Continuous versus intermittent vital signs monitoring in surgical patients

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Sections of Chapter 1 are based on work from two jointly authored publications:

Downey CL, Tahir W, Randell R, Brown JM, Jayne DG (2017). Strengths and limitations of Early Warning Scores: a systematic review and narrative synthesis. *International Journal of Nursing Studies* **76**: 106-119.

Downey CL, Chapman S, Randell R, Brown JM, Jayne DG (2018). The impact of continuous versus intermittent vital signs monitoring in hospitals: A systematic review and narrative synthesis. *International Journal of Nursing Studies* **84**: 19-27.

For both publications, the candidate (CD) was responsible for the concept and design of the work. CD performed the search and selection of manuscripts. Validation of selected papers was performed by TW and SC respectively. CD performed the evidence synthesis and wrote the manuscript. RR, JB and DJ contributed to the drafting and critical revision of the final article.

The trial described in Chapter 3 has been published as a jointly authored publication:

Downey C, Randell R, Brown J, Jayne DG (2018). Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial. *Journal of Medical Internet Research* **20**(12):e10802.

All authors were involved in the concept and study design. CD designed the protocol, obtained ethical and other statutory approvals, recruited participants and performed data collection. CD was also responsible for data management, analysis and interpretation. JB provided trial management expertise. CD wrote the manuscript. RR, JB and DJ contributed to the drafting and critical revision of the final article.

The patient interviews described in Chapter 4 have been published as one jointly authored publication:

Downey CL, Brown JM, Jayne DG, Randell R (2018). Patient attitudes towards remote continuous vital signs monitoring on general surgery wards: An interview study. *International Journal of Medical Informatics* **114C**: 52-56.

CD, RR and DJ were involved in the conception of the work. CD and RR designed the study. RR provided methodological expertise. CD undertook the data collection. CD and RR performed the analysis and interpretation. CD and RR drafted the article. RR, JB and DJ contributed to the drafting and critical revision of the final article.

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CD, RR, JMB and DGJ were involved in the concept and study design. CD provided clinical expertise and was involved in the data collection, analysis and interpretation. JC provided trial management expertise. HB provided statistical expertise. All authors were involved in the protocol development. CD wrote the manuscript. All authors contributed to the drafting and critical revision of the final article.

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Abstract

Despite medical advances, major surgery remains high risk. Up to 44% of patients experience post-operative complications, which can have huge impacts for patients and the healthcare system. Early recognition of postoperative complications is crucial in reducing morbidity and preventing long term disability. The current standard of care is intermittent manual vital signs monitoring, but new wearable remote monitors offer the benefits of continuous vital signs monitoring without limiting the patient's mobility. The aim of this thesis was to evaluate the feasibility, acceptability and clinical impacts of CRM in a surgical population.

Two randomised controlled trials, qualitative studies involving the nursing staff and surgical patients, and an early health economic analysis provide a compelling case for the evaluation of continuous remote vital signs monitoring in a high-risk surgical population. By combining all known literature in the field with a comprehensive range of mixed methodologies, it can be concluded that a future definitive trial should be large, ideally multi-centred, with individual randomisation and clinically relevant outcomes, such as length of hospital stay. A simultaneous economic evaluation is necessary to inform decision-makers after the study is complete, and will provide an opportunity to address the gaps in the literature surrounding postoperative complications. This work has also identified a number of theories regarding the design and implementation of such an evaluation. These theories can now be used to inform future studies, in which the theories themselves can be tested on a wider population of staff, and to optimise any subsequent widespread adoption of such technologies.

Abbreviations and Definitions

ABG	Arterial blood gas
ASA	American Society of Anaesthesiologists (score for pre-operative functional status)
CEA	Cost-effectiveness analysis
CMO	Context-Mechanism-Outcome
CPOX	Continuous pulse oximetry
CRF	Case report form
CRM	Continuous remote monitoring
CUA	Cost-utility analysis
CTRU	Clinical Trials Research Unit
ECG	Electrocardiography
EWS	Early warning score
HDU	High Dependency Unit
ICER	Incremental cost-effectiveness ratio
ICU	Intensive Care Unit
ISOS	International Surgical Outcomes Study
ITT	Intention-to-treat
mITT	Modified intention-to-treat
MRC	Medical Research Council
NEWS	National Early Warning Score
RCT	Randomised controlled trial
TRaCINg	Trial of Remote Continuous versus INtermittent monitoring
UK	United Kingdom
US	United States (of America)

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1 Introduction

Postoperative complications are common following surgical procedures. Vital signs monitoring is a universal tool for the detection of postoperative complications, but unwell patients can be missed in between traditional monitoring rounds. New remote monitoring technologies promise to convey the benefits of continuous monitoring to surgical patients, but existing evidence is limited. This chapter will describe the burden of surgical complications and provide a commentary on current strategies for reducing their impact. The extent of the evidence surrounding continuous vital signs monitoring will be discussed in the context of the difficulties of evaluating such complex interventions. Finally, the structure of this body of work will be outlined to describe a robust and comprehensive evaluation of continuous remote vital signs monitoring on general surgical wards.

1.1 Major surgery and complications

Every year, over 200 million major surgical procedures are undertaken worldwide[1]. This translates into about one operation for every 25 human beings. In the United Kingdom (UK), 1,581,478 major surgeries were performed in 2014[2], with an associated average annual cost of £5,550,530,996. Surgery commands a significant proportion of healthcare resources worldwide, presenting substantial implications for public health planning.

Patients having major surgery are at high risk of postoperative complications, some of which can be life-threatening. Postoperative complications are defined as any deviation from the normal postoperative course after the patient leaves the operating theatre[3], and do not include intraoperative complications. The International Surgical

Outcomes Study (ISOS) found that 17% of patients undergoing inpatient surgery developed at least one postoperative complication[4]. This figure rose to 27% in patients undergoing major surgery. Morbidity rates vary according to the type of procedure. Laparoscopic cholecystectomy (removal of the gallbladder) carries a 6% risk of morbidity[5]; pancreaticoduodenectomy (surgical removal of parts of the pancreas and small bowel) is associated with a 54% risk of morbidity[6]. Rates of complications have been found to be as high as 33-44% in patients undergoing surgery for gastro-intestinal cancers[7].

Postoperative complications vary in severity. Minor events, such as nausea, can be resolved quickly with or without the need for pharmacological intervention. In contrast, serious complications, such as infections, can be life threatening, require multiple interventions, delay patients' discharges and may lead to multiorgan failure or death[3]. Postoperative complications are commonly graded using the Clavien-Dindo Classification of Surgical Complications. This classifies complications into scores I to V, as shown in Table 1.

Grade	Definition
I	Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological interventions. Acceptable therapeutic regimens are: antiemetics, antipyretics, analgesics, diuretics, electrolytes, physiotherapy and wounds opened at the bedside.
III	Complication requiring pharmacological treatment with drugs other than those allowed for Grade I complications
IIIa	Complication requiring surgical, endoscopic or radiological intervention under regional or local anaesthesia
IIIb	Complication requiring surgical, endoscopic or radiological intervention under general anaesthesia
IVa	Life-threatening complication requiring critical care management of single organ dysfunction
IVb	Life-threatening complication requiring critical care management of multi-organ dysfunction
V	Death

Table 1: The Clavien-Dindo Classification of Surgical Complications [3]

1.2 The burden of surgical complications

1.2.1 Patient burden

Postoperative complications are associated with significant morbidity and mortality. A recent review of the literature found that postoperative complications contribute to increased mortality, longer length of stay and an increased level of care at discharge[8]. In the ISOS study, which collected data from 474 hospitals internationally in 2014, 2.8% of patients who developed a postoperative complication died before discharge from hospital[4]. This rises to 5-10% for major surgical procedures[1] and postoperative mortality is the third leading cause of death in the USA[9]. The

occurrence of a postoperative complication has been found to be more important than preoperative risk factors and intraoperative events in determining survival after major surgery[10].

For those that survive a surgical complication, many will experience a long-term decline in physical function[11]. The odds of discharge to an institutional care facility increase 2-fold in patients who experience one or more postoperative complications[12]. In addition to physical disability, a recent meta-analysis found a significant association between surgical complications and mental health problems[13], particularly anxiety and depression. Postoperative complications also have adverse effects on long-term social functioning and quality of life[14]. As such, it has been suggested that quality and process improvement in surgery should be directed toward the prevention of postoperative complications[10].

1.2.2 Burden to the healthcare system

Surgical complications are expensive. Major complications occur in around 20% of patients but account for more than 50% of the total costs in patients undergoing major abdominal surgery[15]. In a single hospital cost-analysis from the Netherlands, the occurrence of a minor complication (Clavien-Dindo grades I and II) almost doubled the average cost of major abdominal surgery (from €8,584.81 to €15,412.96) whilst a major complication (Clavien-Dindo grades III, IV and V) more than tripled the cost (€29,198.23)[15].

The costs of postoperative complications can be attributed to diagnosis, treatment including re-operation, and escalation of care. 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 Units (ICU; Level III). As many as 16% of patients suffering postoperative complications will have an unexpected admission to ICU[4].

Escalation of care comes at significant cost to both the patient and the health service and is associated with worse patient outcomes. The average cost of a Level I (general ward) bed is £433/day, as compared to £1033/day for a HDU bed, and £1351/day for an ICU bed[16]. In addition, there is an increasingly frequent scarcity of critical care beds due to evolving population demographics and technological advances[17].

1.3 Prevention and management of complications

Given the significant implications for the patient and the healthcare system, reducing perioperative morbidity and mortality is an important research area. Much of the work in this field has focussed on identifying and reducing risk factors for anaesthesia and surgery, with comparatively less emphasis on the postoperative period[18].

Numerous risk factors for postoperative morbidity and mortality have been reported. These can be broadly classified into patient factors, therapeutic factors and hospital factors[5]. Extensive efforts have been made to optimise the patient before surgery through adequate risk prediction, management of comorbidities and prehabilitation programmes incorporating exercise and nutrition. Therapeutic factors are also constantly evolving with the advent of laparoscopic and robotic surgery, and enhanced recovery programmes. Hospital factors incorporate the quality of perioperative care, which involves a multi-disciplinary team with the aim of detecting, treating and preventing postoperative complications.

The identification and treatment of postoperative complications is important. Recovery rates from postoperative complications vary between hospitals[5]. Hospitals with high rates of complications do not necessarily have high mortality rates[19], suggesting that key interventions are paramount in preventing deaths.

1.4 Early recognition of postoperative complications

Where preventative measures have failed, early recognition of postoperative complications is crucial. Their severity and associated morbidity are significantly reduced through prompt detection[20]; for patients with septic shock there is an 8% increase in mortality for every hour of delay in antibiotic administration[21]. In addition, early treatment minimises the need for Level II/III care and produces significant cost savings.

It is well recognised that patients who develop postoperative complications become progressively unwell over a period of time. Adverse events are preceded by a period of physiological deterioration[22]. It is estimated that patients show signs of deterioration for up to 6 to 8 hours prior to a cardiac or respiratory arrest[23]; it has been found that 84% of inpatient cardiac arrests are predictable[24]. Early recognition of these events presents an opportunity for earlier intervention that can help stabilise patients before more serious complications occur, thereby decreasing mortality[25,26]. A delay of as little as 15 minutes is associated with a significantly increased risk of unplanned ICU admissions and death[27].

Patient surveillance is therefore an important part of postoperative care. One of the ways patients are monitored for complications is by recording their vital signs; these include blood pressure, heart rate, breathing rate, oxygen saturations and temperature. The recording of vital signs is a ubiquitous method of physiological monitoring in the inpatient setting, and forms an important part of the afferent limb of the deteriorating patient pathway. Once a patient has been identified as unwell, the efferent limb of the pathway will usually include protocolised rapid assessment, often in the form of a critical care outreach service[22].

1.5 Early warning score systems

An early warning score (EWS) is a track-and-trigger system whereby vital signs are documented every few hours, and amalgamated into a numerical score. The more deranged a patient's vital signs, the higher the score, the more frequently they are monitored and the more likely they are to receive medical review[28]. The advantage of EWS over individual vital sign monitoring is that the EWS system allows the user to record and respond to multiple parameters simultaneously, so that subtle changes in vital signs can be used to initiate early emergency management of the patient to reverse abnormal physiological decline[29].

EWS systems have been widely adopted throughout the National Health Service (NHS) in the United Kingdom, and different versions exist. In 2012, The Royal College of Physicians developed the National Early Warning Score (NEWS) as a standardised approach to the assessment and response to critical illness[30].

1.5.1 Advantages of EWS systems[1]

EWS systems have consistently been found to accurately predict adverse outcomes in a number of different populations, including surgical patients. Despite being developed for general medical hospital admissions, a recent retrospective study of 35,174 surgical admissions found that NEWS discriminated deterioration in non-elective surgical patients at least as well as in non-elective medical patients[31].

[1] The following are the abridged findings of the systematic review undertaken as part of the preparatory work for this thesis and published as Downey CL, Tahir W, Randell R, Brown JM, Jayne DG (2017). Strengths and limitations of early warning scores: A systematic review and narrative synthesis. International Journal of Nursing Studies 76:106-19.

EWS have been found to be excellent predictors of cardiac arrest[32], ICU transfer[33] and death on ICU[34] as well as 30-day mortality and length of stay on ICU[35].

In addition to their predictive value, the introduction of EWS systems has been found to improve patient outcomes[36]. However, the introduction of EWS is often accompanied by that of a critical care outreach team, making the individual impact of the early warning score difficult to assess[22].

EWS systems can be implemented in a large range of settings, including across hospital inpatient specialties, in the community and alongside other predictive tools. As such, they provide a common language across healthcare providers and specialties. Qualitative studies have found that quantifiable evidence is the most effective means of referring patients to doctors, and the EWS achieves this by packaging individual vital signs together, providing a 'precise, concise and unambiguous means of communicating deterioration, and confidence in using medical language'[37]. This is particularly important in the surgical population, where deterioration is often acute and timely intervention is paramount. In addition, complex surgical patients are routinely attended by a large multi-disciplinary team, where communication is vital.

1.5.2 Limitations of EWS systems

EWS systems are user-dependent. They rely on time-consuming manual observations and are open to user interpretation. User error can occur in recording vital signs, calculating the score and escalating appropriately. A 2012 study evaluated EWS in patients 48 hours before an adverse event[38]. Despite the fact that 81% of patients had a score indicative of deterioration, recordings were 'mostly incomplete' with respiratory rate documented in 'only 30% to 66%'. This can be partly overcome by automated EWS systems, which highlight erroneous data and improve the accuracy of calculations.

A further significant limitation of EWS systems is their intermittent nature. Vital signs are taken at predetermined intervals with patient deterioration possible between recordings (Figure 1). A patient is only identified as having deteriorated once the observations are recorded and the score is calculated. It has been suggested that the gap between observations is one of the primary failings of the NEWS system[39].

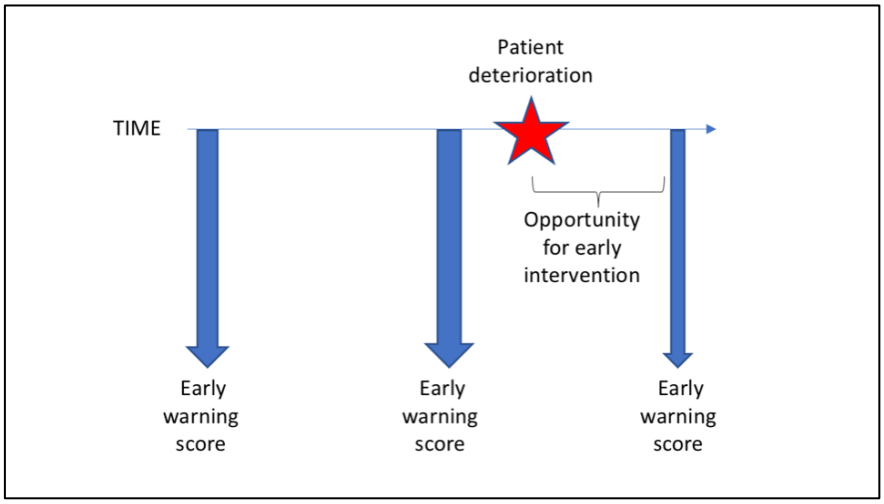

Figure 1: Theoretical model of the deteriorating patient pathway

There is a paucity of research into the effectiveness of vital signs monitoring and the optimal frequency of measurements[36]. Typically, in the postoperative period the EWS 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 EWS may be recorded only twice a day.

Patients who have their vital signs taken every four hours for 5 to 10 minutes are monitored only 2% to 4% of the time (30-60 minutes per day)[40]. This has two important implications. Firstly, deterioration that occurs in between manual observations is more likely to go unnoticed and could result in detrimental outcomes[41]. Secondly, important fluctuations in vital signs can be missed; in a cohort of patients with prolonged oxygen desaturations, manual recordings of SpO_2 did

not reflect the patient's physiological state when compared with continuous automated sampling[40].

1.6 Continuous vital signs monitoring

A solution to the problem of inadequate monitoring frequency is continuous monitoring at the bedside. Continuous monitoring would allow for prompt recognition of deterioration and a timely response. A consensus of international experts in safety and healthcare technology concluded that, if technically possible and affordable, all patients who are for active treatment should be continuously monitored[42].

Until recently, continuous vital signs monitoring was limited to ICUs because it required high staff-to-patient ratios and cumbersome equipment which tethered the patient to the bed-space, thereby inhibiting patient mobility and recovery. When ICU-style monitoring was implemented on a general ward, only 16% of patients remained connected in a 72-hour period due to lack of patient acceptability[43].

1.6.1 Remote vital signs monitoring

New remote monitoring devices, consisting of wearable sensors and aided by wireless data transmission, have the potential to convey the presumed advantages of continuous, ICU-style vital signs monitoring to general wards. Since 2002, a number of such tools have received the United States (US) Food and Drug Administration (FDA) clearance (see Figure 2), indicating that they are safe and effective, but clinical studies are required to demonstrate their clinical utility in the post-surgical setting[44,45].

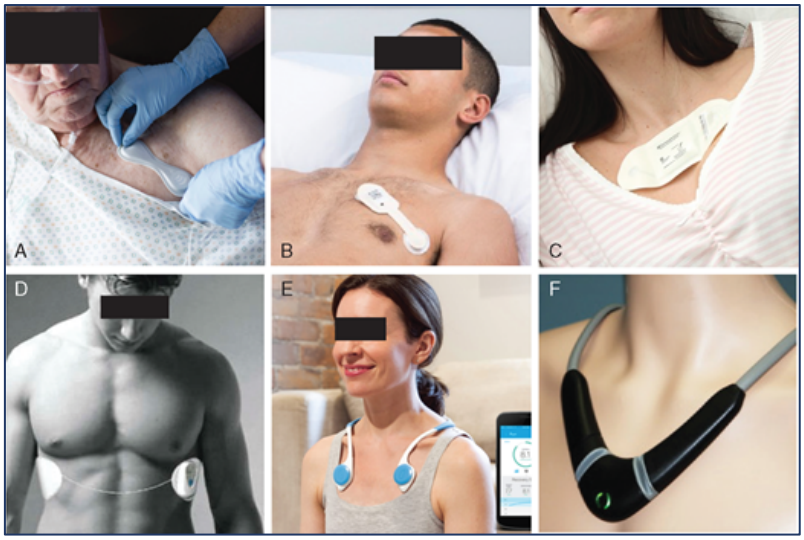

Figure 2: Examples of wearable, wireless sensors[2]. Medical grade adhesive patches (A: VitalConnect, San Jose, CA, USA; B: Isansys, Abingdon, UK; C: Sensium, Abingdon, UK; D: Intelesens, Belfast, Northern Ireland) and necklaces (E: CloudDX, Kitchener, Canada; F: toSense, San Diego, CA, USA).

1.6.1.1 The SensiumVitals® monitoring system

One such device is the SensiumVitals® patch (Figure 3). The device is attached to the patient's chest by two conventional ECG electrodes. When the patch is activated, it records respiratory rate (via impedance pneumography), ECG activity and temperature. Once a physiological signal is acquired, it is processed by an embedded algorithm which results in the transmission of the average values to the nearest hot spot for onward transmission. The algorithms also detect and discard erroneous calculations that arise from signals corrupted by electrical or motion artefacts.

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[2] Reprinted from British Journal of Anaesthesia, Volume 119, Number 1, F. Michard,T.J. Gan,H. Kehlet, Digital innovations and emerging technologies for enhanced recovery programmes, Page 35, Copyright (2017), with permission from Elsevier.

The data are transmitted wirelessly every two minutes to a central monitoring station or a mobile device carried by the patient's nurse (Figure 4). This alerts the healthcare worker when there is deviation from pre-set physiological norms, warning staff to potential patient deterioration. An example of the monitoring output available to ward staff is presented in Figure 5. The patch is discarded when the patient is discharged.

Although there are a number of similar devices on the market (Figure 2), the SensiumVitals® system was chosen for evaluation in this work as it is CE-marked and the company was in a position to support a timely evaluation before aiming for widespread adoption.

Figure 3: The SensiumVitals® patch[3]

[3] Figures 3 and 4 are produced with permission from Sensium, Abingdon, UK.

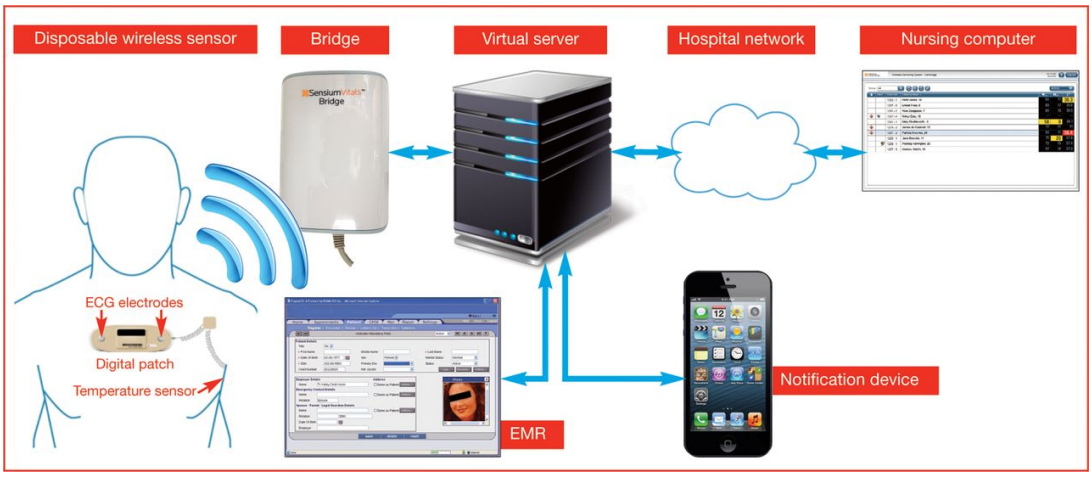

Figure 4: SensiumVitals® monitoring system: wireless transfer of patient's vital signs from the wearable patch to a mobile device carried by the patient's nurse via a network of bridges placed through the ward area

It is hypothesised that continuous vital signs monitoring may allow earlier detection of patient deterioration and thereby improve patient outcomes. Healthcare systems are becoming increasingly reliant on new technologies, and it is easy to assume that all technology imparts patient benefit. Nevertheless, it is important to collate the information available regarding continuous vital signs monitoring before the widespread implementation of new and expensive technology. Doing so will help guide the process to meet the needs of the end-users, and may elucidate alternative solutions.

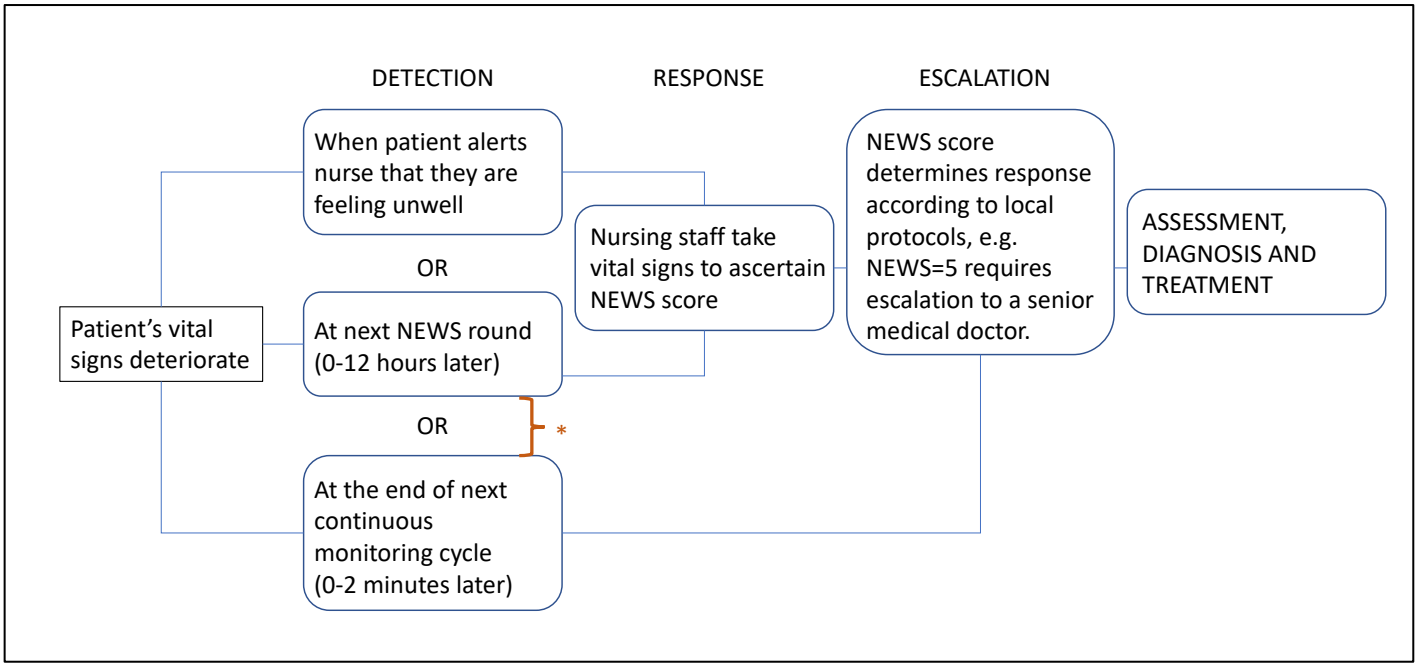

Figure 5: A model of how continuous monitoring may allow earlier identification of deterioration when used in tandem with NEWS. The starred area represents the temporal difference between next NEWS score and next continuous monitoring cycle may provide opportunity for early detection, response, escalation and treatment of patient deterioration.

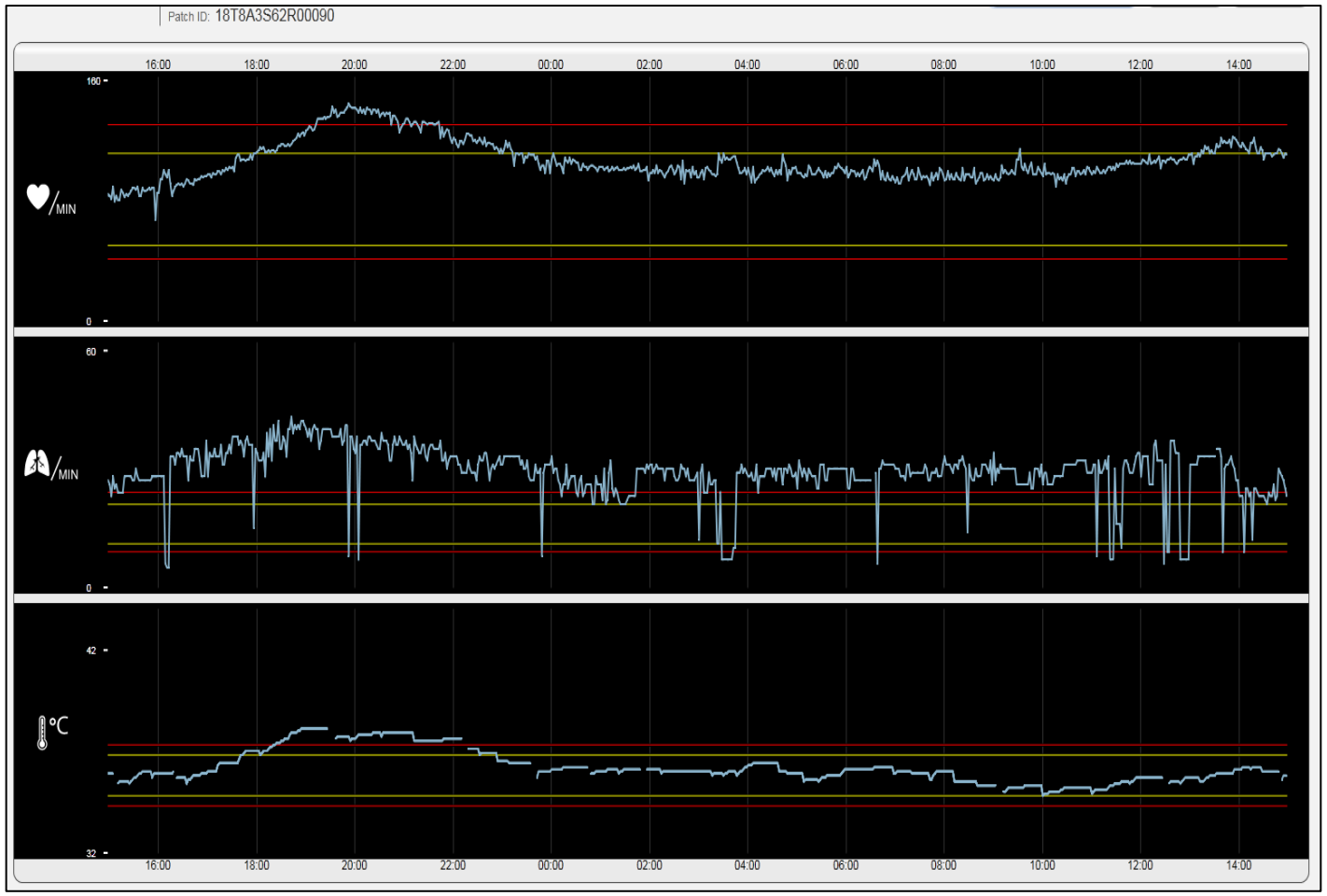

Figure 6: An example of vital signs output from the monitoring system. Heart rate is shown in the top trace, respiratory rate is shown in the middle trace and temperature is shown in the bottom trace.

1.7 Evaluating complex interventions

A continuous remote patient monitoring system is a complex healthcare intervention. The Medical Research Council (MRC) defines a complex intervention as one that contains several interacting components[46]. In the case of continuous remote monitoring (CRM), the complexity lies in a number of domains: the number of components of the system and the interaction between the system and usual patient care, the level of behavioural change required from the nurses delivering the intervention, the number of groups affected by the system, such as patients, visitors and staff, and the number and variability of the outcomes that would be affected, such as clinical outcomes, patient comfort and cost of care.

In assessing the quality of healthcare improvements, the US Institute of Medicine have described a list of performance characteristics which should guide the evaluation of healthcare interventions. The six domains include safety, effectiveness, timeliness, equity, patient-centredness and efficiency[47]. These domains complement the MRC guidance for the development and evaluation of complex interventions. Here, three aspects of evaluation are recommended: assessing effectiveness, understanding processes and measuring cost-effectiveness. In addition, the MRC also recommends a thorough review of the evidence base behind any complex intervention before its implementation and an understanding of the causal assumptions behind the intervention.

1.7.1 Assessing effectiveness[1]

1.7.1.1 Safety

Key to the evaluation of new healthcare interventions is avoiding harm to patients from the care that is intended to help them. The SensiumVitals® patch is CE-marked and FDA-approved and the entire premise of CRM is to improve patient safety during hospital admissions. Nevertheless, safety is an important baseline from which to build the evaluation of such systems.

The safety and feasibility of continuous monitoring outside the critical care setting is evident by the number of centres that report successful implementation: 10 centres in seven countries have published clinical studies. The majority of studies showed benefits in clinical outcome measures, particularly critical care use and length of hospital stay. Studies with large numbers of participants were more likely to associate the intervention with clinical benefit. Smaller observational studies found that continuous monitoring gave a more accurate reflection of the patient's physiological state, but were unable to demonstrate the clinical significance of this.

Taenzer *et al.* and Wan *et al.* compared intermittent oxygen saturation measurements with those collected by continuous pulse oximetry (CPOX)[18,40,48]. Taenzer reported that manually recorded data were significantly higher than those recorded by CPOX, and did not reflect the patients' physiological states[40]. Wan *et al.* found that the

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[1] The following are the abridged findings of the systematic review undertaken as part of the preparatory work for this thesis and published as Downey CL, Chapman S, Randell R, Brown JM, Jayne DG (2018). The impact of continuous versus intermittent vital signs monitoring in hospitals: A systematic review and narrative synthesis. International Journal of Nursing Studies 84:19-27. The protocol for the review was registered with PROSPERO (registration number CRD42017058098).

detection rate of hypoxaemia was poor with arterial blood gas (ABG) measurement compared to CPOX[48]. However, only three of their 20 patients manifested clinical symptoms requiring oxygen therapy, and all three had clinically significant signs on ABG.

Similarly, a study of temperature monitoring found that only 16% of patients had fever 'peaks' identified by continuous monitoring that would not have been found with intermittent tympanic measurements and, in a further 16%, conventional monitoring observed peaks not detected by continuous monitoring[49].

1.7.1.2 Effectiveness

In healthcare, effectiveness refers to care that is based on the use of systematically acquired evidence to determine whether an intervention, such as CRM, produces better outcomes than alternatives[47]. This knowledge allows the provision of services to all who could benefit, whilst refraining from providing these interventions to those not likely to benefit, thereby avoiding overuse and underuse[50].

The literature surrounding the impact of continuous vital signs monitoring on clinical outcomes consists of 12 single-centre studies. Five of these are randomised controlled trials [51–55], one is a non-randomised controlled trial [56], three are controlled before-and-after studies [18,26,57] and three are prospective observational studies [40,48,49]. Outcome measures vary between studies and include mortality, length of hospital stay, ICU admission rate, length of stay on ICU, outcome at discharge and complication rates.

In a retrospective before-and-after study, Kisner *et al.* compared the rates of atrial fibrillation (AF) in cardiac surgical patients who received CPOX, with those who received intermittent monitoring prior to its introduction[57]. No significant difference

was detected between the two groups. A single subgroup of patients (those with coronary bypass graft with or without simultaneous valve surgery) demonstrated a significantly reduced incidence of AF (14% versus 26%, p=0.016), but another subgroup (valvular surgery only) demonstrated increased frequency of AF in the CPOX group.

In a well-designed before-and-after study in over 13,000 patients[18], continuous pulse oximetry significantly decreased the rate of adverse events and critical care transfers in post-operative orthopaedic patients. Control wards showed no change over the same periods. Similarly, a randomised controlled trial of 1219 cardiothoracic patients found that length of stay on ICU was significantly shorter in patients who were continuously monitored[52]. This was despite no change in the rate of ICU transfer between the intermittent and continuously monitored groups. When subgroup analysis was performed on a high-risk group of patients, rates of transfer to ICU were decreased, but the study was not powered for this analysis.

Studies evaluating continuous monitoring of multiple vital signs parameters have shown mixed results. An industry-funded controlled before-and-after study of 7,643 patients[26] found that continuous monitoring on a medical-surgical unit was associated with a total decrease in length of hospital stay from 4.0 to 3.6 days. Although statistically significant, the clinical relevance of a 0.4 day reduction in hospital stay was not described. Total ICU days were significantly lower in the continuous monitoring group, but the rate of ICU admission was unchanged. In the control group a concurrent significant increase in length of ICU stay was observed, although the rate of cardiac arrest calls decreased significantly in both control and intervention arms.

Despite promising preliminary results[54], a randomised controlled trial of 402 high risk medical and surgical patients found that continuous multi-parameter monitoring

showed no effect on adverse events or mortality[55]. However, only 16% of the patients were continuously monitored for the full 72 hours intended.

Three of the selected studies specifically involved the monitoring of acute stroke patients[51,53,56]. The primary outcome measure was outcome at discharge, as assessed by validated scoring tools. These three studies have been well summarised in a recent Cochrane Review[58] which concluded that continuous physiological monitoring significantly reduced death and disability at three months post-discharge (odds ratio 0.27, 95% confidence interval 0.13 to 0.56). The significance of these findings were influenced by a non-randomised controlled trial[56] which had a high risk of bias due to the method of allocation (consecutive patients admitted to different wards based on availability of beds) and lack of blinding of outcome assessment.

Interestingly, Cavallini *et al.*[56] found that patients in the continuous monitoring arm of their study had a significantly greater proportion of adverse changes in vital signs, which required acute medical treatment (64% vs 19%). This was echoed in the findings of Langhorne *et al.* (especially hypotension and tachycardia) and Sulter *et al.* (especially hypoxia, hypotension and arrhythmias)[51,53]. Despite this, the outcome in patients with complications was found to be better in the continuous monitoring arm than the intermittent monitoring arm, and the length of stay in hospital shorter (9.2 days vs 17.1 days). All three studies concluded that continuous physiological monitoring after acute stroke may reduce the risk of poor outcome and death, and that modern specialised Stroke Units should incorporate such intensive monitoring as standard in the first 48 hours of admission.

Although study quality is generally high, many of the aforementioned papers share common limitations. Due to small sample sizes, studies were often underpowered to detect differences in clinical outcome measures. Statistically significant differences found in subgroup analyses may have been due to multiplicity of testing. The

preponderance of observational studies means that causal associations between interventions and patient outcomes have to be interpreted with care. The three largest randomised controlled trials showed conflicting results, and the generalisability of their findings were limited due to poor adherence, single-centre design, diverse patient populations and heterogeneous outcome measures. There is a need for more research in the area of continuous vital signs monitoring.

1.7.1.3 Timeliness

Timely healthcare interventions contribute to reducing potentially harmful delays for both those who receive and those who provide care[47]. CRM is based on the idea that increasing the frequency of vital signs monitoring will reduce the delay between the onset of patient deterioration and the initiation of treatment. To date, no literature exists to support this theory; instead, clinical outcomes such as length of hospital stay are used as proxies for timely intervention. Outcomes such as time to antibiotics after the detection of sepsis could provide the necessary evidence to support theories of timeliness for this healthcare intervention.

1.7.2 Understanding processes

The successful implementation of new technology into routine clinical practice is predicated on engaging both staff and service users. It is crucial to assess the experiences of the people using the technology to identify contextual factors that support or constrain optimal utilisation, which could influence the effectiveness of the device.

1.7.2.1 Patient-centredness

The Institute of Medicine defines patient-centred care as the provision of care that is ‘respectful of and responsive to individual patient preferences, needs, and values and

ensuring that patient values guide all clinical decisions'[47]. Gerteis *et al*. [59] have identified several dimensions of patient-centred care: (i) respect for patients' values, preferences, and expressed needs; (ii) coordination and integration of care; (iii) information, communication, and education; iv) physical comfort; (v) emotional support—relieving fear and anxiety; and (vi) involvement of family and friends. All six of these aspects can be considered when evaluating the processes surrounding patients' experiences of CRM. Patient satisfaction is, however, given limited consideration in the existing literature.

Although a number of studies briefly mention the comfort of the monitoring devices being tested, only one included patient satisfaction as an *a priori* outcome measure[17]. Out of the 25 patients interviewed, 22 felt positively about the continuous monitoring system because it gave them a sense of 'security,' whilst other patients found the monitors to be restrictive or uncomfortable.

Attention to patient comfort and convenience should influence the design of wearable devices to avoid issues with adherence such as those seen by Watkinson *et al.*[55], where only 16% of the patients were continuously monitored for the full 72 hours intended. Consideration of patients' experiences throughout can provide universal benefit through the enhancement of patient safety and satisfaction, and more work is required in this area.

1.7.2.2 Equity

Equitable care is that which does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status[47]. In the post-operative care setting, the most likely source of inequity is the disparity in monitoring frequencies between patients. The level of attention an individual patient

receives is determined by two factors: the patient's presumed risk and the number and training of staff present[42].

Patients perceived to be at high risk of deterioration receive more nursing attention than those who are perceived to be progressing within the expected recovery trajectory[60,61]. CRM has the potential to eliminate this inequity by providing intensive monitoring for all patients, regardless of their perceived level of need. All patients could receive an increased frequency of vital signs monitoring, including those perceived to have less acute needs.

This is important as, in many circumstances, clinicians cannot always predict which patients are most likely to deteriorate[22]. Presumed 'low risk' patients are equally as likely to suffer from unpredictable events such as medication errors, drug side-effects or surgical complications, which may be independent of their risk status[42]. In addition, even in high risk patients, the timing of deterioration is often intrinsically unpredictable. Continuous monitoring offers the chance to detect deterioration throughout the patient's hospital admission independent of their perceived level of need.

