A PROCESS MONITORING EVALUATION OF A NURSE-LED REMOTE AUTOMATED MONITORING AND VIRTUAL CARE INTERVENTION

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ABSTRACT

Clinical trials involving digital health technologies are complex and challenging deployments. The SMArTVIEW trial (n=800), underway, combines remote automated patient monitoring (RAM) in hospital and virtual hospital-to-home nursing support, up to 30-days post-discharge, for patients who have undergone cardiac and major vascular surgery. Cardiac and vascular surgery patients are at risk for postoperative complications, as well as hospital readmission; SMArTVIEW aims to reduce hospital readmissions and emergency department visits. The purpose of this work was to conduct a process monitoring evaluation of the first 100 patients enrolled in order to examine the implementation, mechanisms, context, and specialized nursing role of the SMArTVIEW intervention.

Six data sources were used to examine patient recruitment, daily nursing intervention workflows, RAM technology compliance, technical troubleshooting, patient education, and virtual nursing care. A content analysis was used to identify nursing advice, recommendations, and corrective actions for patients requiring intervention recovering at home.

Fifty patients were allocated to the SMArTVIEW intervention; of these, 34 engaged in all intervention components, both in-hospital and at home. In-hospital RAM technology generated 194 notifications, drawing nurses to the beside for patient reassessment. Forty-two daily nurse reports and 926 virtual nursing care records were audited to determine technology implementation issues and nursing actions to support patient recovery at home. Process monitoring uncovered strengths and limitations in the

initial days of intervention deployment. Strengths included the functionality of RAM technology, facilitating nurse compliance with required workflows, as well as a high degree of patient engagement in the program. SMArTVIEW nurses addressed multiple health concerns for patients, resulting in 1,865 nursing actions over the 30-day intervention course. Patient withdrawals and lack of standardized communication practices were areas requiring improvement. Results were used to refine and standardize intervention workflows in order to scale the intervention for deployment at a second site (United Kingdom).

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LIST OF ABBREVIATIONS

AAA – Abdominal Aorta Aneurism
BP – Blood pressure
BPI – Brief Pain Inventory
CABG – Coronary Artery Bypass Graft
CAM – Confusion Assessment Measurement
CI – Confidence Interval
CIHI – Canadian Institute for Health Information
CNO – College of Nurses' of Ontario
ECG – Electrocardiogram
eCC – eCare Coordinator
eTrAC – Electronic Transition to Ambulatory Care
EWS – Early Warning Score
FoC – Fundamental of Care
HEWS – Hamilton Early Warning Score
HHS – Hamilton Health Sciences
HITS – Health Information Technology Services
H2H– hospital-to-home
ICU – Intensive Care Unit
LHCH – Liverpool Heart and Chest Hospital
MRC – Medical Research Council
NRS – Numeric Rating Scale
ON – Ontario
PHRI – Population Health Research Institute
POISE – Perioperative Ischemic Evaluation Study
RAM – Remote Automated Monitoring
RCT – Randomized Controlled Trial
RR – Respiration Rate
SpO2— peripheral capillary oxygen saturation
SVN – SMArTVIEW Nurse
THE SMArTVIEW CoVeRed – TecHnology Enabled Self-MAnagemenT – VIsion for remote automated patient monitoring and EmpoWerment following Cardiac and VasculaR surgery
UK – United Kingdom

CHAPTER I: INTRODUCTION

In the last 50 years, one of the most major advancements in improving outcomes for people with cardiovascular disease in Canada has been the advancement of cardiac and major vascular surgical techniques in order to relieve symptoms, restore function, and preserve life (Aranki et al., 1996; Chang, Parina, & Wilson, 2015; Iribarne et al., 2014a; Syed et al., 2018). While these surgical procedures, such as coronary artery bypass grafting (CABG), mitral and aortic valve repair and replacement, as well as aortic dissection repair, have become less invasive and more sophisticated in procedural technique, surgeries of this magnitude still confer significant risk to recovering patients (Curran et al., 2014; Price et al., 2013; Zhang et al., 2014). Those who undergo these procedures are at risk for serious postoperative complications including, but not limited to, hemodynamic compromise due to hypotension, hypertension, atrial fibrillation and other arrhythmias; surgical site infection of sternal, abdominal, radial, and saphenous vein graft sites; unrelieved postoperative pain, and fluid volume overload or fluid volume deficit. These complications may occur either during the index hospitalization, or following hospital discharge while patients are recovering at home in the community (Price et al., 2013).

Patients who do experience serious postoperative complications while in hospital often endure protracted lengths of stay, which contribute to increased healthcare costs. Those who sustain postoperative atrial fibrillation, for example, stay an additional two to five days in hospital, and yield an additional $10,000–$20,000 in treatment-related expenditure (Aranki et al., 1996; Greenberg et al., 2017). In addition to extended length

of stay, patients who sustain cardiovascular, infectious or other complications are at high risk for hospital readmission as well as emergency department visits. For example, in a multicentre prospective cohort study (N= 5,185), The Joint National Institutes of Health–Canadian Institutes of Health Research Cardiothoracic Surgical Trials Network found that across 10 North American Health Care centres, nearly 1 in 5 cardiac surgical patients (18.7%) were readmitted to hospital within 60 days following discharge (Iribarne et al., 2014). Among those readmitted, 11.6% were readmitted more than once; the median time to first readmission was 22 days, with the majority (80.6%) of all first readmissions occurring within the first 30 days. In summary, available evidence has demonstrated that postoperative complications contribute to extended length of hospital stay, as well as drive hospital readmissions and emergency department visits, which negatively impacts patients on an individual basis, as well as directly effects healthcare systems and utilization costs.

Inadequate Postoperative Patient Monitoring

From a health systems perspective, a factor contributing to the problem of postoperative complications is the way in which postoperative care is organized and delivered, both in hospital and beyond. In critical care settings, such as the operating room or in the intensive care unit (ICU), sophisticated surveillance technologies are used to continuously monitor patients' physiologic stability, and the use of such technologies is considered to be standard practice. Continuous monitoring provides indication of real-time, accurate detection of patient deterioration, allowing healthcare providers sufficient warning as well as time to intervene in order to prevent serious adverse events. However,

once patients are transferred to the hospital ward setting, the care model and sophistication of monitoring technologies are drastically different. Current standard postoperative surveillance in the ward setting involves providers conducting manual vital sign assessments using rudimentary equipment, once every 4 hours for newly transferred patients for the first 24 hours of ward stay. Thereafter, standard hospital protocols stipulate patient vital signs assessments are required just once every 12 hours (i.e., once per nursing shift), unless otherwise warranted. For majority of the patient's hospitalization, healthcare providers do not possess the insight to detect early signs of patient deterioration and postoperative complications; it is only when signs and symptoms become noticeably apparent that providers are prompted to intervene.

When patients are discharged home, the problem of under surveillance in the postoperative recovery is perpetuated by extended periods of time where patients do not have any contact with a healthcare provider. It is not uncommon for patients to have just one follow up assessment with a healthcare provider in the initial 30-day discharge period at home—the index period of time known for patients to be at increased risk of experiencing postoperative complications.

Inpatient Postoperative Monitoring. The transition from continuous patient vital signs monitoring in the operating room and ICU to infrequent patient vital signs monitoring on surgical wards poses risk to patients as patients experience complications that go undetected. In a prospective study of surgical patients at the Cleveland Clinic, nurses were asked to assess their postoperative patients (n=594) according to standard hospital protocol (i.e., patient vital signs assessment at 4 to 6-hour intervals) and to

document incidences of hypoxemia as observed (Sun et al., 2015). These same nurses were blinded to continuous oximetry monitoring that was applied to their patients (Sun et al., 2015). Through routine observations, nurses detected a 5% incidence of hypoxemia (SpO2< 90%). In comparison, continuous SpO2 monitoring revealed 37% of patients had ≥1ccontinuous episode of hypoxemia lasting >1 hour, and of those patients, 10% had at least one episode lasting more than one hour where SpO2 was <85%; sustained hypoxemia lasting >5 minutes is associated with an increased risk of myocardial ischemia and other serious postoperative complications. This study demonstrated that routine monitoring practices are suboptimal and inadvertently subject recovering patients to undue risk. In summary, conducting manual vital signs assessments intermittently in the initial postoperative period does not provide an accurate depiction of a recovering patient's true hemodynamic stability and moreover, is an inefficient of use of healthcare providers' clinical time.

Healthcare Provider Surveillance. To ensure quality of care and efficiency needs are met from an hospital operationalization perspective, balance between meeting patient needs and nurses' workload must be struck to prevent deteriorating patient outcomes (van den Oetelaar et al., 2018); however, the professional responsibilities of nurses are becoming increasingly task-orientated and time consuming, which detract from direct patient care (Westbrook et al., 2011). A prospective observational study of 57 nurses (observed for 191.3 clinical hours) working on medical and surgical wards examined how frontline nurses distribute their time during a typical shift (Westbrook et al., 2011). This study concluded that 63% of nurses' time was spent on tasks indirectly

related to patient care (i.e., professional communication, documentation, medication tasks, in-transit). Additionally, nurses were found to complete an average of 72.3 tasks per hour and provide approximately 10 direct patient care tasks, which averaged nurses spending 13.3 minutes present at the bedside each hour (Westbrook et al., 2011). With majority of nursing time spent away from the bedside, front line providers—at no fault of their own—miss subtle signs of physiologic deterioration simply because firstly, nurses are limited in both the time that can be feasibly focused towards providing direct patient care while still meeting all other professional responsibilities, and secondly, by the current standard model of care that depends on unsophisticated technologies and manual assessments conducted over prolonged periods of time, which consequently provides a fragmented representation of the patient's true stability and overall recovery.

Outpatient Postoperative Monitoring. Similar to the risk associated with transferring from ICU to surgical ward settings, transferring from the hospital ward to the community setting also possesses risk as patients are expected to self-manage their postoperative recovery at home, often with insufficient knowledge and preparation, as healthcare provider support surveillance is infrequent and fragmented. In the Cardiac Surgical Unit at Hamilton Health Sciences (HHS), upon hospital discharge, discharge teaching includes instruction for patients to follow up with their family physician one week following discharge, their cardiologist at 4 weeks, and their cardiac or vascular surgeon at 8-12 weeks post hospitalization (Hamilton Health Sciences, 2011). In the initial weeks at home, patients may develop complications that did not present at the time of hospital discharge and are unfortunately left to their own knowledge and judgement to

self-manage their recovery and navigate the healthcare system. This responsibility is one that patients and families commonly feel ill prepared for and often report uncertainty on when and where to seek support (i.e., family physician, urgent care, or the emergency department) (Iribarne et al., 2014). Ample literature supports the need for change to the postoperative discharge model. Recently, Lazar (2018) outlined key approaches that are urgently required to integrate into clinical practice in order to limit readmissions following cardiac surgery, which included "early after discharge follow up" wherein a provider (i.e., nurse) makes contact with the patient and family to identify postoperative concerns in a timely manner in the outpatient setting (Lazar, 2018).

In summary, the experience of postoperative recovery in Canada (and beyond) is fragmented. Patients are commonly under monitored as inpatients and are then discharged home with negligible professional recovery support or surveillance in place to prevent or identify further complications when recovering at home. In addition, healthcare providers are under intense duress to cope with ever growing challenges of the current healthcare delivery model the complexity of the cardiovascular surgical population and related postoperative complications, as well as a timely transition from hospital to home, having to cautiously balance patient readiness, stability, and safety with institutional pressures of reducing associated healthcare utilization costs (i.e., extended length of stay, emergency room visits, and hospital readmissions).

Digital Health Solutions: Remote Automated Monitoring

To overcome these postoperative challenges, recent attention has been directed to the utilization of digital health solutions, such as remote automated monitoring (RAM)

that facilitate end-to-end care, using virtual patient monitoring and hospital-to-home care. RAM and virtual care are considered to be subcomponents of telemedicine, which utilize audio, digital, video-based, and wearable technologies to facilitate either continuous or intermittent healthcare delivery and patient monitoring (Boer, Touw, & Loer, 2018; Khanna, Hoppe, & Saugel, 2019; McGillion et al., 2018). In recent years, there have been early studies that have piloted RAM programs. For example, in a single-centre, prospective clinical pilot of cardiac surgical patients (n=443), a tablet and Bluetooth-enabled devices (pulse oximeter, heart rate monitor, blood cuff, weight scale and daily digital symptom, ambulation and medication questionnaires) were used to monitor patient recovery and compared to standard face-to-face perioperative discharge education (McElroy et al., 2016). Results revealed a significant correlation between abnormal physiologic data and the need for clinical intervention based on use of digital health technologies (r=0.62, P=0.001) and concluded by stressing the need for future large-scale trials to assess the benefit of RAM (McElroy et al., 2016).

While early evidence of RAM and virtual hospital-to-home recovery shows promise, a number of trials have been met with considerable challenges in terms of technical integration, logistical amalgamation, and clinical workflow adoption (Baig, Gholamhosseini, Moqueen, Mirza, & Linden, 2017; Boer et al., 2018; Carroll, 2018; Drew et al., 2016; Ertel, Kaiser, Abbott, & Shah, 2016; Subbe, Duller, & Bellomo, 2017; Watkinson et al., 2006; Weenk et al., 2017). For example, Weenk at al. piloted (n=20) remote automated continuous in-hospital monitoring with the Sotera Wireless ViSi Mobile device to capture biometric measurements to detect early signs of physiologic

deterioration. While a limitation of this pilot was that it was underpowered to detect effectiveness or make generalizable assumptions, nonetheless, this trial identified key technical problems, such as connectivity failure, that help to inform refinement of future interventions in order to overcome practical deployment challenges (Weenk et al., 2017). In summary, the last 10 years has seen an emergence of work in RAM and there is promise surrounding feasibility and acceptability of such solutions. To move the field forward, effectiveness studies, employing randomized controlled trial designs, are needed to demonstrate whether the deployment of RAM can improve postoperative incomes.

TecHnology Enabled Self-MAnagemenT – VIsion for remote automated patient monitoring and EmpoWerment following Cardiac and VasculaR surgery" (THE SMArTVIEW CoVeRed)

In response to the inaugural Canadian Institutes of Health Research eHealth Innovation Partnerships Program competition held in 2015, McGillion, Devereaux, and the digital health division at the Population Health Research Institute developed a postoperative RAM model of care using market-ready digital health solutions, entitled "TecHnology Enabled Self-MAnagemenT – VIsion for remote automated patient monitoring and EmpoWerment following Cardiac and VasculaR surgery" (THE SMArTVIEW CoVeRed) (McGillion et al., 2016). SMArTVIEW combines in-hospital RAM and virtual hospital-to-home (H2H) recovery support of postoperative patients from admission to the surgical ward to hospital discharge and continues for the first 30 days following hospitalization. In hospital, patients ware non-invasive wireless devices that capture blood oxygen saturation (SpO_2), heart rate, respiration rate, and blood pressure

and provide real-time physiologic data to frontline nursing staff if subtle signs of deterioration were detected. If deterioration was detected, frontline staff are notified via notification sent to a handheld device, calling attention to the bedside for physical assessment, conformation of patient stability, and intervention if required.

When patients are to be discharged into the community setting, patients are equipped with a blue-tooth enabled vital sign monitoring kit, containing all necessary equipment to complete a full set of vital signs, and tablet preloaded with the Philips' eCareCompanion application to monitor recovery virtually. All data is automatically uploaded to a speciality team of registered nurses, known as SMArTVIEW Nurses (SVN), who monitor these data on a daily basis. SVNs also engaged in daily video calls with every patient, which entailed a thorough head-to-toe assessment, review vital signs entries, address postoperative concerns, provide feedback on recovery process, and if required, assisted patients in navigating appropriate healthcare services.

SMArTVIEW is designed as an international randomized controlled trial (RCT) of 800 post cardiac or major vascular surgical patients, taking place at HHS in Hamilton, Ontario and Liverpool Heart and Chest Hospital (LHCH) in Liverpool, United Kingdom. As each funder has recognized, SMArTVIEW is a highly complex, multi-stage intervention involving multiple components that are interdependent to the success of the intervention deployment. Risks of SMArTVIEW include 1) scale and complexity of the design, which has not previously been tested in the digital health sector; 2) the operational dependence of numerous internal and external working teams (i.e., clinical ward staff, informatics, Philips) at each respective site in order to deploy the intervention; and 3) the

innovative nature of this program design requires the need for a new professional role of the SVN, and as such, the daily practice of the SVN is unknown. Therefore, to ascertain the overall process of the intervention, close monitoring in the early days of intervention deployment is essential to ensure the practicalities and logistical workflows of clinical adaptations are realistic and adherent to study design.

As with any multisite trial, there must be constant attention to consistency of trial execution across sites with respect to participant recruitment, timing and practicalities of randomization, and standardization of intervention delivery and data collection procedures. With respect to intervention delivery per se, multiple operational factors must also be attended to, in parallel, related to site technology workflow standardization and adherence, as well as ongoing technical trouble shooting. The need for this understanding must occur early in intervention deployment to ensure any logistic concerns are addressed prior to initiation at partnering sites, and beyond.

The immediate purpose of this work is to conduct an in-study process monitoring evaluation of the first 100 patient cases enrolled in a complex international randomized controlled trial, entitled SMArTVIEW. This process monitoring evaluation had two primary foci. The first focus was to assess the implementation processes, mechanisms of impact, and context of the SMArTVIEW intervention, guided by the Medical Research Council (MRC) Guidelines for reporting process evaluation of complex interventions. The second objective, guided by Kitson's Fundamentals of Care (FoC) Theory, was to explore the SVN scope of practice to identify what care the SVNs were providing care in

order to meet the everyday physical, psychosocial, and relational needs of cardiac or major vascular surgical patients.

CHAPTER II: REVIEW OF THE LITERATURE AND DESCRIPTION OF SMArTVIEW

As discussed in Chapter One, patients who undergo cardiac and major vascular surgery are subjected to extended lengths of hospital stay, as well as increased risk of hospital readmission and emergency room visits due to postoperative complications that are potentially preventable. Digital health solutions that integrate RAM and virtual H2H care serve as a potential solution in order to facilitate early detection of physiologic deterioration and postoperative complications. The science of RAM and virtual hospital-to-home care is, however, nascent, and randomized controlled trials are needed to examine the effectiveness of these interventions.

This chapter begins with a critical review of the available data pertaining to length of hospital stay, hospital readmissions and emergency department visits among those who undergo cardiac and major vascular surgery. This review will be followed by an examination of common hemodynamic, infectious, and pain-related complications that drive extended lengths of hospital stay, readmission, and emergency room visits. The chapter will then argue that inadequate patient surveillance—both on surgical wards and while patients recover at home following hospital discharge—is a major factor contributing to poor postoperative outcomes following cardiac and major vascular surgery. Specifically, data will be reviewed which support that patients are assessed too infrequently in hospital and that patients are discharged home with little surveillance or professional support to prevent complications, readmission, and mortality. The

consequences of these practices, in terms of what gets missed with respect to patient instability, will also be reviewed.

Following exposition of the clinical problem, the chapter will review early work on postoperative RAM and virtual care initiatives which show promise for improving patient outcomes; the strengths and limitations of this body of work, to date, will also be discussed. A comprehensive description of the SMArTVIEW intervention will then be provided, along with a detailed description of the randomised controlled trial that is currently underway to evaluate its impact on hospital readmission and emergency department visits. This section will conclude with an argument for the need for the current trial process monitoring sub study, given the complex and high-risk nature of the SMArTVIEW intervention, subject to operational and managerial challenges that are common in digital health innovation projects. The need to examine the role and scope of the specialized SVNs, who deliver the SMArTVIEW intervention, will also be argued.

This chapter will conclude with the specific statements of sub study purpose, as well as an overview of the MRC Guidance Framework for monitoring complex intervention trials, and Kitson's FoC Framework, as the conceptual models lending guidance to the trial monitoring process and examination of the work of the SVN role, respectively.

Review of Existing Evidence on Major Complications Following Cardiac and Vascular Surgery

Cardiovascular diseases are leading causes of morbidity and mortality in Canada (Abel et al., 2017). Coronary artery disease, for example, develops as a result of progressive atherothrombotic blockages that develop in main vessels, which lead to an

imbalance of oxygen supply and demand resulting in inadequate myocardial perfusion to meet metabolic demand (Noly et al., 2017). When the clinical presentation of a patient includes acute distressing symptoms that are unresponsive to management strategies (i.e., lifestyle changes and medication), or interventional procedures (i.e., percutaneous coronary intervention) are infeasible or have failed, surgery is often indicated in order to relieve symptoms, restore function, and increase likelihood of survival, with continued medical management (Bojar, 2011). Advancements in surgical techniques for coronary artery, valvular, aortic, and vascular disease have advanced in terms of the sophistication of surgical technique; saphenous vein graft disease, multivessel disease, and occasionally left main disease have the possibility to be approached through less invasive percutaneous coronary interventions and coronary artery bypass grafting (CABG) is now reserved for patients with failed or un-stentable disease.

Annual cardiac and major vascular surgery rates are on the rise in order to treat symptoms and preserve life for affected individuals. In 2014, the median annual number of cardiac surgery cases across Canada was estimated at 30,000 (Noly et al., 2017). The 2017 Canadian Institutes of Health Information (CIHI) Cardiac Care Quality Indicators Report concluded that while Canada is performing well on quality indicators for Cardiac and major vascular surgery, surgery can also precipitate major vascular, hemodynamic and infectious complications necessitating emergency care and hospital readmission, and also conferring risk for postoperative mortality (Abel et al., 2017). The Joint National Institutes of Health–Canadian Institutes of Health Research Cardiothoracic Surgical Trials Network conducted a prospective, multicenter cohort study examining 5,185

patients across 10 centres, and found that nearly 1 in 5 patients were readmitted to hospital within 60 days after discharge (Iribarne et al., 2014).

Reducing hospital readmission following cardiac surgery has become both a research and clinical priority, recognized by several federal agencies, clinicians, and health policy-makers in North America (Berenson, Paulus, & Kalman, 2012; Joynt & Jha, 2012; Syed et al., 2018).

Major vascular surgery in Canada presents a similar scenario. Approximately 800,000 Canadians are affected with peripheral vascular disease (Lovell et al., 2009). Those afflicted with peripheral vascular disease often present with complex health challenges and co-morbidities such as untreated or undermanaged hypertension, hyperlipidemia, and diabetes mellitus (Lovell et al., 2009; Syed et al., 2018). While surgical advancements and improved screening practices have resulted in less invasive procedures (i.e., using endovascular techniques), a substantial proportion of patients still undergo invasive open abdominal procedures. Similar to cardiac surgery, major vascular surgeries are performed to alleviate symptoms associated with impaired blood flow in the vascular or arterial system. Procedures such as abdominal aorta aneurism repairs (AAA) are often invasive, high-risk, and result in lengthy postoperative recovery pathways (Kapila et al., 2018; Scott, 2002). In addition to having high risk of 30-day mortality, patients who undergo vascular surgery yield high rates of hospital readmission and emergency room visits, ranging from 8-54%, dependent on procedure (Beaulieu, Grimm, Lyu, Abularrage, & Perler, 2015; Chang et al., 2015; Curran et al., 2014; Kapila et al., 2018; Syed et al., 2018; Wiseman et al., 2014; Zhang et al., 2014). International data

corroborate these findings. A recent prospective observational cohort study examined a composite rate of hospital readmission or emergency department visit within 30 days after discharge of 128 patients who underwent major vascular surgery (lower extremity revascularization, upper extremity/neck procedures, open aortic repair, endovascular aortic repair and lower extremity amputation) and found nearly 15% of patients went to emergency departments or were readmitted within 30 days of discharge (Syed et al., 2018). In summary, hospital readmission and emergency departments visits are common following major cardiac and vascular surgery.

Postoperative Complications

Cardiac and vascular surgery present challenges in terms of high readmission and mortality. These high readmission and mortality rates are beset by a number of major complications common to both surgical types, including hemodynamic instability, surgical site infection, and unrelieved pain.

