VitalPAC for assessing vital signs of patients in hospital

Medtech innovation briefing
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Summary

- The technology described in this briefing is the VitalPAC mobile clinical software system. It analyses manually entered, or samples automatically captured, patient vital sign data to identify deterioration in a patient’s health. The software operates on the Apple iPod touch, iPad and iPhone and is designed to integrate with hospital clinical systems.

- The innovative aspects are that VitalPAC has the potential to automatically calculate a patient’s early warning score (EWS), and to prompt clinicians to respond in line with hospital protocol.

- The intended place in therapy would be in place of paper records and manual calculations of observations for people who are acutely ill in hospital.

- The key points from the evidence summarised in this briefing are from 1 classroom exercise (involving 21 nurses), 1 feasibility study and 2 before-and-after studies involving 112,218 adults. These suggest that the VitalPAC system reduces errors and that introducing it in hospital is associated with improved outcomes.

- Key uncertainties around the evidence are that the clinical study findings may have been influenced by their uncontrolled study designs in which other factors, such as parallel quality improvement initiatives, may have contributed to the observed differences in outcomes.

- The annual licence cost for the core VitalPAC product is 70p per bed per day (excluding VAT), or 50p per bed per day for a more basic version. An Apple Enterprise Licence at a cost of
around £225 per year must also be purchased. The price includes deployment, training and ongoing support. The devices on which VitalPAC runs must be purchased separately.

The technology

VitalPAC (The Learning Clinic) is a mobile software information system for monitoring the vital signs of adults, including pregnant women, and children in hospital. Using manually entered or automatically captured vital sign data, it is designed to quickly identify deterioration in their condition and alert clinical staff. VitalPAC can also be used to guide decisions about when people are well enough for discharge.

The main VitalPAC system is an integrated suite of 5 VitalPAC applications:

- CORE is a mobile app, used for entering patient data onto an iPod, iPhone or iPad at the bedside, for viewing patient data and giving patient alerts. Cannula insertion can also be recorded if the appropriate module is enabled.

- WARD is a web-based application, optimised for the web browser on an iPad, that can be used for reviewing patient data, location, observations schedule, early warning score (EWS), clinical information and alerts for patients on a particular ward or patients under the care of one or more consultants.

- CLINICAL is a web-based browser application that can be used to review patient data and record some assessments.

- PERFORMANCE is a web-based browser application that can be used by clinical and performance managers to see process, performance and reporting data.

- ADMINISTRATOR is a web-based browser application, used to configure and maintain the system.

Additional clinical modules are available, including infection control; pain escalation alerts; systemic inflammatory response alerts for possible sepsis (if the pathology data integration function is locally enabled); and assessment modules for venous thromboembolism, dementia, alcohol and malnutrition. Other options that can be implemented by local sites include:

- barcode identification of users and patients

- integration with radiology data

- customisation of observational intervals.
Nurses using the system can enter a patient’s vital signs with other clinical observations and assessments at the bedside. VitalPAC automatically calculates a person’s risk score based on clinical observations, immediately alerting staff of deterioration and advising on appropriate actions. VitalPAC also supports trust-specific scores for paediatric and maternity services so that the responses to EWS are appropriate to each trust.

The VitalPAC system uses the National Early Warning Score (NEWS) in its most recent version. A range of paediatric early warning scores (PEWS) are available as options with VitalPAC.

VitalPAC can integrate with several patient administration systems and electronic patient record systems, including Cerner, Meditech and Silverlink. The hardware needed to use the VitalPAC software must be purchased separately.

**The innovation**

The VitalPAC system automatically analyses vital sign data and this could reduce errors in paper-based recording and calculating EWS.

By alerting clinical staff to worsening vital signs, VitalPAC could help to improve care by prompting staff to escalate care. The VitalPAC system can also incorporate other clinical observations, screening tools, assessments and alerts. The system also enables organisation-wide audit and performance monitoring.

**Current NHS pathway**

Currently, nursing staff record the vital signs of people in hospital who are at risk of deterioration, and use them to calculate scores for each patient at that time point. The vital signs recorded are temperature, pulse, blood pressure, respiratory rate, responsiveness and oxygen levels. The scores indicate whether the person needs a higher level of care to prevent further worsening in their condition, and monitoring of these scores can reduce the number of cardiac and respiratory arrests, length of stay, and intensive care unit admissions (Smith et al. 2013).

The NICE guideline on recognising and responding to deterioration in adults who are acutely ill in hospital recommends that:

- physiological track and trigger systems should be used to monitor all adults in acute hospital settings
track and trigger systems should use multiple-parameter or aggregate weighted scoring systems, which allow a graded response and:

- define the parameters to be measured and the frequency of observations
- include a clear and explicit statement of the parameters, cut-off points or scores that should trigger a response.