In the ICU setting, the frequency of monitoring necessitates a patient: nurse ratio of 1:1. On Level III wards, this ratio would be unfeasible and inefficient. Intensive monitoring is impractical in this setting because of work flow, staffing levels and cost constraints[42]. However, studies suggest that increased staffing levels should improve patient observation and decrease the likelihood of the delayed detection of patient deterioration[62,63]. It could be argued, but is as yet unproven, that CRM may compensate for suboptimal staffing levels[42]. This may be especially pertinent during night shifts, when patient: nurse ratios are higher[64]. However, it is critical to remember that clinical staff are able to monitor patients in ways not permitted by current technology. Personal interaction with the patient is required to notice indicators such as agitation, pain and patient concern[61]. Detailed clinical knowledge is necessary to identify patients progressing outside of their expected trajectory. In

addition, a number of studies have identified ‘nursing intuition’ as a means to identify a patient’s decline before any objective evidence of deterioration is present[61,65].

1.7.3 Measuring cost-effectiveness

1.7.3.1 Efficiency

Healthcare institutions must often choose between different patient safety interventions in order to maximise limited resources[66]. These decisions can be based on economic reasons alongside patient benefits. In an efficient health care system, resources are used to get the best value for the money spent[47]. Although there is limited evidence on the healthcare economics of patient monitoring, it appears that there may be a cost benefit with three studies showing cost-effectiveness of both single- and multi-parameter monitoring devices.

Slight *et al.*[66] performed a return-on-investment analysis based on the results of Brown *et al*.[26] who measured unplanned ICU admissions, ICU length of stay and total length of hospital stay in a before-and-after study. Through multiway sensitivity analyses they found a return on investment of 127% for the least favourable conditions, with the most optimistic model returning up to 1739%. Workflow-related issues (e.g. changing nursing practice) were not included in the analysis.

Similar cost-effectiveness studies have been performed based on the results of Taenzer[23] and Ochroch[52]. Ochroch *et al*. examined the cost of patient care in patients who required ICU transfer and found a difference of $28,195 (p=0.04) in favour of patients who received continuous monitoring. Morgan *et al*.[23] estimated annual cost savings at $817,000 in the first year after the implementation of continuous monitoring at a 400-bed tertiary referral centre, driven by reduced ICU transfers.

These economic studies found evidence of extremely cost-effective interventions. However, the results must be interpreted within the limitations of the original study findings. They were limited to single devices, tested in small populations in single hospitals in the US, which may limit their generalisability to other devices and healthcare systems.

Cost-effectiveness must also be weighed against the impact of the interventions in other areas. In the field of remote monitoring, one potential area of burden is alert frequency[18]. Eight studies reported concerns about alert burden. Banks found such a problem with nuisance alarms that monitoring had to be abandoned for two patients because of nursing complacency towards the alarms[17]. Alarm fatigue and data inaccuracy were also reported by Jeskey *et al.*, who found that excessive false-positive alerts interrupted nurses and distracted them from other responsibilities[67]. There was also concern that doctors might become overburdened and desensitised to calls[68].

Three studies have aimed to quantify alert burden. Average number of alerts per patient per day varies from 7[69] to 10.8[70] to 95.6[71]. False alert rates varied between studies; Gazarian identified 32.9% of alerts as 'nuisance alarms'[72], whereas Voepel-Lewis *et al*. found that only one-third of alerts were clinically relevant, and that high alert burden was associated with longer nursing response times[69]. Taenzer *et al*. aimed to pre-empt this alert fatigue by adjusting alert thresholds, and allowing adjustment of these limits on a per-patient basis, to account for abnormal baseline physiology[18]. Similarly, Gross *et al.* were able to reduce their alarm rate by 50% with simple limit adjustments[71].

1.8 Challenges in the evaluation of continuous remote monitoring

The feasibility of continuous monitoring outside the critical care setting is evident by the number of centres that report successful implementation. However, demonstrating significant benefit over intermittent monitoring to offset the practical and economic implications is more difficult. There are several challenges that affect the evaluation of CRM technologies in the Level I hospital ward setting.

1.8.1 Population

In comparison to the ICU patient cohort, the inpatient population on Level I hospital wards is low-acuity and heterogeneous. Rates of acute patient deterioration differ markedly between specialties. Adverse events severe enough to warrant admission to critical care are rare. In order to demonstrate significant differences in hard outcomes such as ICU admissions, there is a need for large, well-controlled studies in high-risk populations.

The surgical population is an ideal cohort, given the high rate of complications in major surgery[4]. Many surgical complications, such as sepsis, are attenuated by early detection. By virtue of their suitability for surgery, patients experiencing severe complications are likely to be candidates for full active management and escalation of care. They are therefore a population likely to benefit from continuous physiological monitoring. Enhanced recovery programmes mandate early mobilisation of postoperative patients; remote monitoring allows the patient to ambulate freely whilst enjoying the presumed advantages of extra monitoring.

1.8.2 Optimisation of the intervention

Despite the fact that continuous monitoring has been used in the critical care setting for decades, its transferability to general surgical wards cannot be assumed. Health information technologies almost always exert changes on existing work systems, and

are therefore disruptive[67]. Factors such as staff: patient ratios, work patterns and patient demographics can influence the acceptability of an intervention.

Technology adoption by healthcare staff is commonly theorised using Davis's technology acceptance model, which is the most widely applied model of users' acceptance and usage of technology[73]. The model consists of perceived usefulness, perceived ease of use and attitude towards the technology[74].

In order to optimise ease of use and perceived usefulness, technology design issues should be evaluated early and frequently during the initial implementation of the device, with flexibility allowed to tailor interventions to specific contexts. Evidence from the literature points to alarm burden as an important barrier to the engagement of nursing staff with continuous monitoring systems[17,67,69,72]. It is therefore crucial to monitor false alert rates and adjust delays and thresholds accordingly.

1.8.3 Engagement with the intervention

The small number of quantitative studies in the field of continuous monitoring have shown mixed results[36]. The success of these technologies is context-dependent, and reliant on both patient and practitioner engaging effectively with the technology. Lack of adherence, such as that seen in the study by Watkinson *et al*., can attenuate the potential benefits of continuous monitoring.

1.8.3.1 Patient engagement

The acceptance of technology by patients is argued to be based on four key influences: personal motivation, personal values, the engagement approach taken by those seeking to promote the technology and the quality of the health technology[75]. By evaluating the patient experience of vital signs monitoring, it may be possible to enhance the environment and the technology to provide optimal patient benefit. This

will need to be offset against potential concerns about personal interaction with clinical staff.

1.8.3.2 Staff engagement

The third component of Davis's technology acceptance model is staff's attitude towards the technology[74]. The clinical and non-clinical efficacy of continuous monitoring systems depend on engagement of the nursing staff with the technology and therefore on their satisfaction. Acceptance by staff may be the single most important determinant of the success of healthcare technologies at a local level[75]. Five studies have reported nursing perception[17,51,67,68,70] and all identified similar themes.

All studies reported that nursing staff could see the potential for continuous monitoring to enhance patient safety. Nurses perceived that greater 'availability and accessibility' of vital signs information would support their decision-making and provide reassurance to patients[68]. The value of continuous monitoring was particularly evident to nurses who were trained and felt confident in its use[51,67], while lack of familiarity with the technology was associated with the perception of increased workload[17]. Banks *et al*. stress the importance of training in time allocated away from clinical duties[17]. Interestingly, Jeskey *et al*. found a more positive perception in nurses looking after higher-acuity patients, such as those just back from surgery[67].

Prgomet *et al*. reported concerns from both doctors and nurses about over-reliance on continuous monitoring leading to decreased bedside interactions[68]. Some nurses were worried that visibility of information and alarms would cause patient anxiety, leading to increased time spent to reassure them. Continuous monitoring devices were also considered to provide opportunities for increased engagement of patients in their own care.

Realist evaluation is increasingly used for the evaluation of complex interventions in healthcare[76]. It is based on the idea that interventions (such as a new monitoring system) offer resources to people, but it is how people choose to respond to the resources that determines their impact[77]. Realist evaluation aims to explain why the intervention works in some circumstances, but not in others.

CRM and its associated devices provide a resource to clinical staff to monitor patients' vital signs uninterrupted and unburdened from traditional monitoring machines. This resource is fixed; it is the response to the resource that determines if the desired outcomes are achieved. This response is determined by the context in which the resource is implemented. For instance, in the *context* of engaged senior colleagues, staff nurses may *respond* by carrying the devices and acknowledging alerts appropriately, leading to recognition of the deteriorating patient (the desired *outcome*).

Alongside and complementary to quantitative outcome measures, future work should aim to identify how, why and in what conditions remote continuous vital signs monitoring is optimally used on general surgical wards. Elucidation of these contextual factors and their effects will inform potential wider implementations of this technology, and may reveal strategies to support staff in the future.

1.8.4 Outcome measures

In the field of continuous patient monitoring, the clinical outcomes of most interest are also the most rare. Mortality and ICU admission rates are important endpoints, but few trials can be powered to detect an effect in such infrequent events[46], even in high-risk populations. Outcome measures universal to all inpatients, such as length of hospital stay, should be considered alongside the rates of uncommon events.

This is compounded by the complex nature of the intervention. Outcomes such as ICU transfer are dependent on many other factors other than the data provided by the continuous monitoring device: bed availability, changing indications for escalation, varying practices among individuals[22]. Case studies are an appropriate way to capture individual benefit from complex interventions. On a larger scale, outcomes such as time to antibiotics after the detection of sepsis could go some way towards supporting the theory that increasing the frequency of vital signs monitoring will reduce the delay between the onset of patient deterioration and the initiation of treatment.

The MRC guidance recommends that evaluations of complex interventions should include feasibility and piloting stages in order to anticipate issues such as acceptability, compliance, recruitment, retention and small effect sizes[46]. Depending on the results, a series of studies may be required to progressively refine the study design, before leading to a definitive, multicentre evaluation.

1.8.5 Cost

In times of financial constraint, it is imperative to assess the cost-effectiveness of new healthcare technologies[22]. Traditional healthcare technology economic analyses focussed on particular devices employed within rigid contexts. Analyses such as those by Slight *et al.*[66] and Morgan *et al.*[23] can only be interpreted within the limitations of the device and population studied. In the case of CRM, there are many systems available with no single market leader at present.

Performed alongside a clinical trial, a health technology economic evaluation can provide the data to inform decision-making regarding continuous monitoring devices. Such an evaluation can help to determine which aspects of continuous remote monitoring [75] have the highest return on investment, and how effective a CRM device would have to be in order to be cost-effective.

1.9 Summary

Complications after major surgery are common. They are associated with significant morbidity and mortality for the patient, and represent a substantial financial burden to the healthcare system. The incidence of postoperative complications can be reduced by identifying and managing risk factors for anaesthesia and surgery. Where preventative measures have failed, early recognition of postoperative complications is crucial. Patient surveillance, and vital signs monitoring in particular, is an important part of postoperative care. Physiological monitoring using early warning score systems is effective but limited by its intermittent nature. It is hypothesised that continuous remote vital signs monitoring using wearable, wireless sensors may allow earlier detection of patient deterioration and thereby improve patient outcomes, but existing evidence is limited, shows mixed results, and has not been translated into clinical practice.

The lack of conclusive evidence may be due to the intricacies involved in evaluating a complex intervention. Effective evaluation of remote monitoring systems requires optimising and standardising practitioner engagement, patient satisfaction, and the intervention itself. Only then can endpoints such as clinical outcome measures and cost-effectiveness be valid and reliable. Only one study in the literature has reported patient satisfaction with remote monitoring systems, despite the fact that attention to patient comfort and convenience can avoid issues with adherence. Nursing engagement and alarm burden are a major barrier to the implementation of remote monitoring systems, but few studies report nursing perspectives.

Demonstrating significant benefit over intermittent monitoring to offset the practical and economic implications of continuous monitoring is difficult, and requires large, well-controlled studies in high-risk populations to demonstrate significant differences in clinical outcomes, such as critical care admissions. Whilst it seems intuitive that

continuous monitoring would confer patient benefit, achieving the maximum value from this technology requires consideration of the practical limitations and engagement of the primary stakeholders.

This body of work aims to form a robust and comprehensive evaluation of continuous remote vital signs monitoring on general surgical wards, based on the findings of two randomised controlled trials described in Chapters 3 and 5. It will take into account staff and patient perceptions (Chapters 4 and 6) alongside clinical and economic outcome data (Chapter 7). If the challenges of implementing such a complex intervention can be overcome, CRM may help to alleviate the clinical and economic burden of postoperative complications and preventable deaths on surgical wards.

2 Aims and Objectives

2.1 Aim

The main aim is to determine whether continuous remote vital signs monitoring confers any benefit over intermittent NEWS monitoring in the general surgical population.

The completed programme of work will form a robust and comprehensive early evaluation of continuous remote vital signs monitoring on general surgical wards. It will take into account staff and patient perceptions alongside clinical and economic outcome data and will provide a foundation for a definitive, multicentre, randomised controlled trial.

2.2 Objectives

1. To evaluate the safety and efficacy of a CRM system for surgical patients, as compared to standard monitoring with the National Early Warning Score system alone, using a randomised controlled trial study design.
2. To determine the feasibility of performing a large, multi-centre trial to test CRM against intermittent monitoring using a feasibility trial design.
3. To evaluate patients' perceptions of the device, compared to standard monitoring alone, using mixed methods including interviews, focus groups and questionnaires.
4. To evaluate the acceptability of the monitoring system for the nursing staff, compared to standard monitoring alone, and to identify how and in which contexts the intervention may provide greatest benefit to patients using a realist evaluation approach.
5. To undertake an early health economic analysis to inform policy makers and guide future evaluations of the technology by using an early cost-utility analysis approach.

3 Continuous versus intermittent vital signs monitoring in patients admitted to surgical wards: a pilot cluster-randomised, controlled trial

It is hypothesised that continuous vital signs monitoring may allow earlier detection of patient deterioration and thereby improve patient outcomes. However, the small number of quantitative studies in this area show mixed results due to major limitations of their methodologies. Some of these limitations may have been mitigated by thorough piloting of the study. In this chapter, we report the findings of a pilot trial designed to investigate whether continuous remote vital signs monitoring is a practical and acceptable way of monitoring surgical patients, and to inform the design of further evaluations of this technology.

3.1 Background

The previous chapters have described the proposed mechanism by which CRM is hypothesised to improve clinical outcomes in hospital inpatients. Despite the obvious theoretical advantages, the anticipated benefits over intermittent monitoring have yet to be conclusively demonstrated by quantitative studies. A recent systematic review identified nine studies assessing the effect of continuous vital signs monitoring on general wards[36]. The authors found no evidence of a significant reduction in adverse events with continuous monitoring, but recognised heterogeneous methods, study populations and outcome measures.

Despite their heterogeneity, many of the studies share common limitations. Due to small sample sizes, studies were often underpowered to detect differences in clinically

relevant outcome measures. The impact of the interventions was undermined by poor implementation fidelity, highlighting the complex nature of the intervention.

As previously noted, the MRC guidance recommends that evaluations of complex interventions should include feasibility and piloting stages in order to anticipate common issues such as acceptability, compliance, recruitment, retention and small effect sizes[46]. The terms 'pilot study' and 'feasibility study' are often used interchangeably, but a recent conceptual framework has been developed to provide explicit formal definitions[78]. A feasibility study asks 'whether something can be done, should we proceed with it, and how.' Pilot studies are a subset of feasibility studies, but always involve the implementation of an intervention, and are thus defined as studies 'in which a future study is conducted on a smaller scale to ask the question whether a definitive trial should be done and how'. Efficient, well designed and conducted pilot studies help to avoid common, and expensive, pitfalls such as failing to recruit to time and target, failure to deliver the intervention within existing clinical services, lack of fidelity to the intervention protocol, and failure to meet sample size assumptions. Pilot studies can also be used to determine the views and needs of support staff to optimise acceptability and adherence[46].

Evaluations of complex interventions are typically designed as pragmatic trials[79]; the trials are undertaken in the 'real world' and with usual care as the comparator, with the aim of helping to support a decision on whether to deliver an intervention[80]. This is in contrast to explanatory trials, which are undertaken in an idealised setting to give the intervention the best chance of demonstrating a beneficial effect[80]. This pilot study was designed to fall on the pragmatic end of the continuum, in order to best predict the effectiveness of CRM under usual conditions.

3.2 Aims

The aim of this study was to evaluate whether continuous remote vital signs monitoring is a practical way of monitoring surgical patients outside of the critical care setting. The pilot data will be used to inform further evaluations to optimise recruitment, treatment compliance and follow-up protocols.

3.3 Methods

3.3.1 Ethical approval and consent to participate

Ethical approval was granted on 30th November 2016 by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, ref: 16/YH/0426. Health Research Authority approval and approved study documents are included in Appendices 1 to 5. The study was prospectively registered on the ISRCTN registry (ISRCTN60999823). No changes were made to the registered protocol. The trial was performed in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki, and is presented according to the CONSORT statement principles[81] and the CONSORT-EHEALTH checklist[82].

3.3.2 Trial design

The study was designed as a cluster-randomised, prospective, parallel-group, controlled single-centre pilot study, comparing remote continuous vital signs monitoring and intermittent monitoring with intermittent monitoring alone.

3.3.3 Study population and setting

The study population were patients admitted to two elective general surgery wards at St James's University Hospital in Leeds, United Kingdom. The hospital is a quaternary referral centre for colorectal surgery and has a strong history of embracing technological advancement. Two colorectal surgery wards participated in the study:

male (J45) and female (J44). The male ward housed 25 beds, whilst the female ward housed 28 beds.

3.3.4 Inclusion criteria

- Patients admitted to one of two elective general surgery wards
- Patients with the capacity to provide informed, written consent on admission
- All ages ≥18 years

3.3.5 Exclusion criteria

- Allergy to adhesives on electrodes
- Cardiac pacemaker in situ

3.3.6 Recruitment

Patients were approached as soon as practical after their admission onto the wards.

3.3.7 Randomisation

Consenting participants were allocated to one of two monitoring arms for the length of their admission, according to the ward bay they were first arbitrarily admitted to. Each ward has four bays containing six beds each. The decision to cluster the randomisation by bay was based on the assumption that it would be easier for the nursing staff to remember which patients were receiving continuous monitoring. It would also theoretically reduce the likelihood of potential contamination between the two arms of the study as all patients in each bay would receive the same amount of nursing attention.

Of the four bays on each ward, three were randomly allocated to one of the monitoring arms; two bays were allocated to receive the patch and one to receive usual intermittent monitoring. Each bay was independently block randomised to an

intervention arm by the clinical fellow using online software: Sealed Envelope Ltd. 2016, available from https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 12 Jan 2017].

The two remaining bays (one on each ward) could not be randomised because they did not have the required hardware installed. Patients in these bays were therefore allocated to receive usual intermittent monitoring alone, but were not included in the primary analysis.

The allocation of patients to each bay was performed by hospital bed managers, who were independent of the trial and unaware of the bay allocations. Due to the nature of the intervention, neither the patient nor their nurse were blinded to the allocated monitoring arm.

3.3.8 Interventions

3.3.8.1 Control arm

All patients in the study received usual intermittent vital signs monitoring. At St. James's University Hospital, this is the National Early Warning Score (NEWS). Early warning scores have been explained in detail in Chapter 1; in brief, NEWS involves intermittent manual charting of vital signs and the calculation of a combined score, giving an indication of patient status. The control arm received intermittent monitoring alone. For postoperative patients, this typically consisted of hourly recording of blood pressure, pulse, temperature, respiratory rate, and oxygen saturation until the patient's condition was stable when the frequency of observations was decreased to two-hourly and then four-hourly. For patients not undergoing an operation, the frequency of monitoring was tailored to their condition.

3.3.8.2 Intervention arm

Patients admitted to an intervention bay received usual intermittent NEWS monitoring, in addition to continuous vital signs monitoring via the SensiumVitals® system (see Chapter 1). All other clinical care remained as normal in the intervention group.

The monitoring system was set up in the wards over a period of six weeks, during which a number of stakeholders were engaged with the project. Early on, permission from the Estates and Information Technology departments was obtained. The ceiling-mounted bridges were installed by the hospital Estates department using existing electrical wiring circuits to ensure compliance with local policies. The monitoring software was integrated with the hospital admissions data system, so that patients could easily be added to the remote monitoring system. All data are stored and retained on the hospital network, alleviating initial concerns about data security by inheriting all hospital security procedures and data backup policies.

General surgeons were informed of the project at local audit meetings. Nursing staff were trained to use the system face-to-face before the commencement of the study over a period of one week, after which ad hoc refresher training was available on request. This involved training in the application and removal of the patch, the use of the mobile application and how to acknowledge alerts. If the mobile devices alerted the nursing staff to abnormal vital signs, the ensuing clinical response was not mandated, but left to the nurse's discretion.

During daily ward visits, the fellow and the research nurse were responsible for changing expired patches and removing patches upon patient discharge. In order to optimise patient comfort and adherence with the device, it was also permitted to adjust or replace electrodes, including after patient washing.

3.3.9 Blinding

Blinding was not applicable for this study. Neither the patients nor the nursing staff could be blinded to the intervention received. The data collection was performed by a research nurse and clinical fellow, who were both administering the monitoring device, and so were necessarily unblinded. However, the objective methods of collecting the outcome data minimised the risk of bias. These data were taken from the clinical records made by the patients' usual care teams, including a succession of junior medical staff on rotation, who were unaware of the study. In addition, the predefined criteria for the outcome measures provided minimal scope for interpretation of their presence or absence by the data collection team. The clinical fellow performed the analysis supervised by an unblinded statistician.

3.3.10 Data collection

The patients were to remain in their allocated study arm for the duration of their hospital stay. If a remotely monitored patient was moved to a critical care bed during their admission, the remote monitoring was temporarily suspended pending reinstatement depending whether they returned to a participating ward. Every effort was made to ensure that participants remained in the study arm to which they were originally allocated, and any non-adherence was recorded.

Patients' participation in the trial ended when they were discharged from hospital. At this point, remotely monitored patients were invited to complete a questionnaire regarding their experiences of wearing the patch (see Chapter 4). Information regarding the admission was collected once the patient left hospital. Information was also collected regarding the number of patients who agreed to take part in the study, those who did not and their reasons for not taking part.

3.3.11 Primary outcome measures

3.3.11.1 Time to antibiotics in cases of sepsis

As described in Chapter 1, measuring the time to the administration of antibiotics after the detection of sepsis could go some way towards supporting the theory that increasing the frequency of vital signs monitoring will reduce the delay between the onset of patient deterioration and the initiation of treatment. Time to antibiotics in cases of sepsis was calculated as the time in minutes between the first evidence of sepsis on either or both monitoring tools and the first administration of antibiotics to the patient. Clinical suspicion of sepsis was 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:(6)

- 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

The decision to prescribe antibiotics was usually made by the junior doctor on the ward, based on local protocols and clinical discretion. The time to antibiotics was determined by review of the observations chart, the SensiumVitals® data, the electronic medications record and the medical notes of the patient during their hospital admission.

3.3.12 Secondary outcome measures

The secondary outcome measures were chosen in accordance with the existing literature on the topic, and due to their clinical relevance.

3.3.12.1 In-hospital mortality

Mortality was defined as the number of patients who died during their index hospital admission. This included deaths of any cause.

3.3.12.2 Number of HDU/ICU admissions

A post-operative HDU/ICU admission was defined as any admission to Level II/III care where admittance was from a participating ward following surgery. This excluded peri-operative admissions to critical care immediately after the surgical procedure.

3.3.12.3 Length of stay in HDU/ICU

The total length of stay in HDU/ICU in days during the hospital stay in which the index procedure occurred, and after admission to J44 or J45, was calculated as the difference in days between date of admission to either HDU/ICU and date of discharge from HDU/ICU. HDU and ICU lengths of stay were amalgamated into a total HDU/ICU length of stay, excluding any peri-operative critical care admission.

3.3.12.4 Total length of stay in hospital

The total length of stay in hospital in days was calculated as the difference in days between the date of admission and date of discharge. This included days spent in perioperative and postoperative critical care wards.

3.3.12.5 30-day readmission rate

The 30-day readmission rate was defined as the number of patients who were admitted to hospital for any reason within 30 days of discharge from their index admission, presented using the number of patients receiving on-trial monitoring as the denominator.

3.3.12.6 Patient acceptability and adherence

Patient adherence was determined by the proportion of patients not wearing a patch for at least 5 days. To assess acceptability, patients in the continuous monitoring group were asked to complete a short 2-question questionnaire. The patients were asked to rank the comfort and sense of safety they perceived from wearing the patch on a scale from 'Strongly Agree' to 'Strongly Disagree'. Patients were also invited to take part in a short face-to-face semi-structured interview during their admission. Patient acceptability is reported in Chapter 4.

3.3.13 Sample size and expected accrual

A formal sample size calculation was not possible given the lack of data surrounding the primary outcome measure, and so assumptions were used to calculate an appropriate sample size. A sample size of 325 was estimated as an appropriate target based on assumed eligibility rate (90%), consent rate (30-50%) and patient turnover (4 patients per bed per calendar month).

3.3.14 Planned analyses

Analysis was on an intention-to-treat basis at the individual patient level. The primary analysis included only the 6 randomised bays. The two non-randomised bays were included in a separate exploratory analysis. Each of the outcome measures was summarised by intervention or control group using descriptive statistics. As there was no formal sample size calculation, no statistical comparison between trial arms was made.

All analyses were performed using Microsoft Excel (Version 16.15, Microsoft, U.S.A.). All percentages were rounded to 1 decimal place. Means, medians, ranges and

standard deviations were summarised to one more decimal place than the data collected.

Baseline characteristics were summarised descriptively overall and by trial arm. No statistical comparison between trial arms was made.

Quantitative secondary outcome measures were summarised descriptively using appropriate summary statistics both overall and by trial arm (mean, standard deviation, range and median for continuous outcomes and frequency and percentages for categorical measures). Proportions of missing data are also presented. Data from patients discharged before the 5 days had elapsed was censored.

3.3.15 Exploratory analysis

The primary analysis included only the 6 randomised bays. The two non-randomised bays were included in a separate exploratory analysis.

3.3.16 Progression criteria

Although no formal progression criteria were defined in the protocol, considerations for the progression to a definitive trial were decided upon discussion with the CTRU statistician and based on relevant literature[83]. The progression criteria included:

- Recruitment rate (at least 325 patients within 9-month recruitment period)
- Protocol adherence (proportion of patients wearing the patch for at least 5 days)
- Suitability of primary outcome measure to inform sample size of definitive trial.

3.3.17 Data management

Personal data collection during the study was handled in accordance with the Data Protection Act 1998. All information collected during the course of the trial was kept strictly confidential.

Information was held securely on paper and electronically at Leeds Teaching Hospitals NHS Trust and the University of Leeds Clinical Trials Research Unit (CTRU). The study site maintained a file of essential trial documentation and kept completed case report forms (CRFs) for the trial.

All vital signs data collected by the SensiumVitals® system were stored and retained on the hospital network. The SensiumVitals® system inherited all the hospital security procedures and data backup policies, to ensure data access and servers were secured.

In line with the principles of Good Clinical Practice guidelines, at the end of the trial data was securely archived for a minimum of 5 years.

3.3.18 Data monitoring and validation

Statistical checks were used to validate the data and check for any missing or inconsistent data. Errors in data input were corrected on the database; otherwise, a query requesting clarification was sent to the study site. Details of corresponding changes were documented.

The final analysis report was prepared with input from the CTRU statistician and was reviewed by both the CTRU statistician and CTRU Scientific Lead.

3.4 Results

A total of 350 patients were included in the study between January and June 2017. A patient flow chart is presented in Figure 7, and patient characteristics in Table 2.

There were 140 patients allocated to receive continuous monitoring alongside standard care. There were 86 patients randomised to the control group. A further 124 patients from non-randomised bays were included in the exploratory analysis.

Two patients in the control arm (both from randomised bays) were given the continuous monitoring intervention at the request of the direct care team.

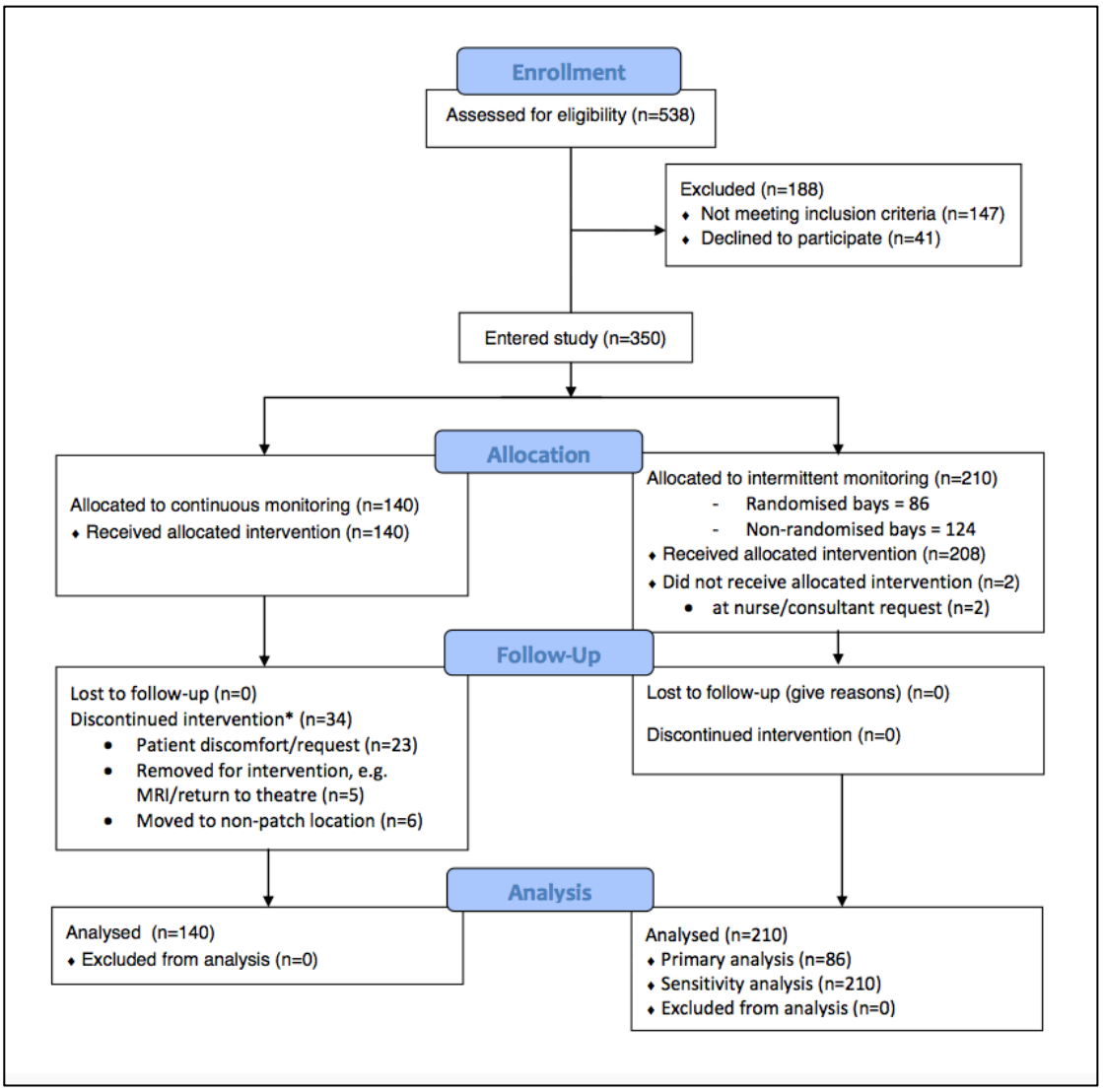

Figure 7: CONSORT flow diagram for the trial

73% of patients (n=253) underwent a surgical intervention during their admission. These were mostly colorectal resections (n=132), stoma formations (n=23), stoma reversals (n=12), hernia repairs (n=20) and other colorectal laparotomies including fistula exploration (n=23). Less common procedures were hepatobiliary (n=14), urological (n=9), appendicectomy (n=7) and abdominal wall repair (n=5). 8 procedures were classified as Other.

There were a similar number of complications and sepsis events across both arms of the study (see Table 3), indicating that both groups had similar baseline risk factors.

One patient died of alcoholic liver disease during their participation in the study. This patient was allocated to receive continuous monitoring.

		SensiumVitals® + Intermittent monitoring *(n=140)*	**Intermittent monitoring alone** *(n=86)*
Males		76 (54.3%)	39 (45.4%)
Females		64 (45.7%)	47 (54.6%)
Age (mean)		65.2 years (range 24-94)	63.7 (range 21-92)
ASA			
	1	9 (6.4%)	9 (10.5%)
	2	62 (44.3%)	35 (40.7%)
	3	42 (30.0%)	22 (25.6%)
	4	3 (2.1%)	3 (3.5%)
	Not documented	24 (17.1%)	17(19.8%)
Emergency admissions		70 (50%)	44 (51.2%)
Elective admissions		70 (50%)	42 (48.8%)
Surgical intervention		103 (73.6%)	62 (72.1%)

Medical outliers	19 (13.6%)	14 (16.3%)

Table 2: Baseline patient characteristics

	SensiumVitals® + intermittent monitoring *(n=140)*	**Intermittent monitoring alone** *(n=86)*
No. patients with complications (all*)	102 (72.9%)	57 (66.3%)
Anastomotic leak	1	1
Bowels not opened	7	5
Chest pain	3	2
Confusion	3	1
Electrolyte disturbance	8	2
Increased stoma output	1	2
Loose stools	3	0
Nausea and vomiting	10	8
Pain	4	5
Pyrexia	5	1
Sepsis	24	12
Rectal bleeding	1	2
Respiratory complication	3	4
Stroke	1	0
Urinary tract infection	5	2
Wound complication	3	3
Other	18	7
No. patients with major complications (Clavien-Dindo >2**)	8 (5.7%)	5 (5.8%)
Sepsis events	24 (17.1%)	12 (14.0%)
Intra-abdominal collection	4	0
Ischaemic bowel	1	0
Venous access infection	1	1
Respiratory tract infection	3	3
Urinary tract infection	2	1
Wound infection	5	2
Unknown source	7	4
Other	1	1

*All complications includes any deviations from the normal post-operative course.

** A Clavien-Dindo score >2 indicates that that the complication required critical care admission or further surgical/radiological intervention, or resulted in death.

Table 3: Complication rates between intervention and control arms

3.4.1 Primary outcome measure

The main results of the study are summarised in Table 4. In the intervention arm, 17.1% of patients (24 out of 140) experienced a sepsis event; this figure was 14% (12 out of 86 patients) in the control arm. Of the 36 sepsis events recorded in randomised bays, there was sufficient data to analyse the time to antibiotics in 34 cases; in two cases the time of antibiotic administration was not documented. The average time from the first evidence of sepsis to the first administration of antibiotics was 626 minutes in the intervention group (n=22, 95% CI 431.7-820.3 minutes). The average time to antibiotics in the control group was 1012.8 minutes (n=12, 95% CI 425.0-1600.6 minutes) (see Figure 8). Wide confidence intervals suggest these differences are not statistically significant. Of the 36 sepsis events, 34 cases were triggered by derangements in heart rate, respiratory rate and/or temperature: heart rate alone (n=1); temperature alone (n=1); heart rate and temperature (n=23); respiratory rate and temperature (n=2); heart rate, respiratory rate and temperature (n=7); unknown (n=2).

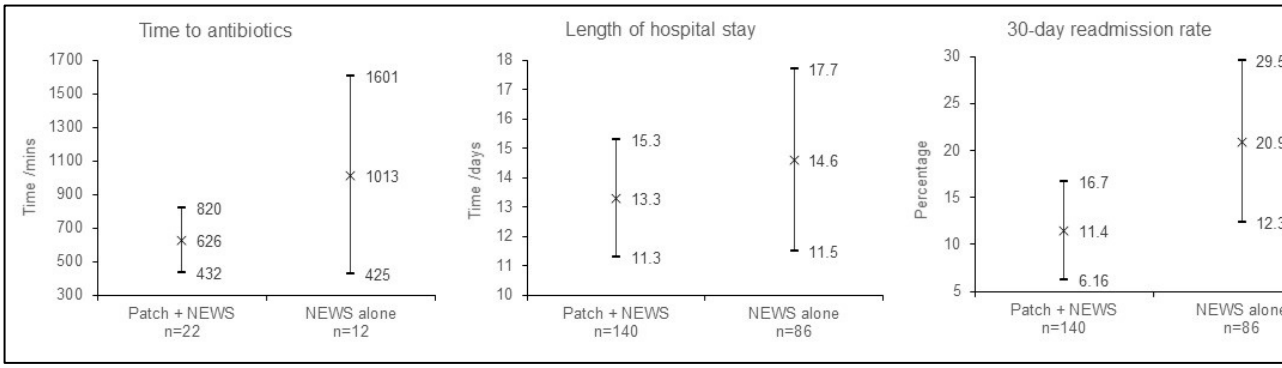

Figure 8: Scatter graphs to show mean (x) and 95% confidence intervals between trial arms for time to antibiotics in sepsis, length of hospital stay and 30-day readmission rate.

	SensiumVitals® + intermittent monitoring *(n=140)*	**Intermittent monitoring alone: randomised bays only** *(n=86)*	**Intermittent monitoring alone: including non-randomised bays** *(n=210)*
Sepsis events	24 (17.1%)	12 (14.0%)	33 (15.7%)
Time to antibiotics in cases of sepsis Mean (95% confidence interval)	n=22 626.0 minutes (95% CI 431.7-820.3)	n=12 1012.8 minutes (95% CI 425.0-1600.6)	n=32 900.0 minutes (95% CI 621.6-1178.4)
Level II/III admissions (95% confidence interval)	3 (2.1%) (95% CI 0%-4.54%)	2 (2.3%) (95% CI 0%-5.51%)	5 (2.4%) (95% CI 0.319%-4.44%)
Length of stay in hospital Mean (95% confidence interval)	13.3 days (95% CI 11.3-15.3)	14.6 days (95% CI 11.5-17.7)	15.5 days (95% CI 10.1-20.9)
Readmissions (95% confidence interval)	16 (11.4%) (95% CI 6.16%-16.7%)	18 (20.9%) (95% CI 12.3%-29.5%)	38 (18.1%) (95% CI 12.9%-23.3%)
Inpatient deaths	1 (0.7%)	0 (0%)	0 (0%)

Table 4: Summary of outcome measures

3.4.2 Secondary outcome measures

There were very few inpatient deaths (n=1) and admissions to Level II/III care (n=5) across both arms of the study. Length of hospital stay was on average 1.3 days shorter in patients who had continuous monitoring (13.3 days, 95% CI 11.3-15.3 days

versus 14.6 days, 95% CI 11.5-17.7 days). The rate of readmissions within 30 days of discharge was lower in the continuous monitoring group (11.4%, 95% CI 6.16%-16.7% versus 20.9%, 95% CI 12.3%-29.5%) (see Figure 8).

Patients in the continuous monitoring group wore the patch for an average of 5 days (range 1-24 days). Of the 142 patients who wore the monitoring patch, 34 had the continuous monitoring discontinued early (see Figure 7); 23 of these were at patient request. Two patients developed a rash under the electrodes. Eighteen patients found it itchy or bothersome. Three patients did not offer a reason for removing the patch.

58 out of 140 (41%) patients in the continuous monitoring group returned a short questionnaire. The number of returned questionnaires was limited to those patients who were discharged during the working hours of the researchers. The results from the questionnaires are described in Chapter 4.

3.4.3 Exploratory analysis

When the two non-randomised bays were analysed alongside the six randomised bays, the results were very comparable with narrower confidence intervals (Table 4).

3.4.4 Progression criteria

In the pilot trial, 350 patients were recruited within 7 months, which is well within the recruitment target. Adherence to protocol was acceptable; 75.7% of patients in the intervention arm (106 out of 140 patients) wore the patch for at least 5 days.

The low rate of sepsis events across both arms of the study has meant that the confidence intervals around the mean time to antibiotics are wide, and it has not been possible to accurately estimate the inter-cluster correlation coefficient for this endpoint from the study data. As such, it is unlikely that the time to antibiotics in cases of sepsis

is a suitable outcome measure to inform the sample size of a definitive trial using the same protocol.

3.5 Discussion

In this single-centre randomised controlled pilot trial, surgical patients with evidence of sepsis tended to receive antibiotics faster if they received continuous vital signs monitoring when compared to those receiving usual intermittent monitoring alone. Patients receiving continuous vital signs monitoring had a shorter average length of hospital stay and were less likely to require readmission within 30 days of discharge.

