Market Analysis and Health Economic Benefits of the Patient Status Engine

Isansys Lifecare Ltd

Patient Status
Continuous, Wireless, Anywhere

The Patient Status Engine provides a solution to many of urgent issues facing healthcare providers today

- *Very high (and essentially unnecessary) costs of patient safety*
- *Shortage of skilled staff and high costs of labour*
- *Need to improve outcomes as insurers move to payment by outcomes / results*

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1 About Isansys Lifecare

Isansys Lifecare is a new generation healthcare company that provides patient surveillance and monitoring services built on an innovative, low cost and scalable digital platform.

Established in 2010 by experienced digital health professionals, the company is now working with leading clinicians and hospitals whose ground-breaking work will bring enormous benefits to millions of patients and their care teams while addressing the spiraling costs of care.

Isansys leverages extensive expertise in bioengineering, data analytics, medically qualified firmware, regulatory processes and mobile and cloud software, to create technology that supports decision-making paradigms to achieve better health and economic outcomes.

To find out more about Isansys please go to www.isansys.com

1.1 About the Patient Status Engine (PSE)

Isansys has created the Patient Status Engine (PSE), a remarkable new CE-Marked patient monitoring platform which collects and analyses patients' vital signs and will alert doctors and nurses if a person's health is deteriorating.

The PSE observes every heartbeat, every breath, oxygen saturation every second, temperature every minute and blood pressure as required to allow doctors and nurses to monitor patients better, more closely, more efficiently, and continuously. All this is done without wires or cables and patients wear tiny wireless smart patches allowing them to move about freely, all the while being monitored as if they were in a high dependency hospital ward.

The PSE uses wireless, sensing and information technologies to collect and analyse patient data. It addresses the increasingly high costs of healthcare, particularly those related to in-hospital patient safety, and the inexorable rise of chronic conditions that demand that care be taken out of the hospital to the patient's home.
The system's hardware comprises wireless body-worn sensors, including the Isansys Lifetouch, the Isansys Lifetemp and third-party devices to collect patient data. The data is then transmitted via Bluetooth to a the Patient Gateway, a tablet-like device that also acts a data entry interface for the healthcare provider or the patient, if the latter is at home. Among its functions, the Gateway is used to identify and validate users, enter patient details, set early warning score thresholds and register sensor devices onto the network.

The Lifeguard Server is the PSE's back-end IT system that collects the data from multiple Patient Gateways installed in and outside of hospitals, and then delivers the data directly to the care teams or to the patient on any browser enabled device, including smart phones and tablets.

Vital signs are normally recorded every one to four hours onto paper charts, but the PSE collects precise, high resolution and continuous patient data and enables care teams, both in and out of the hospital to know the status of their patients at all times. This allows clinical staff to see not only the current status of their patients but it also provides a view into the future status of their patients through data driven methods such as predictive algorithms and new physiologically based biomarkers. This enables a new proactive care paradigm to emerge rather than the current reactive methods currently in use.

2 Introduction

Monitoring vital signs including blood pressure, pulse rate, respiration rate, heart rate, temperature and oxygen saturation, is a crucial aspect of patient care. Vital signs indicate a patient's clinical condition and are necessary to calculate early warning scores which are used to determine the monitoring, escalation and interventions that are subsequently required.

In this document we:

- Explore the evidence describing the current practice of monitoring vital signs
- Describe the possible consequences
- Illustrate the solution to improving the monitoring of vital signs and how the Patient Status Engine can disrupt and transform medicine, allowing clinicians to monitor patients 24/7 while driving proactive, personalised care. The net result will significantly improve the quality of care and help build a more cost-efficient healthcare delivery system.

This paper is part of a series of reports developed to support providers and commissioners who are making decisions about methods and systems to continuously monitor patients on various pathways; who would like to improve patient safety, reduce patient deterioration and would like to ease the pressures and daily burdens on the workforce in their hospitals.
It will also aid healthcare professionals who would like to move care currently provided in acute hospitals to community-based settings and discuss the importance of being able to proactively monitor and care for patients beyond the walls of a hospital or health system.

3 Current practice of monitoring vital signs

3.1 Introduction

Patient safety is a key component of medical care. The UK Department of Health estimates that over 1.2 million in-patient adverse events occurred in 2014/15[1] and 10% of patients admitted to hospital will be unintentionally harmed during their stay[2]. Data from the National Audit Office reveals that in 2013/14 there were 1.2 million reported care incidents[3] and 12,000 of these people were likely to die, half of which could be prevented[4].

An adverse event is defined as an unintended injury or complication leading to prolonged stay in hospital, disability or death due to healthcare mismanagement[5] (Jones et al. 2011). Preventing an adverse event has been a major focus in improving patient safety and quality of care in today's healthcare arena[6] (Hauck et al. 2012).

Patient safety related incidents are costly to the NHS, additional hospital stay costs are £2.5bn a year and negligence claims amount to an extra £1.2bn a year[7]. Associated costs including readmission to hospital and intensive care units are estimated at £1.3bn and the total costs of dealing with patient safety in the UK equates to £5bn in unnecessary spending. These costs are in addition to the ensuing distress for patients, families and frontline staff and the greater bureaucratic burden for

[1] *NHS* "Organisation Patient Safety Incident Reports 23 September 2015"
[2] http://www.who.int/patientsafety/journals_library/Improving_Patient_Safety.pdf, p4
[3] http://m.hsj.co.uk/5081758.article
[4] http://www.ons.gov.uk/ons/rel/subnational-health4/avoidable-mortality-in-england-and-wales/2012/stb-avoidable-mortality--2012.html
[5] Jones, D.A., DeVita, M.A. & Bellomo, R. (2011) Rapid response team. New England Journal of Medicine, 365 (2), 139-146.
[6] Hauck, Katharina, Xueyan Zhao, and Terri Jackson. "Adverse Event Rates as Measures of Hospital Performance." Health Policy (Amsterdam, Netherlands) 104, no. 2 (February 2012): 146–54. doi:10.1016/j.healthpol.2011.06.010.
[7] http://www.nhsla.com/aboutus/Documents/NHS%20LA%20Annual%20Report%20and%20Accounts%202013-14.pdf

management. The financial implications add enormously to the pressures placed upon the NHS, limiting its ability both to treat more patients and to provide higher quality services.
One area that can be addressed to ease these growing problems and reduce these shocking statistics is understanding what is happening to patients at all times, in other words, improved patient monitoring.

