified setup and less intensive monitoring offer the opportunity to redesign OSAHS diagnostic pathways and make them more patient centred and flexible, while relieving pressure on in-hospital sleep laboratories.[2]

Regulatory information

According to NICE, the Sunrise, WatchPAT 300, WatchPAT ONE, AcuPebble SA100 and Brizzy wearable home-testing devices all have appropriate regulatory approval. The NightOwl device is awaiting regulatory approval.

Several of the wearable home-testing devices use smartphone apps and cloud analytics, and therefore services must ensure compliance with NHS data protection standards, which assesses clinical safety, data protection, interoperability, usability and technical security.[2]

Population, setting and intended use

The intended population for these wearable home-testing devices includes adults (≥16 years) with suspected OSAHS. The devices are intended to be used in home and community settings.

Some wearable home-testing devices have specific contraindications that may limit their suitability within the overall eligible patient group. The physiological outputs required for clinical decisions and accurate diagnosis, as well as the device's contraindications and limitations, should be used to guide device selection. In some cases, clinicians may prefer to use an additional oximeter alongside wearable home-testing technologies to ensure comprehensive monitoring.[2]

Current care pathway in Scotland

Across NHSScotland, the use of wearable home-testing devices for diagnosing OSAHS varies between Health Boards. The most widely used wearable device is the Sunrise system, which is currently used in NHS Greater Glasgow and Clyde (GG&C), NHS Tayside, and NHS Highlands and NHS Lanarkshire (trialling).

All the Boards currently using the devices manage distribution locally. The devices are posted directly to patients by the Boards not the manufacturer. (K Sandhu, Programme Manager, NHS Fife. Personal Communication, 15 October 2025)

Public Health Scotland (PHS) collects waiting lists data for sleep studies in Scotland. Data is available on all referral routes, and includes adults and children under 16 years old.[8] PHS data show that between 31 January and 30 June 2025, the total waiting list size for sleep studies across NHSScotland (no data for NHS Grampian) increased from 4,788 to 6,440. This indicates a 34.54% rise over the six-month period. The number of patients waiting 12 weeks or less rose from 1,134 (23.7%) in January to 1,570 (24.4%) in June. The number of patients waiting longer than 12 weeks remained high throughout the period, increasing from 3,654 (76.3%) in January to 4,870 (75.6%) in June. Almost half of all patients had been waiting more than six months (over 26 weeks) for a diagnostic sleep study at the end of June (3,154 waiting (49.0%) in June).[8]

Equality, access and other considerations

We identified two publications that discussed factors relating to equality issues and accessibility of wearable home-testing devices for diagnosing OSAHS. These included 2024 NICE HealthTech guidance (HTG735) and an evidence review.[2, 4]

The NICE guidance noted that wearable home-testing devices for diagnosing OSAHS have the potential to offer benefits for both patients and NHS services. By allowing devices to be sent directly to patients' homes, the technology can make testing more accessible, help reduce waiting times, and support faster diagnosis and treatment.[2]

The guidance also highlighted the importance of ensuring that home testing is suitable for all patient groups, including people who may have difficulty operating the device on their own. People with reduced hand mobility or dexterity issues, such as those affected by arthritis, may find it difficult to attach or operate some of the devices independently. In these cases, access to home support is an important factor in determining whether the device can be used safely and effectively. The guidance further noted that physiological differences, such as variations in chest size, might affect device performance.[2]

Skin tone and ethnicity

The NICE guidance considered how well these devices performed in people with brown or black skin. Devices such as NightOwl and WatchPAT rely on light transmission through the skin to capture physiological data, and therefore they may perform differently across skin tones. The NICE guidance committee considered expert advice indicating that OSAHS diagnosis is informed by both device data and clinical factors, including reported symptoms and the impact of sleepiness on daily functioning. They agreed that skin tone-related differences in light absorption were unlikely to affect diagnostic accuracy. The guidance concluded that wearable home-testing devices that use light-based technology are appropriate to use for people with brown or black skin. [2]