The findings must be interpreted within the limitations of the study. This was a single-centre study, and the findings may not be generalisable to other settings. A formal sample size calculation was not possible given the lack of data surrounding the primary outcome measure and so the findings were limited to descriptive statistics; no formal statistical comparison was possible[84]. Although the wide, overlapping confidence intervals suggest that a statistically significant difference between the two groups is unlikely, with a larger sample size and increased study power it is possible that the observed trends might become statistically significant. In addition, the relatively small number of sepsis cases means there is likely to be imbalance in pre-randomisation variables, which would require adjustment in a formal analysis.

There were very few cases of inpatient mortality or admission to Level II/III care, making comparisons between the monitoring arms difficult. One explanation for this low event rate is that the population contained a high proportion of low-risk patients: medical outliers and those who did not undergo surgery during their admission. A more striking effect might be evident in a higher-risk population.

The limitations of the randomisation technique must also be taken into account. Ideally, the study data would have been analysed at cluster level, but small numbers of patients within each bay necessitated analysis at the individual level. The cluster-randomisation methodology led to differences in the baseline demographics of the treatment arms. One of the female bays allocated to receive continuous monitoring had a proportionally lower turnover of patients than the other bays. This led to an imbalance in the male: female ratio between the two arms. The fact that the control arm was, on average, 1.5 years younger than the treatment arm may have conferred an advantage to this group. There is also uncertainty surrounding whether cluster-randomisation was necessary; it is unclear whether clustering existed and, if it did, the magnitude of the clustering present is unknown. Two ward bays could not be randomised because they did not have the required hardware installed, which limited the use of data from the patients in these bays.

The potential benefits of continuous monitoring may have been underestimated in this study due to the exposure to the patch in the intervention arm. 24% of the patients who were allocated to receive continuous monitoring did not wear the patch for their entire admission. However, this may reflect what can be truly expected in the clinical environment. There were other challenges to implementing the technology. There was initially an unacceptably high number of alerts, as reported by the nursing staff. These were reduced by 90% by adjusting the alarm thresholds to more clinically appropriate levels and increasing the intervals between reminder alerts. Engagement with the new system varied between nursing staff but was aided by support from senior ward nurses. Engagement was further increased with the implementation of changes suggested by the nursing staff themselves, such as smaller devices and louder alert tones.

Many of the limitations of the study have resulted from the pragmatic nature of its design. In order to make the results of the trial applicable to the ‘real world’ clinical environment, the eligibility criteria were broad and did not limit participants to those with

certain characteristics (such as those undergoing high-risk surgeries, or those expected to be highly adherent with the intervention). The cluster-randomised design was chosen to make the trial easy for the nursing staff; it was deemed much easier to remember that certain bays were continuously monitored than individual patients. Patients were free to remove the remote monitoring device when they wished, and were not offered any incentives to remain adherent with the intervention. Other than a research nurse, no additional staff were employed on the participating wards during the trial, so the nursing staff had to fit the intervention into their standard work practices. In addition, there was no mandated response to alerts, so that the nursing staff could respond as normal to the deteriorating patient.

The pragmatic nature of the study is reflected in the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) wheel [80] (Figure 9). This tool ranks nine trial design domains (eligibility, recruitment, setting, organisation, delivery flexibility, adherence flexibility, follow-up, primary outcome and primary analysis) from 1 to 5 in order to enable trialists to more easily determine if the trial design matches its intended purpose. Figure 3 illustrates that the cluster-randomised study is very pragmatic, with all domains scoring 4 or 5. Domains scoring 4 included: eligibility, due to the fact that only patients with the capacity to consent were included; setting, due to the single-site design; organisation, due to the provision of a research nurse to support the ward staff with the intervention; delivery flexibility, due to the presence of the clinical fellow who was able to change alert settings at the nurses' request; and primary analysis, due to the exclusion of the non-randomised bays from the primary analysis.

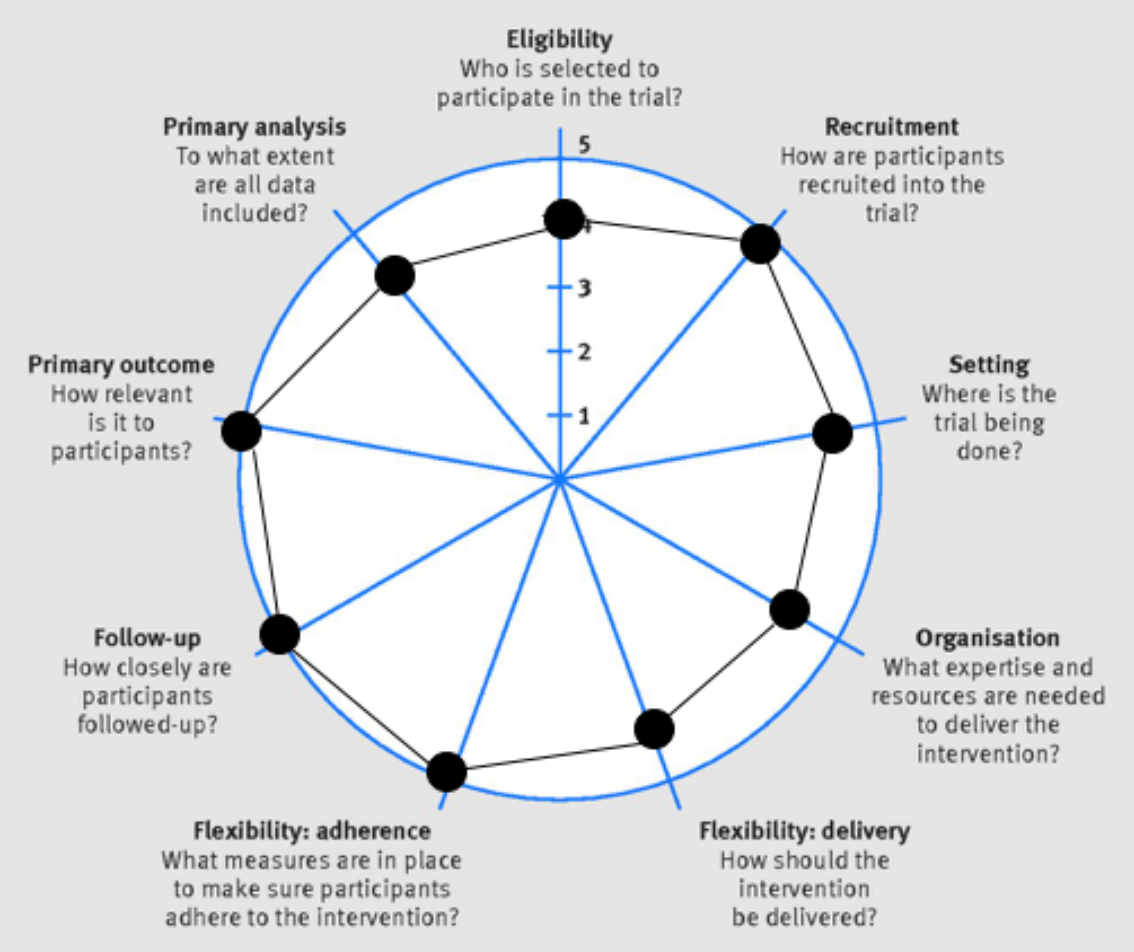

Figure 9: PRECIS-2 wheel for the cluster-randomised study

The limitations of the study therefore have to be balanced against the value of its pragmatic design. A more explanatory approach could eliminate some of the limitations seen in this study, at the expense of its applicability to the 'real world.' In addition to consideration of the progression criteria, these reflections have helped to guide the further evaluation of CRM.

Recruitment, protocol adherence and follow-up are the most common areas of deficiency in pilot trials[83]. Although no formal progression criteria were defined in this pilot study, recruitment and follow-up were excellent, and protocol adherence was acceptable. The incidence of clinically relevant complications, however, indicates that progression to a definitive multicentre trial utilising the same design may not be appropriate. This does not indicate the unfeasibility of the trial, but rather highlights

changes that are required to be made to the protocol and that a further feasibility trial needs to be undertaken before moving to a definitive trial.

In conclusion, this study has demonstrated the practicability of implementing a remote continuous monitoring system in the general surgical ward setting. There is a trend towards clinical benefit. The findings of this study will be used to inform the protocols for further evaluations. Follow-up studies could be individually-randomised and stratified to minimise the baseline differences between the two treatment arms and include a high-risk population with a high rate of adverse events to optimise the clinical evaluation of the intervention. Rare outcomes will be avoided in preference of endpoints that are common to all participants, such as length of hospital stay. Care will also be taken to monitor inadequacies in other areas that might negate the potential benefit of additional monitoring, such as staffing levels, escalation protocols and nursing adherence[85].

4 Patients' experiences of remote continuous vital signs monitoring

A remote patient monitoring system is a complex healthcare intervention; the success of such systems is influenced by the technology, the users and the environment. The small number of quantitative studies in the field of remote monitoring show mixed results. It is possible that the success of these technologies is context-dependent, and reliant on effective engagement with the technology by the patients. In this chapter, we report the findings of questionnaires, semi-structured interviews and focus groups with patients. The aim was to investigate patient perceptions of current monitoring practices and the introduction of continuous monitoring devices on general surgical wards, in order to inform future implementations of this technology.

4.1 Background

Healthcare technology assessment (HTA) refers to the systematic evaluation of properties, effects and impacts of health technology[86]. The efficacy of healthcare technologies is commonly confirmed through carefully designed prospective clinical trials. These are often driven by the collection of quantitative evidence to determine the clinical and cost effectiveness of a health technology[87].

There is growing emphasis on providing patient-focused health care and ensuring patient involvement in the design of health services[87]. In the literature review discussed in Chapter 1, patient satisfaction was found to be given limited consideration. Although a number of studies briefly mention the comfort of the monitoring devices being tested, only one included patient satisfaction as an *a priori* outcome measure[17]. Out of 25 patients surveyed, 22 felt positively about continuous monitoring because it gave them a sense of 'security,' whilst other patients found the monitors to be restrictive or uncomfortable. The results of this study are limited by the

small sample size and the patient selection criteria (the patient group was limited to those with lower acuity illness) but highlight the importance of considering the patient's experience of continuous monitoring. This is particularly important to avoid issues with compliance such as those seen by Watkinson *et al*.[55], where only 16% of the patients were continuously monitored for the full 72 hours intended. Consideration of patients' experiences throughout can provide universal benefit through the enhancement of patient safety and satisfaction, and more work is required in this area.

Robust evidence eliciting participants' perspectives can be obtained through social science research[87]. In this study, a mixed methods approach was chosen to optimise patient participation and elicit rich data from a variety of sources[88]. A questionnaire encourages high participation rates and allows the participant anonymity, but does not allow discussion outside of the set questions[89]. Face-to-face interviews allow sensitive issues to be raised in confidence[88]. The focus group forum encourages participation from groups who may be uncomfortable with individual interviews and capitalises on the free flow of discussion and debate between participants[90].

The aim of this chapter was to investigate patient perceptions of current monitoring practices and the introduction of continuous monitoring devices on general surgical wards, in order to optimise participant engagement and satisfaction with the ultimate goal of expediting the delivery of effective, proven healthcare technologies to the public.

4.2 Methods

4.2.1 Ethical approvals and consent to participate

Research Ethics Committee approval was obtained for this study (REC reference 16/YH/04/26) and written consent was gained from patients.

4.2.2 Study design

Questionnaires, semi-structured interviews and focus groups were undertaken with patients participating in the cluster-randomised controlled study evaluating the SensiumVitals® remote continuous monitoring device (the "patch") on two surgical wards at a single large teaching hospital in England. The methods and quantitative findings of this study are described in Chapter 3.

The purpose of the questionnaires, interviews and focus groups was to glean information about patient experiences of their vital signs monitoring, with particular emphasis on their experiences of intermittent NEWS monitoring and the CRM device.

4.2.3 Data collection

4.2.3.1 Questionnaires

All patients in the continuous monitoring group were asked to complete a short 2-question questionnaire at the bedside during their hospital admission. The patients were asked to rank the comfort and sense of safety they perceived from wearing the patch on a scale from 'Strongly Agree' to 'Strongly Disagree'.

4.2.3.2 Interviews

Participants were recruited during their hospital admission using purposive sampling from those patients who were randomised to the patch arm of the study. We aimed to interview a range of patients including both sexes, different ages and different durations of monitoring. A sample size of 10-15 participants was anticipated based on similar existing studies[91,92] and the researchers' previous experiences.

Interviews were conducted over a 6-week period, face-to-face, at the patient's hospital bedside. The interviewer used a pre-determined topic guide, informed by *a priori* theories developed through informal interactions with patients and ward staff during the day-to-day management of the randomised controlled study. However, data collection was an iterative process and, as recurring concepts emerged, these were added to the interview guide for exploration with remaining participants. Interviewing stopped when data saturation was reached.

4.2.3.3 Focus groups

Participants were recruited after their hospital admission using purposive sampling with the aim to interview a range of participants across including both sexes, different ages and different durations of monitoring. Participants were permitted to bring a friend or family member to support them if they wished. It was aimed to recruit a sample size of 10-20 participants based on existing literature[88,90], the researchers' previous experiences and space considerations at the venue.

Four focus groups were conducted over a single day, face-to-face, at the hospital site. The interviewer used a pre-determined topic guide, informed by *a priori* theories developed by the clinical fellow through literature searching and informal interactions with patients and ward staff during the day-to-day management of the randomised controlled study.

All interviews and focus groups were audio recorded, transcribed verbatim and anonymised. The transcripts were then entered into the software package NVivo 10 for organising and analysing the data.

4.2.4 Analysis

The questionnaires were analysed quantitatively using Microsoft Excel (Version 16.15, Microsoft, U.S.A.). Transcripts of the interviews and focus groups were analysed using Braun and Clarke's thematic analysis, as it provides a rigorous and well-recognised method of analysing qualitative data[93]. First, the data were analysed by reading and searching the transcripts for common attitudes and experiences between participants. Emergent themes were coded, and the codes applied line-by-line to the transcripts. The data were then systematically reviewed to ensure the themes worked in relation to the coded extracts. Codes were then independently verified by RR. Any discrepancies in application of codes to the transcripts were discussed until agreement was reached between the clinical fellow and the other researcher.

4.3 Findings

4.3.1 Questionnaires

58 out of 140 (41%) patients in the continuous monitoring group returned the short questionnaire. As previously stated, the number of returned questionnaires was limited to those patients who were discharged during the working hours of the researchers. The results are shown in Figure 10 and Figure 11. 82% of patients found the patch to be comfortable (35 responded 'Strongly Agree'; 12 responded 'Agree'). 82% of the patients reported feeling safer whilst wearing the patch (24 responded 'Strongly Agree'; 22 responded 'Agree').

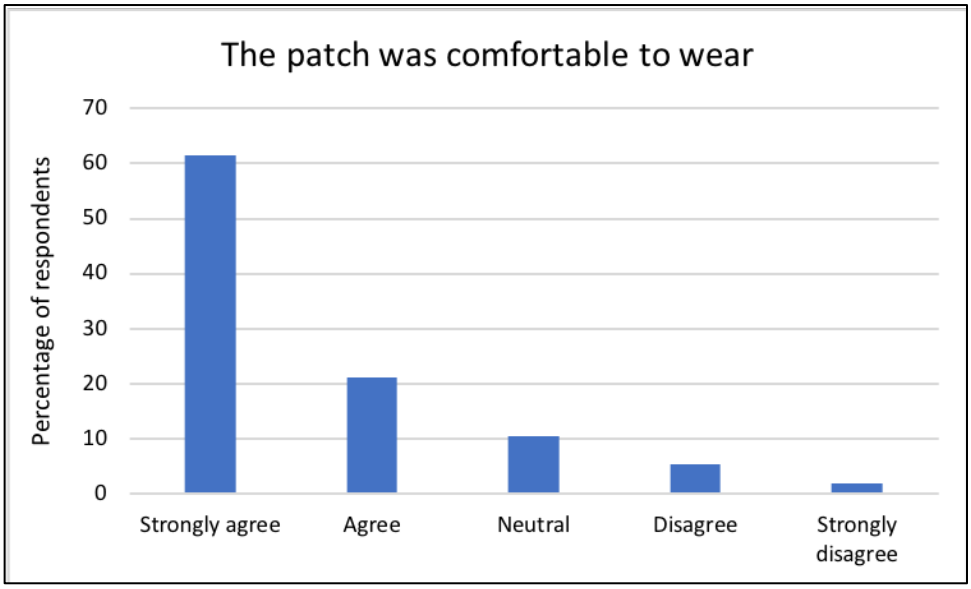

Figure 10: Graph to show participants' perceptions of comfort

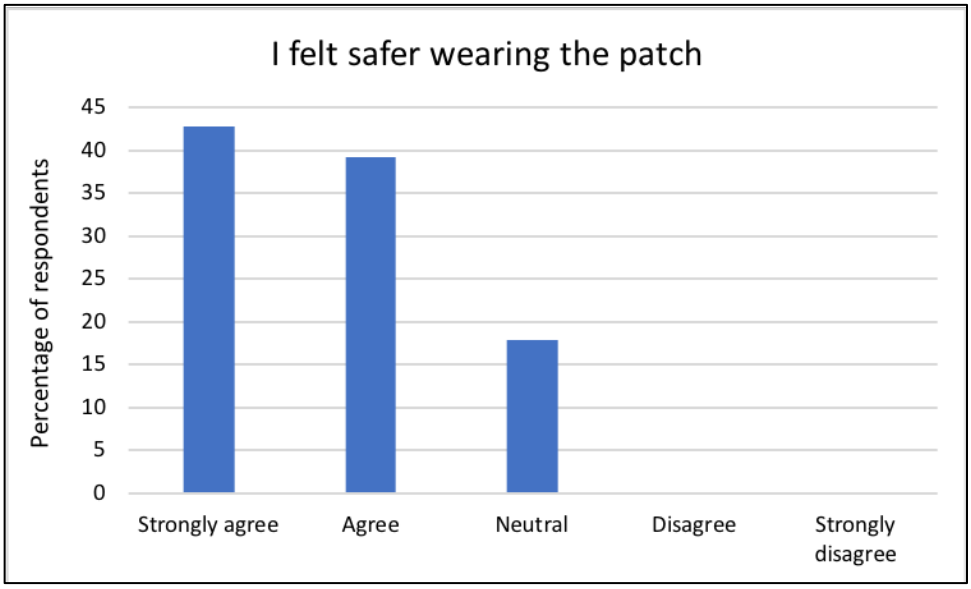

Figure 11: Graph to show participants' perceptions of safety

4.3.2 Demographics of qualitative studies

4.3.2.1 Interviews[2]

[2] The findings of the patient interviews have been published as Downey CL, Brown JM, Jayne DG, Randell R (2018). Patient attitudes towards remote continuous vital signs monitoring on general surgery wards: An interview study. *International Journal of Medical Informatics* **114C**: 52-56.

Twelve patients consented to be interviewed (see Table 5). Six patients were male; 6 patients were female. Their ages ranged from 42 to 83 years. The number of days spent in hospital at the time of interview ranged from 5 to 27 days, and the number of days spent wearing the patch at the time of interview was between 1 and 15 days. Interviews lasted between five and 45 minutes each.

Patient	**Sex**	**Age**	**Number of days spent in hospital***	**Number of days spent wearing patch***
1	Male	42	5	1
2	Female	73	9	8
3	Male	83	27	15
4	Female	82	13	9
5	Male	73	13	9
6	Male	63	11	2
7	Female	73	11	7
8	Female	74	22	5
9	Female	53	8	4
10	Male	81	7	4
11	Female	69	9	8
12	Male	55	7	5

Table 5: Demographics of interviewed patients
*at time of interview

4.3.2.2 Focus groups

Sixteen participants who participated in the SensiumVitals® pilot trial attended the focus groups (see Table 6).

Eight participants were male; 8 participants were female. Their ages ranged from 47 to 84 years. The number of days spent participating in the trial ranged from 3 to 12 days. Each focus group lasted 45 minutes.

Patient	Sex	Age	Number of days spent wearing patch
13	Male	63	6
14	Female	47	4
15	Male	79	6
16	Female	79	3
17	Male	84	5
18	Female	70	5
19	Female	72	3
20	Male	72	4
21	Male	76	3
22	Male	80	4
23	Female	67	3
24	Male	57	8
25	Female	79	3
26	Female	74	12
27	Female	67	4
28	Male	71	5

Table 6: Demographics of focus group participants

4.3.3 Themes from qualitative studies

Six main themes emerged from the transcripts of the interviews and focus groups: (i) importance of nursing contact, (ii) night time burden, (iii) comfort, (iv) sense of security, (v) staffing concerns and (vi) trust of technology.

4.3.3.1 Importance of nursing contact

Overall, patients reported positive experiences of vital signs observation rounds. Patients were keen to emphasise their appreciation of face-to-face nursing contact, and their concerns that remote monitoring might replace this.

> *"The only thing that passes my mind as well is, would you do without… that contact with the nurses, if you're going to be using this?" (Patient 1, Interview)*

Patients were keen to point out that face-to-face contact was necessary in addition to monitoring physiological numbers, as the latter can sometimes be misleading about a patient's state.

> *"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 and have a look at the patient. I just hope it doesn't get rid of nurses." (Patient 2, Interview)*

> *"When it comes to nursing, you can never replace that." (Patient 11, Interview)*

A number of patients expressed that the observation rounds provided much needed social interaction and relief of boredom.

> *"Oh [the nurses] were wonderful. They talked to me and they did help me. I'm quite a funny sort of person and we had a laugh even though I had pain. I like a lot of laughter." (Patient 8, Interview)*

> *"I think you'd get bored, really [without observation rounds]. You'd have nobody to talk to." (Patient 6, Interview)*

> *"I like them to come and see me… I like to have a chat with them." (Patient 5, Interview)*

> *"Patients like to talk to nurses." (Patient 14, Focus group)*

The importance of face-to-face interactions was also highlighted when patients reported using the observation rounds for reasons other than vital signs monitoring. Patients reported asking about "*my wound, going home, diet, things like that"* (Patient

2). Other patients mentioned pain and stoma management as topics they often discussed during observations.

> *"You talk to them and sometimes say to them, 'Well, what's going to happen?' and they'd be able to tell me things." (Patient 8, Interview)*

> *"When I've been in discomfort with my back or whatever, or I've needed a drink, I've asked then." (Patient 7, Interview)*

4.3.3.2 Night time burden

Eight of the 12 interview participants mentioned their irritation at being woken up for observation rounds.

> *"You're dozing off and then they come and take your blood pressure." (Patient 7, Interview)*

> *"I think it's too many times… especially if you're sleeping." (Patient 3, Interview)*

Several patients wondered if CRM could replace manual observations, if only overnight.

> *"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." (Patient 2, Interview)*

> *"I think it will be better just because they're not coming in in the middle of the night. Because then they wake you up all the time, and you end up knackered when you're trying to heal up." (Patient 1, Interview)*

> *"If they're sound asleep, then just leave them alone until the next opportunity!" (Patient 12, Interview)*

However, some patients mentioned that there were other things that kept them from sleep, such as noisy neighbours, bleeping machines, loud air conditioning and the fluorescent lights, and therefore they would have difficulty sleeping regardless of whether or not they were woken up for observation rounds.

> *"It [could] give you another hour's sleep, if you can get any sleep in hospital!" (Patient 23, Focus group)*

4.3.3.3 Comfort

An important issue for patients was that of comfort. Most of the participants found the patch so comfortable that they forgot they were wearing it.

> *"I don't know it's there. I keep thinking, 'What's that doing there?'" (Patient 5, Interview)*

> *"Put it on and forget all about it." (Patient 14, Focus group)*

Others described wearing the patch as inconsequential compared to other aspects of their care.

> *"It was the least of your problems." (Patient 28, Focus group)*

> *"It's just one of many things, sort of stuck on you." (Patient 23, Focus group)*

> *"I just took it like you wear your patient band [hospital identity wristband]. We're not in hospital because we're enjoying it." (Patient 20, Focus group)*

At interview, only one patient found the patch particularly uncomfortable. A number of focus group participants had further complaints.

> *"It feels heavy after a while." (Patient 9, Interview)*

"I had the patch, but I had to have it taken off because it irritated me." (Patient 26, Focus group)

"Every time [I] went to use the ablutions, to wash [myself], mine used to fall off!" (Patient 25, Focus group)

"For me, it didn't stick very well, so after two or three days I took it off anyway." (Patient 20, Focus group)

Whilst they had no complaints about comfort, two patients expressed concerns about the practicalities of wearing the patch.

"You have to be careful… not to knock this temperature one." (Patient 2, Interview)

"I wasn't sure if you could have a shower with one on or not." (Patient 12, Interview)

4.3.3.4 Sense of security

Although many forgot they were wearing the patch, most of the interview participants (11 out of 12) said that they felt safer wearing the continuous monitoring device. This was attributed to the knowledge that they were being monitored more frequently.

"Knowing that they are getting 2-minute updates on my heart and stuff – it's good." (Patient 11, Interview)

Similar views were expressed in the focus groups:

"I remember having to shout for someone because my buzzer had dropped on the floor and I couldn't reach it… You know that somebody… the nurses all sitting at the nurses' station, who are not near to you... they are getting the information without having to walk up and down the ward." (Patient 19, Focus group)

> *"It was the…relative, us, husband, partner, whatever… you're more at ease. You can go home and think, oh, they're still… being monitored… even without having a nurse there all the time." (Partner of Patient 14, Focus group)*

These opinions were particularly prevalent amongst the patients who had seen a consequence of wearing the patch, for instance, a nurse coming to check on them in response to an abnormal reading. Other patients believed the patch would help certain people more than others, *"particularly those that need a lot of monitoring,"* (Patient 9) or *"those that… need more attention"* (Patient 12). However, most patients believed it would benefit everybody.

4.3.3.5 Staffing concerns

This reported sense of security was often linked to concerns about staffing. Nursing staff were described as *"too busy"* (Patient 4) and *"on their feet all the time"* (Patient 2).

> *"I think [remote monitoring] is a very good idea because, you know, there just aren't so many nurses, and there are so many patients… you might not see one for a couple of hours or something, and something can happen in two hours." (Patient 11, Interview)*

Many patients expressed that they saw remote monitoring having the most value for nursing staff. Patients were aware of how busy the nurses were and so could appreciate the benefit of the patch in terms of freeing up nurses' time.

> *"Because of the ratio between patients and nurses, you know, it can be, like I say, a while before they come round. So this [indicating patch] is 24 hours, isn't it? They always know how you are." (Patient 6, Interview)*

> *"The nurses could get on with other things… so it saves time for them as well." (Patient 1, Interview)*

"They're so busy… they're on the go all the time. The advantage [of the patch] is that… they can use this gadget – they don't have to do as many visits, if you know what I mean, to your bedside. But they're always on hand anyway, so… You only have to press your button or give them a shout." (Patient 2, Interview)

4.3.3.6 Trust of technology

A number of patients expressed reservations about the reliability of the technology. One patient expressed concerns about data security. Others were more worried about system failure.

"Where you had some trust in the safety of the systems, obviously I think it would be good for everyone." (Patient 6, Interview)

"I know there's this thing about technology's taking over, but when it comes to nursing, you can never replace that. And then it's reliant on the wi-fi system, et cetera." (Patient 11, Interview)

"What happens if the phone goes down? Or the computers?" (Patient 22, Focus group)

However, the most common reason for mistrusting the technology was the lack of feedback, especially if no notifications were sent by the device.

"You could just feel, 'Well, how do I know this thing's looking after me?' without a physical contact." (Patient 6, Interview)

"We don't know what it does, do we? If it's working or not." (Patient 1, Interview)

4.4 Discussion

The aim of this chapter was to investigate patient perceptions of vital signs monitoring practices and the introduction of continuous monitoring devices on general surgical

wards, in order to inform future implementations of this technology. It was found that patients' experiences of manual observation rounds are generally positive, but they are perceived as burdensome for staff. They are also felt to be onerous for patients themselves at night. Remote monitoring can alleviate some of this burden, but cannot replace the benefits of face-to-face nursing contact.

These findings add novel information to the literature base. The only other study to include patient satisfaction as an *a priori* outcome measure also found that patients generally felt positive about continuous monitoring[17]. However, this study was limited by its short survey design and the patient selection criteria, which was restricted to less unwell patients.

In contrast, we were able to glean a wide variety of ideas by using multiple methods and employing an analytical process with the flexibility to include emergent categories and theoretical ideas in addition to *a priori* concepts. This allowed us to retain diversity in the analysis with respect for the uniqueness of individual cases, as well as finding comparative themes and patterns. The mixed methods approach had implications for the type of comments made and the way in which they were interpreted; for instance, interview participants were less likely to criticise the patch's comfort when compared to focus group participants. This may be due to the interactive nature of the group setting.

Nevertheless, the data from this study is limited to the context in which it was collected and may not be valid in other contexts. Themes such as comfort will only be applicable to this specific device, although it has wider implications for patient compliance across other technologies. While the number of participants was small, data saturation was quickly reached and the clinical fellow was satisfied with the recurrence of themes across a wide demographic.

The introduction of continuous monitoring on general wards is gaining increasing interest. It is tempting to consider such technology as a replacement for nursing contact; however, the importance of clinical acumen and experience cannot be overstated. This study confirms that patients share these perceptions and value the face-to-face nursing interaction of intermittent rounds.

From these findings it can be proposed that remote monitoring is introduced in a phased manner, and initially as an adjunct to usual care. Consideration should be given to replacing manual observations with remote monitoring at night, especially for low-risk patients. Attention to patient comfort and convenience should influence the design of wearable devices. Consideration of patients' experiences throughout can provide universal benefit through the enhancement of patient safety and satisfaction, and the optimisation of nursing time.

5 Trial of Remote Continuous versus Intermittent NEWS monitoring after major surgery (TRaCINg)

Evaluations of complex interventions require multiple phases in order to investigate common issues such as feasibility, acceptability, compliance, recruitment, retention and to estimate potential effect sizes. The results of the cluster-randomised trial reported in Chapter 3 have been used to inform the design of a further study to evaluate the use of continuous remote vital signs monitoring in the surgical population. In this chapter, we report the findings of a feasibility trial designed to determine the viability of performing a large-scale randomised controlled trial of continuous remote monitoring after elective major surgery, and to inform the design of a definitive evaluation.

5.1 Background

Demonstrating significant benefit to offset the practical and economic implications of continuous monitoring is difficult, and requires large, well-controlled studies to demonstrate significant differences in clinical outcomes. As per MRC guidance, the pilot trial described in Chapter 3 was conducted to evaluate common pitfalls[46]. The pilot trial demonstrated that, before a definitive trial is undertaken, there is the need for a further feasibility study focussed not only on clinical outcome measures but also patient and nursing acceptability and adherence. Adherence is unpredictable yet crucial to the adequate assessment of the intervention. If patient or nursing staff refuse to engage with the monitoring device, this would negate the need for a definitive trial. In addition, a feasibility study allows the identification of barriers to recruitment and protocol adherence, and optimisation of the definitive trial design and the technology itself.

The cluster-randomised pilot trial reported in Chapter 3 revealed a number of lessons, on which the following feasibility trial design is based. The heterogeneous population led to very few cases of inpatient mortality or admission to Level II/III care, making comparisons between the monitoring arms difficult. By targeting a high-risk population, the rate of adverse events is likely to be higher and a more striking effect of continuous monitoring might be evident which could be used to design the definitive trial. Traditionally, multi-phase evaluations of complex technologies move from explanatory to pragmatic studies[94]. By sampling only those patients who are expected to be highly responsive to the intervention, the feasibility study may become less pragmatic in its design, in order to determine the outcome measures of interest. This may make the findings less generalisable to certain populations, and care must be taken to report the results within the context of the specific population studied.

In the cluster-randomised study, patients were randomised according to the bay into which they were first admitted on the ward. This method was chosen for practicality, in that it would allow the nursing staff to easily determine which patients were continuously monitored. There was uncertainty surrounding whether cluster-randomisation was necessary, however; it is unclear whether clustering within bays exists and, if it does, the magnitude of the clustering present is unknown. The TRaCINg study will instead employ randomisation at the individual level, and include an assessment of clustering in one of the outcome measures.

Finally, the cluster-randomised study was affected by suboptimal patient adherence and limited engagement of the nursing staff with the technology. Since then, the devices have been modified to be smaller and lighter, with louder alert tones. The alert notifications have moved from an email system to an app to improve usability. Senior nursing staff have been invited to stakeholder meetings to improve engagement and diffuse support for the projects throughout the participating wards.

5.2 Aims

The main aim of the study was to determine the feasibility of performing a large-scale individually randomised controlled trial of CRM after major surgery. A secondary objective was to evaluate the potential safety, efficacy and acceptability of a wearable, remote monitoring system for patients after major surgery, as compared to standard monitoring with the NEWS system alone.

5.3 Methods[3]

5.3.1 Ethical approval and consent to participate

Ethical approval was granted on 10th October 2017 by the Yorkshire & The Humber – Leeds West Research Ethics Committee, ref: 17/YH/0180. Health Research Authority approval and approved study documents are included in Appendices 8 to 10. Informed consent to participate was obtained from all participants in the study. The study was registered on the ISRCTN registry (ISRCTN 16601772). No changes were made to the registered protocol. The trial was performed in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki, and is presented according to the CONSORT statement principles[81] and the CONSORT 2010 extension to randomised pilot and feasibility trials[95].

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[3] The following protocol has been previously described and published as Downey CL, Croft J, Buckley H, Randell R, Brown JM, Jayne DG (2018). Trial of Remote Continuous versus Intermittent NEWS monitoring after major surgery (TRaCINg): Protocol for a feasibility randomized controlled trial. *Pilot and Feasibility Studies* **4**:112.

5.3.2 Trial design

This was a single-centre, feasibility, randomised, controlled, parallel group trial of continuous remote vital signs monitoring for patients who had undergone major elective general surgery. Participants were individually randomised on a 1:1 basis to receive either remote monitoring plus NEWS or monitoring by NEWS alone. Randomisation involved the use of random permuted blocks and was stratified by ASA grade (American Society of Anaesthesiologists comorbidity score) and gender. The planned recruitment period was 12 months. Participant follow-up extended to 30 days after hospital discharge.

5.3.3 Study setting

All participants were recruited from St James's University Hospital, Leeds, United Kingdom. Potential participants were identified from colorectal surgery elective theatre lists. It was anticipated that approximately 80% of the patients undergoing surgery on these lists would return to the study wards.

5.3.4 Inclusion criteria

- Patients undergoing major elective abdominal surgery
- Patients with the capacity to provide informed, written consent on admission
- All ages ≥18 years

5.3.5 Exclusion criteria

- Patients undergoing emergency surgery
- Allergy to adhesives on electrodes
- Cardiac pacemaker in situ

5.3.6 Recruitment

Patients were selected on the basis that they were undergoing elective major abdominal surgery and were anticipated to return to one of the participating wards afterwards. Allowed surgeries included, but were not limited to, colorectal, upper gastrointestinal, liver, pancreas and biliary surgeries.

Patients were identified, recruited and consented for inclusion in the trial on the day of their surgery. This took place on the General Surgical Admissions Lounge where patients attend on the morning of their elective procedures.

The patients were given information in the form of a patient information sheet regarding the study. Following a period of consideration, if they consented to participate in the study they were randomised into one of two monitoring arms.

5.3.7 Randomisation

Following confirmation of eligibility and written informed consent, participants were randomised into the trial by an authorised member of staff at the research site. Randomisation was performed centrally using the University of Leeds CTRU 24 hour randomisation service, either via the telephone or the CTRU website.

Participants were randomised on a 1:1 basis and allocated a unique trial number. Randomisation was conducted using permuted stratified block randomisation with variable block size with sex (male/female) and ASA grade (grades 1-4) as stratification factors.

The randomisation sequence was provided by a statistician in the Leeds CTRU and computer-generated using SAS 9.4 (SAS Institute Inc., United States of America,

2013). This sequence was implemented and delivered by programmers through the Leeds CTRU Gen24 system, a dedicated telephone and web-based randomisation service.

5.3.8 Interventions

Patients randomised to the intervention arm received a SensiumVitals® remote monitoring patch and standard NEWS monitoring.

When the patient came out of theatre, they were nursed in Recovery for a short time before being admitted on to the receiving ward. The patients allocated to receive the remote monitoring, wherever possible, had the patch applied in Recovery by a member of the research team. If for any reason the patch could not be applied in Recovery, it was applied as soon as possible upon the patient's return to one of the participating wards. If a participant was admitted to Level II/III care after surgery and before returning to a participating ward, they had the patch applied in Recovery but the patch was only activated once the patient returned to the participating ward.

Two colorectal surgery wards participated in the study: male and female. The male ward housed 25 beds, whilst the female ward housed 28 beds.

The patch was activated on arrival to the ward and the patient's nurse carried a mobile device to alert them if the vital signs strayed outside of normal parameters. Remote monitoring data was also accessible on the ward computer screens for wider access. There was no dedicated telemetry screen for the patch data.

Nursing staff were provided with thorough training before the commencement of the study. This involved training in the application and removal of the patch, the use of the mobile application and how to acknowledge alerts. If the mobile devices alerted the

nursing staff to abnormal vital signs, the ensuing clinical response was not mandated, but left to the nurse's discretion within the boundaries of hospital protocols.

During daily ward visits, the fellow and the research nurse were responsible for changing expired patches and removing patches upon patient discharge. In order to optimise patient comfort and adherence with the device, it was also permitted to adjust or replace electrodes, including after patient washing.

Patients in the control arm received standard NEWS monitoring alone. All usual nursing and medical care were permitted within both arms of the trial.

5.3.9 Blinding

Blinding was not applicable for this study. Neither the patients nor the nursing staff could be blinded to the intervention received. The data collection was performed by a research nurse and clinical fellow, who were both administering the monitoring device, and so were necessarily unblinded. However, the objective definitions of the outcome data minimised the risk of bias. The predefined criteria for the outcome measures provided minimal scope for interpretation of their presence or absence by the data collection team. These data were taken from the clinical records made by the patients' usual care teams, including a succession of junior medical staff on rotation, who were unaware of the study. The clinical fellow performed the analysis alongside an unblinded statistician.

5.3.10 Data collection

The patients were to remain in their allocated study arm for the duration of their hospital stay. If a remotely monitored patient was moved to a critical care bed during their admission, the remote monitoring was temporarily suspended pending reinstatement depending on whether they returned to a participating ward. Every effort

was made to ensure that participants remained in the study arm to which they were originally allocated, and any non-adherence was recorded.

Patients' participation in the trial ended when they were discharged from hospital. At this point, remotely monitored patients were invited to complete a questionnaire regarding their experiences of wearing the patch (see Appendix 7). Information regarding the admission was collected once the patient left hospital. Information was also collected regarding the number of patients who agreed to take part in the study, those who did not and their reasons for not taking part.

The nursing staff (registered nurses and healthcare assistants) were invited to undertake a semi-structured interview regarding their experiences of providing the new monitoring system (see Chapter 6).

5.3.11 Primary outcome measures

5.3.11.1 Recruitment

Recruitment was determined by recording the number of patients considered, eligible, approached, consented and randomised. Recruitment rate was calculated as the number of patients randomised out of the number of patients eligible. The proportion of ineligible patients was calculated as the number of patients ineligible out of the number of patients considered. The proportion of patients who were classed as 'drop-out' by design (i.e. never being admitted to a participating ward) was calculated using the number of patients randomised as the denominator.

5.3.11.2 Assessment of randomisation

Assessment of the ideal method of randomisation included calculation of the intra-cluster correlation co-efficient (ICC) to investigate whether there was any inherent

clustering in outcomes based on which bay a participant was admitted to. ICC values range from 0 to 1. An ICC of 1 indicates that all participants in a cluster are identical. A small ICC value indicates that the within-cluster variance is much greater than the between-cluster variance[96].

The ICC was estimated from a one way analysis of variance (ANOVA) in Stata (Release 17, StataCorp, Texas, USA) using a cluster size of 7. This cluster size was chosen as it represents the mean number of patients in each bay (range 4-8).

5.3.11.3 Adherence to protocol

Adherence to protocol was defined as the number of patients who did not receive the correct type of monitoring as per randomisation and the number of patients who did not wear the patch for their entire hospital stay or at least five days during their admission. In addition, the closure time at surgery and the time and location of first patch application was also collected. The proportion of patients patched in Recovery was calculated and compared to the proportion patched on the wards. The time between the end of surgery and patch activation was calculated and summarised by patient risk (high- versus low-risk).

