NICE advice

Lifelight First for monitoring vital signs

Medtech innovation briefing
Published: 8 April 2020

www.nice.org.uk/guidance/mib213

Summary

- The **technology** described in this briefing is Lifelight First. It is used for measuring indicative estimates of blood pressure (mmHg), pulse rate (beats per minute), and respiration rate (respirations per minute) in people who need vital sign measurements. This technology is at an early stage of development and this briefing is based on unpublished evidence with limited cost data.
- The **innovative aspects** are that it does not make direct contact with people or medical hardware, potentially limiting cross-contamination. It also uses algorithms to analyse the measurements.
- The intended **place in therapy** would be hospitals, clinics and other healthcare settings and for people that need vital sign monitoring. It may be particularly useful when current methods cannot readily be used.

- The **main points from the evidence** summarised in this briefing are from 2 unpublished studies, a single-arm observational study and a validation study. These studies included a mixed population of 8,712 inpatients, outpatients and healthy volunteers in both clinical and non-clinical settings. These studies show that the accuracy of Lifelight First is similar to some clinical-grade monitoring devices when compared with the Welch Allyn Connex Monitor for measuring heart rate, blood pressure and manual counting for measuring respiratory rate.
- **Key uncertainties** around the evidence or technology are that the evidence base does not evaluate the technology in a clinically relevant population, including people that need routine monitoring of vital signs. The evidence is unpublished, meaning there are uncertainties about the reliability of the findings. The evidence only reports direct statistical comparison of the accuracy data with the Welsh Allyn Connex monitor. Comparisons with other similar technologies are indirect. The evidence does not report diagnostic accuracy data or clinical outcomes, such as how the technology would be used to inform care decisions.
- The **cost** of Lifelight First is £12.50 per healthcare practitioner per month (excluding VAT) as part of a subscription, plus additional costs for training and implementation. The **resource impact** would be greater than standard care. The cost of standard monitors such as the Welch Allyn Connex Monitor for manually monitoring heart rate and blood pressure is approximately £200 (but costs for similar technologies vary from £10 to over £1,000).

The technology

Lifelight First (xim Limited) is used for measuring indicative estimates of blood pressure, pulse, and respiratory rate. It records the face for less than 40 seconds with the camera in an Apple iPad 9.7 as a sensor. It detects tiny colour changes in facial skin each time the heart beats. The software uses algorithms to analyse the data to provide the measurement outputs. A stable internet connection is needed for Lifelight First to work. Because Lifelight First collects data using a camera, the person must be visible and well lit, and must stay still.

Lifelight First may be affected by some drugs, therapies, health and changes to the skin, including cosmetics, facial tattoos and excessive sweat. The company notes that Lifelight First should not be used for direct diagnosis or monitoring of vital physiological processes and does not replace traditional methods of diagnosis or treatment. This is consistent with

the current class I CE mark and is likely to change if the device is re-classified as class II later in 2020 as planned.

The company is developing a newer version of the technology, Lifelight Home. This allows people to monitor their heart rate, pulse rate, respiratory life and oxygen saturation levels from home using a smartphone.

Innovations

Lifelight First is a contactless technology and is designed to avoid direct contact with people when taking measurements, and needs no medical hardware. A fixed artificial intelligence algorithm processes the camera data and calculates measurements. The technology is non-invasive, and the company notes that there is no similar technology available in the NHS. Contactless technology can prevent cross-contamination and improve infection control, such as in COVID-19 cases. However, there is no evidence to support this. To use the technology the iPad should be held approximately 35 cm from the person's face.

Current care pathway

Since the introduction of the Quality and Outcome Framework in 2014, GPs review people with some common chronic conditions such as asthma, diabetes, obesity and hypertension on a regular basis. This involves monitoring any change in blood pressures, pulse and respiratory rates. In current practice, contact-based methods are used to measure these, but such methods may not be tolerated by some patients and may cause distress, and in some cases needs personal protective equipment to prevent cross-contamination.

The NICE guideline on hypertension in adults: diagnosis and management states that hypertension is diagnosed by measuring blood pressure either manually or with an automated blood pressure monitor. Readings are first taken in a clinic and can be followed by ambulatory blood pressure monitoring to confirm the diagnosis. Home blood pressure monitoring (usually done using an automated monitoring device) can be done between 4 to 7 days as an alternative if ambulatory monitoring is unsuitable for the person. Treatment options for hypertension include lifestyle changes or antihypertensive drugs, or both.