The National Institute for Health and Care Excellence (NICE) recommends that all patients should be monitored to help identify those whose clinical condition is deteriorating or is at risk of deterioration[8].

The NICE recommendations state that early warning scoring systems should be widely used in hospitals to track patient deterioration and to trigger escalations in clinical monitoring and rapid response by critical care outreach teams. The scoring systems used to trigger escalation are based on routine observations by ward staff taken every 4 – 6 hours[9].

Evidence of deterioration can be observed 8-12 hours before actual deterioration[10] [11] (Hillman et al. 2001;2002). An estimated 23,000 cardiac arrest and 20,000 unanticipated ICU admissions were preventable through better monitoring[12]. Additionally, it reports that patient observations should be monitored at least every 12 hours, with the frequency increasing if abnormal physiology is detected. By closely monitoring changes in physiological observations, deteriorating patients are more likely to be identified before a serious adverse event occurs. Early identification is important to reduce mortality, avoidable morbidity, length of stay and associated healthcare costs[13].

Evidence shows that inadequate responses to deterioration remain the most common cause of critical incidents to a national database in the UK[14] (Donaldson et al, 2014). In particular, concerns exist that delayed detection and escalation due to current standard patient monitoring, as outlined by Odell et al (2009), undermine the effectiveness of innovations aimed at improving detection[15]. The National Patient Safety Agency (2007a) reported that staff "rarely carry out routine observations, particularly during the night" and that "observations in general are seen as tasks with low priority"[16].

3.2 How big is the problem

Vital sign monitoring is an integral component of nursing care. An integrative literature review explores factors surrounding general ward nursing practice of vital signs monitoring in detecting and

[8] NICE Clinical guideline (2007) Acutely ill adults in hospital: recognizing and responding to deterioration https://www.nice.org.uk/guidance/cg50/resources/acute-illness-in-adults-in-hospital-recognising-and-responding-to-deterioration-975500772037

[9] NICE Clinical guideline (2007) Acutely ill adults in hospital: recognizing and responding to deterioration https://www.nice.org.uk/guidance/cg50/resources/acute-illness-in-adults-in-hospital-recognising-and-responding-to-deterioration-975500772037

[10] Hillman, K. M., P. J. Bristow, T. Chey, K. Daffurn, T. Jacques, S. L. Norman, G. F. Bishop, and G. Simmons. "Antecedents to Hospital Deaths." Internal Medicine Journal 31, no. 6 (August 2001): 343–48.

[11] Hillman, Ken M., Peter J. Bristow, Tien Chey, Kathy Daffurn, Theresa Jacques, Sandra L. Norman, Gillian F. Bishop, and Grant Simmons. "Duration of Life-Threatening Antecedents prior to Intensive Care Admission." Intensive Care Medicine 28, no. 11 (November 2002): 1629–34. doi:10.1007/s00134-002-1496-y.

[12] HNS Report; Recognising and responding appropriately to early signs of deterioration in hospitalised patients, November 2007

[13] HNS Report; Recognising and responding appropriately to early signs of deterioration in hospitalised patients, November 2007

[14] Donaldson, Liam J., Sukhmeet S. Panesar, Pauline A. McAvoy, and Diana M. Scarrott. "Identification of Poor Performance in a National Medical Workforce over 11 Years: An Observational Study." BMJ Quality & Safety 23, no. 2 (February 2014): 147–52. doi:10.1136/bmjqs-2013-002054

[15] Odell, Mandy, Christina Victor, and David Oliver. "Nurses' Role in Detecting Deterioration in Ward Patients: Systematic Literature Review." Journal of Advanced Nursing 65, no. 10 (October 2009): 1992–2006

[16] National Patient Safety Agency (2007a) Recognising and responding appropriately to early signs of deteriorations in Hospitalised patients.
http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60151

reporting deterioration[17] (Mok WQ et al. 2015). Patient variables, nurses' variables and organisational variables were identified into 20 studies to describe the current practices.

Patient variables as physical cues or vital signs changing are two process that confirm or quantify suspicions of deterioration. Unfortunately, reports indicate that nurses were unable to recognise or were unaware of clinical deterioration in more than half the cases[18] (Fuhrmann et al, 2008). Changes in vital signs allow nurses to quantify their suspicions of deterioration, which is not a proactive way to watch out for seriously ill patients. With the expansion of the role of registered nurses, patient monitoring is becoming more and more delegated to non-registered staff – those not trained enough to recognise and interpret the assessment findings[19] (Hogan J. 2006 and Chua W.L. et al. 2013).

Practices also reported that respiratory rate (RR) was usually omitted from routine vital sign assessment[20] (Meester et al. 2013; Chua W.L. et al. 2013). Reasons behind this could be that nurses may view pulse oximetry as a substitute for RR monitoring or maybe because of the lack of RR monitoring equipment[21] (Hogan J. 2006).

