NICE advice

RespiraSense for continuously monitoring respiratory rate

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is RespiraSense. It is used for continuously monitoring respiratory rate.
- The **innovative** aspects are that it is motion-tolerant and continuously monitors respiratory rate while a person is walking or changing body position.
- The intended **place in therapy** would be alongside intermittent nurse-led monitoring for people admitted to hospital who are at risk of respiratory compromise and are having over 4 litres per minute of oxygen or are on high flow or non-invasive ventilation treatment. It can be used across multiple indications, including pneumonia, sepsis, chronic obstructive pulmonary disease, heart failure and COVID-19.
- The **main points from the evidence** summarised in this briefing are from 3 studies (1 retrospective observational study and 2 prospective observational studies) including a total of 106 adults. The evidence suggests that RespiraSense can be used to continuously measure respiratory rate in an acute hospital setting and may be able to predict hypoxic and pyrexic events.

- **Key uncertainties** are that the evidence base for RespiraSense is limited and comes from single-centre observational studies that involve a relatively small number of people. Only 1 study was done in the UK.
- **Experts advised** that RespiraSense could be used in an acute ward setting to continuously monitor respiratory rate. However, 2 experts stated that it would not replace the need for other regular clinical observations and 1 expert felt additional respiratory rate monitoring would provide minimal clinical benefit and increased costs. Experts agreed that more evidence is needed to establish the validity of the device and confirm if it works better than other methods of respiratory rate measurement, as well as the effect on clinical outcomes and costs.
- The average **cost** of RespiraSense per person is approximately £76 (based on an estimated average number of people who would use the device for 1 acute care ward).

The technology

RespiraSense (PMD Solutions) is a motion-tolerant digital technology for continuously monitoring respiratory rate. It is intended to be used by people admitted to hospital who are at risk of respiratory compromise and are having over 4 litres per minute of oxygen or are on high flow or non-invasive ventilation treatment. It can be used across multiple indications, such as pneumonia, sepsis, chronic obstructive pulmonary disease, heart failure and COVID-19.

RespiraSense is a wearable sensor that is made up of 2 parts: a single-use adhesive sensor and a rechargeable plastic lobe, which are joined together and attached to the chest. It continuously records respiratory data when a person is moving or walking. People can wear the device continuously from admission to discharge from hospital. RespiraSense measures the repetitive mechanical movement of breathing by analysing the movements of the chest and abdomen using piezoelectric film sensors. The device processes the breathing signals and uses an algorithm to remove background noise not associated with breathing.

Data collected by the device is transmitted by a Bluetooth connection to a smart device, such as an iPad or smartphone, where it can be viewed by healthcare professionals using the RespiraSense app. The app also allows healthcare professionals to monitor multiple RespiraSense devices at once. Both the device and the smart device will alarm if the respiratory rate changes and is outside of preset limits. RespiraSense can integrate with

any electronic health record system or can be used as a stand-alone respiratory monitor.

Innovations

RespiraSense continuously monitors respiratory rate while a person is walking or changing body position. It processes breathing signals depending on how much motion has been observed and combines 2 respiratory rates (1 from the chest data and 1 from the abdominal data). The company claims that motion tolerance and comparing multiple respiratory signals improves respiratory rate measurement accuracy. The company claims that this could lead to earlier identification of respiratory deterioration and improve patient outcomes.

Current care pathway

RespiraSense is intended to be used for people admitted to hospital who are at risk of respiratory compromise. It can be used across multiple indications to continuously monitor respiratory rate.

Adults in acute hospital settings have physiological measurements taken during their initial assessment or on admission. A clear written monitoring plan should be created that specifies which physiological observations should be recorded and how often. As a minimum, this should include respiratory rate, heart rate, systolic blood pressure, level of consciousness, oxygen saturation and temperature. This should be at least every 12 hours unless decided otherwise based on the person's needs. Respiratory rate should be recorded and acted on by staff who have been trained to do the procedure and understand its clinical relevance.

Early warning score 'track and trigger' systems should be used to monitor all adults in acute hospital settings to alert healthcare professionals to any deterioration in a person's health. The National Early Warning Score (NEWS) 2 uses 6 routinely recorded physiological parameters, including respiratory rate, and is endorsed by NHS England. Changes in respiratory rate should be considered as part of the escalation of treatment for people in an acute care setting.

Respiratory rate is currently measured by manually counting the number of breaths per minute. It can also be measured using impedance pneumography, electrocardiography and capnography (a measurement of carbon dioxide in a person's exhaled breath).

