Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER326
Topic:	A continuous respiratory rate monitor (RespiraSense) for people with multiple respiratory conditions.
Summary of findings:	Health Technology Wales researchers identified three observational studies, one cost-utility analysis and four on-going observational studies relating to the use of continuous respiratory monitors. Three observational studies examine the effectiveness of RespiraSense when compared to manual counting. Findings suggests that measurements with RespiraSense and manual counting are often reported as similar, although it is unclear how impactful a continuous monitor would be in the current pathway at preventing adverse events. Of these studies, one reported the effectiveness of RespiraSense when predicting events in a cohort of people with COVID-19. although this study does not examine the effectiveness of RespiraSense in predicting chronic obstructive pulmonary disease (COPD), pneumonia, or sepsis. We identified one cost-utility analysis which reported a significant cost saving associated with the use continuous respiratory rate monitors. The lack of clinical outcomes from the supporting literature results in some uncertainty surrounding this health economic conclusion reached.

Introduction and aims

RespiraSense is a wireless device which continuously monitors a person's respiratory rate. The current measurement to monitor respiratory rate is capnography or manually counting. This device is indicated for people with illnesses such as pneumonia, sepsis, and COPD. The device does not replace treatment options for the above conditions but aims to detect issues earlier and reduce escalation of care.

Health Technology Wales researchers searched for evidence on the effectiveness, safety, and cost-effectiveness of continuous respiratory rate monitoring (RespiraSense) when compared to standard care.

Health Technology Wales researchers did not refine searches to specific health conditions such as COPD or sepsis.

Evidence overview

Guidance

This topic exploration identified several NICE guidelines relating to the diagnosis and management of the targeted health conditions that could potentially benefit form incorporating RespiraSense into the care pathway. The guidelines make no reference to the clinical effectiveness of RespiraSense specifically.

Individual studies

Health Technology Wales researchers did not identify any systematic reviews or randomised controlled trials relating to the clinical value or effectiveness of RespiraSense compared to current practice in the UK.

We identified three observational studies. All studies included a comparison of continuous monitoring of respiratory rate using RespiraSense with manual counting. One study compared RespiraSense to both manual counting and ECG (n = 48) (Lee 2016). One study compared electronically measured respiratory rate compared to manual counting only (n = 34) (McCartan et al. 2021). One study compared RespiraSense to both capnography and manual counting (n = 17) (Subbe & Kinsella 2018).

RespiraSense compared to manual counting

The respirating rate provided by RespiraSense was found to be similar to manual counting, although it is unclear if the technology is more or less accurate than manual counting as the comparator and how this would lead to better clinical outcomes or predict adverse events. The mean difference for the average respiratory rate between RespiraSense and manual counting was less than 1 breaths per minute (bpm) (Lee 2016). Subbe & Kinsella (2018) found the mean difference in respiratory rate between RespiraSense and manual counting was 0.5 bpm. In a cohort of people with COVID-19 (n = 34) (McCartan et al. 2021), the mean difference of respiratory rate between RespiraSense and manual counting was 1.3 bpm. However, the statistical significance of these outcomes are unclear in the studies.

RespiraSense compared to ECG

Lee (2016) found that the mean difference for average respiratory rate between RespiraSense and ECG is less than 1 bpm.

RespiraSense compared to capnography

Subbe & Kinsella (2018) (n = 17) examined the difference in respiratory rate between RespiraSense and capnography. The mean respiratory rate using LifeSense capnography was of 20.2 compared to 19.8 for RespiraSense. Whether the difference in values would be significant to clinical outcomes when assessing or predicting diseases, is unclear.

Predicting adverse events

Monitoring respiratory rate is a major component of the National Early Warning Score (NEWS). Its purpose is to identify acutely ill patients, including those with sepsis, in hospitals in England. The NEWS scoring system measures six physiological parameters including respiratory rate (NICE 2020).

One study, (McCartan et al. 2021), investigated the ability of RespiraSense to predict pyrexic and hypoxic events in the 12 hours following a RespiraSense observation in a cohort of people with COVID-19. In terms of the NEWS scoring system, 8.4% of NEWS decreased when using RespiraSense instead of manual counting and 33.1% increased with a mean absolute difference of 0.76 (McCartan et al. 2021). If RespiraSense was used instead of manual counting, 23.7% would have had escalated care and 4.2% would have deescalated care, suggesting a difference between the two measurement types (McCartan et al. 2021).

All three observational studies varied in their population, ranging from studies including exclusively those testing positive with COVID-19, excluding patients with COPD, and excluding people with a NEWS score of more than five, suggesting a wide range of different populations.

Safety

None of the above studies report any safety concerns regarding RespiraSense. Although one study highlighted that the device is not to be used during defibrillation, Magnetic Resonance Imaging, X-ray, or other medical imaging procedures as per the instruction's manual (Subbe & Kinsella 2018).

Cost-effectiveness

One cost utility analysis (Javanbakht et al. 2021) examined the cost effectiveness of RespiraSense with and without manual counting (n = 418,113). In this study, a decision analytic model was developed based on a hypothetical cohort of patients who were admitted to hospital with pneumonia in the UK.

Javanbakht et al. (2021) concluded that RespiraSense was a cost-effective intervention. The total QALYs achieved were higher with RespiraSense and it was found to be cost saving.

Ongoing studies

Health Technology Wales researchers identified four on-going studies relating to the effectiveness of RespiraSense referenced below.