Such weighted scoring systems are known as early warning scores (EWS). The Royal College of Physicians has recommended that the National Early Warning Score (NEWS) system for standardising the assessment of acute-illness severity in the NHS be adopted. The Royal College of Nursing has issued guidance on standards for measuring vital signs in infants, children and young people. VitalPAC offers a number of paediatric EWS with different models adapted to different age ranges. No evidence is currently available on VitalPAC for a paediatric group.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to VitalPAC:

- Patientrack (Patientrack)
- Nervecentre (Nervecentre Software)
- Wardware (Airslie)
- Visensia (OBS Medical)
- IntelliVue Guardian EWS (Philips)

NICE has produced a medtech innovation briefing on Visensia for early detection of deteriorating vital signs in adults in hospital and EarlySense for heart and respiratory monitoring and predicting patient deterioration.

Population, setting and intended user

The technology is intended to be used in acute care settings for adults and children. It would be used by nurses who manually record vital signs.

If a patient's health deteriorates, nurses should inform the clinical decision makers of their concerns according to their local protocol. The manufacturer’s deployment and implementation guide recommends that hospitals using VitalPAC should have a defined route of escalation to
provide Executive Board Assurance in order to mitigate risks and maximise benefits from the use of VitalPAC. The VitalPAC system can also provide information to support these activities.

VitalPAC has been used to remotely monitor the health of people in their homes but this use is beyond the scope of this briefing.

Costs

Device costs

The annual licence cost for the VitalPAC software is 70p per hospital bed per day (excluding VAT). A more basic version of the system is available at a cost of 50p per hospital bed per day; this version does not include the function to automatically escalate care to doctors and other clinicians. There are no restrictions on the number of users or on the level of use. The price includes deployment, training and ongoing support.

The software operates on Apple iPod touches, iPads and iPhones, which must be bought separately by the hospital. The hospital must also hold an annual Apple Enterprise Licence at a cost of $299 USD (Apple website June 2016; around £225 at exchange rate 1 USD to £0.76).

Secure sockets layer (SSL) certificates are needed for data encryption to securely send data securely to The Learning Clinic servers located in the Trust. The SSL certificate can be generated by the trust or can be purchased at a cost of less than £100. No other consumables or materials are needed to use the system.

Costs of standard care

High-quality A3 colour printed observation charts are needed for paper-based recording of vital signs and calculation of EWS.

Resource consequences

The manufacturer has stated that the VitalPAC system is in use in 52 NHS sites in 26 NHS trusts. The price of the core system includes deployment, training and ongoing support. However, an NHS trust implementing the VitalPAC system would need to:

- consider whether changes to IT infrastructure are needed
- revise policies on patient observation and escalation
• consider any training requirements additional to that provided by VitalPAC.

Regulatory information

VitalPAC was CE marked as a class 1 device in 2009. The Medicines and Healthcare Products Regulatory Agency (MHRA) has issued the following manufacturer Field Safety Notices for this device:

• In April 2015, a Field Safety Notice reported underscoring of early warning scores (EWS) in VitalPAC V2.3 and V3.0 resulting in possible misclassification of deterioration risk. All affected local users were advised to follow the recommended sequence of steps for vital sign recording and external monitoring, email alerting and daily monitoring reports were offered. A product fix was delivered to affected sites and sites were asked to carry out a case-note review of patients identified as being at possible risk of harm. No harm was reported and the case was subsequently closed.

• In February 2016, a Field Safety Notice reported that clients’ servers sometimes rejected VitalPAC data that had been submitted. On these occasions, VitalPAC behaved as expected, but the record was not saved. The ‘observation due’ clocks stayed unchanged on the patient lists, showing that the observations had not been sent and prompting nurses to resend the set of observations. Local users were advised to carry out a case-note review of patients who had been identified as possibly affected and report back any cases of actual harm. None were reported. A product correction fix was delivered and the case was subsequently closed.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Older people who are unwell are more likely than younger people to be treated in hospital. Age is a protected characteristic under the Equality Act (2010).
Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant/best available published evidence relating to the clinical effectiveness of the technology. The literature search strategy, evidence selection methods and detailed data extraction tables are available on request by contacting mibs@nice.org.uk.

Published evidence

Four studies (Mitchell et al. 2016; Prytherch 2006; Pullinger 2016; Schmidt 2015) relevant to the use of VitalPAC for recording and calculating early warning scores (EWS) are summarised in this briefing (112,218 adults and 21 nurses in total).

Mitchell et al. 2016 evaluated the implementation of a quality improvement initiative, which included using VitalPAC, on reducing outbreaks of nosocomial viral gastroenteritis. The study was a single-centre before-and-after retrospective study and also compared the centre outbreaks with those at regional and national level.