Capnography is considered the 'gold standard' for measuring respiratory rate but is rarely used in a ward setting.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on managing COVID-19
- NICE's medtech innovation briefing on NEWS systems that alert to deteriorating adult patients in hospital
- NICE's guideline on chronic obstructive pulmonary disease in over 16s: diagnosis and management
- Royal College of Physician's NEWS 2
- NICE's guideline on sepsis: recognition, diagnosis and early management
- NICE's guideline on acutely ill adults in hospital: recognising and responding to deterioration.

Population, setting and intended user

RespiraSense is intended to be used by people admitted to hospital who are at risk of respiratory compromise and are having over 4 litres per minute of oxygen or are on high flow or non-invasive ventilation treatment. It can be used across multiple indications, including pneumonia, sepsis, chronic obstructive pulmonary disease, heart failure and COVID-19. RespiraSense should not be used during defibrillation, MRI, X-ray or other medical imaging procedures. The technology should not be used for newborn or baby monitoring.

RespiraSense can be used to measure respiratory rate in an acute hospital setting. The company notes that it could also be used in a person's home as part of monitoring in virtual wards.

The technology can be used by different healthcare professionals, including nurses, physiotherapists and healthcare assistants. Clinical users are trained in device set up, collecting continuous respiratory rate, and reviewing and reporting on the monitoring. They are also trained to select people for monitoring according to local protocols and guidance. The company states that they provide free initial and refresher training, which

typically takes 20 to 30 minutes to complete.

Costs

Technology costs

The company states that the average cost of RespiraSense per person is approximately £76 (based on an estimated average number of people who would use the device for 1 acute care ward).

A RespiraSense kit (including 6 reusable and rechargeable plastic lobes, charging station, and iPad) costs £5,000 per unit (excluding VAT). The disposable wearable sensor costs £35 per unit. The company claims that the rechargeable plastic lobes have a minimum lifespan of 5 years, and the disposable sensors have a lifespan of 168 hours before needing replacement. The company states that there is an initial installation and test cost per hospital of £4,800, and a local Bluetooth network and server connection cost per hospital of £7,200. The company states that 1 kit is needed per hospital ward, and further wards can be added with no increase in IT infrastructure costs. Device costs, installation and data connectivity costs may vary depending on local factors that will be assessed at the design stage of adoption.

Costs of standard care

National 'track and trigger' systems can be automated or paper based. Paper-based early warning score charts are free to download from the Royal College of Physicians website. Wong et al. (2017) reported that it takes 3 minutes 35 seconds of nursing time to do manual observations and early warning score calculations. Based on the agenda for change NHS pay scales 2022/23 band 5 nursing salary, the cost of recording and calculating the early warning score manually is £0.78 per person.

The cost of handheld and bedside capnograph monitors listed on NHS Supply Chain range from around £1,200 to over £2,000. There may be additional costs for replacement accessories. Locally agreed prices may differ.

Resource consequences

The company states that the technology is currently used in 1 NHS trust across 3 acute

respiratory wards.

RespiraSense is intended to be used alongside intermittent nurse-led monitoring and so will initially cost more than current standard care alone. The company claims that the technology could lead to cost savings by identifying people at risk of respiratory deterioration earlier and allowing for earlier interventions, such as ventilatory support or antibiotics. It could also lead to reducing the length of hospital stay, reducing hospital re-admission rates and improving long-term health outcomes.

The company states that typical requirements for technology adoption include additional network and mains power points if none are available. The company claims that no additional personnel are needed to run the system, but a collaborative team approach with hospital IT security and risk assessment departments are needed for successful implementation of the RespiraSense system.

Regulatory information

RespiraSense is a CE marked IIb medical device.

Equality considerations

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

Chronic obstructive pulmonary disease is a chronic condition, which may mean someone is disabled if this has a substantial and long-term effect on their ability to do daily activities. People aged over 65, men and people from black, Asian and ethnic minority groups are disproportionally affected by COVID-19 (Office for National Statistics, 2020). Disability, age, sex and race are protected characteristics under the Equality Act (2010).

The company notes that RespiraSense may be inappropriate for people who are unable to tolerate body-worn devices.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 3 studies summarised in this briefing, including a total of 106 people. The evidence includes 1 retrospective observational study and 2 validation studies.

