NICE advice

Patient Status Engine for wireless monitoring of vital signs

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is the Patient Status Engine (PSE). It uses wireless technology for continuous remote monitoring of vital signs.
- The **innovative aspects** are that the PSE automatically captures data and calculates vital signs from wireless biosensors. This data automatically calculates a person's National Early Warning Score (NEWS) 2 and alerts healthcare teams to decline in a person's health.
- The intended **place in therapy** would be in health or social care settings. It would be used as an alternative to standard bedside monitors or physiological observations in people who need frequent or continuous vital signs monitoring. It is not indicated for use in intensive care units.

- The **main points from the evidence** summarised in this briefing are from 6 studies (1 randomised controlled trial and 5 observational studies) including a total of 499 adults and 992 children. They show that the PSE is as effective or better than standard monitoring in capturing physiological measurements across patient groups.
- **Key uncertainties** around the evidence are that only 1 study reports clinical outcomes. The evidence mostly reports how the PSE is used to detect physiological measurements. More research is needed to show how the PSE affects clinical care and outcomes in health and social care settings.
- The **cost** of the PSE is £10 to £30 (excluding VAT) per person per day. This includes capital and setup costs, training, support, and integration into the site's electronic medical records or hospital information system.

The technology

The Patient Status Engine (PSE; Isansys Lifecare Ltd) is a wireless patient monitoring system that provides automatic and continuous real-time monitoring. It is indicated for people who need frequent or constant vital signs monitoring.

The system uses wireless wearable biosensors to collect vital signs data. These include:

- The Lifetouch sensor. This single-use sensor captures real-time electrocardiogram (ECG) signals and information about heart rate, heart rate variability and respiratory rate. It has a 3-axis accelerometer that gives data on a person's position, activity, and motion. It can be used continuously for 4 to 5 days.
- The Lifetemp sensor. This is a continuous real-time clinical thermometer. It is placed in the armpit to measure core body temperature. The single-use sensor takes temperature readings every 10 seconds and updates every minute. The company states it accurately tracks temperature for approximately 10 days or more and can detect rapid temperature changes.
- The Nonin WristOx2 3150 oxygen saturation monitor. This is a wireless pulse oximeter with Bluetooth connectivity and PPG waveform capability.
- A choice of 2 blood pressure monitors: a standard manually operated inflatable cuff device or an automated ambulatory blood pressure monitor. For both devices, blood pressure readings are automatically uploaded.

The company states other sensors can be integrated into the system. These include a tympanic temperature sensor for people who only need occasional temperature readings. Another third-party pulse oximeter is also being integrated into the system.

Lifetouch and Lifetemp sensors are stuck to the body using a repositionable medical-grade silicone gel adhesive. The company also produces paediatric sensors in different sizes for newborns, babies, and children.

Sensors are paired with an Android tablet with Isansys apps by scanning a QR code on each sensor. Data is transmitted wirelessly by encrypted Bluetooth from the sensors to the tablet and viewed in the Patient Gateway. The Patient Gateway provides a real-time display of vital signs like a wireless bedside monitor. The PSE converts vital signs data into early warning scores, which alert healthcare professionals to a person's physiological deterioration. Healthcare professionals can use the Patient Gateway to set early warning thresholds and to enter patient data. The default early warning score for adults is the National Early Warning Score (NEWS) 2. This is calculated from a person's continuous vital signs data plus manually entered data for air or oxygen and consciousness level.

The Patient Gateway is connected by secure Wi-Fi, 3G or 4G to the Lifeguard Server. This is the IT system that connects to electronic medical records and hospital information systems. Vital signs data can be viewed in real time by healthcare professionals at the central monitoring unit. This is a centralised computer on site that lets healthcare teams monitor vital signs data and alert ward staff should a person need care. Alerts from the PSE can also be sent directly to care teams through connections to nurse call systems and SMS gateways. Healthcare professionals can also view PSE data on authorised mobile devices. Healthcare teams can set the system to let patients view their own vital signs data.