Hemodynamic Instability. Myocardial oxygen demand is increased following surgical procedures due to the rise in catecholamine concentrations which is resultant from increased in heart rate, blood pressure, and free fatty acid concentration (POISE, 2008; POISE Trial Investigators, 2006). This increase of myocardial oxygen demand increases risk for cardiac events following surgery, such as myocardial infarction and stroke. In 2008, a rigorous multi-centre randomized-controlled trial examined the use of beta-blockers, specifically extended-release metoprolol, compared to control following major surgery in 8,351 patients across 23 countries to determine if the use of beta-blockers following major surgery prevented adverse postoperative cardiovascular events

(POISE, 2008; POISE Trial Investigators, 2006). Patients enrolled included those with history of coronary artery disease and peripheral vascular disease. Results of this trial demonstrated use of metoprolol was associated with reduction in myocardial infarction, but also a clinically significant increase in hypotension in the intervention group [Hazard ratio (HR) 1.55; 95% confidence interval [CI] (1.38, 1.74)]. Overall, clinically significant hypotension was associated with the largest population-attributable risk for perioperative death and perioperative stroke following major surgery (POISE, 2008).

Following this trial, POISE-2 was conducted; an international RCT of 10,010 patients with, or at-risk of, vascular disease undergoing major surgery, including vascular surgery (Devereaux et al., 2014). Analyses demonstrated that clinically important hypotension was an independent predictor of myocardial infarction during 30-day follow-up [adjusted HR 1.37; 95% CI (1.16, 1.62)]. These studies demonstrate that hemodynamic instability related to clinically important hypotension is a serious complication that undetected, leads to morbidity and mortality.

Postoperative atrial fibrillation complicates 20-40% of cardiac surgical procedures and 10-20% of non-cardiac thoracic operations with typical onset of 2-4 days following surgery (Dobrev, Aguilar, Heijman, Guichard, & Nattel, 2019). Consequences of postoperative atrial fibrillation include haemodynamic instability, increased risk of stroke, lengthened intensive care unit and hospital inpatient stays and therefore, greater utilization of hospital expenditure. Recently, a 2019 retrospective registry review of 4592 patients who underwent isolated aortic valve replacement were propensity score matched by preoperative and operative variables, and the effects of preoperative beta blockers on

postoperative outcomes. Postoperative atrial fibrillation was more common in patients receiving a preoperative beta blocker (26.9% compared to 23.4%; *P*=0.007), which was associated with longer postoperative ICU admissions (45.2 compared to 47.0 hours; *P*= 0.001) (Schubert et al., 2019). In another retrospective analysis of 999 patients who underwent either CABG, valve surgery or a combination of CABG and valve surgery identified that 24.9% of all patients who preoperatively did not present with arrhythmias, developed postoperative atrial fibrillation (Todorov et al., 2017). In addition, new onset atrial fibrillation was significantly associated with an increased rate of dialysis (8.2% vs. 1.9% in the no atrial fibrillation group). Patients with new onset atrial fibrillation had significantly more positive fluid balance on the day of surgery as well as the first two postoperative recovery days. This finding is in agreement with previous reports, which strongly implies fluid overload as a key player in the initiation of postoperative atrial fibrillation. This evidence suggests that, atrial fibrillation is a common complication following surgery that increases length of hospital stay and increases risk of serious adverse complications such as myocardial infarction, stroke, and mortality (Almashrafi, Emontsri, & Aylin, 2016).

***Surgical Site Infection*.** Risks such as surgical site infections are commonly associated with invasive procedures such as CABG and vascular repairs (Gelijns et al., 2014). While advances in non-invasive procedures help reduce risks associated with surgical site infections, many patients do not qualify for percutaneous interventions. As a result, often the only option for patients is to undergo invasive surgical procedures that require open sternotomy and bilateral saphenous vein harvesting. Population

characteristics of cardiac and major vascular surgery patients often include multiple comorbidities, such as diabetes mellitus or obesity, that compromise wound healing and subject patients to higher risks of developing surgical site infections.

Despite the recognition that surgical site infections are a serious postoperative complication, patients continue to experience major infection after Cardiac and major vascular surgery (Gelijns et al., 2014). For example, The National Health Service hospitals examined postoperative infection prevalence from 2014-2015 and found that 4.3% (n=2,531) of patients who underwent coronary artery bypass grafting and 2.7% of patients (n=1,677) who underwent vascular surgery developed surgical site infections (Troughton et al., 2018). Even in the case of prophylactic antibiotic administration prior to surgery, in a prospective clinical study of 419 cardiac surgery patients, 3.6% (n=15) developed surgical site infections, postoperatively (Tamayo et al., 2008). Importantly, on average surgical site infections did not present until two weeks postoperatively – often beyond hospital discharge, when patients are at home and self-managing their postoperative care (Troughton et al., 2018).

Unrelieved Postoperative Acute Pain. Acute postoperative pain is a leading driver of hospital readmission following surgery. Evidence has demonstrated that unrelieved postoperative pain is associated with poor sleep hygiene and fatigue (Bruce et al., 2003; Gandhi, Heitz, & Viscusi, 2011) anxiety and depressive disorders (Gureje, Von Korff, Simon, & Gater, 1998; McWilliams, Cox & Enns, 2003; Ohayon & Schatzberg, 2003), poor perceived self-efficacy as well as poor self-rated health (Bruce et al., 2003; Mäntyselkä, Turunen, Ahonen, & Kumpusalo, 2003). In addition, unrelieved

postoperative pain is associated with a number of complications. For example, prospective studies have found that unrelieved acute pain in the severe range (i.e., Numeric Rating Scale (NRS) ≥ 7/10) at postoperative day three is associated with increased risk of transition to chronic postsurgical pain (adjusted odds ratio [OR] 2.67, 95% confidence interval [CI] 1.74–4.11) (Choinière et al., 2014). While effective postoperative pain assessment and management are key to optimal recovery, little is done to address unrelieved acute pain as a leading driver of readmission (Iribarne et al., 2014). For example, a retrospective database study was completed that examined the readmission rates of surgical procedures in academic, tertiary care institutions identifying 20,817 patients who underwent surgery (Coley et al., 2002). Of the total patients, 1,195 patients returned to the hospital within 30 days of surgery, and 313 patients who returned to hospital, were readmitted. Of the patients who were readmitted, the most common reasons were due to pain (38%), in addition to surgical bleeding, and adverse drug events contributing to readmission. This group concluded that not only are there great physiologic concerns that drive readmission, but also, significant financial burden with over 2.4 million in charges generated by a total of 313 patients at this single center (Coley et al., 2002).

Then in 2017, a correspondence article in response to the 2002 data presented by Coley et al (2002) was published to provide an update on pain-related hospital readmission examining if readmissions have decreased over the last decade (Herbst et al., 2017). Of 28,647 patients who underwent surgery, 1597 patients returned to hospital within 30 days following surgery and of those readmitted, 23.3% were readmitted directly

due to surgical pain. While the 2017 update concluded through their analyses that some improvements in postoperative pain management techniques have been made, some readmissions could have been prevented. Between both retrospective chart reviews, these data corroborate that postoperative pain is a serious complication that is driving hospital readmission up to 30 days following surgery.

Additionally, complications persist when acute postoperative pain is not adequately managed following surgery. Patients risk development of acute postoperative pain transitioning to persistent postsurgical pain; persistent pain lasting longer than three months and beyond expected healing (Macrae, 2008; Treede et al., 2015). Prevalence rates of persistent postsurgical pain in patients who underwent either CABG, valve replacement or combination of both, has been estimated at 41% (n=87/212) at 12 weeks following surgery (Routledge et al., 2009), and remains prevalent in 10% of patients up to 2 years following surgery (n=93/976) (Choinière et al., 2014). Moreover, when acute pain is not adequately and timely addressed following surgery, it negatively affects health related quality of life and derails their postoperative recovery, but also necessitates further access to healthcare services. Among those who develop persistent postsurgical pain, many are required to endure prolonged wait times to access publicly funded expert pain-related care, if able to access specialized care at all given that many regions of Canada lack any access to multidisciplinary pain care (Lynch, 2011; Patrick et al., 2004).

In summary, patients who undergo cardiac and major vascular surgery are subjected to a multitude of risks that develop into serious complications that are detected far too late, particularly within the first 30 days postoperatively. Late detection of

deterioration is in part due to inadequate monitoring models both in-hospital and post-discharge. In hospital, ward nurses are expected to care for multiple, highly acute patients, yet are inundated with task-orientated responsibilities that deter nurses from allocating sufficient time for patient care and thorough assessments. For example, it is not uncommon for a complete set of vital signs to be measured once every 4-12 hours. The environment is often reactive and responsive to emergencies and critical deteriorations, limiting the ability to catch early signs and symptoms of deterioration.

Inadequate Postoperative Surveillance

In the operating room and ICU, patients are continually monitored both by advanced technologies that monitor for subtle physiologic changes as well as constant healthcare provider observation. The purpose of this insensitive observation is to provide sufficient timing for clinicians to respond to patient deterioration; ample data supports that early recognition and timely management of mild or moderate complications has impact on the trajectory of prognosis and outcomes (Berwick et al., 2006; Boer et al., 2018; McGillion et al., 2018; Walston et al., 2016). However, following surgery, patients are transferred to surgical ward settings, wherein vital sign monitoring is routinely assessed once every 4-8 hours within the first 1-2 postoperative days, and up to once every 12 hours thereafter (McGain et al., 2008; Mitchell & Van Leuvan, 2008). With such long measurement intervals, there is considerable time for deterioration that goes undetected, leading to postoperative complications, which often could have been preventable if caught and addressed earlier (Boer et al., 2018). This is in part due to the technology available on surgical wards, wherein continuous monitoring is not standard

practice. When the sole information source of a patient's physiologic data is collected using rudimentary equipment, patients' subtly deteriorate and the early opportunity to intervene to the signs of complication is missed. For example, in a study based out of the Cleveland Clinic, Sun et al., (2015) analyzed oximetry data collected from a prospective cohort study of adults(n=594) undergoing noncardiac surgery and focused on vascular complications and compared continuous pulse oximetry monitoring with routine monitoring to assess the incidence of detected hypoxemia (Sun et al., 2015). By comparison of nurse-documented episodes of hypoxemia to blinded continuous monitoring, a 5% incidence of hypoxemia (SpO2< 90%) was detected by manual nursing assessment, whereas blinded continuous SpO2 data revealed that 37% of patients had ≥1 continuous episode of hypoxemia for ≥1 hour, and that 10% of patients had at least 1 continuous episode (≥1 hour) of hypoxemia where SpO2 was <85%. Sustained hypoxemia lasting > 5 minutes is associated with increased risk of myocardial ischemia and other serious postoperative complications, which moreover infers that routine monitoring practices are suboptimal and unsafe.

Hypertensive and hypotensive episodes also occur following major surgery and are often undetected through routine monitoring practices. For example, Turan et al., (2019) conducted a prospective blinded observational study (n=312) examining incidence of hypotension and hypertension below and above mean arterial pressure during the first 48-postoperative hours, respectively (Turan et al., 2019). Almost a quarter of patients had hypotensive episodes where arterial pressure <65mmHg lasting >15 minutes, of which, nearly half of episodes were undetected by routine vital sign assessments [(47%); 95%CI

34%,61%]. Episodes of mean arterial pressure >110 mmHg lasting 30 minutes or longer were observed in 42% (95% CI, 37%, 42%) of patients; 13% had mean arterial pressure >130 mmHg for at least 30 min, 98% of which were missed by routine assessments (Turan et al., 2019). While this study has only a moderate sample size and while their continuous monitoring equipment met FDA guidelines, a limitation of this study is that non-invasive blood pressure techniques cannot be referred to the 'gold standard' of blood pressure monitoring methods. Hypotension and hypertension occur following surgery and are more often missed; which could have severe clinical impact on postoperative morbidity and mortality. Large randomized trials are needed to further determine population-level incidence and associated risk. In summary, vital signs assessments conducted manually using equipment that does not monitor continuously disadvantages patients, as providers then lack the knowledge of when patients have subtle signs of deterioration.

Healthcare provider surveillance. Postoperative patient surveillance is also limited to the provider in which is conducting the monitoring and assessment. Nurses are often the provider identified to spend the most time with patients, however the professional responsibilities of nurses are becoming increasingly task-orientated and time consuming which detract from direct patient care (Westbrook et al., 2011, Yen et al., 2018). A prospective observational study of 57 nurses were observed for 191.3 clinical hours, working on medical and surgical wards, examined how frontline nurses distribute their time (Westbrook et al., 2011). This study concluded that 63% of nurses' time was spent on tasks indirectly related to patient care (i.e., professional communication,

documentation, medication tasks, in-transit). Additionally, nurses were found to complete an average of 72.3 tasks per hour and provide approximately 10 direct patient care tasks, which averaged nurses spending 13.3 minutes present at the bedside each hour (Westbrook et al., 2011). In another time-motion study of nurses' time allocation and multitasking activities, in a 4-hour observation, approximately 10% of nurses' time was spent on tasks that could have been delegated to trained support staff, including vital sign observations (Yen., 2018). Observational workflow, as described by the clinical manager on the Cardiac Surgical Unit at HHS, corroborate findings of available data. In a nurse's typical 12-hour shift (720 minutes), the clinical manager revealed that a newly admitted postoperative patient receives approximately 60-90 minutes of direct bedside monitoring and assessment, which accounts approximately 13% of a nurses' available time. Further, a seemingly stable patient, nurses generally are able to provide 45-60 minutes of direct patient care during their 720-minute shift. With majority of nursing time spent away from the bedside, front line providers—at no fault of their own—miss subtle signs of physiologic deterioration simply because nurses are limited in both the time that can be feasibly focused towards providing direct patient care while still meeting all other professional responsibilities, and by the current standard model of care that depends on antiquated technologies and manual assessments conducted over prolonged periods of time, which consequently provides a partial representation of the patient's true stability and overall recovery.

In summary, patients experience serious postoperative complications that contribute to hospital readmission and emergency department visits. The driving

infectious, hemodynamic and pain related postoperative complications responsible for readmission could be attenuated with earlier, more accurate and consistent surveillance models of care. Digital health solutions built with sensitive monitoring intelligence may address this clinical gap, addressing the ever-growing need for sustainable health system management in both acute in-patient settings, as well as community out-patient environments – working in conjunction with healthcare providers to monitor patients, postoperatively.

Timely Nature of Remote Automated Monitoring: Ontario Cardiac Care Network strategic plan 2017-2022

Digital health solutions, including RAM and virtual care programs, has the potential to advance of healthcare by improving patient and system level outcomes which has gained the recognition of healthcare leadership and governing bodies. The Cardiac Care Network and the Ontario Stroke Network have jointly collaborated on a provincial wide strategic plan (2017-2022) to advance cardiac, stroke, and vascular care for patients in Ontario. The current strategy outlines three specific themes as follows: 1) Focus on Quality and Patient Outcomes; 2) Emphasis on Secondary Prevention Rehabilitation and Recover; and 3) Increased Engagement of Partners, Clinical Leadership, and Patients (Berwick, Calkins, McCannon, & Hackbarth, 2006; McGillion et al., 2018; Turan et al., 2019; Walston et al., 2016). The network explicitly states their view that a comprehensive approach to cardiac, stroke and vascular care—inclusive of population health, patient experience, and clinical quality—can significantly improve patient outcomes and decrease associated healthcare costs (CorHealth Ontario, n.d.). In addition, there is

provincial support for innovative care models to better address patient needs, as well as increase efforts to identify and integrate with existing data sources to capture data across the continuum of care. This timely provincial mandate giving primacy to improve cardiac, vascular, and stroke care in Ontario speaks to the need to implement evidence-based programs that address support patients through the continuum of care—from the time diagnosis, preoperatively, intraoperatively, postoperative, and thereafter— using innovative, accessible, and cost-effective methods.

Role of Remote Automated Monitoring

RAM and virtual care are considered to be digital health solutions that are subcomponents of telemedicine, which utilize audio, digital, video-based, and wearable technologies to facilitate healthcare delivery and patient monitoring. Wearable systems, sensors, and monitoring devices can be worn on the body, continuously or intermittently, for data retrieving, and are connected to at least one other device to close a data transmission loop. RAM devices are widely used to measure key health indicators such as ECG, blood pressure, heart rate, body temperature, blood oxygen saturation, posture, and activity (Baig et al., 2017). Data can be transmitted and stored in clouds or local servers (i.e., cloud computing, Internet of Things) for data for processing and then sent back to users via alerts, reminders, warnings, or notification for further action via cell phones, tablets, or desktops (Sanfilippo & Pettersen, 2015; Stergiou et al., 2018). In healthcare, wearable monitoring devices are used in three modalities: biopotential-specific sensor units (i.e., ECG, electromyography (EMG) and electroencephalography (EEG) sensors), motion sensor units (i.e., accelerometers and gyroscopes), and environmental sensor units

[(i.e., video cameras, vital signs monitors (heart rate, pulse rate and temperature) and pressure sensors] (Baig et al., 2017; Deshmukh & Shilaskar, 2015). Ample literature discusses the possibility and potential to use wearable patient monitoring in clinical environments highlighting the potential impact on patient monitoring, safety, as well as earlier detection of deterioration, however, several limitations and challenges exist. Limited evidence of end-to-end solutions in surgical patient populations, that facilitate patient monitoring throughout the entirety of their medical journey have been reported on in the academic literature.

Perioperative Remote Automated Monitoring: Literature Review Search Strategy

The field of postoperative RAM has recently gained traction in clinical settings and in research trials, however, remains a burgeoning field with limited rigorous trials conducted to date. A literature search of postoperative RAM was conducted to extrapolate existing literature of postoperative RAM, with specific interest in feasibility, acceptability, and clinical integration outcomes, as well as programs that discuss nursing practice or impact on the nursing role. The following databases were searched: Medical Literature Analysis and Retrieval System (MEDLINE), Excerpta Medica Database (EMBASE), Cochrane Central Register of Controlled trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Web of Science. Relevant articles in the following categories were extrapolated: population (medical and surgical), intervention/exposure (RAM), type of study (randomized controlled trials and observational) using a combination of keywords and database specific subject heading including the following: “automated remote monitoring”, “hospital to home”, and “vital

sign monitoring". Search criteria included only studies conducted in English and those that focused on adults (>18 years). This search yielded six relevant studies examining both in-hospital or at-home RAM in the perioperative context. Studies examined both feasibility and effectiveness of programs and included pilot and randomized controlled trials (Table 1).

Table 1. Summary of Studies Found in Postoperative RAM

Study	Design	Population	Intervention	Comparator	Outcome
In-Hospital Monitoring					
Harsha et al. (2019) Feasibility	Unblinded pilot RCT	N=250 Age Standard = 57.5 (15.8) monitored = 58.0 (13.9) Sex Standard= males 38.1% Monitored = Males 24.2%	Continuous monitoring using Covidien Alarm Management system (wireless respiratory monitoring system)	Standard monitoring on two surgical wards	Average patient recruitment rate of 14 patients per week (target of 15 per, week) 12/124 of patients in the intervention refused to consent to the wireless monitoring during allocation 86.6% (84/97) patients completed the monitoring program 12 incidents of monitoring malfunction

Ochroch et al.(2006) Effectiveness & Feasibility	Single-centre, Randomized controlled trial	N=1219 Age: unmonitored =59.9 (SD15.3) monitored =61.8 (13.3) Sex: unmonitored = males 64.4% monitored = males 59.9%	Continuous pulse oximetry monitoring	Standard routine monitoring on the 33-bed post cardiothoracic surgery care unit	Monitored patients transferred to ICU earlier (day 3 versus day 4, Student's *t*-test, *P*=0.091) Mean estimated costs from enrollment to censoring were lower in monitored versus unmonitored patients ($15,481 versus $18,713 USD; Student's *t*-test, *P*=0.038) (Mean estimated cost for ICU stay was $23,262 USD less for the monitored than the unmonitored group (Bootstrap, *P*=<0.0001)
Watkinson et al. (2006) Effectiveness	Single-centre, Randomized controlled trial	N=402 Age: Unmonitored =73 (23-100) Monitored =72 (19-92)	Continuous monitoring of ECG, HR, RR, BP, oxygen saturation, temperature, connected to a multiparameter monitor for 72hrs	Standard ward care in high risk medical and surgical unit	In 96-hours following randomization, 113 (56%) of patients in monitored group versus 116 (58%) patients had a major event (OR 0.94, 95% CI: 0.63, 1.04, *P*=0.76)

		Sex: unmonitored = males 62% monitored = males 60%			An acute change in treatment was made in 107 (53%) of monitored patients versus 101 (50% of unmonitored patients (OR 0.55, 95% CI: 0.87, 1.29) 30-day mortality was similar between monitored and unmonitored patients (34, 35, respectively)
Weenk et al. (2017) Feasibility	Single-centre, Pilot randomized controlled trial	N=20 Age=49.9 (SD13.4) Sex= males 65%	Continuous and simultaneous monitoring using two automated devices – ViSi Mobile and HealthPatch ViSi Mobile—wrist and chest worn device, linked to a stand-alone tablet pre-installed with ViSi software, records 5-lead ECG, HR, RR, BP, oxygen saturation, and temperature	Manual VS measurements	In 15% (n=13) and 27% (n=23) of patients with Visi-Mobile and HealthPatch respectively, clinically relevant differences in early warning scores were based on inconsistent RR registrations VS measurements in both technologies were generally consistent with nurse measurement

			Health Patch— a lightweight patch worn on the chest, connected via Bluetooth to a nurse's mobile device, recorded 2-lead ECG, HR, RR, temperature, posture, fall detection, activity		
In-Home Monitoring					
Ertel et al. (2016) Effectiveness & Feasibility	Single-centre, Observational non-randomized pilot study	N=20 Age= 56 (SD7) Sex= males 80%	Tablet-based home-monitoring of VS and educational video program during the perioperative period	Printed post-transplant instruction manual and class	30-days readmission rate of 20% and 90-days rate of 30% Median LOS for 30-day readmission was 5.5 days compared to 7 days for those not enrolled No patient who responded to 100% of the daily assessment questions or recorded their VS were readmitted to hospital within the 30-days

McElroy et al. (2016) Effectiveness & Feasibility	Single-centre, Prospective clinical pilot trial	N=443 Age= unmonitored =65.9 (14.1) monitored =62.9 (9.8) Sex: unmonitored = males 65.9% monitored = males 85.2%	Digital health kit (Bluetooth-enabled tablet linked to pulse oximeter, HR monitor, BP cuff, weight scale and daily digital symptom, ambulation and medication questionnaires	Face-to-face perioperative education and discharge education booklet	No significant difference in rate of readmission between control and intervention groups (9.9% versus 7.4%, Welch's t-test *P*=0.65) Significant correlation between abnormal biometric and the need for intervention (*r*=0.62, *P*=0.001) Mean patient and healthcare provider satisfaction scores 4.9±0.5, and 4.9±0.2, respectively

Remote automated monitoring interventions.

Three studies continuously monitored patients in-hospital and the other two studies focused on out-patient monitoring systems. This review is reflective of 2,104 patients with age ranging from 19-100 years.

In Hospital Setting. Watkinson et al. (2006) conducted a single centre randomized controlled trial of 402 patients (186 postoperative patients, 218 high-risk medical patients) comparing physiologic monitoring (electrocardiogram [ECG], heart

rate, respiration rate, BP, SpO2, and temperature) against routine monitoring over the first 96 hours following hospital admission. Of the 201 intervention patients, 690 occurrences of 'normal physiologic metrics' to 'abnormal physiologic metrics' while in hospital, with abnormal vital signs occurring more than once in the majority of these patients (59%); of which, 652 episodes were verified to be true physiologic deterioration. 33 patients experienced technical issues with the devices which prevented complete recordings of all metrics over the whole monitoring period. Results of this study demonstrated no statically significant difference between intervention and control monitoring groups in terms of effect physiological monitoring on the proportion patients requiring urgent medical attention or intervention, as well as no direct effect on the mean number of interventions per patient, patient survival or hospital stay was found. While a limitation of this study is the small sample size, this trial provided insight on how to improve RAM systems. Only 16% of patients in the intervention arm were monitored for the full 72 hours; removal reasons included nurses removing monitoring equipment in order to ambulate or mobilize patients (37%), or the patient removed the device themselves (30%).