Beside this professional practice deviation, the impact on workloads and interaction with ward patients has been identified to influence the quality of vital signs monitoring. Nurses reported they are often overwhelmed to fit in time for the patient's observation[22] (Hogan J. 2006). 42% of the non-qualified staff felt distracted by other patient needs during the time of observation[23] (James et al. 2010). Another study shows that surgical nurses are being distracted approximately five times by other patients' needs when they take vital signs from patients.[24] (Wheatley I. 2006).
In a NHS report in 2007[25], comments from staff were noted:

"When staff come on duty, they've got several must-dos. Patients must get their breakfast, drugs have to be given out and staff have to prepare for 10 o'clock hospital discharges. This is also the time to start ward rounds. There's a lot of pressure in the early part of morning. So when do you fit in doing your obs?" [senior nurse]

"In some wards a lot of the issue is with sickness – people come in sick because there are hardly any nurses left. With two nurses and one auxiliary split between one ward and trying to do the washes in the morning – you wouldn't be able to physically do observations even if you wanted to." [staff nurse]

"I recently went to see a patient, where they had been poorly...They had been doing perfect hourly obs and had been asked to do them overnight – but staff had stopped at ten-to-six and hadn't done anything again until just before handover. Nothing had happened but the potential was there." [senior nurse]

[17] Mok, Wen Qi, Wenru Wang, and Sok Ying Liaw. "Vital Signs Monitoring to Detect Patient Deterioration: An Integrative Literature Review." International Journal of Nursing Practice 21 Suppl 2 (May 2015): 91–98. doi:10.1111/ijn.12329

[18] Fuhrmann L, Lippert A, Perner A, Ostergaard D. Incidence, staff awareness and mortality of patients at risk on general wards. Resuscitation 2008; 77: 325–330.

[19] Hogan J. Why don't nurses monitor the respiratory rates of patients. British Journal of Nursing 2006; 15: 489–492.

[20] De Meester K, Bogaert PV, Clarke SP, Bossaert L. In-hospital mortality after serious adverse events on medical and surgical nursing units: a mixed methods study. Journal of Clinical Nursing 2012; 22: 2308–2317, Chua, W. L., S. Mackey, E. K. C. Ng, and S. Y. Liaw. "Front Line Nurses' Experiences with Deteriorating Ward Patients: A Qualitative Study." International Nursing Review 60, no. 4 (December 2013): 501–9. doi:10.1111/inr.12061.

[21] Hogan J. Why don't nurses monitor the respiratory rates of patients. British Journal of Nursing 2006; 15: 489–492.

[22] Hogan J. Why don't nurses monitor the respiratory rates of patients. British Journal of Nursing 2006; 15: 489–492.

[23] James J, Butler-Williams C, Hunt J, Cox H. Vital signs for vital people: an exploratory study into the role of the healthcare assistant in recognising, recording and responding to the acutely ill patient in the general ward setting. Journal of Nursing Management 2010; 18: 548–555.

[24] Wheatley I. The nursing practice of taking level 1 patient observations. Intensive and Critical Care Nursing 2006; 22: 115–121.

[25] NHS Report: Recognising and responding appropriately to early signs of deterioration in hospitalised patients, November 2007

"You sometimes feel flooded with jobs to do, desperately trying to juggle them all. Therefore it becomes more difficult to prioritise and to try and be in more than one place at once. You have to try and prioritise whoever is most sick." [junior doctor]

"There are times I've been on certain wards when a patient has not had obs done the previous day… the patient has been stable… so they get complacent." [staff nurse]
"Because obs become so routine, it's very easy to not attach importance to them." [junior doctor]

In the report it highlighted that when early warning scoring systems are in place observations are taken, but the overall scores are sometimes not completed or are calculated incorrectly. Equally, respiratory rates are frequently not recorded.

"Respiratory rate is not done accurately or left off, when actually it's a useful indicator of how unwell someone is." [junior doctor]

Early warning scores were in general seen as useful. However, participants of the focus groups described these as not always being tailored to the specifics of different patients. They risk being over sensitive, causing too many alerts and consuming resources inappropriately. Too frequent triggering might reduce appropriate response and staff may suffer 'trigger fatigue'.

Deteriorating vital signs, when cues are picked up by nursing staff, need to be reported. Issues about difficulty in expressing subtle changes in patients by inexperienced nurses who use social language, can be a problem for physicians who need quantifiable evidence to prioritise workloads and make decisions properly[26] (Andrews et al 2005). Transferring information on vital sign deterioration to the nurse in charge is also detected as a serious implication for the delivery of quality patient care[27] (Chua W.L. et al. 2013).

Another problem is the monitoring of patients overnight[28]. A study in a Scottish teaching hospital found that nearly all early warning charts for patients causing overnight clinical concern were incomplete, with 64% having one or more observations omitted[29] (Gordon and Beckett, 2011). In a large study from a single centre in Southern England, the frequency and documentation of observation were less consistent with the hospital protocol at night[30] (Hands et al, 2013); only 13% of the 950,000 vital signs records were taken between the hours of 23:00 and 05:59, and observations were rarely taken during these hours for low-acuity patients. Even for those patients whose last early warning score between 20:00 and 23:59 indicated that there was a requirement for observations to be taken hourly or more frequently, only 57% had an observation recorded between midnight and 05:59. Compliance was much higher during the day although still far from optimal.

Another organisational variable is the documentation of the observation charts – documents where vital signs are periodically recorded. They are designed according to the subjective preference of healthcare professionals and lead to a lack of standardisation[31] (Christofidis et al. 2013). This lack of standardisation and the consideration of a human factor perspective lead to issues in accuracy and speed of chart users, and also to the completion of vital sign monitoring. The chart design that delivered the best result in all the review studies shared similar features of integrating track and

[26] Andrews T, Waterman H. Packaging: a grounded theory of how to report physiological deterioration effectively. Journal of Advanced Nursing 2005; 52: 473–481.
[27] Chua, W. L., S. Mackey, E. K. C. Ng, and S. Y. Liaw. "Front Line Nurses' Experiences with Deteriorating Ward Patients: A Qualitative Study." International Nursing Review 60, no. 4 (December 2013): 501–9. doi:10.1111/inr.12061.
[28] August, 31, and 2015. "Vital Signs Monitoring in Hospitals at Night." Nursing Times. Accessed May 9, 2016. http://www.nursingtimes.net/clinical-archive/assessment-skills/vital-signs-monitoring-in-hospitals-at-night/5089989.fullarticle
[29] Gordon CF, Beckett DJ (2011) Significant deficiencies in the overnight use of a Standardised Early Warning Scoring system in a teaching hospital. Scottish Medical Journal; 56: 1, 15-18.
[30] Hands C et al (2013) Patterns in the recording of vital signs and early warning scores: compliance with a clinical escalation protocol. BMJ Quality and Safety; 22: 9, 719-726.
[31] Christofidis MJ, Hill A, Horswill MS, Watson MO. A human factors approach to observation chart design can trump health professionals' prior chart Cardiff experience. Resuscitation 2013; 84: 657–665.

trigger systems, presenting observations in graphical form and using colour coding and banding to highlight abnormal readings[32] [33] (Preece et al, 2012; Christofidis et al. 2013).