The PSE will generally be used for continuous monitoring for a few days to about a month. The company states that batteries typically last 4 to 5 days.

Innovations

The PSE automates the taking of continuous vital signs measurements. The company claims this may lead to better nurse efficiency, fewer errors from incorrect data entry, and fewer adverse events. The PSE aims to replace wired bedside monitors, which may limit movement because of cables and leads. It would let people move more easily while still being closely monitored.

Current care pathway

The PSE is for people who need frequent or continuous monitoring of their vital signs. It is not limited to specific medical conditions.

Adults in acute hospital settings have physiological measurements taken during their initial assessment or admission. This should include heart rate, respiratory rate, systolic blood pressure, level of consciousness, oxygen saturation, and body temperature. These vital signs should then be monitored at least every 12 hours unless decided otherwise based on the person's needs.

Early warning score 'track and trigger' systems are used to alert healthcare professionals to any deterioration in a person's health. The NEWS is endorsed by NHS England and NHS Improvement and is currently used in all ambulance trusts and 76% of acute trusts. Vital signs monitoring may also be done in babies and children using the appropriate early warning scoring system for their age.

Physiological measurements are usually taken by healthcare professionals who manually enter the data into electronic health records. A person may also be continuously monitored using a wired bedside monitor which is connected to them by cables and leads. There should be a clear written monitoring plan of which vital signs measurements should be taken and how often.

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

- NICE's guideline on acutely ill adults in hospital: recognising and responding to deterioration
- Royal College of Physicians' National Early Warning Score (NEWS) 2
- Royal College of Nursing's standards for assessing, measuring and monitoring vital signs in infants, children and young people
- British Association of Perinatal Medicine's Newborn Early Warning Trigger and Track (NEWTT): a framework for practice
- NICE's medtech innovation briefing on National Early Warning Score systems that alert to deteriorating adult patients in hospital

- NICE's medtech innovation briefing on EarlySense for heart and respiratory monitoring and predicting patient deterioration
- NICE's medtech innovation briefing on Visensia for early detection of deteriorating vital signs in adults in hospital
- NICE's guideline on transition between inpatient hospital settings and community or care home settings for adults with social care needs.

Population, setting and intended user

The company describes the PSE as a universal patient monitoring system. It can be used by most patients and particularly people who need more monitoring than others. The technology can be used in secondary, tertiary, and social care settings including:

- postoperative care
- home care when intensive monitoring is needed
- care homes
- paediatric and neonatal care.

It is not indicated for use in intensive care units because the PSE has not been fully tested and validated with the other equipment in this setting. The PSE is also not intended to be used by people in high isolation wards or people with diseases caused by prions. The device's quick start guide states that the PSE has not been tested:

- in people with pacemakers, implantable defibrillators, or neurostimulators
- in people who are very mobile
- on broken or irritated skin
- near imaging equipment, for example MRI
- with high frequency surgical equipment such as diathermy
- in an oxygen rich environment.

So, it should not be used by these people or in these circumstances.

Healthcare professionals should read and follow the safety information in the quick start guide that comes with the device before use.

The PSE can be used by doctors and nurses. Training is needed on how to set up and use the technology. The company states that this could be done with 2 hours of formal training. Training can be delivered in person or online through the company's training platform. This includes video and written training materials, and self-learning modules. Training is included in the technology costs.

Costs

Technology costs

The company states the costs of the PSE depend on the size of the installation, including how many people and which vital signs are being monitored. The technology is estimated to cost £10 to £30 (excluding VAT) per person per day. This includes the costs of the technology, setup, training, support, and integration into the site's electronic medical records or hospital information system. The company recycles used Lifetouch and Lifetemp sensors and claims there are no costs to clean the devices or change batteries. The company claims the technology costs less than standard care and is cheaper to scale. There is no published evidence to support this.