In addition, there are further abstracts evaluating the accuracy and acceptability of RespiraSense in a bariatric setting (Albom et al. 2019 and Albom 2022) and a cost–utility analysis comparing the technology with intermittent nurse-led monitoring for pneumonia (Javanbakht et al. 2021) that are not included in this briefing.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence base for RespiraSense is limited and comes from single-centre observational studies that involve a relatively small number of people. Two studies are validation studies comparing RespiraSense with the industry standard (nurse-led manual counting). Only 1 of these compared the technology with the 'gold standard' capnography. Only 1 study included clinically relevant outcomes and only 1 study was done in the UK. The evidence suggests that RespiraSense can be used to continuously measure respiratory rate in an acute hospital setting and may be able to predict hypoxic and pyrexic events. One study reported that it was also easy to use and well tolerated. Further evidence would benefit from larger multicentre randomised controlled trials looking at the clinical significance of early detection of changes in respiratory rate and how this influences escalation or de-escalation of treatment for acutely ill adults.

McCartan et al. (2021)

Study size, design and location

Retrospective cohort study of 34 people admitted to hospital with COVID-19 in Ireland.

Intervention and comparator

Electronically measured respiratory rate (EMRR) using RespiraSense compared with visually measured respiratory rate (VMRR).

Key outcomes

A total of 3,445 visual and 729,117 electronic respiratory rate measurements were recorded from 34 people. The distribution characteristics of VMRR compared with EMRR were significantly different in Wilcoxon signed-rank test ($p<0.0001$; $z=6.001$). Of all measurements taken at the same time, 37.7% of VMRR were above the corresponding EMRR value, 12.2% were the same and 52.1% were below. The mean difference between EMRR and VMRR was 1.3 (standard deviation [SD] 4.6), with EMRR being larger on average. The dataset contained 59 hypoxic events affecting 14 people, and 27 pyrexic events affecting 10 people. An elevated EMRR was predictive of hypoxic (hazard ratio 1.8 [1.05 to 3.07]) and pyrexic (hazard ratio 9.7 [3.8 to 25]) episodes over the following 12 hours. A total of 70.6% of people would have had a change of treatment during their admission based on the UK's National Early Warning System if EMRR was used in place of VMRR.

Strengths and limitations

This study was done retrospectively and had a small sample size. Some comorbidity data was collected, but there was not enough to establish the effect that comorbidities may have on electronic respiratory rate measurements. Healthcare professionals taking visual measurements of respiratory rate were unaware that their measurements would be studied, reducing the chance of observer bias.

Lee (2016)

Study size, design and location

Prospective pilot study of 48 people admitted to a post-anaesthesia care unit in Ireland.

Intervention and comparator

RespiraSense compared with electrocardiogram (ECG), and manual observation by nursing staff.

Key outcomes

Out of a total of 144 recorded data points, 115 time points were available for analysis. The remaining 29 time points were lost because of delays in connecting the ECG monitor, laptop shutdown, disconnection of the RespiraSense device and failure of ECG to generate meaningful respiratory rate data. The mean difference for average respiratory rate between RespiraSense and ECG was less than 1 beat per minute (bpm), mean (SD) was -0.41 (1.79). The 95% confidence interval for the difference in average was -3.9 to 3.1, which did not exclude the clinically relevant difference of 3 bpm. The difference was greater than 3 bpm for 9 intervals (7.8%). The mean difference for average respiratory rate between RespiraSense and the nurse evaluation was less than 1 bpm, mean (SD) was -0.58 (2.50). The 95% confidence interval for the difference in average respiratory rate was -5.5 to 4.3, which does not exclude the clinically relevant difference of 3 bpm. The difference was greater than 3 bpm for 23 intervals (20%). Only 3 of the 23 intervals also showed a difference of greater than 3 bpm in average respiratory rate for RespiraSense compared with ECG. RespiraSense and ECG had a Pearson product-moment correlation coefficient of 0.84, and RespiraSense and nurse evaluation had a Pearson product-moment correlation coefficient of 0.78. Using a verbal rating scale, all patients rated RespiraSense as 10 out of 10 for comfort, and all nurses rated it 10 out of 10 for ease of use.

Strengths and limitations

This study suggests that RespiraSense measures respiratory rates with clinically relevant agreement with those from ECG and manual measurements taken by nursing staff. Limitations of the study include lack of blinding, and lack of comparison to a 'gold standard' for respiratory rate monitoring.

Subbe and Kinsella (2018)

Study size, design and location

Prospective controlled exploratory study of 24 people admitted to an acute medical unit in the UK.

Intervention and comparator

RespiraSense compared with capnography, and manual counting of respiratory rate.

