Leeds Teaching Hospitals NHS Trust

Research Protocol

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Study Short Title: Remote vital signs monitoring in surgical patients

Study Full Title: An evaluation of remote, near-continuous vital signs monitoring in patients admitted to general surgical wards

Sponsor Name: University of Leeds

REC number: awaited

Details of previous amendments

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1.0 Lay Summary

1.1 Background

Patients having surgery are at high risk of complications, some of which can be life threatening. Identifying complications early makes them easier to treat and improves the outcome for the patient.

One of the ways patients are monitored for complications is by charting their vital signs: blood pressure, heart rate, breathing rate and temperature. The nurse looking after the patient will usually check these signs every four hours in the first few days after surgery. The vital signs are used to form a score, the National Early Warning Score (NEWS), which can alert if the patient becomes unwell. One of the problems with NEWS is that patients can deteriorate in the interval between monitoring, which can delay vital treatment.

The SensiumVitals® monitoring system measures heart rate, breathing rate and temperature continuously, and sends the information to a mobile phone carried by the nurse every two minutes. It is a wearable, wireless patch that is applied to the patient's chest after surgery, and alerts the nurse if the patient's vital signs become abnormal. This could help detect unwell patients earlier than traditional NEWS monitoring.

1.2 Aims

In order to test this theory, a study will be done comparing the SensiumVitals® system with NEWS monitoring. The main aim is to provide important information about whether the patch works and if it improves outcomes for patients admitted to surgical wards.

1.3 Participants

Patients will be asked to join the study if they are admitted to one of four surgical wards at St. James's University Hospital, Leeds. Many of these patients will be admitted prior to, or after, undergoing a surgical procedure. They will be given information about the study and will be allowed time to decide whether they would like to take part.

1.4 Methods

Patients will be randomly chosen to receive standard NEWS monitoring or both the SensiumVitals® patch and NEWS monitoring based on the bed they are admitted to on each ward. This decision is made by hospital bed managers, who are not involved in the study: it is a 'random' process and roughly half of the patients will be offered the new system. Patients will be followed during the course of their hospital stay, including any operation they have.

Information about the patients' hospital stay will be collected. This information will include the number of patients who develop sepsis (infection) and how quickly they are treated, whether they are moved to high-dependency wards and how long they stay in hospital. Information will also be collected regarding the number of patients who agree to take part in the study, those who do not and the reason for not taking part.

An important part of the study will be to assess how patients and nurses feel about the SensiumVitals® system. The patient's perspective of the study will be assessed in a number of ways: interviews, questionnaires and focus groups. Nurses' feedback will also be assessed in the form of interviews and a questionnaire.

1.5 Distribution of results

The results of this study will provide important information about the performance of the SensiumVitals® system, how patients and clinical staff feel about the system, and whether the new monitoring system improves outcomes for surgical patients. The results will be communicated to healthcare professionals, patients and the public through journal articles, press releases and presentations to charities, NHS Trusts and the media.

2.0 Background

2.1 Major surgery and complications

Surgery is important in the management of many medical conditions, accounting for 4.5 million hospital admissions, 11.2 million hospital bed-days, and a cost to the NHS of £1.5 billion per year(1). Surgery is high risk, with complication rates between 30% and 40% for major abdominal procedures. Complications add to the financial burden to the NHS and cause significant morbidity, and occasional mortality.

Patients who develop postoperative complications become progressively unwell, often over a short period of time. Early recognition of postoperative complications is crucial in reducing morbidity and preventing long term disability; for patients with septic shock there is an 8% increase in mortality for every hour of delay in antibiotic administration(2). Recognition of this important statistic has led to the national introduction of the Sepsis CQUIN (Commissioning for Quality and Innovation) which rewards Trusts for prompt recognition of sepsis and the initiation of intravenous antibiotics within one hour(3), ensuring that monitoring of patient deterioration will assume high priority.