Costs of standard care

Costs of multiparameter patient monitors listed on NHS supply chain range from around £800 to £15,000 (excluding VAT). The number of vital signs measured varies depending on the monitor used. The costs of single use sensors are approximately £30 to £550 (excluding VAT) while multiuse sensors range £40 to £1,500 (excluding VAT). There may be additional costs for replacement cables and leads. Locally agreed prices may differ.

Resource consequences

In the UK, the PSE has been used for the continuous monitoring of people with advanced cirrhosis, people with cancer having chemotherapy, people with COVID-19 in hospital, people in care homes, children admitted for elective procedures or emergency care, and premature babies. The PSE is also being used to explore new care pathways, such as the development of a new standard care pathway for paediatric wards using continuous

monitoring. The company believes continuous monitoring using wireless technology and data-driven clinical decision support tools will become standard care for all patients.

The company believes using the PSE will lead to benefits, including:

- fewer avoidable adverse events
- shorter hospital stays with an increase in home care
- fewer nurse shortages because time taking vital signs can be used elsewhere.

Imperial College Healthcare NHS Trust described resource benefits from the use of digital bedside vital signs monitors to generate NEWS. These were not the PSE, but the trust's experiences provide information about the resource consequences of using digital monitors instead of standard care. Using digital bedside monitors resulted in standardised patient assessment and automatic entry of vital signs data to the medical record. Improved outcomes included more accurate information, increased referrals and patient safety, and decision-making support for healthcare professionals. The technology also led to more streamlined and integrated care.

For full system connectivity, the PSE needs secure and reliable Wi-Fi to connect the Patient Gateway to the Lifeguard Server. For home care, good 3G or 4G connectivity is preferred but Wi-Fi can also be used. Loss of wireless connectivity will not cause data loss as the data is stored in the sensors and the Patient Gateway until connectivity returns.

Regulatory information

The Patient Status Engine is a CE-marked class IIa 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.

The Patient Status Engine (PSE) can be used for all ages, including newborns, babies and children. It can be used across health and social care settings. The Older People's Advocacy Alliance highlighted the importance of independent advocacy for people who

are offered continuous health monitoring. This would allow them to understand the potential effects of using the technology before giving informed consent. Age is a protected characteristic under the Equality Act 2010.

People using the technology for home care would be provided with the device through their healthcare setting. The PSE needs good 3G or 4G connectivity, or Wi-Fi. Most people have good 4G coverage or Wi-Fi in their homes, but some people might be unable to access a decent internet connection. Care homes have less access to digital technology and connectivity than the general population. About 7,000 care homes in England do not have an adequate internet connection. During the COVID-19 pandemic NHSX and NHS Digital worked to get more care homes and care providers connected to the internet.

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.

Published evidence

This briefing summarises 6 studies, including a total of 499 adults and 992 children aged 0 to 17 years (n=1,491).

The evidence includes 1 randomised controlled trial and 5 observational studies with 1 reported in abstract. The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The Patient Status Engine (PSE) is a Tier C interventional technology for active monitoring based on NICE's evidence standards framework for digital health technologies. The evidence assessed meets the best practice criteria for these technologies. Studies compared the PSE with appropriate standard care physiological measurements. The evidence included 1 randomised controlled trial that compared the PSE with standard care and showed its effect on clinical outcomes. Three of the 6 studies were done in the UK.

The evidence reports the use of the PSE with children and adults, and across different medical conditions in line with the technology's indicated use.

Most studies reported the feasibility of the PSE for continuous monitoring of physiological measurements. Only 1 study explored how the PSE affects clinical outcomes, with 3 studies stating they were not powered for this. All studies were done in secondary care.

Further research is needed to show:

- how the PSE affects clinical outcomes and clinical decision making
- how the full PSE system is used within health and social care settings
- the use and outcomes of the PSE in care homes and home care.

