The impact of enhanced postoperative vitals monitoring in-hospital and at home vs. standard care after inpatient abdominal and vascular surgery: A pilot two-centre randomized controlled study

Short title: Enhanced postoperative vitals monitoring

Study Protocol

Principal Investigator:

Janny Xue Chen Ke, MD, MSc, FRCPC, Department of Anesthesia, Providence Health Care; Department of Anesthesiology, Pharmacology and Therapeutics, Faculty of medicine, University of British Columbia

Co-Investigators:

Su-Yin MacDonell, MD, FRCPC, Department of Anesthesia, Providence Health Care; Department of Anesthesiology, Pharmacology and Therapeutics, Faculty of Medicine, University of British Columbia

Charles V Yu, MD, FRCPC, Department of Anesthesia, Providence Health Care; Clinical Instructor, Department of Anesthesiology, Pharmacology and Therapeutics, Faculty of medicine, University of British Columbia

Jesse Greiner, MD, FRCPC, Division of General Internal Medicine, Department of Medicine, Providence Health Care

Carl Brown MD MSc FRCSC, Department of Surgery, Faculty of Medicine, University of British Columbia, Vancouver, Canada

Dr. Amandeep (Anu) Ghuman, MD MPH FRCSC, Department of Surgery, Faculty of Medicine, University of British Columbia, Vancouver, Canada

Jason Sutherland, PhD, Centre for Health Services and Policy Research, School of Population and Public Health, The University of British Columbia, Vancouver, BC, Canada.

Study Coordinators: Nicola Edwards

Patient Partner: Renée Lukacs

1 Lay summary

After surgeries, patients are at risk of a variety of complications. Close monitoring of vital signs may facilitate early detection and treatment of complications. However, the existing standard of care of intermittent monitoring in-hospital and no monitoring the first week after discharge may be too infrequent to capture vital sign derangements for early detection of complications. In this pilot randomized controlled trial, we will obtain preliminary data on whether enhanced monitoring of vital signs in-hospital and at-home makes a difference on patient morbidity and mortality outcomes, and report feasibility and logistics considerations for the design of a larger multi-centre randomized controlled trial.

2 Background

Background
After surgeries, patients are at risk of a variety of complications, thus requiring monitoring for early detection and treatment of complications. The current standard of care consists of continuous monitoring of vital signs during and after anesthetic and/or in the high-acuity and intensive care units, followed by intermittent measurement of vital signs once the patient is in the ward. Once the patient is at home, there is no monitoring nor follow-up.

However, it has been well-established that existing intermittent monitoring of vital signs are too infrequent to capture important vital sign derangements. For example, in an observational study of 312 patients who underwent abdominal surgery, 18% of patients had blood pressure <65 mmHg for at least 15 minutes that were not detected by conventional intermittent monitoring[1]. Nevertheless, it remains unknown the optimal method and duration of increased monitoring for medium-to-high risk surgical patients in-hospital and at home. In a randomized controlled trial (RCT) involving 905 adults undergoing non-elective surgery, remote automated monitoring with virtual care did not reduce the number of days alive and at home 30 days after surgery (DAH30) compared to standard of care[2]. However, there are signals of increased detection of drug errors, decreased pain, and benefits in patients in centres with more escalations in care.

3 Objectives

3.1 To obtain pilot data on the enhanced monitoring of vital signs in patients undergoing inpatient major abdominal (general surgery, urology, or gynecology) and vascular surgery, (i.e. continuous monitoring of vital signs in-hospital during the day time for three days postoperatively (POD0-POD3) followed by twice-daily monitoring at home for 3 days after discharge), with a protocol for care escalation if needed, compared to standard monitoring (intermittent monitoring in-hospital and no monitoring at home), on the following trial outcomes:

a. **Primary outcome:** Days alive and at home within 30 days after surgery (DAH30)
b. **Secondary outcomes:**
    i. Major morbidity (complications associated with 30-day mortality: major bleeding, myocardial injury after noncardiac surgery (includes myocardial infarction), myocardial infarction (3rd Universal Definition), sepsis, infection without sepsis, acute kidney injury with new dialysis, stroke,

venous thromboembolism and congestive heart failure[3]) within 30 days postoperatively
ii. Mortality within 30 days postoperatively
iii. Emergency visit after discharge within 30 days postoperatively
iv. Readmission within 30 days postoperatively
v. Urgent walk-in clinic visit within 30 days postoperatively
vi. Family doctor clinic visit within 30 days postoperatively (not urgent walk-in clinic) with details of planned (for suture/staple removal, or other reason) vs. unplanned
vii. Surgeon visit (with details of method [email, phone call, or clinic visit] vs. in-person [planned vs. unplanned])
viii. Postoperative length of stay
ix. Quality of recovery (QoR-15 questionnaire) on 14 and 30 days postoperatively (patients will do baseline questionnaire at study enrollment)

3.2 To explore the feasibility of the intervention of enhanced monitoring of vital signs in patients undergoing inpatient major abdominal (general surgery, urology, or gynecology) and vascular surgery. The primary feasibility outcome is defined as >80% completion of the monitoring protocol; with *a priori* definition of the completion being 3 blood pressure readings per day for 3 days in-hospital (or the duration of the hospital stay, whichever is shorter) and at 2 times a day at home each for 2 times a day for 3 days The additional feasibility outcomes are

c. Participation measures (recruitment and retention rates)
d. Acceptability
i. patient use of the monitoring devices (frequency, duration, problems encountered, reason for discontinuation)
ii. patient feedback about enhanced monitoring (Systems Usability Scale questionnaire at the end of the monitoring intervention in hospital and at home)
e. Clinical resource utilization (frequency and type of vital sign derangements detected by enhanced monitoring and the resulting care escalation from the start to the end of the monitoring intervention), time between vital sign alert and care escalation, logistics of device use (time spent on education, initiation, discontinuation, cleaning, collection, and troubleshooting of devices), issues that arise in the workflow
f. Evaluation of potential harm or safety issues (mobility and anxiety questions at the end of the monitoring intervention in hospital and at home)

3.3 Logistics of the study questionnaires: completion rates, method of completing the questionnaires, caregiver and technical support required

Findings from both the trial and feasibility outcomes will inform the design of a future large-scale multicentre trial. The DAH30 outcomes data will allow the estimation of precision for future sample size calculation.

4 Methodology

4.1 Design and Setting

This study is a single-blinded, parallel-group, pilot RCT, with an exploratory feasibility analysis. The study will be registered on ClinicalTrials.gov prior to patient recruitment, and reported according to the Consolidated Standards of Reporting Trials (CONSORT) pilot RCT standards[4].