The more unwell a patient becomes, the more likely they are to require higher level care, either on High Dependency Units (HDU; Level II) or Intensive Care (ICU; Level III). Escalation of care comes at significant cost to both the patient and the health service. Admission to Level II/III care is associated with poor patient outcomes. The average cost of a Level I bed is £433/day, as compared to £1033/day for a HDU bed, and £1351/day for an intensive care bed(4). Early detection and treatment of complications minimises the need for Level II/III care, improves patient outcomes, and produces significant cost savings.

2.2 Vital signs monitoring

2.2.1 National Early Warning Score

The current standard of care for monitoring patients in the postoperative period is to record their vital signs (blood pressure, pulse, temperature, respiratory rate) using the National Early Warning Score (NEWS). Derangements in individual vital signs are scored according to their magnitude, and the scores summated to reflect the patient's overall condition. A higher score indicates patient deterioration, the need for escalation of care, and is linked to an increased chance of death.

The NEWS is calculated intermittently, at intervals directed by the patient's condition. Typically, in the postoperative period NEWS will be calculated half hourly for the first few hours, and if the patient remains stable the frequency will decrease to 2-hourly and then 4-hourly, until the patient is ready for discharge when the NEWS may be recorded only twice a day.

Although NEWS has proven benefit, it suffers from several drawbacks. A 2012 study evaluated early warning scores in patients 48 hours before an adverse event (5). 81% of

patients had a score indicative of deterioration, but recordings were 'mostly incomplete' with respiratory rate documented in 'only 30% to 66%'.

NEWS relies on manual observations, is time-consuming, and open to user interpretation. Vital signs are taken at predetermined intervals (typically 4-hourly), with patient deterioration possible between recordings. It has been suggested that the gap between observations is one of the primary failings of the NEWS system (6).

2.2.2 Continuous monitoring

A solution to the problem of inadequate monitoring frequency is continuous monitoring at the bedside. Continuous monitoring is used in Level II/III care, but is limited by "hard-wired" equipment, which tethers the patient to the bed space. This hinders patient mobility and potentially slows their recovery. One study tested ICU-style monitoring on a general ward and found that only 16% of patients remained connected in a 72-hour period (7).

2.2.3 SensiumVitals® monitoring system

SensiumVitals® is a new monitoring system that combines the benefits of a wearable, wireless patch with continuous monitoring of vital signs. The SensiumVitals® patch (see Figure 1) is CE marked and monitors heart rate, respiratory rate and temperature continuously. The data is transmitted wirelessly every two minutes to a central monitoring station or a mobile device carried by the nurse (see Figure 2). This alerts the healthcare worker when there is deviation from pre-set physiological norms, alerting staff to potential patient deterioration.

2.3 Rationale for the proposed study

It is hypothesised that the SensiumVitals® system, as an adjunct to standard NEWS monitoring, will allow earlier detection of postoperative complications. This should reduce morbidity, which in turn should result in a decreased need for high dependency/intensive care.

3. Study objectives

To evaluate the safety, efficacy and acceptability of a new, wearable, remote monitoring system (SensiumVitals®) for patients admitted to surgical wards, as compared to standard monitoring with the National Early Warning Score system alone.

4. Study design

This is a single-centre feasibility study. Patients will be selected on the basis they are admitted to one of four general surgery wards. We will include 500 patients, most of whom will undergo a surgical procedure during their hospital stay.

When patients are admitted to a general surgery ward, they are allocated a bed by a team of 'bed managers' based on clinical need and availability. Each of the participating general surgery wards is divided into 'bays' of four or six beds, and 'side rooms' which contain only one bed. Prior to the commencement of the study, each bay and side room on each of the participating wards will be randomly allocated to receive 'patched' patients, or NEWS-monitored controls. The randomisation of bays will be balanced for ward type, taking account of patient gender and surgical subspecialty.