Koppel et al. (2021)

Study size, design and location

Prospective observational study of 155 adults admitted to a labour and delivery suite in the US at the time of labour (more than 35 weeks gestational age and less than 6 cm cervical dilation). This study measured maternal temperature during labour as a risk factor for early onset sepsis in newborns.

Intervention and comparator

Intervention: Lifetemp sensors. Data was transmitted every minute.

Comparator: Manual intermittent temperature measurements taken every 3 to 6 hours following clinical protocols.

Key outcomes

Over 90% of Lifetemp data was valid in 98 people, and over 75% of data was valid in 127 people. Lifetemp continuous measurements of temperature correlated with manual measurements ($r=0.399$, $p<0.001$). Manual temperature measurements missed 32 fevers above 38°C and 13 fevers above 38.5°C that were found by Lifetemp. Review of this data showed these episodes of fever were missed because they happened between manual

measurements. Lifetemp missed 7 fevers above 38°C and 5 fevers above 38.5°C that were found by manual measurements. This was likely related to low-grade fevers on the alert threshold. Both Lifetemp and manual measurements detected fever above 38°C in 15 people. Of these, 13 were found earlier by Lifetemp continuous measurements, with 9 detected more than 1 hour earlier compared with manual measurements.

There were no reports of discomfort or adverse events from using Lifetemp.

Strengths and limitations

This study suggests using Lifetemp is feasible in taking continuous temperature measurements during labour. Issues with non-adherence were not reported despite some invalid data capture. It was unclear from the study methods if the healthcare professionals who took the manual temperature measurements were blinded to Lifetemp data. Authors stated the study could not be powered to assess the occurrence or outcome of early onset sepsis in newborns because of the low incidence of this disease. The study only assessed the use of Lifetemp sensors and not the overall PSE system.

Duncan et al. (2020)

Study size, design and location

Prospective observational study of 982 children (birth to 17 years) admitted for elective or emergency care in a specialist paediatric hospital in the UK providing intermittent and continuous monitoring and care.

Intervention and comparator

Intervention: The RAPID Index calculated from the PSE, which used Lifetouch (electrocardiogram [ECG]-derived heart rate and respiratory rate) and Nonin WristOx2 sensors (pulse oximetry and derived pulse rate). Data was transferred every minute.

Comparator: Paediatric Early Warning (PEW) score recorded manually every 1 to 4 hours. The PEW score includes respiratory rate, respiratory distress, pulse oximetry, inspired oxygen, heart rate, systolic blood pressure, and capillary refill time.

Key outcomes

The study showed the feasibility of using the PSE to collect valid clinical data wirelessly for at least 50% of the intended monitoring time. Final data capture as a proportion of intended monitoring time was 93% for Lifetouch and 55% for WristOx2. The final proportion of valid clinical data recorded was 63% (Lifetouch) and 50% (WristOx2).

Findings showed 29 children had 36 significant clinical deteriorations during the study period. The RAPID Index identified the onset of deterioration within 72 hours for 97% (35 of 36) of these events compared with 86% (31 of 36) by the PEW score. The onset of deterioration was detected earlier by the RAPID Index (mean 46.9 hours before significant deterioration) than the PEW score (mean 40.2 hours before significant deterioration).

The RAPID Index demonstrated high sensitivity (97%) and negative predictive value (NPV; 99%) compared with the PEW score (sensitivity 86%, NPV 99%). However, the PEW score had overall better predictive discrimination (specificity 81%, positive predictive value ([PPV] 21%), with the RAPID Index having a high rate of false alarms (specificity 25%, PPV 7%). Clinical review found 14 children who had significant deterioration could have benefited from earlier review. Of these, 4 children had potentially avoidable respiratory and cardiac arrests. Authors suggested these could have been avoided had the PSE and RAPID Index been reviewed.