Having access to technology and electronic vital signs monitoring equipment are usually favored for their efficiency as they decrease monitoring time. Unfortunately, current standard electronic monitoring equipment does not routinely measure a patient's respiration rate (RR)[34] (Holan J. 2006). A larger scale multi-centre study sponsored by Philips used manual RR and blood pressure, continuous temperature and continuous pulse rate from an oxygen saturation probe (a notoriously noise prone source). Even this less than ideal arrangement found the use of even some automated electronic vital signs was significantly associated with faster acquisition data and greater improvement in the survival rate of patients[35] (Bellomo et al. 2012).

Biomedical instrumentation should alarm in an accurate manner to avoid false alarms and not add to the burden of alarm fatigue. Two studies highlight that only 34% and 63% of critical alarms were true[36] [37](Gross et al. 2011; Fagan et al. 2012).

To date, alarm studies have been conducted in critical care with few alarm studies conducted in a ward environment. Paediatric intensivists and nurses working on the RAPID (Real-time Adaptive Indicator of Deterioration) project, a large wireless monitoring project at Birmingham Children's Hospital aimed at developing smart alarms, conducted a study to observe the frequency of monitor alarms in two paediatric cardiac wards[38].

In the report, four easily visible bed spaces were observed over two 24-hour periods. Using a standardized reporting tool, the nurses collected the cause and response times of all alarms during this period together with clinical obs data for each patient. Using set criteria, every alarm was categorized into valid, false or technical. The valid alarms that required an action such as a nurse review were identified as valid and actionable.

During the 24 hour observational periods on both wards there was a total of 453 alarms in the 8 chosen bed spaces. **248 were false**, **80 were technical** and **125 were valid.** Of these alarms only 50 were actually valid and actionable.

3.3 Impact on patient outcomes

Effectively detecting, and acting on, patient deterioration are complex issues. Vital signs observation is a key part of the 'chain of prevention' re quired to avoid deterioration, cardiac arrest and death[39] (Smith, 2010). A Patient Safety Observatory report into potentially preventable deaths in acute general hospitals identified 64 incidents related to vital sign observations, including failure to take basic observations; two-thirds of these incidents occurred in the evening or overnight[40] (NPSA, 2007).

[32] Preece MHW, Hill A, Horswill MS, Watson MO. Supporting the detection of patient deterioration: observation chart design affects the recognition of abnormal vital signs. Resuscitation 2012; 83: 1111–1118.
[33] Christofidis MJ, Hill A, Horswill MS, Watson MO. A human factors approach to observation chart design can trump health professionals' prior chart Cardiff experience. Resuscitation 2013; 84: 657–665.
[34] Hogan J. Why don't nurses monitor the respiratory rates of patients. British Journal of Nursing 2006; 15: 489–492
[35] Bellomo R, Ackerman M, Bailey M et al. A controlled trial of electronic automated advisory vital signs monitoring in general hospital wards. Critical Care Medicine 2012; 40: 2349–2360.
[36] Gross B, Dahl D, Nielsen L. Physiologic monitoring alarm load on medical/surgical floors of a community hospital. Biomedical Instrumentation & Technology: Alarm Systems 2011; 45: 29–36.
[37] Fagan K, Sabel A, Mehler PS, MacKenzie TD. Vital sign abnormalities, rapid response, and adverse outcomes in hospitalized patients. American Journal of Medical Quality 2012; 27: 480–486.
[38] Macdonald A., Sultan S, Loughhead R, Akerele L, Fule B, Matam, RB, Duncan H: "Majority of alarms are false and non-actionable in a ward environment". Birmingham Children's hospital poster results, 2015
[39] Smith, G.B., In-hospital cardiac arrest: is it time for an inhospital 'chain of prevention'? Resuscitation, 2010. 81(9): p. 1209-11.
[40] National Patient Safety Agency, The Fifth report from the Patient Safety Observatory. Safer care for the acutely ill patient: learning from serious incidents. 2007

It has been reported that deaths with lower frequency of vital signs recordings were more likely to be classified as potentially preventable[41] (De Meester et al, 2013).

Missed reporting of vital signs are reported to relate to skill mix, nurse:patient ratios, bed shortages, and the nurses' view regarding the importance of patient rest and negative effects of sleep disruption[42] (Yoder et al, 2013). In the UK, vital signs observations were clustered, with peaks in observation frequency occurring during 06:00 and 07:00, and 19:00 and 22:00, irrespective of the level of assessed risk. This suggests the timing of observation is driven by ward routines[43] (Hands et al, 2013) rather than the needs of patients and clinicians.

It has been revealed that there is an urgent need for continuous professional development to improve vital signs monitoring and that the reporting of vital sign observations needs to be prioritised in workload planning[44].

The importance of patient monitoring and early detection of deterioration is reflected in NICE guidelines and the Royal College of Physicians (RCP) National Early Warning Score initiative[45] [46].

3.4 Limitations of "Electronic Obs" Systems

A number of UK hospitals have developed or adopted "electronic obs" systems. These typically involve a nurse carrying out manual obs and entering the data into a wireless tablet or handheld device. While such systems lead to standardized reporting and reduction of in-ward paper based systems, they remain prone to data entry errors and lead to even greater workloads for nurses as most such systems include prompts to take the obs from individual patients at specific times. Deviations from the prompted time are noted, adding a layer of electronic surveillance to already overworked nurses, juggling with patients and priorities. The more frequent the obs, the more nurse time is taken. The very nature of electronic obs systems means that they cannot improve in-ward nurse efficiencies.