The NICE clinical guideline on acutely ill adults in hospital: recognising and responding to

deterioration recommends that adult patients in acute hospital settings should have physiological observations recorded at the time of their admission or initial assessment. After admission, these physiological measurements should be monitored regularly (tracked) with predetermined response criteria to changes (triggers) to identify deteriorating physiological status or risk of deterioration.

NICE has produced a medtech innovation briefing on National Early Warning Score systems, which gives advice about scoring systems intended to alert to deteriorating patients in hospital. These scoring systems measure respiratory rate, oxygen saturation, blood pressure, pulse rate, level of consciousness and temperature.

Population, setting and intended user

Lifelight First is intended to give an indicative estimate of blood pressure (mmHg), pulse rate (beats per minute), and respiration rate (respirations per minute). The device is for adults who need their vital signs monitoring. It is not intended for children.

Lifelight First would be used by qualified healthcare practitioners in various healthcare settings, including hospitals, clinics and GP practices.

Costs

Technology costs

Lifelight First costs £12.50 per user per month (excluding VAT) as part of a subscription. A user refers to each individual healthcare practitioner with access to the technology, and has a unique login. There is no limit on the number of people the technology can be used on every month. The company offers training and support, including electronic health records integration and maintenance, at an additional cost. The cost of training depends on the size and complexity of the healthcare setting.

Costs of standard care

National 'track and trigger' systems can be automated or paper based. Paper-based early warning score (EWS) 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 EWS calculations. Based on the agenda for change NHS pay

scales 2019/20 band 4 nursing salary the cost of recording and calculating the EWS manually is £0.98 per patient.

The cost of the automated system ranges from £30,000 to £90,000 for system installation, configuration and set up, and costs a further £0.35 to £0.70 per acute bed, every day. Wong et al (2017) reports that automated EWS systems reduced nursing time to 2 minutes 30 seconds.

The cost of the equipment for measuring heart rate and blood pressure ranges from £20 to over £1,000. The cost of the Welch Allyn Connex Monitor, described in the evidence, is approximately £200 per unit, not including maintenance costs.

Resource consequences

The technology is being used in a small number of UK NHS trusts.

It costs more than standard care, but may be resource releasing because of faster consultations (releasing staff resource) and improved patient care. This is particularly relevant in cases when current care cannot be readily used, such as in mental health settings, or to avoid cross-contamination.

The company claims that the technology reduces the time for a GP to complete vital sign observations from 3 minutes to 1 minute. The company also claims the technology offers contactless monitoring and reduces the need for personal protective equipment to do clinical observations. However, there is currently no evidence to support these claims.

Regulatory information

Lifelight First is a CE-marked class I 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.

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. 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.

Evidence summary

There is a considerable scientific evidence for using a camera to measure changes in the skin's absorption of light, to indirectly measure vital signs (remote photoplethysmogram). However, there is currently no published evidence for Lifelight First. The preliminary results of 2 ongoing studies, including a mixed population of 8,712 inpatients, outpatients and healthy volunteers, have been summarised 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 current evidence base lacks peer-reviewed published evidence. The data summarised in this briefing are made up of a single-arm observational study and a validation study including healthy volunteers. Because the evidence is unpublished there are significant uncertainties such as reproducibility of the data and reliability of the findings. The evidence base would benefit from a published, well-designed validation study comparing the clinical observation recorded by Lifelight First with best practice for people having routine monitoring for heart rate, blood pressure and respiratory rate.

Both studies reported in this briefing were done in the UK, comparing measurements by Lifelight First with current gold standard practice in the NHS.

Vision D study (unpublished)

Study size, design and location

Single-arm observational study evaluating the safety and performance of Lifelight First in a mixed population of 8,585 inpatients, outpatients and healthy volunteers from the UK.

Intervention and comparator(s)

Lifelight First compared with UK standard care measures using Welch Allyn Connex Monitor (heart rate and blood pressure) and manual counting (respiratory rate).

Key outcomes

The unpublished manuscript reports the accuracy of Lifelight First using root mean square (rms) differences in measurement readings. Lifelight First is comparable to other medical-grade benchmark technologies but has a slightly increased rms than the gold standard, a difference of about 1 to 2 beats per minute. The respiratory rate measures had similar accuracy to clinical-grade impedance tomography devices but was less accurate than pulse oximeters. Blood pressure measurements achieved mean error values that met national standards (BS EN ISO 81060-2:2014) and 95% Bland Altman limits were comparable to the limits published for widely used blood pressure monitors.