Patients will be identified as potentially eligible to participate in the study and approached on admission to the surgical wards. At this point they will be given further information in the form of a patient information sheet regarding the study. Following a period of consideration,

if they have decided to participate in the study they will receive the appropriate monitoring. Information will also be collected regarding the number of patients who agree to take part in the study, those who do not and the reason for not taking part.

For the duration of the study, when a patient is admitted to one of the participating wards, they will be allocated to one of the two study arms according to the bay or side room to which they are allocated by the bed managers. The bed managers are removed from ward-based care and the allocation of a patient to a particular bed is 'random' and avoids selection bias. Eligible patients in the 'patch' bays/side rooms will receive a patch and standard NEWS monitoring. Patients in the 'control' bays/side rooms will receive standard NEWS monitoring alone.

All usual nursing and medical care are permitted within both arms of the trial. This includes fluid balance monitoring, neurological observations, etc.

Roughly half of the patients (250) will be offered the new system. The devices are designed to be lightweight and unobtrusive, with a battery life of 5 days. Patients will be expected to wear the device for the duration of their hospital admission. The device will monitor the patient's heart rate, respiratory rate and temperature continuously, and send this information every two minutes to a mobile device carried by the patient's nurse. The information is also available on the ward computer monitors.

The patients will remain in their allocated study arm for the duration of their hospital stay. If a 'patched' patient is moved to a critical care bed during their admission, the SensiumVitals® monitoring will be temporarily suspended pending reinstatement depending on the ward bed to which they return. Every effort will be made to ensure that patients remain in the study arm to which they were originally allocated, and any non-compliance will be recorded. Analysis will be on an intention-to-treat basis.

Patients' participation in the trial will end when they are discharged from hospital. At this point, 'patched' patients will be invited to complete a questionnaire and /or undertake a structured interview regarding their experiences of wearing the patch. Patients will also be invited to attend one or more focus groups after discharge from hospital. Information regarding the admission will be collected once the patient has left hospital.

The staff nurses will be invited to complete a paper questionnaire in the form of a Modified System Usability Score. They will also be invited to undertake a structured interview regarding their experience of providing the new monitoring system.

4.1 Outcome measures

4.1.1 Primary outcome measure

- Time to treatment of sepsis, specifically time to administration of antibiotics after first evidence of sepsis.

According to a revised consensus conference definition in 2001, sepsis is defined by the presence of a likely source of infection and 2 or more criteria from a collection of clinical signs and laboratory investigations as follows (8)

  - Temperature >38.3°C or <36.0°C

- Tachycardia >90 beats per minute
- Tachypnoea >20 breaths per minute
- pCO^2 <4.3 kPa
- Hyperglycaemia (blood glucose >6.6 mmol/) in the absence of diabetes mellitus
- Acutely altered mental status
- WBC count >12×10^9/L or <4×10^9/L

Of these, temperature, heart rate and respiratory rate will be the most pertinent to this study as it is these parameters that are monitored by both the NEWS score and the SensiumVitals® monitoring system. The primary outcome measure will be the time interval between the first evidence of sepsis on either or both monitoring tools and the administration of antibiotics to the patient.

4.1.2 Secondary outcome measures

- Number of HDU/ICU admissions
- Length of stay in HDU/ICU
- Total length of stay in hospital
- Postoperative complications, graded using the Clavien-Dindo classification
- Re-interventions
- Patient acceptability, as determined by the patient questionnaire and structured interviews, and focus groups
- The number of patients failing to complete SensiumVitals® monitoring for 5-days, or length of hospital stay (and reasons)
- Nursing acceptability, as determined by the Modified System Usability Score and structured interviews

4.2 Research tools (please see Appendices)

4.2.1 Patient questionnaire

A simple three-question questionnaire will be administered to all 'patched' patients, on discharge from hospital. This will primarily assess the comfort of the patch to wear, and whether or not the patient felt safer wearing the patch. Further feedback shall be encouraged with a white box question.