The study will be conducted at St Paul's Hospital (SPH), Providence Health Care, in Vancouver, BC, Canada, an academic tertiary care hospital affiliated with the University of British Columbia. **Based on data from Jan 2022 to Aug 2023, the volume of inpatient general surgery is 107 per month, with a median postoperative length of stay (LOS) of 3 days, ER visit rate of 13%, and readmission rate of 6%. The volume of inpatient vascular surgery is 11 per month, with a median postoperative LOS of 5 days, ED visit rate of 10%, and readmission rate of 6%.**

The SPH anesthesia and surgical program already has a strong perioperative care focus, featuring enhanced postoperative support available for high risk patients including 1) surgical high-acuity unit (SHAU) with continuous monitoring, run by anesthesiologists, 2) Perioperative Outreach Team that rounds on patients daily for as long as clinically indicated, run by anesthesiologists, 3) multidisciplinary collaboration and support from perioperative internal medicine and/or geriatric teams, with daily rounding for as long as clinically indicated and availability for preoperative consultation and post-discharge follow-up in rapid access clinics, and 4) protocolized monitoring for myocardial injury after non-cardiac surgery for three days according to the Canadian Cardiovascular Society guidelines[5].

4.2 Inclusion criteria

a. Aged 19 years or older
b. Undergoing inpatient major abdominal (general surgery, urology, or gynecology) or vascular surgery at St. Paul's Hospital (SPH) and Mount Saint Joseph (MSJ) Hospital
c. Length of stay is at least 48 hours (planned by the clinical team, or by the Canadian Institute of Health Information Discharge Abstract Database Expected Length of Stay (ELOS) for the surgical case mix group)
d. Self-reported fluency in reading and speaking in English
e. Living within British Columbia, Canada and in an area that is covered by Bell cellular network (the Cloud DX device has cellular LTE using the Bell network).

4.3 Exclusion criteria

a. Patient refusal
b. Transplant surgery, since these patients have a unique set of considerations and postoperative course.
c. Inability to communicate with research personnel, perform self-monitoring of vital signs, or complete study surveys due to cognitive, language, visual, or hearing barriers
d. Lack of capacity to consent to the study (including under the active influence of sedative medication or having received general anesthetic within the past 24 hours)
e. Unable to use (or does not have a caregiver who can help put on/take off) study monitoring device at home

f. Preoperatively known planned discharge to a nursing home or rehabilitation facility
g. Patient with known allergic reactions to any part material of the device
h. Unable to monitor blood pressure accurately noninvasively using arm blood pressure cuffs, such as due to underlying vascular anatomy or non-pulsatile blood flow physiology
i. Unlikely to be able to return the home monitoring kit (no fixed address, living too far away from site, etc.)

4.4 Recruitment and Consent

An initial list of patients will be obtained daily from the hospital's operating room schedules (including patients who are on the emergency room waitlist), surgeon's clinic schedules (vascular and abdominal surgery), and the anesthesia preadmission clinic schedule, accessible through Cerner. The table below indicates the locations where patients undergoing elective vs. urgent/emergent surgeries will be approached preoperatively. No recruitment will be done postoperatively.

Table. Potential locations and points of approach

Urgent/Emergent surgery	Elective surgery
Ward Operating room holding area (where patients from the ward may wait prior to going to the operating room) SHAU	Anesthesia preadmission or surgeon clinics (in-person or phone call) Surgical Day Care Ward (if admitted to the ward preoperatively)

The study coordinator will review the patient's chart on Cerner and screen the patients against the inclusion and exclusion criteria of the study to identify those who are eligible. The research team will confirm that the patient has agreed to a member of the patient's circle of care that they are amenable to being approached about research. Once this approval is confirmed, the study coordinator will approach the patient, explain the study, answer questions, and obtain the written consent. Each participant will receive a copy of the consent for their record. For patients whose preoperative clinic visits are through Telehealth, the consent form will be read on the phone and/or emailed to the patient by the research team. If the patient agrees to participate, a verbal consent will be obtained. The written consent will be signed preoperatively when the patient is in the hospital for the surgery.

4.5 Randomization

Randomization is conducted after informed written consent has been obtained from a patient who is eligible to the study. Participants will be randomized 1:1 to either the intervention group or the control group (standard of care), stratified by sex. The computer-generated random allocation sequence will be created by Centre for Advancing Health Outcomes, Providence Health Care, who has no involvement in any other research activities of the study. The algorithm will be administered through the Cerner Careflow research interface. There will be 12 blocks of 4 and 8 blocks of 6 in random order, with n = 96 patients per strata (the total sample size is n = 110, per sample size calculation section below).

4.6 Blinding

In order to prevent the treating physicians from adjusting patient disposition to the ward on the assumption that the patient will have increased monitoring as part of the study, blinding will be

done to the care team and patient until the patient has been ordered to be medically transferred to the ward from the recovery room, high acuity unit, or intensive care. The intervention to increased monitoring vs. standard of care will only be unveiled at that point, and the intervention arm patients will be placed on increased monitoring monitors at that time. Blinding is not possible to the patient on the ward due to the nature of the intervention (more frequent monitoring). Blinding is not possible to the ward care team and outcome assessors due to the potential need for care escalation from enhanced monitoring. The data analyst analyzing the primary and secondary outcomes will not be involved in the rest of the study conduct (recruitment, consent, data collection, and data cleaning) and will be blinded to the group assignment which will only be unmasked once the data analysis is submitted to the Principal Investigator. The feasibility outcomes will be analyzed by a separate data analyst, as most of the outcomes are within the intervention group and blinding will not be possible.

4.7 Control Group

Participants in the control group receive the standard of care monitoring after the surgery as prescribed per the care team at St. Paul's Hospital, according to the patient's needs. Monitoring as deemed by the care team will never be withheld from the patient for any study purpose (e.g. if clinically needed the patient in the control group will receive continuous monitoring in HAU and/or ICU per standard of care). Appendix A. shows the monitoring guidelines for postoperative patients (i.e. to the most frequent monitoring required by the clinical situation), adopted from the current nursing protocols at SPH and MSJ. Vital signs measured are blood pressure (BP), heart rate (HR), temperature (T), respiratory rate (RR), oxygen saturation (SpO_2), Pasero Opioid Sedation Scale (POSS), and pain assessment (Pain), and are documented in Cerner automatically from the monitor and/or manually. Since end-tidal carbon dioxide monitoring is not part of the study objectives, patients on the sleep apnea protocol will continue to receive extended Post Anesthetic Care Unit (PACU) stay and end-tidal carbon dioxide monitoring per standard of care. Once the patient is discharged from the hospital, the current standard of care is no monitoring of vital signs at home.

4.8 Intervention Group

Patients randomized to the intervention group will receive **enhanced (i.e. additional) monitoring using Health Canada approved devices in-hospital during the day** for three days after surgery (POD0-POD3 inclusive) or until discharge, whichever occurs first, **followed by twice-daily monitoring at home for 3 days after discharge, with a protocol for clinical escalation if vital sign alert thresholds are exceeded**. Except for the increased frequency of monitoring, all aspects of the patient's care will be per standard of care (e.g. the study has no impact on the decision to discharge home). The table below has the detail of the enhanced monitoring.