Physical or cultural considerations

The guidance highlighted that certain physical or cultural factors may influence the suitability of these devices. Skin conditions, scars or body hair can interfere with attachment and signal quality. In some cases, users may need to remove hair for correct placement, which may not be acceptable to individuals who maintain beards for personal, religious or cultural reasons. The choice of the device should consider the most appropriate body attachment site for the individual.[2]

Digital access and usability

The NICE guidance reported that devices vary in their requirement for smartphone or internet connectivity during setup, data collection and transmission. Some devices can operate without an internet connection or a smartphone during the sleep study, while others rely on an app or internet connection for setup, monitoring or data upload. Some device manufacturers can provide compatible and fully setup smartphones where required.[2]

Some people may have limited digital access (limited data plans or poor network signal coverage) or low confidence in using smartphones. This digital divide could create barriers to participation if not addressed. The technical requirements of each device and the digital capabilities of patients should be assessed when deciding if home testing is appropriate.[2]

Environmental sustainability factors

NICE guidance also considered the environmental implications of reusable versus single-use devices. Reusable systems (such as AcuPebble SA100, Brizzy and WatchPAT 300) may help reduce waste, but they need to be returned, cleaned and reallocated. Lost or delayed returns could temporarily reduce service capacity. Single-use devices (such as NightOwl, Sunrise and WatchPAT ONE) simplify logistics and eliminate reprocessing but they generate more medical waste.[2]

Wearable devices can be posted to patients, which contributes to lower carbon emissions compared with patients travelling to clinics or having to pick up or drop off equipment.[2]

Summary of clinical evidence

NICE guidance includes the following recommendations on the use of wearable home-testing devices for diagnosing OSAHS in people aged 16 years and over:[2]

1. ‘Use the following home-testing devices as options to diagnose and assess the severity of OSAHS in people 16 years and over:

- AcuPebble SA100
- Sunrise
- WatchPAT 300
- WatchPAT ONE.

2. When considering whether to use these devices in place of home respiratory polygraphy or home oximetry, take into account:

- whether the device can provide the outputs that are needed for decisions about care, including whether a third-party oximeter can be used, particularly for identifying OSAHS in people with comorbidities
- whether the person has hair in the area that the device attaches to that would need to be removed, and if this is acceptable for the person
- whether the person has physical features such as skin conditions or scars that may affect how well the device attaches
- the internet and smartphone access that would be needed to use the device
- if attaching or using the device would be difficult for the person, and if they will have support with using the device.

3. These devices can only be used once they have appropriate regulatory approval and NHS England's Digital Technology Assessment Criteria (DTAC) approval.'

NICE noted that more research was required on:

- the accuracy of the Brizzy devices in people aged 16 years and over
- how accurately the wearable home-testing devices diagnose and assess the severity of OSAHS in people with black or brown skin.

The evidence underpinning the NICE recommendations was primarily based on diagnostic accuracy studies that were mostly conducted in hospital settings rather than home settings. Only two studies (one study for the AcuPebble SA100 and one study for the Sunrise device) assessed diagnostic performance under home-use conditions. The guidance recognised that home-based studies were more relevant to the topic but noted that, in practice, new devices are commonly validated in controlled, hospital-based environments before being used at home.[2]

The guidance concluded that although the setting may influence some operational aspects of device use, the core physiological signals measured would not be expected to vary substantially between hospital and home settings. It considered that diagnostic accuracy data from the hospital-based studies were acceptable alternatives for estimating performance in home environments.[2]

Evidence published after NICE guidance (DG62)

A well-conducted Cochrane systematic review (van Doorn et al), published in 2025, assessed the clinical impact of diagnostic and treatment strategies using limited channel home-sleep studies (level III and IV) compared with the gold standard level I PSG in adults (aged 18 years and older) with suspected OSAHS. Level III sleep studies measure two respiratory variables and level IV measures only one or two respiratory parameters. The review examined whether using the test, followed by treatment decisions, improves patient and clinical outcomes. This approach also helps to identify any unintended harms or benefits from correct or incorrect diagnoses.