4.2.2 Modified System Usability Score

Nursing staff satisfaction shall be quantified using the system usability score (8), a well-recognised, robust and versatile tool for obtaining a subjective rating of a product by the user (9). Further feedback shall be encouraged with a white box question.

4.2.3 Topic guide for patient interviews

On discharge from hospital, every 'patched' patient will be invited to participate in a structured interview with the researcher. The purpose of these interviews is to obtain information about the patients' opinions, beliefs, experiences and feelings in regard to the way they have been monitored during their hospital stay. Patients who did not complete the SensiumVitals® monitoring trial will be included to understand their reasoning and choices.

The topic guide encourages open and neutral questions. The use of a topic guide will assist with comparability between interviews at the analysis stage. It is anticipated that each interview will last approximately 10-30 minutes.

4.2.4 Topic guide for nursing staff interviews

At the end of the study period, members of the nursing staff will be invited to participate in a structured interview with the researcher. Participants will be recruited using purposive sampling. Three members of the nursing staff from each of the four participating wards will be interviewed. It is anticipated that each interview will last approximately 10-30 minutes.

Interviews will be recorded with the interviewee's consent, transcribed verbatim, anonymised and uploaded to NVivo 10.

4.2.5 Topic guide for focus groups

It is anticipated that two focus groups will be held, which will include approximately 6 patients. Each focus group will last 1 hour, and be attended by at least one member of the research team, one facilitator and a PPI (patient and public involvement) representative.

The first focus group will have two aims:

- To allow further information gathering about patient experience of the patch, to add to data already gleaned from one-to-one structured interviews.
- To gain the patient's perspective of the study itself: its conduct and progress. This will help to optimise the study protocol to improve the patients' experience of being involved in the research.

The second focus group will have two aims:

- To feed back the results of the study to the participants
- To gain patients' perspective about how to maximise the impact of the results, including feedback on lay summaries.

5. Trial subject selection

5.1.1 Inclusion criteria

All patients admitted to the participating surgical wards, most of whom will have undergone/be undergoing major surgery:

- emergency and elective admissions
- male and female patients
- benign or malignant diseases
- all ages >16 years and comorbidities
- includes pregnant and breastfeeding women

5.1.2 Exclusion criteria

- those who do not consent
- allergy to adhesives on electrodes
- cardiac pacemaker in situ

5.1.3 Statistical analysis

Analysis will be on an intention-to-treat basis. Each of the outcome measures will be summarised by intervention or control group using appropriate descriptive statistics. As this is a feasibility study no formal comparison between the study arms will be undertaken. Subgroup analysis will be performed, specifically to determine any differences between low- and high-risk patients.

Framework analysis will be used for analysis of the qualitative data. A thematic framework will be developed and applied to all the transcripts. The data will be summarised in matrix displays to facilitate comparison between participants.

5.1.4 Concurrent clinical trials

Patients will be screened for inclusion in other clinical trials. Providing there is no conflict, patients may be included in this and other trials.

5.2 Recruitment, consent and randomisation processes

5.2.1 Recruitment

All patients admitted to the participating adult general surgical wards will be eligible to participate in the trial. The patient will be approached to join the trial as soon as possible after admission to the ward.

Patients will be initially approached by a member of the nursing staff, or one of the researchers. A verbal explanation of the trial and Patient Information Sheet will be provided for the patient to consider. This will include detailed information about the rationale, design and implications of the study. Patients will be allowed a period for consideration, and discussion with relatives if required, before signing the consent form.

An orange notice will be placed in the front of the patient's notes to alert other healthcare providers that they are included in the trial, and to act as a reminder of the patients' allocation for reference should they be moved off one of the participating wards, or return to a participating ward from HDU/ICU.