Strengths and limitations

This is an unpublished manuscript that has not been peer reviewed. This large study reports the findings from real-world data obtained in the NHS. The reference standard, comparators and the clinical setting are relevant to the NHS. The manuscript states that data are still being reviewed, so findings reported in this briefing may change. No accuracy outcomes such as sensitivity and specificity were reported. The data are being used to improve the algorithm, so the technology described in the manuscript is likely to be different than the commercially available product.

Validation study (unpublished)

Study size, design and location

Validation study evaluating the safety and performance of Lifelight First in 127 healthy volunteers during rest and exercise under laboratory conditions in the UK.

Intervention and comparator(s)

Lifelight First compared with UK standards of standard care measures using Welch Allyn Connex Monitor (heart rate and blood pressure) and manual counting (respiratory rate).

Key outcomes

Heart rate measurements reported by Lifelight First had an rms difference of 4.2 beats per minute. The rms difference for respiratory rate was 3.4 beats per minute. 89.5% of measurements had an error of 5 beats per minute or fewer. Lifelight First's mean error for blood pressure measurements meets national standards (BS EN ISO 81060-2:2014) and achieves grade D (systolic measures) and grade B (diastolic measures) when assessed against British Hypertension Society protocol requirements for cuff-type sphygmomanometers.

Strengths and limitations

The study is reported as an unpublished manuscript and has not been peer reviewed so may change before it is published. The study is primarily to report the safety and performance of the technology and is not intended to present clinical outcome data. The study includes post-hoc analysis which may bias findings. Additionally, the people included and the setting of the study are not generalisable to a clinical care population and setting.

Sustainability

The company claims there would be a reduction in consumables needed for monitoring vital signs in current care, as well as reduced need for personal protective equipment because the technology is contactless. There is no published evidence to support these claims.

Recent and ongoing studies

- Vital sign comparison between Lifelight First and standard of care - development (VISION-D) ClinicalTrials.gov identifier: NCT04003662. Status: recruiting. Population: inpatients, outpatients and healthy volunteers. Devices: Lifelight First. Date: last updated July 2019, expected completion date May 2020. Country: UK.
- A single center study to demonstrate the safety and performance of Lifelight® First software application. ClinicalTrials.gov identifier: NCT03998098. Status: recruiting. Population: healthy volunteers. Devices: Lifelight First. Date: last updated June 2019. Complete, results not yet published. Country: UK.

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.

Five experts were involved in the development of this briefing, 4 experts were familiar with the technology and had used it before.

Level of innovation

Three experts said Lifelight First is a novel and innovative design and 2 said the technology is a significant change and advancement in care.

Potential patient impact

All experts felt the technology could improve clinical outcomes if it is proven to be accurate. Experts felt that the technology could improve the detection of abnormalities and increase more timely treatment, to improve patient experience. They acknowledged the technology would be particularly useful in situations when it would be beneficial to reduce physical contact, such as monitoring in premature babies, people with mental health conditions or infectious conditions, including COVID-19.

Potential system impact

Most of the experts believed the technology would be timesaving for healthcare professionals. They thought it has the potential to be cost saving if it is proven to be accurate, although an initial capital cost would be expected. Two experts believed the technology would reduce patient harm and the number of serious incidents. One expert believed the technology might reduce the length of hospital stay as a result of improved care because of better monitoring of clinical observations. One expert believed the technology could result in a shift in care from trained healthcare professionals completing manual clinical observations to non-medical staff using Lifelight First.

General comments

All experts agreed that training needed to use the device would be minimal, although a short learning curve would be expected. All experts noted the technology would be suitable for people with a range of conditions, but agreed that published evidence is needed to demonstrate the accuracy of the technology.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Anthony Leung, general practitioner, Badgerswood Surgery. Dr Leung is a partner of the Badgerswood and Forest Surgeries and is an adviser for the Wessex Academic Health Science Network, which has evaluated the technology.
- Dr Christopher Roberts, managing director and consultant physician, UCLPartners Academic Health Science Network. Dr Roberts is involved in an ongoing evaluation of this technology.
- Dr Jim Forrer, general practitioner partner, NHS Claremont Medical Practice. Dr Forrer has a non-financial working relationship with the company and has assisted them with grant requests and a project to test the technology.
- Professor Anoop Chauhan, director of research and innovation, professor of respiratory medicine, consultant respiratory physician, Portsmouth Hospitals NHS Trust. Professor Chauhan is a chief investigator for a study that is evaluating the safety and accuracy of the technology.

- Mr John Welch, consultant nurse, critical care and critical care outreach, University College Hospitals London. Mr Welch is involved in the EU Horizon 2020 Nightingale project to develop a patient monitoring system and has been involved in a monitoring development workshop.

Development of this briefing

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

ISBN: 978-1-4731-3757-8