Table. Enhanced (additional) monitoring parameters

Patient location	**Monitoring frequency**	**Monitoring device**
In hospital (PACU, HAU, ICU)	No study monitoring will occur as standard of care monitoring (See Appendix A.) is the same or more frequent.	
In hospital (ward) 8am – 5pm	**HR and SpO_2**: continuously **Noninvasive BP**: automatically q60 minutes	**Philips Intellivue M450** monitors (same as what is used at the SPH PACU) with Nellcor.

At home (discharged)	**HR, SpO_2, noninvasive BP**: two times a day (approx.. once during 8am-12:30pm, and 12:31pm-5pm) **Temperature** (once daily)	**CloudDX Kit** (includes blood pressure monitor, pulse oximeter (HR and SpO_2), thermometer

Note: Vital signs from the study monitors will be transmitted securely to the PHC CareFlow

In hospital, while the study patients are encouraged to keep the monitoring on whenever is reasonable to the patient, the patient and medical circle of care team can pause or terminate the enhanced monitoring for any reason (e.g. mobilization, physiotherapy, toileting, shower, meals, and naps), and this will be documented in the patient study diary. A patient can connect or disconnect as often as they wish. Patients and caregivers will be educated how to put on and off the devices by the research coordinator. If there is any issue, the study coordinator will visit the patient and assist. The regular clinical care team is not expected to assist with the study device. The Philips monitor study device used in hospital is the same as the monitor that is being used in the SPH PACU. The nurses within the circle of care do not need to be involved in the setup, monitoring, troubleshooting, nor removal of the study devices.

Importantly, patients in the intervention group will still receive all monitoring as deemed necessary by the standard of care, and monitoring will never be withheld from the patient as clinically indicated. For example, the patient may receive continuous HR, SpO_2, and arterial BP monitoring in the SHAU, operating room (e.g. during a reoperation), or ICU. If the clinically-indicated monitoring per standard of care is equal or greater than the frequency listed in the below table, the patient does not need to use the study device nor clinical escalation - i.e. the existing monitor in SHAU, operating room, or ICU would be sufficient, and the research coordinator will not monitor the alerts, since this will already be done by the treating team as the standard of care. To summarize, if any of the components from the standard of care are exactly the same as or more than what the enhanced monitoring provides (e.g. patient already has a functioning arterial line as part of the standard of care), then the patient will not require the additional study monitors (unless the patient still needs the study monitor for another vital sign).

The circle of care will not have access to the data from the enhanced monitoring. If the alert thresholds are reached per the following table (guided by the NEWS2 score), an alert will be sent to the study cell phone by text messaging and by study email with the de-identified study ID and type of abnormal vital sign. For consistency and safety, the thresholds will not be adjusted for individual patients in this study.

To avoid the excess of alerts that are not related to clinically relevant events for patients, the alert to the study coordinator will be sent if the vital sign remains abnormal for 1 minute or more when the vital signs is monitored continuously (HR and SpO2). The study personnel will only alert the patient's care team if the vitals are worse than what is already documented on Cerner and worse than the previous alert (i.e. if the patient's systolic blood pressure has been 90mmHg and the patient's care team was already previously alerted about this, the patient's care team will not be alerted again. However, if the systolic blood pressure is now 80mmHg, then the patient's care team will be alerted). The study monitors will be silenced as to not disturb the patient or the

care team, but all derangements that are new and not already documented in Cerner will be notified to the care team.

Vital sign	**Thresholds for alert**
Systolic BP (mmHg)	<=100, or >=220
Saturation of Peripheral Oxygen (SpO_2) (%) for non-COPD patients	<=93
Saturation of Peripheral Oxygen (SpO_2) (%) for COPD patients (if they have been prescribed a COPD-specific threshold of 88-92% while in hospital)	<=87, or >=93 on oxygen
Heart Rate (HR) (beats per minute)	<=50, or >=91
Temperature (at home)	<=36.0 or >=38.1

The research coordinator will review the alerts in the above table between 8am and 5pm, for the day of surgery until 3 days after surgery (POD0-POD3) in hospital and the first 3 days at home after discharge from the hospital. **The role of the research coordinator is to triage according to the escalation protocol, alert patients and refer to standard of care, but not provide further clinical assessment nor treatments** (i.e. it would be similar to if a patient does a BP at a pharmacy and it's abnormal, what resources the patient has access to). The research coordinator will consult with the study team physicians if there is any uncertainty.

- If the patient is in-hospital, the study personnel will first check Cerner to see if the abnormal vital sign is already documented within the past hour. If so, no contact with the care team is needed, since the same vital sign is already known to the care team per standard of care and the intervention do not contain additional information that will change care. If the abnormal vital sign is not documented in Cerner, the study personnel will contact the patient's main care team regarding the vitals, and the care escalation will be according to the existing standard of care per the circle of care. Note the study personnel will not engage with the care team beyond the initial notification to the care team.
- If the patient is at home, the study personnel will contact the patient (or if the patient cannot be reached after 3 tries by phone, then the emergency contact up to 3 times) within 2 hours of the alerts. The recommendation from the research coordinator for all patients with alerts is to call the BC 811 nursing line and go to the urgent care clinic or ER to be assessed. Patients will be informed why they need to go (the abnormal vital[s]), why it is important to go and what are the consequences for not going. There will be no further clinical assessment from the research coordinator, as this is not the standard of care.
- The patient will also be provided a handout for what is normal and what is abnormal for vital signs per NEWS2 at the same moment of providing the home device. The care team may contact the study physicians during day time hours (8am to 5pm) about further questions. At any time, all outpatients have access to standard of care: day time e.g. surgeon's office numbers, ERAS patients have access to the ERAS nurse who calls them within 24h and can be contacted by phone/email for a week, FP/NP; night time e.g 811, ER, urgent care. While we provide 9 hour monitoring to alert the patients if the vital signs are outside of the usual range, patients may still be having issues that may not lead to abnormal vital signs and the research coordinator may not receive an alert. Patient should still monitor for symptoms and reach for help as instructed by their hospital team at

discharge, and contact the standard of care team with any concerns/issues even if there are no abnormal signs.

- Once a patient is labeled with Awaiting Long-term Care status per PHC standard of care, they will be considered at home and will be given the CloudDX devices even when they are in hospital. If needed, the research coordinator will help the patient with the measurements.

The notification of the care team in-hospital and patient/caregiver at home will be documented within the study data collection form. The escalations required (table below) will be documented by a combination of asking the patient's care team their next course of action, referrals required, and/or chart review. Multiple escalations may apply for the same patient, at multiple time points.