5.2.2 Consent

Assenting patients will be formally assessed for eligibility and invited to provide informed, written consent. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. A copy of the consent will be given to the patient, filed in the Trial Master File and the hospital notes. The written consent will be taken by a healthcare professional, who has signed the staff delegation log. The process of obtaining written consent will be clearly documented in the patient's medical notes.

5.2.3 Randomisation

Randomisation of bays and side rooms as either intervention or control will be performed prior to patient recruitment by the Leeds Clinical Trials Unit. Whilst the allocation of patients to their bed on the ward is not truly a random process, the bed managers are removed from both the study and ward-based care, thus minimising selection bias.

5.2.4 Blinding

Blinding is not applicable for this study.

5.2.5 Patients who withdraw consent

In line with usual clinical care, cessation or alteration of regimens at any time will be at the discretion of attending clinicians or the participants themselves. The PI, or delegate, will make every effort to ensure that the specific wishes of any participant who wishes to withdraw consent for further involvement in the study are defined and documented. All patients will be able to withdraw from the study at any time, and will be reassured that this will not influence their subsequent standard of care.

5.2.6 Definition for the end of study

The 'end of trial' will be defined as the last recruited patient's date of discharge. At this point, the 'end of trial notification' will be submitted to the relevant ethics committee.

6. Product information

6.1 SensiumVitals® remote monitoring system

The SensiumVitals® Wireless Monitoring Application System is intended for use by health care professionals for routine monitoring of patient physiological parameters to include, heart rate, respiratory rate and axillary temperature, in a hospital setting. The patient-facing device is a CE-marked patch which will be used within its market-intended purpose. Data is transmitted wirelessly over medical grade radio frequency (915/866 MHz) to hospital secured server. Data transmitted over the air has no patient identifiers.

All data are stored and retained on the hospital network. The SensiumVitals® system utilizes the hospital's Active Directory as its authentication mechanism for handling user logins to the application and access to data. Active Directory provides centralized management of the staff who will be using the application in the hospital.

The SensiumVitals® system therefore inherits all the hospital security procedures and data backup policies, to ensure data access and servers are secured. Communication to the SensiumVitals® Windows client is done using an Advanced Encryption Standard Secure Sockets Layer (SSL) certificate with encryption. Data is backed up frequently as per hospital procedures. In case of system failure, the patch will automatically buffer data for up to three hours continuously until the hospital server is back online.

7.Trial schedule

7.1 Study timeline

May 2016 – August 2016: Set-up: 3-months to include study design, protocol writing, regulatory approvals (Ethics and R&D), and staff training.

August 2016 – May 2017: Patient recruitment: recruitment of 500 patients to either SensiumVitals® + NEWS monitoring or NEWS monitoring alone. Data collection including time to treatment of sepsis, Level II/III care utilisation and patient/staff satisfaction surveys.

Qualitative analyses using focus groups and with the help of the NIHR HTC in Colorectal Therapies.

May 2017 – August 2017: Data analysis and dissemination, writing of manuscript for publication, and presentation to clinical and patient and public forums.

7.2 Project milestones

May 2016: Completion of study, including regulatory approvals

August 2016: Patient recruitment starts

May 2017: Completion of patient recruitment

August 2017: Results dissemination and publication. End of study

8. Reporting of adverse events

8.1 Defining adverse events (AE)

An AE is any untoward medical occurrence in a patient during or following administration of an investigational product or procedure and which does not necessarily have a causal relationship with treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of the product, whether or not considered related to the trial product.

8.2 Defining serious adverse events (SAEs)

A SAE is defined in general as an untoward (unfavourable) event, which:

- is fatal. Death may occur as a result of the basic disease process. Nevertheless, all deaths occurring within 30 days of the last administration of the study agent must be treated as an SAE and reported as such. All deaths which may be considered as related to the trial agent, regardless of the interval, must be treated as a SAE and reported as such.
- is life-threatening
- requires or prolongs hospitalization
- results in persistent or significant disability or incapacity
- is a congenital anomaly or a birth defect, or
- may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above

Any other significant clinical event, not falling into any of the criteria above, but which in the opinion of the investigator requires reporting.

