Final report

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Innovating for Improvement

Evaluation of a wearable wireless patch for vital signs monitoring after major surgery

Leeds Teaching Hospitals NHS Trust

The Health Foundation

About the project

Project title: Evaluation of a wearable wireless patch for vital signs monitoring after major surgery

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Partner organisation(s): Sensium Healthcare Ltd

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Part 1: Abstract

The Problem

Vital signs monitoring is a universal tool for the detection of complications after surgery, but unwell patients can be missed in between traditional observation rounds. This can lead to delayed treatment and a worse result for the patient.

The Intervention

Until now, continuous patient monitoring has been limited to intensive care units but new remote monitoring devices can be used on general hospital wards. The SensiumVitals® monitoring patch is worn on the patient's chest and monitors their pulse, breathing and temperature every two minutes. It sends a message to the patient's nurse if these vital signs become abnormal. This has the potential to improve patient outcomes through earlier detection of deterioration.

Our study

We tested the SensiumVitals® monitoring patch on two general surgery wards at a large teaching hospital in Leeds. All patients were offered either standard vital signs monitoring or a combination of standard monitoring and the SensiumVitals® patch, according to which hospital bay they were admitted to. We wanted to evaluate the safety and effectiveness of the device so we followed the patients throughout their hospital stay and collected information on complications they experienced. We also asked patients how they felt about monitoring in hospital.

What we found

We studied 350 patients. 140 patients wore the new monitoring patch. The patched patients tended towards a shorter stay in hospital and were less likely to be readmitted once they were home. They also tended to receive antibiotics faster when they got an infection.

Patients told us they liked the idea of the monitoring patch, particularly overnight so that they wouldn't be woken from sleep. However, patients appreciate face-to-face monitoring as it gives them reassurance, social interaction, and an opportunity to ask questions about their care.

Discussion

The results from our study are promising and will now be used to design a formal trial comparing the two types of monitoring. Although there were some initial challenges with the new technology, the success of the project can be attributed to engagement of the nursing staff at all stages and the development of a constructive relationship with the device company.

Part 2: Progress and outcomes

Introduction

Major surgery is high-risk, with up to 30-40% of patients experiencing a major complication. Monitoring patients' vital signs (blood pressure, pulse, breathing rate and temperature) helps to detect deterioration early and improve the outcome for the patients. The current standard of care is intermittent observation rounds. The nurse looking after the patient will typically measure their vital signs every four hours after surgery, and use them to form a score called the National Early Warning Score (NEWS). The higher the NEWS score, the more unwell the patient is, and the more frequently they will be monitored. Once the NEWS score reaches a certain threshold, a doctor will be called.

The problem with the NEWS score is that patients have the potential to deteriorate in between checks, leading to delayed recognition and treatment of complications. One solution to this problem is continuous monitoring. The SensiumVitals® system consists of a small, wireless patch which is worn on the patient's chest and monitors heart rate, breathing rate and temperature continuously. The data is transmitted wirelessly every two minutes to a mobile device carried by the nurse. This alerts the nurse when there is a change in the patient's condition.

We hypothesised that continuous vital signs monitoring may allow earlier detection of patient deterioration. We know that the faster patients get antibiotics when they develop an infection, the better their chance of surviving. We wanted to know if patients wearing the continuous monitoring patch received antibiotics any faster than those getting standard monitoring alone. We also wanted to see if the patch reduced the need for intensive care admissions and decreased the overall length of stay in hospital. In addition, we were interested to see how many patients were readmitted once they were allowed home.

Methods

We tested the patch on two general surgical wards at St James's Hospital, Leeds. Every patient admitted to these wards between January and June 2017 was invited to take part. They were then allocated to receive either SensiumVitals® monitoring and NEWS, or NEWS monitoring alone, according to which bay they were admitted into. Of the 4 bays on each ward, 3 were randomly allocated to one of the monitoring arms; two bays were allocated to receive the patch and one to receive normal monitoring. The two remaining bays (one on each ward) could not be randomised because they did not have the right hardware installed. Patients in these bays had to receive NEWS monitoring alone, and we collected data on them as well.