The study included three randomised controlled trials (RCTs) involving a total of 1,143 participants, with follow-up durations ranging from 4-6 months. There was no overlap between

the studies included in the NICE guidance and this review. All the trials were conducted in academic hospital settings. The primary outcome of the review was sleepiness, which was assessed with the Epworth Sleepiness Scale (ESS). Secondary outcomes included quality of life, all-cause mortality, serious adverse events cardiovascular events and correlating risk factors such as body mass index and blood pressure. The review conducted meta-analyses to compare the clinical outcomes. Findings were reported as mean difference (MD), standardised mean difference (SMD) with 95% confidence interval (CI) and heterogeneity (I^2) was evaluated using the I^2 statistic. Risk of bias was assessed using the Cochrane risk of bias 2 (RoB 2) tool for randomised trials.[3]

Level III versus level I PSG

The review reported high-certainty evidence that compared with fully supervised PSG (level I), level III studies resulted in no significant difference in sleepiness (MD = 0.47, 95% CI: −0.23 to 1.18, p = 0.19, I^2 = 0%, 2 trials, n=701) or quality of life (SMD = 0.01, 95% CI: −0.14 to 0.16, p = 0.93, I^2 = 0%, 2 trials, n=701). No clinically relevant differences were reported for cardiovascular events, correlated risk factors or serious adverse events (low certainty evidence). None of the included studies reported all-cause mortality.[3]

Level IV versus level I PSG

The review found low certainty evidence that there was no difference in the mean change in ESS score (sleepiness) between baseline and follow-up in participants in level IV studies compared with level I PSG (MD = 0.66, 95% CI: −0.41 to 1.72, p = 0.23, I^2 = 39%, 2 trials, n=573). There was also low certainty evidence of no meaningful difference in cardiovascular events or related risk factors between level IV and level I tests. The evidence for quality of life and serious adverse events was very uncertain. The high risk of bias in the level IV versus level I sleep study trails was mainly because of missing outcome data, lack of blinding and participants including subjective outcome measurements. No study reported mortality outcomes.[3]

The review concluded that level III home-based studies are clinically comparable to in-laboratory PSG (level I) in terms of their impact on sleepiness, quality of life and cardiovascular outcomes. The authors summarised that this makes level III tests a viable alternative to PSG for diagnosing OSAHS. Level IV studies demonstrated inconclusive evidence, with only low- to very-low- certainty data supporting equivalence on major clinical outcomes. The authors highlighted that the current evidence base remains limited and additional RCTs are needed to confirm long-term outcomes, particularly mortality, cardiovascular events and patient-reported measures in home settings.[3]

Summary of safety evidence

We did not identify any studies regarding the safety of wearable home-testing devices for OSAHS diagnosis.

The Cochrane review highlighted that while wearable home-testing devices are quicker to administer than fully supervised PSG, they may have different diagnostic performance profiles,

including higher risks of false-positive or false-negative results. These can lead to inappropriate treatment decisions (such as offering therapy to people without OSAHS or failing to treat those who do have the condition), which may in turn result in unfavourable clinical outcomes.[3]

Summary of economic evidence

Technology costs

Table 1: Technology costs

Device	Cost of first test (£)	Cost of repeat test (£)
Interventions		
AcuPebble SA100	74	1
Brizzy	70	28
NightOwl	111	13
Sunrise	83	84
WatchPAT 300	82	30
WatchPAT ONE	103	25
Comparators		
Pulse oximetry	18	212
Respiratory polygraphy	212	212

Indicative budget impact

Table 2: Budget impact of introducing the new technology

Device	Budget impact (£)
AcuPebble SA100	937,771
Brizzy	901,200
NightOwl	1,425,486
Sunrise	1,163,501
WatchPAT 300	1,051,536
WatchPAT ONE	1,315,560

Table 2 presents the estimated budget impact of introducing wearable home-testing devices in NHSScotland. The calculations were based on the assumption that the wearable home-testing devices would be supplied in the amount that will allow to diagnose all patients currently on the waiting list in each NHSScotland Boards, thus eliminating the case backlog. The number of patients on the waiting lists for sleep studies was obtained from the NHSScotland Boards. The missing observations were imputed based on the values from the Boards having similar population size.