Strengths and limitations

It is unclear from the study methods whether the nurses who measured clinical observations and PEW scores were blinded to the RAPID Index score. Sensor usability differed between the Lifetouch and WristOx2. The WristOx2 captured and recorded less valid clinical data leading authors to suggest a better and more tolerable device was needed. The RAPID Index was recorded more often than the PEW score. Authors suggested this partly explained the high sensitivity and false alarms of the PSE. Authors concluded that the data was preliminary, and the technology needed more research to establish efficacy and cost effectiveness before it could be adopted.

Elvekjaer et al. (2020)

Study size, design and location

Prospective observational study of 30 adults with acute exacerbations of chronic

obstructive pulmonary disease admitted to a single-centre hospital in Denmark.

Intervention and comparator

Intervention: Continuous monitoring with Lifetouch (heart rate and respiratory rate), Nonin WristOx2 3150 (arterial oxygen saturation), and Meditech BlueBP-05 (intermittent blood pressure). Data was transmitted every minute, except for blood pressure which was recorded every 15 to 30 minutes.

Comparator: Early warning score (EWS) done with routine equipment. Measurements taken every 12 hours with increased monitoring with worsening EWS.

Key outcomes

Continuous monitoring using Lifetouch and Nonin WristOx2 3150 sensors detected more abnormal vital signs than EWS. Continuous monitoring with the Nonin WristOx2 3150 found moderate oxygen desaturation events in 27 people (n=30) compared with 4 with EWS ($p<0.001$). Only 1 person had a moderate desaturation event detected by EWS that was not found by continuous monitoring. This was due to missing data. Continuous monitoring found severe oxygen desaturation events in 19 people. No severe desaturation events were found by EWS.

Lifetouch sensors found tachycardic events in 15 people compared with 4 reported with EWS ($p=0.005$). All tachycardic events reported by EWS were also found by the Lifetouch sensors. Lifetouch sensors detected tachypnoeic events in 17 people compared with 7 with EWS ($p=0.02$). EWS found tachypnoeic events in 3 people that were not detected by Lifetouch. Continuous monitoring with Lifetouch found bradypnoea in 16 people, with no episodes reported by EWS ($p<0.001$).

Meditech BlueBP-05 found hypotension in 7 people during the study period compared with 2 people by EWS ($p=0.15$). EWS recorded 3 hypotensive events in the same person, which was not detected by wireless monitoring.

Strengths and limitations

The small sample size of 30 people reflected time limitations and the pilot study design. The study was not powered to find differences in clinical outcomes. Healthcare professionals and patients were blinded to vital signs data from the continuous monitoring

devices. Researchers saw patients daily to encourage adherence and to change device batteries as needed. They hoped this would ensure high-quality data. However, the study reported some missing data from continuous monitoring because of technical difficulties (battery power, Bluetooth connectivity issues, and the bedside gateway being off) and non-adherence. Authors cautioned that further research was needed to determine the clinical significance of abnormal physiological values and to identify which vitals and thresholds are most predictive of adverse outcomes.

Jansen et al. (2019)

Study size, design and location

Prospective observational study assessing heart rate variability (HRV) in 119 adults at risk of cirrhosis decompensation. The study included 49 people presenting with acute decompensation admitted to hospital in the UK and 70 people with stable cirrhosis having community care in Germany.

Intervention and comparator

Intervention: Lifetouch system used by inpatients in the UK.

Comparator: Holter ECG recording used by outpatients in Germany.

Key outcomes

Continuous remote monitoring of HRV using Lifetouch was feasible in people with cirrhosis. HRV was measured using standard deviation of beat-to-beat intervals (SDNN). HRV was analysed for all inpatients monitored using Lifetouch (n=49) compared with 89% (62 of 70) of outpatients with Holter ECG monitoring. There were no statistically significant differences in SDNN between Lifetouch and Holter when controlling for disease severity.