In another pilot trial (n=20), remote automated continuous in-hospital monitoring with the Sotera Wireless ViSi Mobile device was deployed to capture early signs of deterioration (Weenk et al., 2017). This device captures continuous, cableless ECG, heart rate, respiration rate, temperature, oxygen saturation, and non-invasive blood pressure measurement (using pulse wave velocity in the ear). While this trial was underpowered to make generalizable assumptions at population levels, this trial did however identify technical problems and user experiences. Results indicated that nearly 70% of all reported

artifacts were generated by connection failure (i.e., loss of WiFi connectivity), a notable consideration when working with remote automated devices, however 74% of the generated artifacts lasted less than five minutes. The important key message is that adherence and compliance is critically important for the use and success of RAM systems. It is imperative that future continuous monitoring systems must be able to negotiate system interruptions, for example, removal for patient diagnostic tests. In addition, intelligent alerts which reach clinicians in real time (wherever they may be located) are lacking in trials conducted to date. For example, in the trial conducted by Watkinson et al. (2006), many alarms went unnoticed by the most responsible provider (i.e., bedside nursing staff) because no automated risk score calculation or protocolized response was in place that would reach nurses directly on a handheld device. Solutions that integrate notifications with action items to direct front-line nurses to respond, for example when patients remove devices, or in true instances of deterioration, would improve the utility of remote automated interventions (Watkinson et al., 2006; Weenk et al., 2017).

Out-Patient Setting. Patients require solutions that extend beyond institutional walls. Previous data indicated that 30-day morbidity and mortality remain a prominent clinical challenge; RAM solutions that continue close monitoring into the home setting could attenuate postoperative complications leading to hospital readmission. Some studies have examined feasibility and effectiveness of in-home monitoring and found promising results in surgical populations (Ertel et al., 2016; McElroy et al., 2016). In a single-centre, prospective clinical pilot trial (n=443), McElroy et al (2016), compared the use of

"Digital health kit" (Bluetooth-enabled tablet linked to pulse oximeter, HR monitor, BP cuff, weight scale and daily digital symptom, ambulation and medication questionnaires) to face-to-face perioperative education and a discharge education booklet. Results of this pilot revealed a significant correlation between abnormal biometric and the need for intervention (r=0.62, P=0.001), however no significant difference in rate of readmission between control and intervention groups (9.9% versus 7.4%, Welch's t-test P=0.65) (McElroy et al., 2016). In another pilot study (n=20), patients received a tele-health home monitoring and an educational video program following liver transplant for at-home management. Results of this program on hospital readmission, patients enrolled in the pilot study had a 30-day readmission rate of 20% and 90-day rate of 30%, while the control group readmission rate was 40% and 45%, respectively (Ertel et al., 2016). These data suggest that patients benefit from not only managing their vital signs in the home setting, but also decreases hospital readmission rates in perioperative populations. These data are encouraging and support comprehensive hospital-to-home RAM models, in terms of perceived individual patient benefit, as well as from a health systems perspective.

Perception of remote automated monitoring interventions.

Accrual and Attrition of RAM Interventions. The perceptions perceived by end-users (e.g., patients, families, nurses) has been explored in relation to the use of RAM. One common barrier to intervention uptake was the perceived intensity of the intervention, or the how involved and committed the user had to be in order to participate in the program. If the RAM program was perceived to be too intensive or overwhelming (e.g., time commitment) patient accrual and attrition rates were affected. (Ertel et al.,

2016; Weenk et al., 2017). For example, in the pilot trial conducted by Weenk et al., (2017), 5 of the 25 invited patients declined to participate in the RAM program as the patients reported that wearing the technology would be too much mental or physical burden and thus refused to participate (Weenk et al., 2017).

Acceptance and Perceived Usefulness of RAM. In some RAM programs, acceptance of and percieved usefulness of wearing devices that continually monitor patients were examined. Overall, many studies report positive feedback from patients and families. In the pilot trial conducted by Weenk et al., (2017), they examined the practical usability of user experience using semi-structured interviews with 20 patients, 7 family members, and 4 nurses, following the use of remote automated patient monitoring intervention. Patients reported feelings of increased safety (being continiously monitored), and positively reviewed that they were generally unaware of the devices when worn, with minimal restriction to movement. Nurses valued ease of use and application to patients, as well as the quality (i.e., adhesive) of the devices.

Clinical Integration Considerations. Important considerations when integrating RAM from evidence to date has indicated that stakeholders, such a frontline staff and hospital leadership must be engaged for clinical adoption and integration into workflow as well as provide meaningful information for healthcare providers that lessen workloads. In addition, careful attention to alarm fatigue; continual false-positive alerts drive healthcare providers away from timely response and trusting RAM (Harsha et al, 2019). For example, a recent evaluation of a continuous pulse oximetry and notification delivery e-health intervention conducted by Harsha et al (2019), examined issues and challenges

faced to clinical integration. This evaluation found that workflow changes, wireless network connectivity fails, alarm fatigue, and equipment malfunction all led to decreased clinical adoption and concluded that in order to overcome these challenges, primacy must be given to both processes and 'people' aspects of digital health interventions (Harsha et al., 2019).

In summary, there are some studies published to date that have deployed constituents of RAM technologies– the need for improved patient monitoring is clear. RAM has major potential to improve patient outcomes by virtue of earlier detection of physiologic instability and technological integration that works *with* clinicians. Interventions that continue care into the home is necessary in order to provide patients with seamless, end-to-end surveillance. Large randomized controlled trials are needed in order to generate population-level conclusions, of the clinical effectiveness and utility of RAM in surgical populations.

Rationale for SMArTVIEW

Through an innovative approach to address this clinical gap, McGillion, Devereaux, et al, developed a continuous model of care using digital health solutions entitled "TecHnology Enabled Self-MAnagemenT – VIsion for remote automated patient monitoring and EmpoWerment following Cardiac and VasculaR surgery" (THE SMArTVIEW CoVeRed) (McGillion et al., 2016). SMArTVIEW combines in-hospital RAM and virtual hospital-to-home recovery support of postoperative patients from admission to the surgical ward to hospital discharge and continues for the first 30 days following hospitalization.

Detailed examination of SMArTVIEW. SMArTVIEW is an international, parallel arm randomized controlled trial of 800 seniors who have undergone cardiac or major vascular surgery, taking place at Hamilton Health Sciences, Hamilton, Ontario, Canada and Liverpool Heart and Chest Hospital, Liverpool, United Kingdom. This study has been approved by local ethics board approval (HiREB) (Project ID#3641).

RCT inclusion/exclusion criteria. Patient are included in SMArTVIEW, based on the following criteria: patients are ≥ 65 years; has undergone cardiac or major vascular surgery and has been admitted post-op to the surgical floor; has an anticipated length of stay on the surgical floor is ≥ 48 hours; is randomized within 12 hours of arriving on the surgical floor; and able to provide consent autonomously. Patients are excluded if they are unable to communicate with research staff, complete surveys and questionnaires, or a telephone interview (i.e. language barriers, language, vision, or hearing); has an intolerance/allergy to adhesive; unable to complete 30 days of at-home follow up impairment due to planned placement at a nursing home or rehabilitation facility after discharge; has radial graft site; is CAM positive preceding randomization or within 12 hours of arriving on surgical floor; and if they reside in a known area without cellular network coverage.

Usability testing. Prior to RCT deployment, usability testing of the SMArTVIEW intervention was completed with both cardiac or vascular surgical patients and nurses (McGillion et al., 2020). Using an observational 'out of the box' usability testing approach with production equivalent, ready-for-use medical devices, the intent of the usability testing was to refine the approach to clinician and patient training as well as

inform systems configuration (e.g., display settings for optimal visual access and readability). Twenty-six nurses from Canada (n= 15) and the UK (n= 11) participated in Guardian or eTrAC user testing and a total of 11 patients (Canada: n= 6; UK: n= 5) participated in eTrAC user testing (McGillion et al., 2020). Results of user-testing indicated that the program was user-friendly and that the majority of nurse and patient participants were able to complete most required tasks associated with deploying the intervention. Both patients and nurses discussed the perceived benefit of this new monitoring model however, it was commonly stressed from both user groups the need for additional opportunities to use and practice assigning the wireless devices in order to proficient with the SMArTVIEW intervention and meet role expectations (McGillion et al., 2020).

Intervention: In hospital monitoring (phase 1) with Philips' guardian system. Once patients are admitted to the surgical ward and randomized to receive the SMArTVIEW intervention, nursing staff initiate phase 1 of the intervention— the Philips Guardian wearable monitoring solution. (Figure 1) Guardian equipment includes a portable bedside vital sign monitor (A), three cableless wearable patient sensors, and central monitor located at the nursing station. The wearable devices continuously monitor 1) blood oxygen saturation ($SP0_2$), and heart rate, using a wrist worn sensor (C), 2) respiration rate, using a sensor applied to chest on the left costal margin and held in place with an adhesive sticker (D), capturing minute-by-minute physiologic patient data. Additionally, patients wear a non-invasive blood pressure cuff (B) that automatically collects blood pressure every two hours from 0800-2000 hours, and every four hours from

2000-0800 hours. All devices communicate with the bedside monitor through short range radio. The Guardian solution is configured to institutional early warning score (EWS) systems; EWS indicate level of deterioration using a numeric scale. EWS values are calculated based on vital signs, oxygen requirements, and confusion assessment. With each score, a standardized set of recommendations are provided based on level of deterioration severity. Guardian is programmed with reassurance safeguards to prevent alarm fatigue. Guardian will trend patient physiologic data for 15 minutes (3 checks at 5-minute intervals) to ensure measurement accuracy. In the event that deterioration is suspected, a notification is sent to the assigned ward nurse via Thoughtwire handheld device indicating the suspected EWS and respective physiologic values, calling the nurse to attend the bedside, complete a thorough patient assessment, and confirm patient stability.

Figure 1. Guardian In-Hospital Monitoring System

The Guardian System hosted by Philips is of the first highly sophisticated products to facilitate continuous patient monitoring. Subbe et al. (2017), used the Guardian system in a prospective before (n=2139) and after (n=2263) study. This study evaluated remote automated in-hospital monitoring of medicine patients. If patient deterioration was detected early warning score was generated and an alert was sent to the nursing station with a colour coded notification and clinical action recommendation; “safe range” in white; “observe range” in yellow; “warning range” in orange, and “urgent range” in red. Notifications were sent to the rapid response team for further action

assessment. A statistically significant difference was found between the total number of serious events (268 in 2139 patients, 125 per 1000 patients) reported in the control period compared to the intervention period (185 in 2263 patients, 82 per 1000 patients) ($p < 0.001$). In addition, during the intervention period, the number of rapid response team notifications increased from 405 to 524 ($P = 0.001$; 1.43 notifications per patient) that prompted a change in care plan, including initiation of fluid therapy, bronchodilators, or antibiotics (Subbe et al., 2017). While the patient population did not include surgical patients, a generalizable assumption could be made that the sensitivity of the technology will be well suited for postoperative monitoring

As a part of transfer of accountability, bedside staff provide report on SMArTVIEW trends and EWS escalations each shift. Using RFID badging, at each change of shift, the oncoming nurse will associate their hospital charting account with the bedside monitor in order for vital signs to be documented accordingly. Additional responsibility of the oncoming nurse is to replace all wearable devices with charged devices to ensure continuity of RAM as each device has a battery life of approximately 12 hours. All SMArTVIEW patients are continuously observed on telemetry monitoring as per institutional orders. Patients wear the wireless devices for the entirety of their hospitalization.

Intervention: Out-patient monitoring (phase 2) with Philips' electronic transition to ambulatory care (eTrAC) system.

Following hospital discharge, patients are activated to the Philips' Electronic Transition to Ambulatory Care (eTrAC) system. eTrAC is a bidirectional clinical platform using the

eCareCompanion for patient use and the eCareCoordinator for healthcare provider monitoring.

Patient Interface: eCareCompanion. The patient interface—eCareCompanion— is a password protected application displayed on a tablet solely designated for the use of the SMArTVIEW intervention. Each patient is discharged with a remote monitoring kit that includes the eCareCompanion tablet and set of Blue-tooth enabled vital sign equipment (blood pressure cuff, pulse oximeter, weight scale), as well as a standard thermometer (Figure 2).

Figure 2. eTrAC Hospital-to-Home Kit

From home, patients complete a full set of vital signs three times per day, wherein data are automatically uploaded to the eCareCompanion tablet. eCareCompanion displays trends based on daily, weekly, and monthly entries. Vital sign data are automatically transferred to the eCareCoordinator platform for remote SVN monitoring and review. eCareCompanion prompts brief, user-friendly, daily surveys for patients to answer in order to provide further information to the SVN regarding their health status. The tablet also supports secure video calling using Vidyo Software between patient and SVN.

Clinician interface: eCareCoordinator. The clinician interface—eCareCoordinator—displays all active patients enrolled in the eTrAC system and triages patient profiles based on vital sign entries and standardized survey responses (See appendix C for patient profile example). If warranted, additional surveys may be added to the patient profile if relevant to the individual patient recovery (i.e., increase in frequency of sleep surveys if sleep is a postoperative concern). Patient triage scores are colour coded based on severity (red = high risk triage severity >[range]; orange =moderate risk severity [range], no colour = no risk). Each patient profile contains patient history, surgical history, postoperative medications, postoperative complications, survey responses, calendar with appointments and scheduled surveys, and nursing assessment documentation. Alerts are cleared on a daily basis and any patient concerns are addressed by the SVN. Nursing documentation is listed in descending order from the initial postoperative call to Day 30.

SMArTVIEW Nurse.

The innovative nature of this program design requires the need for a new professional nursing role, as no program alike has included nursing staff that facilitate an end-to-end

intervention. Given the surgical population, registered nurses with expertise in cardiac and vascular surgical wards deployed the SMArTVIEW intervention. The concern to be considered when conceptualizing a hybrid role that is both research and clinical in nature is defining a detailed description of the SVN role, role expectations and day-to-day operational workflow. A priori, the role of the SVN includes daily video calls with intervention patients via Vidyo to complete a nurse assessment. The SVNs received initial onboarding training 1) in Good Clinical Practice Clinical Research training through the online CITI program , as mandated by the Population Health Research Institute and HHS for new staff, 2) a two-day in-person training seminar hosted by Philips which provided an in-depth overview of the eTrAC application, and 3) cybersecurity training hosted through Xahvive Cybersecurity. All SVNs were required to complete each training requirement and attain a certificate of completion. The daily patient assessments were conducted by the SVNs using critical thinking and clinical judgement (i.e., complete review of systems or specific system assessment). Using the eCareCoordinator clinical platform, the expectation for SVNs were to conduct a medication reconciliation review and weekly goal setting with patients on H2H Day 3, 10, 17, 24, and 30 of program; Brief Pain Inventory (BPI) on hospital discharge, Day 7 and 14 of program; and digital literacy questionnaire on Day 30 of program. The SVNs utilized Philips' eCareCoordinator; a desktop based clinical tool used to maximize clinical efficiency through risk prioritization based on vital sign entries recorded by patients. SVNs were upheld to standards set by the College of Nurses of Ontario (CNO), specifically reviewing the "Telepractice" CNO

guideline (CNO, 2017). SVN monitoring was deployed as a daytime service, seven days a week from 0800-2000.

In summary, the undertaking of SMArTVIEW was at high risk of failure by virtue of the complexity of design and unknown operational workflow. Risks of SMArTVIEW included 1) scale and complexity of the design, which had not previously been tested in the digital health sector; 2) the operational dependence of numerous internal and external working teams (i.e., clinical ward staff, informatics, Philips) at each respective site in order to deploy the intervention; and 3) the innovative nature of this program design required the need for a new professional role of the SVN, and as such the scope of position has undefined responsibilities and expectations. Therefore, to ascertain the overall implementation and execution of the intervention, close monitoring in the early days of intervention deployment was essential to ensure the practicalities and logistical workflows of clinical adaptations were realistic and adherent to study design. In addition, the unknown scope of the SVN required definition and clear expectation to ensure optimal clinical workflow.

Rationale and Problem Statement: Need for In-Study Process Monitoring Evaluation within the SMArTVIEW Trial

Multicentre large-scale randomised trials are complex projects with many operational uncertainties. it is important to recognise that most, if not all, multicentre trials undergo some modification, and also have regular reassessment of the recruitment strategy, during their life course (Cook et al., 2016). Intervention implementation failure

of some trials can be solely due to practical problems with trial management rather than scientific problems or problems with the research question. The ability to constantly review and adapt the project plan is crucial as a trial can be impacted negatively by external events outside of the control of the study team (e.g., unforeseen circumstances that delay recruitment). Sensible risk assessment, tailored quality assurance management systems and real-time monitoring are essential if a trial is to optimise its potential and provide reliable evidence (Farrell et al., 2010).

Problem Statement.

Current postoperative monitoring following major cardiac and vascular surgery is inadequate. As a consequence, many instances of patient deterioration following these surgeries go undetected. Digital health solutions—featuring postoperative RAM—have the potential to detect early signs of deterioration and facilitate early intervention. To date, a few small trials have demonstrated promise in this area. Now, adequately powered randomized controlled trials are needed to examine the effectiveness of RAM for facilitating early detection of patient deterioration, and for reducing postoperative adverse events and related hospital readmissions. SMArTVIEW is a current randomized controlled trial looking at this question, featuring an intervention that deploys RAM systems both in hospital, on the surgical ward, and at home following patient discharge. As such, the SMArTVIEW intervention is complex, with effective deployment relying on synchronous operation of intervention subsystems with operational and managerial independence. To bring these RAM systems together, a large international stakeholder group is involved, along with significant investment by industry partners. Given that

SMARTVIEW represents the first RAM deployment of its kind, an in-study process monitoring evaluation was required, in the early phase of the trial, to examine the nuances of intervention implementation, optimize workflows, and refine trial processes. Therefore, the goal of in-study process monitoring evaluations is to purposely develop a strategic, tactical, and operational management plan that is individualized to the project itself in the early stages of execution to ensure all trial goals are being met.

In order to develop an operational management plan, the following elements of the trial required examination: (1) to assess the implementation processes, mechanisms of impact, and context of the SMArTVIEW intervention, guided by the Medical Research Council (MRC) Guidelines for reporting process evaluation of complex interventions, and (2) explore the SVNs' scope of practice to identify what care the SVNs were providing care in order to meet the everyday physical, psychosocial, and relational needs of cardiac or major vascular surgical patients, which was guided by Kitson's Fundamentals of Care (FoC) Theory.

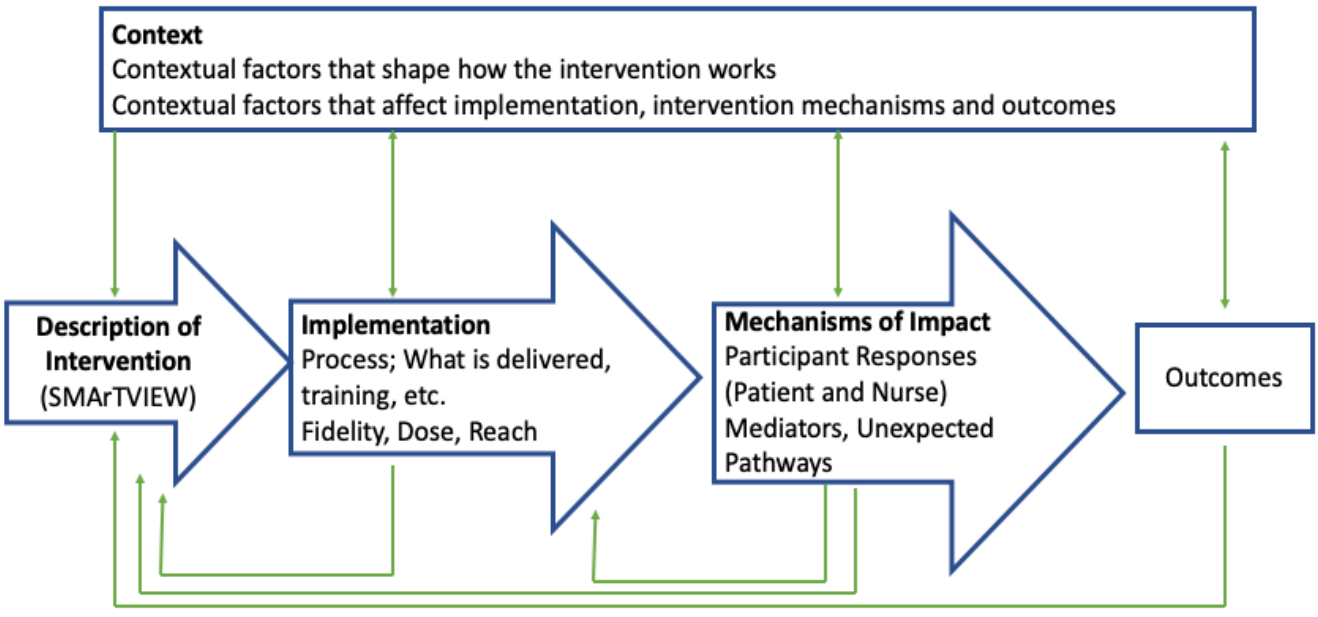
Medical Research Council (MRC) Guidelines for reporting process evaluation of complex interventions.

The MRC framework highlights three core functions of process evaluations: firstly, examining the implementation process and the content (fidelity adaptation, dose and reach); secondly, understanding the mechanisms of impact (participants' response to the intervention; mediators; unexpected pathways and consequences) and lastly, investigating the influence of the context of the intervention (Cassarino et al., 2019a; Moore et al., 2015) This framework enables researchers to capture the complexities of

developing and implementing an intervention and offer useful insights for future quality improvement (Figure 3).

With respect to SMArTVIEW, constant attention must be given to trial execution in Canada with respect to participant recruitment, timing and practicalities of randomization, and standardization of intervention delivery and data collection procedures. With respect to intervention delivery, multiple operational factors must also be attended to, in parallel, related to site technology workflow standardization and adherence, as well as ongoing technical trouble shooting. The need for this understanding must occur early in intervention deployment to ensure any logistic concerns are addressed prior to initiation at partnering sites (i.e., Liverpool Heart and Chest Hospital), and beyond.

Figure 3. MRC Framework (adapted for SMArTVIEW)



Kitson's framework on the Fundamentals of Care (FoC).

Kitson's framework on the Fundamentals of Care (FoC) focuses on the routine, every day physical, psychological, and relational needs of patients, emphasizing the nurse-patient relationship and practical aspects of patient care such as mobility, sleep, comfort, feeling safe, being respected, and encouraging autonomy (Kitson, 2018). See Figure 4 for the Fundamentals of Care Model.

Challenges to conceptualizing care in this integrated way include the disaggregated manner personal care is often managed in the acute care setting wherein nursing activities are often graded according to complexity of technical task rather than providing holistic care experiences for patients (Bridges et al., 2013; Kitson et al., 2014) and the rapidity with which patients move through acute care settings, which can foster a dissonance between what is happening to the patient and how they are making sense of their experience (Ball et al., 2016).

While this theory is relatively new to nursing and application of this theory in practice is nascent, some nursing studies have applied the theory in varying populations and environments. For example, in a qualitative study using positive organizational scholarship and video-reflexive ethnography of inpatient geriatric patients living with dementia, this theory provided a framework for the authors to reflect on how nurses deliver fundamental care (Collier et al., 2019). The authors discussed the challenge of operationalizing person-centered care; building trust with patients, maintaining dignity, and understanding a persons' reality (Collier et al., 2019). In another discussion paper that deliberates the "Kapakapa Manawa Framework*"* – a compassionate care framework and

the relationship component of the FoC theory for patients at end of life byway of two cases examples (Robinson et al., 2019). The authors conclude their discussion in stating the FoC has to potential to improve nursing care, as it brings attention to the detailed intricacies of the nurse-client relationship and how relationships develop, however, this discussion lacks the consideration of policy and health system factors. While these articles articulate the use or partial use of the FoC theory, other publications lack conceptual clarity in description and utilization of this theory.