5.3.11.4 Amount of missing clinical data and loss-to-follow-up

The amount of missing data for a data item was calculated as the proportion of missing data for that item out of the number of patients randomised and admitted to a participating ward. Loss-to-follow-up took into account withdrawal and death. The proportion of participants withdrawing from the trial was defined as the number withdrawing at each level (from trial monitoring only, from further follow-up and from further data being collected from medical notes) out of the modified intention-to-treat population (see Section 5.3.14).

5.3.11.5 Optimal outcome measures to test effectiveness

This was determined by observing the secondary outcome measures (see below) such as time to administration of antibiotics in cases of sepsis, critical care admission rate and length of hospital stay and assessing their potential as primary outcome measures for the definitive study. Assessment of the optimal outcome measures considered the amount of missing data and summary statistics for each potential outcome.

5.3.11.6 Estimation of parameters to input into the sample size calculation for a definitive RCT

An estimation of the sample size for a definitive trial was calculated using a two-group Satterthwaite t-test of equal means and unequal variances using NQuery (Version 3.0, Statistical Solutions Ltd., Boston, USA). A range of sample sizes were calculated using the upper and lower limits of the 95% confidence intervals of both the ICC and the outcome measure of interest (length of hospital stay), to provide 80% and 90% power at 5% level of significance, allowing for 15% attrition.

5.3.12 Secondary outcome measures

5.3.12.1 Number of postoperative complications

Postoperative complications were defined as any complication occurring after the patient left the theatre complex and returned to a participating ward and before discharge from hospital. Complications were graded using the Clavien-Dindo classification[3]. Data on complications which occurred during HDU/ICU care was collected separately.

5.3.12.2 Number of reinterventions

Reinterventions were defined as the medical, radiological and surgical interventions required to treat postoperative complications. The proportion of patients receiving at

least one re-intervention was presented using the number of patients in the modified intention-to-treat (mITT) population as the denominator. The modified ITT population excluded any participants who were classed as 'drop-out' due to design, i.e. those who were never admitted to a participating ward (see Section 5.3.14).

5.3.12.3 Time to antibiotics in cases of sepsis

Time to antibiotics in cases of sepsis was calculated as the time in minutes between the first evidence of sepsis on either or both monitoring tools and the first administration of antibiotics to the patient. Clinical suspicion of sepsis was defined by the presence of a likely source of infection and two or more criteria from a collection of clinical signs and laboratory investigations as follows:(6)

- 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

5.3.12.4 Number of HDU/ICU admissions

A post-operative HDU/ICU admission was defined as any admission to Level II/III care where admittance was from a participating ward following surgery. This excluded peri-operative admissions to critical care immediately after the surgical procedure.

5.3.12.5 Length of stay in HDU/ICU

The total length of stay in HDU/ICU in days during the hospital stay in which the index procedure occurred, and after admission to participating ward, was calculated as the difference in days between date of admission to either HDU/ICU and date of discharge from HDU/ICU. HDU and ICU lengths of stay were amalgamated into a total HDU/ICU length of stay, excluding any peri-operative critical care admission.

5.3.12.6 Total length of stay in hospital

The total length of stay in hospital in days was calculated as the difference in days between the date of admission and date of discharge, including the first day of the admission. This included days spent in perioperative and postoperative critical care wards.

5.3.12.7 30-day readmission rate

The 30-day readmission rate was defined as the number of patients who were admitted to hospital for any reason within 30 days of discharge from their index admission, presented using the number of patients in the modified intention-to-treat population as the denominator.

5.3.12.8 Patient acceptability

Patient acceptability was determined by the data gathered in the patient questionnaire, and the number of patients not wearing a patch for at least 5 days out of all participants allocated to the continuous monitoring arm.

5.3.12.9 Nursing acceptability

Nursing acceptability was determined using a questionnaire and semi-structured interviews (see Chapter 6).

5.3.13 Sample size and expected accrual

As the trial was designed to assess the feasibility of conducting a future definitive large-scale trial, a formal power calculation was not considered appropriate as effectiveness is not being formally evaluated.

According to the findings of Teare *et al*.[97], at least 120 subjects (60 in each group) were required in the feasibility RCT to estimate event rates in binary endpoints in the intervention arm with adequate precision. It was anticipated that a binary endpoint, such as admissions to critical care, would be the outcome measure of interest; for continuous endpoints, however, a smaller sample of 70 participants (35 per group) would have been sufficient.

Anticipating an estimated consent rate of 30-50%, it was planned to approach between 240 and 400 patients in order to recruit 120 participants. In addition, it was possible that not all participants were assigned a bed in a participating ward. Allowing for 20% of patients going to non-participating wards, with the expectation that this was likely to be balanced between the study groups, this necessitated that 300 to 500 patients would need to be approached and approximately 150 participants randomised in order to have monitoring data on 120 participants in total. With a 12 month recruitment period, this equated to 6-10 patients being approached on average per week.

Patients who were not admitted to a participating ward were classed as ‘drop-out’ due to design, and were not included in the modified intention-to-treat analysis.

5.3.14 Planned analyses

Analyses were pre-specified in a statistical analysis plan. The analysis of the primary and secondary outcome measures was undertaken when all participants had been

followed up (i.e. 30 days after the last recruited participant's date of discharge). No interim analyses were planned or undertaken.

Analysis was carried out following the principles of modified intention-to-treat (ITT). The modified ITT (mITT) population included all participants randomised to the trial, analysed according to the treatment group to which they were randomised, regardless of adherence to the protocol. The modified ITT (mITT) population excluded any participants who were classed as 'drop-out' due to design (i.e. those who were never admitted to a participating ward).

Analysis was carried out in SPSS (Version 23.0 or later, IBM Corp., New York, USA), apart from the ICC calculations (Stata, Release 17, StataCorp, Texas, USA) and the sample size calculations (NQuery, Version 3.0, Statistical Solutions Ltd., Massachusetts, USA).

Unless otherwise stated, percentages were calculated using the total number of participants in the mITT analysis population as the denominator.

All percentages were rounded to 1 decimal place. Means, medians, ranges and standard deviations were summarised to one more decimal place than the data collected.

Baseline characteristics were summarised descriptively overall and by trial arm. No statistical comparison between trial arms was made.

As this is a feasibility study no formal comparison between the study arms was undertaken. Summaries were produced by prespecified subgroup to determine any differences between low- and high-risk patients. High-risk patients were defined as

ASA >2 undergoing Major+ surgery, or ASA =>2 with a perioperative critical care admission.

Quantitative secondary outcome measures were summarised descriptively using appropriate summary statistics both overall and by trial arm (mean, standard deviation, range and median for continuous outcomes and frequency and percentages for categorical measures). Proportions of missing data are also presented.

Qualitative secondary outcomes such as nurse acceptability were analysed using a thematic analysis approach (see Chapter 6).

5.3.15 Data management

Personal data collection during the study was handled in accordance with the Data Protection Act 1998. All information collected during the course of the trial was kept strictly confidential.

Information was held securely on paper and electronically at Leeds Teaching Hospitals NHS Trust and the University of Leeds CTRU. The study site maintained a file of essential trial documentation and kept copies of completed CRFs for the trial. Completed CRFs were sent to the CTRU for entry onto the secure trial database.

All vital signs data collected by the remote monitoring system were stored and retained on the hospital network. The monitoring system inherited all the hospital security procedures and data backup policies to ensure data access and servers were secured.

In line with the principles of Good Clinical Practice guidelines, at the end of the trial data was securely archived for a minimum of 5 years.

5.3.16 Data monitoring and validation

Day to day monitoring for completeness and quality of trial data was conducted centrally at the CTRU by the Data Manager or their delegate. Every effort was made to ensure that as much data as possible were available and that reasons for unobtainable data were recorded. For a feasibility study of this nature and duration, a separate Data Monitoring and Ethics Committee was not required.

The Data Manager (or their delegate) performed verification of the forms in real time, as data was received, in accordance with the guidelines developed for the study. This ensured that data were complete, consistent and up-to-date. Key data items were 100% checked by the Data Manager or their delegate. In addition, statistical checks were used to validate the data and check for any missing or inconsistent data. Errors in data input were corrected on the database; otherwise, a query requesting clarification was sent to the study site. Details of corresponding changes were documented.

The final analysis report was prepared by the clinical fellow with input from the CTRU Statistician and was reviewed by both the CTRU statistician and CTRU Scientific Lead.

5.3.17 Progression criteria

The pre-specified criteria to indicate that progression to a definitive randomised controlled trial would be feasible were:

- The recruitment of 120 patients within 12 months who received monitoring on the trial
- Missing data limited to no more than 20% attrition (drop-out by design, loss to follow-up or withdrawal from monitoring).

5.4 Results

136 patients were included in the study between October 2017 and April 2018. A patient flow chart is presented in Figure 12, and patient characteristics in Table 7.

Of the 173 patients assessed for eligibility, 24 were excluded prior to approach because they did not meet the inclusion criteria: ten patients went to theatre before approach; seven patients had a pacemaker; four patients were in source isolation; two patients lacked capacity; one patient was in a conflicting research trial. Of the 149 patients approached, 13 declined to participate because they did not want to be involved in research in general or because they felt too anxious about their impending surgeries.

Consent was obtained from 136 patients, all of whom were subsequently randomised. 67 patients were allocated to receive continuous monitoring alongside standard care. 69 patients were allocated to the control group.

Eleven patients were excluded from the modified intention-to-treat population. These were patients who had their surgery cancelled on the day (n=2: one participant per arm) or who did not return to a participating ward (n=9: six in the intervention arm, three in the control arm). The modified intention-to-treat population consisted of 60 participants in the intervention arm, and 65 participants in the control arm.

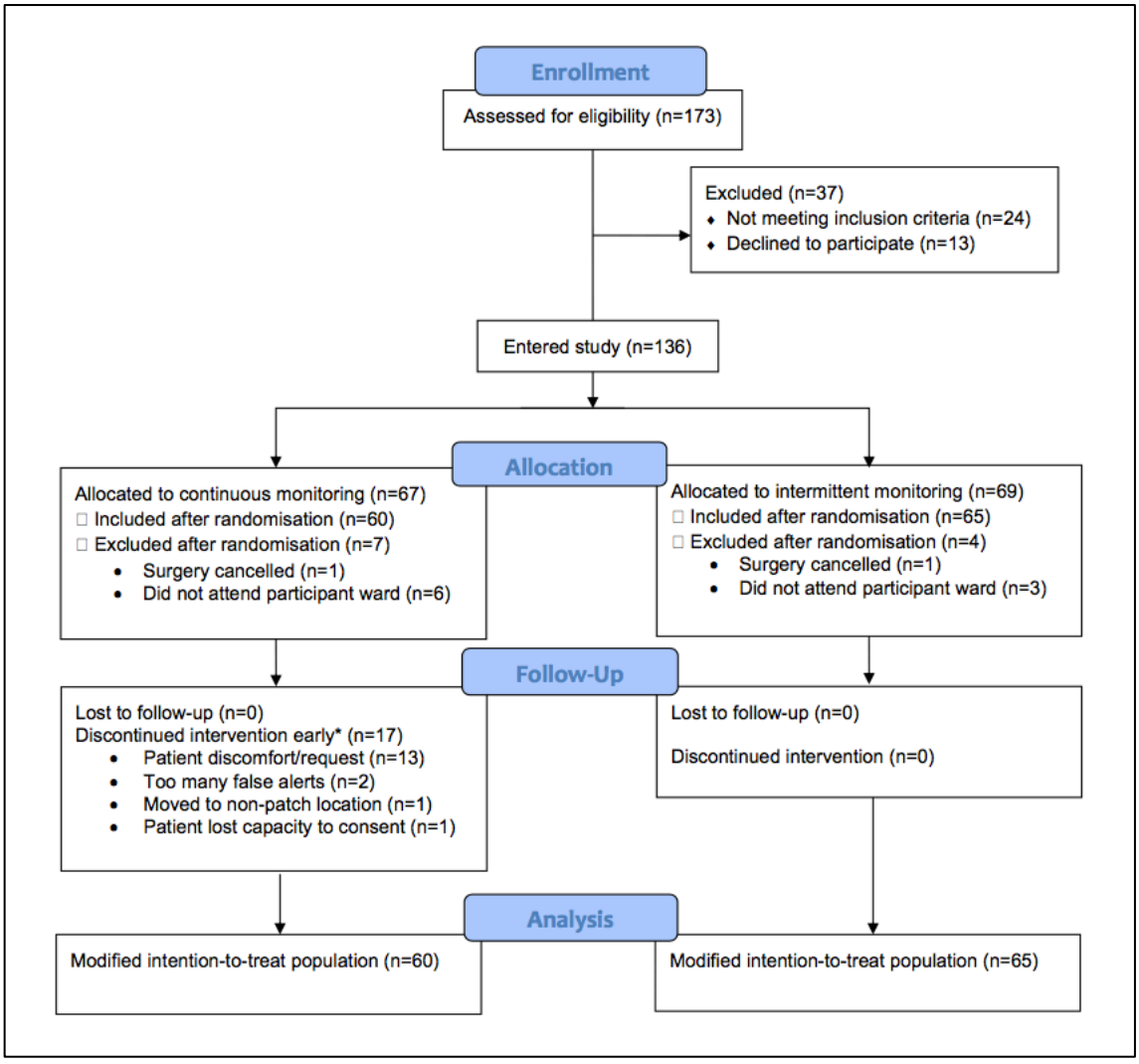

Figure 12: CONSORT flow diagram for the trial (*Early discontinuation of the intervention was defined as not wearing a patch for at least 5 days or until discharge from hospital).

The participant characteristics at baseline were well balanced across both arms of the study (Table 7). Both arms were similar in terms of the types of surgery the participants underwent, and the postoperative and perioperative complications they experienced (Table 8 and Table 9). Further details on the type of surgery undergone by the participants is presented in Appendix 6.

	NEWS alone n=65	SensiumVitals® + NEWS n=60	Total n=125
Males n (%)	35 (28.8%)	31 (24.8%)	66 (52.5%)
Females n (%)	30 (24.8%)	29 (23.2%)	59 (47.2%)
Age (mean, range)	62 (22 – 87)	65 (36 – 85)	63 (22 – 87)
ASA n (%)			
1	6 (4.8%)	4 (3.2%)	10 (8.0%)
2	40 (32.0%)	39 (31.2%)	79 (63.2%)
3	19 (15.2%)	17 (13.6%)	36 (28.8%)
4	0	0	0
Not documented	0	0	0

Table 7: Baseline patient characteristics

	NEWS alone n=65	SensiumVitals® + NEWS n=60	Total n=125
Type of surgery			
Colonic resection	55 (44.0%)	53 (42.4%)	108 (86.4%)
Small bowel resection	1 (0.8%)	3 (2.4%)	4 (3.2%)
*Other**	9 (7.2%)	4 (3.2%)	13 (10.4%)

Mode of surgery for colonic resections			
Laparoscopic	32 (25.6%)	32 (25.6%)	64 (51.2%)
Open	18 (14.4%)	17 (13.6%)	35 (28.0%)
Converted	3 (2.4%)	2 (1.6%)	5 (4.0%)
Assisted	2 (1.6%)	2 (1.6%)	4 (3.2%)
Other	0	0	0
Complications (intraoperative)	14 (11.2%)	13 (10.4%)	27 (21.6%)

Table 8: Intraoperative demographics (*see Appendix 6 for further details of type of surgery)

	NEWS alone n=65	**SensiumVitals® + NEWS n=60**	**Total n=125**
HDU admissions	22 (33.8%)	24 (40.0%)	66 (73.8%)
Planned	22	22	44
Unplanned	0	2	2
Patients experiencing perioperative complications	15 (23.1%)	13 (21.7%)	28 (44.8%)
Total complications CDC 1*	17	11	28
2	30	16	46

3a	0	0	0
3b	0	0	0
4a	0	1	1
4b	0	1	1
Highest complication CDC 1*	1	4	5
2	14	7	21
3a	0	0	0
3b	0	0	0
4a	0	1	1
4b	0	1	1

Table 9: Perioperative demographics (*CDC=Clavien-Dindo complication score)

5.4.1 Primary outcome measures

5.4.1.1 Recruitment

Recruitment figures are summarised in Table 10. The eligibility rate of all considered patients was 86.1% (13.9% of patients were ineligible). The recruitment rate was 91.3% out of those eligible. The proportion of patients who were classed as 'drop-out' by design was 8.1%. The trial recruited to target and ahead of time, as illustrated in Figure 13.

Number of patients considered	173
Number of patients eligible	149
Number ineligible	24
Reasons ineligible	
Lack of capacity	2
Allergy to adhesives	0
PPM	7
Source isolation	4
Already in a conflicting research trial	1
Surgery cancelled before approach	4
Patient went to theatre before approach	6
Number approached	149
Number consented	136
Number declined	13
Reasons declined	
Did not want to be involved in research	3
Patient anxious about surgery	10
Number randomised	136

Table 10: Summary of recruitment (PPM = permanent pacemaker)

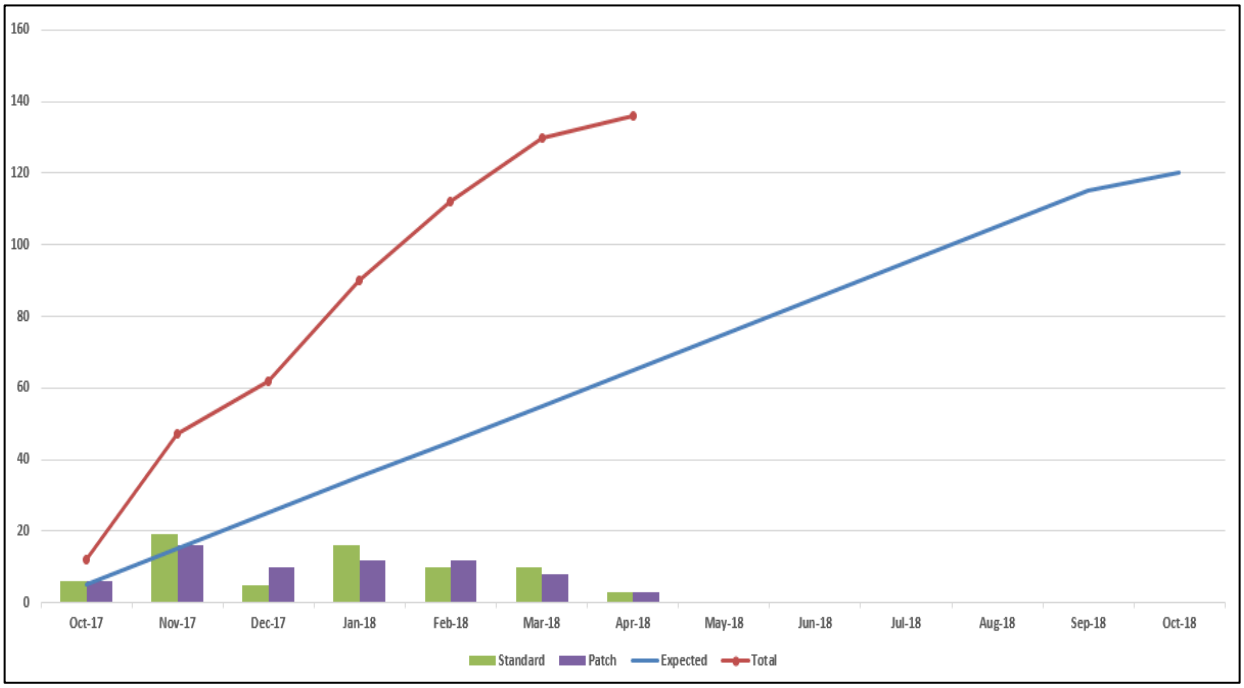

Figure 13: Graph to show recruitment to the trial over time

5.4.1.2 Assessment of randomisation

The intra-cluster correlation co-efficient was calculated based on 121 observations; participants who were transferred between different bays during their admission (n=3) were excluded from this analysis, as was the single participant who was withdrawn from the study (n=1). Length of hospital stay was chosen as the outcome measure of interest for this analysis for three reasons:

1) It is an outcome likely to be of relevance in a definitive study
2) There were likely to be data for every participant in the trial
3) Other potential candidates for the primary outcome in a definitive study were likely to exhibit too few events in the feasibility trial to calculate a meaningful ICC. This includes outcome measures such as readmission rates, time to antibiotics in sepsis and critical care admissions.

The ICC was found to be moderate (ICC= 0.06150, 95% CI = 0, 0.18839), indicating that the bay into which a participant was admitted had some effect on their length of hospital stay.

5.4.1.3 Adherence to protocol

Participants in the control arm were 100% adherent to protocol. From the intervention arm, 17 participants (28.3%) did not adhere to protocol. Eight participants (13.3%) did not receive the intervention at any point during their admission as they declined the patch after their return to the ward. Of note, 7 of the 8 participants who did not have the patch applied were categorised as high-risk. Nine participants discontinued the intervention before discharge and within 5 days of application. Reasons for this included patient discomfort or skin reaction (n=5), too many false alerts (n=2), transfer to non-participating ward (n=1) and incorrect assumption of imminent discharge (n=1).

The number of patients patched in Recovery was 11 (18.3%); the number patched on the participating wards was 41 (68.3%). The number of patients patched in Recovery was lower than anticipated, and was attributed to the short length of time patients typically spent in Recovery before being moved to the wards. The time between the end of surgery and patch activation is summarised by patient risk in Table 11. High-risk participants had a longer mean time to activation of the patch; this is because high-risk participants were more likely to have a planned admission to critical care before being admitted to a participating ward.

	High-risk participants	**Low-risk participants**	**Total n=125**
n (%)	22 (42.3%)	30 (57.7%)	52 (100%)
Mean time to activation of patch	5459 minutes	1636 minutes	3253 minutes
s.d.	6405 minutes	2507 minutes	4910 minutes
95% confidence interval	2782 – 8135 minutes	739 – 2533 minutes	1919 – 4588 minutes

Table 11: Time to activation of patch by risk subgroup in participants who received a patch (n=52)

5.4.1.4 Amount of missing clinical data and loss-to-follow-up

No participants were lost to follow-up. Eight participants from the intervention group did not receive the intervention at any time during their admission; these participants declined the intervention after their return to the ward. One participant was withdrawn from the study after they lost capacity to consent during their hospital admission; no further study data was collected after the participant lost capacity. Data up to the point of lost capacity has been included in the report. Missing data was limited to

questionnaire responses; 14 patients did not fill in the questionnaire as they left hospital before it could be administered.

5.4.1.5 Optimal outcome measures to test effectiveness

Assessment of the optimal outcome measures took into consideration the amount of missing data and summary statistics for each potential outcome. Two potential outcome measures displayed compelling differences between the two trial arms: rate of critical care admission and length of hospital stay (Table 16). There was no missing data for any of these outcome measures; however, data from the one withdrawn participant was censored at the time of withdrawal, forfeiting data regarding their length of hospital stay and any subsequent complications.

The length of hospital stay has a number of advantages as a primary outcome measure. Length of hospital stay data are available for every participant and, using the summary statistics from this feasibility study, shows a high likelihood of demonstrating effectiveness over intermittent monitoring alone. It is an outcome measure which has relevance to the individual, to society and to the healthcare system. Whilst a shortened length of hospital stay has no direct influence on an individual's quality of life, it is likely to benefit patients by reducing their exposure to hospital-acquired infections, venous thromboembolism, prescription errors and falls[98]. Shorter admissions also ensure more efficient use of hospital beds, which is particularly relevant in a healthcare system burdened by a changing population and increased demand for services[99]. In addition, reducing the length of hospital stays has direct cost consequences to the healthcare system which can be easily derived from available data[100]. However, the effect on length of hospital stay may not directly attributable to the intervention. Hospital admissions are influenced by a number of factors which are difficult to control for in a trial setting[99], and any influence may not necessarily be reflective of the success of the intervention. Well patients may, for instance, be kept in hospital whilst

awaiting a social care plan; this problem could be overcome by instead using the outcome measure, 'length of hospital stay until medically fit for discharge.'

In contrast, the rate of critical care admissions can more easily be attributed to the intervention as continuous vital signs monitoring is hypothesised to prevent the escalation of postoperative complications through early detection of physiological deterioration. Like length of hospital stay, this outcome measure has direct cost consequences. However, like time to administration of antibiotics in cases of sepsis and readmission rate, the event rate even in a high-risk population is likely to be low. The sample size would be inflated to reflect such a low event rate, increasing the costs of the trial as a whole. This does not necessarily preclude the rate of critical care admissions as the primary outcome measure, as recruitment is likely to be successful given the high consent rates in the feasibility study, and a small difference in critical care admissions has great potential value. Practically, it may be difficult to implement given that different hospitals have different admission and discharge criteria to critical care[101], and so the effect of clustering would have to be taken into account if critical care admission rate was to be used as the primary endpoint in a pragmatic definitive trial.

5.4.1.6 Estimation of parameters to input into the sample size calculation for a definitive RCT

Given the available data, estimation of the sample size range for a definitive trial was calculated using the observed effect sizes for length of hospital stay.

Based on the mean length of hospital stay from the feasibility study data and using the point estimate for the ICC, the target sample size for a definitive trial was calculated as at least 602 participants (301 per arm), which provides 80% power at the 5% significance level to detect a 2 day difference in length of hospital stay, allowing for

15% attrition. To provide 90% power, at least 808 participants would be required (404 per arm).

To provide 80% power, the sample size could range from 84 participants per arm (using the lower limit of the 95% confidence interval for the ICC and the upper limit of the 95% confidence interval for the chosen endpoint) to 3719 participants per arm (using the upper limit of the 95% confidence interval for the ICC and the lower limit of the 95% confidence interval for the chosen endpoint) (see Table 12).

To provide 90% power, the sample size could range from 111 participants per arm (using the lower limit of the 95% confidence interval for the ICC and the upper limit of the 95% confidence interval for the chosen endpoint) to 4978 participants per arm (using the upper limit of the 95% confidence interval for the ICC and the lower limits of the 95% confidence intervals for the chosen endpoint) (see Table 13).

		Design effect (DE)		
		Using lower 95% CI limit of ICC (ICC_{low} =0, DE_{low} =1)	Using ICC (ICC=0.06, DE = 1.36)	Using upper 95% CI limit of ICC (ICC_{upp} =0.2, DE_{upp} = 2.14)
Sample size calculation using length of hospital stay as primary endpoint	Lower 95% CI limits (LCI_C =11.3, LCI_T =9.5)	1738	2364	3719
	Mean (M_C =16.2, M_T=11.6)	222	301	474
	Upper 95% CI limits (UCI_C =21.2, UCI_T =13.7)	84	114	179

Table 12: Participants required per group to provide 80% power. ICC_{low} = lower limit of ICC, *ICC* = point estimate of ICC, ICC_{upp} = upper limit of ICC, DE_{low} = lower limit of DE, *DE*= point estimate of DE, DE_{upp} = upper limit of DE, LCI_C = control group lower limit, LCI_T = intervention group lower limit, MC= control group mean, MT= intervention group mean, UCI_C = control group upper limit, UCI_T = intervention group upper limit.

		Design effect (DE)		
		Using lower 95% CI limit of ICC (ICC_{low} =0, DE_{low} =1)	Using ICC (ICC=0.06, DE = 1.36)	Using upper 95% CI limit of ICC (ICC_{upp} =0.2, DE_{upp} = 2.14)
Sample size calculation using length of hospital stay as primary endpoint	Lower 95% CI limits (LCI_C =11.3, LCI_T =9.5)	2326	3164	4978
	Mean (M_C =16.2, M_T=11.6)	297	404	635
	Upper 95% CI limits (UCI_C =21.2, UCI_T =13.7)	111	151	237

Table 13: Participants required per group to provide 90% power. ICC_{low} = lower limit of ICC, *ICC* = point estimate of ICC, ICC_{upp} = upper limit of ICC, DE_{low} = lower limit of DE, *DE*= point estimate of DE, DE_{upp} = upper limit of DE, LCI_C = control group lower limit, LCI_T = intervention group lower limit, MC= control group mean, MT= intervention group mean, UCI_C = control group upper limit, UCI_T = intervention group upper limit.

5.4.2 Secondary outcome measures

5.4.2.1 Postoperative complications and reinterventions

There were more complications in the control arm than the intervention arm in every Clavien-Dindo classification group[3], as summarised in Table 14. This was especially evident in the number of participants experiencing major complications (Clavien-Dindo III or IV): 10 in the control arm (15.5%) versus 3 in the intervention arm (5.0%).

The proportion of participants receiving at least one re-intervention, as defined by the Clavien-Dindo complications classification, was 76.9% in the control arm and 80.0% in the intervention group (Table 14).

	NEWS alone n=65	**SensiumVitals® + NEWS n=60**	**Total n=125**
Number of complications (all)	180	124	304
I	85	59	144
II	82	62	144
IIIa	3	1	4
IIIb	5	1	6
IVa	3	0	3
IVb	2	1	3
Number of participants experiencing major complications (Clavien-Dindo >II)	13 (10.4%)	4 (3.2%)	17 (13.6%)
Number of reinterventions			

Medical	170	121	291
Radiological	3	1	4
Surgical	7	2	9
Total	180	124	304
Number of participants having at least 1 reintervention n (%)	50 (76.9%)	48 (80%)	98 (78.4%)

Table 14: Summary of postoperative complications and reinterventions

5.4.2.2 Time to antibiotics in cases of sepsis

From the modified intention-to-treat population, 35 participants were suspected of having sepsis at least once during their hospital admission: 16 from the control arm (24.6%) and 19 from the intervention arm (31.7%). Of these, sepsis was confirmed in 22 cases. 21 patients received antibiotics: 9 from the control arm (75%) and 12 from the intervention arm (52.5%). The sources of sepsis are summarised in Table 15.

Source of sepsis	**NEWS alone n=65**	**SensiumVitals® + NEWS n=60**	**Total n=125**
UTI	0	3	3
Anastomotic leak	2	0	2
Pneumonia	5	5	10
Wound	2	1	3
Collection	4	2	6

Table 15: Sources of confirmed sepsis (some participants experienced more than one source per sepsis event)

The mean time to antibiotics was 527 minutes in the control arm (range 56 – 1474 minutes, 95% CI 199 minutes, 856 minutes) and 551 minutes in the intervention arm (range 14 – 1165 minutes, 95% CI 296 minutes, 805 minutes).

In the intervention arm, 5 out of 19 events were first identified by the SensiumVitals® remote monitoring system (26.3%). The remaining events were first identified by the NEWS system.

5.4.2.3 HDU/ICU admissions

Six participants were admitted to HDU or ICU from a participating ward following surgery. Five participants were from the control arm with an average critical care stay of 3 days. One participant was from the intervention arm; their length of stay in critical care is unknown as they were withdrawn from the study due to lack of capacity (see Table 16).

5.4.2.4 Total length of stay in hospital

As shown in Table 16, participants in the control arm had a longer average length of hospital stay (16.2 days, 95% CI 11.3 days, 21.2 days) compared to those in the intervention arm (11.6 days. 95% CI 9.5 days, 13.7 days).

5.4.2.5 30-day readmission rate

Eleven participants (8.9%) were readmitted to hospital within 30 days of discharge from their index admission. Five were from the control arm (7.7%, 95% CI 2.5%, 17.0%)

and six from the intervention arm (10.2%, 95% CI 3.8%, 20.8%). All readmissions were emergency admissions.

	NEWS alone n=65	**SensiumVitals® + NEWS n=60**
Level II/III admissions		
n	5	1
Length of stay in Level II/III (days)		
Mean (s.d.)	3 (2.0)	* (.)
Length of stay in hospital (days)		
Mean (s.d.)	16.2 (20.3)	11.6 (8.2)
95% confidence interval	11.3 – 21.2	9.5 – 13.7
Readmissions**		
n (%)	5 (7.7%)	6 (10.2%)
95% confidence interval	2.5% - 17.0%	3.8% - 12.8%
Inpatient deaths	0	1

Table 16: Summary of critical care admissions, length of hospital stay, readmission rates and deaths (*the length of stay in Level II/III is unknown for this participant as they were withdrawn due to loss of capacity; **the denominator for readmissions was the total number of participants in each respective arm of the study; however, readmission data was not collected for the participant who was withdrawn from the study).

5.4.2.6 Subgroup analysis of secondary outcome measures

In the pre-specified subgroup analysis, the intervention arm had a higher proportion of high-risk participants (48.3%) than the control arm (41.5%) (Table 17).

Of the high-risk participants, those in the control arm experienced more unplanned critical care admissions, but fewer sepsis events than those in the intervention arm, as summarised in Table 11. High-risk participants in the control arm had a longer average length of hospital stay (23.3 days, 95% CI 12.4, 34.2 days) compared to those in the intervention group (15.7 days, 95% CI 11.9, 19.5 days), and were no more likely to be readmitted back to hospital within 30 days of discharge.

Subgroup analysis of low-risk participants revealed similar trends across all secondary outcome measures: lower rates of major complications, sepsis events and critical care admissions in the intervention group. Low-risk participants in the control arm had a longer average length of hospital stay (11.2 days, 95% CI 8.8, 13.7 days) compared to those in the intervention group (7.9 days, 95% CI 7.1, 8.6 days), but were less likely to be readmitted back to hospital within 30 days of discharge.

	NEWS alone: High-risk	**SensiumVitals® + NEWS: High-risk**	**NEWS alone: Low-risk**	**SensiumVitals® + NEWS: Low-risk**
n (%)	27 (41.5%)	29 (48.3%)	38 (58.5%)	31 (51.7%)
Number of complications (all)	91	70	89	54
Number of major complications (Clavien-Dindo >2)	8	3	5	0

Sepsis events n (%)	8 (29.6%)	12 (41.4%)	8 (21.1%)	7 (22.6%)
Time to antibiotics in cases of sepsis (minutes)				
n	6	5	6	4
Mean	588	433	466	697
95% confidence interval	0 - 1247	54 - 813	281 - 651	381 - 1013
HDU/ICU admissions				
n	4	1	1	0
Length of stay in HDU/ICU (days)				
Mean	3.5	*	1	N/A
Length of stay in hospital (days)				
n	27	28	38	31
Mean	23.3	15.7	11.2	7.9
95% confidence interval	12.4 – 34.2	11.9 – 19.5	8.8 – 13.7	7.1 – 8.6
Readmissions				
n (%)	4 (14.8%)	4 (14.3%)	1 (2.6%)	2 (6.5%)
95% confidence interval	4.2% – 33.7%	4.0% – 32.7%	0.1% – 13.8%	0.8% – 21.4%

Table 17: Summary of secondary outcomes by risk subgroup (*the length of stay in Level II/III is unknown for this participant as they were withdrawn due to loss of capacity)

5.4.2.7 Patient acceptability

Of the 52 participants who wore the patch, 7 discontinued wear due to discomfort (n=5) or inconvenience from false alerts (n=2). The patient acceptability questionnaire was completed by 46 participants (88.5%). Fourteen participants did not complete the questionnaire as they were discharged from hospital before the questionnaire was administered. Most participants found the patch comfortable and felt safer wearing it, as shown in Figure 14 and Figure 15.

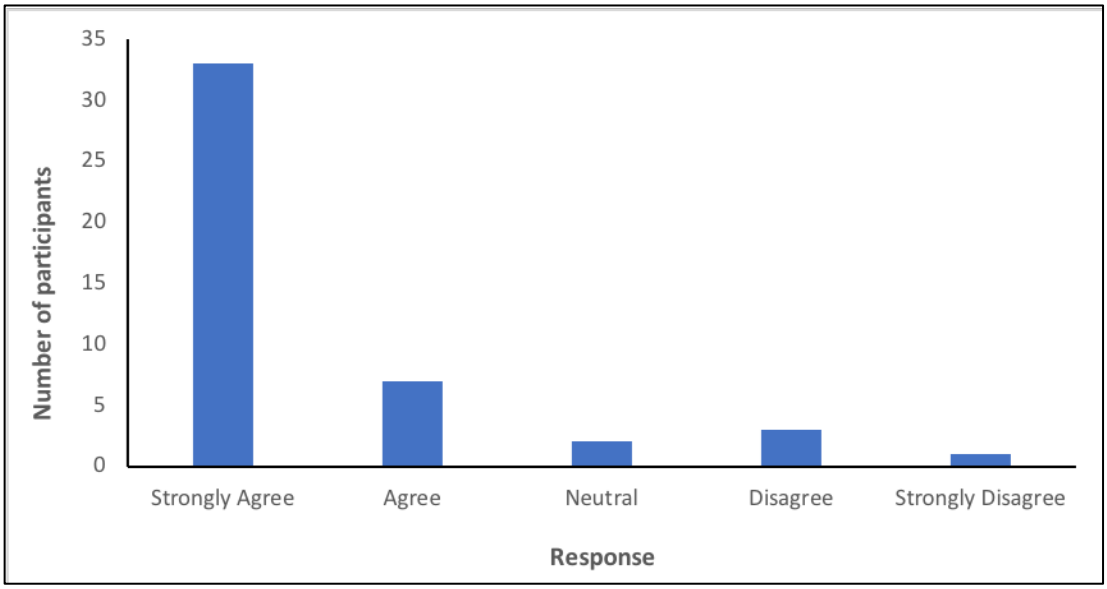

Figure 14: Responses to the statement, 'The patch is comfortable to wear.'

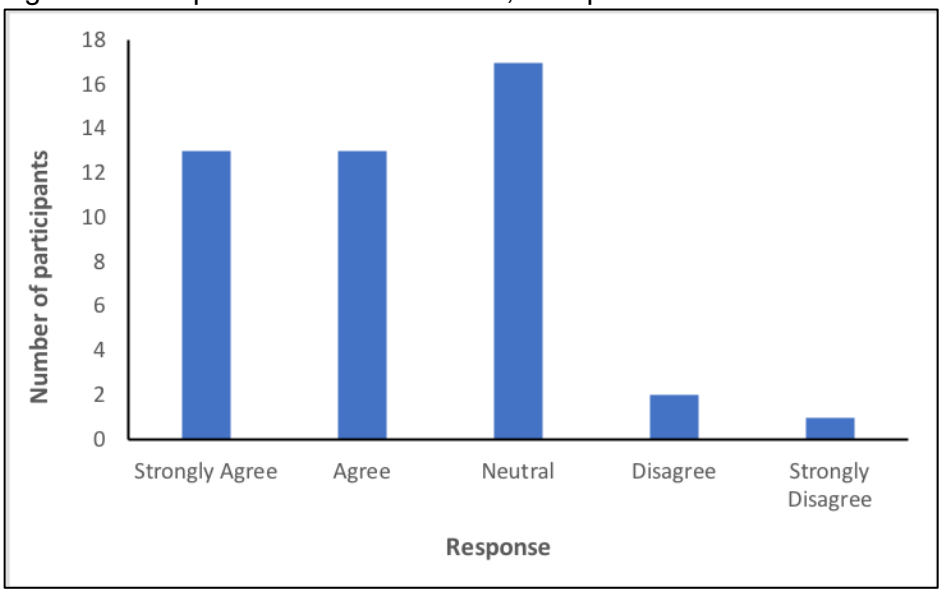

Figure 15: Responses to the statement, 'I felt safer wearing the patch.'

5.4.2.8 Nursing acceptability

Nursing acceptability is reported in Chapter 6.

5.4.3 Progression criteria

The criteria for progression to a definitive randomised controlled trial were met.

- The recruitment of over 120 patients was achieved well within 12 months. The study opened to recruitment on 20th October 2017 and closed on 10th April 2018 with 125 participants receiving monitoring on the trial.
- Missing data was limited only to questionnaire responses; no participants were lost to follow-up. One participant was withdrawn due to loss of capacity.

5.5 Discussion

In this single-centre randomised controlled trial, the feasibility of performing a large-scale randomised controlled trial of CRM after major surgery has been confirmed. The recruitment target was met within six months with a high rate of eligibility and consent; the recruitment rate was higher than expected and enhances the generalisability of the findings to this population. The number of patients classed as 'drop-out' due to design were less than anticipated and there were no participants who crossed over into the alternative trial allocation group. Missing data was limited only to questionnaire responses; no participants were lost to follow-up and one participant was withdrawn due to loss of capacity.

The rate of critical care admissions and length of hospital stay are potential primary outcome measures for a definitive trial. Length of hospital stay data are applicable to every participant and, using the summary statistics from this feasibility study, shows a likelihood of demonstrating efficacy over intermittent monitoring alone. It is an outcome measure that is relevant for the individual patient, society and the healthcare system.

However, the effect on length of hospital stay may not be directly attributable to the intervention.

In contrast, the rate of critical care admissions is an outcome measure that can more easily be attributed to the intervention. By alerting the healthcare provider at the earliest sign of deterioration, continuous monitoring may detect complications earlier than intermittent vital signs monitoring, allowing for prompt treatment and potentially reducing the need for Level II/III care. However, the event rate, even in a high-risk population, is likely to be low, necessitating an inflated sample size with its associated costs; however, recruitment to a higher target is likely to be successful given the high consent rates in the feasibility study. Practically, it may be difficult to implement given that different hospitals have different admission and discharge criteria to critical care[101], which may produce a further clustering effect.