While removing some of the time required for calculating EWS, the sparse and sometimes inaccurate nature of the input data in electronic obs, means that the automatically calculated EWS is fundamentally no better an indicator of deterioration than when the EWS is arrived at through an entirely manual set of procedures.

[41] De Meester, Koen, Peter Van Bogaert, Sean P. Clarke, and Leo Bossaert. "In-Hospital Mortality after Serious Adverse Events on Medical and Surgical Nursing Units: A Mixed Methods Study." Journal of Clinical Nursing 22, no. 15–16 (August 2013): 2308–17. doi:10.1111/j.1365-2702.2012.04154.x.

[42] Yoder, Jordan C., Trevor C. Yuen, Matthew M. Churpek, Vineet M. Arora, and Dana P. Edelson. "A Prospective Study of Nighttime Vital Sign Monitoring Frequency and Risk of Clinical Deterioration." JAMA Internal Medicine 173, no. 16 (September 9, 2013): 1554–55. doi:10.1001/jamainternmed.2013.7791.

[43] Hands, Chris, Eleanor Reid, Paul Meredith, Gary B. Smith, David R. Prytherch, Paul E. Schmidt, and Peter I. Featherstone. "Patterns in the Recording of Vital Signs and Early Warning Scores: Compliance with a Clinical Escalation Protocol." BMJ Quality & Safety 22, no. 9 (September 1, 2013): 719–26. doi:10.1136/bmjqs-2013-001954.

[44] http://intqhc.oxfordjournals.org/content/27/3/207

[45] NICE Clinical guideline (2007) Acutely ill adults in hospital: recognizing and responding to deterioration https://www.nice.org.uk/guidance/cg50/resources/acute-illness-in-adults-in-hospital-recognising-and-responding-to-deterioration-975500772037

[46] National Early Warning Score (NEWS), Standardising the assessment of Acute-illness severity in the NHS. Report of a working party; July 2012 https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news

4 The Patient Status Engine - An Effective Solution

4.1 Introduction

Isansys Lifecare has developed the Patient Status Engine (PSE), a powerful end-to-end solution that is now available to providers across the healthcare landscape.

The PSE is a complete patient safety monitoring platform which can be deployed hospital-wide either as a stand alone system or integrated with any current or proposed hospital information system or electronic patient record. It collects patient vital sign data continuously and in real-time then uses this data to predict individual patient outcomes while promoting superior care for all patients.

Unlike all other monitoring systems, the PSE enables clinicians to gain access to continuous vital sign data from patients in the hospital, at home, at work, and in the community. It uses wireless body-worn sensors to automatically collect and analyse patients' vital signs. This data is then streamed via a patient gateway to a central server from where it is aggregated and delivered to the nurses' station or made available remotely to clinicians. This data can then be used to automatically provide early warning scores (EWS) or other predictive notifications and audit trails. The use of EWS has been reported to perform better than single parameter systems in identifying deteriorating patients and, when combined with rapid response have the potential to reduce cardiac arrest and unplanned ICU admissions[47] (Chan et al. 2010).

The PSE automatically captures and uploads 6 vital signs – heart rate, respiration rate, temperature, oxygen saturation, blood pressure and coma score and calculates a real time NEWS score that is displayed locally, at the nurses station or on the clinicians smart phone. Behind the minute by minute measures, the PSE also provides accurate beat by beat information (R – R intervals) for heart rate variability applications, second by second saturation levels, ECG and PPG on request. All data may be viewed locally at the patient gateway or remotely via the Lifeguard server portal.

Both a medical device and a clinical digital data platform, the PSE includes standard and custom manual data entry screens, providing an electronic obs system as a subset of its extended capabilities.

Current Monitoring

Wired, manual, labour intensive constricting, error-prone

The Patient Status Engine

Wireless, freedom, real-time, automatic data collection

[47] Chan, Paul S., Renuka Jain, Brahmajee K. Nallmothu, Robert A. Berg, and Comilla Sasson. "Rapid Response Teams: A Systematic Review and Meta-Analysis." Archives of Internal Medicine 170, no. 1 (January 11, 2010): 18–26. doi:10.1001/archinternmed.2009.424.

4.2 At scale PSE deployments and potential economical outcomes

Already the Patient Status Engine has been used to monitor many hundreds of adult and paediatric patients and has logged over 40,000 hours of data. It has proven itself to be simple to use, liked by patients and clinical staff, and able to present accurate clinically relevant information.

From a clinical perspective, the key benefits are the early detection of deterioration in the condition of a significant number of patients and the efficiencies gained by releasing nursing staff for other tasks and accurate real-time data for clinicians. Studies are currently being carried out to show the exact percentage of patients where deteriorations are detected early but already clinicians, nurses and patients can see the benefits of using this complete, wireless monitoring system compared to current standard patient monitoring equipment.

Dr Heather Duncan, principal investigator and clinical lead for the RAPID project at the Birmingham Children's Hospital, says: "We're using wearable wireless technology to identify and predict deterioration in children earlier, so that we can avoid life-threatening events. The technology uses biotelemetry and wireless sensors to collect real-time data on vital signs such as heart rate, breathing rate and oxygen levels. This data is then analysed to predict when a child's condition may be deteriorating, providing an early warning system that can be acted on immediately."

For the patients and families, the Patient Status Engine offers reassurance, mobility, and unimpeded personal contact. For patients and the wider health economy, it offers improved patient outcomes, reduced length of stay, and avoids higher treatment costs through earlier detection.