Evidence standards

RespiraSense is a digital health technology and was determined to be a Tier C technology according to the Evidence Standards Framework for Digital Health Technologies**.** Tier C evidence standards apply to digital health technologies that function as interventions. This includes technologies that

are designed to calculate, i.e., a calculator that impacts on treatment, diagnosis, or care. For technologies of this classification, it is recommended that the best practice standard to demonstrate effectiveness would be to draw on randomised controlled studies carried out in a setting relevant to the UK health and social care system, comparing the digital health technology with a relevant comparator. The studies should demonstrate consistent benefit including clinical outcomes in the target population, in addition to using validated condition-specific outcome measures.

Areas of uncertainty

- It is unclear as to how impactful a continuous monitor would be in the current pathway regarding improving clinical outcomes and/or preventing adverse events.
- There is uncertainty to the clinical impact of patients identified as requiring escalated/deescalated care following the use of continuous respiratory rate monitoring.
- Evidence is limited to a subgroup of COVID-19 patients when assessing how exactly this technology identifies earlier patient deterioration. It is therefore unclear how exactly RespiraSense would lead to earlier identification in people with multiple respiratory conditions.

Literature search results

Health technology assessments and guidance

NICE. (2020). National Early Warning Score systems that alert to deteriorating adult patients in hospital. Published: 18 February 2020. Medtech innovation briefing [MIB205]. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/advice/mib205 [Accessed 12 January 2022].

NB: Several guidance reports relating to the diagnosis and management of targeted health conditions that could potentially benefit form incorporating RespiraSense have been identified by the topic proposer, although these make no reference to the effectiveness of RespiraSense specifically. Please note that CG191 has been withdrawn due to COVID-19.

NICE. 2018. Chronic obstructive pulmonary disease in over 16s: diagnosis and management. Published 5 December 2018. NICE guideline [NG115]. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/NG115 [Accessed 13 January 2022]

This guideline looks at the diagnosis and management of COPD. It aims to help people with COPD to receive a diagnosis earlier so that they can benefit from treatments to reduce symptoms.

NICE. 2016. Sepsis: recognition, diagnosis, and early management. Published 13 July 2016. NICE guideline [NG51]. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/ng51 [Accessed 13 January 2022]

This guideline covers the recognition, diagnosis, and early management of sepsis for all populations.

NICE. 2014. Pneumonia in adults: diagnosis and management. Published 3 December 2014 (currently withdrawn). NICE Clinical guideline [CG191] National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/cg191 [Accessed 13 January 2022]

Evidence reviews and economic evaluations

Javanbakht M, Moradi-Lakeh M, Mashayekhi A, et al. (2021). Continuous Monitoring of Respiratory Rate with Wearable Sensor in Patients Admitted to Hospital with Pneumonia Compared with Intermittent Nurse-Led Monitoring in the United Kingdom: A Cost-Utility Analysis. Pharmacoecon Open. 1-11. doi: 10.1007/s41669-021-00290-7. https://pubmed.ncbi.nlm.nih.gov/34387850/

Individual studies

Lee PJ. (2016). Clinical evaluation of a novel respiratory rate monitor. J Clin Monit Comput. 30(2): 175-83. doi: 10.1007/s10877-015-9697-4. https://pubmed.ncbi.nlm.nih.gov/25900144/

McCartan TA, Worrall AP, R ÓC, et al. (2021). The effectiveness of continuous respiratory rate monitoring in predicting hypoxic and pyrexic events: a retrospective cohort study. Physiological measurement. 42(6). doi: 10.1088/1361-6579/ac05d5. https://pubmed.ncbi.nlm.nih.gov/34044376/

Subbe CP, Kinsella S. (2018). Continuous Monitoring of Respiratory Rate in Emergency Admissions: Evaluation of the RespiraSense Sensor in Acute Care Compared to the Industry Standard and Gold Standard. Sensors (Basel, Switzerland). 18(8): 2700. doi: 10.3390/s18082700. https://pubmed.ncbi.nlm.nih.gov/30126085/

Ongoing research

Jones MT, Heiden E, Fogg C, et al. (2020). An Evaluation of Agreement of Breathing Rates Measured by a Novel Device, Manual Counting, and Other Techniques Used in Clinical Practice: Protocol for the Observational VENTILATE Study. JMIR Res Protoc. 9(7): e15437. doi: 10.2196/15437

An on-going prospective observational study based in the UK. As of 2020, recruitment was still pending and at the time of writing this report, we were unable to find the results in full. This study aims to assess the accuracy of the RespiraSense device in comparison with other methods currently used in clinical practice. The secondary objective is to assess the accuracy of the RespiraSense device in participants in different positions and when reading aloud.

RespiraSense Versus Capnography & Manual Counting (2017). PMD solutions. NCT03148873. Clinical Trials.

An on-going observational study of 24 participants with an actual study completion date of June 2017, however at the time of writing this report, we were unable to find this study published in full. This study aimed to assess the effectiveness of RespiraSense against the current accepted methods i.e., capnography and manual counting.

Sensor Validation Study – Quality Assurance. (2017). PMD Solutions. NCT03306537. Clinical Trials.
An on-going observational study of 34 participants with an actual study completion date of September 2018, however at the time of writing this report we were unable to find the results published in full. This study aimed to assess the effectiveness of RespiraSense in people with a BMI below and above 50. This research study is intended to validate that this technology is effective and accurate on people with a bigger body mass.

Can Respiratory Rate Predict the Risk of Deterioration of Septic Patients. (2018). PMD solutions. NCT03752047. Clinical Trials.
An on-going observational study of 132 participants with an actual completion date of November 2017, however at the time of writing this report, we were unable to find the results published in full. This study aimed to determine if the trend in Respiratory Rate measurements provided by RespiraSense can be used to predict an increase in Sequential/Sepsis-related Organ Failure Assessment (SOFA) score.

Date of search:	January 2022
Concepts used:	Continuous monitoring of respiratory rate; RespiraSense; RespiraSense Sensor; Continuous respiratory rate monitoring; respiratory rate monitor