In this study, the intra-cluster correlation co-efficient and the balanced preoperative demographics between arms suggest that the randomisation method employed in the trial was appropriate. Of interest is the fact that, despite using ASA grade as a stratification factor, there were more postoperative complications in the control arm than the intervention arm in every Clavien-Dindo classification group. Whilst the difference in the number of participants experiencing major complications (Clavien-Dindo III or IV) could be explained by the intervention preventing escalation of care in the event of complications, the difference in the minor complications (Clavien-Dindo I and II) is less predictable. Possible causes of these differences include: the intervention preventing escalation of complications; a failure of randomisation, which may indicate that the ASA score is not sufficiently specific to stratify participants in terms of their risk; or that the complications occurred by chance, in which case larger numbers of participants would be required to avoid this risk in a definitive trial.

The moderate ICC estimate indicates that there is some effect of clustering on the endpoint selected (length of hospital stay) based on which bay a participant was admitted to. The ICC and the confidence interval limits were used to calculate a sample size range for a potential definitive trial. Using mean length of hospital stay as the primary endpoint would require a sample size of 602 participants (301 per arm), which provides 80% power at the 5% level of significance to detect a 2 day difference in length of hospital stay, allowing for 15% attrition to account for participants who drop out by design and those who withdraw from monitoring during the study (12.8% of the study sample in the feasibility trial). The sample size calculation uses the ICC estimated from the feasibility study, and refers to bays as the clusters in question. In a definitive trial, clusters may be larger; for instance, randomisation may be clustered by wards rather than bays. In this case, larger clusters may require higher numbers of participants to maintain 80% power.

A secondary objective was to evaluate the safety, potential efficacy and acceptability of a wearable, remote monitoring system for patients after major surgery, as compared to standard monitoring with the NEWS system alone. In this study, participants who had undergone major abdominal surgery were less likely to have an unplanned critical care admission and had a shorter average length of hospital stay if they received continuous vital signs monitoring when compared to those receiving usual intermittent monitoring alone. This might be attributed to the earlier detection of complications preventing escalation of care to Level II/III wards and prolonging patient recovery. There was no difference in the time taken to receive antibiotics in cases of sepsis. This is in contrast to the findings of the cluster-randomised trial described in Chapter 3. This may also be explained by the higher-risk participant population in the second trial, who may have been receiving more frequent nurse-led monitoring when compared to the more heterogeneous sample in the cluster-randomised trial, and may have less to benefit from CRM.

Subgroup analyses was performed in order to delineate which patients would benefit most from continuous monitoring. Patients were divided into 'high-risk' and 'low-risk' categories based on their ASA score and whether they had a planned perioperative critical care admission; these two factors are known to be indicators of risk in surgical patients[102]. This subgroup analysis showed that the difference in length of hospital stay was particularly pronounced in 'low-risk' patients. This finding is limited by the small subgroup numbers, but could indicate that this group may be most likely to benefit from CRM, especially if their 'high-risk' counterparts already receive extra clinical attention due to their perceived risk of deterioration.

The findings must be interpreted within the limitations of the study. Due to the feasibility nature of the study, a formal sample size calculation was not required and the findings were limited to descriptive statistics; no formal statistical comparison was possible[84]. Although the nature of this study does not permit conclusions to be drawn about the efficacy of the intervention, the observations give sufficient confidence that further evaluation within a larger randomisation comparison is justified. Such a study should consider preoperative risk factors for complications, in addition to ASA grade, as stratification factors to ensure that groups are balanced in terms of frequency of complications. Consideration should also be given to maximising protocol adherence in the intervention group. The study was unblinded; although it is difficult to blind the nursing staff or the patients to the treatment allocation, future trials could blind the assessor, or ensure independent verification of their coding in a sample of patients to minimise the risk of bias.

The potential benefits of continuous monitoring may have been underestimated in this study due to the exposure to the patch in the intervention arm. Although most patients found the patch comfortable and felt safer wearing it, eight participants withdrew from the intervention before monitoring had commenced and a further nine participants discontinued the intervention before discharge and within 5 days of application.

Adherence to the monitoring protocol could be improved in a future trial by optimising patient comfort through choice of device, minimising the number of false alerts through better signal processing and encouraging participation until discharge through regular bedside visits.

Previous studies have found the main barriers to the implementation of remote monitoring are nursing engagement and alarm burden[26]. In this trial, these issues were addressed through a concurrent process evaluation. Nurses were provided with thorough training and their engagement in the use of the device and perceptions of the adequacy of the training was explored through semi-structured interviews (Chapter 6).

This daily interaction has informed the pragmatic nature of the feasibility trial, as depicted in the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) wheel [80] (Figure 16). Described in Chapter 3, this tool ranks nine trial design domains from 1 to 5 in order to enable trialists to more easily determine if the trial design matches its intended purpose. Figure 4 illustrates that this feasibility study is fairly pragmatic, with most domains scoring 4 or 5, but it is less pragmatic than the previous study. Domains scoring 3 included: eligibility, due to the fact that only patients expected to be highly responsive to the intervention (those undergoing major surgery) were included, whilst those without the capacity to consent were excluded; and delivery flexibility, due to the presence of the clinical fellow and research nurse who were able to respond to the queries of the nursing staff during daily ward visits, and the fact that patients were patched by the research team before they came to the ward. Domains scoring 4 included: setting, due to the single-site design; organisation, due to the provision of a research nurse to support the ward staff with the intervention; and primary outcome, due to the feasibility outcomes being of limited clinical importance to patients.

The counterintuitive decrease in pragmatism between the two studies illustrates the difficulties of evaluating complex interventions. Demonstrating significant benefit over intermittent monitoring to offset the practical and economic implications of continuous monitoring requires the optimisation of the intervention to the mutual satisfaction of nursing staff and patients alike. This feasibility study focussed not only on clinical outcome measures but also patient and nursing acceptability and adherence to the intervention. This allowed the identification of barriers to recruitment and protocol adherence, and optimisation of the definitive trial protocol.

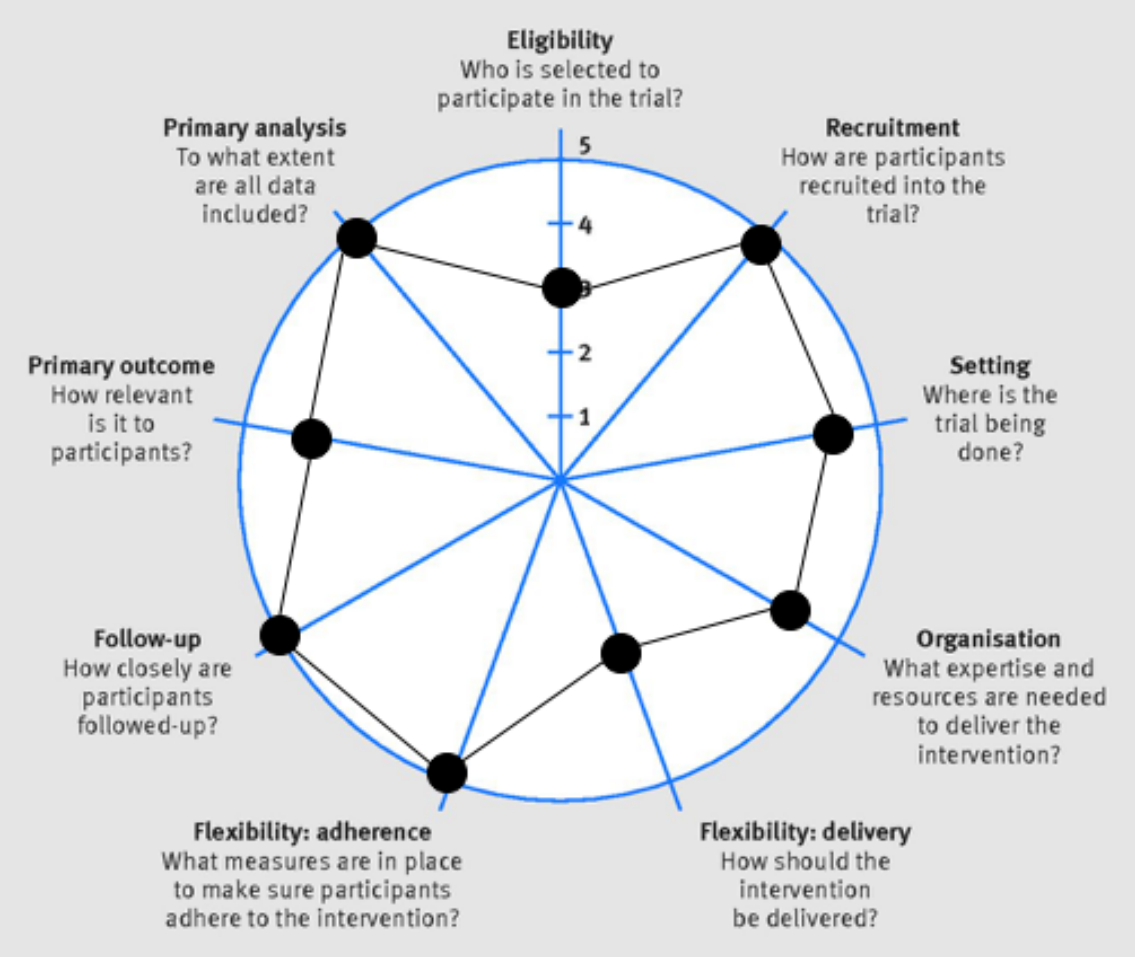

Figure 16: PRECIS-2 wheel for the TRaCINg study

In conclusion, this study has demonstrated the feasibility of performing a large-scale randomised controlled trial of CRM after major surgery. The purpose of this study was not to assess the clinical efficacy of the intervention, but the observed differences in the length of stay between the two groups suggest that this might serve as an appropriate

end-point for a larger study. This must be balanced against the small number of participants and the potential failure of randomisation in the study. Progression to a definitive multicentre randomised controlled trial would be appropriate, with reassuringly high rates of patient recruitment. Participants should be individually-randomised and stratified to minimise the baseline differences between the two treatment arms; ASA might be replaced by more specific risk stratification tools such as the PPOSSUM (Portsmouth Physiological and Operative Severity Score for the enumeration of Mortality and morbidity) score[103]. The ICC should be taken into account in the sample size calculation to account for potential clustering of outcomes at bay or ward level. Care should also be taken to monitor and address inadequacies in other areas that might mask the potential benefit of additional monitoring, such as patient adherence.

6 A realist feasibility evaluation of nursing staff perspectives of remote continuous vital signs monitoring on surgical wards

Staff attitude towards technology is a crucial component of technology acceptance. The clinical and non-clinical efficacy of continuous monitoring systems depend heavily on the engagement of the nursing staff. In this chapter, we report the findings of a realist feasibility evaluation designed to elicit the perceptions of nursing staff regarding how, why and in what conditions remote continuous vital signs monitoring is optimally used in surgical patients.

6.1 Background

The successful implementation of new technology into routine clinical practice is predicated on engaging both staff and service users. It is crucial to assess the experiences of the people using the technology to identify contextual factors that support or constrain optimal utilisation, which could influence the effectiveness of the device. Alongside the TRaCINg feasibility randomised controlled trial, a realist feasibility evaluation has been undertaken to understand how nursing staff perceive and subsequently implement the continuous monitoring system and the contextual factors that influence this.

Realist evaluation is increasingly used for the evaluation of complex interventions in healthcare [76]. It is based on the idea that interventions (such as a new monitoring system) offer resources to people, but it is how people choose to respond to the resources that determines their impact [77]. Realist evaluation aims to explain why the intervention works in some circumstances, but not in others.

There is increasing interest in using realist evaluation at the feasibility stage of testing interventions. The Medical Research Council guidelines recognise the need to optimise complex interventions prior to a full trial through greater understanding of the underlying theory and formative process evaluation[46]. Process evaluation helps to identify the mechanisms responsible for the impact of interventions and the effect that context can have on implementation[104]. A realist approach is considered to be complementary to the design of RCTs and, in comparison to other methods, provides greater explanatory power of the different outcomes that may be seen in an RCT[105].

A realist approach at the feasibility stage develops theories that can inform implementation of a complex intervention at scale by adapting it to different contexts, such as local service provision[106]. The resultant theories can then be tested and further refined during the definitive evaluation.

CRM and its associated devices provide a resource to clinical staff to monitor patients' vital signs uninterrupted and unburdened from traditional monitoring machines. This resource is fixed; it is the response to the resource that determines if the desired outcomes are achieved. This response is determined by the context in which the resource is implemented. For instance, in the *context* of engaged senior colleagues, staff nurses may *respond* by carrying the devices and acknowledging alerts appropriately, leading to recognition of the deteriorating patient (the desired *outcome*). Realist theories are often expressed as context + mechanism = outcome (CMO configurations)[105].

This study aimed to elicit the perceptions of nursing staff regarding how, why and in what conditions remote continuous vital signs monitoring is optimally used on the surgical wards of an NHS teaching hospital. Elucidation of these contextual factors

and their effects will inform potential wider implementations of this technology, and may reveal strategies to support staff in the future.

6.2 Objectives

The study had the following research objectives:

1. To contribute to the reporting of the TRaCINg feasibility trial by investigating how and in what contexts nursing staff perceptions vary regarding the continuous remote monitoring of patients' vital signs.
2. To provide data to inform the development of such technologies according to the contexts in which they will be delivered and with a focus on end-users.
3. To provide data to inform future adoptions by investigating nursing staff perceptions of how and in what contexts the optimal implementation of such technologies occurs.
4. To develop theories regarding the use of the technology in different contexts that can be tested in a definitive evaluation.

6.3 Methods

The realist feasibility evaluation included two phases: theory elicitation and theory refinement [107]. Theory elicitation describes the search for and discovery of theories which may be relevant to the research question. These theories are then synthesised so that similar theories are matched and grouped to allow for ease of refinement. Once the elicited theories are synthesised, they are refined by testing them against the experiences and perceptions of the nursing staff. This allows theories which are not relevant to the research question to be discarded, whilst those that are relevant are taken forward for further testing in a definitive trial.

Ethical approval for the study was obtained from the Yorkshire & The Humber – Leeds West Research Ethics Committee, REC reference 17/YH/018 on 13th October 2017.

6.3.1 Phase 1: Theory elicitation

Theory elicitation can be carried out in a number of ways, such as reviewing empirical literature on the topic, reviewing relevant theoretical literature or interviewing stakeholders[108]. Multiple methods were used to elicit theories about factors likely to facilitate or impede the successful implementation of remote continuous vital signs monitoring.

This included a literature review, consultation with patients and observational work conducted during the TRaCINg study. In addition, *a priori* theories developed by the clinical fellow through informal interactions with patients and ward staff during the day-to-day set-up of the study were included. Identified theories were expressed as CMO configurations to further develop the theories for refinement in Phase 2.

6.3.1.1 Literature review

A review of the literature was undertaken to identify stakeholders' ideas about how and in what contexts the optimal use of a new technology is achieved. This represented the theory elicitation stage of a realist review; in a full realist review, published evidence is used to test and refine stakeholders' theories[109], whereas the purpose of this stage of the work was solely to identify potential theories to be refined in the next stage of the study.

The literature review included grey literature such as editorials, websites of healthcare providers, patient portals and patient information websites, where stakeholders' ideas are most likely to be found. In addition, the introduction and discussion sections of systematic reviews and primary research studies were examined as these have also been found to contain such theories[108].

6.3.1.1.1 Search strategy

MEDLINE®, MEDLINE® In-Process, EMBASE, CINAHL and The Cochrane Library were searched for articles published from the dates of inception of the databases (the earliest being 1947) to October 2017.

The search strategy included a combination of keywords and subject headings related to vital signs (Vital signs OR Vitals OR Heart rate OR Pulse OR Blood pressure OR Respiratory rate OR Temperature OR Oxygen saturation OR Electrocardiograph* OR ECG OR EKG) and monitoring (Observation* OR Monitoring OR Monitor* OR Telemetry OR Oximetry) in combination with keywords Continuous AND Intermittent. The websites of professional journals (*Nursing Times*, *Health Service Journal*) were searched. Finally, a search was run on Google (Google™, Mountain View, CA, USA). To ensure literature saturation, citations and reference lists of selected studies were reviewed to identify any missed papers.

6.3.1.1.2 Selection of studies

All retrieved abstracts, studies and citations were collected, stored on an EndNote reference management database (Clarivate Analytics, London, U.K.), and reviewed. Publications were selected using a staged review of titles and abstracts, followed by full text review. Selection decisions were recorded in a Microsoft Excel (2007) document. The selection and appraisal of identified papers was based on relevance to the review question, as is the case in the theory elicitation phase of a realist review [108]. Papers were included if they contained theories about staff perceptions regarding continuous remote monitoring of patients' vital signs. These included empirical studies, theoretical literature, review articles and grey literature. Quality appraisal of the selected papers was not undertaken as the purpose was solely to identify potential theories to be refined in the staff interviews, rather than evaluate the truth of the theories at this stage.

6.3.1.1.3 Data extraction and synthesis

Theories were extracted from the selected studies by the clinical fellow, and recorded in a working document with links to the original sources. Similar theories were grouped together and refined as the review progressed. Conflicting theories were also included for exploration in Phase 2 of the realist evaluation, with care being taken to note the context in which these contradictory ideas were founded.

6.3.1.2 Patient consultation

Patients' ideas about nursing perceptions of CRM were gleaned from face-to-face interviews at the hospital beside[110], informal interactions during the day-to-day management of the TRaCINg study and two patient focus groups conducted as part of the Patient and Public Involvement work ahead of the feasibility trial. The full methodology of the interviews and focus groups has been published elsewhere[110]. Relevant patient theories were added to those identified in the literature review for refinement in Phase 2.

6.3.1.3 Non-participant observation

During the TRaCINg study, the clinical fellow dedicated approximately 20 hours to observation of the ward staff during vital signs monitoring (NEWS observation rounds and CRM monitoring). During daily visits to the wards, field notes were taken to document staffing levels and the proportion of senior nursing staff on shift, alongside informal comments from ward staff and observations of interactions between and within staff members and patients, and with the technology itself. These field notes were reviewed after the end of the TRaCINg study and new theories were drawn out concerning the perceptions of nursing staff with regard to the CRM devices. These theories were added to those identified through the literature review and patient

consultation alongside *a priori* theories developed by the clinical fellow through informal interactions with patients and ward staff during the day-to-day set-up of the study.

6.3.2 Phase 2: Theory refinement

Once the theories were elicited, they were summarised as context-mechanism-outcome configurations and integrated into a topic guide to facilitate semi-structured interviews [111] with nursing staff on the participating wards. The aim of these interviews was to refine the theories to reflect the experience of nursing staff, to allow their prioritisation for testing in the definitive trial.

6.3.2.1 Participant recruitment

Thirteen interviews were conducted over a 6-week period, face-to-face, in the ward environment. Participants were recruited using a combination of 'snowball' and purposive sampling from nurses working on the participating wards of the TRaCINg study. The Nurse in Charge on each ward was interviewed, and then invited to suggest other nurses interested in participating in the study, with the aim of interviewing a range of nursing staff across both wards, including both sexes, different ages and a range of nursing experience in terms of years. Care was also taken to recruit nursing staff who had previously expressed polar attitudes towards CRM.

6.3.2.2 Data collection

Realist evaluation recommends that a teacher-learner cycle approach be used when undertaking interviews [92]. The interviewer used a pre-determined topic guide, informed by the theories elicited in Phase 1. First, the interviewee was taught the main ideas from the literature and invited to use their experience of the technology to reflect on these theories, describing how and to what extent the theories fitted in with their personal experiences. Interviewees were encouraged to build on these ideas, as well

as introduce ideas of their own, thereby teaching the interviewer. Data collection was an iterative process and, as new theories emerged, these were added to the interview guide for exploration with remaining participants. All interviews were audio recorded.

Interviewing stopped when no further revisions to the theories, and no new theories, emerged. Interviews were transcribed verbatim and anonymised. The interview transcripts were then entered into the software package NVivo 10 for organising and analysing the data.

6.3.2.3 Analysis

The transcripts were analysed using the inductive thematic analysis procedure described by Braun and Clarke[93]. First, the data were analysed by reading and searching the transcripts for common attitudes and experiences between participants. Emergent themes were coded, and the codes applied line-by-line to the transcripts by the clinical fellow. These codes focussed on capturing how the theories elicited in Phase 1 were reported by the nursing staff, to determine how different contexts shape the mechanisms through with CRM was perceived. The data were then systematically reviewed to ensure the themes worked in relation to the coded extracts. Codes were then independently verified by one of the project supervisors. Any discrepancies in application of codes to the transcripts were discussed until agreement was reached by the clinical fellow and the supervisor.

The transcripts and the NVivo documents were made available to the advisory team to aid transparency.

The initial theories, developed in Phase 1, were compared and contrasted with the nursing staff perspectives gathered in Phase 2 and synthesised to offer explanations as to how nursing staff perceive and subsequently implement the continuous

monitoring system and the contextual factors that influence this. CMO configurations were redrawn in the contexts of this synthesis, to explain the causal mechanisms which produce different outcomes in different contexts.

6.4 Findings

6.4.1 Phase 1: Theory elicitation

6.4.1.1 Literature review

The search retrieved over 1,000 references. After the selection process, a total of 84 sources were identified. Three papers were systematic reviews of studies of continuous vital signs monitoring; one article was a non-systematic review. There were 25 individual studies of CRM, including both quantitative and qualitative data. These were evaluated together with 16 editorials and 39 websites. There was considerable repetition of theories across the sources identified.

6.4.1.1.1 Theories regarding nursing perceptions of CRM

Five studies specifically reported nursing perceptions of continuous monitoring systems [17,51,67,68,70] and all identified similar themes. These studies have been described in detail in Chapter 1. In general, nursing staff could see the potential for continuous monitoring to enhance patient safety. Context did appear to have a role in determining the perceptions of nursing staff. Jeskey et al. [67] found that nurses with prior telemetry experience were more likely to perceive the monitoring device as beneficial and more clearly understood the device. It was also suggested that the devices were perceived to be more beneficial by night staff rather than during day shifts, potentially due to more frequent monitoring of high-acuity patients ‘in the immediate post-surgical period’[67].

A conflicting yet recurring theme across the literature was that of staff burden. High-acuity wards were identified as places where the visibility of information and alarms would cause patient anxiety[41,68]. Van Loon *et al.* highlighted the fact that remote monitoring devices typically collect large amounts of information, which has the potential to overwhelm users and dilute important indicators of deterioration[41]. Other studies reported concerns that CRM overburdens busy ward staff or takes nursing staff away from other tasks[112], particularly during day shifts, when staff are typically busy with a wider variety of duties than during night-time hours[67]. Eight studies reported concerns about alert burden. These studies shared a common context of high acuity patent populations and higher patient: nurse ratios[17,67].

6.4.1.1.2 Theories regarding development of CRM technologies

Three articles commented on the limitations of current CRM devices, outside of concerns about false alerts. In addition to patient comfort [41,68], it is suggested that nursing staff should also feel comfortable with the devices [22] to avoid losing confidence in the technology as a whole. Other theories suggested that merely notifying caregivers of abnormal readings is inadequate, and that the usability of the devices would be improved by incorporating a suggested action in response to notifications [41]. Basing these responses on local policy could enhance the perception of CRM as integrated into the usual care pathway [22].

Another potential way to improve integration is to remove the notification devices from individuals and instead promote a ward-based responsibility for CRM, by incorporating big screens at the nurses' station [26,66]. This could help overcome another limitation of individual nurse responders: that single nurses would only be able to see the benefit of CRM on a patient-by-patient basis, and only in those patients who have deteriorated, rather than on a wider scale. This may mean that the impact of the technology is underestimated by individual nurses and impair their engagement with CRM devices.

6.4.1.1.3 Theories regarding the implementation of CRM technologies

A number of theories emerged regarding nursing perceptions of the optimal strategy for implementation of CRM technologies. In the literature, these theories were most often found in the non-systematic review by Taenzer *et al*. First and foremost was the theory of optimising the intervention as much as possible before implementation to avoid examples of early technology failure which might lead to mistrust from the end users [22]. Another suggested tactic to improve the engagement of early adopters was incentivising staff to use the devices appropriately [52]; suggested incentives ranged from updating staff about recent patient success stories, ranking wards against each other or providing 'gifts' to highly engaged teams.

Other theories involved the context of initial implementation. One broad idea was the need to ensure that innovation is supported in the local hospital culture [22]. In the case of CRM, pilot ward/patient selection emerged as a recurring theme. Jeskey *et al.* found a more positive perception of CRM in nurses looking after higher-acuity patients, such as those just back from surgery [67]. A conflicting theory emerged in that high-acuity wards often have a high turnover of staff, which may cause difficulties when trying to implement a new intervention which requires initial training and sustained engagement.

Embedding the new technology within existing local processes was another recurring theme. Nursing staff are potentially more likely to successfully integrate CRM into their working practices if it is incorporated into local monitoring protocols alongside explicit escalation guidance [22,41]. To this end, it might be helpful to extend staff training in the new technology to non-ward-based staff such as doctors and outreach teams [68]. Incorporating CRM alongside traditional observations could increase perceptions of its utility, encourage nursing staff engagement and incite wider institutional acceptance.

6.4.1.2 Patient consultation

The full analysis of the patient interviews and focus groups has been explored in Chapter 4. A predominant theme emerging from the patient interviews regarding nursing perceptions were concerns about workload. Nursing staff were described as "too busy" and "on their feet all the time". Patients expressed that they saw CRM as having value for nursing staff in terms of freeing up nurses' time for other tasks. One patient said, "[The nurses] can use this gadget – they don't have to do as many visits… to your bedside." Another echoed this theory: "The nurses could get on with other things… so it saves time for them." A conflicting theory emerged from the focus groups. Patients were concerned that the extra monitoring would increase workload. This was mentioned in combination with the theory of false alerts causing interruptions and distractions from essential tasks: "I'd think [the nurse] would have enough to do, without pandering to me."

6.4.1.3 Non-participant observation

This was a particularly rich source of theories which incorporated informal, 'throwaway' comments from ward staff and close observation of interactions between and within staff members and patients. One of the most striking observations was the impact of the attitudes of senior nursing staff on ward engagement with CRM. In wards where the Nurse in Charge was ambivalent about the technology, staff engagement required substantially more input from research staff when compared to wards where the senior nurse was enthusiastic about the devices and their potential. Senior staff engagement may be a crucial component when considering how to implement new technology at ward level.

Another important observation emerged when new staff members started work on the wards, and highlighted issues regarding staff training. Prior to commencement of the

TRaCINg study, nursing staff were trained in a single, hour-long drop-in session, with sessions available throughout a single week. There was no provision for formal training for staff who started work after the training period. In addition, there were a number of staff members who requested 'refresher' training during the TRaCINg study. This highlighted the importance of regular training opportunities to keep up with the high level of staff turnover and the need for retraining of current staff. A similar theme emerged when technical problems occurred with the CRM devices. The absence of on-site technical support for minor issues led to loss of confidence and rapid disengagement by one affected staff member, as evidenced by her reluctance to carry the device during the rest of the trial.

An unanticipated theory emerged from nursing staff working with older patients. Nurses were reluctant to use the CRM devices within view of their patients because they resembled mobile phones; nursing staff perceived that their patients would assume they were undertaking personal tasks rather than clinical work. In addition, staff would turn down the volume of the alerts so that patients could not hear them, in case patients mistook the alarms for personal messages. This led to a delay in responding to some notifications. This may have implications for future device development.

6.4.1.4 A priori theories

Theories were developed by the clinical fellow through informal interactions with patients and ward staff during the day-to-day set-up of the study. These were broad speculative concepts regarding the nursing staff's perception of CRM and vital signs monitoring as a whole. They included a number of conflicting theories to be refined in Phase 2. One such theory is that of the value of vital signs to nursing staff. Some papers have suggested that nurses consider vital signs monitoring to be inadequate in the detection of patient deterioration, or not part of the work of a staff nurse, given that

most observation rounds are delegated to healthcare assistants. This raised the question of whether continuous vital signs monitoring would address these concerns by the provision of more data, or simply provide more perceived unnecessary information. In addition, if nursing staff lack confidence in the efferent arm of the deteriorating patient pathway, it would be difficult to perceive additional monitoring as providing any downstream patient benefit.

A conflicting theory is that nursing staff perceive traditional vital signs monitoring to be sufficient to detect patient deterioration. This may be reinforced by the fact that national guidance currently dictates the frequency of manual vital signs observations. In this case, CRM is likely to have little perceived benefit. Instead, it may be perceived as a threat to autonomy when deciding whether to escalate unwell patients.

Theories were also developed regarding the implementation of the CRM technology. In the TRaCINg study, the research team were removed from ward-level monitoring but provided weekday technical assistance by undertaking the application, replacement and removal of the CRM devices when necessary. One theory was that by removing these tasks from the ward staff, they might perceive CRM as outside of their responsibility and fail to engage with the technology. It was anticipated that this would potentially be more evident on high-acuity wards where the nursing staff may feel that they are unable to manage the extra burden of CRM. This would be compounded at weekends, when the research team are absent, and if the devices were perceived to be difficult to use.

Appendix 11 summarises the elicited theories at the end of the realist synthesis as context-mechanism-outcome configurations.

6.4.2 Phase 2: Theory refinement

6.4.2.1 Demographics of participants

Thirteen members of the nursing staff were interviewed, six from each ward (see Table 18). Participants included 11 qualified nurses (Bands 5 to 7, including the Research Nurse assigned to the TRaCINg study) and 2 care support workers (Band 2). Their ages ranged from 21 to 56 years. Their nursing experience ranged from 6 months to 32 years. Most participants had used the CRM system for 3 years; newer members of staff had less experience with the device. Participants from Ward 1 (female patient population) were more likely to have a negative perception of CRM (5/6) than participants from Ward 2 (male patient population: 2/6).

Participant	Gender	Age	Banding	Ward	Nursing experience (years)	Experience with device (years)	Perception of remote monitoring
1	Male	51	7	2	32	3	Positive
2	Female	45	7	1	21	3	Negative
3	Female	31	7	1	9	3	Negative
4	Female	34	6	2	11	3	Positive
5	Female	32	6	2	10	3	Positive
6	Female	32	6	1	10	2	Positive
7	Female	36	6	1	3.5	3	Negative
8	Female	23	5	2	2	0.5	Negative
9	Male	47	5	2	3.5	1.5	Negative
10	Female	21	5	1	0.5	0.5	Negative
11	Male	22	2	2	2.5	1.5	Positive
12	Female	38	2	1	8	3	Negative
13	Female	56	6	Research Nurse	20	1.5	Positive

Table 18: Demographics of interview participants

6.4.2.2 Nursing perceptions of CRM

Across all levels of experience and qualifications, nursing staff had a good understanding of the theoretical principles behind CRM.

> *'The thought process behind it is extremely good… It's great to know that three hours before you next do your set of obs, you can start your treatment. Sensium's offering you accurate information about a patient that is deteriorating before you're getting a chance to recognise it.' – Participant 1, Band 7 (Ward 2)*

There were a number of positive aspects of the remote monitoring system that were highlighted, predominantly from the Ward 2 nursing staff. These commonly involved the advantages of bringing the nurse to the patient (when the device alerted) and the benefits of personalised care in addition to the generic NEWS system.

It was recognised that there was a lack of adherence with the device in some areas, especially on Ward 1. A range of reasons were suggested, such as the failure to incorporate the remote monitoring into the daily routine. There were a number of contextual factors that contributed to engagement or lack thereof.

6.4.2.2.1 The eminence of NEWS

One of the theories that emerged from Phase 1 was that if nursing staff perceive vital signs monitoring as valuable they are more likely to engage with the CRM system. In exploring whether nurses consider vital signs monitoring in general to be either superfluous or sufficient, it emerged that staff place a high value on vital signs monitoring, and by extension the wards' existing intermittent monitoring system. The perceived ubiquity of this system influenced nursing staff's attitudes towards CRM.

The National Early Warning Score (NEWS) was first developed by the Royal College of Physicians in 2012 as a standardised approach to the assessment and response to critical illness[30]. St James's University Hospital was one of the first hospitals to adopt the system and it is well established on the study wards.

As such, nursing staff are experienced in using the NEWS system. They reported finding it simple to use, and trust its outcomes.

> *'It's pretty fool proof really… It is very much an idiot's guide' – Participant 2, Band 7 (Ward 1)*

> *'The thing with NEWS is that everybody understands it… So I think people have got more confidence.' – Participant 2, Band 7 (Ward 1)*

Having been shown to be valid [113] and easy to use [114], the NEWS system has been widely adopted throughout the UK National Health Service. It is therefore reported to be well recognised by staff and forms a common language when communicating with people from within and external to the hospital.

> *'Even with the reliance on agency staff and temporary staff, you know even they can come and calculate somebody's NEWS.' – Participant 2, Band 7 (Ward 1)*

> *'It gives you a good basis if you're trying to handover someone poorly: 'Their NEWS is a 7.' So it kind of highlights to everyone else... It gives you extra leverage.' – Participant 5, Band 6 (Ward 2)*

Given the eminence of the NEWS system on the study wards, on receiving an alert from the CRM device, nursing staff reported that they would 'always go and check on their obs anyway' (Participant 5, Band 6, Ward 2).

> *'I'm not really going to pay any attention to [the device]. I'm going to say, 'What do my obs say?' And that's what I'll go by.' – Participant 7, Band 6 (Ward 1)*

This apparent duplication of work led a number of nursing staff to wonder if the remote monitoring was necessary.

> *'It's not really going to benefit the staff in anyway, because we're doing our regular monitoring anyway every so many hours.' – Participant 6, Band 6 (Ward 1)*

This was reinforced by the fact that adherence with the CRM system was not mandated or audited. This is in direct contrast to the NEWS system.

> *'If it's not on the metrics, if it's not getting audited, it's the lowest in my priority list.' – Participant 3, Band 7 (Ward 1)*

NEWS has recognised drawbacks, however, especially in terms of the equipment provided to the wards. A number of nursing staff mentioned their concerns about the wards' overreliance on flawed technology.

> *'It's the way the data is collected for the NEWs that is the problem… The BP cuff isn't very good – it's single use, they're a bit cheap, it's*

not the best… We are limited with the information we can get from them with the machines that we've got.' – Participant 3, Band 7 (Ward 1)

Nursing staff reported that they recognised that the NEWS system risks undetected patient deterioration through inadequate frequency of monitoring, and that other forms of observation are required to optimise patient safety.

'NEWS isn't enough because we have especially young patients who will tick along quite easily with a low NEWS and compensate, and suddenly go… If we're constantly monitoring, and suddenly there's a cardiac event or sudden sepsis event, we can spot that immediately in between our routine sets of observations.' – Participant 4, Band 6 (Ward 2)

Senior nursing staff were also keen to highlight that vital signs are just one part of patient monitoring, and cannot replace nursing intuition.

'Even if I can't give you a statistic or the numbers, and I just have a feeling… I feel like I have that ability to say.' – Participant 3, Band 7 (Ward 1)

'You've still got to use technology, but also use your eyeballs and your instincts… I wouldn't ever leave a situation thinking, 'His obs look fine but he looks dreadful, that'll be alright.' – Participant 1, Band 7 (Ward 2)

In summary, interviews with the nursing staff identified some of the contextual factors that lead nurses to perceive CRM positively or negatively alongside their normal monitoring practices. The original theory was that if nursing staff perceive vital signs monitoring as valuable they are more likely to engage with the CRM system. Although the NEWS score was universally regarded as valuable, this did not always translate into positive perceptions of CRM. Because NEWS is a national system, it is well recognised and forms a common language when communicating with people outside the wards. This is in contrast to the CRM system, which was only implemented on the two study wards and did not contribute to nurses' reporting of patient deterioration. In addition, the NEWS was reported to be trusted above the CRM system, leading nursing staff to double-check CRM alerts with manual observations and further increasing their workload. These contextual factors led to the perception of the CRM system as superfluous to the detection of deteriorating patients, decreasing engagement with the devices. Another factor that contributed towards lack of engagement was the fact that adherence with the CRM system was not mandated or audited. In contrast, when staff reported their recognition of the drawbacks of the NEWS system, they were more likely to recognise the value of CRM and engage with the devices. These refined theories are summarised in Table 19.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
NEWS is well established throughout the hospital. NEWS forms a common language between staff members.	The remote monitoring system is only used on the study wards.	Remote monitoring does not contribute to nurses' reporting of patient deterioration. CRM perceived as superfluous.	Nursing staff fail to engage with remote monitoring system.
Staff have experience of NEWS; staff trust NEWS.	Remote monitoring is a new intervention.	Ward staff double-check remote monitoring alerts by taking a set of NEWS observations. CRM perceived as duplication of work,	Nursing staff fail to engage with remote monitoring system.

		and therefore unnecessary.	
Adherence with NEWS is audited.	Adherence with remote monitoring is not mandated or audited.	Remote monitoring is not perceived as an institutional priority.	Nursing staff fail to engage with remote monitoring system.
NEWS has recognised drawbacks, especially intermittency of observation.	Remote monitoring allows continuous physiological monitoring.	Staff feel reassured that vulnerable patients are more frequently assessed. Staff recognise the value of the device.	Staff continue to engage with the system.

Table 19: Context-mechanism-outcome configurations of theories regarding the eminence of NEWS

6.4.2.2.2 Acceptance of healthcare technology

One paper identified in the literature review suggested that if nursing staff have previous experience of remote monitoring, then they will be more likely to perceive the potential benefits. This theory was corroborated by the staff interviews.

> *'I worked in HDU, so I do like that continuous monitoring… Having it on the nurse's station, you had a continuous feed of it all the time, so it was quite nice.' – Participant 6, Band 6 (Ward 1)*

In exploring the relevance of this specific context, other theories emerged surrounding the acceptance of healthcare technologies. The more senior nurses identified a number of their staff as having distrust in technology, which they perceived as having a negative influence on engagement with the remote monitoring system.

> *'I'm not averse to technology at all, but I have a lot of staff that are. There's a girl who doesn't even know how to use a computer.' – Participant 2, Band 7 (Ward 1)*

This was reported to be particularly prevalent in the lower banded staff members.

> *'It's a lot of my Band 2s and Band 5s that are technophobic… They don't use it enough… It still tends to just be me and the Band 6s that update [the local computer record] and stuff.' – Participant 2, Band 7 (Ward 1)*

A number of participants offered context to this theory, by revealing that there had been a significant amount of technological change enforced on the two wards in recent years.

> *'Everything came in at the same time… It was a lot of technology at the same time. But it's going that way, isn't it?' – Participant 3, Band 7 (Ward 1)*

In addition, not all of the technological advances were associated with benefits for the nursing staff.

> *'Some people that are IT literate feel like the process is longer… It's almost like we're going a step ahead before the systems allow us to… Everybody's promoting 'paper-free' [a local initiative] as the way to go but then when we try, we just get problems.' – Participant 2, Band 7 (Ward 1)*

Many of the participants reported that they could see a role for remote monitoring in the future, if not necessarily at present.

'It will happen, but probably not in 5 years. Maybe in 10 years. It's coming and it would definitely fit in... As long as it's not duplicating work.' – Participant 3, Band 7 (Ward 1)

In summary, the original theory suggested that if nursing staff have previous experience of remote monitoring, then they will be more likely to perceive the potential benefits. The staff interviews corroborated this theory, and provided new theories regarding the contexts which influence the acceptance of healthcare technologies such as CRM. In the contexts of rapid concurrent technological change with limited benefits perceived by the nursing staff, new technologies are distrusted leading to reduced engagement with CRM. This may be particularly relevant to lower banded staff members, who historically required less access to computer systems than their senior colleagues and who may now resent the subsequent burden of technology on their work. These new theories are summarised in Table 20.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Recent rapid technological change on wards	Remote monitoring is one of many technologies introduced simultaneously.	Staff prioritise their engagement with certain technologies over others.	Remote monitoring does not receive the high levels of engagement required for optimal use.
Some new technological advances have slowed down processes.	Remote monitoring technology takes time to set up.	Nurses perceive technology as a waste of their time. Distrust of all technological advancements and failure to engage with innovation	
Lower banded nursing staff have less need to access computer systems.	Remote monitoring system requires logins to the computer programme.	HCAs have difficulty with technology, e.g. remembering passwords. Technology is perceived as a burden and staff less likely to engage.	
Nurses rotate through high dependency	Qualified nurses have experience of CRM.	Qualified nurses perceive remote monitoring as beneficial	Qualified nurses more likely to accept remote

wards during their training.		in acutely unwell patients.	monitoring on general wards.