Prytherch et al. 2006 carried out a classroom exercise comparing processing of clinical datasets using pen and paper with VitalPAC. Using VitalPAC reduced errors and the number of instances in which errors affected clinical decisions.

Pullinger et al. 2016 carried out a before-and-after feasibility study on using VitalPAC instead of pen and paper to record EWS in the emergency department. Although results showed that more EWS were recorded when VitalPAC was used, fewer data from the patients included in the pen-and-paper stage were available for analysis, possibly introducing bias.

Schmidt et al. 2015 used statistical process-control charts to study trends in in-hospital seasonally-adjusted mortality associated with the 56 diagnoses used to monitor UK-hospital performance over the period in which VitalPAC was implemented in 2 UK general hospitals. There was some evidence that seasonally-adjusted mortality for these conditions was lower in both hospitals and within medicine, surgery and trauma, and orthopaedics grouping after VitalPAC was introduced. Other changes over the study period could have influenced the findings and total mortality and deaths in the immediate period after discharge were not considered.

Table 1 summarises the clinical evidence as well as its strengths and limitations.
Table 1: Summary of selected studies

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<thead>
<tr>
<th>Study</th>
<th>Details of intervention and comparator</th>
<th>Outcomes</th>
<th>Strengths and limitations</th>
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<tr>
<td>Mitchell et al., 2016</td>
<td>Pre-intervention practice regarding norovirus infection was compared with a multi-dimensional quality-improvement initiative which included VitalPAC.</td>
<td>The annual number of outbreaks dropped after the quality-improvement initiative when compared with the period before the initiative and with regional and national data.</td>
<td>The quality-improvement initiative included the introduction of 3 other interventions: a public health education campaign; targeted norovirus care and control bundle; and the opening of a new hospital block. The interventions were not introduced in a controlled manner and so it is not possible to quantify the influence of VitalPAC on outbreak reduction.</td>
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<td>Prytherch et al. 2006</td>
<td>VitalPAC was compared with pen and paper. Participants were asked to rate their preference for pen and paper or VitalPAC using a 5-point Likert scale.</td>
<td>Fewer errors in input and charting occurred with VitalPAC resulting in fewer incorrect EWS and fewer consequent incorrect clinical actions. Data entry with VitalPAC took less time. Participants preferred VitalPAC.</td>
<td>Although the study quantified errors and times associated with processing clinical data, results from a classroom situation may not be directly applicable to the hospital environment. The design could have been strengthened by randomising participants and the order in which the datasets were processed.</td>
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<td>Calculating early warning scores – a classroom comparison of pen and paper and hand-held computer methods. Single-centre classroom comparison of processing 5 clinical data sets UK 21 nurses</td>
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VitalPAC was compared with pen and paper. Participants were asked to rate their preference for pen and paper or VitalPAC using a 5-point Likert scale. Fewer errors in input and charting occurred with VitalPAC resulting in fewer incorrect EWS and fewer consequent incorrect clinical actions. Data entry with VitalPAC took less time. Participants preferred VitalPAC. Although the study quantified errors and times associated with processing clinical data, results from a classroom situation may not be directly applicable to the hospital environment. The design could have been strengthened by randomising participants and the order in which the datasets were processed.
Pullinger et al. 2016
Implementing an electronic observation and early warning score chart in the emergency department: a feasibility study. Patients over 16 years from the 'majors' area of the emergency department: stage 1 (paper charts) 3,219 patients; stage 2 (VitalPAC) 3,352 patients.
Before-and-after study
Single emergency department
UK

Stage 1: paper charts.
Stage 2: VitalPAC.

More patients in the VitalPAC stage had accurate EWS recorded in available documentation. There were no statistically significant differences in mortality, length of hospital admission, transfers to the resuscitation room or intensive therapy unit, and cardiopulmonary events. People whose records were processed using VitalPAC were slightly more likely to be admitted.

A weakness was data availability which was poorer in stage 1 than stage 2. This finding was actually part of the benefit of introducing VitalPAC – more patients had more observations done, and those data could be easily retrieved.

A before-and-after single-centre design cannot adequately adjust for changes over the period studied other than the intervention measured.
Schmidt et al. 2015

Impact of introducing an electronic physiological surveillance system on hospital mortality.
Number of patients admitted pre- and post-implementation:
Hospital 1: 27,959; 29,676.
Hospital 2: 21,771; 26,241.
Number of deaths before discharge pre- and post-implementation:
Hospital 1: 2,168; 1,904.
Hospital 2: 1,648; 1,614.