8.3 Reporting AEs

AEs will be collected for all patients and will be evaluated for duration and intensity according to the NCRI Common Toxicity Criteria.

Safety will be assessed by review of adverse events from the time of registration into trial to 30 days post-operatively.

Information about AEs, whether volunteered by the patient, discovered by the investigator questioning or detected through physical examination, laboratory test or other investigation will be collected and recorded.

A copy of all reported AEs will be sent to the sponsor if requested.

8.4 Reporting SAEs

SAEs will be collected for all patients until discharge from hospital.

SAE reporting for non-CTIMPS must be made to the sponsor within 1 working days of the research team becoming aware of the SAE and following a clinical review by the chief investigator. The SAE also must be reported to the main research ethics committee (REC) on the health research authority (HRA) approved non CTIMP SAE report form by the research team within 15 days of the CI becoming aware of the event. The sponsor will also be informed of the event on governance-ethics@leeds.ac.uk.

Identifiable patient data, other than linked anonymised data required by the SAE form will not be included when reporting SAEs.

8.5 Pregnancy

Pregnancy will not be a contra-indication to study participation.

8.6 Annual reports

An annual report describing the general progress and any relevant safety data related to the trial must be submitted to the main REC and the sponsor.

8.7 End of trial report

Upon completing the trial, as defined in 5.2.6, an end of trial report must be submitted to the main REC within 90 days. A copy of this end of trial report should also be submitted to the sponsors office and supplied to all support departments involved in the study, for example pharmacy and or radiology.

The CI must sign and date the report.

9. Data management

9.0 Data collection, source data and confidentiality

The SJUH site will maintain a file of essential trial documentation (Investigator Site File, ISF) and will keep copies of completed CRFs for the trial, or a file note to their location, as well as copy of the patient enrolment and allocation log within the ISF.

Data will be collected using paper case report forms (CRFs). CRFs will only be completed by personnel authorised to do so by the Principal Investigator.

All information collected during the course of the trial will be kept strictly confidential.

Information will be held securely on paper and electronically at Leeds Teaching Hospitals NHS Trust.

The trial group will comply with all aspects of the Data Protection Act 1998 and operationally this will include:

- consent from patients to record personal details including name, date of birth, address and telephone number, NHS ID, hospital ID, GP name and address
- appropriate storage, restricted access and disposal arrangements for patient personal and clinical details
- consent from patients for access to their medical records by responsible individuals from the research staff, the sponsor or from regulatory authorities, where it is relevant to trial participation
- consent from patients for the data collected for the trial to be used to evaluate safety and develop new research

9.2 Data archiving

In line with the principles of GCP guidelines, at the end of the trial, data will be securely archived for a minimum of 5 years. This data will include that collected in the clinical reporting forms and will also include recordings.

Arrangements for confidential destruction will then be made. If a patient withdraws consent for their data to be used, it will be confidentially destroyed immediately. No records may be destroyed without first obtaining written permission from the sponsor.

Study documentation / data will not be destroyed without the approval of the sponsor.

10. Statistical considerations

10.1 Sample size

This is a single centre feasibility study, and as such no formal sample size calculation has been made.

11. Data monitoring

11.1 Data monitoring

As this is a feasibility study, data will be monitored prospectively by the research team. Any clinical concerns, or complications occurring in excess of those normally experienced in this type of surgery, will be reported by the PI to the sponsors and appropriate action taken to suspend or terminate the study until such time that patient safety can be assured in line with national guidelines for patient outcomes in surgery.

11.2 Quality assurance

The Sponsor has systems in place to ensure that there is reporting and appropriate action taken in respect of:

- Serious breaches of GCP and the trial protocol

- Urgent safety Measures
- Protocol violations

A “serious breach” is a breach which is likely to effect to a significant degree:

- The safety or physical or mental integrity of the subjects of the trial; or
- The scientific value of the trial”.