Table 20: Context-mechanism-outcome configurations of theories regarding the acceptance of healthcare technology

6.4.2.2.3 Trust in the remote monitoring technology

A recurring theory from the literature was that if nursing staff experience high levels of false alerts from the CRM system then this will lead to potential disillusionment with the technology and reduced engagement. All the interviewed participants made reference to the high levels of false alerts seen, sometimes before being directly asked, especially when describing the early phase of implementation. Staff reported becoming frustrated with the technology, and losing trust in the validity of the alerts.

> *'If it was giving you a false reading, you would have to go and check and do a set of obs, just to check it's not that. Even though your initial thinking is, looking at the patient, they're okay. You can't go and ignore that it's telling you something and that it's alerting. So you are doing something that you don't need to do.' – Participant 8, Band 5 (Ward 2)*

> *'It is the 'boy that cried wolf' scenario. Because there were so many false alerts… a lot of staff just don't trust it.' – Participant 2, Band 7 (Ward 1)*

Staff reported becoming desensitised to the alert system, and beginning to ignore potential signs of deterioration.

"I think we'd probably end up ignoring them, if there was so many I think they'd acknowledge the latest one and ignore all the rest.' – Participant 6, Band 6 (Ward 1)

In contrast, other participants, and in particular more senior nurses, perceived false alerts as an unavoidable aspect of a sensitive system, and were happy to take on the extra workload in exchange for potential patient benefit.

'It might not be the right alert but you have gone to the patient and checked them, when you probably may not have done as quickly as you would have done… It gives you a nudge.' – Participant 3, Band 7 (Ward 1)

When asked how many false alerts they would tolerate for every true alert, most participants said a 5-to-1 ratio would be acceptable.

'I think if it had got to more than 5 per 1 that this is correct, then I would be feeding back to the company that this is wrong and something's got to be done because I can't. We've got too much to do, to be beeping all the time.' – Participant 3, Band 7 (Ward 1)

The original theory was that if nursing staff experience high levels of false alerts from the CRM system then this will lead to reduced engagement. The interviews with the nursing staff provided further insight into the negative potential impacts of false alerts including losing trust in the technology, becoming desensitised, and failing to respond to alerts. In contrast, other participants, and in particular more senior nurses, were happy to tolerate false alarms in exchange for potential patient benefit. These theories are summarised in Table 21.

Context	Mechanism		Outcome
	Resource	Response	
Nursing staff, especially junior staff, do not perceive potential benefits of CRM.	Remote monitoring devices are typically very sensitive, but lack specificity. There are a number of false alerts.	Nursing staff experience alert fatigue, desensitization and failure to respond	Disengagement from remote monitoring technology
Nursing staff perceive potential benefits of CRM, especially more senior nurses.		Nursing staff accept false alerts as unavoidable.	Staff continue to engage with the remote monitoring system.

Table 21: Context-mechanism-outcome configurations of theories regarding nursing staff's trust in remote monitoring technology

6.4.2.2.4 Impact on workload

A theory that emerged from both the literature and from patient interviews was that if nursing staff perceive CRM as having a negative impact on their workload then engagement with the system would be impaired. This theory was corroborated in the interviews. Given that the remote monitoring system is designed to be an adjunct to usual care, most participants reported that the remote monitoring system added to their workload and this was frequently perceived in a negative light.

> *'I suppose it's just seen as like an extra thing that they're having to do and anything that's an extra thing, they don't really like, do they?'*
> *– Participant 7, Band 6 (Ward 1)*

The extra tasks were particularly unwelcome in the context of the busy study wards. These wards have a high acuity patent population which confers a high workload to the nursing staff compared to other wards.

'[The wards have] got different age groups, different people coming in with different operations… They're quite acutely unwell on the wards most of the time.' – Participant 6, Band 6 (Ward 1)

Participants were keen to highlight the differences between the two study wards in terms of workload. Ward 1 admits female patients; Ward 2 admits male patients.

'This [ward] is female though and we're never out of the bays long enough to know… we're constantly in the bay. It is so much more demanding on the female ward.' – Participant 2, Band 7 (Ward 1)

'Hands down. [Female patients] are a lot more needy than the men, by far… I think if [the workload] is heavy, if you've got that little bit of extra to do, then you are a little bit more grumbly.' – Participant 6, Band 6 (Ward 1)

Workload was also more likely to be a factor for more junior staff members, and on wards with a high proportion of temporary or agency staff (see Section 1.4.2.4.1), who would not be trained to use the CRM system, thus placing a disproportionate burden on permanent nursing staff.

'Quickly they realised it was going to be a lot of extra work… Because it's tended to be mainly on my clinical support workers and my band 5's, that are already really hard working and really busy.' – Participant 2, Band 7 (Ward 1)

In contrast to most participants' concerns about the additional workload, four of the nursing staff perceived the remote monitoring device as no extra burden, particularly referencing the short amount of time required to acknowledge an alert.

> *'I think we had enough time to deal with it... It was just a quick response, wasn't it? On the handheld device. And then you'd check the patient but, it was fine.' – Participant 6, Band 6 (Ward 1)*

> *'It's only like answering a buzzer or answering a phone. It's no more time consuming than that.' – Participant 4, Band 6 (Ward 2)*

One participant even felt that the remote monitoring relieved the staff of work.

> *'I think it would give us more time to do other things.' – Participant 1, Band 7 (Ward 2)*

The difference in perception was attributed to different personality types.

> *'I suppose people deal with their workload in different ways, don't they? Like they might feel more pressured to deal with it if they had the handheld device or felt like it was something else to do.' – Participant 6, Band 6 (Ward 1)*

Another participant explained that attitudes were changing as the implementation process progressed.

'I think what the negativity initially was all about is that extra bit – speaking to the patients, getting the consent, putting the equipment on, going to the computer … All that kind of thing, for [the nursing staff], is just taking that bit more extra time. But once these protocols were on, we were sorting it and it did give you alerts and these alerts were positive for us because it alerted us to problems.' – Participant 1, Band 7 (Ward 2)

The original theory stated that if nursing staff perceive CRM as having a negative impact on their workload then engagement with the system would be impaired. The interviews provided further insight into the contexts in which this was perceived to be particularly true, such as in high acuity areas, wards with a high proportion of temporary staff and wards with female patients. A contextual factor which improved the engagement of staff was the perception that protocols around the CRM system had been refined to make the system simpler and quicker to use. These theories are summarised in Table 22.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
The surgical wards are high acuity. The nurses are very busy.	The CRM system is an adjunct to usual care.	Staff cannot fit the extra work into their day.	Nursing staff fail to engage with the CRM system.
Staff perceive that the CRM system is quick to use.		Staff perceive that the device is no extra burden.	Nursing staff engage with the CRM system.
Female wards are busier than male wards.	The CRM system has same set-up time across both sexes.	Staff cannot fit the extra work into their day.	Nursing staff from female wards less likely to engage with the CRM system.
Lower banded nursing staff are the most busy.	Lower banded nursing staff are tasked with vital signs monitoring.	Extra work from new device perceived as burden.	Nursing staff fail to engage with the CRM system.

The CRM system is only used on the study wards.	Temporary staff and those from external agencies are unable to use the CRM system. Permanent nursing staff must take responsibility for CRM.	Nursing staff feel disproportionately overburdened and resentful towards the CRM system.	Nursing staff fail to engage with the CRM system.

Table 22: Context-mechanism-outcome configurations of theories regarding the workload associated with remote monitoring technology

6.4.2.2.5 Disruption to workflow

A further theory that emerged from the literature review was that if the CRM system was disruptive to the workflow of the nursing staff's normal day then engagement with the system would be impaired. When this theory was explored in the interviews, many participants expressed that the remote monitoring system would be disruptive to workflow regardless of the perceived volume of work. This is in the context of many formal and informal clinical routines that take place on the wards every day.

> *'You can guarantee… if you walk in this unit at 6 o'clock at night, the qualified nurses will be going around with the medicines trolleys and the CSWs [care support workers] will be going around with Dynamaps.' – Participant 2, Band 7 (Ward 1)*

Some participants believed that the disruptions would compromise other tasks, and perhaps patient safety.

> *'It would be taking nurses away from their everyday nursing duties.' – Participant 2, Band 7 (Ward 1)*

'It is disruptive, it really is. It goes out of routine. But I suppose the flipside of that is that 'well, is it good to go outside of routine because it's picking up on stuff in between?' Maybe.' – Participant 2, Band 7 (Ward 1)

The disruptive effect of the monitoring system was thought to have less effect during night shifts. This was attributed to the fact that night shifts tended to have a lower workload with fewer mandatory tasks to complete.

'It's a lot easier to monitor in the night than it is in the day just because of the hustle and bustle of the day shift. It sometimes you would find it alerting and you'd find yourself constantly in the middle of the drugs, CDs [controlled drugs, which require extra attention], and you'd get an alert and it's like you literally just have to switch off to the noise that's going off in your pocket. Nights are busy but not as, and you can sit and go through it, look at the trends, stuff like that. Whereas on a day shift, you feel like you don't have time to do that.' – Participant 8, Band 5 (Ward 2)

Participants reported that the remote monitoring system could have added value during night shifts, especially in the context of fewer nursing staff on shift.

'You'll have 14 patients on a night, and if you had all of them monitored, it'd be nice… You switch the lights off and they go to sleep, and it's daunting. It's 14 people to keep an eye on. If they're all patched and they had a monitor on, it's quite nice. You know, if their breathing got low or if their heart rate wasn't quite right, it'd pick up on it quick.' – Participant 6, Band 6 (Ward 1)

In contrast, night shifts are more likely to be filled with temporary staff, who are likely to be unaware of the remote monitoring system.

> *'We have a lot of agency staff at night, and they ain't got a clue… So it's more useful in the day, really… Because there's more of our own staff around.' – Participant 7, Band 6 (Ward 1)*

The original theory stated that if the CRM system was disruptive to the workflow of the nursing staff's normal day then engagement with the system would be impaired. The interviews provided further insight into the contexts in which this was perceived to be particularly true, such as during day shifts when staff are more busy and there are more formal routines as part of patient care such as medication rounds. The CRM system may also provide reassurance during night shifts when there are fewer staff on the wards. As a counterpoint, the reliance on temporary staff during night shifts may impact negatively on staff engagement with the CRM system. These theories are summarised in Table 23.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Wards have formal and informal routines throughout the day.	Continuous monitoring can alert at any time of day.	Nurses are taken away from their everyday duties. CRM is perceived as disruptive.	Nursing staff fail to engage with CRM system.
Night shifts are less busy than day shifts.	Nurses have more time to engage with the devices.	Alerts are responded to promptly. Nursing staff perceive benefit from the devices, rather than disruption.	Nursing staff more likely to engage with CRM system.
Night shifts have fewer	The remote monitors monitor	Nursing staff are reassured that their patients are being	Nursing staff more likely to

staff on duty than day shifts.	all patients at once.	monitored despite fewer staff.	engage with CRM system.
Night shifts rely more heavily on agency staff.	The remote monitoring system requires training.	Agency staff are unable to use it, and the burden falls disproportionately on permanent staff.	Nursing staff fail to engage with CRM system.

Table 23: Context-mechanism-outcome configurations of theories regarding the disruption to workflow associated with remote monitoring technology

6.4.2.2.6 Perceptions of patient benefit

Another theory that emerged from the literature was that if the CRM system was positively perceived by patients then nursing staff would be more likely to engage with the technology. This theory was corroborated in the interviews, where nursing staff reported that the increased workload associated with the devices was tolerable if there was an obvious benefit to the patient.

> *'It doesn't work if it becomes a burden. Something becoming a burden for the nurses is absolutely fine as long as it works for the patients.' – Participant 9, Band 5 (Ward 2)*

Most participants felt that remote monitoring was a positive thing for the patients, particularly because it was not burdensome to wear.

> *'Once it's been on a little while, they totally forget about it. I've had a patient go home with one! That's how non-invasive it is for the patient.' – Participant 1, Band 7 (Ward 2)*

Many participants described some patients as perceiving an increased sense of safety.

'Most of them forgot it was there. A handful of them felt 'ooh, I'm getting watched a bit closely' and quite liked that feeling.' – Participant 3, Band 7 (Ward 1)

This sense of reassurance was reported to have a beneficial effect for the nursing staff.

'I think that it gives the patients reassurance more than the nursing staff and that serves a purpose, because then the knock on effect of that is that they're not then pressing their nurse-call button every 5/10 minutes because of their anxiety-related issues, thinking that nobody's coming near them.' – Participant 2, Band 7 (Ward 1)

A number of nurses from both wards mentioned patients in side rooms and those who had recently stepped down from a critical care ward as being the people most likely to benefit from this reassurance. Others were keen for patients who were immediately post-operative to have the extra monitoring.

'I like the monitoring on a night and additionally when they're first post-op. But when you're looking down the line, a few days later, I don't think it'd be needed. I think the first few days after surgery it's beneficial for the patient to have this extra monitoring.' – Participant 6, Band 6 (Ward 1)

'ICU step downs: they come from an environment where they get 1-to-1 or 1-to-2 care, with constant monitoring, in a fairly newish building… It's a massive shock… because it's 1 nurse to 8 patients

and they can feel quite vulnerable. So for those particular patients, I think it would ease anxiety.' – Participant 4, Band 6 (Ward 2)

The original theory was that if the CRM system was positively perceived by patients then nursing staff would be more likely to engage with the technology. The staff interviews corroborated this theory, and provided new theories regarding the contexts which influence the patients' perceptions of CRM. These included patients who were has been stepped down from critical care areas and those who were isolated in side rooms who may both be reassured by the extra monitoring from the devices. In addition, the comfort and perception of safety associated with wearing the devices were reported to help patients feel better. These new theories are summarised in Table 24.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Patients stepping down from critical care areas feel anxious over the reduction in nursing contact when they arrive on surgical wards.	The CRM system monitors patients continuously throughout their ward admission regardless of their location on the ward.	Remote monitoring helps to reassure patients and relatives. Burden on nursing staff to reassure patients and relatives is reduced by continuous monitoring devices.	Nursing staff more likely to engage with CRM system.
Patients in side rooms are isolated from other patients and may have less nursing contact.			Nursing staff more likely to engage with CRM system.
Patients perceive no disadvantage to wearing remote monitoring.	The device is comfortable to wear.	Patients feel better. Nursing staff perceive improved attitudes in patients who are wearing the devices.	Nursing staff more likely to engage with CRM system.

Table 24: Context-mechanism-outcome configurations of theories regarding patient perceptions of the remote monitoring technology

6.4.2.2.7 The influence of senior staff

A theory elicited from non-participant observation of the nursing staff was that if senior nurses were enthusiastic about the CRM system then more junior staff would become engaged with the technology. This may explain the different levels of engagement across the two wards. The senior nurse on Ward 2 described their role as follows:

> *'If we're [the senior nursing staff] not on board, then nobody'll take it on… We have had a great deal of changes, but it's how I take that and manipulate that to encourage the staff on the ward to take it on board.' – Participant 1, Band 7 (Ward 2)*

Other participants agreed that the attitudes of the senior nursing staff were important to encourage engagement from the more junior members of staff.

> *'[Senior nurse on Ward 1] does have a lot of influence over how we feel about certain things and if her first attitude is 'I don't like it', that feeds into the staff. And if [senior nurse on ward 2] had been very positive about it, they absolutely adore him. If he says it's amazing, then it's amazing and they would take it at face value.' – Participant 3, Band 7 (Ward 1)*

This was felt to be particularly important for the newest members of staff.

> *'I think you're quite easily influenced by colleagues, especially when you're new. So if other people are a bit unsure about it, then you*

don't sort of go out of your way to find out more, do you?' – Participant 10, Band 5 (Ward 1)

One participant suggested another ward as a good place to introduce new technology, simply because of the attitudes of the staff.

'[Senior nurse on alternative ward] and sister team is amazing, and they are very proactive with change, and [when] something new happens they dive in with two feet and they're all over it. Very, very, very good at initiating change and the staff just go with it.' – Participant 3, Band 7 (Ward 1)

Another ward was contrasted for its lack of acceptance of change.

'You maybe wouldn't have had a welcome on [alternative ward], because [the senior nurse on the ward] doesn't like change. She still works very much how she did 15 years ago. That's fine and it works for her, but she doesn't like how things change often.' – Participant 3, Band 7 (Ward 1)

The original theory was that if senior nurses were enthusiastic about the CRM system then more junior staff would become engaged with the technology. The staff interviews corroborated this theory, and allowed it to be refined as summarised in Table 25.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Senior staff are disenchanted with remote	The CRM system involves extra work for nursing staff.	Attitudes of senior staff filter down to other nursing staff. Advantages of	Junior nursing staff are less likely to engage

monitoring technology.		remote monitoring not seen to outweigh the extra workload.	with the CRM system.
Senior staff are motivated to engage with remote monitoring technology.		Senior staff are sure to highlight the advantages of the devices to their more junior nurses.	Junior nursing staff are more likely to engage with the CRM system despite extra workload.

Table 25: Context-mechanism-outcome configurations of theories regarding the influence of the senior nursing staff on engagement with remote monitoring technology

6.4.2.3 Nursing perceptions of the development of CRM technologies

In exploring the theories around the development of CRM systems, the interview participants shared a wealth of suggestions about how the technology could be developed to improve nursing engagement.

6.4.2.3.1 Perceptions of the mobile devices

A prominent theory in the literature was that if nursing staff feel comfortable with the mobile devices then engagement with the technology as a whole is enhanced. The mobile devices used in the TRaCINg study were iPods. The cluster-randomised trial relied on a smartphone device. Nursing staff reported different views on the devices; some felt the devices were too bulky to carry in their pockets.

A theory elicited from non-participant observation was that if nursing feel unprofessional whilst using the mobile devices then they are less likely to engage with the CRM technology. When this theory was explored in the interviews, this was reported to be a common concern from all levels of nursing staff.

'If I see somebody approaching a patient with what looks to be a phone, I don't know if it's a Sensium device or if it's their personal mobile phone. It does look unprofessional.' – Participant 2, Band 7 (Ward 1)

'I always feel the need to remind people that it is just obs and that I'm not just playing on an iPad.' – Participant 10, Band 5 (Ward 1)

Nursing staff were conflicted about which group of patients they felt were more likely to be offended by the use of mobile devices on the wards. Some felt that the elderly would be the most suspicious of technology. Others felt that medicated patients could easily miss information about the devices. There was also concern that relatives would perceive the staff in a poor light if they were seen with the devices.

This in in the context of issues having recently been raised on these wards about staff using personal mobile phones during work hours. In addition, it was reported that patients on other wards have expressed concerns about personal devices on the wards.

'We have heard from other places that our colleagues were using the phone and then the patient would take it in the wrong way.' – Participant 11, Band 2 (Ward 2)

The issue has been compounded by the recent introduction of mobile devices for a range of clinical duties, including NEWS observations and medication rounds.

'We've recently gone to the Eobs and that… requires we're on the iPads more. Nurses feel they're always on an iPad or a phone that they've always got their head looking down at a screen... Patients don't always understand that it's something we're using for work. So I don't like the idea of nurses looking at phones all the time.' – Participant 7, Band 6 (Ward 1)

A number of nursing staff mentioned ways to avoid feeling unprofessional whilst handling mobile devices on the wards, including prominent posters on the walls, ensuring that the devices were always highly visible, and explaining their function to the patients as early as possible.

'If I've got my phone out, I'll be explaining to the patient why I've got my phone out. If I've got a group of visitors in at that time, I'll go around and make a joke of it. It'd be there and I'd be explaining what I were doing. Once you've done a couple of meds rounds, they understand.' – Participant 1, Band 7 (Ward 2)

The original theory was that if nursing staff feel comfortable with the mobile devices then engagement with the technology as a whole is enhanced. Whilst nursing staff reported that the devices could be easier to carry, their primary concern was that patients and relatives would perceive them as unprofessional when using the devices, especially in the context of a number of other mobile devices having recently been introduced on the wards. This was thought to be particularly problematic when caring for elderly patients and their relatives. In addition, in the context of strict rules about personal device use on the wards, nursing staff felt uncomfortable using the CRM devices in front of other staff. These contextual factors decreased engagement with

the CRM system as a whole, although some nursing staff suggested ways of mitigating these concerns. These theories are summarised in Table 26.

Context	Mechanism		Outcome
	Resource	Response	
Nursing staff are required to carry everything on their person.	Mobile devices are bulky and heavy.	Nursing staff can't fit anything else in their pockets and so prioritise other clinical tools.	Nursing staff fail to engage with the CRM system.
Nursing staff frequently attend to older patients and their relatives.	Remote monitoring devices look like mobile phones.	Nursing staff are afraid that patients and relatives will assume the devices are their personal phones. Nursing staff refuse to carry the devices or check notifications on the ward.	Nursing staff fail to engage with the CRM system.
Nursing staff are not permitted to carry personal devices on the wards.	Remote monitoring devices look like mobile phones.	Nursing staff are afraid that senior staff will assume the devices are their personal phones. Nursing staff refuse to carry the devices or check notifications on the ward.	Nursing staff fail to engage with the CRM system.
Recent introduction of a number of other mobile devices. Nursing staff feel they spend too much time on these devices.	Remote monitoring requires another mobile device to be used on the wards.	Nursing staff refuse to carry the devices or check notifications on the ward.	Nursing staff fail to engage with the CRM system.
Patients are accustomed to seeing staff using mobile devices as part of their care.	Devices are very visible on the wards.	Nursing staff feel comfortable using remote monitoring devices.	Nursing staff continue to engage with the CRM system.

Table 26: Context-mechanism-outcome configurations of theories regarding the perceptions of the mobile devices

6.4.2.3.2 Perceptions of a ward-based screen

Another theory from the literature suggested that if that nursing staff are only able to see the benefit of CRM on a patient-by-patient basis then the impact of the technology may be underestimated by individual nurses and impair their engagement with the CRM system. When this theory was explored in the interviews, many participants reported that they support the idea of moving away from mobile devices and displaying the remote monitoring data on a ward screen, accessible to all staff. It was suggested that this would help to distribute the responsibility of responding to alerts in addition to allowing easier information sharing.

> *'I think that if it was keyed up with the whiteboard observations… it would make us much more engaged, because we're constantly checking it all of the time, during handovers and everything like that.' – Participant 4, Band 6 (Ward 2)*

> *'I think it would have detracted from that 1-to-1 responsibility of having that device and it's just you.' – Participant 2, Band 7 (Ward 1)*

An alternate viewpoint suggested that, by removing the individual's responsibility, alerts to patient deterioration could be ignored or missed. This was thought to be a risk if staffing levels were low, or if staff were busy.

> *'You've got to respond to your patients, don't you? You have to do your responses. So whether it would get missed, you know, if it was at the nurse's station, I don't know.' – Participant 6, Band 6 (Ward 1)*

The original theory was that if that nursing staff are only able to see the benefit of CRM on a patient-by-patient basis then they may underestimate the impact of the technology. The interviews identified the contextual factors that lead the nursing staff to feel positively or negatively about the idea of sharing the CRM data on a ward screen. The fact that nursing staff are used to working collaboratively and the current presence of large screens for information sharing would support the idea of a shared screen for CRM. In contrast, the busy nature of the wards may mean that alerts are missed if individual nurses are not responsible for their patients' monitoring. These theories are summarised in Table 27.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Nursing staff work collaboratively to look after all ward patients.	The remote monitoring mobile device is the individual nurse's responsibility.	Nursing staff perceive this personal responsibility as a burden.	Nursing staff fail to engage with the CRM system.
All wards have a large electronic whiteboard displaying patient information.	The whiteboards allow sharing of patient details to all staff.	Information sharing helps to reduce to burden on individual staff members.	Nursing staff are more likely to engage with the CRM system.
	The nursing staff are accustomed to using the whiteboards to check patient details.	Staff could easily incorporate continuous vital signs monitoring into their daily routines.	Nursing staff are more likely to engage with the CRM system.
The surgical wards are often busy and understaffed.	A shared ward screen would distribute the responsibility for each patient.	Nursing staff would no longer be individually accountable for the patients' monitoring.	There is the potential for missed patient deterioration, especially during busy periods.

Table 27: Context-mechanism-outcome configurations of theories regarding perceptions of a ward-based screen to display CRM data

6.4.2.3.3 Perceptions of prompts

A theory from the literature was that if the CRM system incorporates explicit escalation guidance during alerts then nursing staff are more likely to successfully integrate CRM into their working practices. The electronic vital signs monitoring system, recently installed on the participating wards, incorporates such prompts. This idea was supported by a few junior members of staff, but widely rejected by others, largely because it was felt they were unnecessary, would duplicate information and that staff already had the required skills to act appropriately to alerts.

> *'I think when you're newly qualified, you always worry, don't you? When someone's observations are off, 'Have I missed anything?' I think prompts are always a good thing.' – Participant 10, Band 5 (Ward 1)*

> *'No… We've all had training on what to do. If it was a high NEWS when we went to the patient, we'd know what to do, so it's a similar thing.' – Participant 6, Band 6 (Ward 1)*

The original theory was that if the CRM system incorporated explicit prompts for action during alerts then nursing staff would be more likely to engage with the technology. When this theory was explored in the interviews, it received mixed reviews. Junior staff may be most likely to benefit from prompts, but other contextual factors such as a diverse patient population and the repetition of current escalation protocols would lead prompts to impair staff engagement with the CRM system, as summarised in Table 28.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Some nursing staff are very junior. They lack confidence in their ability to	Remote monitoring could incorporate prompts for	Junior staff value prompts that ensure the appropriate response to patient deterioration.	Junior staff are more likely to engage with the CRM system.

manage abnormal physiology.	clinical actions in the event of an alert.		
Protocols for the management of deteriorating patients are already in place.	The remote monitoring system would echo these institutional protocols.	Nursing staff perceive duplication in the information they receive. Nursing staff do not perceive value from extra prompts.	Nursing staff fail to engage with the CRM system.
The surgical wards care for a diverse patient population.	Automatic prompts would be standardised across all patients.	Protocolised prompts do not allow staff to deliver individualised care. Nursing staff perceive remote monitoring as restrictive and detrimental to patient care.	Nursing staff fail to engage with the CRM system.

Table 28: Context-mechanism-outcome configurations of theories regarding perceptions of prompts for clinical escalation

6.4.2.3.4 Integration into local workstreams

A prominent theory in the literature was that if the innovation is supported in the local hospital culture and embedded within existing local processes then staff are more likely to successfully integrate CRM into their working practices. When this theory was explored in the interviews, duplication of information was a common concern reported by participants. It was widely felt that the remote monitoring data could be integrated into the current electronic vital signs monitoring system to reduce workload and improve efficiency.

> *'We couldn't have a policy where we had to do two of the same things because it wouldn't make any sense… If we could, somehow, make the systems talk to each other, [that] would be amazing.' – Participant 3, Band 7 (Ward 1)*

A refinement of this theory is summarised in Table 29.

Context	Mechanism		Outcome
	Resource	Response	
Electronic observations are already in place on the wards.	CRM can be integrated into existing monitoring pathways.	Nursing staff perceive reduced workload and improved efficiency.	Nursing staff more likely to engage with the CRM system.

Table 29: A context-mechanism-outcome configuration of the theory regarding the integration of the CRM system into local workstreams

6.4.2.4 Nursing perceptions of implementation of CRM technologies

Although having research undertaken on the wards was universally acknowledged to be a good thing, participants were keen to share their perceptions of the positive and negative aspects of how the remote monitoring technology was implemented across the two participating wards.

6.4.2.4.1 Choice of wards

A prominent theory in the literature was that if technology is implemented in a setting with high acuity patients then nursing staff are more likely to see the benefit of CRM. Participants expressed contrasting perceptions about the suitability of the two participating wards to host the research. These concerns were predominantly about staffing levels, staff experience and patient acuity.

The two wards are similar in the types of patient that they admit. The main difference lies in the patient gender, the impact of which has already been discussed. The wards typically admit high acuity patients with a mix of ages and surgical pathologies. In general, these patients were perceived to be the most appropriate to receive continuous remote vital signs monitoring.

'I think it's a perfect group of patients, they're the sickest.' –

Participant 3, Band 7 (Ward 1)

The two wards are very different in their staffing levels. Ward 1 has 60% vacancy rate and relied heavily on temporary 'agency' staff, whereas the staffing on Ward 2 is fully established. It was suggested that low staffing levels and high turnover was a reason for the lack of engagement of staff on Ward 1.

The senior nurse on Ward 1 suggested that the remote monitoring system was a reason why staffing levels were low.

'With the introduction of E-meds and E-obs, we were one of the first wards to roll out that in the Trust... So when people came and they didn't know about it, they were all a bit panicked. But when you told them it was going to be rolled out everywhere, they very quickly learned that they needed to do the training… Whereas for Sensium, because it's just here, if they don't like it they won't be coming back.'

– Participant 2, Band 7 (Ward 1)

When asked about which members of staff should carry the mobile devices and respond to alerts of patient deterioration, the majority of participants perceived staff nurses (Band 5) to be the best recipient of the devices, rather than the care support workers (also known as healthcare assistants, or 'healthcares') or the nurses in charge. This is in the context of care support workers (Bands 2 and 3) usually having responsibility for the manual vital signs observation rounds.

'The CSWs do all the observations but they've got a lot to do already with everything else so I think it's better with the Band 5s… If there is

a problem, they can deal with it straight away.' – Participant 6, Band 6 (Ward 1)

'I think the nurses should [carry the phones] so that you're not running back and forth telling them because when it's going off in your pocket, you've got to go tell the nurse so I think the nurses should just carry it really so they can see it themselves.' – Participant 12, Band 2 (Ward 1)

The participants reported that they recognised that experience and individual capabilities would also determine who was best to carry the devices.

'If I'm confident with the people I'm training, I'd be more than happy for them [to carry the devices] because… they've got the skills.' – Participant 1, Band 7 (Ward 2)

The original theory was that if technology is implemented in a setting with high acuity patients then nursing staff are more likely to see the benefit of CRM. Whilst most participants agreed that the patient population was appropriate, the interviews also identified the contextual factors that affect the engagement of staff within this high acuity environment. These included the staffing levels and the dependence on temporary staff, in addition to the experience and competence of the staff on shift, regardless of their seniority. These theories are summarised in Table 30.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
The wards have a high acuity patient population.	CRM has more potential to detect patient deterioration.	Nursing staff perceive the benefits of CRM more frequently than in less acute settings.	Nursing staff more likely to continue to

			engage with the CRM system.
Some wards have low staffing levels.	The CRM system involves extra work for nursing staff.	Remote monitoring is perceived as a burden.	Nursing staff are less likely to engage with the CRM system.
Some wards have a high dependence on temporary staff.	CRM is not the standard of care.	Temporary staff perceive remote monitoring as an unnecessary extra burden on surgical wards.	Temporary staff choose not to work on surgical wards, thereby disadvantaging permanent staff.
CSWs usually perform vital signs monitoring on general wards.	Remote monitoring alerts are usually escalated to qualified nurses.	Nursing staff perceive remote monitoring as a duplication of work for all staff.	Nursing staff disengage from the non-mandatory monitoring tool.

Table 30: Context-mechanism-outcome configurations of theories regarding how the setting for the implementation affects engagement with the technology

6.4.2.4.2 Optimisation of the product

A prominent theory in the literature was that if the intervention is optimised as much as possible before implementation then early technology failure may be avoided which might lead to disengagement of the nursing staff. When this theory was explored in the interviews, perceptions of two very different contexts were reported.

The senior nursing staff from each ward reported different perceptions regarding the maturity of the remote monitoring system when it was first introduced. The staff nurses from Ward 1 perceived the system as a 'finished product,' which led to false expectations around its utility. This led to early disappointment when the system required small changes, and rapid disengagement by the staff.

> *'We got told it was a fully functioning, completely finished article and we very quickly realised it wasn't. Absolutely everything that they*

gave us the information about was positive, there wasn't any negative bits at all… I feel a little bit duped in a way.' Participant 2, Band 7 (Ward 1)

'We didn't know it was a work in progress until we arrived at the meeting and they were like 'Oh, we could tweak this'… Had it been rolled out a bit better, we would have been a bit more welcoming towards it.' – Participant 3, Band 7 (Ward 1)

In contrast, the senior nurse on Ward 2 reported perceiving the product as a 'work in progress' (Participant 1, Band 7)

'It's not the finished article because we needed to have our input on it. We wanted to have a say on what we needed because it had to be beneficial for us. People came in, updating things, getting rid of all of the viruses and all the other bits and problems that we've had. And I think our lot appreciate that that was what they could do.' – Participant 1, Band 7 (Ward 2)

It was suggested by one participant that there could have been better information sharing.

'They maybe could have brought us altogether and done a presentation and said, 'This is what we want. This is the overall goal, but we're going on this massive journey together.' – Participant 3, Band 7 (Ward 1)

When the theory of optimising the technology was explored, many participants perceived that the remote monitoring system had become easier to use over time. Many participants reported that they appreciated that their feedback about the system had been acknowledged and acted upon. It was perceived that the changes improved the system for the nursing staff, thereby increasing engagement.

> *'It's got easier. People have obviously been listening to us.' –*
>
> *Participant 1, Band 7 (Ward 2)*

The original theory was that if the intervention is optimised as much as possible before implementation then staff engagement would be enhanced. The interviews identified some of the contextual factors that lead nurses to perceive CRM positively or negatively throughout its implementation. Representation of the system as a 'finished product' did not encourage engagement, especially during early technology failures. When nursing staff were aware that the system was a 'work in progress,' and were able to see the results of their feedback, engagement was enhanced. Engagement was also improved simply by virtue of having the same system in place for a prolonged period of time. These new theories are summarised in Table 31.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Device is promoted to ward staff as 'finished product' with unrealistic promises of benefit.	Device has innate problems, e.g. false alerts.	Nursing staff perceive device as beyond improvement.	Nursing staff disengage from the CRM system.
Device is promoted as a 'work in progress'.		Staff expect the product to be improved over time.	Nursing staff continue to engage with the CRM system.
Members of staff have remained relatively stable	The remote monitoring device has	Nursing staff have become accustomed to the remote	The system performs better and potential

throughout the implementation of remote monitoring.	been in place for three years.	monitoring system and how to use it.	benefits are realised.
Nursing staff have been encouraged to give feedback on the device since its implementation.	The device has been improved in response to staff feedback.	Nursing staff perceive changes and improvements over time. Nursing staff perceive a common goal with researchers.	Nursing staff continue to engage with the CRM system.

Table 31: Context-mechanism-outcome configurations of theories regarding how optimisation of the intervention affects staff engagement with the technology

6.4.2.4.3 Training

Theories regarding staff training were elicited from the literature and from non-participant observation; if staff are trained thoroughly and appropriately then engagement with the CRM system is enhanced.

Staff training on the new system was undertaken individually or in small groups. Trainers were available on the wards for four weeks, and trained staff opportunistically during their working day. Refresher training was available on an ad hoc basis. Some participants reported finding this type of training to be sufficient.

> *'I know the teaching that I was given was very thorough and I felt very confident in rolling it out to others.' – Participant 1, Band 7 (Ward 2)*

Other participants suggested that training would be better undertaken as part of a dedicated training day, when participants were not expected on the wards. Other suggestions were online training, and drop-in sessions. Other barriers to effective training were a perceived lack of purpose, a single training session and unapproachability of trainers.

'I think when you don't understand why something's even being put in place, you're not as on board with it.' – Participant 10, Band 5 (Ward 1)

'I think more than one training session would have been beneficial.' – Participant 3, Band 7 (Ward 1)

'The person who [initially] rolled it out was very, 'What's happening? Go do it.' And wasn't very approachable which didn't help.' – Participant 3, Band 7 (Ward 1)

The original theory was that if staff are trained thoroughly and appropriately then engagement with the CRM system is enhanced. The interviews identified some of the contextual factors that influence the perceptions of nursing staff regarding the best way to be trained. In the context of busy working days with unpredictable schedules, opportunistic sessions may be appropriate. In order to allow nursing staff time away from their distractions of the ward, dedicated group sessions may be more suitable. By optimising the style of training provided, staff confidence and engagement in the technology would improve. These theories are summarised in Table 32.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Nursing staff cannot plan their days.	Training is provided opportunistically on the wards.	Staff can fit training into their working day with limited disruption.	Nursing staff are well trained and feel confident to use CRM.
Nursing staff are busy when they are on the wards.	Formal group-based sessions would allow nursing staff to come off the wards	Staff are able to engage better without ward distractions.	

Table 32: Context-mechanism-outcome configurations of theories regarding how training affects engagement with the remote monitoring technology

6.4.2.4.4 The role of the research team

A theory elicited from non-participant observation was that if research staff are involved in tasks associated with the CRM monitoring then ward staff might perceive CRM as outside of their responsibility and fail to engage with the technology. When the theory was explored in the interviews, participants reported feeling that there was adequate support from the research team.

> *'If someone had forgotten something, there would be someone that could go, 'Oh, you need to do that'… There was always a contact number.' – Participant 4, Band 6 (Ward 2)*

Despite concerns that research team involvement on the wards would decrease engagement with the remote monitoring system, nursing staff reported that they were happy to be relieved of part of the workload.

> *'Since we introduced the patch into Recovery, that's made life a lot easier… It was manageable.' – Participant 6, Band 6 (Ward 1)*

The original theory was that if research staff are involved in tasks associated with the CRM monitoring then ward staff might fail to engage with the technology. This theory was inconsistent with the perceptions of the nursing staff; rather, the interviews identified some of the contextual factors that positively influence the perceptions of nursing staff regarding the research team's involvement. These included the busy ward setting, where nurses appreciated the extra help, and the fact that nursing staff

are well accustomed to only participating in discrete aspects of a patient's care. These theories are summarised in Table 33.

Context	Mechanism		Outcome
	Resource	Response	
The nursing staff are very busy	The research team consent patients and apply the monitoring devices.	Nursing staff appreciate the assistance of the research team in reducing the workload of continuous monitoring.	Nursing staff exhibit improved engagement with the CRM system.
Nursing staff are accustomed to taking over patient care from other teams, e.g. theatre staff	The research team consent patients and apply the monitoring devices.	Nursing staff do not perceive a problem with fragmenting the delivery of the continuous monitoring.	Nursing staff engage in the efferent arm of the monitoring pathway, despite being removed from the afferent arm.

Table 33: Context-mechanism-outcome configurations of theories regarding perceptions of the research team's involvement in implementing the remote monitoring technology

6.4.2.4.5 Incentives

A theory from the literature suggested that if incentives were offered to participating staff then engagement with the technology would be enhanced. In the interviews, a number of participants reacted strongly to the idea that nursing staff could be incentivised to engage with the CRM system.

> *'We'd like to think that they wouldn't need incentives if it's relating to patient care, really.' – Participant 2, Band 7 (Ward 1)*

Other participants made suggestions for incentives, in the context of a number of new initiatives in the hospital to promote compliance with clinical targets.

'Incentives help with a lot of things, don't they? A bit of a well done for [a nurse] or [a nurse] or somebody: 'You responded the most,' or I don't know.' – Participant 3, Band 7 (Ward 1) '

Some nursing staff reported that they were incentivised by gaining CPD (Continuing Professional Development) points during training sessions.

'There were a couple of people who did actually want to do a whole Sensium training with me and they wanted to put that in their revalidation portfolio.' – Participant 13, Research Nurse

One participant suggested that incorporating it into the routine tasks of the nursing staff would be the best way to encourage engagement.

'Have a care plan because that is the best prompt, isn't it?' – Participant 10, Band 5 (Ward 1)

The original theory was that if incentives were offered to participating staff then engagement with the technology would be enhanced. When this theory was explored in the interviews, the responses were mixed. A contextual factor which contributed to a positive response to the idea of incentives was the fact that the nursing staff have a large number of competing priorities; incentives may put CRM monitoring to the forefront of their minds. In contrast, in the context of recent rapid technological change, some nurses may feel the incentives are patronising as they are already accustomed to implementing new technologies. These theories are summarised in Table 34.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	

Nursing staff have a large number of clinical priorities.	Incentives reward staff for engagement with continuous monitoring.	Nursing staff are motivated to respond to alerts.	Nursing staff exhibit improved engagement with the CRM system.
There has recently been rapid technological change on the wards.	Nursing staff are accustomed to integrating new technology into their care pathways.	Incentives are perceived as patronising.	There is reduced engagement despite incentivisation.

Table 34: Context-mechanism-outcome configurations of theories regarding incentives to engage with the remote monitoring technology

6.4.2.4.6 Dissemination of success

The theory explored in Section 1.4.2.3.2 was that if that nursing staff are only able to see the benefit of CRM on a patient-by-patient basis then the impact of the technology may be underestimated. In the interviews, this theory was further explored with respect to implementation strategies.