To facilitate the tracking of in-hospital vital signs derangements, alerts and their corresponding escalation, the study personnel will provide an escalation report sheet, that will be attached to the patient's monitor. Care Team will record the date, time, abnormal vital sign and escalation made after every abnormal vital sign notification.

4.8.1 Clinical escalation protocol

If there are no alerts, no escalation will occur, regardless of location. If there is an alert, while in hospital, the study team and/or care team will confirm that it is not an error. If it is an error, it will be documented as an artifact measure. The table below describes the protocol for escalation. The care team will be asked to record and specify if any escalation occurred.

Table. Definitions of escalation types

Definition	In-hospital	At Home
Escalation	The patient's care team: 1. **Performed an action as a direct result of the additional information** (e.g. remind OSA patient to take a deep breath, will check in with the patient more closely, cycled vitals or will cycle vitals that were not planned prior to the alert) **2. Informed the most responsible physician or designate** 3. **Ordered additional testing** (e.g. lab, imaging) 4. **Ordered additional therapy** (e.g. medication, oxygen, intubation, surgery) 5. **Had a Physician assess the patient in-person**, 6. **Moved the patient to a higher acuity ward** (e.g. SHAU, ICU), **7. Called Critical care outreach team or perioperative outreach team** **8. Consulted specialist** 9. **Other** (specify)	The Research Team: Advised patient or caregiver by phone to call the BC 811 nursing line and/or go to urgent care clinic or ER to be assessed. (contact will be attempted 3 times)

4.9 Device Teaching, Initiation, Removal, and Collection

The study personnel will check the data stream daily to ensure no issues and to make sure the device is functioning. The study coordinator will email the Cloud DX Support team with

patient's discharge date and patients will be contacted some time between 10-2pm the day of discharge (unless the patient prefers another time). The Cloud DX technical team will reach out to participants to support the use of the home monitoring devices. Cloud DX will also call patients between 11am and 1pm to remind them to take measurements if a set of measurements is missed. Appendix B. lists the logistics of the study devices and Appendix C describes the device components.

4.10 Outcomes

4.10.1 Trial outcomes

Appendix D lists the detailed outcome definitions.

a. Primary trial outcome:

i. Days alive and at home within 30 days after surgery – DAH_{30}[7]

b. Secondary trial outcomes from both the intervention group and the control group

ii. Major morbidity, as defined by complications associated with 30-day mortality: major bleeding, myocardial injury after noncardiac surgery (includes myocardial infarction), myocardial infarction (3rd Universal Definition), sepsis, infection without sepsis, acute kidney injury with new dialysis, stroke, venous thromboembolism and congestive heart failure within 30 days postoperatively

iii. Mortality within 30 days postoperatively

iv. Emergency visit after discharge within 30 days postoperatively

v. Hospital readmission within 30 days postoperatively

vi. Urgent walk-in clinic visit within 30 days postoperatively

vii. Family doctor clinic visit within 30 days postoperatively (not urgent walk-in clinic) with details of planned (for suture/staple removal, or other reason) vs. unplanned

viii. Surgeon visit (with details of method [email, phone call, or clinic visit] vs. in-person [planned vs. unplanned])

ix. Postoperative length of stay

x. Quality of recovery (QoR-15 questionnaire) on 14 and 30 days postoperatively (patients will do baseline questionnaire at study enrollment)

c. Secondary trial outcomes from the intervention group only

xi. Characterize quantitatively and qualitatively vital sign derangements (extent, frequency, clinical impact) detected through continuous vitals monitoring that were missed by standard of care monitoring (i.e. what is documented in Cerner)

xii. Characterize the type of care escalations required as a result of the additional data from continuous vitals monitoring

4.10.2 Feasibility outcomes

a. Participation measures

i. # of patients meeting the clinical inclusion criteria

ii. # of patients excluded and the reasons, based on the exclusion criteria

iii. # of patients approached for recruitment

iv. # of patients provide consent

v. # of patients withdrawal

b. Acceptability

vi. patient use of the devices (frequency, duration, problems encountered)

vii. what were the reasons that patients took the monitors on and off (e.g. charging/battery life, showers, eating, mobilization/physiotherapy) – patient daily log sheet

viii. Instances of interruption in monitoring > 4 hours

ix. patient feedback about enhanced monitoring (Systems Usability Scale once at the end of the in-hospital monitoring and again at the end of the home monitoring, with the questionnaire being open for 1 week for patients to complete)

c. Clinical resource utilization

x. frequency and type of vital sign derangements detected by enhanced monitoring and the resulting care escalation within the duration of monitoring

xi. time between vital sign alert and care escalation

xii. logistics of device use (time spent on education, initiation, discontinuation, cleaning, collection, and troubleshooting of devices)

xiii. issues that arise in the workflow

d. **Evaluation of potential harm or safety issues**

a. Any patient-reported adverse events

b. Feedback questionnaire filled out by the patient at the end of enhanced monitoring in hospital and at home

i. To what extent did the enhanced monitoring affect your ability to move around after surgery? (Likert scale)

ii. To what extent did the enhanced monitoring affect your daily activities (e.g. going to the bathroom, eating, showering) ability to move around after surgery? (Likert scale)

iii. To what extent did the enhanced monitoring make you anxious about your health? (Likert scale)

e. Cost analysis

xiv. Study costs (for planning for multicentre study)

xv. Compared to standard of care group (staffing, healthcare utilization, equipment)

4.10.3 Logistics of the study questionnaires

a. completion rates

b. method of completing the questionnaires

c. caregiver and technical support required

4.11 Data Collection

Data will be collected through the following methods:
(1) PHC Cerner: A data dictionary file will be provided to the PHC analytics team to set up the automated data extraction from Cerner. The time range of the data to be extracted is from one

month prior to hospital admission to 31 days after surgery. Extracted data will be transferred to PHC CareFlow platform for storage, filtering and downloads.

(2) Chart review: For clinical data that is not available through the automated data extraction from Cerner or is available but extracted with error, the research coordinator will conduct chart reviews to collect or verify data.

(3) CareFlow: Vital signs data captured by the enhanced monitoring devices (Philips in hospital and Cloud DX at home) will be transmitted to PHC CareFlow for storage and downloads.