We collected data throughout the patients' hospital admissions and for 30 days after they went home. We also undertook interviews with 12 patients wearing the patch to see how they felt about the new technology.

Results

Ninety percent of the patients we approached agreed to be in the study. 370 patients were recruited in total. Twenty patients were part of the Optimisation Phase of the study which helped us to test the technology, but we did not collect data about their hospital stays.

Of the remaining 350, 140 patients received the SensiumVitals® patch; 210 received NEWS monitoring alone.

In the table we have described the characteristics of each group. There were slightly more male than female patients in the patched group, and more females than males in the NEWS group. Other differences included a younger average age in the NEWS group, and a lower percentage of complications, including infections, when compared to the patch group. This suggests that the patch group was a more high-risk population than the control group, especially because they were more likely to be admitted to intensive care or return to theatre after their operation. The only death in the study was also in the patch group.

Of the 140 patients who wore a patch, 34 had the patch removed early. Six patients were moved to a non-study ward, 5 returned to theatre and 23 removed the patch due to discomfort, usually itchiness or inconvenience.

Despite this, our results show that the patch group tended towards a shorter stay in hospital and were less likely to be readmitted once they were home. This might be because their complications were picked up earlier, which is supported by the fact that patients in the patch group tended to receive antibiotics faster when they got an infection, when compared to those in the NEWS group.

When we interviewed patients, they told us they could see the value in remote, continuous monitoring, particularly overnight so that they wouldn't be woken from sleep.

"Knowing that they are getting 2-minute updates on my heart and stuff – it's good."

"I think what it would be an advantage for is the overnight things. I know they've got a job to do, but they keep waking you up. With this, you could just, you know, keep sleeping and they could monitor you through that."

However, patients were keen to mention their appreciation of face-to-face monitoring as it gave them reassurance, social interaction, and an opportunity to ask questions about their medical care.

"It gives you readings but it doesn't really tell you how you're feeling. Do you know what I mean? …So you still need your nurses to go round."

Discussion

The results suggest a trend in favour of continuous monitoring when compared to intermittent NEWS monitoring alone. On average, patients who wore a patch had

a shorter stay in hospital and were less likely to be readmitted once they were home. They were also more likely to receive antibiotics faster if they developed an infection, although the range was very variable, reflecting the diagnostic challenge of identifying true sepsis in a post-operative population.

We have presented the results for all the patients in the study. When we looked at just the 6 randomised bays, the results were fairly similar; the trend favouring continuous monitoring was still present. However, this study was small and was not designed to find definitive differences between the groups; no statistical analysis has been performed. The results are promising and can now be used to design a formal trial comparing the two types of monitoring. We are also undertaking an evaluation of staff satisfaction and the impact of continuous monitoring on their work.

	SensiumVitals +NEWS (n=140)	NEWS alone (n=210)
Males	76 (54.3%)	77 (36.7%)
Females	64 (45.7%)	133 (63.3%)
Age (mean)	65.2 years (range 24-94)	60.5 years (range 18 – 93)
ASA (median)	2	2
Emergency admissions	70 (50%)	113 (53.8%)
Elective admissions	70 (50%)	97 (46.2%)
Surgical intervention	103 (73.6%)	153 (73%)
Medical outliers	19 (13.6%)	27 (13%)
Number of complications (all*)	100 (71.4%)	142 (67.6%)
Number of major complications (Clavien-Dindo >2**)	8 (5.7%)	17 (8.1%)
Sepsis events	24 (17.1%)	32 (15.2%)
Time to antibiotics in cases of sepsis (mean)	n=21 626.0 minutes (range 66-1413) s.d. = 438.3	n=32 900.0 minutes (range 87-3093) s.d. = 772.2
Level II/III admissions	3 (2.1%)	4 (1.9%)

Return to theatre	5 (3.6%)	7 (3.3%)
Length of stay in hospital (days) (average)	13.3 days (range 1-69) s.d. = 11.8	15.4 days (range 2-163) s.d. = 20.3
Inpatient deaths	1	0
Readmissions	16/140 (11.4%)	38/210 (18.1%)

Table 1: Summary of patient' characteristics in both patched and control arms
*All complications includes any deviations from the normal post-operative course, from minor (such as nausea) to major (such as death).
** Clavien-Dindo is a scale for the severity of complications. A Clavien-Dindo score >2 indicates that that the complication required critical care admission or a further surgical procedure, or resulted in death.