Although all the participants could see the potential advantages of the new system, many of the nursing staff interviewed reported that they had not personally seen any patient derive benefit from wearing the CRM device, including all those from Ward 1. In contrast, three participants from Ward 2 had seen benefits for their patients, and the other members of staff had heard about them. The experience of seeing tangible benefits was perceived to improve engagement with the technology, whereas a lack of experience had the opposite effect. Participants described how sharing success stories would have improved engagement,

> *'I had more of a positive experience and I thought, 'Oh, this is actually really good'… You try encourage everybody else when you're having a good experience with something, because you want everybody else to enjoy it.' – Participant 8, Band 5 (Ward 2)*

The original theory was that if that nursing staff are only able to see the benefit of CRM on a patient-by-patient basis then the impact of the technology may be underestimated. When this theory was explored in the interviews, participants agreed that seeing or hearing about a success story related to the CRM system would encourage their engagement with the technology. This is difficult in the context of nursing staffing only tending to a few patients each day; time dedicated to sharing success stories between staff would improve engagement. These theories are summarised in Table 35.

Context	**Mechanism**		**Outcome**
	Resource	**Response**	
Nurses care for 7 to 10 patients at one time.	The CRM mobile device is the individual nurse's responsibility.	A single nurse may not personally see patient benefit from CRM.	Nursing staff less likely to engage with the CRM system.
Nursing staff share patient details during the handover between shifts.	Successes of the CRM system could be highlighted at handover times.	Nursing staff would be more aware of the benefits of CRM.	Nursing staff would continue to engage with the CRM system.

Table 35: Context-mechanism-outcome configurations of theories regarding dissemination of success relating to the remote monitoring technology

6.5 Discussion

The study had four objectives:

1. To contribute to the reporting of the TRaCINg feasibility trial by investigating how and in what contexts nursing staff perceptions vary regarding the continuous remote monitoring of patients' vital signs.
2. To provide data to inform the development of such technologies according to the contexts in which they will be delivered and with a focus on end-users.
3. To provide data to inform future adoptions by investigating nursing staff perceptions of how and in what contexts the optimal implementation of such technologies occurs.

4. To develop theories regarding the use of the technology in different contexts that can be tested in a definitive evaluation.

6.5.1 Implications for the reporting of the TRaCINg feasibility study

The TRaCINg study found that patients allocated to CRM suffered fewer complications when compared to those receiving usual intermittent monitoring alone. Participants receiving CRM were less likely to have an unexpected critical care admission and had a shorter average length of hospital stay. However, there was no difference in the time taken to receive antibiotics in cases of sepsis.

When evaluating the effects of complex interventions such as CRM, it is crucial to monitor inadequacies in external influences, such as patient and staff adherence, that might negate the potential benefit of additional monitoring. This realist feasibility evaluation is the first of its kind to investigate how and in what contexts nursing staff perceptions vary regarding the CRM of patients' vital signs. It has revealed contexts which could potentially explain the different levels of engagement seen between the two study wards, which in turn may have affected the effectiveness of the intervention.

Contextual factors can be subdivided into individual, interpersonal, institutional and infrastructural levels.

6.5.1.1 Contexts at an individual level

Nursing staff had a good understanding of the theoretical principles underlying CRM. Contexts at an individual level which affected engagement with CRM included the nursing staff's acceptance of technology. This was enhanced if they had previous experience with telemetry, but reduced if staff had a previous negative experience with

new technology or did not usually require access to technology in their working day. More senior staff were more likely to engage with CRM than their junior counterparts.

6.5.1.2 Contexts at an interpersonal level

There were two main interpersonal contexts which affected the engagement of nursing staff with CRM. The first was their relationships with the patients and relatives; if nursing staff perceived the patients to be anxious about their care, they were more likely to engage with CRM to try and improve the patients' experiences. The second important interpersonal relationship was that between senior nursing staff and their junior counterparts. The attitude of senior nurses towards CRM was highly influential in determining their colleagues' engagement.

6.5.1.3 Contexts at an institutional level

Contexts at an institutional level included the type of wards that CRM was implemented on. Wards with good staffing levels and less reliance on temporary staff were more likely to demonstrate engagement with the technology. Staff from busier wards, and especially the female ward, were more likely to perceive CRM as a burden. Night shifts, which are generally less busy than day shifts, were perceived as an ideal setting for CRM. In the context of rapid technological change on the wards, CRM was likely to be lost in amongst the barrage of new technologies, especially as CRM was not perceived as an institutional priority because it was not audited like other patient care pathways.

6.5.1.4 Contexts at an infrastructural level

An important infrastructural context is the dominance of the NEWS score throughout the healthcare system. Nursing staff reported taking a repeat NEWS score in response to any sign of deterioration in order to facilitate communication between other

healthcare professionals about deteriorating patients. In supplementing the NEWS score with CRM, nursing staff queried the perceived duplication of work. In contrast, when staff reported their recognition of the drawbacks of the NEWS system, they were more likely to recognise the value of CRM and engage with the devices.

6.5.2 Implications for the development of CRM technologies

The hardware involved in CRM was an important factor in determining engagement with the system. If devices were perceived to be bulky or heavy, nursing staff were less likely to engage with them. If devices looked too much like personal mobile phones, nursing staff were likely to feel uncomfortable using them in front of patients, relatives and other staff members, for fear of appearing unprofessional. This could be avoided by introducing ward-based screens to display CRM data, rather than relying on personal devices.

6.5.3 Implications for the implementation of CRM technologies

Whilst acknowledging that the theories regarding implementation remain to be empirically tested, the findings suggest that, for organisations seeking to introduce CRM, the following strategies may be beneficial:

1) Incorporating CRM into institutional guidelines and introducing metrics for their use.
2) Integrating CRM into the current electronic vital signs monitoring system to reduce workload and improve efficiency. Although prompts for suggested escalations of care were not considered to be beneficial by the nursing staff, integration of the CRM into existing escalation pathways would reduce the perception of duplication of work.

3) Choosing candidate wards with care. The ideal ward would care for a high acuity population, but have adequate long-term staffing levels and minimal reliance on temporary staff.
4) Communicating the stage of product development at the outset to encourage shared goals.
5) Optimising the training format to suit all members of staff.
6) In the evaluation context, allowing members of the research team to assist nursing staff in the delivery of CRM to reduce workload and disruptions.
7) Disseminating success across all members of staff to encourage continued engagement.

6.5.4 Strengths and limitations of the study design

The realist feasibility evaluation has elicited theories regarding CRM and refined these theories through interviews with the nursing staff. A strength of this study is the comprehensive methods use to elicit theories, including a systematic literature review, real-time observations of nursing practice through daily wards visits as part of the TRaCINg study, and interviews with patients who had experience of wearing the CRM device. This allowed a wide range of theories to be elicited, including contradictory ideas.

The study was limited by its sample population. Interviewed participants were nursing staff from only two study wards, from a single institution. Although the contrasting settings of the two wards may widen the applicability of the findings, the refined theories may not be applicable in other wards or institutions, and this should be taken into account when testing the theories in different settings.

The semi-structured interviews started after the trial, which limited any potential impact of the refined theories on the management of the trial itself. These theories can now be used to inform future studies, in which the theories themselves can be tested.

6.5.5 Implications for future research

There is emerging interest in integrating realist evaluation across all phases of evaluation for complex interventions[106]. Feasibility and pilot studies are an ideal setting in which to theorise the contextual conditions in which an intervention will be successful[115]. The refined, untested theories gleaned from this realist feasibility evaluation could be used to inform the implementation of CRM for future studies but should also be tested in a process evaluation alongside a definitive trial. In doing so, realist evaluation can facilitate the translation of complex interventions into routine practice.

7 An early economic evaluation exploring the potential cost-effectiveness of continuous remote monitoring of vital signs following major colorectal surgery

The National Health Service is a healthcare system with finite resources. New interventions must prove to be cost-effective before they can be widely adopted. This chapter describes a cost-utility analysis conducted using decision-analytic modelling, with transition probabilities derived from the TRaCINg study described in Chapter 5. The SensiumVitals® remote monitoring system is shown to be cost-effective when compared to standard NEWS monitoring from an NHS payer perspective, although there is considerable uncertainty and the model is susceptible to changes in the baseline transition probabilities. Suggestions are made regarding the direction of future research in order to provide a robust economic analysis as part of a definitive evaluation of the technology.

7.1 Background

In many healthcare systems, fixed budgets mean that decisions about new treatments cannot be made only on the basis of clinical effectiveness alone; cost-effectiveness is crucial in allocating limited resources. Economic evaluation ensures that the benefits of implemented interventions exceed their opportunity costs (the health benefits that could have been achieved had the money been spent on the next best alternative intervention[116]). This is important in the field of CRM as these systems are not without financial cost. System prices are around US$1500, and the cost of disposable patches varies[45].

As described in Chapter 1, there are three existing economic evaluations which all concluded that their respective continuous monitoring devices were cost-effective. One study was a return-on-investment analysis; two studies were cost-effectiveness analyses. These studies have four major limitations. Firstly, they do not express outcomes in terms of a generic measure of health, such as a quality of life score, which is comparable across different clinical areas. Secondly, all three studies are based on data from the USA; they seek to inform decision-making in the USA and, as such, some of the parameter estimates and assumptions may be inappropriate for NHS practice. Thirdly, none undertake probabilistic sensitivity analysis to depict the uncertainty in their evidence. Finally, all three studies were limited to single devices, tested in small populations in single hospitals, which may limit their generalisability to other devices and populations. Further research is required to reduce the uncertainty as to whether continuous postoperative monitoring offers a significant benefit over intermittent monitoring and can be justified for routine care in terms of cost effectiveness.

Economic evaluation is the comparative analysis of alternative courses of action in terms of their costs and consequences. Often, the comparator is usual care. There are different types of economic evaluations. Whilst a cost-effectiveness analysis (CEA) is simple to carry out, the outcome measures are specific to the interventions being tested, which means that interventions with different objectives cannot be compared. For instance, one potential outcome of a CEA of a remote monitoring system may be cost per critical care admission avoided after major surgery. This outcome cannot be compared with programmes and interventions in other specialties and disease areas that are competing for the same finite healthcare resources; a common outcome measure is required to compare different interventions. In addition, the relationship between some outcome measures and health is not always clear; for instance, if CRM reduces hospital readmissions when compared to intermittent monitoring alone, whilst

this has obvious monetary benefits, it is not clear if the patient is healthier in the long term by not being readmitted to hospital.

Cost-utility analysis (CUA) extends CEA to incorporate quality of life. It is the methodology recommended by the NICE Reference Case. In CUA, cost is measured in monetary value, and outcomes are utility values such as quality of life measures, which permits comparisons between, as well as within, healthcare programmes. Comparisons are made in terms of incremental cost effectiveness ratios (ICERs). The ICER represents the cost per quality-adjusted life year (QALY) and is compared to the NHS willingness to pay threshold which is currently £20,000 to £30,000. One disadvantage of the CUA approach is that outcomes are limited to health benefits; effects on productivity, for instance, are not typically included. In addition, the utility values of different health states can be challenging to derive.

No economic evaluation is complete without capturing uncertainty. A decision-analytic model is a systematic approach to decision making under conditions of uncertainty, in which the probability of each possible event, along with the consequences of those events, is explicitly stated[117]. The ideal decision model is populated with appropriate, good quality evidence and reflective of current clinical practice. It should be valid, transparent and reproducible, and take into account areas of uncertainty[118]. A linked-evidence approach is required for this economic analysis because the TRaCINg study did not collect data on quality of life; intermediate outcome measures were used such as number of complications. It is hypothesised that continuous remote vital signs monitoring may prevent the escalation of postoperative complications through early detection of physiological deterioration; it is known that the severity of complications affects patients' quality of life[119]. The linked-evidence approach allows for data from multiple sources (in this case, the TRaCINg study and the literature) to be used to inform the model parameters.

The aim of this health economics package was two-fold:

1) To evaluate the potential cost-effectiveness of the SensiumVitals® monitoring system in NHS patients following major colorectal surgery.
2) To characterise the uncertainty surrounding the cost-effectiveness of this technology.
3) To determine to which parameters the ICER is most sensitive.
4) To identify the priorities for further evidence development and propose efficient designs for relevant future research.

7.2 Methods

7.2.1 Ethical approval

Research Ethics Committee approval was obtained for this study (REC reference 17/YH/0180).

7.2.2 Study design

A cost-utility analysis of the CRM system, SensiumVitals®, was conducted using decision-analytic modelling. The base-case analysis took an NHS perspective. The time horizon for the model was 6 weeks post-surgery, as evidence from the literature suggests that the impact of complications on quality of life is evident at this stage, but may not be sustained at one year post-surgery[119,120]. The evaluation is presented in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement principles[121] (see Appendix 12).

7.2.3 Phase 1: Data collection

Input parameters relied on evidence collected during the TRaCINg randomised controlled feasibility trial and the published literature.

7.2.3.1 The TRaCINg Study

The protocol for the trial has been described in Chapter 5. Transition probabilities and their parameter values for the model were taken exclusively from the study data.

7.2.3.2 Literature review

The costs and utility values associated with surgical complications were obtained from published literature. MEDLINE®, EMBASE and The Cochrane Library were searched for articles published from the dates of inception of the databases (the earliest being 1947) to October 2018. To enhance literature saturation, citations and reference lists of selected studies were reviewed to identify any relevant papers. Data based on recent UK studies were prioritised.

The search strategy included a combination of keywords and subject headings related to surgical complications (Complicat* OR Clavien-Dindo OR Surg*) and economic evaluation (Cost* OR Economic*).

The selected costs were converted to pound sterling (GBP) using the exchange rate on 16th May 2019 (0.86 GBP to 1 Euro). Costs were adjusted for inflation to 2018 values using the online Bank of England Inflation Calculator.

7.2.4 Phase 2: Primary analysis

A decision-analytic model was developed to evaluate the impact of the monitoring systems under evaluation. The model was used to simulate the recovery pathways of hospital inpatients following major colorectal surgery until discharge from hospital. Given the clinical pathways and the short time horizon, the most appropriate model was a decision tree. A decision tree model was chosen in accordance with the

guidance from Gray, *et al*.[122] which states that a decision tree is most appropriate where there is no important interaction nor recursive events.

The decision tree is represented in Figure 17. The branches of the initial decision node represent the two monitoring strategies to be compared: continuous monitoring plus NEWS versus NEWS alone. The chance nodes of the decision tree model represent the potential pathways of patients experiencing different grades of postoperative complications. It is hypothesised that continuous remote vital signs monitoring may prevent the escalation of postoperative complications through early detection of physiological deterioration. It has been shown that postoperative complications have significant implications on quality of life and healthcare costs. In order to make the decision tree pathways mutually exclusive, the worst complication experienced by the patient (the complication with the highest Clavien-Dindo score) was used.

The untimed, static, aggregate model was developed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Model structure and assumptions were informed by what is known about postoperative surgical care pathways and the recovery of surgical patients.

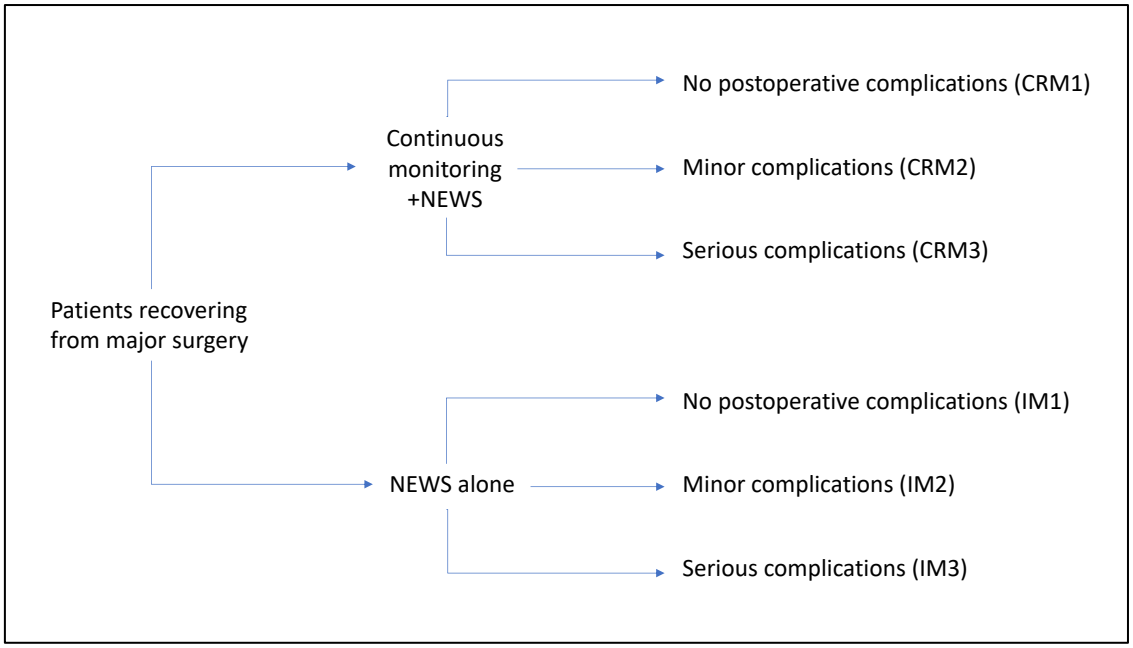

Figure 17: Decision tree

7.2.4.1 Structural assumptions

In structuring the model, a series of assumptions has been made.

1. Each ward admits 350 eligible high-risk surgical patients per year.
2. Every patient who is eligible will receive the remote monitoring patch.
3. Each patient will wear two SensiumVitals® patches during their hospital admission.
4. The most severe complication experienced by a patient will have the most impact on their quality of life.
5. The time commitment required by the ward nurses to use the two types of monitoring is equivalent.
6. The model takes an NHS perspective focussed on secondary care costs alone.

7.2.4.2 Description of the model pathways

On the basis of these assumptions, it is possible to describe the pathways of patients in the decision tree model, shown in Figure 17.

- For pathway CRM1, patients receive CRM and have no complications after their surgery (normal recovery).
- For pathway CRM2, patients receive CRM and have one or more complications rated no higher than II on the Clavien-Dindo complications score.
- For pathway CRM3, patients receive CRM and have one or more complications rated higher than II on the Clavien-Dindo complications score (III, IV or V).
- For pathway IM1, patients receive intermittent monitoring alone and have no complications after their surgery (normal recovery).
- For pathway IM2, patients receive intermittent monitoring alone and have one or more complications rated no higher than II on the Clavien-Dindo complications score (I or II).
- For pathway IM3, patients receive intermittent monitoring alone and have one or more complications rated higher than II on the Clavien-Dindo complications score (III, IV or V).

7.2.4.3 Analytical methods

The economic evaluation followed contemporary methods for model-based economic evaluation as specified in the NICE guidance on the methods of technology appraisal and the ISPOR taskforce[123,124]. Outcomes comparing the SensiumVitals® remote monitoring system with standard NEWS monitoring were presented as incremental cost-effectiveness ratios (ICERs).

To characterise uncertainty in the model parameters, a probabilistic sensitivity analysis was carried out, based on ten thousand simulations parameterizing the model from the pre-specified parameter distributions. The simulated ICERs were presented in a cost-effectiveness plane. All analyses were conducted in Microsoft Excel (Microsoft

Corporation, Redmond, WA, USA). The cost-effectiveness plane was produced in R (Version 3.4.1, R Foundation for Statistical Computing, Massachusetts, USA).

7.2.5 Stage 3: One-way sensitivity analyses

One-way sensitivity analyses were conducted around alternative input parameters. Each parameter was recalculated as 25% above and 25% below the baseline value. The ICER was recalculated for each alternative input parameter, and the resultant change from the base-case value was depicted as a tornado plot.

7.3 Results

7.3.1 Phase 1: Data collection

7.3.1.1 Transition probabilities

Transition probabilities for the model were taken exclusively from the TRaCINg study data. Parameter values reflected the confidence intervals associated with each probability in the data.

7.3.1.2 Costs

The literature review produced six papers as potential sources of costs for the model. These are summarised in Table 36. Of the seven papers, Simkens *et al.*[125] was selected as the source of the costs for the model due to:

- The recency of publication (2018).
- The setting where the data was collected; the Dutch healthcare system is similar to the NHS.
- The presence of cost data for patients with no complications.

- The aggregation of complication data into well-established groups: no complications, minor complications (Clavien-Dindo grades I and II), and severe complications (Clavien-Dindo grades III, IV and V).

The paper described both mean and median costs for each level of complication. Due to the skewed nature of the data, median values were used as the cost parameters for the model.

The per patient cost of the SensiumVitals® remote monitoring system was estimated at £531 using data provided by Sensium Healthcare, and based on the assumptions that each patient would wear two patches during their admission, and that annual subscription charges would be split between 350 eligible patients per ward per year (based on screening and eligibility data from the TRaCINg study).

Source	Year	Country	Population	Currency	Clavien-Dindo classifications: Mean costs							
					0	*I*	*II*	*IIIa*	*IIIb*	*IVa*	*IVb*	*V*
Gomez-Rosado[126]	2018	Spain	General and digestive surgery n=639	Euro		4197	6198	8449	9451	15070	24068	18398
Vonlanthen[127]	2011	Switzerland	Colorectal surgery n=1200	US$	26420	29166	43370	59822	95550	159345		
Simkens[125]	2018	Netherlands	Cytoreductive surgery in peritoneal metastases n=161	Euro	10340	13729		32188				
Straatman[15]	2015	Netherlands	Major abdominal surgery n=399	Euro	8584	15412		29198				
Breitenstein[128]	2010	Switzerland	Liver resection n=615	US$	36931			94545				
Wilson[129]	2014	USA	Pancrea-tectomy N=46	US$	11424	17431		37618				

Table 36: Potential sources of costs for the decision tree model

7.3.1.3 Utility values

The literature review produced one paper as a potential source of utility data for the model. Bosma *et al*.[120] describes another Dutch study examining the change in quality of life associated with different grades of post-operative complications in a colorectal population. The authors measured quality of life using the World Health Organisation Quality of Life (WHOQOL-BREF) score. Complications were grouped into 'no complications', 'minor complications' and 'severe complications' as described above. A change in quality of life was evident at 6 weeks after surgery when the patient had experienced a 'severe complication.' This change was not sustained at a year after surgery, and determined the time horizon for the model.

The paper reported only the change in utility values over time, and not the absolute values required for the model. Correspondence with the lead author of the manuscript did not yield these values. Instead, the relevant figure from the manuscript was analysed using DigitizeIt plot digitizer software (Version 4.0, Alcasa, Riegelsberg Germany) to determine the absolute values, and the standard error was estimated as 0.2 of the mean[130].

The parameter inputs incorporated into the model and their pre-specified parameter distributions are detailed in Table 37.

Parameter		Point estimate	PSA distribution	Source
Transition probabilities	*CRM1*	0.2	Beta	TRaCINg study
	CRM2	0.75	Beta	
	CRM3	0.05	Beta	
	IM1	0.23	Beta	
	IM2	0.62	Beta	
	IM3	0.15	Beta	
Costs (GBP)	*No complications*	11,330.94	Gamma	Simkens *et al.*[125]
	Clavien-Dindo I or II	15,041.58	Gamma	
	Clavien-Dindo III,IV or V	35,272.53	Gamma	
Cost of the SensiumVitals® remote monitoring system (GBP) per patient		531	Normal	Sensium Healthcare
Utility values	*No complications*	7.45	Gamma	Bosma *et al*.[120]
	Clavien-Dindo I or II	7.27	Gamma	
	Clavien-Dindo III,IV or V	6.33	Gamma	

Table 37: Model parameter values

7.3.2 Phase 2: Primary analysis

For a 6-week time horizon, the SensiumVitals® remote monitoring system was cost-effective when compared to standard NEWS monitoring from an NHS payer perspective. ICER was -£1,460 (95% CI -£6,780, £9701) per every one-point increase in overall quality of life on the abbreviated World Health Organization Quality of Life (WHOQOL-BREF) score. The average incremental cost was -£1314 and the average incremental utility was 0.9 WHOQOL-BREF points. For the probabilistic sensitivity analysis, the results of the Monte-Carlo simulations are shown in Figure 18. This analysis indicates that the probability of cost-saving is 69.9% and the probability of benefit to quality of life is 58%.

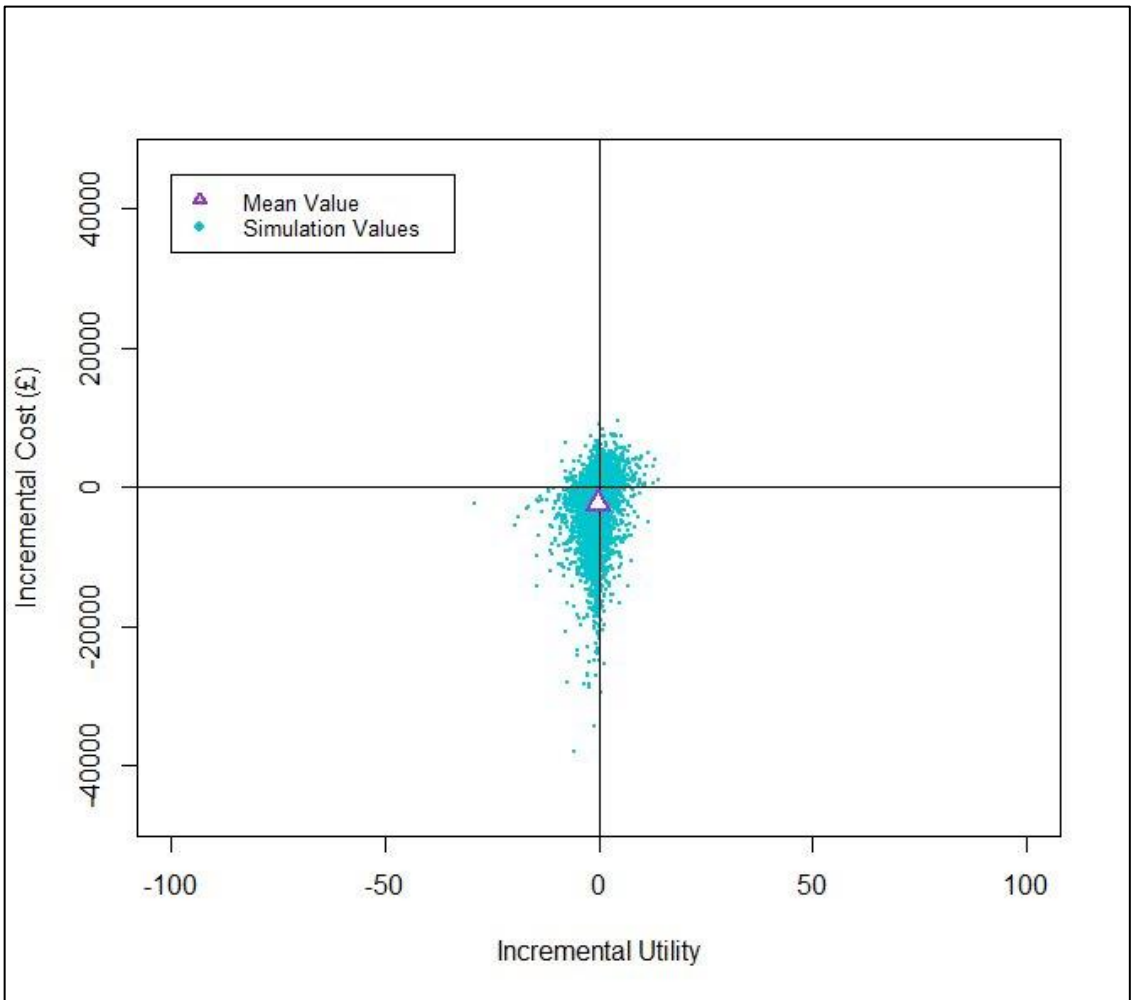

Figure 18: Cost-effectiveness plane

7.3.3 Phase 3: One-way sensitivity analysis

The tornado plot of the one-way sensitivity analysis (Figure 19) indicates that the ICER is most sensitive to variation in the probability of experiencing a serious complication, and least sensitive to variation in the costs of the complications.

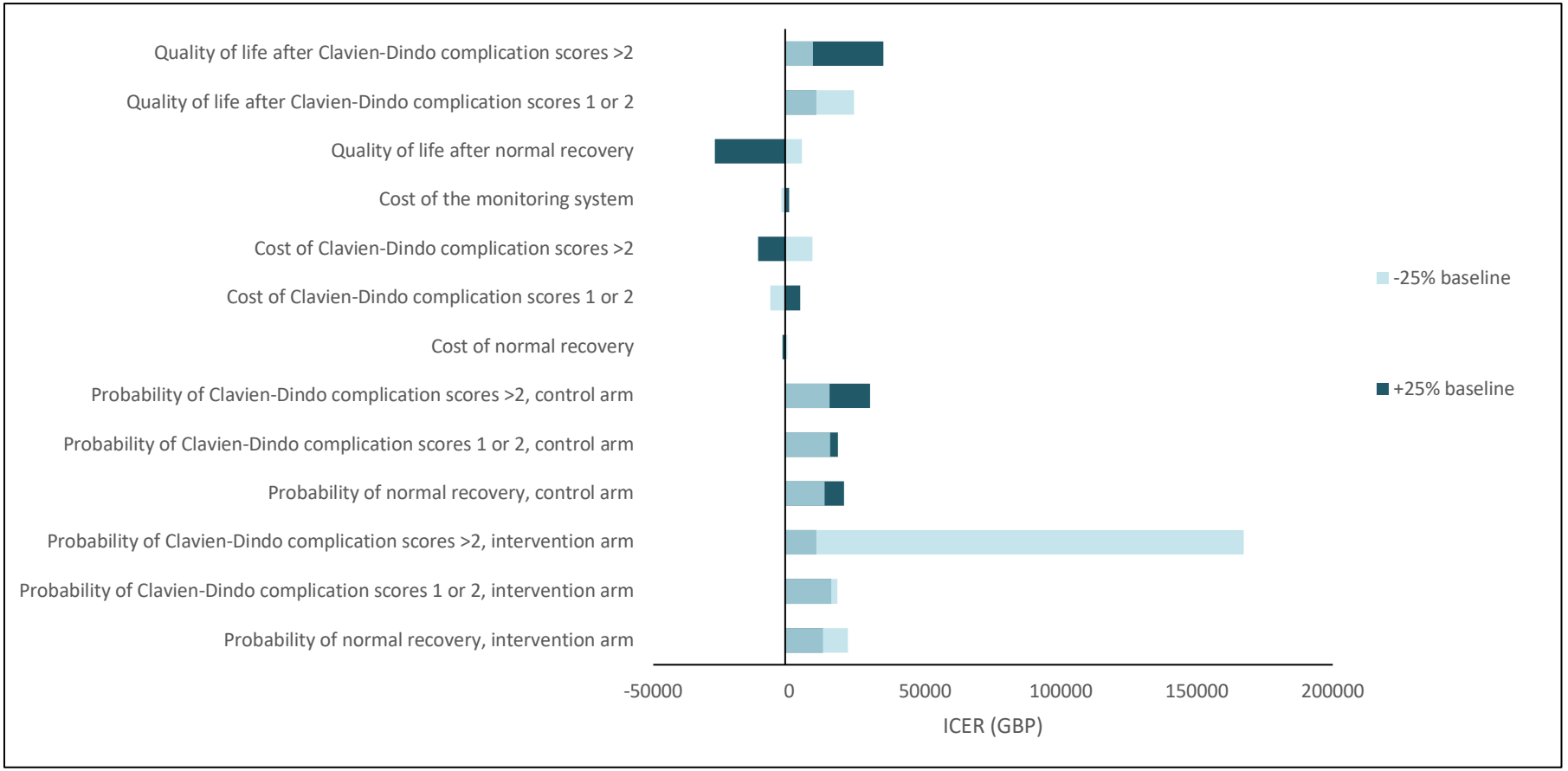

Figure 19: Tornado plot depicting one-way sensitivity analyses with a base-case ICER of -£1460.

7.4 Discussion

The evaluation presented here provides the first cost-utility analysis of a continuous remote vital signs monitoring system compared to standard early warning score monitoring. The SensiumVitals® monitoring system was evaluated for potential cost-effectiveness in NHS patients following major colorectal surgery. The results show that the remote monitoring system is potentially cost-saving when compared to standard NEWS monitoring from an NHS payer perspective, although there is considerable uncertainty and the model is susceptible to changes in the baseline transition probabilities.

The analysis is based on the most relevant evidence in the literature, and this evidence has been synthesised and incorporated into the model as fully as possible. Variability and uncertainty are present in all evaluations, however, and may limit the applicability of the results. There are a number of sources of uncertainty in this evaluation.

Sampling variation may mean that the population studied in the TRaCINg study are not representative of the wider surgical population. The one-way sensitivity analysis indicates that the ICER is most sensitive to variation in the probability of experiencing a serious complication, and the small sample population allows parameters to be swayed easily by small number of events. The PSA allows this uncertainty to be described and provides credible ranges for the ICER. There is structural uncertainty within the model: patients may have more than one complication at more than one level of severity, which may have profound impacts on quality of life. Like previous economic evaluations in this field, the results are limited in their generalisability; the transition parameters were taken from UK data at one institution, for a single monitoring system tested on a specific population.

The cost-utility analysis was limited by the lack of data surrounding the impact of post-operative complications on quality of life. The results are based on the findings of a single study which used the WHOQOL-BREF instrument to measure quality of life following colorectal surgery[120]. It was not appropriate to calculate quality of life in terms of QALYs, and therefore it was inappropriate to apply a willingness-to-pay threshold to the cost-effectiveness plane. As a consequence, the ICER has limited usefulness and there is considerable uncertainty in the model, reflected by the large confidence interval surrounding the ICER. Future evaluations should include quality of life measurements using the EuroQol five dimension scale (EQ-5D). The National Institute for Clinical Excellence (NICE) Guide to the Methods of Technology Appraisal expresses a preference for using the EQ-5D for adult populations to estimate the QALY impact of different technologies[131].

In summary, the results of this early economic evaluation support existing evidence in showing the potential for cost-effectiveness of a remote continuous vital signs monitoring system when compared to standard NEWS monitoring in a surgical population. To reduce the considerable uncertainty around the findings, any definitive evaluation should incorporate preferred quality of life measurements before and after undergoing major surgery. Future models could include the possibility of multiple complications. The applicability of the findings would be enhanced by studying a multicentre, perhaps multinational, population.

8 Discussion

8.1 Aims and objectives of this work

The main aim of this body of work was to determine whether continuous remote vital signs monitoring confers any potential benefit over intermittent NEWS monitoring in the general surgical population. Specific objectives were:

1. To evaluate the safety and efficacy of a CRM system for surgical patients, as compared to standard monitoring with the National Early Warning Score system alone.
2. To determine the feasibility of performing a large, multi-centre trial to test CRM against intermittent monitoring.
3. To evaluate patients' perceptions of the device, compared to standard monitoring alone.
4. To evaluate the acceptability of the monitoring system for the nursing staff, compared to standard monitoring alone, and to identify how and in which contexts the intervention may provide greatest benefit to patients.
5. To undertake an early health economic analysis to inform policy makers and guide future evaluations of the technology.

The completed programme of work has formed a robust, novel and comprehensive early evaluation of continuous remote vital signs monitoring on general surgical wards. The TRaCINg trial is the first study of this technology to evaluate feasibility outcomes, and thereby inform the practical and statistical aspects of further trials. By evaluating the effects of continuous vital signs monitoring on patients and nursing staff, this work has added to the body of knowledge around the assessment of this healthcare technology. The realist feasibility evaluation is the first of its kind to evaluate the

contexts, mechanisms and outcomes that affect the use of such technology, and provides potential explanations for the mixed results seen in previous work and suggests solutions to improve intervention fidelity in future studies. The health economic evaluation is the first to evaluate continuous vital signs monitoring using the methodology recommended in the NICE Reference Case, and has identified areas of deficiency in the literature to be addressed before further cost-utility research should be performed.

8.2 Conclusions

8.2.1 Chapter 3: Cluster-randomised pilot study

This single-centre randomised controlled pilot trial demonstrated the practicability of implementing a remote continuous monitoring system in the general surgical ward setting. There was a trend towards clinical benefit: surgical patients with evidence of sepsis tended to receive antibiotics faster if they received continuous vital signs monitoring when compared to those receiving usual intermittent monitoring alone; patients receiving continuous vital signs monitoring had a shorter average length of hospital stay and were less likely to require readmission within 30 days of discharge.

The limitations of this study informed the design of the second trial described in Chapter 5. A higher-risk population was chosen in an attempt to avoid the low event rate in mortality and admissions to Level II/III care. The cluster-randomisation was abandoned in order to ensure minimal baseline variance between the two study arms. The unacceptably high level of false alerts sent to nursing staff were addressed by adjusting the alarm thresholds to more clinically appropriate levels and increasing the intervals between reminder alerts. Nursing staff engagement was enhanced by implementing their suggestions about the technology, such as the provision of smaller devices and louder alert tones.

8.2.2 Chapter 4: Patient perspectives

The potential benefits of continuous monitoring may have been underestimated in the cluster-randomised pilot study due to the exposure to the patch in the intervention arm; 24% of the patients who were allocated to receive continuous monitoring did not wear the patch for their entire admission. In order to optimise participant engagement and satisfaction in future evaluations, questionnaires, semi-structured interviews and focus groups were undertaken with patients participating in the study.

It was found that patients' experiences of manual observation rounds are generally positive, but they are perceived as burdensome for staff. They are also felt to be onerous for patients themselves at night. Remote monitoring can alleviate some of this burden, but cannot replace the benefits of face-to-face nursing contact. Attention to patient comfort and convenience influenced the design of the follow-up evaluation. Participants were approached and consented before their admission to the wards, in order to avoid approaching patients in a vulnerable, post-anaesthetic state. Wherever possible, the participants had their monitoring patch applied in the Recovery Room, to avoid interrupting their nursing care in the busy first hours after ward admission. ECG electrodes suitable for sensitive skin were sourced in order to maximise participant comfort.

8.2.3 Chapter 5: Feasibility randomised controlled trial

In this single-centre randomised controlled feasibility trial, the feasibility of performing a large-scale randomised controlled trial of CRM after major surgery has been confirmed. The recruitment target was met ahead of time with a high rate of eligibility and consent. The randomisation method was appropriate and missing data was limited only to

questionnaire responses; no participants were lost to follow-up and only one participant was withdrawn, due to loss of capacity.

Participants had fewer unplanned critical care admissions and had a shorter average length of hospital stay in the continuous vital signs monitoring group. There was no difference in the time taken to receive antibiotics in cases of sepsis.

The results of this study can now be used to inform the design of a much larger, multi-centre, randomised, controlled trial. An issue which remains to be overcome is that of patient adherence to the monitoring protocol, as 28% of participants did not wear the patch for the intended 5 days. Future evaluations should focus attention on intervention fidelity (the degree to which the intervention is delivered as intended)[132], in order to avoid Type II error, where potentially effective treatments are found to be ineffectual. Despite its importance in the evaluation of complex interventions[104], implementation fidelity is rarely reported, which may help to explain the apparent inconsistency between positive evaluation findings in the literature and the difficulties with long-term adoption[75].

8.2.4 Chapter 6: Nursing staff perspectives

Implementation fidelity also relies heavily on the nursing staff, who are required to carry the devices and act on any alerts. The realist feasibility evaluation conducted during the TRaCINg study found that nursing staff had a good understanding of the theoretical principles underlying remote monitoring, but that their engagement was affected by a number of personal, interpersonal, institutional and infrastructural contexts. These contexts can be exploited in the future development and implementation of CRM technologies; for instance, by choosing the trial wards so that they are high acuity but have adequate long-term staffing levels and minimal reliance on temporary staff,

nursing staff will be able to see tangible benefit from the devices whilst minimising their associated burden. This would improve engagement and implementation fidelity, improving the reliability of future evaluations.

8.2.5 Chapter 7: Early economic evaluation

Arguably the most important aspect of the evaluation of healthcare technologies is an assessment of cost-effectiveness. By synthesising the findings of the TRaCINg study and the most current available literature, the early economic evaluation allowed the cost of the remote monitoring system, the cost of complications and the effectiveness of the technology to be combined in a cost-utility analysis. This work showed the potential of the remote monitoring system to be cost-effective when compared to intermittent monitoring alone in the postoperative population. The high level of uncertainty reflects the early nature of the work, and highlights areas of need to guide future evaluations of the technology. In addition to providing a large sample for study, a definitive trial should include a rigorous assessment of quality of life following postoperative complications.

8.3 Limitations

This work provides a robust foundation for a definitive trial of CRM in the surgical population, although there are certain limitations inherent in its design. The realist feasibility evaluation has highlighted that the success of such an evaluation is heavily dependent on the context in which it is performed; data from these studies is limited to the context in which it was collected and may not be valid in other contexts. The applicability of the results of a study can never be assured, because of the 'complexity of patients, health professionals, clinical settings, cultures, and healthcare systems'[94]. Evaluations of different devices will yield different responses from staff and patients. Changes in the population demographics can dramatically alter the

outcomes which can be expected after surgery. The study setting, its organisational structure and its stakeholder engagement will be critical in ensuring the success of a future evaluation.