The study reported several clinical outcomes related to the use of SDNN in cirrhosis. SDNN was inversely related to validated clinical scores and was the only independent predictor of 90-day mortality. These patient clinical outcomes were unrelated to the performance of the PSE so are not described further. Authors suggested remote monitoring of SDNN may detect inflammatory activity in people at risk of acute decompensation. This could lead to closer clinical review or early intervention before organ failure.

Strengths and limitations

The study was a multicentre study including a liver and transplantation unit in the UK. It included 2 patient groups with differing disease severity. Only the inpatient group in the UK were offered the Lifetouch system. People were recruited sequentially to this group based on the availability of the technology. The limited number of Lifetouch monitors meant only a small sample of people had repeated measurements beyond baseline SDNN. It is unclear how many people had continuous monitoring with Lifetouch beyond baseline. Authors acknowledged that the study was underpowered for data analysis on long-term SDNN monitoring.

Using Lifetouch for continuous remote monitoring of HRV in the community is not reflected in the findings. The comparison of HRV data captured by Lifetouch compared to Holter is limited by the differences in the healthcare settings where the devices were used. One researcher did all SDNN analyses. They were blind to individual patient data and outcomes and used standard methods in analysing data from both sites. This likely increased the consistency of the analysis but limited interrater reliability.

Skraastad et al. (2019)

Study size, design and location

Randomised controlled trial of 195 adults having acute or elective surgery who were expected to be hospitalised more than 24 hours postoperatively at a single-centre site in Norway.

Intervention and comparator

Intervention: PSE in combination with efficacy safety score (ESS, a validated clinical decision-making tool). ESS was done hourly during the first 4 hours after discharge from the post-anaesthesia care unit, and then every 2 hours after.

Comparator: Standard care (paper-based National Early Warning Score [NEWS] at least every 12 hours along with postoperative pain assessment at least every 8 hours).

Key outcomes

Use of the PSE with ESS resulted in earlier postoperative mobilisation (mean 10.1 hours)

compared with standard care (mean 14.2 hours, p=0.008; hazard ratio 1.54).

The intervention group received higher opioid doses (mean 25.5 mg) than standard care (mean 15.2 mg, p=0.001), with the former reporting lower average pain intensity (p<0.001) and higher patient satisfaction (p<0.001). Authors suggested that nurses may have felt more comfortable administering higher opioid doses because of their increased attention to and communication with patients. A mean of 6.7 pain evaluations were documented in the intervention group, compared with 1.4 for standard care (p<0.001). Pain was not documented for 17 people in the standard care group. Similarly, more NEWS were recorded for people in the intervention group (mean 8.2) than standard care (mean 3.4, p<0.001). Supplementary oxygen was provided to 26% more people in the intervention group (57 of 96) than standard care (32 of 99; p<0.001).

There were no observed serious complications in the intervention group. There were 2 serious events in the standard care group (1 severe bradycardia and 1 stroke), but the authors cautioned that the study had not been powered to make conclusions about safety issues. Five people in the intervention group were identified as needing additional treatment and follow up: 2 for pain, 2 for hypotension, and 1 for atrial fibrillation. Mean length of hospital stay was similar for both groups (70.9 hours for intervention compared with 76.6 hours for standard care; p=0.58).

Strengths and limitations

Authors reported the study was powered to identify meaningful effects of the intervention on the primary outcome of time to full mobilisation. The study used robust methods to randomise people to the intervention or standard care group, including a random number generator and allocation concealment. Patients and healthcare professionals were not blinded to group allocation at the ward due to the obvious differences between the PSE and standard care.

The care delivered in the standard care group was clearly outlined and followed the hospital's clinical guidelines. The intervention group was assessed significantly more often than people in standard care. As such, it is not clear whether the findings reported are wholly because of the tools used (PSE and ESS) or the increased attention from nurses. The PSE was assessed in combination with ESS. The effects of the PSE alone can therefore not be inferred from these findings.

Kirolos et al. (2018; abstract)

Study size, design and location

Prospective observational study investigating the feasibility of wireless monitoring to assess autonomic function in 10 newborns during parent holding episodes in a single centre in the UK.