Part 3: Cost impact

There was no formal health economic evaluation incorporated into this study. However, the data we have collected will be used to inform an early health economic model to estimate the cost implications of the new monitoring system when compared to standard care.

It is difficult to determine the costs of current postoperative monitoring using the NEWS system, because it is fully integrated into surgical care pathways. The main costs are equipment (blood pressure monitor, pulse oximeter, etc.) and nursing time to record observations. The costs of implementing the SensiumVitals® monitoring system include the set-up of the infrastructure, (installation of wireless hubs, integration of software, set-up of mobile devices) and the cost of training. The cost of the hubs is £1250 per ward, which was covered in kind by Sensium Healthcare. Thereafter, ongoing costs include purchasing of the patch and nursing time.

Despite Sensium Healthcare being sold and having to renegotiate terms with the new company, we managed to keep the cost of the patches at the original quote price of £35 (RRP £100). If this technology is shown to be of benefit, the cost of the patches and the associated hardware will have to be balanced against the financial gains to the Trust, such as reduced length of stay in hospital. Given that the average cost of a general hospital bed is £433 per day, there is scope for cost savings. The financial costs/implications of the project will only be known once the health economics analysis is performed.

Part 4: Learning from your project

At the start of the project we hoped to recruit approximately 500 patients to the study. We anticipated that potential barriers to this might be a low patient consent rate, and poor nursing compliance. However, the most substantial barriers came from outside the hospital setting.

Firstly, we encountered a number of delays to the start of our recruitment. Other research teams will be well aware of the long administrative delays associated with Health Research Authority approvals when the application system changed in 2016. These delays were outwit the control of the Research Team or the Trust but were nonetheless frustrating.

Dealing with industry has also proved challenging at times. Initially, there were administrative issues when the company who manufactures the device was sold to a larger organisation. Terms had to be renegotiated with the new company and new agreements drafted.

The study itself was not without technical difficulties. Once the relevant approvals were granted, the Optimisation Phase of recruitment was commenced. This phase was suspended upon identification of a software problem with the SensiumVitals® system. We noticed that acknowledgements to notifications via the phones were not getting logged. After a number of weeks, the source of the problem was identified. Since the pilot project in 2015, the NHS has upgraded its email servers, which no longer allow plain text authentication. Upon identification of the problem, Sensium Healthcare changed its authentication method, and usability was restored. Recruitment recommenced at this point.

During the study, we have continued to identify a number of potential improvements that could be made to the technology and are learning how to engage with the manufacturer of the device to the benefit of patients. We are learning about the practicalities of undertaking remote vital signs monitoring within the clinical environment, its impact on patients, and its acceptance by healthcare professionals. We have also identified further areas of research need, such as helping clinicians identify sepsis in a complex patient population who are already exhibiting a normal stress response to surgery.

It has been particularly encouraging to see the enthusiasm of patients for the new technology. Despite our initial concerns about recruitment, we had a 90% consent rate into the study and lots of interest from patients and their families.

Engagement of the nurses and other members of the clinical team has been crucial to the success of the study. There is naturally a culture of mistrust when new technologies are implemented in hospital, and we aimed to overcome this by maintaining wide channels of communication and daily visibility on the wards. This was particularly helped by the recruitment of a dedicated research nurse to the project, who provided a daily point of contact for the ward staff. We also produced leaflets for the nurses to show how the project was progressing.

We engaged the consultant body by giving presentations at monthly audit meetings to inform them of the study and ensure their continued support. We provided frequent recruitment updates on departmental Twitter and Facebook pages to encourage enthusiasm on the wards. We held 3-monthly stakeholder meetings with key members of the ward staff, the device company and the Research Team to provide updates and stimulate discussion about challenges and successes from all parties.

It is important to realise that the implementation of new technology within a complex healthcare environment requires the engagement of a huge number of stakeholders. Due to the promising results of this study, we will be continuing to evaluate the SensiumVitals® system on the general surgical wards. This has necessitated a further update of all the hardware which required extensive communications with the hospital Estates and IT departments. In addition, the development of a new app has required the retraining of staff for the next phase of the evaluation.