Key outcomes

Data from 17 out of 24 people was included in the study analysis. There were 62 data points available from the primary end point. At rest, RespiraSense had a mean respiratory rate of 19.8 (SD 4.52), compared with 20.2 (SD 4.54) for capnography and 19.3 (SD 4.89) for manual counting. At rest, RespiraSense had a bias of 0.38 and limits of agreement of 1.0 to 1.8 bpm when compared with capnography (R^2=0.99), and a bias of -0.70 and limits of agreement of -4.9 to 3.5 bpm when compared with manual counting (R^2=0.90). Agreement of measurements was within pre-defined limits for capnography compared with RespiraSense. Respiratory rate was also measured during a period with permission of movement. During this period, RespiraSense had a mean respiratory rate of 21.1 (SD 4.15) compared with 19.34 (SD 4.61) for manual counting. With movement, RespiraSense had a bias of -1.72 and limits of agreement of -6.8 to 3.3 bpm when compared with manual counting (R^2=0.83).

Strengths and limitations

This study suggests that RespiraSense delivers measurement of respiratory rate comparable to capnography and manual counting at rest. The main limitation of this study is the lack of randomisation, which increases the risk of selection bias. The study was funded by PMD Solutions.

Sustainability

The company claims that the technology could reduce the number of care miles travelled when used in a community setting. There is no published evidence to support these

claims.

Recent and ongoing studies

- A retrospective study to evaluate the predictability of abnormal arterial blood gas measurements through novel observations of continuous trends in electronically measured respiratory rate in a mixed cohort of respiratory compromised patients. ClinicalTrials.gov identifier: NCT05384314. Status: recruiting. Indication: respiratory failure, chronic obstructive pulmonary disease, pneumonia, community-acquired pneumonia, COVID-19 and pulmonary disease. Device: RespiraSense. Estimated study completion date: 12 December 2022. Country: Ireland.
- The company claims that from March 2020, RespiraSense has become standard care for monitoring people who are at risk of respiratory compromise in 50 wards across 23 hospitals in the Irish healthcare system. Over 40,000 people in Ireland per year are being cared for using continuous respiratory rate monitoring.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

One out of 3 experts was familiar with and had used this technology before.

Level of innovation

Two experts thought that RespiraSense is an innovative technology and 1 expert said that it was a minor variation on an existing procedure. One expert said that continuous pulse oximetry and heart rate monitoring deliver the same information as RespiraSense clinically and are widely available.

Potential patient impact

Two experts noted that respiratory rate is often poorly recorded and is an important indicator of deterioration. One expert said that RespiraSense may recognise respiratory

deterioration earlier, which could lead to earlier intervention, improved outcomes, avoidance of admission to critical care, and reduced length of hospital stay. One expert stated that the benefit from additional respiratory rate monitoring is marginal. Two experts felt that any acutely ill person could benefit from continuous respiratory rate monitoring with RespiraSense, particularly for those whom respiratory rate has been shown to be a prognostic factor, such as people with pneumonia or sepsis. Experts noted that RespiraSense may also be beneficial in a virtual ward setting, or could be used for infection control purposes, allowing nurses to record respiratory rate remotely with minimal contact with patients.

Potential system impact

Experts agreed that RespiraSense would be used in addition to standard care. Two experts felt that it would not replace the need for other regular clinical observations, and 1 felt it could make monitoring people in acute care more burdensome. All experts agreed that RespiraSense would initially cost more than standard care, and 2 felt that it would cost significantly more than standard care in the long term. One expert noted that there is no evidence to suggest RespiraSense would lead to reduced costs by reducing length of stay or critical care admission. One expert felt that, despite the initial cost, improved outcomes could lead to cost savings quickly in the correct setting. Two experts noted that good Bluetooth and Wi-Fi connections, as well as significant support from IT departments would be needed, which could be challenging in older hospitals. Experts agreed that training on device use and maintenance would be needed.

General comments

Two experts stated that no clinical harms have been identified but noted that the current evidence base is limited. One expert said that small potential risks include a reaction to the device sticky pad, patient disturbance because of device alerts, and potential loss of data and failure to identify early deterioration if the lobe runs out of battery. However, it was noted that these risks were not seen during their experience using RespiraSense.

Experts agreed that further research is needed to establish the validity of the device and confirm its superiority against other methods of respiratory rate measurement, as well as the effect on clinical and financial outcomes. Beneficial outcomes for future research may include detection of deterioration, time of intervention, length of stay, unplanned admission to critical care, mortality rate and patient acceptability.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Ben Messer, consultant in critical care medicine and home ventilation, Newcastle upon Tyne Hospitals NHS Foundation Trust. Received speaker fees and education support from Fisher and Paykel.
- Ms Fiona Morcom, independent nurse consultant. Did not declare any interests.
- Dr Rahul Mukherjee, consultant respiratory physician, University Hospitals Birmingham NHS Foundation Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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