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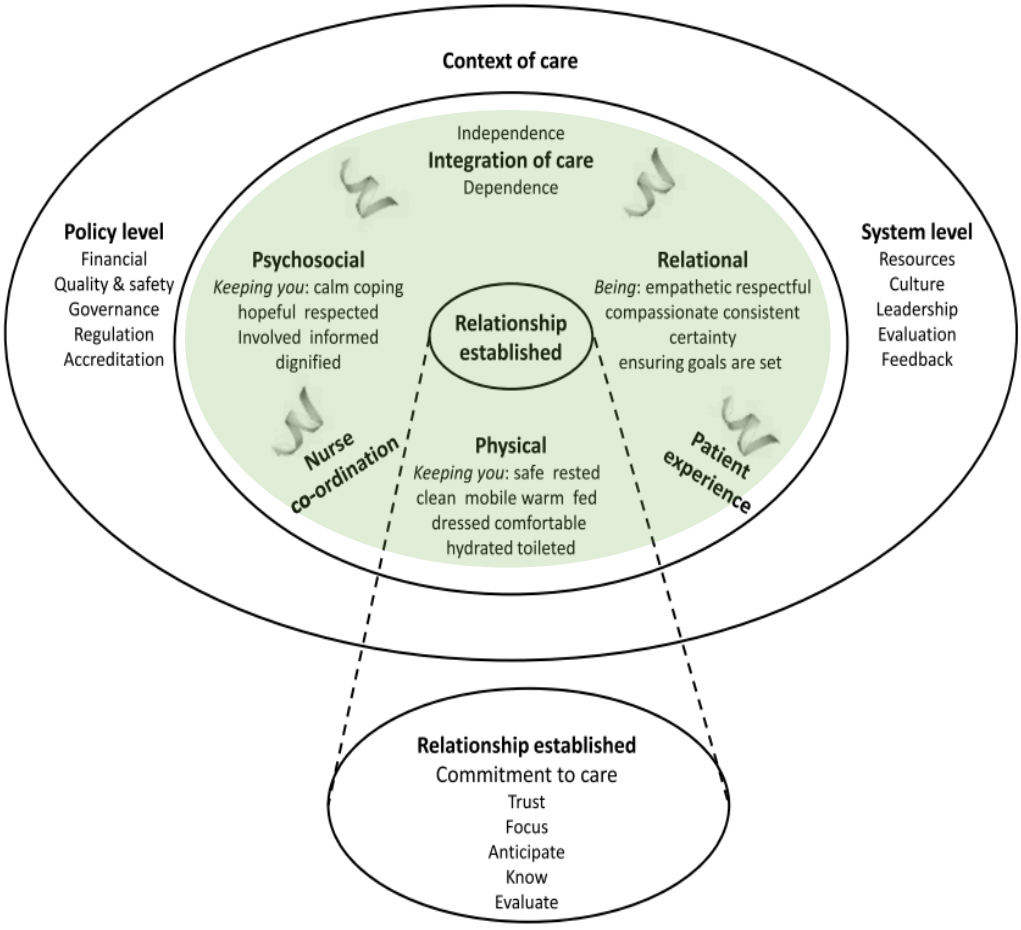
The initial idea of the SVN role was to redirect how care is provided, affording nurses the time to focus on supporting patient recovery– the physical (mobility, nutrition, sleep, comfort), psychosocial (support), and relational (empathy, goal setting) needs of patients enrolled in the SMArTVIEW trial. In the H2H phase of SMArTVIEW, SVNs are

able to focus on the fundamentals of care through virtual follow up and build relationships with patients over 30-days. All interactions between the SVNs and patients are detailed in the eTrAC documentation, providing insight as to what care practices are being provided by the SMArTVIEW nursing team. Therefore, SMArTVIEW represents an opportunity to operationalize this nursing theory, recognizing inherent challenges associated with the theory, and adapting the intervention design early in the research process to drive the intervention focus on the patient and their recovery experience, ensuring patients' fundamentals of care needs are met in their postoperative recovery.

Figure 4. FoC Theory Framework (adapted with SMArTVIEW)



CHAPTER III: METHODOLOGY

Purpose

The purpose of this work is to conduct an in-study process monitoring evaluation of the first 100 patient cases enrolled in a complex international randomized controlled trial, entitled SMArTVIEW. This process monitoring evaluation had two primary foci. The first focus was to assess the implementation processes, mechanisms of impact, and context of the SMArTVIEW intervention, guided by the Medical Research Council (MRC) Guidelines for reporting process evaluation of complex interventions. The second objective, guided by Kitson's Fundamentals of Care (FoC) Theory, was to explore the SVNs' daily nursing practice in order to identify what aspects of care the SVNs were providing in order to meet the everyday physical, psychosocial, and relational needs of cardiac or major vascular surgical patients enrolled in the SMArTVIEW trial intervention arm.

Research Questions

Foci (1): Implementation processes, mechanisms of impact, and context of the SMArTVIEW intervention.

What are the implementation processes of the SMArTVIEW intervention?

1. How is program delivery achieved? (i.e., training, resources)
2. To what extent does the SMArTVIEW intervention align or diverge from protocol? (i.e., implementation fidelity)
3. What is the quantity of SMArTVIEW intervention delivered?

4. What proportion of the targeted population (eligible patients) were enrolled in the SMArTVIEW intervention? What was the attrition rate?

What are the mechanisms of impact in the SMArTVIEW intervention?

1. How did patients respond to, and interact with, the SMArTVIEW intervention?
2. What aspects of the intervention influenced its implementation? (i.e., people, operations, relations)
3. Were there any unforeseen or unexpected factors that may have influenced implementation?

What are the contextual factors that affect the implementation and outcomes of the SMArTVIEW intervention?

1. What factors external to the SMArTVIEW intervention influenced its implementation and in which way?

Foci (2): A detailed exploration of the SMArTVIEW Nurses' practice

1. What are the corrective actions or recommendations imparted by the SVNs in order to prevent or address postoperative complications for patients enrolled in the Hospital-to-Home Program?

Research Design

A process monitoring evaluation using a mixed-method approach was used to address the research questions, in relation to the SMArTVIEW multisite RCT. A provide pragmatic information on the implementation process, necessary structures, resources, and roles, as well as any unforeseen factors that enhance or hinder intervention deployment (Cassarino et al., 2019b; Craig et al., 2008; Oakley et al., 2006). To explore

the scope of the SMArTVIEW nursing role, a content analysis of eTrAC nursing notes was conducted to identify what practical nursing recommendations or interventions were provided that helped patients manage their care following major surgery.

Sample and Setting

Sample. For the purposes of this in-study process monitoring evaluation, the first 100 patients who underwent cardiac or major vascular surgery, met RCT eligibility criteria, and were enrolled in the SMArTVIEW trial will be assessed using a sequential sampling technique. The MRC guidelines suggest purposely selecting a sample size that balances both providing sufficient insight producing a manageable amount of data (Moore et al., 2015). Based on the recruitment schedule outlined in the trial protocol, 100 patients were feasibly recruited within 13 weeks of active recruitment, thus providing an adequate number of patients to provide meaningful data while still in early stages of the trial deployment. In addition, this in-study process monitoring evaluation included the cardiac (n=3) or vascular (n=1) surgical nurses appointed as the SVNs who facilitate intervention delivery. All nurses held the designation of Registered Nurse, with clinical experience ranging from novice to experienced nurse (1– 29 years) and were recruited from either the cardiac or vascular surgical ward at HHS.

Setting. SMArTVIEW trial was first initiated at Hamilton Health Sciences Centre (HHS), Canada, and was later followed by Liverpool Heart and Chest Hospital, United Kingdom, approximately 18-months thereafter. Therefore, this evaluation included the

first 100 patients enrolled at HHS. The Canadian SVN team had designated office space, situated on the Cardiac Surgical Ward at the Hamilton General Hospital site within HHS.

Data Sources used for Process Evaluation

Recruitment logs. Patients expected to fulfill eligibility criteria were approached and invited to participate by study personnel. Patients were approached prior to, or as soon as practically possible following surgery, to complete the informed consent process. At the time of consent, patients and if possible, families, were explained the study details and given the opportunity to ask questions. Patients were shown a brochure with images of all equipment. Patients were informed the study would begin following transfer from, the ICU. Weekly Recruitment logs kept ongoing records of the total number of patients enrolled as well as total number of patients screened for eligibility, number of patients who met eligibility criteria, number of eligible but not consented, number of patients consented prior to surgery, number of consented patients but not randomized, and reason for non-consent and non-randomization.

Guardian and ThoughtWire data logs. Using the Guardian MP5SpotCheck Bedside patient monitor, ward nurses collected vital signs at intervals which calculated an EWS based on the patient's vital signs. Each set of vital signs were saved as a SpotCheck record. The Guardian Patient Monitors sent patient data to the Guardian System application using a wired or wireless network connection. If no connection was available at the time of data collection, the data was stored in the monitor's local database (unencrypted) and sent to the Guardian application when a network connection became available**.** Guardian provides export of patient physiological data via the Heath Level 7

(data transfer standards) interface to the respective electronic medical record, known as Meditech. All patient data were stored in the Guardian database and validated results were sent to EMR. The paging devices carried by ward nurses alert if suspected deterioration is detected, through an application managed by Thoughtwire; Thoughtwire pulls vitals and EWS data from Meditech for the purposes of alerting staff if required. If an alert was generated, the most responsible nurse acknowledged the alert directly on the Thoughtwire handheld device and then protocol stipulated the nurse return to the bedside to complete and validate a full set of vital signs. As per protocol, Thoughtwire alerts were to be acknowledged within two minutes and a completed set of vital signs within 15 minutes. See Appendix A for Guardian Pathway.

eTrAC participant profile. Using the eCareCoordinator platform, SVNs created a patient profile for every patient enrolled in the SMArTVIEW intervention. This profile served as a record for relevant patient history, prescribed medications, assigned blue-tooth vital signs monitoring equipment, and a prepopulated 30-day program calendar with scheduled tasks outlining the frequency and timing of daily vital signs monitoring, SVN video visits, and daily symptom survey completion. SVNs also used the eTrAC participant profile to document daily head-to-toe virtual assessments and narratively describe any incidences requiring an escalation of care. See Appendix B for example of patient profile.

Daily activity report. As part of daily transfer of care, at the end of every shift SVNs documented in a daily report recruitment activities, patient flow updates (i.e., from the intensive care unit to the hospital ward, number of active patients in hospital and

number of patients followed at home), concerns with the Guardian program (e.g., connectivity issues, incorrect vital sign entry), concerns with the hospital-to-home program (e.g., connectivity, escalations of care), and housekeeping items to be communicated within the SMArTVIEW nursing team, hospital staff, or research staff.

Patient teaching logs. Prior to patient discharge, SVNs facilitated a 30-minute checklist-oriented rehearsal of all eTrAC features that included a review of all equipment (both vital sign equipment and tablet practice) and mock video conference call. The SVNs also provided opportunity to answer patient questions and provide further teaching if needed. The H2H patient teaching was documented using a standardized check list developed by the SVN team to ensure all patient education was captured accurately to the intervention requirements (See Appendix C).

Daily Guardian device report. While in hospital, as previously discussed, patients wore devices that continuously monitored respiratory rate, heart rate, SpO2, and intermittently monitored BP and temperature. Physiologic data was collected and stored in the Guardian monitor database and then sent to the Guardian server if the wireless connection is available. The Guardian server stored and displayed them in the 'Guardian Patient Workbook' on a central monitor located in the SVNs' office. Data was displayed in the Patient Workbook on a minute-to-minute basis. In addition, completed vital sign assessment were displayed with an associated HEWS score. Missing data was displayed as a question mark symbol. In the Daily Guardian Device Report, SVNs recorded reasons for all device interruptions as well as length of time of interruption; reasons included

connectivity, patient request for removal, physiotherapy, diagnostic imaging, physician request, ICU readmission, delirium, and other.

Data Collection and Analysis Plan

Using the MRC process evaluation framework, the process evaluation focused on the elements and research questions is outlined in Table 2.

Implementation. To examine the process of how the SMArTVIEW intervention was delivered on a daily basis, as well as describe how the SVNs operationalized their daily roles and associated tasks with the aim of deploying the SMArTVIEW intervention, daily activity logs were analyzed. By manually reviewing each daily activity log, a sequential time-map was made of all events that took place noted by the SVNs specifying the type of event, what occurred, and what (if any) next steps were carried out to resolve issues. Patient teaching logs were manually reviewed to determine if all H2H teaching occurred in accordance to protocol.

To examine the implementation fidelity and the dose of the SMArTVIEW intervention, in-hospital Guardian device compliance, hospital-to-home patient daily vital sign entry and video call completion were reviewed.

In-hospital device compliance. As previously discussed, upon transfer to the surgical ward, the SMArTVIEW Guardian monitoring equipment was applied and provided continual physiologic SpO2 and pulse rate, and respiratory rate data when worn by the patient. As per protocol, blood pressure was measured every 2 hours during the day and every 4 hours at night, with the option of increasing frequency on demand, as required. Sensors were intended to remain on all patients in the intervention group for the

duration of their hospital stay. If devices were removed or not recording for >15 minutes, the SVN documented the amount time the patient was unmonitored and the rationale for device removal. A manual review of all intervention patients' device compliance forms was undertaken. Frequencies were generated to describe the categorical nominal data for removal reasons and number of occurrences wherein devices were removed.

Guardian device reports. To examine the use of the Guardian system and compliance from the ward nursing staff, counts of the number of notifications from Philips to Thoughtwire, from Thoughtwire to nurse, attended notifications, reminder notifications, number of escalations to the charge nurse were pulled from a secure server at the host site. In addition, measures of central tendencies examining maximum, minimum, and average number of notifications (HEWS score, response time, pre-HEWS generated per patient) were generated and evaluated.

Patient vital sign entry. As per SMArTVIEW protocol, the set frequency of daily vital signs monitoring was 3 times a day for the first 14 days, and then twice a day from day 15 until 30 days post-discharge. Through a manual review of eCareCoordinator, patient vital sign compliance was assessed examining the frequencies of vital sign entries per patient.

Daily video call assessment. As per SMArTVIEW study protocol, the SVNs conducted daily 15-minute virtual check-ins (eTrAC video visits) with patients. Completion of each call was documented in the patient's chart. Frequencies of amount of video calls per patient were completed.

To examine the reach of the SMArTVIEW Intervention, participant logs were examined from the recruitment team at the Population Health Research Institute. The recruitment team documented all patients who were approached, consented, proceeded to randomization, proportion of patients receiving the intervention to complete the 30-day program to inform the reach of the SMArTVIEW intervention.

Mechanisms of Impact. To review participants' responses to and interaction with the SMArTVIEW intervention, a manual review of the daily activity reports, patient teaching logs, and eTrAC patient profile were conducted to identify nominal data of any reports of patient interaction or feedback of the intervention. Daily activity reports were reviewed in a similar method to categorize nominal data that pertained to mediators and unexpected pathways that occurred within the first 100 patients. The purpose of conducting frequencies of nominal data was used to help inform of the practicalities of study deployment and then inform how the intervention needed to be refined to optimize workflow.

Context. Barriers and facilitators that either enabled or hindered intervention deployment were explored. The Daily Reports were manually analyzed, and any barriers or facilitators reported by the SVNs were extrapolated and generated into themes. The purpose of composing nominal data into themes was to provide insight into what was and was not working during intervention deployment and then inform what refinements or reinforcements were needed to ensure continued success of end-to-end intervention delivery.

Table 2. Implementation Process, Mechanism of Impact and Context of SMArTVIEW

Implementation Process, Mechanism of Impact, and Context of SMArTVIEW

Implementation	Element	Research Question	Data Source
	Process	How is the SMArTVIEW program delivery achieved?	Daily activity logs
		How do the SVNs operationalize their daily roles and associated tasks with the aim of deploying the SMArTVIEW intervention	Daily activity report, Patient teaching log
	Fidelity	To what extent does the SMArTVIEW intervention align or diverge from protocol?	Daily Activity report, Guardian Thoughtwire Reports, Guardian Device Reports, Patient Teaching Logs
	Dose	What is the quantity of SMArTVIEW intervention delivered?	Guardian Device Reports, Patient Teaching Logs
	Reach	What proportion of the targeted population (eligible patients) were enrolled in the SMArTVIEW intervention?	Recruitment logs

		What was the attrition rate?	Recruitment logs
Mechanism of Impact	Participant's responses to and interaction with the intervention	How did patients respond to, and interact with, the SMArTVIEW intervention?	Daily activity report, Patient teaching log, eTrAC participant profile
	Mediators	What aspects of the intervention influenced its implementation?	Daily activity report
	Unexpected Pathways and Consequences	Were there any unforeseen or unexpected factors that may have influenced implementation?	Daily activity report
Context	Barriers and Facilitators	What factors external to the SMArTVIEW intervention influenced its implementation and in which way?	Daily activity report Guardian Device Reports

SMArTVIEW Nurse Scope of Practice: Nursing Recommendations and Corrective Actions

Using Kitson's Fundamentals of Care Framework, a content analysis was undertaken to explore the SVNs' scope of practice to identify what care the SVNs were providing in order to meet the everyday physical, psychosocial, and relational needs of cardiac or major vascular surgical patients (Table 3).

Table 3. Kitson's Fundamentals of Care Framework

Kitson's Fundamentals of Care Framework

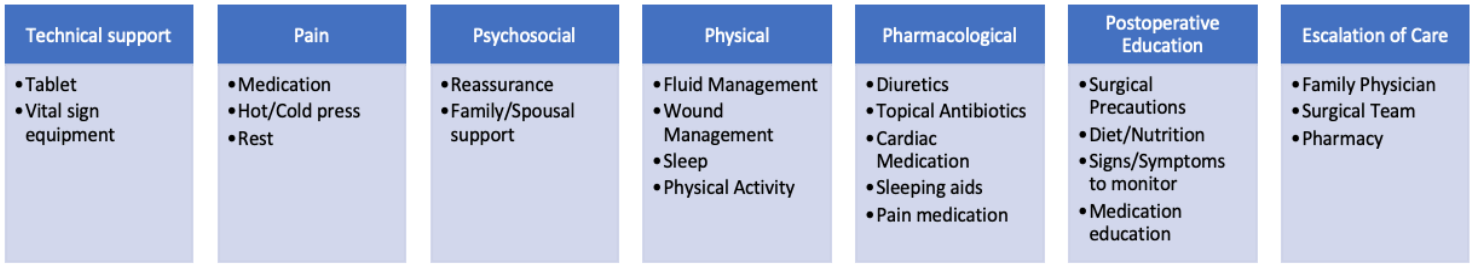
A detailed exploration of the scope of the SMArTVIEW nursing role to identify what patient-related supports are required of the SVNs are to deploy the intervention.		
Element	Research Question	Data Source
Practice Process	What are the corrective actions imparted by the SVNs in order to prevent or address postoperative complications?	eTrAC participant profile

As previously discussed, SVNs followed the H2H Video Visit Template Guide which provided a guide on how to review with patients their vital signs, survey responses, wound assessment, and concluded with an open-ended dialogue to discuss patient concerns. SVNs conducted full systems assessments or focused assessments, according to clinical judgement. Using the eCareCoordinator platform, SVNs then documented their interaction and assessment findings following each patient interaction. SVNs were instructed to document relevant findings as well as any recommendation or intervention made by the SMArTVIEW nursing team.

For analysis of the eTrAC patient profile and audit of SVN documentation, access was given the eCareCoordinator platform which provided an active list of all users enrolled in the H2H program. Using de-identified patient identifiers, a cumulative list of all nursing entries was generated. Guided by the second tier of Kitson's FOC theory which identified the integration of care, relational, physical, and psychosocial needs of

patients, as well as in consultation with the SVNs, a list of common recommendations was developed; the main themes and subcategorized themes were identified in figure 5. The structure of the coding scheme was interactive and modified as new themes and insights emerged.

Figure 5. Preliminary Themes



In the sample of the first 100 patients, the documentation of all intervention patients who participated in the H2H program were included and based on 1:1 randomization strategy, approximately 50 patients would be enrolled in the intervention arm. Each patient received 30 days of the intervention and therefore, assuming 30 daily video assessments with the SMArTVIEW nursing team (n=1500 notes). The daily documentation recorded by the SVNs, pertaining to the video assessment, details the nurses' assessment. To analyze the SVNs' documentation, a binary categorical coding scheme was used to audit each nursing note (1=action completed, 0=action not completed) for each major theme and sub-theme reported. Due to the subjective nature of documentation interpretation, all documentation was audited by two coders. Inter-rater reliability was achieved though weekly meetings where all coding results were compared, and discrepancies were discussed to resolve conflict using a third rater. The data

abstraction tool was piloted with a random sample of 10 SMArTVIEW patients (10% of total sample) to determine validity prior to completion of the total sample. To ensure reliability, all coders received standardized training and calibration sessions, led by the investigator. Descriptive statistics were used to describe sample characteristics and frequencies of each major theme and subtheme were calculated.

CHAPTER IV: RESULTS

This chapter presents the results of the in-process monitoring evaluation of the first 100 patients enrolled in the SMArTVIEW trial in six sections. First, derivation of the sample, randomization, and attrition are described. Subsequently, frequencies of various intervention components are used to describe 1) the in-hospital Guardian system use, 2) the eTrAC program compliance, 3) the H2H patient teaching log, 4) the daily activity report, and 5) the Guardian device removal reports, and 6) the eTrAC nursing documentation to explore the advice and recommendations SVNs are providing in the H2H program. The SMArTVIEW trial initiated on March 19, 2018, with the first patient enrolled on March 21st and the 100th patient enrolled on June 22, 2018 and remained in hospital until June 30, 2018.

Derivation of the Sample

SMArTVIEW recruitment. Weekly recruitment logs are presented in Table 4. Of the 228 eligible patients meeting study criteria, 110 patients proceeded to randomization. The first surgical patient enrolled in the SMArTVIEW study was on March 21, 2018 and the 100th SMArTVIEW patient was enrolled on June 22, 2018, spanning 13.2 weeks (93 days). On average, 8 patients were recruited per week (M= 7.9, SD=± 3.2), with a range of 13 patients (Min=3, Max =16). Weekly recruitment projections fluctuated in order to meet patient recruitment goals, averaging eight to 12 patients per week, indicating recruitment rates were on average, meeting study goals. Recruitment logs were captured weekly, on Wednesdays, and due to date overlap, we

were unable to parse out the exact values at the specific date wherein the 100th patient was enrolled for the following categories: for eligible, eligible but not consented, consented prior to surgery, and consented but not randomized. Therefore, all weeks up to and including the 100th patient were including, resulting in Table three including 110 patients.

Table 4. Weekly Recruitment Log

Weekly Recruitment Log							
Week	Date (Week of)	Total Screened	Eligible	Eligible (not consented)	Consented Prior to Surgery	Consented but not randomized	Proceeded to randomization
1	2018-03-19	35	22	12	10	2	8
2	2018-03-26	28	18	12	6	3	3
3	2018-04-02	22	14	6	8	2	6
4	2018-04-09	32	21	7	14	3	11
5	2018-04-16	33	17	10	7	2	5
6	2018-04-23	29	14	4	10	4	6
7	2018-04-30	26	14	3	11	3	8
8	2018-05-07	31	16	6	10	2	8
9	2018-05-14	29	10	2	8	3	5
10	2018-05-21	22	9	2	7	1	6
11	2018-05-28	30	13	4	9	1	8
12	2018-06-04	30	18	5	13	3	10
13	2018-06-11	33	23	10	13	3	10
14	2018-06-18	33	19	0	19	3	16
Total		412	228	83	145	35	110

A total of 83 patients were not consented for the following reasons (Table 5): patient or family refusal (53 participants), pre-existing medical condition preventing participation (1 participant), enrolled in another trial using a wearable devices

(PREVENA ™) (25 participants), and surgery was moved to a later date (3 participants). Of the patients refusing to consent and those in the PREVENA trial, it was commonly reported in the field notes that patients perceived the program to be "too intensive" and were "unable to commit at the present time" because of the overwhelming nature of undergoing major surgery.