Before-and-after study with analysis of seasonally-adjusted monthly mortality rate using statistical VitalPAC electronic physiological surveillance system was compared with previous paper-based EWS systems.
The monthly number of observation sets was used to track implementation of VitalPAC.
Results were considered for medicine, surgery and trauma, and orthopaedics specialty groups.

In both hospitals crude mortality for 56 diagnosis groups used by the UK NHS to monitor and compare hospital performance at the point of hospital discharge fell after implementation and seasonally-adjusted mortality fell after VitalPAC was fully implemented. In both hospitals, seasonally-adjusted mortality showed some evidence of special cause variation with lower death rates after VitalPAC implementation. Within both hospitals, results for medicine, surgery and trauma, and orthopaedics were consistent with overall results.

Strengths included that 2 unselected hospital populations were studied; mortality data were from an external source; mortality was seasonally adjusted.
Limitations included that there was no comparison with control hospitals retaining paper-based EWS systems (other changes may have influenced hospital death rates over the period observed); total mortality rates were not used; mortality rates were not adjusted for age, sex or other factors, apart from seasonality; relatively short period observed after implementation; mortality at the point of hospital discharge may have missed the effect of later deaths.
Strengths and limitations of the evidence

There is limited evidence showing that using the VitalPAC system may be associated with improved recording and calculating of EWS and patient outcomes.

Given the uncontrolled before-and-after design of the studies identified, it is possible other factors may have influenced the findings. A feasibility study in an ED showed an improvement in the recording of EWS with VitalPAC rather than pen and paper, as did a classroom study. The study design could have been strengthened by randomising the order of pen-and-paper and VitalPAC processing as well as the order of dataset processing. Real-life experience in the hospital environment might differ from a study environment. A reduction in the outbreak numbers of nosocomial norovirus infections was reported, although the decrease has to be attributed to a combination of the quality improvement initiatives and not exclusively to the implementation of VitalPAC.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

The commentators were generally positive about the potential for improvement offered by VitalPAC. They noted that there was an ongoing move towards electronic recording of vital signs and alerting of deterioration, and that several similar systems were available to do this. Electronic systems can improve the recognition and treatment of clinical deterioration and this can offer clinical benefit to patients, provided appropriate action is taken and the accuracy of vital sign assessment is ensured. One commentator added that electronic systems had potential to improve early warning score (EWS) scoring by eliminating arithmetic errors and allowing monitoring of completeness and compliance. In addition they can help with patient tracking and clinical and continuous audit, whereas paper-based systems can be difficult to audit.
One commentator noted that in standardising documentation practice and increasing transparency of risk assessments, VitalPAC could be used to drive cultural change unlike other interventions in the current NHS. But 2 commentators noted that the use of systems such as VitalPAC would be a part of a wider package of process management improvements needed in the acutely ill and deteriorating patient pathway. How alerts are triggered and how care is escalated would also need to be reviewed.

Some practical issues were raised for consideration in the implementation of systems such as VitalPAC. Reliable WiFi or other networking infrastructures would be needed. Another commentator said that they found it difficult to view trends in observation data on the small screens of the iPod devices.

Two commentators reflected that as VitalPAC does not monitor vital signs directly, there was potential for transcription errors to be made when entering vital sign data into the system. Similarly, alerting could be delayed if vital signs are not entered into VitalPAC immediately. Additionally, one noted that qualitative data, such as clinicians' concerns or patients' complaints are not recorded and therefore may be lost. Another commentator noted that blood test results cannot be incorporated into the alerting system.

One commentator was concerned by the 2 field safety notices relating to technical issues with VitalPAC, as users of the system tend to assume that the outputs of monitoring systems are correct. Another stated that 1 downside of VitalPAC was that the manufacturer does not make users' data available for open research or evaluation. One noted that the new clinical definition of sepsis reduced the importance of the alert for systemic inflammatory response syndrome.

Specialist commentators

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.

The following clinicians contributed to this briefing:

- Chris Subbe, Consultant in Acute, Respiratory and Critical Care Medicine, Ysbyty Gwynedd Hospital. Chris Subbe has done consultancy work for Philips, which offers vital sign monitoring with some comparable functionality to VitalPAC and has worked with the team which developed VitalPAC on several related projects, but not on VitalPAC.
• Patrick Nee, Consultant in Emergency Medicine and Intensive Care Medicine, Whiston Hospital, no conflicts of interest declared.

• Simon Mackenzie, Medical Director, St. George's University Hospitals NHS Foundation Trust, no conflicts of interest declared.

• John Welch, National Outreach Forum and Consultant Nurse, University College London Hospitals, no conflicts of interest declared.

• Deborah Dawson, Consultant Nurse Critical Care, St George's University Hospitals NHS Foundation Trust, no conflicts of interest declared.

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