Investigators will promptly notify the Sponsor of the following within the required timeframe, once they become aware of:

- Serious breaches of GCP and the trial protocol
- Urgent safety Measures
- Protocol violations
- Any amendments to the trial

12. Ethical considerations

The trial will be performed in accordance with the recommendations guiding ethical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 48th General Assembly, Somerset West Republic of South Africa, October 1996. Informed written consent will be obtained from the patients prior to registration into the study. The right of a patient to refuse participation without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment. The study will be submitted to and approved by a REC.

13. Statement of indemnity

Clinical negligence indemnification will rest with the participating NHS Trust or Trusts under standard NHS arrangements. The Trust does not provide indemnification against claims arising from non-negligent harm.

14. Publication policy

Credit for the main results will be given to all those who have collaborated in the study, through authorship and contributorship. Authorship decisions will be guided by standard requirements for authorship relating to submission of manuscripts to medical journals. These state that authorship credit should be based only on the following conditions being met:

- Substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data
- Substantial contribution to drafting the article or revising it critically for important intellectual content
- Substantial contribution to final approval of the version to be published.

15. Appendices

1) Patient questionnaire
2) Modified system usability score

3) Topic guide for interviews with nursing staff
4) Topic guide for interviews with patients
5) Topic guide for focus group 1
6) Topic guide for focus group 2

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15. Appendices

1) Patient questionnaire

Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Comfort					
The SensiumVitals® Patch was comfortable to wear.					
Quality of Care					
I felt safer because my vital signs were being monitored constantly.					
We welcome any additional comments you may have:					

2) Modified system usability score

	Strongly disagree				Strongly agree
I think that I would like to use this product again	1	2	3	4	5
I found the product unnecessarily complex	1	2	3	4	5
I thought the product was easy to use	1	2	3	4	5
I think that I would need the support of a technical person to be able to use this product	1	2	3	4	5
I found that the various functions in this product were well integrated	1	2	3	4	5
I thought that there was too much inconsistency in this product	1	2	3	4	5
I would imagine that most people would learn to use this product very quickly	1	2	3	4	5
I found the product very awkward to use	1	2	3	4	5
I felt very confident using the product	1	2	3	4	5
I needed to learn a lot of things before I could get going with this product	1	2	3	4	5

3) Topic guide for interviews with nursing staff

Documentation of demographic details (anonymised)

Introduction

- Thanks for helping
- Introduce the aim of the interview
- Emphasise confidentiality and anonymisation
- There are no right or wrong answers: "This is simply about your experience of the way we monitor patients on this ward."
- Introduce dictaphone
- Invite questions

Questions

Over the last few months you've been involved in the study of the SensiumVitals® monitoring system, patching patients in your care.

How did you feel when you were told you would be using the new monitoring system?

- What was your experience of using the patch system?
- Were there good things about the system? If yes, what were they?
- Were there bad things about the system? If yes, what were they?

Additional prompts, if needed:

- Did the patients like it?
- Did it cause you any bother?
- Did you like it? Why/Why not?
- Did you feel the patients were safer wearing it?
- Would you have changed anything about it?
- Would you use it again?
- Would you recommend it to other wards? If yes, what would you say?
- What suggestions would you make to improve the system?
- How could the system be made to be more appealing to nurses like you?

Whilst studying the SensiumVitals® system, you still administered regular NEWS rounds to all of your patients.

- What is your experience of these observation rounds?
- Are there good things about them? If yes, what are they?
- Are there bad things about them? If yes, what are they?

- How would you feel if you didn't do NEWS rounds, and just used the SensiumVitals® system?

- How do you think we can improve the way we monitor patients in hospital?