Table 5. Reasons Patients were not Consented

	Reason Patient was not Consented			
	Patient/Family Refusal	Medical Condition prevented randomization	PREVENA Study	Surgery Date Moved
TOTAL: 83	53	2	25	3

Following surgery, patients were not randomized for the following reasons (Table 6): CAM positive following surgery (6 participants), patient or family refusal (12 participants), patients were transferred to the surgical ward, however the research team was not notified within four hours of ward admission and therefore could not be randomized (6 participants), medical condition prevented participation (i.e., radial graft sites; 2 participants), patient expired before ward transfer (7 participants), and other (2 participants) which included one patient's partner died during the patient's surgery and one patient was directly transferred to their local hospital following the intensive care unit.

Table 6. Reason Patients were Consented but not Randomized

	Reasons patients were consented but not randomized					
	CAM+	Patient/Family Refusal	Outside timeframe	Medical Condition prevented randomization	Expired	Other
TOTAL: 35	6	12	6	2	7	2

Allocation. Using a 1:1 randomization method, 50 patients were randomized to receive the SMArTVIEW intervention, and 50 patients were allocated to receive standard care. 100% of patients underwent cardiac surgery.

Retention. Of the 50 intervention patients, all started in the in-hospital (Guardian system) monitoring, however, 15 participants withdrew from the study prior to hospital discharge and discontinued from the program, therefore giving a dropout rate of 30%. The documented reason for all 15 patients discontinuing from the program related to the cumbersome nature of wearing all three wireless devices at all times; patients expressed feeling overwhelmed immediately following ICU transfer with numerous healthcare providers completing assessments and some patients experiencing nausea or pain. All participants agreed to long-term follow up. In addition, one patient was randomized to the intervention arm but was quickly transferred back to the intensive care unit never returned to the cardiac surgical unit. Therefore, 34 patients were retained in the intervention arm and completed the in-hospital and H2H program. All 34 patients participated for the entirety of the 30-day H2H program as no patients withdrew from the program once at home.

Demographics. Demographic data of the first 100 SMArTVIEW patients is presented in table 7. All patients enrolled underwent cardiac surgery. The majority of

participants enrolled in the SMArTVIEW program were male (82%). The average age of participants was 74.5 years, with a range of 66-88 years. There was minimal ethnic diversity among the first 100 patients as 97% of participants were Caucasian. In regard to level of education, all participants received some level of formal education with 42% of participants attaining some or complete high school level education, 24% attaining some or complete college level education, and 25% completing university or post-graduate level education. All patients were located within the Hamilton-Niagara region in South Western Ontario.

Table 7. Patient Demographics

Demographics of the First 100 SMArTVIEW Patients (N=100)		
Characteristic	Variable	n(%)
Sex		
	Male	82 (82)
	Female	18 (18)
Ethnicity		
	Caucasian	97 (97)
	Black/African Descent	1(1)
	Hispanic/Latino	0(0)
	Asian	1(1)
	Middle Eastern descent	1(1)
	Indigenous	0(0)
Education		
	No education	0(0)
	Some grade school	1(1)
	Grade school graduate	2(2)
	Some high school	14(14)
	High school graduate	28(28)
	Some College	3(3)
	College Graduate	21(21)
	Some University	0(0)
	University graduate	12(12)
	Post-graduate Studies	13(13)
	No entry	6(6)

Age (years)	M(SD) 74.5 (5.4)	Range (min-max) 66.6-88.0

In-Hospital Guardian System Use

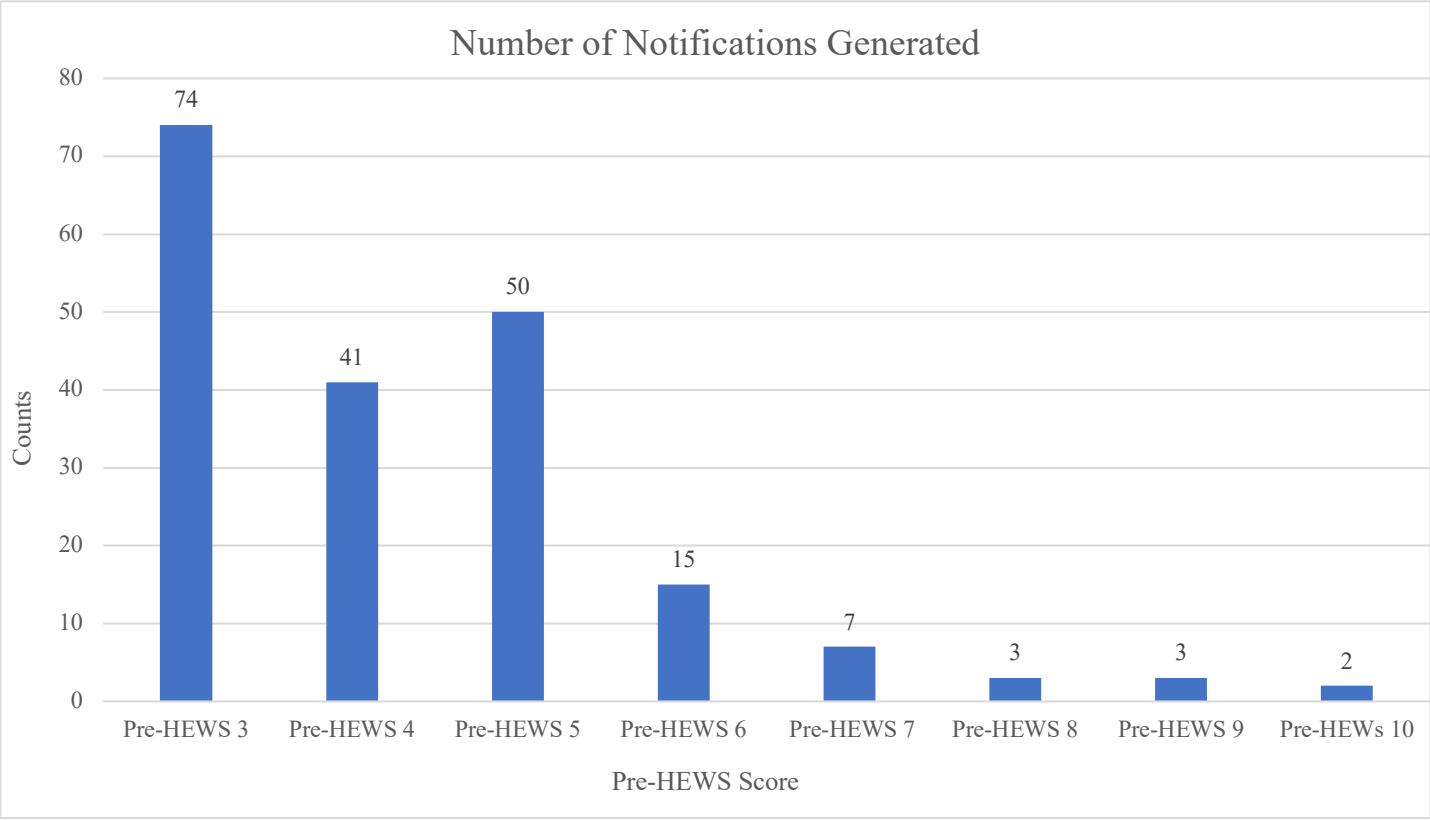
In-hospital monitoring data was captured by 50 patients, as all patients initially began on the SMArTVIEW equipment and therefore generated in-hospital monitoring notifications, prior to participant withdrawal. In this sample, there were 195 notifications generated to alert ward nursing staff, of which, 174 were acknowledged by the bedside nurse (Table 8). The median response time to acknowledge an alert notification was 15 minutes and interquartile range was 00:04:26-01:53:23 (hh:mm:ss). Majority of the notifications generated, 84.6% (165/195), were between the risk band ranges of 3-5 (see Figure 6). The average Pre-HEWS score generated across all notifications was a level 4 (range 3-10). The average number of notifications generated per patient was 4 notifications (range 0-23 notifications during hospitalization).

Table 8. In-hospital Monitoring Metrics

In-Hospital Monitoring Metrics	
Metric	Frequency
Number of Notifications sent from ThoughtWire to End User	195
Number of notifications acknowledged by bedside nurse	174
Number of Notifications Escalated to the Charge Nurse	106
Number of Reminder Notifications	127
Maximum pre-HEWS Score Associated w/ the Notification	10

Minimum pre-HEWS Score Associated w/ the Notification (no alerts generated below a score of 3)	3
Average Pre-HEWs Score generated	4
Average number of Pre-HEWS generated per patient	4
Minimum number of Pre-HEWS generated per patient	0
Maximum number of Pre-HEWS generated per patient	23

Figure 6. Notification Frequencies



Patient Teaching Logs

All 34 patients who participated in the H2H program received formal training on how to use the equipment and video call with the SVN team. The eTrAC checklist was

developed by the SVN team and compliance scores for teaching provided are as follows: 1) explain the purpose of the pods and importance of daily home monitoring (n=34, 100%) , 2) explain that the system is for collection of information only and does not replace or substitute a 911 emergency call (n=34, 100%), 3) explain the monitoring equipment is to be used only by the participants enrolled in the program, (n=34, 100%) 4) teach how to apply and use the monitoring equipment; provide a demonstration and have patient try equipment while present to support as needed, (n=34, 100%), 5) explain importance of measuring vital signs at the assigned time each day (n=34, 100%), 6) review that survey are reflexive of condition (n=34, 100%), 7) explain temperature must be entered manually (n=34, 100%), 8) review blood pressure cuff placement (n=34, 100%), 9) review weight measurement (n=34, 100%), 10) provide participant with SVN contact information (n=34, 100%), 11) obtain baseline set of vital signs and reinforce teaching if necessary (n=34, 100%), and 12) advise patient to not lift, push, or pull equipment box (n=34, 100%). All teaching began on ward day two or three, depending on patient readiness and family availability, and program review was completed on the day of discharge.

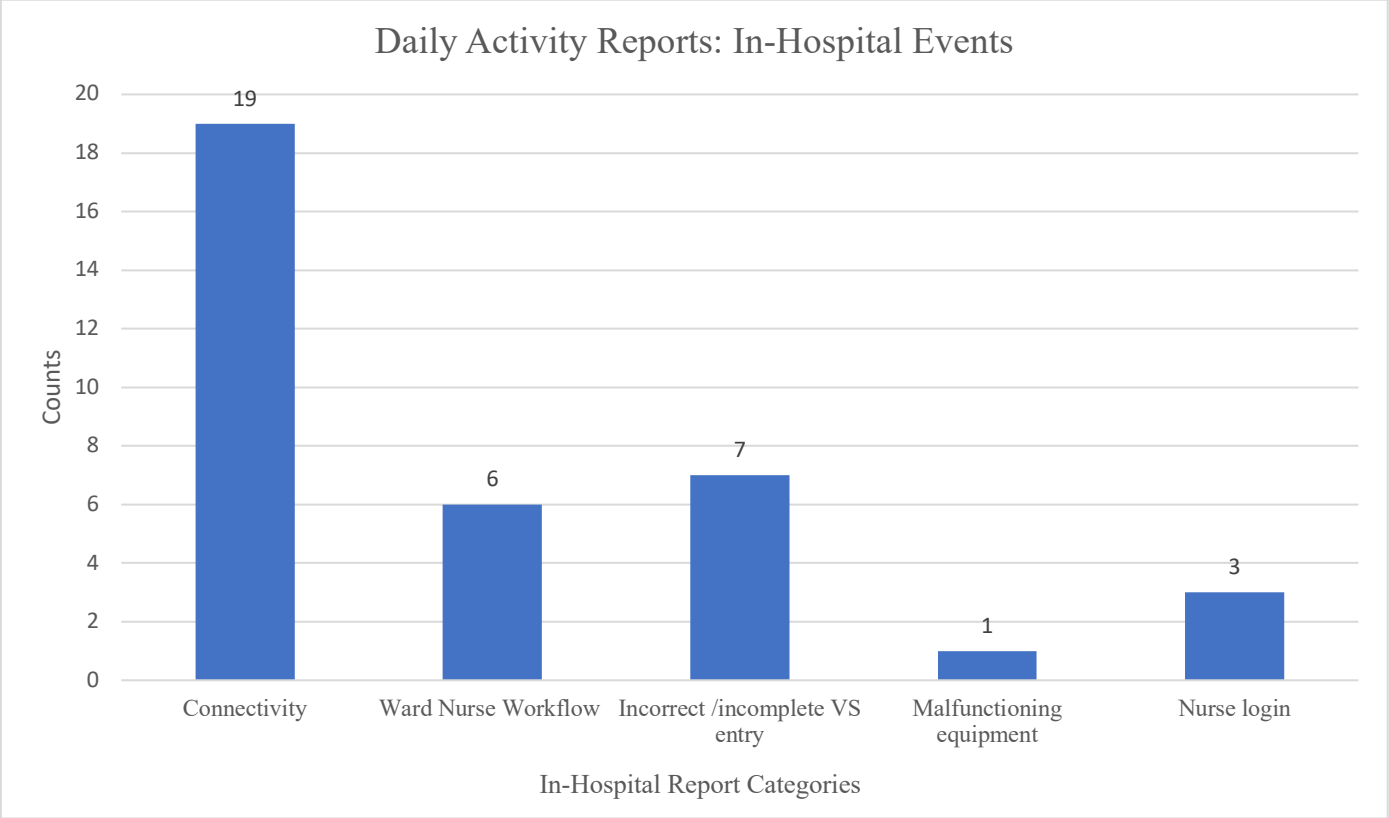
Daily Activity Reports

Daily activity reports began on April 17th, 2018 – almost a month into study recruitment— when the SVN and study leadership teams recognized a need for a standardized approach to communicating day-to-day operations, on a routine basis. Reports generated by the SVN team indicated daily concerns, organized by month,

categorized by 1) in-hospital monitoring, 2) H2H monitoring, and 3) Daily 'House-Keeping'. A total of 42 daily reports were generated between March 19, 2018 and June 30, 2018 (Appendix D-F).

In-hospital themes. A total of 36 in-hospital issues were reported on the daily activity reports (Appendix D). Majority of issues interrupting daily workflow were related to device connectivity failure (Figure 7). There were 19 documented instances of connectivity challenges wherein either the MP5SpotCheck Monitor or the handheld devices lost connectivity. Resolutions to address connectivity included contacting support teams (e.g., Philips, Thoughtwire, HITS), restarting, rescanning, or reprogramming devices in order to resolve and restore connection. 36% of the documented in-hospital issues related to responding to and completing an attended set of vital signs at the bedside using the SMArTVIEW equipment; 6 instances of ward nurse workflow challenges and 7 instances of incorrect or incomplete vital sign entry. Resolution of workflow and vital sign entry challenges were mitigated through the support of the SVNs.

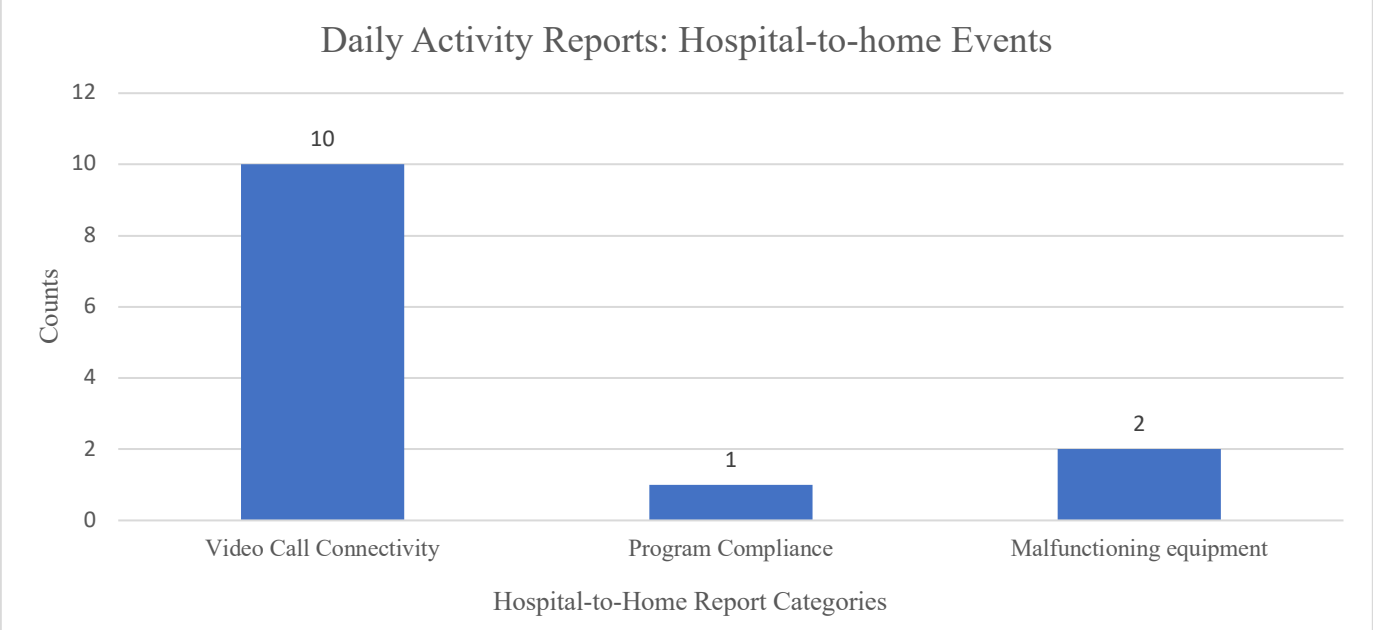
Figure 7. Daily Activity Reports: In-hospital Events



Hospital-to-Home theme. A total of 13 H2H events were documented in the daily reports in the study period (Appendix E), and categorized by 1) video call connectivity, 2) program compliance, and 3) equipment malfunction (Figure 8). The majority of issues raised related to the quality of the video call wherein the SVN team were unable to connect with patients and therefore unable to perform a virtual care assessment. Commonly, the SVN would substitute the video call by completing the virtual assessment via telephone or reschedule for a later time or date. Only one occurrence was reported in the daily activity reports regarding program compliance wherein a participant did not join the video call at the scheduled time. The patient 'forgot about the call and did not realize he had to start the next day' following hospital

discharge; thereafter the participant continued in the program with no further concerns regarding compliance.

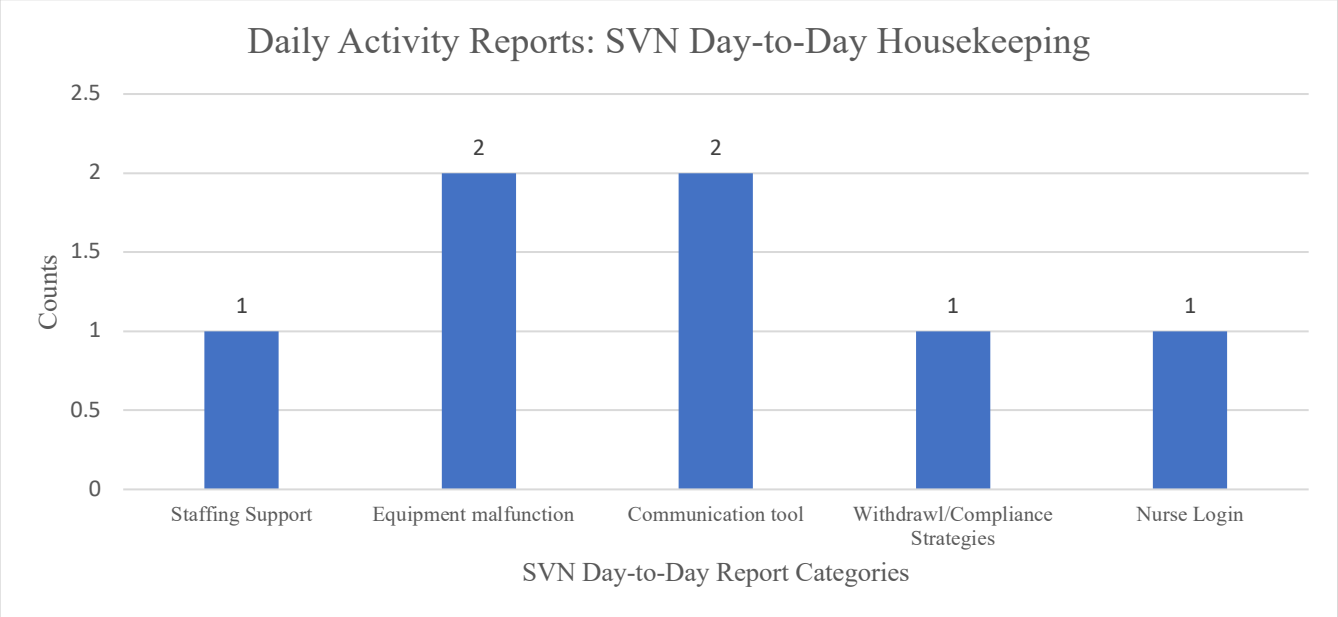
Figure 8. Daily Activity Reports: Hospital-to-Home Events



SVN Housekeeping items. A total of 7 housekeeping items the SVNs reported during the study period (Appendix F), with five main themes: 1) staffing support, 2) equipment malfunction, 3) communication tool, 4) withdrawal/compliance strategies, and 5) nurse login (Figure 9). In the early days of the trial, discussion on staffing support was raised as the initial model for SVN was one SVN on shift per day, but the team felt more support was required to facilitate both the in-hospital and H2H components of the program. Communication tools to assist bedside staff were also discussed in the 'housekeeping' remarks. SVNs were noticing that ward staff were preparing to discharge SMArTVIEW intervention patients without contacting the SVN team. To address the

discharge transition and streamline processes for H2H patients, neon green stickers were added to the standard practice discharge checklists for patients enrolled in the H2H program, instructing ward staff to discuss discharge plan with the SVN team prior to patient discharge. In addition, the SVNs made note of discussion on how to improve in-patient device compliance, wherein a proposed solution was to have study leadership round on patients, daily, to ensure patient concerns were addressed in a timely and consistent manner.

Figure 9. Daily Activity Reports: SVN Day-to-Day Housekeeping



Daily Guardian Device Report

Overall, there were 220 occurrences that at least one of the in-hospital monitoring devices were removed or not capturing physiologic data for 15 minutes or more. The following reasons and frequencies device removal are presented in Table 9.

Table 9. Daily Guardian Device Report

Daily Guardian Device Report		
Device	Reason	Frequency
Blood Pressure Cuff		
	Patient request	7
	Physiotherapy	1
	Diagnostic Imaging	14
	Physician Request	0
	Equipment Malfunction	17
	ICU Readmission	0
	Delirium	0
	Other	21
SpO2 Device		
	Patient request	13
	Physiotherapy	1
	Diagnostic Imaging	19
	Physician Request	0
	Equipment Malfunction	38
	ICU Readmission	0
	Delirium	2
	Other	22
Respiratory Device		
	Patient request	2
	Physiotherapy	1
	Diagnostic Imaging	12
	Physician Request	0
	Equipment Malfunction	33
	ICU Readmission	0
	Delirium	0
	Other	17

Device removal reasons were categorized as the following: patient request, physiotherapy, diagnostic imaging, physician request, equipment malfunction, intensive care unit readmission, delirium, and other. Overall, there were no occurrences wherein a physician requested device removal, and no recorded instances of device removal due to readmission to the intensive care unit. The most commonly recorded reason was

documented as “other” however, further explanation to the removal rationale was lacking, regardless of the option to document in the comment section on the device record. One patient requested to have a “overnight break” and resumed wearing the monitoring devices the following morning.

Blood pressure device. The blood pressure cuff was removed a total of 60 times. 23% of blood pressure cuff removal was due to diagnostic imaging (14 times), 28% due to equipment malfunction, and 35% (21 times) recorded as Other. Some comment fields were entered provided to describe “Other”, which included broken tubing (1 time), bloodwork (1 time), and connectivity (4 times).

SpO2 device. The SpO2 device was removed a total of 95 times. 40% (38 times) was attributed to device malfunction. There were 4 documented instances where measurements were not detected due to “cold fingers” indicating that the sensitivity of the devices was not able to detect oxygen saturation if the patient presented with poor peripheral perfusion. In addition, there were 25 documented occurrences that the device “fell off” the patient’s finger or wrist.