(4) Questionnaires: Participants in both groups will be asked to complete two questionnaires: Enrollment Questionnaire for demographics, and the Quality of Recovery (QoR-15) questionnaire preoperatively and on the 14th day and 30th day after surgery. QoR-15 is a 15-item short survey to evaluate the early postoperative health status of patients. Additionally, participants in the intervention group will be asked to complete the following questionnaires: (a) Daily log sheet while they are under the enhanced monitoring in hospital and at home. The daily log includes questions regarding the utility of the study devices, such as how long and how often participants use the devices, reasons for taking off, and any concerns or issues about the usage. (b) Systems Usability Scale (SUS) at the end of enhanced monitoring in hospital (POD4 or discharge, whichever is earlier) for Philips monitor and at the end of enhanced monitoring at home (post-discharge day 4) for CloudDx. This is a simple, 10-item scale to evaluate participants' assessments of the device usability. (c) Feedback on Enhanced Monitoring Questionnaire at the end of enhanced monitoring in hospital (POD4 or discharge, whichever is earlier) for Philips monitor and at home (post-discharge day 4) for CloudDx. This questionnaire is composed of three Likert scale questions regarding adverse reactions from the monitoring intervention, as well as an open text field where patients can write more detail. Participants will be offered with options to complete the questionnaires online (through UBC REDCap), through telephone with research coordinator, on hard copies. Those choosing the hard copies will be asked to take photos of their answers and email to the research coordinator prior to mailing the questionnaires back using the return envelopes.

(5) Phone call follow-up: The research coordinator will call participants in both groups on the postoperative day 31 or later to verify study outcomes, such as hospital readmission, emergency, urgent care or family doctor clinic visits, and major morbidity, particularly when these variables cannot be obtained by chart review.

Table: Questionnaires used in the study

Questionnaire	**Group**	**Time point of measurement**
Enrollment questionnaire	Both	At enrollment, after randomization
QoR-15	Both	Preoperative, POD 14 & POD 30
Daily Log Sheet	Intervention	Daily while under enhanced monitoring (Postoperative days 0 to 3 or discharge, whichever comes first) in hospital, and at home post-discharge days 0 to 3 for Cloud Dx Kit
SUS	Intervention	Postoperative day 4 or discharge, whichever comes first, for Phillips), and at home post-discharge day 4 for Cloud Dx

Feedback questionnaire	Intervention	Postoperative day 4 or discharge, whichever comes first, for Phillips), and at home post-discharge day 4 for Cloud Dx

4.12 Honorarium

Patients will receive a $40 gift card which will be distributed at the time when the research coordinator makes the last phone call with the patients to collect the final data around secondary outcomes within 30 days postoperatively. At the end of the phone call, patients will be offered with options to receive the gift card by email or by taking the claim code over the phone.

4.13 Analysis Plan

4.13.1 Pre-processing

Data from study questionnaires, chart review, Cerner data pull, and Careflow data pull will be linked by study ID.

4.13.2 Missing data

The % missing values for each variable will be quantified and reported.

4.13.3 Cohort characteristics

a. **Patient (demographics, medical, and surgical factors)**
   i. Age, gender, ethnicity, height, weight, body mass index (BMI), NT-proBNP, troponin
   ii. Reason(s) for perioperative team follow up
   iii. RCRI score and components, ASA score, components and total score for Charleson Comorbidity Index [via Cerner-CIHI DAD extraction and also manually confirmed via chart review]
   iv. Urgency of procedure
   v. Surgical service
   vi. Admissions to HAU/ICU
   vii. demographic predictors of nonparticipation and reasons for early drop outs, and how we can support them (e.g. phone connectivity, language issue, discomfort)
   viii. Total operation time
   ix. Reoperation(s) (with postoperative day information)
b. **Type(s) of clinical escalation and timeline** [copy from Outcome section above]
c. **Morbidity and mortality**
   x. Length of stay and days alive and at home 30 days after surgery
   xi. Mortality
   xii. Postoperative complications
   xiii. Healthcare utilization (ED, readmission, reoperation)
   xiv. Discharge destination
d. **Characterize quantitatively and qualitatively vital sign derangements** (extent, frequency, clinical impact) detected through continuous vitals monitoring that were missed by standard monitoring
e. **Characterize the type of care escalations** required as a result of the additional data from continuous vitals monitoring. Escalation will be further characterized as using

i. Per person rate and extent of change in clinical management because of the continuous data
ii. Timeframe (hours) of each step of escalation

f. Quantitative data on how long and how often did patients use this monitoring
g. Qualitative data (through patient study diary) on what were the reasons that patients took the monitors on and off (e.g. charging/battery life, showers, eating, mobilization/physiotherapy)
h. Staffing requirements for device use (time spent teaching, putting devices on, taking devices off, collecting devices, education of perioperative and ward nurses)

4.13.4 Analysis of outcome

The rates of outcomes will be reported. The median (IQR) or mean (SD) of DAH30 will be reported, depending on the distribution. Since this is a pilot study, no tests of significance will be performed. Intention-to-treat will be used, with a per protocol sensitivity analysis.

For patient outcomes, the effect size will be estimated using univariable and multivariable analyses (logistic regression for binary outcomes and generalized linear model for continuous outcome). The planned *a priori* variables adjusted in the multivariable models are age, sex, surgical urgency and surgical service.

4.13.5 Questionnaire data

Descriptive statistics of questionnaire results will be performed.

4.13.6 Sample Size

Based on the below recommendation from Advancing Health, PHC, the sample size will be n = 100 (n = 50 per group). Accounting for a drop out rate of 10%, we will recruit **n =110.**

As a feasibility study, it is recommended that the sample size considerations be based on an acceptable precision for the feasibility outcomes of interest, often expressed as the width of a confidence interval for specific endpoints. While it can be given some consideration, the sample size for a feasibility study should not be based on a clinical outcome of interest.[i]

For a range of sample sizes, the following table lists the range of confidence interval widths for an endpoint expressed as a proportion (eg. % of participants who complete the study). For outcomes expressed as a proportion, confidence intervals are widest when the proportion is around 0.5 and gets narrower as the expected proportion decreases/increases to close to 0 and 1.

The interpretation is: With X participants per arm we would be able to estimate the proportion of participants who completed the study with a maximum confidence interval width of Y (in each arm); where X and Y are read from the appropriate row of the table.

Sample Size/arm	95% Confidence Interval Width	
	Minimum	Maximum

[i] Teresi JA, Yu X, Stewart AL, Hays RD. Guidelines for Designing and Evaluating Feasibility Pilot Studies. Med Care. 2022 Jan 1;60(1):95-103.PMID: 34812790

	(proportion ~0.1/0.9)	(proportion ~0.5)
30	0.24	0.37
40	0.21	0.32
50	0.18	0.29
60	0.17	0.26

The data collected during a feasibility study can be used to gather data to allow for an accurate measure of variability in a clinical outcome of interest in the specific study population. It may be useful to report a possible confidence interval limit for a clinical outcome in support of the chosen sample size based on the feasibility outcome. In the table below, the estimated width of a confidence interval for the outcome number of days at home alive up to 30 days (DAH_{30}) has a reported using standard deviations reported in different sources. Where the data were reported as median and IQR, the 'rule of thumb' estimate of (75^{th}%ile – 25^{th}%ile)/1.35 was used.[ii] MCID of DAH_{30} has been reported as 3 days.[iii]

Sample Size/arm	95% Confidence Interval Width		
	Jareth et al[iv] IQR=24-27 -> SD~2.2	McGillon et al [v] SD=3.9	Bell et al[vi] IQR=23-29 -> SD~4.4
30	1.64	2.91	3.28
40	1.41	2.49	2.81
50	**1.25**	**2.22**	**2.50**
60	1.14	2.01	2.72

In a non-feasibility study, the usual interpretation of the above information would be: with 40 participants per arm if the SD of the outcome is 2.2 in each arm the study would have 80% power to detect a difference of 1.4 DAH_{30}. If the SD of the outcome is 4.4, the detectable difference is 2.8.