Dr Duncan adds: "The PSE has the ability to transform our perspective on things. In healthcare, it's usual for us to think of things as 'normal' and 'abnormal' – either the heart rate is 'high' or the heart rate is 'low', for example. This technology is enabling us to identify what is normal for a particular individual too. In our first study, a few years ago, the process of getting to know the patient in this way took 30 to 40 minutes - but now we can do it in five minutes. So we get a sense of the patient's specific 'normal' and we get to see the patterns - which can be a lot more reliable than an early warning system which aggregates 'higher' or 'lower' thresholds – within minutes and that makes for a very powerful tool.
"This new wireless technology is much more usable and more reliable. It's also better at reducing false alarms. There are no risks that we are aware of. We use a specific bandwidth for our wireless data transfer, for example and so the data is secure. The wearables are also very low power, so there's no physical risk to the patient either. This technology essentially allows us to have fewer expensive monitors and at the same time to monitor a lot of patients, generating a lot of data."

5 Health Economic Benefits of the Patient Status Engine

5.1 Case 1 – In hospital monitoring of high dependency patients

Background

The Patient Status Engine is provided under Isansys *Vitals as a Service* model as a managed service without capital cost or technology risk for the hospital. It is used on 25% of patients in a critical/acute care facility deemed to be at greatest risk of deterioration. Cost is £25 per patient per day.

The following model was prepared by Xcelerate Health Outcomes:

General Ward setting assumptions using preventable adverse event approach

- Continuous Vital sign monitoring will reduce avoidable adverse events and lead to reduction in hospital bed days
- Preventable adverse events account for 5% of all admissions resulting in 8.5 additional bed days per incident [48] (mean LOS is 5.2 all admissions at average cost of £3,366) [49]
- Inadequate clinical monitoring accounts for 25% of preventable adverse events
- Using continuous Vital Signs monitoring will eliminate 75 % of the adverse events occurring
- Based on a 400 bed hospital 20 patients will be affected resulting in 170 additional bed days. 5 of those patients (20%) were due to inadequate clinical monitoring
- PSE used on 100 patients (beds) deemed most at risk
- 5x8.5 days at additional bed cost of £294 per day = £12,495 of which £9,371 could be saved
- Cost of Vital sign monitoring for 100 patients assuming 3.2 days in general ward and 2 days in ICU is £8,000 = £25 per patient per day x 3.2

Conclusions

- Positive financial benefit for hospital to adopt PSE based vital sign monitoring for at-risk patients
- Large benefit for those patients and families where the PSE averted an adverse event
- Great opportunity to increase the sensitivity and capability of the PSE to prevent greater number of adverse events and provide even greater savings

[48] Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322(7285):517-519

[49] Health and Social Care Information Centre, Hospital Episode Statistics for England, Inpatient Statistics, 2012/13.

5.2 General Ward Setting Overall reduction in (Length of Stay) LOS scenario

Background

The Patient Status Engine is provided under Isansys *Vitals as a Service* model as a managed service without capital cost or technology risk for the hospital. In this case it is assumed that it would be used on all 400 beds in the hospital. As in earlier model, cost is £25 per patient per day.

This model also prepared by Xcelerate Health Outcomes:

Key Assumptions

- PSE Vital Sign monitoring can reduce the average admission costs of £3,366 (5.2 days) due to earlier discharge as more confidence in patient stability as well as reduced incidence of adverse events
- 400 bed hospital same assumptions 3.2 days on Lifecare £32,000
- Cost of all admissions £1.346m
- Reduction in LOS cost by 2.5% will be cost neutral
- Reduction from 5.2 to 5.0 days will be cost effective, £51,000 saved

Conclusions

- High financial benefits for providers for widespread adoption of PSE monitoring
- A compelling case to produce the evidence to show that the PSE enables reduced LOS

5.3 Resource savings scenario in general ward setting

Background

In this analysis, the cost of nurse time to take manual observations is made and compared against a nominal £25 per patient per day *Vitals as a Service* cost.

This model also prepared by Xcelerate Health Outcomes:

Key Assumptions

- The PSE continuous monitoring will reduce nurse time in collecting data
- The associated benefit of much higher quality, real-time data for better and faster clinical decision making is NOT quantified in this analysis
- Study showed that observation time could be 12 mins per patient based on manual inputting of data [50]
- 6 readings over a 24 hour period is 72 mins

[50] Meccariello M, Perkins D, Quigley LG, Rock A, Qiu J. Vital time savings: evaluating the use of an automated vital signs documentation system on a medical/surgical unit. J Health Info Management. 2010;24(4):46–51.

- Continuous Vital sign readings reduce this to 2 mins using the PSE as some periodic readings need to be made

- Based on a FTE salary rate of 34p per minute[51] saving of 10 min per patient observation or £3.40 and 60 mins per day or £20.40

- Cost of monitoring is £25 per day but when readings are taken more frequently 7-8 observations it would be cost neutral

Conclusions

- Manual observations have a cost regardless of whether the data entry is manual or electronic

- For 4 hourly obs, the PSE at £25 per patient per day is more expensive when only the time is taken into account

- For more frequent obs for higher dependency patients, the PSE rapidly approaches cost neutrality and moves quickly into a positive benefit

5.4 Overall conclusion – the PSE is cost saving in hospital settings

The three in-hospital models shown above consider only the direct financial gains from using the PSE to reduce the costs of adverse events, to reduce the length of stay and to reduce the costs of nurse's time (or increase nurse efficiency).

Key observations

1. The PSE provides savings or cost neutrality in each of the three model scenarios. However these are *additive* (and in no sense mutually exclusive) hence the overall savings include elements of each scenario, leading to even greater direct financial benefits enabled by the PSE.