Respiratory device. The Respiratory pod was removed a total of 65 times. Over half of the respiratory device removal reasons (51%; 33 occurrences) related to equipment malfunction with the device falling off the patient. It was specifically documented 7 times that measurements were not recorded due to the battery requiring charging. The respiratory device did not record measurements 12 times because the patient was in diagnostic imaging (x-ray or echocardiogram).

eTrAC Profile

In 34 patients enrolled in the H2H program, 926 video calls were completed over the 30-day virtual monitoring program and a total of 748 assessments included patient's reflexive survey answers. Overall, program compliance was well adhered to with 44% of patients (n=15) had 100% video call compliance for the 30-day program and the mean number of video calls completed was 28 calls (M=28.1, SD=1.79) (table 10). Across all patients, the maximum number of requested days off from H2H nursing video call was three days, and two patients experienced one program day wherein the SVN and patient mutually agreed for a day off due to technical difficulties with video conferencing software. Patients scoring below 24/30 calls were related to postoperative or medical complications that hindered the patients unable to complete the video call.

Table 10. H2H Program Compliance

H2H Program Compliance	
Calls Completed (in days)	N=Participants (%)
30	15(44.1)
29	9(26.5)
28	1(2.9)
27	4(11.8)
26	2(5.9)
25	0(0.0)
24	1(2.9)
Below 24	2(5.9)
Surveys Completed (on days of the program)	N=participants (%)
0-5 assessment calls with surveys completed	1(2.9)
6-10 assessment calls with surveys completed	3(8.8)
11-15 assessment calls with surveys completed	4(11.8)
16-20 assessment calls with surveys completed	4(11.8)
21-25 assessment calls with surveys completed	6(17.6)
26-30 assessment calls with surveys completed	16(47.1)

Vital Sign Entry (> 1 complete set) per day	N= participants (%)
0-5 days with VS entry	0(0.0)
6-10 days with VS entry	1(2.9)
11-15 days with VS entry	0(0.0)
16-20 days with VS entry	0(0.0)
21-25 days with VS entry	2(5.9)
26-30 days with VS entry	31(91.2)

Calls with technical concerns (of 30-day program)	N=participants (%)
0-5 days with technical trouble	33(97.1)
6-10 days with technical trouble	0(0.0)
11-15 days with technical trouble	0(0.0)
16-20 days with technical trouble	1(2.9)
21-25 days with technical trouble	0(0.0)
26-30 days with technical trouble	0(0.0)

Vital sign entry compliance was well adhered to, with an overwhelming majority of patients [n=31, (91.2%)] entering at least one complete set of vital signs, 26 or more days, of the 30-day H2H program. Survey response compliance was less adhered to compared to vital sign entry with 47% of patients (n=16) responding to at least one survey, 26 or more days of the 30-day program (table 13). A total of 61 occurrences of technical difficulties were documented, with nearly all participants [n=33, (97.1%)] experiencing less than 5 days of technical trouble over their 30-day program. On average, each patient experienced 2 video calls of their 30 where they experienced technical difficulty [(i.e. unsuccessful video connection) (M=1.79, SD= 3.2, range 0-18)]. One outlier experienced majority of their video calls with technical difficulty (18/30 days), which was due geographic location of the patient and having poor cellular reception which impacted the video quality.

eTrAC Nursing Documentation

A team of five coders (CO, SP, AM, JC, JB) reviewed a total of 926 individual documentation records for the 34 patients enrolled in the eTrAC hospital-to-home program.

Themes. Using Kitson's Fundamentals of Care theory to lend structural guidance, the high-level themes that emerged were categorized as 1) Call description, 2) Psychosocial support, 3) Postoperative Pain, 4) Postoperative Education, 5) Pharmacologic, 6) Physical Assessment, 7) Escalation of Care. These high-level themes were then subcategorized as follows: 1) Call description detailed technical issues, call completed independently, call completed with family, survey completed. 2) Psychosocial support detailed reassurance and family/spousal support. 3) Postoperative pain detailed chest pain, acetaminophen recommendation, use of prescribed analgesic, contact physician, hot or cold compress, and repositioning. 4) Postoperative education detailed pharmacologic education, cardiac precautions, nutrition, anti-thrombolytic stockings, and program technology support. 5) Pharmacologic support was categorized into recommendation, follow-up, and error or correction and then specified by sleeping aid, cardiac (i.e., beta-blocker, ace-inhibitor), pain, antibiotics, diuretics, statin, and electrolyte replacement (i.e., potassium). 6) Physical assessment was grouped as fluid management, (subcategorized into leg elevation, anti-embolism stockings, foot pumping exercises, deep breathing and coughing, increasing fluid intake, decreasing fluid intake, and use of diuretics, wound management (subcategorized into dressing change, chest splinting, and signs and symptoms of infection to monitor for), sleep (sleep hygiene review, and use of

natural sleeping aid), and physical activity (subcategorized into encouraging rest, encouraging balance, and encouraging activity as tolerated). 7) Escalation of care was categorized as SVN contact outside of scheduled call, to physician, to pharmacy, and thrombosis services.

Frequencies. Of the 926 video calls documented, majority were completed solely between the patient and SVN, with only 29% of video calls including a family member on the call. In total, 88% of patients (30/34) completed at least 27 of 30 daily scheduled video calls. Table 14 outlines frequencies of occurrence across all coding themes. In total, there were 1865 records a corrective action or advisement provided by a member of the SVN team (See Figure 10). Over half [n=1,169 (62%)] of the corrective actions or nursing advisements documented were related to the Physical Assessment theme [n=718/1865 (38%)] and Pharmacologic care [n=451/1865 (24%)] theme. Postoperative education routinely was reinforced in the video calls, with 269 documented occurrences, mostly focusing on pharmacologic education (i.e., teaching what a medication is used for), and reinforcing postoperative surgical precautions (i.e., restricting to weight bearing to <10lbs).

pharmacologic. Commonly, SVNs followed up on medications already prescribed (i.e., "is the acetaminophen helping to manage your pain?") as opposed to recommended (i.e., "Try taking Tylenol every 4-6 hours to manage your pain"). Twenty-three documented occurrences of a medication dose adjustment or error was detected through this review. Amiodarone was prescribed two times and discontinued once by the surgical team because of symptomatic hypertension (trending consistently >150mmHg systolic),

and symptomatic bradycardia (trending heart rate consistently <50), respectively. Ticgregalor was held by one of the cardiac surgeons on one occurrence due to a patient experiencing persistent epistaxis. The SVN team noticed on two occurrences that furosemide was ordered on the discharge prescription without potassium supplementation; the SVNs informed the surgical team and the order was corrected. Beta-blockers (Metoprolol and Bisolprolol) were adjusted 17 times to titrate the dose primarily when the patient presented with trends of symptomatic hypertension or hypotension. Lastly, an analgesic error was detected by the SVN team on one occurrence where the wrong medication (e.g., Tylenol #3 instead of Hydromorphone) was dispensed by pharmacy; the SVN team detected the error through the H2H Day 3 medication reconciliation and brought to the attention of the surgical team.

Pain management. Majority of the pain management strategies documented by the SVNs were pharmacologic in nature (i.e., taking over the counter or prescribed analgesics) regularly following hospital discharge. On two occasions, it was documented that the SVN advised the participant to contact their physician for further pain management strategies (e.g., pain was unmanaged with acetaminophen, referral to chronic pain clinic for pre-existing pain condition). On few occasions, the SVN team recommends alternative management strategies including hot or cold compress and repositioning.

Physical health. Physical health assessments were the most commonly documented recommendations made by the SVN team. Edema was commonly reported to which leg elevation, diuretics, and TED stockings were advised or reviewed. Over two-thirds [67% (118/177)] of the total wound care advisements were in regard to reviewing

signs and symptoms of surgical site infection to monitor for. 30 occurrences of sleep hygiene review were documented, as some patients reported feeling distressed that following discharge, patients would sleep during the day and therefore be unable to achieve a restful sleep at night. SVNs provided advice to limit caffeine intake or avoid naps during the day.

Psychosocial support. There were 61 documented occurrences of psychosocial support found, primarily provided to patients directly [(85%) 52/61], but also included family members [(15%) 9/61]. SVNs commonly provided reassurance following hospital discharge and also documented when patients stated they were feeling "overwhelmed or anxious" with their recovery, reinforcing the SVN team was a support for them/their family during recovery.

Reassess vital signs/continue to monitor. The SVN team documented 107 times for patients to reassess their vitals based on a reading received that was out of parameter (e.g., SpO2 <92%) or suggested at the nurses' clinical judgement.

Escalation of care. In 34 patients, there were 131 documented occurrences of an SVN escalating care. 90% of the escalations were between the SVNs contacting patients outside of the scheduled call (e.g., vital signs received and called to re-assess) and escalating to a physician (e.g., resident or surgeon at HHS or family physician). SVNs also assisted with facilitating care between services such as pharmacy or the thrombosis service (e.g., contacting thrombosis service on behalf of patient as patient was unsure of Warfarin dose and the thrombosis team did not contact the patient).

In summary, the SVNs demonstrated through their daily documentation that patients require recovery support across a variety of health domains when at home. SVNs were not only providing corrective advice, such as addressing postoperative complications, but also preventatively managing care and encouraging health promotion techniques, such as deep breathing and coughing practices. Postoperative education was commonly required following discharge, regardless of receiving discharge teaching while in hospital as a standard practice. SVNs commonly escalated care, directing patients to seek further healthcare support as needed and involving the surgical team to intervene when necessary. Through confirming findings with the SVN team, the nurses reported that patients often consult the team for advice and rely on their support to guide their recovery.

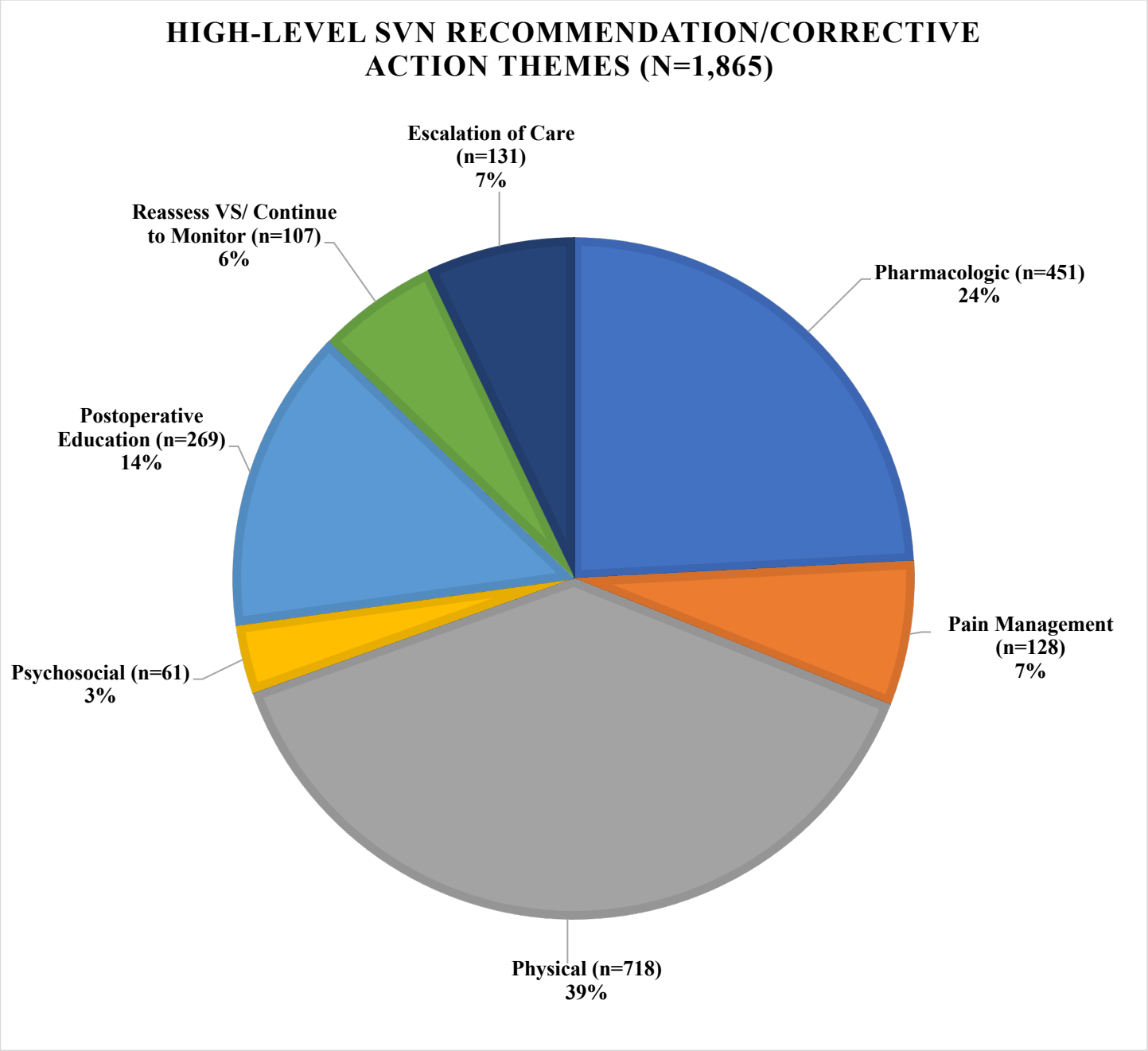
Table 11. Frequencies of eTrAC SVN Corrective Action/Recommendation

Frequencies of eTrAC SVN Corrective Action/Recommendation	
Theme	Count (frequency)
Call description	
Call completed independently	661
Call completed with family	265
Survey completed	748
Program technology support	429
Pharmacologic	451
Pharmacologic Recommendation	124
Medication Corrections	23
Medication Follow up	275

Sleeping aid	22
Cardiac	91
Pain	152
Antibiotics	51
Stool Softener	26
Diuretics	22
Iron Supplementation	42
Statin	4
Electrolyte replacement	12
Pain Management	128
Monitoring symptoms of chest pain	5
Acetaminophen recommendation	92
Use of prescribed analgesic	22
Contact physician	2
Hot or cold compress	4
Repositioning	3
Physical Health	718
Fluid Management	340
Leg elevation	156
Anti-embolism stockings	11
Foot pumping exercises	23
Deep breathing and coughing	88
Increasing fluid intake	45
Decreasing fluid intake	4
Diuretics	13
Wound Management	177
Dressing change	20

Topical antibiotic	18
Chest splinting	21
Signs and symptoms of infection to monitor for	118
Sleep	42
Sleep hygiene review	30
Sleep Aid (melatonin)	12
Physical Activity	159
Encouraging rest	66
Encouraging increased activity	45
Encouraging activity as tolerated	48
Psychosocial Support	61
Patient Support	52
Family Support	9
Postoperative Education	269
Pharmacologic education	131
Surgical precautions	79
Nutrition	40
Anti-thrombolytic stockings	19
Reassess Vital Signs/Continue to Monitor	107
Escalation of Care	131
SVN contact outside of scheduled call	51
Physician	68
Pharmacy	8
Thrombosis services	4
TOTAL:	1,865

Figure 10. SVN Recommendation/ Corrective Action Themes



CHAPTER V: DISCUSSION

This process monitoring evaluation offered insight into the initial deployment of the SMArTVIEW intervention in order to determine if SMArTVIEW was delivered as intended and understand how implementation was achieved, by way of two main objectives. First, this monitoring evaluation examined the implementation processes, mechanisms of impact, and context that influenced or facilitated the SMArTVIEW intervention. Second, this evaluation explored the SVNs' daily nursing practice within a RAM and virtual care intervention. In what follows, the findings of the process monitoring evaluation are discussed in relation to current, yet limited, available literature, and lessons learned through the evaluation are described with real-world application within the multisite RCT. This chapter will then relate to the SVN role and available evidence in telehomecare nursing, with attention drawn to the FoC theory, and finally conclude discussing limitations of this process monitoring evaluation.

Implementation

Following the MRC process evaluation framework, the first major objective was to examine implementation of the SMArTVIEW intervention by evaluating four elements –process, fidelity, dose, and reach. The following section will discuss the findings and practical implications relevant to each component, respectively.

Process. When examining how program delivery is reached and how the SVNs operationalize their roles and associated responsibilities, the daily activity logs were reviewed and thematized. The SVNs followed study protocol and never reported major deviations in terms of routine from protocol. SVNs did report that they required more

than one nurse working per day, in order to support both the Guardian and H2H programs. In order to strategize and time-manage to meet role responsibilities, the SVNs began their shift at 0800 instead of 0700, in order to support ward staff at change of shift. They also allocated the first hour at the beginning and ending of each shift to support ward nurses with Guardian training, patient onboarding, and troubleshooting. Therefore, to meet ward demands, patient calls were scheduled between the hours of 0900 and 1900, in half-hour increments. In terms of meeting role responsibilities, the SVN teaching documentation demonstrated that every patient enrolled in the H2H program received training on the equipment, with 100% completion in all patient teaching logs.

Some process evaluations have focused on implementation change, namely in mental health (Gask et al., 2010), maternal and child health (Hind et al., 2017; Hooker et al., 2015, 2016), self-management (Kennedy et al., 2014), however no process evaluations in the context of surgical postoperative care were found. Process evaluations are specific to the respective intervention in which they are examining, in order to optimize workflows, identify roles and responsibilities, and uncover facilitators and barriers to implementation, all dependent on the unique context, environment, and goals identified for successful deployment. For example, Gask et al. (2010), found in their work that a key implementation strategy needed for successful intervention deployment included engaging team members and patients in a structured manner throughout the intervention as well as a need for acquisition of skills related for phone interactions. Kennedy et al, (2014) uncovered why self-management support was not embedded in primary care, as originally intended by the researchers. This group identified that while

some implementation aspects worked, (e.g., healthcare provider training was perceived as valuable), challenges associated with organizational changes, loss of staff, and shifting priorities led to implementation failure, which was a beneficial learning to uncover within the beginning of the larger trial. Like in SMArTVIEW when it was identified that the SVN start time required modification to optimize workflow and ward support, implementation strengths and challenges are unique to the context in which they are embedded and when examining implementation, it is critical to closely examine the barriers and facilitators that impact intervention deployment.

Fidelity. In order to understand how closely the SMArTVIEW intervention aligned with protocol, the daily activity reports, Guardian Thoughtwire reports, Guardian Device Compliance reports and Patient Teaching Logs were examined. Based on all available documentation during this study period, no major events occurred that deterred the execution of the intervention.

The Guardian Device Reports indicated that within the intervention group, 195 notifications were generated calling attention back to the patient. Of the notifications generated, 37.9% (n=74) generated a Pre-HEWS of 3, 21.0% (n=41) generated a Pre-HEWS of 4, indicating that majority of system generated notifications, 58.9% (n=115) were within mild-moderate acuity level. In a validation study, Fernando et al (2019) published retrospectively analyzed prospective data collected using the HEWS scoring system and found that in 5491 adult patients, 53% of the HEWS scores (n= 2913) were <5 (Fernando et al., 2019). Further examination will be required in the full trial to confirm associations between the Pre-HEWS and HEWS scores, examining accuracy, sensitivity

and specificity, however, preliminary data suggest the Pre-HEWS are alerting ward staff to true indication of deterioration. Nonetheless, the results of these data demonstrate that notifications are being generated and attention is being drawn back to the bedside for further assessment.

The most common protocol deviation related to the in-hospital Guardian monitoring equipment compliance. Patients commonly removed equipment or the equipment failed to capture continuous data, which therefore compromised the reliability of the continuous monitoring devices and response of a healthcare provider, should the patient show indication of physiologic deterioration. This problem is not uncommon in the burgeoning field of RAM. In a clinical-validation study examining the use of multiple wearable sensors, technical performance of heart rate and respiratory measurements, captured in hours, and similarly noted that device connectivity emerged as a concern when implementing RAM interventions. This group noted connectivity or data loss for the heart rate device (range 47-83 hours) and respiration rate (range 83-250 hours), wherein no data was captured; this data translated to the wireless systems providing data for 73% and 62% of the time, respectively. Similar to the Guardian device removal, wireless monitoring technologies are limited by connectivity failure or patients' removing devices.

Apart from addressing and overcoming the challenge of impacted device capture, the intervention was closely aligned to protocol, which in part was achieved through a comprehensive user-testing study (McGillion et al., 2020). The purpose of completing a user-testing study of the SMArTVIEW trial was to examine both patient and nurse

performance in regard to engaging with the various intervention components as well as gain an understanding of RAM and virtual care technologies, in order to inform trial processes prior to intervention deployment. In doing so, it also engaged frontline staff and provided an opportunity to integrate ward staff and hospital leadership into the development of the protocol in attempt to optimize intervention delivery.

Dose. All patients were offered the entirety of the SMArTVIEW intervention however only 68% of the intervention patients completed the entirety of the program. There were no concerns regarding device availability as all patients were assigned both in-hospital and H2H equipment. In terms of receiving SMArTVIEW program training, all H2H patients were trained and educated by the SVN prior to discharge. In addition, SVN support was provided consistently, with no staffing shortages, as SVNs were strategically staffed to have 2 nurses present at all times for facilitate the Guardian monitoring process alongside bedside staff and deploy the H2H intervention.

In regard to the quantity of the intervention being delivered, one of the commonly reported challenges related to connectivity. The execution of SMArTVIEW intervention was dependent on reliable connectivity and as described in the Daily Activity Reports, connectivity failed 19 times in hospital and 10 times at home. In other studies that utilized remote postoperative monitoring care, poor connectivity coverage (i.e., cellular reception) warranted exclusion criteria. For example, McGillicuddy excluded 12.2% of the approached patients who agreed to participate in their remote medication monitoring program due to poor connectivity in their homes (McGillicuddy et al., 2013). SMArTVIEW utilizes cellular reception to facilitate the H2H program and when faced

with poor cellular reception, the quality of the H2H program was affected as some calls could not be completed and had to be completed via telephone. To address this problem, Guardian devices were routinely checked for connectivity signal, ward staff were taught how to troubleshoot all Guardian equipment, and postal codes were checked for strong cellular reception for those completing the H2H program.

Reach. Of the 228 patients undergoing cardiac or major vascular surgery during this study time period, only 110 proceeded to randomization. The main reasons for patients declining to participate was due to refusal; both patient and families commonly reported feeling overwhelmed with not only the impending surgical procedure but then felt the intervention would be too intensive to balance with postoperative recovery. In addition, as previously mentioned, patients who were enrolled in the PREVENA trial, as previously mentioned, were applied two to three vac portable vac dressings which would have led patients to wearing up to six devices, in addition to a telemetry pack. Therefore, those who enrolled in PREVENA were not approached to participate in the SMArTVIEW intervention.

Of the intervention patients, 50 patients began in the program, however, 15 patients withdrew during the in-hospital phase and one patient deteriorated excluding from enrolment into the H2H program. The program was not modified to accommodate those who withdrew from the in-hospital program. Strategies to improve withdrawal rates were addressed in the Daily Activity Reports, wherein study leadership made provisions to show potential participants the devices that would be worn for the duration of the hospitalization. In addition, it was made explicitly clear at the time of consent that

patients would not be sent home with continuous monitoring devices, but rather remote automated devices. Pamphlets with images of the SMArTVIEW equipment were given at the time of consent so prospective participants could visualize all equipment, which provided a better sense of the involvedness of the program. These modifications provided further clarity to the patients and ensured full understanding of all components of the intervention.

Rate limiting factors of SMArTVIEW. Two rate limiting factors were identified in the SMArTVIEW intervention that dictated the number of patients enrolled per week. The first factor was the ability of the SVNs to facilitate all aspects of the intervention. SVNs communicated with the recruitment team in order to determine the number of patients that could feasibly be managed in the H2H program as each H2H patient required at least 30 minutes of SVN uninterrupted assessment time, per day. The second rate-limiting factor was equipment availability. There were 30 sets of in-hospital and H2H equipment available for patient use and it was imperative that a complete H2H kit be available to intervention patients. If a component of a kit (e.g., tablet) was malfunctioning or required updating, the kit would not be designated as 'ready for patient use' and limited the number of complete kits available.