Due to the single-centre setting of this work, participant numbers were small, especially in the qualitative studies. This may compromise the validity of the study findings; however, in both the patient and nursing staff interviews, data saturation was quickly reached and there was considerable repetition of themes across a wide demographic. In addition, using multiple methods (questionnaires, interviews and focus groups) allowed participants a number of opportunities to reflect on and express their views, ensuring a thorough understanding of the participants' attitudes and perceptions.

The quantitative work described in this thesis has succeeded in the aim of proving the feasibility of a definitive trial in this area. It is not possible to draw conclusions regarding the observed impact of CRM on clinical outcomes, because the studies were not powered to detect statistically significant differences in outcomes such as critical care admissions or length of hospital stay. The economic evaluation was limited by the small number of existing studies regarding the quantitative impact of postoperative complications on quality of life, and this is illustrated in the level of uncertainty around the main findings.

8.4 Implications for future research and implementation

8.4.1 Future trial design

Progression to a definitive multicentre randomised controlled trial would be appropriate at this stage. This should include at least 602 high-risk participants (301 per arm) and consider length of hospital stay as the primary endpoint. Participants should be individually-randomised and stratified to minimise the baseline differences between the

two treatment arms and reduce the effect of clustering. Recruitment and follow-up, traditional areas of deficiency in clinical trials, are unlikely to be barriers. Care should also be taken to monitor and address inadequacies in other areas that might negate the potential benefit of additional monitoring, such as patient and staff adherence. Attention to patient comfort and convenience should heavily influence the design of a definitive evaluation. Staff engagement should be optimised by implementing and testing the theories suggested in Chapter 6.

8.4.2 Long-term adoption of the technology

The engagement of staff may also influence any subsequent widespread adoption of continuous remote vital signs monitoring. There are a number of successful small evaluations of such technologies reported in the literature[18,26,40,48,49,51–57], but anecdotal evidence suggests that many of the interventions do not move past the evaluation phase to long-term or widespread adoption. The field of novel patient monitoring systems has been described as being cursed by a 'plague of pilots'[133], reflecting the difficulties in progressing past the initial stages of evaluation. This lack of sustainability is echoed across studies of diffusion of innovations in healthcare[75]. Many promising technological interventions are characterised by non-adoption or abandonment after the initial short-term evaluation[75].

The problem of non-adoption is often blamed on suboptimal implementation of the intervention[134]. Implementation is defined as the structures, resources and processes through which the delivery of the intervention is achieved, and the quantity and quality of what is delivered[104]. Failure to manage the implementation process may limit successful adoption and the realisation of potential benefits[67]. By engaging key stakeholders, such as the nursing staff, at the implementation stage, their attitudes

and perceptions can be used to optimise this process for the benefit of patients, staff and decision-makers alike.

8.5 Summary

In conclusion, the work in this thesis provides a compelling case for the evaluation of continuous remote vital signs monitoring in a high-risk surgical population. By combining all known literature in the field with comprehensive range of mixed methodologies, it can be concluded that a definitive trial should be large, ideally multi-centred, with individual randomisation and clinically relevant outcomes, such as length of hospital stay. A simultaneous economic evaluation is necessary to inform decision-makers after the study is complete, and will provide an opportunity to address the gaps in the literature surrounding postoperative complications. This work has also identified a number of theories regarding the design and implementation of such an evaluation. These theories can now be used to inform future studies, in which the theories themselves can be tested on a wider population of staff, and to optimise any subsequent widespread adoption of such technologies.

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Appendices

Appendix 1: Health Research Authority approval for cluster-randomised trial

NHS
Health Research Authority

Professor David Jayne
Professor of Surgery
St James's University Hospital
Leeds
LS9 7TF

Email: hra.approval@nhs.net

06 December 2016

Dear Professor Jayne

Letter of HRA Approval

Study title:	**An evaluation of remote, near-continuous vital signs monitoring in patients admitted to surgical wards**
IRAS project ID:	**204340**
REC reference:	**16/YH/0426**
Sponsor	**University of Leeds**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

IRAS project ID	204340

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **204340**. Please quote this on all correspondence.

Yours sincerely

Natalie Wilson
Assessor

Email: hra.approval@nhs.net

Copy to: *Miss Candice Downey, Leeds Teaching Hospital NHS Trust, Student researcher*
Ms Anne Gowing, Leeds Teaching Hospitals NHS Trust, Lead NHS R&D contact

NIHR CRN Portfolio Applications Team

IRAS project ID	204340

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]	1	11 September 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Leeds Indemnity Certificate]	N/a	22 September 2015
GP/consultant information sheets or letters [GP Letter]	2	05 September 2016
Instructions for use of medical device [SensiumVitals User Manual]	N/a	01 September 2016
Interview schedules or topic guides for participants [Patient Interview Topic Guide]	2	18 August 2016
Interview schedules or topic guides for participants [Staff Interview Topic Guide]	2	18 August 2016
Interview schedules or topic guides for participants [Focus Groups Topic Guides]	2	18 August 2016
IRAS Application Form [IRAS_Form_20092016]		20 September 2016
IRAS Application Form XML file [IRAS_Form_20092016]		20 September 2016
IRAS Checklist XML [Checklist_26102016]		26 October 2016
IRAS Checklist XML [Checklist_27102016]		27 October 2016
Letter from funder [Draft agreement from Heath Foundation]	Draft	08 March 2016
Non-validated questionnaire [Patient questionnaire]	1	18 August 2016
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 1, 11/11/16	16 November 2016
Other [204340_StatementofActivities]	2	05 December 2016
Other [204340_ScheduleofEvents]	2	05 December 2016
Participant consent form [Consent form]	3	02 November 2016
Participant consent form [Nurse consent form]	1	11 November 2016
Participant consent form [Interview consent form]	1.0	28 November 2016
Participant information sheet (PIS) [Nurse information sheet]	1	11 November 2016
Participant information sheet (PIS) [Patient Information Sheet]	3	26 October 2016
Research protocol or project proposal [Research Protocol]	2	09 November 2016
Summary CV for Chief Investigator (CI) [Prof DG Jayne CV]	1	01 September 2016
Summary CV for student [C Downey Summary CV]	1	11 September 2016
Summary CV for supervisor (student research) [Prof DG Jayne CV]	1	01 September 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart]	1	18 August 2016
Validated questionnaire [Modified Usability Score]	1	18 August 2016

IRAS project ID	204340

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Candice Downey
Email: c.l.downey@leeds.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Minor amendments have been made to the consent form post-REC to ensure conformity to HRA standards.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial, single site study taking place in the NHS. A Statement of Activities has been submitted. This will act as the agreement between Sponsor and participating NHS organisations, therefore no other agreements are expected.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional

IRAS project ID	204340

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			indemnity provided by their medical defence organisation covers the activities expected of them for this research study. Sensium Healthcare has provided separate indemnity for servers/equipment used for the research. Sensium Healthcare will replace any damaged/broken equipment.
4.3	Financial arrangements assessed	Yes	Funding for the research will provide the salary for a local research nurse. This will also cover the cost of patches used at participating NHS organisations. Sensium Healthcare will loan monitoring equipment and mobile devices to the Trust.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	Sponsor has confirmed that a data sharing agreement will be in place between themselves and a third party transcription service.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	
6.3	Devices – MHRA notice of no objection received	Not Applicable	

IRAS project ID	204340

Section	HRA Assessment Criteria	Compliant with Standards	Comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a non-commercial, single site study. There is only one site-type involved in the research. Research activity includes a range of activities as described in the protocol.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

IRAS project ID	204340

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator (PI) is expected at participating NHS organisations. Sponsor expects local research team members to undertake Good Clinical Practice training via e-learning. Sensium Healthcare will provide product specific training to relevant staff. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
It is expected that research staff will be employed by the local NHS Trust or hold Honorary Clinical Contracts. Therefore, no Honorary Research Contracts, Letters of Access or pre-engagement checks are expected.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 2: Patient information sheet for cluster-randomised trial

The Leeds Teaching Hospitals NHS
NHS Trust

IRAS reference number: 204340

John Goligher Colorectal Unit
Research Office
Ground Floor Lincoln Wing
St James University Hospital
Beckett Street
Leeds
LS9 7TF
Tel: 0113 20 64672

Version 3

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

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been invited to take part in a research study. Before you decide if you want to take part, we would like to explain why the research is being done, how we will use the information we have about you, and what the study will involve.

Please read this information carefully, and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

Once you have read this information, the study team will talk to you about the study again and you can ask any questions you like.

Part 1 tells you the purpose of the study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study will investigate the use of remote, near-continuous monitoring in patients admitted to one of four general surgical wards at St. James's University Hospital, Leeds.

Unfortunately, despite the best efforts of the clinical team, up to a third of patients who undergo major surgery will experience a significant complication. These often include infections, such as pneumonia or wound infections, which require urgent antibiotics.

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 few hours in the 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.

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 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.

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.

Why have I been invited?

Four general surgery wards at St. James's University Hospital are taking part in the study. You will be asked to join the study if you are admitted to one of these wards, regardless of whether you are having surgery or not. You will be given information about the study and you will be allowed time to decide whether you would like to take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive. In the unlikely event that, during the study, you are no longer capable of agreeing to take part, you will remain in the study until you are well enough to give permission again. Your close relatives' views of your wishes may be taken into account.

What will happen to me if I take part?

If you choose to take part in the study your care in hospital will not differ from standard care.

Patients who enter the study will be randomly allocated to one of two study groups. All of the patients who enter the study will receive standard NEWS monitoring, as usual. Half of the patients who enter the study will also receive the SensiumVitals® monitoring. This decision is made at random, and it is not possible for you or the clinical team to change it.

If you are in the SensiumVitals® group, you will be asked to wear the patch on your chest for the whole of your admission, in addition to receiving usual NEWS monitoring. You will be given a full explanation of the SensiumVitals® remote monitoring system at this time.

Everyone who enters the study will be followed during the course of their hospital stay, including any operation they have.

Information about your hospital stay will be collected by the research team. This information will include any complications you experience, including infections, and how quickly they are treated. You will also be followed up if you are moved to a high-dependency ward. Information will be gathered about how long you stay in hospital.

An important part of the study will be to assess how patients and nurses feel about the SensiumVitals® system. If you receive the SensiumVitals® monitoring system, you will be invited to fill out a questionnaire and undertake a short interview (15-30 minutes) at the end of your hospital admission.

Once you are discharged form hospital, your participation in the trial will be over. If you like, the results of the study can be sent to you at a later date, either by email or by post, according to your preference.

What do I have to do?

After you have had time to consider if you would like to participate in the trial, a member of the team will approach you to find out your decision.

What is being tested?

We are testing a device that continuously monitors vital signs: heart rate, breathing rate and temperature. This information is transferred remotely to a mobile phone carried by the nurse, which alerts if the vital signs stray beyond normal parameters.

It is thought that continuous monitoring might help detect complications early, but not enough is known about this technology to say for sure. This is why it has to be tested against the current national standard of care: NEWS monitoring.

All data will be anonymised and coded. It will only be accessible to the researchers.

What are the alternatives for diagnosis or treatment?

Whether or not you choose to take part in the study you will receive the standard treatment: NEWS monitoring. This study will not change any further treatment you may require during or after your hospital stay.

What are the possible disadvantages and risks of taking part?

If you are in the group that receives standard NEWS monitoring alone, your care will not vary from that of someone who is not taking part in the research, although information about your hospital stay will be collected.

If you are in the group of patients that receives the SensiumVitals® patch, you will be required to have the patch applied when you are admitted to the ward. This process is painless, but will take about 10 minutes and may involve some skin preparation of the area on the chest where the patch is applied. This sometimes includes shaving small areas for the patch to stick to. The patch's battery lasts for five days. You will be expected to wear a patch for the whole of your hospital stay. This may mean getting the patch changed a number of times, if you are in hospital for a few weeks.

Once you are wearing the patch, you are free to move about as normal. The patch is not connected to any machines and so it should not limit your movement.

It is important to remember that your doctors and nurses may not be able to detect complications even if you are wearing the patch, so if you are feeling unwell or have any concerns you should alert a member of staff.

At the end of your hospital stay, the patch will be removed and you will be asked to fill out a questionnaire. You will also be invited to undergo a short interview before going home and/or return to the hospital at a later date to take part in two focus groups, lasting an hour each. If you are not comfortable sharing your views about the patch, you may decline these. The interviews and the focus groups will be audio recorded. If you decide to take part in the focus groups, you will be reimbursed for your time and travel expenses.

What are the possible benefits of taking part?

If you receive the SensiumVitals® monitoring, there is the possibility that any complications you experience may be detected earlier. However, although you may enjoy wearing the monitoring device, participating in this study may not directly benefit your health during your stay in hospital. Information gathered from this study may benefit future patients and pave the way for improved care.

What happens when the research study stops?

Your involvement in this study will stop once you are discharged from hospital. After this time your follow up will be as standard treatment. This will vary according to your needs and the reason for your admission.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you have a complaint about the care you have received you can contact the Patient Advice and Liaison Service (PALS) at:
Patient Relations Department
Trust Head Quarters
St James's Hospital
Leeds LS9 7TF
Tel 0113 2066261
Email: patient experience.leedsth@nhs.net

Will my taking part be kept confidential?

If you decide to participate in this study the information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act. Please refer to Part 2 for further details.

Contact Details

If you have any further questions about your illness or clinical studies, please discuss them with your doctor.

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: +44 (0)207 670 5452; website www.ukcrc.org

Your contact telephone numbers:

.....

.....

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if new information becomes available?

Sometimes during clinical research, new information becomes available regarding the systems being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study treatment, and/or follow-up, your data will remain on file and will be included in the final study analysis.

If you leave the study and do not wish for any further information to be collected, you should inform your clinical care team of this in order that no further follow-up information is collected from your medical records.

Please note the study team may be required to continue to collect some limited information about you in the case of any unwanted effects you may have as a result of taking part in the trial. This will only be collected if required by the regulatory authorities. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

Will my taking part in this study be kept confidential?

If you decide to participate in this study, the information collected about you will be handled in accordance with the consent that you have given and also the 1998 Data Protection Act.

- The information needed for study purposes will be recorded on paper forms and collected by the researchers at St James's University Hospital, Leeds. These forms will be kept for five years and then destroyed. Access to the forms will be limited to the researchers involved in the study.
- You will be allocated a study number, which will be used along with your initials to identify you on each paper form. Your full name will be included on your consent form and a copy of this will be collected by the researchers and stored securely at St James's University Hospital.
- Every effort will be made to ensure that any further information about you that leaves the hospital will have your name and address removed so that you cannot

be recognised from it; this information will usually be removed by a member of the study team at your hospital.

- Any audio recordings will be anonymised and destroyed once the relevant information has been obtained.
- If you would like to be informed of the results of the study, your contact details will be collected and stored securely.

Your data will be entered onto a secure database held on an encrypted laptop belonging to the University of Leeds in accordance with the 1998 Data Protection Act.

Any of your data uploaded to the SensiumVitals® system will be linked to your name for clinical purposes. However, Sensium Healthcare will not have access to any personal clinical information about you. Data uploaded to the SensiumVitals® system will be downloaded onto a secure computer held at St James's University Hospital at the end of the study and deleted from the SensiumVitals® system.

Your healthcare records may be looked at by authorised individuals from the research team, Leeds Teaching Hospitals NHS Trust, the University of Leeds or the regulatory authorities to check that the study is being carried out correctly.

Informing your General Practitioner (GP)

Your GP, and the other doctors involved in your healthcare, will be informed of your participation in this study.

What will happen to the results of the research study?

When the study is complete the results may be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor.

Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

.....

.....

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A

copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

Appendix 3: Consent form for cluster-randomised trial

The Leeds Teaching Hospitals NHS
NHS Trust

IRAS reference number: 204340

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

Patient consent form

Patient ID: …….. Initials: …….. Date of Birth: ……..

Patient initial each point

1. I confirm that I have read and understand the information sheet dated _____ (version _____) for the above study, have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. In the unlikely event that, during the study, I am no longer capable of agreeing to take part, I am aware that I will remain in the study until I am well enough to give permission again. I agree to take part in the study. _____

2. I understand that my medical records may be looked at by authorised individuals in the research team, from the Sponsor for the study, the UK Regulatory Authority, Independent Ethics Committee or from the NHS Trust. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study and any further research that may be conducted in relation to it. I also give permission for copies of my consent form to be stored securely at St James's University Hospital. _____

3. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. _____

4. I consent to the storage of personal information for the purposes of this study. This may include electronic and audio information. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication. _____

5. I understand that I may be contacted after my hospital stay and invited to attend focus groups. I consent to this and understand that I am free to decline attending these meetings. _____

6. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study. _____

_____	_____
Name of the patient	Patient's signature and the date the patient signed the Consent form
_____	_____
Name of the Investigator taking written consent	Investigator's signature and date the Investigator signed the consent form

Appendix 4: Consent form for patient interviews

The Leeds Teaching Hospitals NHS
NHS Trust

IRAS reference number: 204340

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

Patient and staff interview consent form

Participant ID: …….. Initials: …….. Date of Birth: ……..

Participant initial each point

I consent to undertake a semi-structured interview with the researcher. I understand that the researcher has a set of questions designed to help guide the interview; however, over the course of the interview, additional clarifying questions may be asked. _____

I understand that I am free to skip any questions that I would prefer not to answer, and may end my participation at any time. _____

I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the study, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. _____

I understand that the interview will be audio recorded. I understand that the electronic and audio information will be stored securely until it is transcribed, whereupon it will be destroyed. I understand that any information that could identify me will be kept strictly confidential. _____

I consent to the storage of personal information for the purposes of this study. I understand that no personal information will be included in the study report or other publications but I consent to the use of direct quotes from my interview. _____

I give permission for copies of this consent form to be stored securely at St James's Hospital. _____

_____	_____
Name of the participant	Participant's signature and the date the participant signed the Consent form
_____	_____
Name of the Investigator taking written consent	Investigator's signature and date the Investigator signed the consent form

Copies of the consent form will be sent to:
- Investigator Site File
- Participant

Appendix 5: GP letter for cluster-randomised trial

The Leeds Teaching Hospitals NHS
NHS Trust

IRAS reference number: 204340

John Goligher Colorectal Unit
Research Office
Ground Floor Lincoln Wing
St James University Hospital
Beckett Street
Leeds
LS9 7TF

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

Dear Dr _____

Patient name _____ D.O.B _____

Notification of patient entry into trial

The above-named patient from your practice has consented to enter the above trial and has agreed to my contacting you. Please keep this letter as a record of your patient's involvement.

This is a feasibility study to investigate a newly developed system to remotely monitor patients' vital signs during hospital admission to surgical wards. The SensiumVitals® remote monitoring system continuously monitors the patient's heart rate, respiratory rate and temperature via a wearable wireless patch, and transmits this data every two minutes to a mobile device carried by their nurse.

Following hospital admission to one of four general surgical wards at St James's University Hospital, patients will be randomized to receive either traditional vital signs monitoring (the National Early Warning Score system, or NEWS) or SensiumVitals® monitoring and NEWS. The patients will be followed during the course of their admission and data gathered regarding any surgery they undergo, complications experienced, the use of the sepsis pathway and length of stay in hospital and critical care beds. Patients in the SensiumVitals® group will be invited to undertake an interview and/or attend focus groups about their experience of wearing the patch.

Although the aim of this study is to initially to assess the feasibility and acceptability to patients of this system, the ultimate purpose of establishing remote continuous patient monitoring in the inpatient setting is to allow earlier detection of post-operative complications, reduce the need for critical care admissions and shorten the overall length of hospital stay.

This patient is consented on the understanding that the role of remote vital signs monitoring is currently not established and therefore this does not replace any services delivered by primary or secondary care.

The patient has been given the information leaflet (a copy of which is attached) and is aware that s/he can withdraw from the study at any time without giving a reason. Data will be collected by a member of the research team from entry into the study until the day of discharge from hospital. This should not entail any additional workload for you.

If you require any further details about this study, please do not hesitate to contact Professor David Jayne on 0113 2065281

Appendix 6: Details of surgical procedures received by participants in the TRaCINg study

	NEWS alone n=65	SensiumVitals® + NEWS n=60
Ileocaecal resection	3	1
Right hemicolectomy	9	12
Wedge resection	1	0
Sigmoid colectomy	2	1
Anterior resection	22	22
Abdominoperineal resection	6	8
Proctectomy	3	1
Subtotal colectomy	2	2
Total colectomy	1	0
Panproctocolectomy	2	1
Resection of recurrent rectal cancer	2	0
Resection of pelvic sidewall recurrence	0	1
Pelvic exenteration	2	1
Resection of anastomosis	0	2
Intestinal bypass	1	0
Stoma formation	4	1
Small bowel resection	1	3
Division of adhesions	1	3
Abdominal wall reconstruction	1	0
Stricturoplasty	1	0
Exploratory laparotomy	1	0
Patient did not proceed from anaesthetic room	0	1

Appendix 7: 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:					

Appendix 8: Health Research Authority approval for TRaCINg study

NHS
Health Research Authority

Miss Candice Downey
NIHR Academic Clinical Fellow
Leeds Teaching Hospitals NHS Trust
Level 7, Clinical Sciences Building
St James's University Hospital
Beckett Street, Leeds
LS9 7TF

Email: hra.approval@nhs.net

28 July 2017

Dear Miss Downey

Letter of HRA Approval

Study title:	**Trial of Remote Continuous vs Intermittent Vital Signs Monitoring after Major Surgery**
IRAS project ID:	**224765**
REC reference:	**17/YH/0180**
Sponsor	**University of Leeds**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

IRAS project ID	224765

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

IRAS project ID	224765

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **224765**. Please quote this on all correspondence.

Yours sincerely

Kevin Ahmed
Assessor

Telephone: 0207 104 8171
Email: hra.approval@nhs.net

Copy to: *Mrs Anne Gowing, R&D Contact, Leeds Teaching Hospitals NHS Trust*
Prof David Jayne, Academic Supervisor, St James's University Hospital

IRAS project ID	224765

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement [Contract between Funder and Chief Investigator]	4	06 December 2016
Covering letter on headed paper [Covering letter]	1	10 May 2017
Covering letter on headed paper [Covering letter]	1	10 July 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Leeds Indemnity Certificate]		08 September 2016
Instructions for use of medical device [SensiumVitals User Manual]	N/A	01 September 2016
Interview schedules or topic guides for participants [Patient Interview Topic Guide]	1	10 May 2017
Interview schedules or topic guides for participants [Staff Interview Topic Guide]	1	10 May 2017
Interview schedules or topic guides for participants [Topic Guide for Focus Groups]	1	10 May 2017
IRAS Application Form [IRAS_Form_04072017]		04 July 2017
Letter from funder [Funding provision (P.50)]	1.0	06 December 2016
Non-validated questionnaire [Patient questionnaire]	1	10 May 2017
Other [Statement of Activities]	1	05 July 2017
Other [Schedule of Events]	1	05 July 2017
Participant consent form [Consent Form for Patients]	1	25 April 2017
Participant consent form [Consent Form for Staff]	1	10 May 2017
Participant consent form [Participant consent form]	2	28 June 2017
Participant information sheet (PIS) [Participant Information Sheet for Patients]	2	05 May 2017
Participant information sheet (PIS) [Participant Information Sheet for Staff]	1	10 May 2017
Participant information sheet (PIS) [Participant Information Sheet]	3	28 June 2017
Research protocol or project proposal [Protocol]	4	28 June 2017
Summary CV for Chief Investigator (CI) [Summary CV]	1	10 May 2017
Summary CV for student [Summary CV]	1	10 May 2017
Summary CV for supervisor (student research) [Summary CV Prof DG Jayne]	1	02 January 2017
Summary CV for supervisor (student research) [Prof J Brown CV]		17 May 2017
Summary CV for supervisor (student research) [Dr R Randell CV]		18 May 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Patient flowchart]	1	10 May 2017
Validated questionnaire [Modified Usability Score]	1	10 May 2017
17.YH.0180 Further Info Fav Opinion 28.07.17		28 July 2017

IRAS project ID	224765

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Tel: 0113 343 7587
Email: governance-ethics@leeds.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. The sponsor is not requesting, and does not require any additional contracts with study sites.

IRAS project ID	224765

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	External study funding has been secured from the NIHR. No study funding will be provided to sites, as detailed at Schedule 1 of the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

IRAS project ID	224765

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

All participating NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

NHS organisations in England that are participating in the study **will be expected to formally confirm their capacity and capability** to host this research.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Principal Investigator should be appointed at study sites.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

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HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 9: Patient information sheet for TRaCINg study

The Leeds Teaching Hospitals NHS
NHS Trust

IRAS reference number: 224765

John Goligher Colorectal Unit
Research Office
Ground Floor Lincoln Wing
St James University Hospital
Beckett Street
Leeds
LS9 7TF
Tel: 0113 20 64672

Version 4

TRaCI-g

Trial of Remote Continuous vs Intermittent Vital Signs Monitoring after Major Surgery

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been invited to take part in a research study. Before you decide if you want to take part, we would like to explain why the research is being done, how we will use the information we have about you, and what the study will involve.

Please read this information carefully, and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

Once you have read this information, the study team will talk to you about the study again and you can ask any questions you like.

Part 1 tells you the purpose of the study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Take time to decide whether or not you wish to take part.

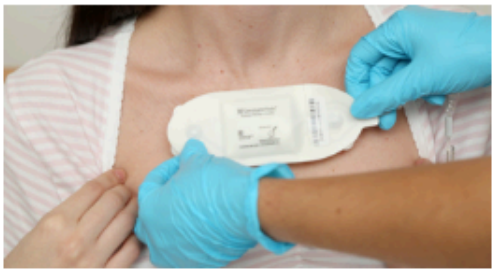
Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study will investigate the use of continuous vital signs monitoring in patients having planned major surgery at St. James's University Hospital, Leeds.

Unfortunately, up to a third of patients who have major surgery will experience a serious complication, such as infection. 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 few hours in the 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.



We are testing a wireless monitoring patch that continuously monitors vital signs: heart rate, breathing rate and temperature. This information is sent wirelessly to a mobile phone carried by the nurse, which alerts if the vital signs become abnormal.

It is thought that continuous monitoring might help detect complications early, but not enough is known about this technology to say for sure. This is why it has to be tested against the current national standard of care: NEWS monitoring.

In order to test this theory, a study will be done comparing the patch system with NEWS monitoring. The main aim is to provide information about whether the research works, and if the patch improves results for patients having major surgery.

Why have I been invited?

Two general surgery wards at St. James's University Hospital are taking part in the study. You will be asked to join the study if you are having planned major surgery and you are likely to return to one of these wards afterwards. You will be given information about the study and allowed time to decide whether you wish to take part.

Do I have to take part?

No. It is up to you to decide whether to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive. In the unlikely event that, during the study, you are no longer capable of agreeing to take part, any intervention outside of normal care (such as the monitoring patch) will be removed. Information will still be collected

about your hospital stay until you are well enough to give permission again. Your close relatives' views of your wishes may be taken into account.

What will happen to me if I take part?

If you choose to take part, your care in hospital will not differ from standard care.

Patients who enter the study will be randomly allocated to one of two groups. All of the patients will receive standard NEWS monitoring, as usual. Half of the patients who enter the study will also receive the continuous patch monitoring. This decision is made at random, and it is not possible for you or the clinical team to change it.

If you are in the patch group, the patch will be applied in the Recovery Room after your operation. You will be asked to wear the patch on your chest for the whole of your admission, in addition to receiving usual NEWS monitoring.

Two wards at St. James's University Hospital are taking part in the study. If you go to another ward after your surgery, you will not be able to receive a patch. If you go to a high-dependency bed after surgery, but then return to one of the study wards, the patch will be activated when you arrive on the ward. If you move off the study ward during your admission, your patch can be removed.

Everyone who enters the study will be followed during the course of their hospital stay. The information collected will include any complications you experience, including infections, and how quickly they are treated. You will also be followed up if you are moved to a high-dependency ward. Information will be gathered about how long you stay in hospital.

An important part of the study will be to assess how patients and nurses feel about the patch monitoring system. If you receive a patch, you will be invited to fill out a questionnaire and undertake a short interview (15-30 minutes) before you go home.

Once you are discharged from hospital, your participation in the trial will be over.

What are the possible disadvantages and risks of taking part?

If you are in the group that receives standard NEWS monitoring alone, your care will not vary from that of someone who is not taking part in the research, although information about your hospital stay will be collected.

If you are in the group of patients that receives the monitoring patch, you will have the patch applied in the Recovery Room after your operation. This process is painless, but will take 5-10 minutes and may involve some skin preparation of the area on the chest where the patch is applied. This sometimes includes shaving small areas for the patch to stick to. The patch's battery lasts for five days. You will be expected to wear a patch for the whole of your hospital stay. This may mean getting the patch changed a number of times, if you are in hospital for a few weeks.

Once you are wearing the patch, you are free to move about as normal. The patch is

not connected to any machines and so it should not limit your movement.

It is important to remember that your doctors and nurses may not be able to detect complications even if you are wearing the patch, so if you are feeling unwell or have any concerns you should alert a member of staff.

At the end of your hospital stay, the patch will be removed and you will be asked to fill out a questionnaire. You will also be asked to undergo a short interview before going home and/or return to the hospital at a later date to take part in two focus groups, lasting an hour each. If you are not comfortable sharing your views, you may decline these. The interviews and the focus groups will be audio recorded. If you decide to take part in the focus groups, you will be reimbursed for time and travel expenses.

What are the possible benefits of taking part?

If you receive the patch, it is possible that any complication you experience may be detected earlier. However, although you may enjoy wearing the patch, participating in this study may not directly benefit your health. Information gathered from this study may benefit future patients and pave the way for improved care.

What happens when the research study stops?

Your involvement in this study will stop once you are discharged from hospital. After this time your follow up will be as standard treatment.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed due to negligence then you may have grounds for legal action but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you. If you have a complaint about the care you have received you can contact the Patient Advice and Liaison Service (PALS) at: Patient Relations Department, Trust Head Quarters St James's Hospital, Leeds LS9 7TF. Tel 0113 2066261
Email: patientexperience.leedsth@nhs.net

Will my taking part be kept confidential?

If you decide to participate in this study the information collected about you will be handled strictly in accordance with the consent that you have given and the 1998 Data Protection Act. Please refer to Part 2 for further details.

Your contact telephone numbers:

Surgical Trials Unit at St James's Hospital: (0113) 206 4184.

Part 2

What if new information becomes available?

Sometimes during clinical research, new information becomes available regarding the systems being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, you will be told why.

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study treatment, and/or follow-up, your data will remain on file and will be included in the final study analysis.

If you leave the study and do not wish for any further information to be collected, you should inform your clinical care team in order that no further information is collected.

Please note the study team may be required to continue to collect some limited information about you in the case of any unwanted effects you may have as a result of taking part in the trial. This will only be collected if required by the regulatory authorities.

Will my taking part in this study be kept confidential?

If you decide to participate, the information collected about you will be handled in accordance with the consent that you have given and the 1998 Data Protection Act. The information needed for study purposes will be recorded on paper forms and collected by the researchers at St James's University Hospital, Leeds. These forms will be kept for five years and then safely destroyed. Access to the forms will be limited to the researchers involved in the study and the University of Leeds Clinical Trials Research Unit (CTRU).

You will be allocated a study number, which will be used along with your initials to identify you on each paper form. Your full name will be included on your consent form and a copy of this will be collected by the researchers and stored securely at St James's University Hospital. A copy, including your name, will also be sent to the CTRU. All other information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Any audio recordings will be anonymised and destroyed once the relevant information has been obtained. The recordings will be transcribed by a transcription service who will not have access to your name or personal details.

If you would like to be informed of the results of the study, your contact details will be collected and stored securely in a locked office at St. James's University Hospital.

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Your data will be entered onto a secure database held at the CTRU and on an encrypted laptop belonging to the University of Leeds in accordance with the 1998 Data Protection Act.

Any of your data uploaded to the monitoring system will be linked to your name for clinical purposes. However, Sensium Healthcare (the company who manufacture the patch) will not have access to any personal clinical information about you. Data uploaded to the monitoring system will be downloaded onto a secure computer held at St James's University Hospital at the end of the study and deleted from the monitoring system.

Your healthcare records may be looked at by authorised individuals from the research team, Leeds Teaching Hospitals NHS Trust, the University of Leeds or the regulatory authorities to check that the study is being carried out correctly.

What will happen to the results of the research study?

When the study is complete the results will be used to inform a PhD degree for the lead researcher. The results may be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor. Anonymised results will be shared with the patch company, but they will not receive any names or personal details.

The results of this study will be used to design a much larger study looking at continuous vital signs monitoring, with the potential to help many future patients.

Contact for further information

Please ask any questions you wish before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns, please contact:

Candice Downey or Pauline Walton: (0113) 206 4184 .....
.....

If you decide to take part, please read and sign the consent form. You will be given a copy of this information sheet. Copies of the consent form will be filed in your notes, with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

Appendix 10: Consent form for TRaCINg study

The Leeds Teaching Hospitals NHS Trust

IRAS reference number: 224765

TRaCI-g

Trial of Remote Continuous vs Intermittent Vital Signs Monitoring after Major Surgery

Participant consent form

Patient ID: ..... Initials: .....

Participant to initial each point

1. I have read and understand the information sheet dated _____ (version _____). I have had the opportunity to ask questions. I understand that my participation is voluntary and I am free to withdraw at any time without my medical care or legal rights being affected. I agree to take part in the study. _____

2. If, during the study, I am no longer capable of agreeing to take part, I am aware that any intervention outside of normal care will be removed. Information will still be collected about my hospital stay until I am well enough to give permission again. _____

3. I understand that my medical records may be looked at by authorised individuals in the research team, from the Sponsor for the study, the UK Regulatory Authority, Independent Ethics Committee or from the NHS Trust. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study and any further research that may be conducted in relation to it. _____

4. I understand that even if I withdraw from the above study, the data collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. _____

4. I consent to the storage of personal information for the purposes of this study. This may include electronic and audio information. I understand that any information that could identify me will be kept confidential and that no personal information will be included in any study publication. _____

5. I understand that I may be contacted after my hospital stay and invited to attend focus groups. I consent to this and understand that I am free to decline attending these meetings. _____

6. I understand that a copy of this consent form, including my name, will be sent to the Leeds Clinical Trials Research Unit for storage. _____

.

_____	_____
Name of the participant	Participant's signature and the date the participant signed the Consent form
_____	_____
Name of the Investigator taking written consent	Investigator's signature and date the Investigator signed the consent form

Appendix 11: Summary of the elicited theories at the end of the realist synthesis as context-mechanism-outcome configurations

Source	Context	Mechanism		Outcome
		Resource	Response	
Patient interviews	Nurses too busy for an extra task		Nurses fail to engage with devices	Clinical deterioration goes unrecognised
Patients and literature	CRM devices are programmed to be very sensitive to patient deterioration	A high number of false alerts [22,26,112]	Alert fatigue, desensitization and failure to respond	Clinical deterioration goes unrecognised by staff
Literature	Nurses not confident with technology	Devices require some technical capabilities	Nurses fail to engage with devices	Clinical deterioration goes unrecognised
	Vital signs monitoring is considered to be exclusively a nursing task	Training in CRM is specific for nursing staff [68]	Nurses unable to use remote monitoring vital signs when triggering escalation protocols	Nursing staff don't consider remote monitoring to be worthwhile
		There is a large amount of information gathered by the remote monitoring devices [41]	Nursing staff feel overwhelmed by information compared to NEWS	Nursing staff lack confidence when interpreting and acting on notifications
		There is no suggested action for notifications [41]	Nursing staff do not know how to respond to notifications	Nursing staff fail to act on notifications
	Patients find devices		Nursing staff consider	Failure to engage with

	uncomfortable, or feel anxious being continuously monitored [41,68]		devices offer more harm than good	remote monitoring technology
	Nurses are engaged in other tasks [68]	Remote monitoring notifications take nursing staff away from other tasks [112]	Nursing staff get frustrated by interruptions. Nurses prioritise other tasks over responding to alerts	Usual tasks take longer due to interruptions. Frustrated nursing staff fail to engage with the devices. Clinical deterioration goes unrecognised.
	There is a high rate of staff turnover on high-acuity wards [22]	New staff are not aware of the remote monitoring devices	New staff do not use remote monitoring as per protocol	Clinical deterioration goes unrecognised
	Wards are divided into sections, each of which is the responsibility of a single staff nurse	Nurses are solely responsible for the remote monitoring receiving device for their section [26,66]	Nurses perceive device as an individual burden	Decreased responsiveness to alerts
	Nursing staff only see benefit/burden on a patient-by-patient basis [52]		Nursing staff fail to appreciate global impact of device	Failure to engage with remote monitoring technology
	Nursing staff only perceive benefit in patients who have deteriorated [58]	Devices are silent in patients with normal vital signs	Nursing staff fail to appreciate global impact of device	Nursing staff ignore ‘low-risk’ patients

	Nurses are not incentivised to respond to alerts [52]		Nursing staff are not motivated to engage with devices	Nursing staff do not respond to alerts
	Continuous monitoring is not included in local policy documents [22]	Nursing staff perceive NEWS as sufficient to detect deterioration.	Nursing staff ambivalent about continuous monitoring	Failure to engage with remote monitoring technology
	Research and innovation is not supported in the local hospital culture [22]		Nursing staff are intolerant of novel devices	Failure to engage with remote monitoring technology
	Previous iterations of continuous monitoring have been poorly implemented [22]	Nursing staff have seen examples of technology failure [49]	Nursing staff do not trust the new technology	Failure to engage with remote monitoring technology
Observations	Training provided over a single session	Staff insufficiently trained		Nursing staff not confident with technology
	Nursing staff workload is higher in daytime hours, but nurse:patient ratios are lower at night		Nursing staff perceive continuous monitoring as a burden on over-stretched staff throughout the 24-hour day	Nursing staff fail to exchange the devices at handover periods at the end of a shift. Failure to engage with remote monitoring technology.
	There was no on-site technical support available	Technical malfunctions could not be rectified immediately [22]		Loss of confidence in the technology and failure to engage
	Nursing staff frequently	Remote monitoring	Nursing staff are afraid that	Nursing staff refuse to carry

	attend to older patients	devices look like mobile phones	patients will assume the devices are their personal phones	the devices or check notifications on the ward
	Senior nurses dismissive of remote monitoring technology		Staff nurses perceive remote monitoring as unnecessary	Failure to engage with remote monitoring technology
a priori theories	Diminished researcher presence at weekends		Staff nurses forget about study	Failure to collect monitoring devices
	Remote monitoring implemented on a ward with high-acuity patients	Staff are extremely busy with clinical duties	Staff unable to manage the extra burden of remote monitoring	Failure to engage with remote monitoring technology
	Nursing staff have experience of vital signs failing to detect deterioration		Nursing staff consider vital signs to be inadequate in detecting deterioration Nursing staff cannot perceive any downstream patient benefit from improving vital signs monitoring	Failure to engage with remote monitoring technology
	Context in which nursing staff perceive CRM as a replacement for EWS?		Remote monitoring is perceived as a potential replacement for manual observations. Nurses perceive remote monitoring as	Nurses avoid using remote monitoring in their patients

			a threat to autonomy	
	Nursing staff are busy undertaking skilled tasks	Healthcare assistants are in charge of collecting vital signs	Staff nurses perceive vital signs as not part of their work	Failure to engage with remote monitoring technology
	Nursing staff have bad experiences of the efferent arm of the deteriorating patient pathway	Escalation protocols	Nursing staff do not have confidence in the efferent arm of the deteriorating patient pathway. Nursing staff cannot perceive any downstream patient benefit from improving vital signs monitoring	Failure to engage with remote monitoring technology
	National guidance dictates frequency of manual observations		Nursing staff feel that current observation intervals are sufficient	Nursing staff fail to perceive the benefit of continuous monitoring over normal care
	Continuous monitoring is implemented as part of a research study	Research staff are responsible for patching patients	Staff nurses perceive remote monitoring as not part of their work	Failure to engage with remote monitoring technology
		The devices are difficult to use	Nursing staff are not confident using the technology	Failure to engage with remote monitoring technology

Appendix 12: Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study.	
		Present the study question and its relevance for health policy or practice decisions.	
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	

Section/item	Item No	Recommendation	Reported on page No/ line No
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	
	11b	*Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	

Section/item	Item No	Recommendation	Reported on page No/ line No
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	
Results			

Section/item	Item No	Recommendation	Reported on page No/ line No
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	
Discussion			

Section/item	Item No	Recommendation	Reported on page No/ line No
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	