Intervention

Intervention: ECG recorded using the PSE. HRV was calculated before, during, and after parent holding using Kubios HRV software.

Key outcomes

The study showed that wireless ECG monitoring is feasible in newborns and may make parent holding easier because of the lack of wired connections. A total of 140 parent holding episodes were analysed. The PSE was acceptable to parents and healthcare professionals. Data was not analysed in 20 cases because of sensor detachment during holding. There was a significant reduction in newborns' heartrate when they were held by their parents ($p<0.001$). Parent holding was found to be associated with autonomic stability in newborns.

Strengths and limitations

The study is limited by its small sample but benefits from its repeated measures design to analyse HRV of each newborn before, during, and after parent holding. The study was reported in an abstract which limits details on research methods and quality. The medical conditions of the newborns were unclear as was the length of the parent holding episodes and monitoring periods.

Sustainability

The company claims the single use sensors can be recycled 10 times or more in a fully certified off-site recycling process. This complies with infection control requirements with minimal environmental impact. The company also states that the PSE uses less energy and produces less waste than standard care. There is no published evidence to support these

claims.

Recent and ongoing studies

- COntinuous Signs Monitoring In Covid-19 Patients (COSMIC-19). ClinicalTrials.gov identifier: NCT04581031. Status: Recruiting. Indication: COVID-19. Devices: PSE. Last updated: April 2021. Country: UK.
- Continuous Vital Sign Monitoring in Newborns. ClinicalTrials.gov identifier: NCT04154618. Status: Recruiting. Indication: healthy newborns. Devices: PSE. Last updated: July 2020. Country: US.
- Remote Monitoring of Patients at Risk of Sepsis (REACT). ClinicalTrials.gov identifier: NCT04260230. Status: Not yet recruiting. Indication: cancer. Devices: Lifetouch, Lifetemp. Last updated: February 2020. Country: UK.
- Wireless Assessment of Respiratory and Circulatory Distress in Chronic Obstructive Pulmonary Disease - Validation Study. ClinicalTrials.gov identifier: NCT04248842. Status: Recruitment completed. Indication: chronic obstructive pulmonary disease. Devices: Lifetouch, Meditech Blue BP-05, and Nonin WristOx2 3150 compared with Phillips IntelliVue. Last updated: June 2020. Country: Denmark.
- Wireless Assessment of Respiratory and Circulatory Distress in Chronic Obstructive Pulmonary Disease - an Observational Study (WARD-COPD). ClinicalTrials.gov identifier: NCT03660501. Status: Recruitment completed. Indication: acute exacerbation of chronic obstructive pulmonary disease. Devices: Lifetouch, Isansys wireless blood pressure monitor, Nonin WristOx2 3150, Empatica E4, and Radiometer TCM5 FLEX monitor. Last updated: August 2020. Country: Denmark.

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.

Three experts provided comments on the Patient Status Engine (PSE). Two experts had used the PSE and were involved in research on the technology. One expert was familiar with the PSE and similar technologies.

Level of innovation

Two experts thought the PSE is novel in its reliable measurement of continuous vital signs using wireless sensors. One expert noted that using an accelerometer to monitor patient movement was also novel, because this is rarely recorded in hospital inpatients. Another expert believed the PSE was innovative because it uses cheap upgradeable tablets instead of expensive bedside or mobile monitors. One expert commented that the PSE was not novel but was advancing an existing procedure. All experts noted there are other technologies offering continuous vital signs monitoring, but the PSE monitors a larger range of vital signs. It can also easily integrate into hospital information systems and can be used across health and social care settings. One expert noted that not all systems measure the vital signs needed to calculate an early warning score.