2. None of the other benefits associated with better, real time and predictive data that are available to clinical teams at any time on any device are taken into account

3. No quantified estimates are included of the economic impact on those patients who are able to leave hospital earlier or have not had to suffer an adverse event as a result of being monitored with the PSE

4. No human costs on patients and families are considered

5. When all these factors are taken into account the case for widespread adoption of the PSE wireless patient monitoring platform is overwhelmingly positive

[51] PSSRU. Unit costs of health and social care 2013. Canterbury 2014

6 Case Study - The Economic benefits of the PSE in the battle against sepsis

6.1 Definition of Sepsis:

Currently, a variety of terms are used across the system to describe different severities of sepsis. This can be confusing, as professionals will not always share the same understanding of any given term. Sepsis arises when the body's response to an infection causes systemic effects, which are manifested by two or more Systemic Inflammatory Response Syndrome (SIRS) criteria. In the absence of organ failure, this is termed 'uncomplicated sepsis'. 'Severe sepsis' occurs when there is organ failure, and 'septic shock' is used when there is resistant to fluid therapy.[52]

6.2 Epidemiology and Prevalence in the UK

- Approximately 123,000 cases of sepsis per year in England[53]
- Around 44,000 associated deaths [54] [55]
- Suggests 200,000 cases of sepsis a year in the UK and up to 60,000 deaths [56].
- The numbers recorded by the NHS are likely to be an underestimated due to the way data is coded. [57]

Sepsis is a more common reason for hospital admission than heart attack and has a higher mortality[58].

- Consensus point about incidence: 200-337 cases per 100,000 people annually
- Septic shock = 50% mortality rate → Responsible of 44,000 deaths in the UK
- Episode of severe sepsis costs approx. 25,000€ = £20,000
- Costs £2.5 billion a year
- Neutropenic sepsis ➔ 5% go to IUC
- Lack of data for admission data from NHS. Approx. 2,125 patients for febrile neutropenia with malignancy
- 20,000 admissions with neutropenic sepsis

Sepsis is one of our biggest killers. The UK Sepsis Trust states that sepsis claims 44,000 lives every year in the UK and costs the NHS £2.5 billion a year[59]. In comparison, breast cancer claims less than 8,000 lives a year[60].

We need to reduce the catastrophic deaths, life-altering consequences, and high costs of sepsis, but this can only be done by acting quickly to diagnose and treat it in the early stages when symptoms first arise.

Campaigners want to reduce sepsis cases by 20 per cent by 2020[61] and make the word sepsis a 'household name', but in order for us all to achieve this, more has to be done.

[52] Royal College of Physicians, Acute Care Toolkit: Sepsis, September 2014
[53] Hospital Episode Statistics, Health and Social Care Information Centre 2015. Information available at: Parliament website
[54] Daniels R. Surviving the first hours in sepsis: getting the basics right (an intensivist's perspective). J Antimicrob Chemother 2011;66(suppl ii):11–23.
[55] Vincent JL, Sakr Y, Sprung CL et al. Sepsis in European intensive care units: results of the SOAP study. Crit Care Med 2006;34:344–53
[56] Just Say Sepsis! A review of the process of care received by patients with sepsis
[57] Just Say Sepsis! A review of the process of care received by patients with sepsis
[58] Liu V, Escobar GJ, Greene JD, Soule J, Whippy A, Angus DC, Iwashyna TJ: Hospital Deaths in Patients With Sepsis From 2 Independent Cohorts. JAMA 2014
[59] The UK Sepsis Trust. 2016. Available at: http://sepsistrust.org (accessed 28 January 2016).
[60] The UK Sepsis Trust. 2016. Available at: http://sepsistrust.org (accessed 28 January 2016).

Existing research highlights early detection of patient deterioration is vital to improving patient safety and avoiding preventable deaths.

One solution to this is the PSE. This will continuously collect and analyse patient data, especially from those patients deemed clinically to be most at risk of contracting sepsis. Research shows that subtle variations in the patterns of a patient's vital signs such as heart rate, respiration rate and temperature indicate the early onset of sepsis and other inflammatory conditions.

Change in current practices

The Sepsis Six care bundle as a whole has been shown to reduce the relative risk of death by 46.6 percent[62] when delivered to patients with severe sepsis within one hour.
Close monitoring and regular review can identify patients who do not improve with the Sepsis Six, prompting urgent referral to critical care[63].

The Sepsis Six care bundle comprises:

- Give oxygen to maintain saturations >94%
- Take blood cultures and consider source control
- Administer empiric intravenous antibiotics
- Measure serum lactate and send full blood count
- Start intravenous fluid resuscitation
- Commence accurate urine output measurement

Improvement is possible

At a national level the spotlight on sepsis as a key source of avoidable mortality and morbidity has been intensifying.

- Only a third of the patients suffering from Sepsis received good quality care[64].

Financial savings

The reliable delivery of basic care has been shown to save between £2,000 and £5,000 per case in reduced bed days alone[65]. The UK Sepsis Trust has estimated that a typical medium-sized general hospital could save £1.25 million annually through improved management of sepsis, and that achieving 80% delivery of the basic standards of care is likely to save 10,000 lives per year and around £170 million annually for the National Health Service.[66]

The longer term fiscal cost – contributed to by reduced productivity in survivors and victims' – has not yet been estimated, but is likely to be even greater.

Measuring vital signs is a crucial step

- It has been reported that 18% of patients who suffered from Sepsis did not have vital signs recorded at all and only 27% of patients had an Early Warning Score employed in aiding diagnosis of sepsis. [67]

Taking and recording patients' vital signs is critical in enabling the detection of a deteriorating patient.

The National Early Warning Score provides a mechanism to assess patients and identify deterioration.

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[61] The World Sepsis Declaration, March 2015.
[62] Daniels R, Nutbeam T, McNamara G et al. The sepsis six and the severe sepsis resuscitation bundle: a prospective observational cohort study. Emergency Medicine Journal 2010; 28(6):507-12
[63] Sepsis action plan NHS 2015
[64] 'Sepsis: Just Say Sepsis!', NCEPOD, 2015
[65] Castellanos Ortega et al. Impact of the Surviving Sepsis Campaign protocols on hospital length of stay and mortality in septic shock patients: results of a three-year follow-up quasi-experimental study. Critical Care Medicine, 2011
[66] UK Sepsis Trust Briefing, 2013 available at NHS England's website
[67] 'Sepsis: Just Say Sepsis!', NCEPOD, 2015

Guidelines from the Royal College of Surgeons of England recommend that surgical or radiological measures should be undertaken to achieve source control immediately (within 3 hours) in patients with septic shock, within 6 hours for patients with severe sepsis, and within 18 hours for patients with uncomplicated sepsis[68].