The budget impact was estimated as the number of patients on the waiting lists multiplied by the expected cost of OSAHS diagnosis using the wearable home-testing device. The expected cost was the weighted sum of costs in two events: (i) the test provided the results at the first attempt, and (ii) the test had to be repeated. These costs were weighted by the probability of each event. The cost data and probabilities of retesting were published by the 2024 HealthTech guidance (HTG735).

This short-term budget impact result assumes the new devices would be initially used to eliminate the case backlog. In the longer term, the budget impact analysis would have to focus on comparing the wearable home-testing devices with the currently used methods of testing, such as sleep studies, respiratory polygraphy and pulse oximetry.

Further analyses of cost effectiveness and/or budget impact of wearable home-testing devices for diagnosing OSAHS may focus on capturing the following aspects as part of the overall value proposition:

- improvements in diagnosis rate and time-to-diagnosis of OSAHS
- preventing the complications of OSAHS by improving diagnosis and time-to-treatment
- lower costs of diagnosis
- higher utility for the treated patients with OSAHS
- potential longer term outcomes including:
    - the lifetime healthcare costs generated by the patients
    - the number of hospitalisations caused by the OSAHS complications
    - the number of surgical interventions connected to the OSAHS complications.

Wearable home-testing devices for diagnosing OSAHS use a technology that aims to improve diagnosis rates and time-to-treatment for the patients with OSAHS. Using these devices is a diagnostic intervention and is not likely to directly provide any health benefits. The value of a diagnostic intervention depends on the cost effectiveness of the treatment offered, uptake and adherence to the treatment.

Published evidence

Economic evidence comes from the 2024 HealthTech guidance (HTG735). The cost-utility analysis was conducted from a healthcare and social services provider perspective. The

incremental net monetary benefit (INMB), a measure that translates the value of the intervention into monetary terms for a given value of the cost-effectiveness threshold, was estimated using a decision analytic model with a lifetime horizon and discounting rate of 3.5% for costs and health benefits.

The interventions evaluated in the study were six wearable home-testing devices for diagnosis of OSAHS:

- AcuPebble SA100
- Brizzy
- NightOwl
- Sunrise
- WatchPAT 300
- WatchPAT ONE

These devices were compared with:

- home respiratory polygraphy
- home pulse oximetry

A hybrid model was used for an adult population (over 16 years): a decision tree with a time horizon of 12 months to capture the diagnosis of OSAHS and a Markov model to estimate lifetime costs and consequences. Five possible complications of OSAHS were included: stroke, myocardial infarction, transient ischaemic attack, unstable angina and stable angina. The model also took into account increased risk of road accidents in the adult OSAHS population. The treatments offered to the diagnosed patients were (depending on the severity of OSAHS): conservative management, continuous positive airway pressure (CPAP) devices and mandibular advancement devices.

All wearable home-testing devices in the analysis were shown to yield lower costs and quality-adjusted life years (QALYs) than respiratory polygraphy, and higher costs and QALYs than pulse oximetry. The incremental analysis results showed that wearable home-testing devices compared with pulse oximetry had a positive INMB at thresholds of £20,000 and £30,000. In comparison with respiratory polygraphy, AcuPebble and Sunrise offered a reduction in costs that was considered cost effective taking into account a small QALY loss. Any differences in model inputs were small between devices, and therefore the devices were not compared with each other. NICE concluded that AcuPebble SA100, Sunrise, WatchPAT 300 and WatchPAT ONE devices were cost-effective alternatives to home oximetry and home respiratory polygraphy. The NightOwl device was not included in the recommendations because it was awaiting appropriate regulatory approval.

Generalisability

The model proposed in the diagnostic assessment report could be appropriate for use in the Scottish setting. However, a consultation with Scottish clinical experts is advised to list the relevant comparators and validate the care pathway.

A possible limitation to the generalisability of the English-based model is the disparity in services for diagnosing and treating OSAHS between England and Scotland. The NHSScotland currently runs ten sleep clinics, while in England there are over 170 sleep clinics. Taking into account the differences in the population size in both countries, in Scotland there is about 60% more patients per clinic. The longer waiting times for a diagnosis affect time-to-treatment was shown to be a key driver of health benefits in the model.