Potential patient impact

Potential patient benefits from using the PSE included: more rich patient data for people monitored on hospital wards, earlier detection of clinical deterioration or improvement, individualised targets and treatment, improved patient self-management, and improved patient outcomes. All experts reported high patient acceptance and preference for wireless monitoring. They believed that all people at risk of deterioration would benefit from the technology. Specific patient groups thought to particularly benefit included: critical care step down, postoperative care, acute admissions and ward-based patients with serially elevated early warning scores, fetal monitoring in high-risk pregnancies, and home care.

Two experts stated it was unclear how continuous monitoring using the PSE would affect clinical outcomes compared with standard care. One expert noted that it was uncertain how much the PSE improved the early detection of deterioration or improvement in adult inpatients. Another noted that there is a lack of understanding of the effect of continuous monitoring on rates of activation of hospital rapid response systems if the technology is applied widely on hospital wards. One expert stated that for the technology to be useful, it needs to be appropriately integrated into the rapid response system.

Two experts reported that adverse events from the use of the PSE included minor skin reaction or redness from the electrocardiogram (ECG) stickers. This occurred in less than 1% of people and was reduced with frequent changes. Other very rare potential harms could include injury or discomfort from the pressure of the continuous pulse oximetry finger probe or repeated blood pressure cuff inflation. One expert reported experience of

missing data capture resulting in false negative reports and missed deterioration. There is also a potential risk of over assessment and treatment because of false alarms. One expert commented that healthcare professionals may experience alarm fatigue if the trigger thresholds for alerts were not set in line with patient needs.

Potential system impact

Two experts stated the PSE had the potential to change the current care pathway by replacing standard monitoring with continuous wireless monitoring and electronic patient records. One expert stated the PSE would not replace standard care but would supplement and improve continuous monitoring of people at risk of deterioration. They added this would be a major advantage to rapid response teams as the alerts would allow them to quickly respond to deterioration and changes in a person's condition. Two experts believed the PSE would reduce the time to take vital signs but one added that it would not replace bedside assessment. One expert noted the importance of healthcare professional-patient interaction to verify a person's clinical state.

The experts all believed the PSE could be cost saving compared with standard care but there were some uncertainties of the cost impact. One expert felt it was likely to cost the same as standard care but could lead to improvements in quality of care. Resource needs included reliable Wi-Fi coverage or 3G or 4G connectivity and access to server space. One expert stated that the automated blood pressure cuff and wrist mounted pulse oximeter require a supply of disposable batteries that typically need to be changed every 48 hours. High quality ECG electrodes are also needed to secure the Lifetouch ECG sensor. One expert commented that the Lifetouch and Lifetemp sensors expire after about 6 months, which should be considered when keeping a large amount of stock for widespread use. All experts agreed that training was needed to use the PSE.

General comments

All experts stated the PSE is not widely used in the NHS. All experts stated the PSE could be used in most or all district general hospitals. They also described potential use in community and social care settings. Two experts felt uptake within the NHS would be slow. One expert noted this was because of the costs of widespread implementation and the lack of trial evidence that continuous monitoring offers tangible benefits over traditional monitoring in hospital inpatients. They added that the system would need changes to governance procedures, rapid response teams, and escalation pathways.

Some usability issues raised included the need to configure alarms within existing technological systems, unreliable Bluetooth connectivity between sensors and the Patient Gateway, and uncertainty as to how to incorporate axillary skin temperature measurements from the Lifetemp sensor into early warning score algorithms. All experts stated that additional research about the PSE was needed, including efficacy trials in adults and fetal monitoring during pregnancy, research about its use in home care, and comparison of the PSE with traditional vital signs monitoring in ward-based settings.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Heather Duncan, consultant in paediatric intensive care, Birmingham Women's and Children's NHS Foundation Trust. Is planning research with the company.
- Dr Anthony Wilson, consultant in anaesthesia and critical care, Manchester University NHS Foundation Trust. Has discussed doing research with the company.
- Dr Isabel Gonzalez, consultant critical care, The James Cook University Hospital. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. NICE's 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.

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