In a feasibility study, usually only estimates with confidence intervals are reported; statistical comparisons between groups are not conducted.

[ii] Higgins JPT, Green S: Cochrane Handbook for Systematic Reviews of Interventions. 2008, Wiley Online Library

[iii] Ferguson MT, Kusre S, Myles PS. Minimal clinically important difference in days at home up to 30 days after surgery. Anaesthesia. 2022 Feb;77(2):196-200. Epub 2021 Nov 19. PMID: 34797923.

[iv] Jerath A, Austin PC, Wijeysundera DN. Days Alive and Out of Hospital: Validation of a Patient-centered Outcome for Perioperative Medicine. Anesthesiology. 2019 Jul;131(1):84-93. PMID: 31094760.

[v] McGillion MH, Parlow J, Borges FK, Marcucci M, Jacka M, Adili A, et al; PVC-RAM-1 Investigators. Post-discharge after surgery Virtual Care with Remote Automated Monitoring-1 (PVC-RAM-1) technology versus standard care: randomised controlled trial. BMJ. 2021 Sep 30;374:n2209. PMID: 34593374

[vi] Bell M, Eriksson LI, Svensson T, Hallqvist L, Granath F, Reilly J, Myles PS. Days at Home after Surgery: An Integrated and Efficient Outcome Measure for Clinical Trials and Quality Assurance. EClinicalMedicine. 2019 Apr 27;11:18-26.PMID: 31317130

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2. McGillion MH, Parlow J, Borges FK, Marcucci M, Jacka M, Adili A, et al. Post-discharge after surgery Virtual Care with Remote Automated Monitoring-1 (PVC-RAM-1) technology versus standard care: randomised controlled trial. BMJ. 2021 Sep 30;374:n2209.
3. Vascular Events in Noncardiac Surgery Patients Cohort Evaluation (VISION) Study Investigators, Spence J, LeManach Y, Chan MT, Wang CY, Sigamani A, et al. Association between complications and death within 30 days after noncardiac surgery. CMAJ Can Med Assoc J J Assoc Medicale Can. 2019 Jul 29;191(30):E830–7.
4. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016 Oct 24;355:i5239.
5. Pelland A, Chau A, Shin HJ, Prabhakar C. Improving adherence to a monitoring protocol for myocardial injury after non-cardiac surgery. Can J Anesth Can Anesth. 2020 Oct 1;67(10):1475–7.
6. Vernooij JEM, Koning NJ, Geurts JW, Holewijn S, Preckel B, Kalkman CJ, et al. Performance and usability of pre-operative prediction models for 30-day peri-operative mortality risk: a systematic review. Anaesthesia [Internet]. [cited 2023 Mar 10];n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/anae.15988
7. Jerath A, Austin PC, Wijeysundera DN. Days Alive and Out of Hospital: Validation of a Patient-centered Outcome for Perioperative Medicine. Anesthesiology. 2019 Jul 1;131(1):84–93.
8. Southern DA, Burnand B, Droesler SE, Flemons W, Forster AJ, Gurevich Y, et al. Deriving ICD-10 Codes for Patient Safety Indicators for Large-scale Surveillance Using Administrative Hospital Data. Med Care. 2017;55(3):252–60.

Appendix A. Standard of care monitoring by unit and clinical situation at St. Paul's Hospital

Unit	Clinical Situation	Monitoring Guidelines
PACU	If unconscious	**Arterial BP (if needed), HR and SpO_2**: automatically collected continuously **Noninvasive BP**: q5min **T, RR, POSS and Pain:** q5min until awake or POSS of 3 or less Nursing: patient ratio 1:1
	If awake	**Arterial BP (if needed), HR and SpO_2**: automatically collected continuously **Noninvasive BP**: q5min **T, RR, POSS and Pain:** q15 min x 8 then q 30 min x 4, then q 1h until discharge from phase 1 or PACU Nursing: patient ratio 1:2
SHAU	All patients	**Arterial BP (if needed)**: automatically collected continuously **Noninvasive BP, RR, HR and SpO_2**: q30min x 4 then q1h, may be done more frequently depending on the clinical situation **T and Pain:** q1h until discharge from SHAU Nursing: patient ratio 1:1 if unconscious, 1:2 if awake
	Patients on the Obstructive Sleep Apnea protocol	**End-tidal Carbon Dioxide and SpO_2:** continuously
Wards, PACU, or SHAU	All patients	**Vital Signs:** q4h x 48 hours, then q8h x 48hours, then BID until discharge or as ordered by physician or nurse practitioner
	Ketamine Infusion	**Vital Signs:** q1h X 4 hours, then q4h for duration of infusion
	Lidocaine Infusion	**BP, HR, T, RR, and SpO_2**: q15 min x 1 hour, then q1h x 4 hours, then q4h and PRN for duration of infusion **POSS:** q15 min x 1 hour, then q 1h x 4 hours, then q2h and PRN for duration of infusion **Pain:** q15 min x 1 hour, then q1h x 4 hours, then q2h and PRN for duration of infusion
	Patient Controlled Analgesia (PCA)	**POSS, RR, and Pain:** q15 min x 30 min, then q1h x 4 hours, then q2h x 24 hours, then q 4h for duration of therapy **SpO_2, BP and HR:** q 15 min x 30 min, then q 1h x 4 hours, then q 4h for duration of therapy
	Epidural Analgesia	**BP and HR:** q 15 min x 4, then q 30 min x 1 hour, then q 4h (start in PACU) & PRN **Postural BP and HR:** Prior to first ambulation **RR, SpO2, Pain, and POSS:** q 1h x 12 hours, then q 2h x 12 hours, then q 4h & PRN

Abbreviations: blood pressure (BP), heart rate (HR), temperature (T), respiratory rate (RR), oxygen saturation (SpO_2), Pasero Opioid Sedation Scale (POSS), and pain assessment (Pain)