Implementation Summary. In summary, digital health interventions using RAM and virtual care are more commonly being integrated into healthcare systems but—as observed in SMArTVIEW—not without implementation challenges. The most prominent factors influencing the implementation of SMArTVIEW intervention included the adherence of Guardian equipment; removing in-hospital monitoring equipment devices

for extended periods of time mostly due to connectivity or patient request, loss of connectivity of both Guardian and H2H devices, daily role adaptation of the SVN workflow and adequate staffing to optimize workflow efficiency, and support both the in-hospital and H2H program. Some studies have reported implementation issues using RAM devices within trials; for example, Harsha et al., (2019) examined the implementation challenges within an RCT (VIGILANCE Study) that used continuous pulse oximetry and a wireless clinician notification system on 1030 postsurgical patients. Similarly, as found in the implementation of SMArTVIEW, this study identified the most common challenges related to RAM program implementation were categorized by 1) people (nursing workflow, patient withdrawal), 2) organizational (connectivity issues, monitoring technology issues), and 3) implementation (lack of prior testing, lack of stakeholder involvement).

When considering next steps to facilitate the remainder of the SMArTVIEW program, research teams need to maintain strong interprofessional relationships through continued communications (i.e., continue sending daily reports and updates to team members), continue to partner with intervention champions to support the program (e.g., physicians to 'check-in' with patients to ensure patients feel supported and satisfied with the program), ensure effective communication with all teams to address connectivity challenges (e.g., HITS, Thoughtwire) as well as train staff to monitor for gaps in device connectivity, and lastly, ensure ongoing engagement and solicitation of feedback from all parties interacting with the intervention (e.g., frontline nursing staff, SVNs, hospital

leadership, industry partners), in order to improve the implementation process of SMArTVIEW.

Mechanisms of Impact

Following the MRC process evaluation framework, the second objective within the framework was to examine and identify the mechanisms of impact within the SMArTVIEW intervention by way of the participant's responses and interaction with the intervention, any mediators, and unexpected pathways or consequences associated with intervention deployment.

Participants' responses and interactions with intervention. Nurses and patients were consistently engaged in the SMArTVIEW intervention. Of the 195 notifications sent to the handheld devices indicating possible deterioration, 174 notifications were acknowledged by the bedside nurse, indicating (regardless of response time) that the notifications being generated were being recognized by nursing staff. On average, response time to acknowledge a notification was 15 minutes. Key challenges with frontline nursing staff responding to notifications related to the practical challenges of carrying the handheld device at all times as well as ensuring the volume on the device was of high enough volume to be audible to the ward staff. The devices would commonly be left at the nursing station, leaving the charge nurse to respond and contact the most responsible nurse to respond, which contributed to the delay in response time. As Harsha et al. (2019) reported when identifying deployment issues, key stakeholders such as nursing staff experiencing a work culture shift, (e.g., using handheld devices for a new purpose) receive adequate support from the research/implementation team. In addition,

considerations related to efficiency and care coordination are critical to consider in order to ensure that interventions do not deter from patient care or overwhelm staff, as success stems from working *with people* as opposed to *doing to* people (Harsha et al., 2019). A solution for the SMArTVIEW intervention included the SVNs assisting with daily reminders to keep handhelds on the most responsible nurse at all time and demonstrating how to transfer notifications to a partner nurse if the primary nurse is not available. In addition, the SVN team had an open-door policy, inviting ward staff to approach the SVN team at any time for question clarification and further support.

Of the 34 patients who continued in the H2H program, 91% of patients completed ≥26/30 video calls, and 91% completed vital signs ≥26/30 days, which indicated majority of were highly engaged in the program and completing the program to its' entirety. Based on the overall adherence to the SMArTVIEW intervention, some assumptions can be made that (as previously mentioned) retaining patients in-hospital was a challenge, however, once patients transitioned to the H2H program, patients were highly engaged in the program and committed to monitoring their recovery progress. In addition, all of the kits that were used in the H2H program were returned undamaged, and all patients were prompt with returning kits upon study completion, as directed by the SVN team.

In the literature, engagement in RAM and virtual care programs is related to the perceived value of the intervention (Radhakrishnan et al., 2016). Some in-hospital monitoring studies for example, Subbe et al (2017) used the Philips Guardian System in a prospective before-and-after study and indicated no concern with feasibility of device application or discussion of patient withdrawal due to the RAM devices. The main

findings demonstrated clinically meaningful results between groups with increase of the rapid response team notifications [405 to 524 (p=0.001)] warranting clinical intervention (e.g., fluid therapy), and resulting in decreased intensive care unit admission and overall mortality (p=0.004). Based on their results, patients were engaged in the RAM intervention, otherwise notifications would not have been generated. Conversely, Harsha et al. (2019) noted that common reasons for withdrawal in RAM programs is often due to the technology itself (e.g., uncomfortable equipment, noises, false alarms). In SMArTVIEW, patients commonly remove equipment, fully aware of the implications that no notifications would be generated should the patient show signs of deterioration. Future RAM in-hospital technology is promising with less invasive market ready devices emerging (McGillion et al., 2018), in hopes to mediate this common barrier. With less invasive, bothersome wearable devices, the future of RAM is promising to transform how vital sign and physical assessments are conducted.

While some challenges persist with in-hospital RAM, it appears through the literature that when patients are engaged in at-home programs, such as telehomecare, compliance is rarely reported as a concern. Qualitative interviews on patient experience with RAM and virtual care report that patients perceive health monitoring as important, and therefore are highly engaged in participating in such programs, particularly in the chronic condition populations (Clarke et al., 2013; Huang et al., 2019; Radhakrishnan et al., 2016). In a pilot study examining telehomecare support for patients with multiple chronic conditions, patients were “overwhelmingly positive towards home health monitoring” (pg. 12) with some patients engaged for up to 339 days (Libby et al., 2008).

Only 3/22 participants (13.6%) requesting to have systems removed because they did not use them or found them to be inconvenient (Liddy et al., 2008). Another example, within the Ontario Telehealth Network (OTN)'s six-month telehomecare program for patients with congestive heart failure and chronic obstructive pulmonary disease (COPD) (Ontario Telehealth Network (OTN), n.d.), found through a qualitative analysis exploring facilitators and barriers to their at-home monitoring program that the patients' motivation to participate in their care was a key facilitator for continued involvement with the program and related activities (Hunting et al., 2015). When considering mechanisms in the context of RAM, program compliance is influenced by the devices themselves and has shown to be an area of improvement for future advancements in the field.

Mediators. A systematic review conducted by Radhakrishnan, Xie, Berkley, and Kim (2016) addressed that interprofessional communication is vitally important to the success of complex digital health solutions, such as telehomecare. Ensuring all healthcare providers are informed of patient care especially in times of responding to abnormal patient data requires a method of communication that all team members agree on (Lamothe, Fortin, Labbé, Gagnon, & Messikh, 2006; Radhakrishnan et al., 2016). When considering specific aspects of the SMArTVIEW intervention that influenced its' successful deployment, the Daily Reports indicated a need for standardized communication among SVNs and staff. SVNs developed a standardized tool to communicate with research leads (Blinded Daily Report), and a tool to communicate between SVNs regarding patient care as a handover tool that excluded research leadership due to patient identifying information. In addition, the SVN team developed a

'troubleshooting' binder that compiled troubleshooting techniques for Guardian and H2H programs respectively, and it was essential that in times when connectivity issues were not resolved, contacting the most appropriate resource team (i.e., Philips, Thoughtwire) was essential in ensuring continuity of SMArTVIEW intervention delivery.

Unforeseen factors. Unforeseen factors that may have influenced implementation included the need to facilitate a discharge transition program in the H2H portion of the intervention. Patients expressed concern at the end of the 30-day program that they were without recovery support and ending without transition was abrupt. Recognizing this need, the SVNs strategized on day 25, 27, and 29, reminders were given to the patient regarding the discharge process and how many days were left in their program. On the last video call assessment, the SVNs reviewed how to return the equipment and guidance on who to contact should concerns arise beyond the 30 days. This transition model provided guidance and structure for patients to ease the anxiety of ending the program.

Mechanism of impact summary. In summary, challenges associated with the mechanisms of impact in the SMArTVIEW trial affect both nurses and patients. Inferences were made on the engagement of nurses and patients based on the interactions associated with both the in-hospital and H2H program. Communication tools to facilitate both interprofessional (between the research, HHS, and SVN teams) and intraprofessional (between SVNs) were needed to facilitate a standardized approach to care and ensure all team members were kept informed on study activities. It was unforeseen that a discharge plan would be required to transition patients from the H2H program to independently managing their postoperative care. Following trial completion, there will be a sub-study

of SMArTVIEW trial that examines the patient and nurse experience with considerations made from a social justice perspective.

Context

The final component of the MRC framework focuses on Context; what barriers and facilitators external to the SMArTVIEW intervention influenced implementation**.**

Barriers and facilitators. Within the study period, minimal external contextual factors influenced implementation as determined through analysis of the Daily Activity reports and Guardian Device Reports. Similarly found to Harsha et al (2019), similar contextual factors included the 'People' that served as both barriers and facilitators to program deployment (Harsha et al., 2019). In terms of facilitators, the surgical team supported the initiative by helping to facilitate both in-hospital and H2H programs. For example, when an SVN felt the need to escalate care, the HHS surgical team (senior resident) was often willing to review the patient case and make adjustments to the plan of care, as required (i.e., medication dose adjustment) in collaboration with the SVNs. In addition, positive culture changes on the ward were facilitated by nurses who were self-directed "Champions of SMArTVIEW", who acted as supports for nurses learning the system when SVNs were not available during the day or during night shift. Opposingly, a barrier to program deployment pertained to some frontline ward staff unwilling to learn the Guardian system. In order to facilitate change management, SVNs dedicated one-on-one teaching sessions with every nurse and allowed the nurses to practice with the Guardian equipment prior to having to apply the devices to an intervention patient. The clinical manager was also consulted to make the integration of the SMArTVIEW

technologies a part of the staff performance review. Lastly, ‘reminder posters’ were placed around the surgical ward, providing a visual prompt of the specific fields required to be entered on both the bedside MP5 Spotcheck monitor and handheld device, in order to comply with hospital documentation requirements.

Context Summary. The ‘people’ external to the SMArTVIEW intervention were identified to both facilitate and challenge the integration and deployment of the SMArTVIEW intervention. A challenge in identifying external barriers and facilitators is the limitation of available documentation to address this question; the Daily Activity reports and Guardian Device Reports were completed by the SVN team and may have not accurately depicted barriers and facilitators as a part of their routine documentation. Moving forward, it is essential the SVN team communicate with research leadership any external factors that influence SMArTVIEW in order to promote certain facilitators and address any barriers.

SMArTVIEW Nurse Role

Lastly, the role of the SVN was examined using Kitson’s FoC theory. The role of the SVN is specifically constructed to meet the operational needs of the SMArTVIEW intervention, supporting both in-hospital continuous postoperative monitoring and virtual H2H postoperative care, while placing patients at the centre of care.

Virtual Care Nursing. The role of the SVN shares responsibilities between patient monitoring, equipment and technology management, patient teaching and education, and administrative duties. This role promotes complex practice and leadership skills wherein the team of registered nurses practice an extended scope of practice, in

accordance with the CNO's "Telepractice" guideline (*CNO*, 2017), that guides nurses delivering care using virtual methods.

Similar advance nursing roles have been established in the telehomecare field; some of which are facilitated by a nurse practitioner. Liddy et al (2008) interviewed nurse practitioners that allocated a portion—approximately 18% —of their patient load to telehomecare and found that the nurse practitioners found virtual visits useful, which provided the opportunity for health-related decisions to be made in a more-timely fashion (Liddy et al., 2008). Similar findings were reported from Hunting et al (2015), who conducted semi-structured interviews and ethnographic observations with program nurses as well as a document review (Hunting et al., 2015). Hunting et al., (2015) concluded that the uniqueness involving telehomecare nurses involves large amounts of data management, close patient monitoring, and supportive coaching for patients, which was enjoyed by those enacting the role. In another telehomecare study examining the role of remote nursing care activities, in 10 patient visits (observations), 1183 tasks were coded in three categories: "data management (290 tasks), people (managing care and patient monitoring) (559 tasks), and technology support (coded as 'things') (334 tasks)" (Dansky, Yantm Jenkins, & Dellasega, 2003). Based on the available literature, nurses both in the designation of Registered Nurse or advanced nurse role (e.g., Nurse Practitioners) have been strong advocates and leaders in directing virtual care for patients at home. Providing the opportunity for ward nurses within HHS to participate in an innovative trial, such as SMArTVIEW, by molding the SVN role has contributed to the successful integration of the SMArTVIEW intervention within Cardiac and Vascular surgical program.

SVN Role. When developing the SVN role, it was important to establish the nurse-patient relationship while in hospital. As the core of the FOC theory, this provided an opportunity for patients and family to meet the SVN team through the equipment teaching session to establish trust, focus on the intent and plan of the intervention, and prepare for the virtual care model when patients were to be discharged home. The purpose of establishing this relationship early was to form trust, which then transpired into a sense of security for patients entrusting their care with the SVN team. In available telehomecare literature, patients generally perceive an increase sense of reassurance and security when provided care on a continual basis (Fairbrother et al. 2013; Gale and Sultan 2013; Hardisty et al. 2011). By establishing the relationship, the second dimension surrounding the integration of care, relational, psychosocial, and physical components could be established.

The second dimension of the FOC theory focuses on how the patient's individual care needs are met. The SVN virtual assessment was standardized to address both the physical and psychosocial care needs. As the SMArTVIEW intervention progressed, it was important to standardize specific days to address particular health-coaching topics. On Day 3,10,17,24, and 30 of the H2H program, thorough medication reviews were completed as, unknowing to the research team, medication errors and changes frequently arose. Standardizing the approach provided consistency in SVN care and ensured medication safety. In addition, social isolation became a prominent theme, particularly for patients who often completed calls without the presence of family. The SVNs developed a script on how to ask about their psychosocial health, inquiring how they felt supported

and if they had resources at home (e.g., friends and family). This process developed over the course of the first 34 H2H patients, as it was a common theme that surfaced, initially unbeknown to the study leadership.

When considering the balance between dependence and independence in integration of care, some literature has shown that some clinicians express concern on patients' reliance on clinicians when enrolled in daily telehomecare programs (Radhakrishnan et al., 2016) while, as previously mentioned, patients often develop a sense of security and are content to rely on a trained healthcare provider. With over 1800 recommendations and interventions initiated or advised by the SVN team, careful consideration towards promoting patients to be autonomous active managers in their postoperative care while recognizing that patients desire dependence on a professional (i.e., SVN) who possesses the knowledge, skill, and judgement to make advisements and recommendations. Further considerations could be focused on patient teaching and training patients on recovery processes. To this end, SMArTVIEW-to-GO has been conceptualized as a continuation of the SMArTVIEW intervention, wherein patients use commercially available tools (e.g., personal BP measurement device) with self-management, education, and active patient participation to empower patients to facilitate their own care beyond the 30-day program. SMArTVIEW-to-GO is currently in the preliminary planning and development stage, aiming to be deployed the latter of 2020.

The last and outermost component of this care model focuses on system level support. Implementing and integrating interventions into clinical practice beyond the scope of an RCT has been a challenge documented for decades, with sole research foci

geared towards implementation sciences (Rapport et al., 2018). Challenges related to context of prospect clinical environments feasibly adopting the intervention, hospital leadership willing to support the intervention and integrate into routine practice (introducing culture change), and financial support and sustainability are all key considerations that the FoC theory outline (Kitson, 2018). Gitlan and Leff (2016) report contextual fit, referring to the match between intervention strategies and procedures with the alignment to the values, skills, and resources available in a setting, is a fundamental assessment that should be evaluated to establish if there is adequate fit. This fit assessment was established between site lead investigators in HHS and LHCH to ensure that all SMArTVIEW processes could be replicated. In addition, the leadership at LHCH demonstrated interest and value in the trial, with leadership supporting all components of the intervention, similarly to HHS. The leadership involved in SMArTVIEW have had invested interest in the program, recognizing the clinical need and therefore, the intervention has benefited from such strong institutional, research, and clinical support.

A last key context care consideration regarding the policy and system level surrounds the financial and resource support to sustain an intervention. While making this trial possible, it is essential to recognize that beyond the financial and in-kind support of grants and awards, to sustainably implement an intervention as complex as SMArTVIEW, careful consideration to intervention uptake beyond the scope of a trial should be considered. A detailed economic evaluation will be conducted upon trial completion to examine the health service utilization-related costs as well as patient-level cost recovery. This will provide tangible data to present to institutional leadership for

future goals of implementing the intervention more widely across varying sites and patient populations.

In summary, the FoC theory provided a pragmatic tool to consider all aspects of the SMArTVIEW intervention deployment; considerations spanned from attention to the intimate relationships built between nurse and patient wherein the core values of the commitment to care were identified, expanding to the integration of care that focused on the nurse co-ordination and patient experience of the intervention, with final considerations to the context of care, which identified the core components between policy and system level considerations that are needed in order to facilitate an intervention successfully. The FoC theory highlighted the importance of a holistic perspective and drew attention to micro to macro needs (in nursing and beyond) of the SMArTVIEW intervention deployment by virtue of the in-study process monitoring evaluation.

Limitations

A number of limitations should be addressed that influenced the findings of this in-study process monitoring evaluation. First, the MRC framework for process monitoring evaluation of a complex intervention, published in 2008 and updated in 2015, is a relatively new framework that suggests that rather than effectiveness, the emphasis is placed on understanding *how* complex interventions are successfully implemented (Craig et al., 2008; Richards & Hallberg, 2015). While this, in-of-itself, is not necessarily limiting, the emphasis on understanding per se allows for the interpretation and subjectivity of the investigator conducting the evaluation. It would therefore have been

ideal to have two investigators conduct all aspects of this process evaluation and cross-validate their findings. Instead, inter-rater comparisons (and coding discrepancies) were addressed only with respect to SVN virtual care practice elements. The remainder of the evaluation was conducted by a single investigator, in consultation with trial staff.

Second, this evaluation only pertained to cardiac surgical patients, as no vascular patients were recruited during the study period; many vascular surgical procedures within HHS have a length of stay of <48 hours and patients who undergo amputation are repatriated to a rehabilitation facility. Since the time of this evaluation, measures have been taken to improve the recruitment of patients undergoing vascular surgery. The fundaments of SVN virtual care practice in supporting the recovery of these patients is assumed to be similar to what was found in this evaluation, but this is yet to be confirmed.

Third, all SVN care examined related to patients who were local to the Hamilton region. This is reflective of the early days of intervention deployment, before the logistics and costs associated with long-distance video conferencing were addressed. Hence, aspects of the SVNs' practice, which pertain to patients who live as far away as Thunder Bay, ON, may differ from what was found in this evaluation. For example, practical nursing recommendations related to patient access of community resources during recovery will differ in northern rural communities, compared to the Hamilton-Wentworth region. Moreover, the technical aspects of the SVN role, related to technical trouble shooting will differ with respect to signal interference and cellular infrastructure and

reception. These considerations will be evaluated as process monitoring continues during the SMArTVIEW trial.

Fourth, the patient teaching logs were evaluated to have 100% compliance across all patients, as indicated by the SVN documentation; further exploration is needed into the patient teaching experience and in-depth investigation of any challenges patients had with respect to learning how to use the equipment is needed. This gap provides an opportunity to revisit documentation for patient teaching records and expand data collection in this respect. Finally, this process evaluation is subject to reporting bias as this evaluation relies on the documentation, charting, reporting, and inter and intra team communications that have been documented, only. It is likely that not all challenges were documented and reported to study leadership if a resolution was achieved in a timely manner, therefore underreporting process concerns, such as connectivity issues.

CHAPTER VI: CONCLUSION

Application of results

Upon site initiation the secondary study site at LHCH, the SMArTVIEW lead investigator (M McGillion) and SVN leaders (C Ouellette, L Femiak) facilitated site initiation remotely, and then engaged in an in-person training course for local SVNs in Liverpool, one week into site recruitment. This training course was prepared for the UK SVNs to reinforce intervention workflows, teach role expectations, monitor data management techniques, provide communication tools, and guide patient teaching techniques to ensure all technology implementation and virtual nursing care practices were standardized across both sites. UK study leadership and SVNs participated in an in-person meeting to discuss study progress, as well as strengths and barriers experiences to date. Team members (C Ouellette, L Femiak) reviewed through presentation format study protocols and intervention objectives. Following training, a half-day observation session was completed to ensure the UK SVNs understood and applied all learnings to the intervention deployment. A complete manual of operations, including the results of this evaluation were included and provided to the UK team for reference. Upon completion of the two-day training course, all three UK SVNs were prepared to deploy the SMArTVIEW intervention in the same method as the lead site at HHS. To date, the implantation of SMArTVIEW at LHCH has been a successful deployment, executing all components of the intervention as well as the SVN role.

Future directions and implications for RAM and Virtual Care Nursing

Since the initiation of SMArTVIEW, two key opportunities have arisen, related to advancing the agenda for RAM and virtual care nursing. First, digital health has gained momentum as key indicator for shaping healthcare re-design in Ontario, with specific attention drawn to the development of innovating and adopting roles – like the SVN role – to improve access to and delivery of health care to all. The Ministry of Health and Long-Term Care's Chief Nursing Officer, Dr. M Acorn, attended a presentation at HHS (delivered by C Ouellette, M McGillion), reviewing the role of the SVN and related RAM and virtual care models, with respect to integration of these models within the Hamilton Ontario Health Team. In this presentation, our team argued that registered nurses have the potential to lead innovation and healthcare system change when empowered and well-positioned to do so, as demonstrated by the role of the SVN. The Chief Nursing Officer recognized the importance of impowering nurses to enact roles, such as the SVN, and expressed interest in collaborating with future research and clinical endeavours. Progress reports to Dr. Acorn are ongoing, at her bequest; a final debriefing with her office will take place upon the conclusion of the SMArTVIEW trial. Particular focus will be given to the application of this thesis work as a framework for guiding nursing interventions enacted through digital and virtual means.

This process monitoring evaluation has demonstrated that the SVNs engaged in postoperative RAM and related technical trouble shooting, were able to support patient recovery by virtual means. Moreover, the SVN role is an engaging nursing role, as indicated by onboarding and retention of 12 SVNs (n=9 Canadian, n=3 UK), who have become recognized as leaders in caring for cardiac surgical patients beyond hospital

'walls'. The potential of the SVN role extends beyond cardiac surgical populations; this novel nursing role and related workflows are designed as a 'prototype' for RAM and hospital-to-home care, across divergent patient populations.

To this end, the SVN role is being adapted for application to the high-risk oncology populations at Juravinski Hospital, HHS. Funding was secured from Roche in order to establish "SMArTVIEW – Oncology". Our team will be supporting the oncology program to establish the role of the SVN at the JCC, and the results of this process monitoring evaluation will lend guidance to the design and implementation of SMArTVIEW in this setting; bi-weekly planning meetings are commencing in February 2020.

Conclusion

In conclusion, this process monitoring evaluation of the SMArTVIEW trial was an informative exercise to assess intervention process and implementation, as well as to review the daily practice of the SVNs. Through this work, key aspects of virtual nursing care have been identified, related to meeting the everyday physical, psychosocial, and relational needs of patients who are recovering from cardiac surgery. Based on the results of this evaluation, the processes required to execute SMArTVIEW have been optimized and streamlined to meet the needs of patients, ward nurses, hospital leadership, study leadership, and SVNs in both Canada and the United Kingdom. Patients were actively engaged, completing the program expectations according to protocol, with no major deviations compromising the validity of the randomized controlled trial, to date. Minor adjustments, based on the results of this evaluation, were integrated and implemented,

such as 1) communication methods between team members and team leadership were standardized, and 2) the daily workflow practices both in-hospital and during H2H virtual nursing care were refined. These adjustments have since been implemented at both study sites. Next steps include consultation with the health informatics team at HHS to discuss the possibility of developing and integrating machine learning algorithms to analyze SVN documentation for the total sample (n=800). At present, the HHS team will recruit approximately 200 more patients and the LHCH team will recruit 150 more patients to reach study completion. Study leadership have agreed that future large-scale trials with multisite SMArTVIEW deployments will utilize the process monitoring approach, established through this evaluation in the early days of deployment in order to fully understand and optimize workflows. The SMArTVIEW trial will address questions about clinical effectiveness of the intervention and the SVN role.