Conclusion

- Signpost the end of the interview
- Invite further questions
- Thanks for taking part
- Ask if the nurse would like to be kept informed about the study

4) Topic guide for interviews with patients

Documentation of demographic details (anonymised)

Introduction

- Thanks for helping
- Introduce the aim of the interview
- Emphasise confidentiality and anonymisation
- There are no right or wrong answers: "This is simply about your experience of the way you were monitored during your stay in hospital."
- Introduce dictaphone
- Invite questions

Questions

During your hospital stay, you wore a patch on your chest which helped the nurses monitor your progress.

How did you feel when you were told that you had been put into the group wearing the patch?

- What was your experience of wearing the patch?
- Were there good things about wearing the patch? If yes, what were they?
- Were there bad things about wearing the patch? If yes, what were they?

Additional prompts, if needed:

- Was it comfortable?
- Did it bother you in any way?
- Did you like it? Why/Why not?
- Did you feel safer wearing it?
- Would you have changed anything about it?
- Would you have it again?
- Would you recommend this intervention to other patients? If yes, what would you say?
- What suggestions would you make to improve the patches?
- How could the patches be more appealing to patients like you?

During your hospital stay, you will also have been monitored by one of the nursing staff, coming round every few hours to check your blood pressure, etc. with a machine.

- What was your experience of these observation rounds?
- Were there good things about them? If yes, what were they?
- Were there bad things about them? If yes, what were they?
- How would you feel if you were just monitored in this way, without the patch?
- How would you feel if you just had the patch?

Additional prompts, if needed:

- Did it bother you in any way?
- Did you like it? Why/Why not?
- Did it make you feel safer?
- Would you have changed anything?

"The two monitoring techniques (patch vs. nurse with machine) help to keep an eye on your progress, and let the nurses know if anything is going awry."

- What do you think about the way we monitor patients in hospital?

Conclusion

- Signpost the end of the interview
- Invite further questions
- Thanks for taking part
- Ask if the patient would like to be kept informed about the study
- Invite to focus groups

5) Topic guide for focus group 1:

Documentation of attendees (anonymised)

Introduction

- Thanks for helping
- Housekeeping (fire exits, etc.)
- Introduce the facilitators
- Introduce the aim of the focus group and time schedule
- Emphasise confidentiality and anonymisation
- There are no right or wrong answers: "This is simply about your experience of the way you were monitored during your stay in hospital."
- Introduce dictaphone
- Invite questions

Questions

During your hospital stay, you wore a patch on your chest that helped the nurses monitor your progress.

How did you feel when you were told that you had been put into the group wearing the patch?

What was your experience of wearing the patch?

- Were there good things about wearing the patch? If yes, what were they?
- Were there bad things about wearing the patch? If yes, what were they?

Would you have changed anything about it?

What was your experience of being in the study?

- Did you enjoy being in the study? Why?
- Were there things you didn't like about being involved in the study? What were they?

How would you change the study to make it better for other patients taking part?

Conclusion

- Signpost the end of the focus group

- Invite further questions
- Thanks for taking part
- Explain how information will be used

6) Topic guide for focus group 2:

Documentation of attendees (anonymised)

Introduction

- Thanks for helping
- Housekeeping (fire exits, etc.)
- Introduce the facilitators
- Introduce the aims of the focus group and time schedule
- Emphasise confidentiality and anonymisation
- There are no right or wrong answers.
- Reintroduce dictaphone
- Invite questions

Questions

Since we last met, is there anything you wanted to add regarding your experience of the patch, or the study itself?

Brief summary of results so far, including patient interviews. Outline of plans for dissemination.

Questions

You were sent a summary of the study via email. It is intended to be read and understood by members of the public.

- Did you understand it?
- How could it be made more clear?

How would you like to see the results of the study used? Who needs to know about this?

Conclusion

- Signpost the end of the focus group
- Invite further questions
- Thanks for taking part
- Explain how information will be used

Figures

1) SensiumVitals® patch

2) SensiumVitals monitoring system: wireless transfer of patient's vital signs to mobile device