Appendix B. Study device logistics

Task	In-hospital monitoring	At home monitoring
Teaching patient and caregiver how to use the device	After consent and prior to the surgery preferably, may teach within 24h postoperatively if needed	Prior to discharge. Patients will be assigned a username and password for using the device
Device initiation	By study personnel	By patient or caregiver, once at home. Study personnel may provide guidance through Telehealth.
Device troubleshooting and servicing	Study personnel will review in-person, and contact Medtronic if needed	Cloud DX Support Line for patient to call directly (may also call study personnel) Cloud DX Support: Tel:1-888-543-0944 Email: support@clouddx.com Hours (PT): Monday-Friday 5:30am-5:00pm; Weekend & Holidays 6:00am-2:00pm
Device charging and/or battery change	By patient or caregiver, with guidance from study personnel. Will be provided with spare batteries where needed.	By patient or caregiver, once at home. Study personnel may provide guidance through Telehealth. Will be provided with spare batteries where needed.
Device removal	By patient or caregiver (e.g. physiotherapy, shower) with guidance from study personnel. By study personnel prior to discharge if required.	By patient at home
Device return and collection	Study personnel (device may be left in the ward if the study personnel cannot get to the patient in time or during evenings/weekends).	Prepaid shipping label and box provided to the patient and caregiver
Device cleaning and removal of data from previous patient	Study personnel	Study personnel (once received device back in hospital), using Cavi wipes or 70% alcohol wipes. Data from previous patient will be removed on the devices, which removes any saved login information to the Connected Health app, i.e., access to app and any data within the app.

Appendix C. Study devices Components

Device Name	Device Components	Description	Power Supply	Location of Usage
Medtronic Philips Intellivue 450	One piece monitor	A portable monitor with multi-measurement module	Plug-in	In hospital
Cloud DX Health Kit	Blood pressure monitor	A non-invasive, wireless device intended for spot-checking of blood pressure and pulse rate in the home healthcare environment	4 AA batteries	At home
	Thermometer	A digital infrared device intended for spot-checking of body temperature	1 button cell battery	
	Pulse oximeter	A non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate	2 AAA batteries	
	Android tablet	A pre-programmed cellular tablet with a data plan to support all the companion Apps, communications and data transfer.	Rechargeable Lithium-Ion battery	

Appendix D. Definitions of Outcomes

Name of Outcomes	Definition
Days alive and at home within 30 days (DAH30) [vii] [viii]	Number of days within 30 days of surgery when participant is alive and at home, without visiting an emergency department or urgent care centre or being admitted to a hospital. Home refers to their own home, or a residence of a relative, friend or acquaintance, but excludes a nursing home or a rehabilitation facility. Participants lose days alive at home if they: go to an emergency department or urgent-care centre; become inpatients at a hospital; or die. If a participant visits an emergency department or urgent care centre, or is admitted to a hospital any time between midnight and 23:59 on a given day, they will lose that day as a day alive at home. If they remain in the care facility past midnight into the next day, then they lose 2 days alive at home. They will continue to lose days alive at home until the day in which they are home from midnight for an entire day. In other words, a day alive at home can be counted only when participants spend an entire day from midnight to 23:59 at home, without being stay at an emergency department, an urgent-care centre or a hospital. DAH30 will be counted within 30 days after surgery, with the day of surgery as day 0.
Major bleeding[ix]	Within 30 days postoperatively. The diagnosis of major bleeding requires that the bleeding has resulted in a drop in hemoglobin to <70 g/L, transfusion of ≥1 unit of packed red blood cells, or death.
Myocardial injury after non-cardiac surgery (MINS)**Error! Bookmark not defined.**	Within 30 days postoperatively. MINS will be measured by Troponin T (hsTnT) assay. The diagnostic criteria for MINS are an elevated postoperative hsTnT (20 to <65 ng/L with an absolute change ≥5 ng/L or an hsTnT ≥65ng/L) judged as resulting from myocardial ischemia, without the requirement of an ischemic feature.
Sepsis**Error! Bookmark not defined.**	Within 30 days postoperatively. Sepsis is defined by the presence of both infection and a systemic inflammatory response. Systemic inflammatory response requires ≥2 of the following factors: core temperature >38º C or <36º C; heart rate >90 beats per minute; respiratory rate >20 breaths per minute; white blood cell count >12 x 10^9/L or <4 x 10^9/L.
Infection without sepsis**Error! Bookmark not defined.**	Within 30 days postoperatively. Infection is defined as a pathologic process caused by the invasion of normally sterile tissue or fluid or body cavity by pathogenic or potentially pathogenic organisms. Infection without sepsis has to fulfill the definition of infection without fulfilling the definition of sepsis.

[vii] Myles PS, Shulman MA, Heritier S, Wallace S, McIlroy DR, McCluskey S, Sillar I, Forbes A. Validation of days at home as an outcome measure after surgery: a prospective cohort study in Australia. BMJ Open. 2017;7:e015828.

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Acute kidney injury with new dialysis**Error! Bookmark not defined.**	Within 30 days postoperatively. It is defined as an acute kidney injury that resulted in new dialysis
Stroke[x]	Within 30 days postoperatively. Stroke is defined as either: 1) a new focal neurological deficit thought to be vascular in origin with signs or symptoms lasting ≥24 hours or leading to death; or 2) a new focal neurological deficit thought to be vascular in origin with signs or symptoms lasting <24 hours with positive neuroimaging consistent with a stroke.
Venous thromboembolism**Error! Bookmark not defined.**	Within 30 days postoperatively. Venous thromboembolism was a composite of deep venous thrombosis and pulmonary embolism. Deep venous thrombosis of the leg or arm is defined as having any one of the following: 1) a persistent intraluminal filling defect on contrast venography; 2) non-compressibility of one or more venous segments on B mode compression ultrasonography; or 3) a clearly defined intraluminal filling defect on contrast enhanced CT. Pulmonary embolus is defined as having any one of the following: 1) a high probability ventilation/perfusion lung scan; 2) an intraluminal filling defect of a segmental or larger artery on a helical computed tomography(CT) scan; 3) an intraluminal filling defect on pulmonary angiography; or 4) a positive diagnostic test for deep venous thrombosis (e.g., positive compression ultrasound) and one of the following - non-diagnostic (i.e., low or intermediate probability) ventilation/perfusion lung scan, or a non-diagnostic (i.e., subsegmental defects or technically inadequate study) helical CT scan.
Congestive heart failure**Error! Bookmark not defined.**	The definition of congestive heart failure required at least one of the following clinical signs - an elevated jugular venous pressure, respiratory rales/crackles, crepitations, or presence of S3, with at least one of the following radiographic findings - vascular redistribution, interstitial pulmonary edema, or frank alveolar pulmonary edema.
Death	All cause mortality within 30 days of surgery
Emergency department visit	Participant visit to an emergency department after discharge within 30 days of surgery
Hospital readmission	Participant readmission to a hospital after discharge within 30 days of surgery
Urgent care centre visit	Participant visit to an urgent care centre after discharge within 30 days of surgery
Family doctor clinic visit	Participant visit to a family doctor clinic after discharge within 30 days of surgery
Postoperative length of stay	The time from the date of the surgery to the date of discharge from the hospital
Quality of recovery (QoR-15)[xi]	Measured preoperatively and at 14 and 30 days postoperatively. QoR-15 is a 15 item patient-reported outcome measurement that measures quality of recovery after surgery and anesthesia. It has been validated by multiple clinical trials and found to have good content validity, good internal consistency and essential unidimensionality.