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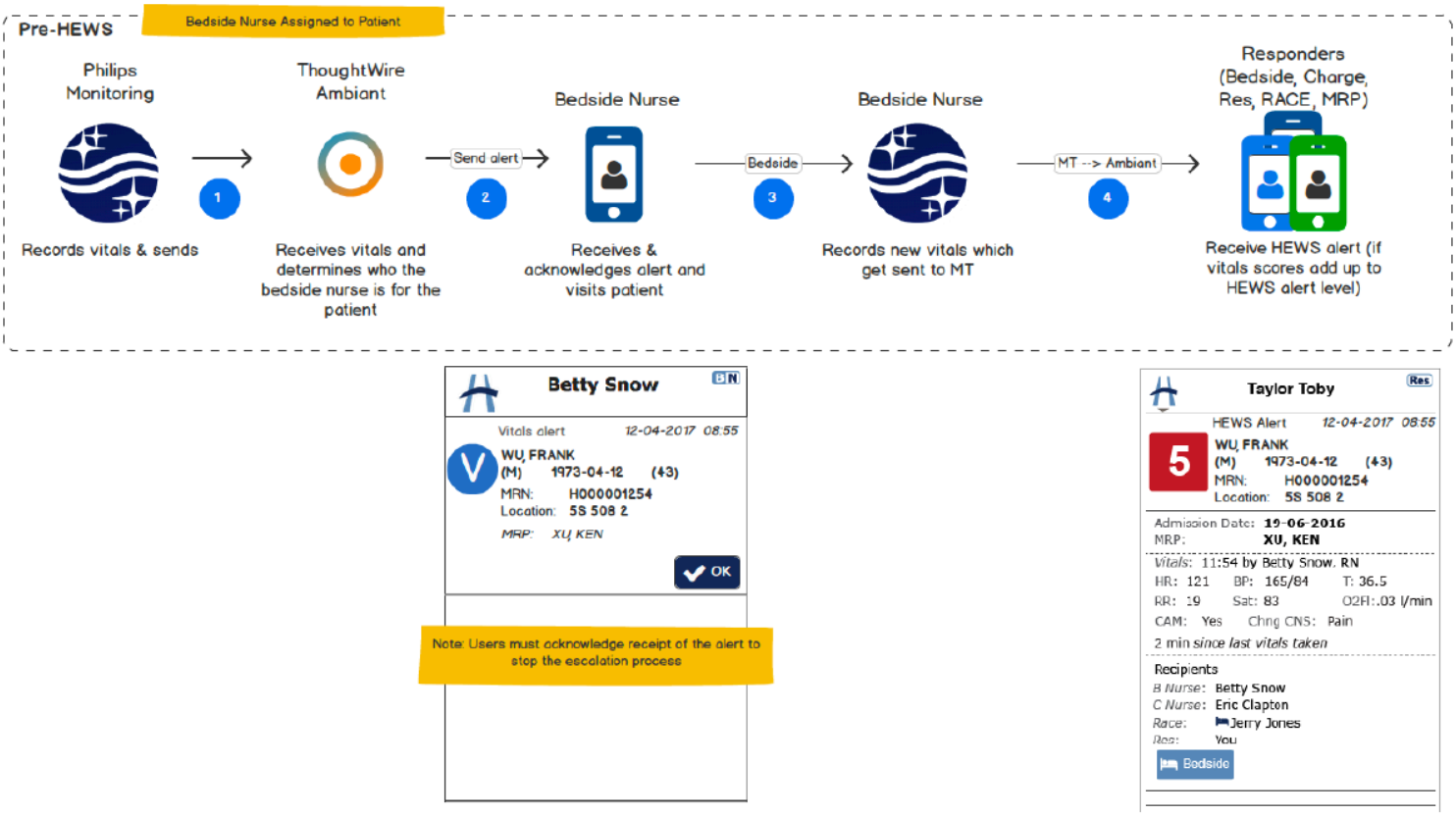
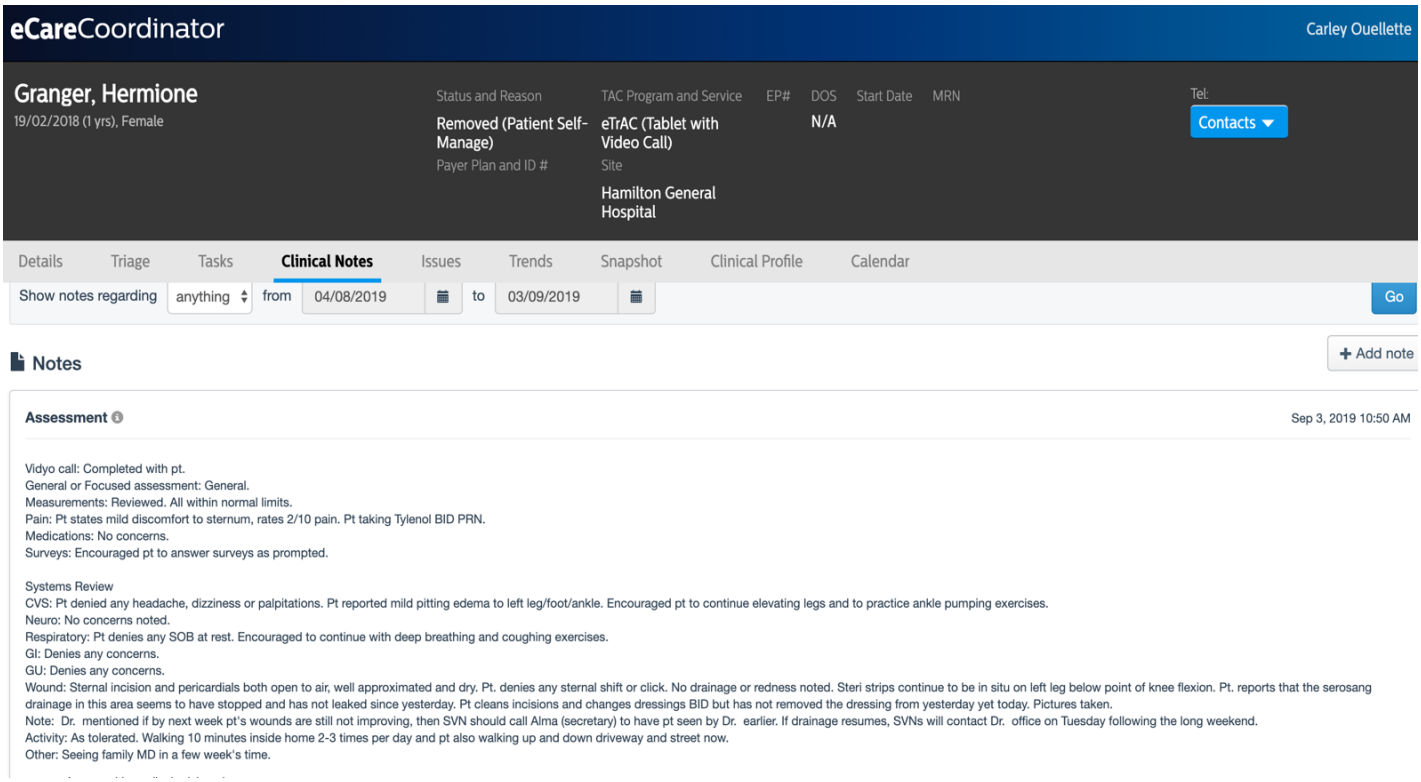
APPENDICES

Appendix A: Guardian Pathway



Appendix B: Example of eCC Patient Profile



Appendix C: Patient Teaching Checklist

THE SMArTVIEW CoVeRed

Patient Teaching Checklist – eTrAC Hospital-to-Home Equipment

Participant ID: _____ Completed by: _____ Date completed: _____

Task	Check & Initial
Explain the purpose of the eTrAC monitoring equipment and the importance of daily home monitoring	☐
Explain the system is for collection of information ONLY and does not replace or substitute a 911 emergency call	☐
Explain the monitoring equipment is to be used only by the participants enrolled in the SMArTVIEW program. Other members of the household should not wear or use the devices as this information will be recorded.	☐
Teach how to apply and use the monitoring equipment; provide a demonstration and have patient try equipment while present to support as need	☐
Explain importance of measuring vital signs at the assigned time each day and that a nurse will follow up on results daily or as needed	☐
Review that surveys are reflective of condition/surgery and reflexive surveys are sent based on vital measurements	☐
Explain temperature must be entered manually; all other equipment is Bluetooth-enabled	☐
Review blood pressure cuff placement - Above the elbow - Arm at heart level, resting on a table during reading - Limit moving as it will influence reading - Feet flat on the ground	☐
Review weight measurement - Measure weight at same time every day, preferably before breakfast - Wear lightweight clothing - Empty bladder prior to measurement - Avoid holding onto furniture while taking a weight measurement	☐
Provide participant with SMArTVIEW nurse contact information - Call cellphone - Call office - Instant message via R&R tablet	☐
Obtain a baseline set of vital signs. Watch participant complete measurements and answer survey. Reinforce teaching if necessary.	☐
Advise patient to not lift, push, or pull equipment box or scare due to weight restriction of lifting, pushing, or pulling objects more than 4.5kg/10lbs following surgery.	☐

Appendix D: Table of In-Hospital Reports

In-Hospital Report					
Date	Report	Implication	Action	Resolution	Theme
April 2018					
04/16/2018	Nurses continue to be educated on filling in all fields and the importance of assigning in handhelds to the patients on Guardian. Also stressed that any Vitals escalation mandates that the patient be reassessed and a full set of vital signs with a HEWS score be redone and stored and validated.	Untimely response to patient	re-education done with dayshift staff regarding Importance of responding immediately to HEWS escalations	Ongoing education regarding workflow	Ward nurse workflow
04/16/2018	Guardian client vital signs screen showing vitals only showing vitals only every 15 minutes	Gaps in vital sign data	Philips representative consulted and arranged to have the monitors reprogrammed	Monitors were reprogrammed to connect to multiple channels	Connectivity
04/17/2018	Reinforced at rounds that it is extremely important to return to the patient when there is a vital signs escalation or HEW alert to redo another set of vital signs via the Guardian client and to validate the new set of vitals to avoid protocol deviations.	Untimely response to patient	Re-education done with dayshift staff	Ongoing education regarding workflow	Ward nurse workflow
04/17/2018	Problems with MP5SC connectivity resulting in a gap in data. Noticed that the small flag icon in the top left-hand corner of the screen was empty.	Gaps in vital sign data	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
04/20/2018	One SMArTVIEW assigned nurse was not able to log into	Unable to receive handheld	Thoughtwire team emailed	Nurse account added and was able to log in	Handheld connectivity

	Thoughtwire for some reason. But with co-worker assistance and SVN back up we were able to notify her when there was a vitals escalation to recheck vitals	notification of deterioration			
04-20-2018	No immediate response from nurse to vitals escalation. Protocol deviation completed.	Untimely response to patient	Re-education done with dayshift staff regarding Importance of responding immediately to HEWS escalations	Ongoing education regarding workflow	Ward nurse workflow
04-21-2018	Handheld devices were lost network connection	Notifications were not being triggered to alert bedside nurse of potential deterioration	ThoughtWire team contacted	ThoughtWire team fixed handheld connectivity	Connectivity
04-23-2018	Guardian Client was not capturing minute-to-minute vital sign entries	Gaps in vital sign data	Philips representative consulted and arranged to have the monitors reprogramed.	Monitors were reprogrammed to connect to multiple channels	Connectivity
04/28/2018	Incorrect vitals entered by nurse. Continued teaching surrounding adequate documentation and filling in all applicable fields on monitor and how to edit entries in Meditech as required. how to correctly respond to a PREHEWS escalation.	Incorrect vital sign entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry
04/30/2018	Guardian problems with swiping resp. pod into MP5SC monitor 11 in room 7. Tried several	Certain rooms have poorer connectivity than others	Changed monitor/ new pods	Connected to pods outside in hallway in certain rooms	Connectivity

	times then finally connected when it was taken into the hallway under the hot spot. Everything on the monitor looked ok (full connectivity flag on the top left hand corner, had no problems with BP pod and Sp02. Then when returned into room, SP02 pod dropped off. Returned to hallway and swiped again under hot spot, again no problem. Returned a third time to room then blood pressure pod dropped off. Swapped out monitor 11 for another monitor. No further issues.				
MAY 2018					
05/01/2018	We have had a couple of times today where the bed numbers for room 2 and room 14 drop off the network. Rescanned bed numbers and no further issues this evening. Pods drop off spontaneously after initial set up in room 11 today, requiring them to be rescanned and no further issues noted. We also lost connectivity in room 11 where we noticed that the MP5SC monitor 11 lost its “flag” in the top left hand corner of the monitor. Monitor was rebooted and no further issues noted.	Certain rooms have poorer reception than others	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
05/06/2018	I can see when reviewing Guardian, nurses on night shift did ot complete the fields correctly with	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry

	respect to O2 methods and amounts. Nurses should know that Optiflow is an options with a %.				
05/27/2018	Due to the hospital wide connectivity issues experienced today, we were not able to stay connected to Thoughtwire or Guardian client. Thoughtwire rep was present this afternoon and gave us an update and we relogged in after 3 pm and had no further issues.	Hospital wide connectivity loss	Site initiated support from Thoughtwire	Connectivity issue was resolved	Connectivity
05/28/2018	Learning moment: we had a patient on Guardian with a syncope episode. BP sat 60/30 with resp 11 and because it was not sustained, did not trigger an alert to the bedside nurse, but still required attention to the bedside. Then when the bedside nurse was trying to store multiple BP's without a full set, the BP didn't always save. We saw it appear on the screen and pod but then it disappeared which I do not know why it happened. We should reinforce that the technology didn't fail as it is designed to ignore "artifact" entries.	Expectation of monitoring alerts to rapid deterioration went undetected by SMArTVIEW equipment.	Supported staff through event and education regarding equipment deterioration detection	SVN assisted	Ward nurse workflow
05/28/2018	Beds are still dropping off – it seems to be irrelevant of monitor/pt location..	Certain rooms have poorer reception than others	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
05/31/2018	MP5SC MON-15 in room 14 bed 5 dropped off the	Certain rooms have poorer	Shut down MP5SC and	SVN intervened and resolved issue	Connectivity

	room. Rescanned and no further issues.	reception than others	connection restored.		
JUNE 2018					
06/02/2018	MP5SC MON-15 in room 14 bed 5 dropped off the room again. Rescanned and no further issues.	Certain rooms have poorer reception than others	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
06/4/2018	Room number on MON-8 and MON-13 still dropping off. QR codes rescanned and no further issues occurred.	Gaps in vital sign data	Rescanned QR code	SVN intervened and resolved issue	Connectivity
06/4/2018	One entry was caught where one of our bedside nurses did not indicate Y/N for oxygen. I sat with the bedside nurse and showed her how to correct this.	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry
06/5/2018	Room number on MON-8 and MON-13 still dropping off. QR codes rescanned and no further issues occurred.	Gaps in vital sign data	Rescanned QR code	SVN intervened and resolved issue	Connectivity
06/5/2018	When I came in this morning I noticed something strange on the Client screen from night shift. One of our bedside nurses had completed two entries during her shift where ALL fields were entered and a HEWS score was generated but in one instance her name was not attached to the entry and so it did not go through, and in the other instance the entry just did not go through to Meditech. I have sent a very polite email asking this nurse to re-enter the	Incorrect nurse log in	Contacted bedside nurse	SVN assisted with manual entry of vital signs	Nurse login

	values whenever she gets a chance since she only works nights.				
06/08/2018	One entry where bedside nurse did not indicate Y/N for Oxygen. Nurse approached at 1800 and asked to correct in Meditech.	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry
06/09/2018	Guardian - Issues with There were several entries from yesterday's night shift that were missing information: - Missing BP - Missing O2 Flow Rate - Missing Hews Score - Missing Oxygen Y/N Neither of these nurses was back in tonight so I emailed them the entries with a request to edit them whenever they are back in.	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry
06/09/2018	One of the night shift nurses tonight was having a lot of difficulty scanning in her RFID tag tonight. When this nurse scans her RFID tag the username which is correct pops up, however, when she tried to store and validate under this username it did not work. We tried going in to the client to reset her password and under her name it showed that her username is "bennetta"? When we tried manually typing "bennetta" in to the monitor with her pin, everything worked	Incorrect nurse log in	Contacted bedside nurse	SVN assisted with new username and ensure data entered under correct nurse	Nurse login

06/10/2018	There was only one entry today where the nurse did not enter the oxygen flow rate, otherwise all entries were perfect.	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry
06/10/2018	MON-7 completely lost signal and dropped off all of the pods around 1645. When I looked at the monitor the flag in the left hand corner was empty and flashing. I turned the monitor off and back on and there were no more issues.	Gaps in vital sign data	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
2018/06/11	MON-5 completely lost signal and dropped off all of the pods around 1936. MP5SC rebooted and no further issues.	Gaps in vital sign data	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
06/12/2018	MON-5 dropped off bed number 10-2 again today . Rescanned no further issues	Gaps in vital sign data	Rescanned QR code	SVN intervened and resolved issue	Connectivity
06/13/2018	There was only one entry today where the nurse entered the oxygen flow rate under FiO2 in error. Correction has been made.	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry
06/13/2018	Correction has been made. I had issues with one of the night shift nurses logins this evening. We spent about an hour trying to troubleshoot. The nurse has two mneumonics in the Client. After resetting all passwords, changing passwords, manually logging her in, we got it to work but I have added	Incorrect nurse log in	Contacted bedside nurse	SVN assisted with new user name and ensure data entered under correct nurse	Nurse login

	her to the list of nurses who need a new RFID tag.				
06/14/2018	We had multiple monitors fall off today (# 5, 7,12) and the nurse assigned to the monitor also fell off, which has never happened before. Contacted Michelle for guidance regarding this issue.	Gaps in vital sign data	Shut down MP5SC and contacted Philips' representative	Philips' rep assisted with troubleshooting and attempted to replicate problem	Connectivity
06/15/2018	MON-12 completely lost signal and dropped off all of the pods around 1945. When I looked at the monitor the flag in the left hand corner was empty and flashing. I turned the monitor off and back on and there were no more issues.	Gaps in vital sign data	Shut down MP5SC and connection restored.	SVN intervened and resolved issue	Connectivity
06/15/2018	Incorrect O2 entry – a nurse did not enter mandatory field. Nurse is not on shift tonight. Will email nurse to correct field.	Incorrect VS entry	Contacted bedside nurse	SVN assisted with documentation correction	Incorrect /incomplete VS entry

Appendix E: Table of Hospital-to-Home Reports

Hospital-to-Home Report					
Date	Report	Implication	Action	Resolution	Theme
04/22/2018	Verified with patient that has broken Sp02 probe if the clip of the probe was just dislodged. There is an actual broken off piece of plastic missing from the probe that requires the patient to hold probe in place with other hand to get reading.	Unable to take vital sign measurement at home	SVN informed; new probe sent to patient	New equipment was sent to patient; broken equipment was fixed by the SVN team	Malfunctioning equipment
04/27/2018	had some issues connecting with pt 001-023 via vidyo so she rescheduled the appointment and when she tried reconnecting at a later time there were no issues.	Unable to complete video call and virtual assessment.	Call scheduled for later time	Call completed with no further issues	Vidyo visit connectivity
May 2018					
05/06/2018	Unable to connect to iHHS (limited) HITS contacted twice. Tried to fix it remotely but couldn't access. Attempted 1.1.1.1 with no success All Vidyo visits were completed via telephone	Unable to complete video call and virtual assessment.	HITS contacted	Internet connection restored	Video call connectivity
05/31/2018	Issues with connectivity during vidyo calls with pts. 001054 -Vidyo very choppy and freezing at	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code	Patients screened for reception	Video call connectivity

	times but still able to get pictures. 001062. Patient out in Freelton had most issues with vidyo dropping off and freezing, unable to keep vidyo going long enough to get photos, completed rest of call via telephone.		search prior to randomization		
June 2018					
06/04/2018	Still having issues connecting to vidyo with pt 001-062 in Freelton.	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code search prior to randomization	Called via telephone	Video call connectivity
06/05/2018	Still having issues connecting to vidyo with pt 001-062 in Freelton and now discovering the same issues with pt 001-069 in Simcoe. Addresses have been emailed to Karla and Carley will try to get the SIM Card Numbers from these patients tomorrow during their visits. Funny enough pt 001062 was travelling in a car from Burlington today and decided to bring his tablet with him and we were able to connect and complete his first vidyo visit to date with no issues so I am thinking that these folks just live in "dead zones" where reception is terrible.	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code search prior to randomization	Called via telephone	Video call connectivity

06/06/2018	I was able to connect with pt 001-062 in Freelton and pt 001-069 in Simcoe. Vidyo would not connect for 1 pt today – 001-028. Tried to add account again, confirm same account etc. but could not troubleshoot problem successfully. Will try again tomorrow.	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code search prior to randomization	Called via telephone	Video call connectivity
06/07/2018	Some vidyo connection issues with 001-028.	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code search prior to randomization	Patients screened for reception	Video call connectivity
06/09/2018	Calls for 001-062 and 001-028 were extremely choppy and I actually lost connection several times and had to reconnect.	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code search prior to randomization	Called via telephone	Video call connectivity
06/10/2018	Issues with connectivity during vidyo calls with pts. 001 054 -Vidyo very choppy and freezing at times but still able to get pictures. 001 062. Patient out in Freelton still having issues with vidyo. Today only seeing black screen on vidyo, no audio. Visit completed via telephone.	Unable to complete video call and virtual assessment.	Geographic location/ reception issue. Implemented postal code search prior to randomization	Called via telephone	Video call connectivity
06/10/2018	Calls for 001-062 and 001-028 were	Unable to complete	Geographic location/	Called via telephone	Video call connectivity

	extremely choppy and I actually lost connection several times and had to reconnect.	video call and virtual assessment.	reception issue. Implemented postal code search prior to randomization		
06/11/2018	No vidyo call for 001-028. Messages left with house number as well as cell number and no call back.	Unable to complete video call and virtual assessment	Called patient; continued following day	Pt resumed calls the following day	Program Compliance
06/12/2018	Also the thermometers are continuing to give us very low readings even after walking patients step by step with instructions.	Unreliable reading for temperature	Study leadership notified	New thermometers ordered	Equipment malfunction

Appendix F: Table of SVN 'House-Keeping' reports

SVN (Other) Report			
Date	Report	Action	Theme
April 2018			
04/17/2018	would be easier with a second person on shift due to workload	Reconsidered SVN staffing to support role requirements	Staffing support
May 2018			
05/12/2018	We need more BP hoses as they are malfunctioning for the Guardian monitor. Only 3 left in our office	Ordering more supplies	Equipment Malfunction
June 2018			
06/01/2018	Discussion with staff regarding Discharge check list. Please add sticker to checklist to prompt staff to check with SVN re: discharge questions .	Addressing H2H discharge preparation/informing ward staff of required teaching	Communication tool
06/02/2018	SVN has put up all the QR bedside number codes on 4 West and has completed some further staff education	Reinforce SV program with staff	Communication tool
06/04/2018	I spoke with Krysten today about the SVNs going in with Lindsay after a patient is randomized to SMArTVIEW to be introduced to the patient rather than Prathiba and Stephen coming in. I believe that we will be trialing this approach going forward.	Implementing further supports to address amount of participants withdrawing from intervention	Strategies to reduce withdrawal rates/ Improve in-hospital compliance
06/11/2018	Discussed at huddle that we would need a list of new staff members so that Michelle Decker can create some RFID tags when she visits us next time. In the meantime we can set new staff up to enter passwords manually.	SVN supporting ward staff with ID login, Philips' representative contacted	Nurse login

06/11/2018	We have received a new pod from Phillips but I didn't get a chance today to speak with Bio Med if any thing needs to be done with the pod prior to putting into circulation.	Pod sent to Biomed at HHS	Equipment malfunction