6.3 Isansys initial focus on neutropenic sepsis UK market

Neutropenic sepsis/febrile neutropenia (NS/FN) is a potentially fatal complication of chemotherapy
Neutropenic sepsis is the second most common reason for hospital admission among children and young people with cancer, with approximately 4,000 episodes occurring annually in the UK. [69]

Need to provide attention to high-risk patients

Preventing avoidable cases of sepsis is a huge part in the NSH Sepsis action plan.
Most chemotherapy is given in a day-case or outpatient setting so episodes of fever in a potentially neutropenic person, and obvious sepsis, will predominantly present in the community. People receiving chemotherapy and their careers are informed of the risk of neutropenic sepsis and the warning signs and symptoms[70].

Business Model - PSE Monitoring of Chemotherapy Patients at Home

Isansys Vitals as a Service eliminates the need for any capital investment by purchasers, and reduces the operating risk (the providers would not be required to provide, install, monitor or support the technology and consumables involved). The current cost is £25 per patient per day.

A simple evaluation of the cost of current admissions for neutropenic sepsis is possible using NHS reference cost, activity and tariff data. We have already seen that the reference cost data for the code used by NICE for neutropenic sepsis indicates that there are approximately 1,700 non-elective admissions for this condition in England in 2012-13. The reference cost data also shows that the average cost of these admissions (weighted between short stay and long stay) was £4,919. The total cost of these admissions in 2012-13 was £8.4m. There are relatively few short stay admissions (length of stay of less than 2 days), representing just under 10% of the total. The average length of stay for the admissions overall was just under 6 days.

If we accept that the coded activity within the reference cost data seems too low, and use instead the estimated 20,000 admissions estimated by Simmons[71] with the current casemix of 90% long stay and 10% short stay, that implies an annual cost to the NHS of £97.9m.

The PSE cannot stop people developing sepsis; it can only detect them earlier. Therefore, patients will still require treatment.

However, the recent NICE guidance on the management of sepsis suggests that the vast majority of patients who develop neutropenic sepsis currently are admitted to hospital and managed as inpatients, which seems plausible given the reported six-day average length of stay, the cost of £4,919, and the very low number of short stay admissions recorded. The guidance goes on to suggest that with earlier detection, significantly more of these patients could be managed as outpatients, on cheaper oral rather than IV antibiotics, and without incurring hospital inpatient costs at all.

If hospital providers were to use the PSE to monitor patients likely to present with neutropenic sepsis for 30 days, the cost would be: 4,000 patients x £25 per patient per day x 30 days = £3m

[68] The higher risk general surgical patient. Towards improved care for a forgotten group. Royal College of Surgeons of England and Department of Health.2011 Available at: The Royal College of Surgeons of England website
[69] Neutropenic sepsis: prevention and management of neutropenic sepsis in cancer patients. NICE Guideline CG151 2012
[70] Neutropenic sepsis: prevention and management of neutropenic sepsis in cancer patients. NICE Guideline CG151 2012
[71] Ref?

The cost saving to the hospital provider by using the PSE to monitor patients and detecting the early onsets of sepsis in order to treat it more quickly and more efficiently = £8.4 - £3m = £5.4m saving

It is estimated that 30% of patients receiving chemotherapy may be at greater risk of sepsis due to underlying health conditions. If that proportion is applied to the total number of patients receiving chemotherapy per year, it can be seen that 44,000 patients may fall into the higher risk group. If all these patients were to be offered remote monitoring for the full 30-day period, that would generate annual revenues of £33m for Isansys, assuming each patient only has one cycle of chemotherapy (*44,000 x £25 per patient x 30 days = £33m*).

Obviously this is a simplistic approach – many patients will have more than one cycle of chemotherapy, and clinicians may feel they can effectively narrow down the group of patients who will benefit from this technology to less than a third of all patients.

From the assumptions above, the annual cost to the hospital provider of this technology could be £33m. There are clearly many benefits which accrue from it, which include both tangible (reduction in mortality and morbidity, reduction in hospital admissions, reduction in drug spend, reduction in intensive care costs, reduction in length of stay) and intangible benefits (reduced anxiety to patients and carers, more efficient working by clinicians).

Current trials for early detection of the onsets of Sepsis

Isansys received £1 million funding from the Small Business Research (Healthcare) Initiative (SBRI) to carry out a study, with the Queen Elizabeth Hospital in Birmingham, where it is working with the clinical team to use data from the PSE to develop an early warning score for patients who have just undergone chemotherapy and are at high risk of neutropenic sepsis.
Results are due to be reported soon but there are already indications of:

- Earlier, lower cost and less traumatic interventions
- Halting the progression of sepsis in its early stages, potentially allowing more patients to be successfully treated for neutropenic sepsis without requiring admission to hospital
- Presentation of early warnings to the patient and (remotely) to the care team
- Reducing hospital stay for those who are admitted, and significantly improving outcomes.

This work is an unprecedented opportunity for Isansys to show the ability of the PSE platform to capture and analyse data from multiple patients in multiple remote locations. Isansys believes that this is the first time that such high resolution patient data will be captured from such high risk, potentially acute, patients in the community.

Conclusions

The use of the PSE across a large at-risk population of chemotherapy patients at home will provide cost savings for providers by reducing the number of admissions of patients with neutropenic sepsis. Although the costs of monitoring thousands of patients are high, the costs of dealing with septic patients are higher. Also, as volumes build, the cost of the PSE components will fall, providing better margin opportunities for Isansys and on-going lower costs for providers.

As in the previous section's healthcare economic analyses, there is no consideration of the human and social costs for patients and their families should they develop sepsis and become seriously unwell or even die. The PSE has a very significant role to play in early detection of sepsis, particularly against a background of increasing antibiotic resistance of many infectious agents.