[x] Borges FK, Nenshi R, Devereaux PJ. Fast track pathway to accelerated cholecystectomy versus standard of care for acute cholecustitis (FAST) Pilot trial protocol. Forthcoming 2021.

[xi] Kleif J, Waage J, Christensen KB, Gögenur I. Systematic review of the QoR-15 score, a patient- reported outcome measure measuring quality of recovery after surgery and anaesthesia. Br J Anaesth. 2018 Jan;120(1):28-36. doi: 10.1016/j.bja.2017.11.013. Epub 2017 Nov 22.

Vital sign derangement[xii]	Detected during the enhanced continuous monitoring period. It is defined as a vital sign value exceeds the following thresholds: Systolic BP <=100, or >=220 mmHg SpO2 <=93% for non-COPD patients; or <=87%, or >=93% on oxygen for COPD patients HR <=50 or >=91 beats per minutes Temperature <=36.0ºC or >=38.1ºC The extent, frequency and clinical impact of the derangement as well as the derangements that are missed by standard of care monitoring will be recorded.
Escalation of care	See the "Definitions of escalation types" in the protocol. The escalated care required, and time between vital sign alert and care escalation will be documented during the enhanced continuous monitoring period.
Patient experience of device use	During the enhanced continuous monitoring, participants in the intervention group will be asked to record the frequency, duration and problem encountered when using the continuous vitals monitors. The reasons that participants took the monitors on and off, any adverse events, and to what extent the monitors may have affect their daily life will also be recorded.
System Usability Scale (SUS)[xiii] [xiv]	Measured at 4 days postoperatively (for Phillips) and 4 days post-discharge (for Cloud Dx). SUS is a patient-reported measurement which includes ten 5-point rating scales of usability of a system. The suitability of using SUS for evaluating medical devices has been well established.
Technical support required	Technical issues encountered and the technical support needed during the enhanced continuous monitoring period.

[xii] Royal College of Physicians . National Early Warning Score (NEWS) 2: Standardising the assessment of acute-illness severity in the NHS. RCP, 2017.

[xiii] Brooke J. SUS: a quick and dirty usability scale. ResearchGate. 1995. Nov, [2021-11-21]. https://www.researchgate.net/publication/228593520_SUS_A_quick_and_dirty_usability_scale.

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Appendix E: Study variables and data sources

Outcome	Variable	Group	Data source
Patient characteristics	*Demographics:* Age at surgery Gender Ethnicity Education BMI	Both	Enrollment questionnaire & Cerner & Chart review
	Health condition before surgery: Smoking Chronic pain Obstructive sleeping apnea Myocardial infarction Atrial fibrillation Congestive heart failure Transient ischemic attack COPD Peripheral arterial disease Stroke Deep vein thrombosis Pulmonary embolism Diabetes Cancer Need assistance with activities of daily living Charlson comorbidity index ASA RCRI CVA	Both	Chart review & Cerner
	Surgery information: Date of surgery Surgery type Urgency of surgery Anesthesia Procedure End of surgery Postoperative disposition	Both	Cerner & Chart review
Trial Outcomes			
Primary trial outcome	DAH_{30}	Both	Cerner
Secondary trial outcomes	Morbidity (within 30 days postoperatively): Major bleeding Myocardial infarction after non-cardiac surgery Acute myocardial infarction	Both	Chart review

	Sepsis Infection without sepsis Acute kidney injury with new dialysis Stroke Venous thromboembolism Congestive heart failure		
	Mortality (within 30 days postoperatively)	Both	Cerner
	Health care utilization within 30 days postoperatively: Emergency Hospital Urgent walk-in clinic Family doctor clinic	Both	Chart review & Phone call follow up
	Postoperative length of stay	Both	Cerner & Chart review
	Quality of recovery (QoR-15) – before surgery	Both	QoR-15 questionnaire
	Quality of recovery (QoR-15) – before surgery	Both	QoR-15 questionnaire
	Quality of recovery (QoR-15) – before surgery	Both	QoR-15 questionnaire
	Vital sign derangements (extent, frequency, clinical impact) detected through continuous vitals monitoring: In hospital, that were missed by standard monitoring At home	Intervention group	Chart review & CareFlow & Research tracking files
	Care escalation required as a result of the additional data from enhanced monitoring: In hospital At home	Intervention group	Chart review & CareFlow & Research tracking files
Feasibility Outcomes			
Participation measures	# of patients meeting the clinical inclusion criteria	Both	Research tracking files
	# of patients excluded and the reasons, based on the exclusion criteria	Both	Research tracking files
	# of patients approached for recruitment	Both	Research tracking files
	# of patients provide consent	Both	Research tracking files
	# of patients withdrawal	Both	Research tracking files
Accessibility	Participant use of the devices	Intervention group	Daily log sheet

	Reasons for taking the device on and off	Intervention group	Daily log sheet
	Instances of interruption in monitoring > 4 hours	Intervention group	Daily log sheet
	Participant evaluation of the enhanced monitoring	Intervention group	Daily log sheet & System Usability Scale (SUS)
Clinical Resource Utilization	Frequency and type of vital sign derangements detected by enhanced monitoring and the resulting care escalation	Intervention group	Hospital charts & Cerner & Research tracking files
	Time between vital sign alert and care escalation	Intervention group	Hospital charts & Cerner & Research tracking files
	Logistics of device use (time spent on education, initiation, troubleshooting etc.)	Intervention group	Research tracking files
	Issues that arise in the workflow	Intervention group	Research tracking files
Evaluation of potential harm or safety issues	Any participant-reported adverse events	Intervention group	Research tracking files & Daily log sheet
	Mobility affected by enhanced monitoring	Intervention group	Daily log sheet
	Daily activity affected by enhanced monitoring	Intervention group	Daily log sheet
	Anxiety caused by enhanced monitoring	Intervention group	Daily log sheet
Cost analysis	Staffing required for recruitment and consenting	Overall sample	Research tracking files
	Costs related to randomization	Overall sample	Research tracking files
	Honorarium for participants	Overall sample	Research tracking files
	Research staff costs compared to standard of care monitoring	Intervention group	Research tracking files
	Costs related to device collection	Intervention group	Research tracking files
Logistics of the Study questionnaires	Completion rates	Both	Research tracking sheet
	Method of completing the questionnaires	Both	Research tracking sheet
	Support needed in completion of questionnaires	Both	Research tracking sheet