When implementing a device such as the SensiumVitals® system, we would recommend approaching all stakeholders at an early stage to identify administrative and technical barriers promptly. We would advise a multi-media approach to keeping stakeholders informed and motivated throughout the project. We would recommend high visibility and regular visits, particularly during the initial stages of implementation, and frequently supplemented with cake.

Part 5: Sustainability and spread

The results of the Health Foundation study have allowed us to get a better understanding of the surgical patient population and how continuous monitoring might work best for this group. This information has guided the protocol for another evaluation on the same hospital wards, particularly looking at how high-risk patients could benefit from this technology. This trial has been funded by the National Institute of Health Research (NIHR) and will start recruitment in September 2017. If this evaluation is successful, we plan to roll out the study to other wards and hospitals across the country as part of a multi-centre randomised controlled trial. The findings will be disseminated throughout the NHS and made available to Sensium Healthcare to promote the technology for wider adoption.

We have developed a constructive relationship with the device company. We have been able to provide valuable feedback and have helped with the design of a new mobile app which will make the system easier to use for nursing staff. In addition, feedback from patients has highlighted the need for an integrated thermometer within the patch; we are working alongside Sensium and a Japanese engineering company to integrate a heat flux thermistor into the patch for better functionality and improved patient satisfaction.

We are using the data from the Health Foundation study to populate an early health economics model, which will help to inform a business case for the continued use of the device. In addition, we have been able to make contacts within hospitals in Amsterdam and London and share knowledge about the challenges of implementing new technologies in healthcare. The remote monitoring technology can be implemented across a range of patient groups, and sharing our experiences has helped to streamline the process in other settings.

We also have two scientific manuscripts and a case report in preparation for journal submission, which will make our results accessible to the wider scientific community. We will be presenting our results at a number of national conferences in the coming year, starting with the NHS Innovation Expo in September 2017.

Appendix 1: Resources and appendices

Leaflet we handed out to the nursing staff to encourage engagement in the project:

Any questions?

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The Sensium study

Phase 2

Recap

What is it?

The SensiumVitals® system is a new way of monitoring patients' vital signs. It consists of a wireless patch which is worn on the patient's chest; it measures

- heart rate
- respiratory rate
- temperature

every 2 minutes. It transmits this data to a mobile phone via hubs installed on the ceilings of the wards. When a patient's vital signs become abnormal, a message is sent to the phone.

Study questions

- Does vital signs monitoring every 2 minutes improve clinical outcomes for patients when compared to NEWS monitoring?
- Do patients like it?
- Do staff like it?

Pilot study

In June 2015, the SensiumVitals® system was installed on Wards J44 and J45. A pilot study was conducted to test if the technology worked and how patients and staff felt about it.

Results of pilot study

- The technology works at St. James's Hospital.
- Patients find it comfortable and feel safer wearing it.
- Staff were initially positive but had 2 important reservations:
  - the number of false alerts sent by the patch to the phone
  - the time it took to identify, consent and patch the right patients alongside all the usual admissions paperwork.

What's new?

Why is there another study?

The purpose of the pilot study was to check if the technology could work on the surgical wards of St. James's.
The purpose of Phase 2 is to see if the new monitoring improves outcomes for patients, perhaps by allowing us to detect complications earlier.

What's changed?

In addressing the concerns of staff from the pilot study, important changes have been made:

- The number of false alerts from the patch has been reduced by 90%.
- All of the recruitment, consent and patching will be done by research support staff, and NOT by ward staff.
- The ward staff will still hold the phones and respond to alerts.
- There will be daily support from the research team in case of any questions.

Study design

In contrast to the pilot study, ALL patients admitted to Wards J44 and J45 will be eligible to take part in the study. There will be 'patch' bays and 'non-patch' bays. Patients will be included in the study for their whole admission.
We will also be asking for your opinions on the device through questionnaires and short interviews.

Study approvals

The study has been granted approvals from the Research Ethics Committee and the Trust's Research and Innovation department.
The lead consultant for the project is Prof David Jayne.