Patient or user experience

The NICE guidance drew upon evidence from three diagnostic studies that explored patients' experiences with wearable home-testing devices for diagnosing OSAHS — one study each for Sunrise (a prospective randomised study), AcuPebble SA100 (a prospective cohort study) and WatchPAT 300 (a prospective randomised study). Patient measured outcomes included acceptability, usability, perceived sleep quality, test-related discomfort and patient requirements.[2]

The NICE guidance reported that patient experts described several advantages of using wearable home-testing devices. Users valued their ease of use and comfort. As wearable home-testing devices can be sent to people's homes and returned by post, users also valued the convenience of completing the full sleep test process at home without any need to travel. This was preferred over travelling to hospital to collect and return respiratory polygraphy test kits or for in-hospital sleep testing. The NICE committee noted that the devices have the potential to improve access to diagnosis and treatment, and reduce waiting times by limiting the need for in-person clinic visits. This improved accessibility was considered particularly beneficial for individuals with limited mobility, those living far from specialist sleep centres and those unable to take time off work or manage travel expenses.[2]

The guidance also emphasised that wearable home-testing devices should be implemented only as part of an agreed and integrated sleep care pathway.[2]

Conclusions

The evidence reviewed indicates that wearable home-testing devices for diagnosing OSAHS offer a promising, clinically effective and potentially more accessible alternative to respiratory polygraphy and hospital-based PSG for adults with suspected OSAHS.

Across the evidence identified (NICE HTG735 and the Cochrane systematic review by van Doorn et al.), wearable home-testing devices demonstrated comparable diagnostic and clinical outcomes to fully supervised PSG. Diagnostic accuracy estimates showed no meaningful differences in sleepiness, quality of life or cardiovascular outcomes. These findings support the

use of wearable devices as clinically valid and resource-efficient diagnostic tools within clearly defined sleep pathways.

The evidence for level IV devices remains less certain and their role in routine diagnostic practice is not yet established. Low to very low certainty evidence suggests no difference in sleepiness or cardiovascular events between level IV devices and PSG. Findings on quality of life for level IV devices were inconclusive. Further research is needed to confirm equivalence in accuracy and patient outcomes for level IV devices.

Wearable home-testing devices were associated with improved accessibility and greater convenience, particularly for people with limited mobility and those living far from specialist sleep centres. Patient-reported experiences indicated positive user acceptability. Issues relating to dexterity, device placement, skin tone, patient literacy, internet and smartphone access must be considered when implementing these technologies. Adoption will also require consideration of digital literacy, patient support at home and inclusive design features that accommodate diverse physical and cultural needs.

The economic evidence from the recent NICE diagnostic assessment report showed that wearable home-testing devices could provide an alternative to the other testing methods. They are cost effective compared with the pulse oximetry, and they can save the costs with an acceptable QALY loss compared with respiratory polygraphy. To ensure this innovation would be beneficial to the NHSScotland, an economic analysis in this setting is required. The analysis should establish the additional diagnostic yield caused by introducing the wearable home-testing devices, identify possible difficulties with providing treatment to diagnosed patients in timely manner and estimate the budget impact of this new technology.

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What is an IMTO?

An Innovative Medical Technology Overview (IMTO) provides a high-level summary of health and care innovations. IMTOs include a description of the technology and its potential use in Scotland, and an overview of the evidence to help gauge the potential impact of the technology on people and health and care services.

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Appendix 1: Abbreviations

AHI	apnoea hypopnoea index
CI	confidence interval
CPAP	continuous positive airway pressure
DG	diagnostics guidance
DTAC	Digital Technology Assessment Criteria
ECG	electrocardiography
EEG	electroencephalography
EMG	electromyography
EOG	electro-oculography
ESS	Epworth Sleepiness Scale
GG&C	Greater Glasgow and Clyde
IMTO	Innovative Medical Technology Overview
INMB	incremental net monetary benefit
MD	mean difference
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OSA	obstructive sleep apnoea
OSAHS	obstructive sleep apnoea hypopnoea syndrome
PHS	Public Health Scotland
PSG	polysomnography
QALYs	quality-adjusted life years
RCT	randomised controlled trial
RoB 2	risk of bias 2
SMD	standardised mean difference
UK	United Kingdom