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Feasibility of Post-Operative Mobile Health Monitoring Among Colorectal Surgery Patients

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Abstract

Post-operative readmission following colorectal surgery is a common and costly occurrence. Remote health monitoring via mobile applications has the potential to reduce post-operative readmissions by early identification of complications. This intervention depends on patient acceptance and compliance with available technology. The feasibility of home monitoring using automated daily surveys and wound photo uploads, delivered via a mobile health application, was tested in the immediate post-operative period after colorectal surgery. Patient compliance, the association between generated alerts and readmissions, and patient satisfaction were measured. Patient satisfaction was high; 80.5% of patients reported that they felt safer going home knowing that they were monitored and 76.2% of patients reported that they would use the current app for post-operative monitoring again. However, only 37.0% of patients answered the survey at least 80% of the time in the first 2 weeks following discharge. Patient compliance significantly limited the feasibility of post-operative monitoring using our mobile health application.

Keywords

Colorectal surgery, mHealth, mobile monitoring, home monitoring

Summary for Lay Audience

About 11% of patients are readmitted to hospital within one month of colorectal surgery. As technology improves and becomes more accessible, mobile applications may be utilized to monitor patients once they go home from hospital. This has the potential to reduce post-operative readmissions by identifying complications early, which may allow physicians to treat complications on an outpatient basis before they progress to requiring an emergency department visit or admission to a hospital inpatient bed. Identifying complications earlier may also reduce the length of stay if a hospital admission is required for treatment. However, home monitoring requires participation from patients, and it is not known if colorectal surgery patients, who typically are older, will use a mobile application for this purpose. We designed an automated monitoring program consisting of prompted daily surveys and wound photo uploads delivered via a mobile application for post-operative monitoring of colorectal surgery patients following discharge home. We then surveyed patients about their experience with using the mobile application for post-operative monitoring and tested how often they used the mobile application and evaluated whether the alerts generated from patient responses were associated with hospital readmissions and emergency department visits. Most patients reported that they would use the application again for home monitoring following surgery and voiced that they felt safer going home from hospital knowing that they were monitored by the app. However, patients were still unlikely to consistently use the mobile application to report their symptoms to healthcare providers. This limits the healthcare team's ability to monitor patients through the application and identify patients who are not recovering as expected.

Co-Authorship Statement

A retrospective review of early post-operative readmissions among the colorectal surgery patients at the London Health Sciences Centre was conducted. Anna Mierzwa assisted with chart review and data collection. A systematic review of mobile health monitoring applications was also conducted. Sydney Selznick independently screened titles, abstracts and papers for inclusion along with Tanya Kuper. Nathalie Carey acted as a blind arbitrator of disagreements between Sydney and Tanya. Chadia El Khatib assisted with patient consent and recruitment for the mobile health monitoring study. Julie Ann Van Koughnett was the senior author on all included papers and assisted with study design and critical manuscript revisions.

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Preface

Throughout this thesis we will utilize the definition of readmission used by Canadian governmental agencies, such as Cancer Care Ontario (CCO), for quality assessment and funding allocation.¹ Here we will define early readmission as an unexpected return to hospital within 30 days of discharge resulting in an emergency department assessment or inpatient readmission.

Early post-operative hospital readmissions following colorectal surgery are common and costly.^{2,3} Notably, the early readmission rate following colorectal surgery has traditionally been higher at London Health Sciences Centre (LHSC), with 14% of colorectal patients being readmitted to hospital or presenting to the emergency department within 30 days of discharge over the two fiscal years preceding this research. Moreover, the overall readmission rate for surgical patients has been consistently higher at LHSC in comparison to other teaching hospitals, the average Ontario rate, and the average Canadian rate in the five years preceding this project, as per data provided by the Canadian Institute for Health Information (8.2% vs 7.1%, and 7.2% vs 6.9% respectively). This elevated readmission risk was the impetus for several quality improvement projects instituted simultaneously over the last 2 years in the Division of General Surgery at LHSC, including perioperative bundles to reduce surgical site and urinary tract infections. The feasibility of post-discharge monitoring for early identification of sentinel postoperative problems was also explored among the colorectal population and is the focus of this thesis.

With the ubiquity of mobile technologies in our society, mobile health (mHealth) applications have become attractive tools for advancing patient care. Hospital readmission

following surgery may often be preventable with better preoperative patient optimization and patient education, in-hospital teaching, and closer post-discharge monitoring.⁴⁻⁹ These applications can increase patient engagement in their own recovery, connect patients with their health care providers and flag patients at risk for readmission, facilitating potential early outpatient interventions. Several pilot studies have shown high patient compliance and satisfaction with post-operative mHealth applications.¹⁰⁻¹² However, study populations have been younger than the average age of the elective colorectal surgery population in London, with the mean age of studied patients falling between 50-55 years.¹⁰⁻¹² The colorectal surgery population is unique and has many risk factors for readmission, including complexity of surgical intervention, advanced patient age, potential for surgical site infections, dehydration risk (in the subset of patients who have a new ostomy), and risk of ileus and altered bowel habits after surgery. Studies demonstrating feasibility of mHealth monitoring within this patient population have been heterogeneous in their design and have produced mixed results.¹³⁻¹⁶

In light of this, we have conducted a literature review of early-postoperative hospital readmissions in the colorectal surgery population, have reviewed our own institutional readmissions among this patient population and have performed a systematic review of mHealth technologies utilized in the colorectal population. This information was used to inform and design an automated mHealth application for post-discharge monitoring among the colorectal surgery population at our own institution. This population includes patients undergoing resection of the colon and rectum for a variety of benign and malignant pathologies. Many of these patients additionally undergo staged procedures requiring reversal or creation of diverting ostomies. Following design of our mHealth monitoring tool,

we then tested the feasibility of post-discharge monitoring among a sample of the LHSC colorectal surgery population.

Chapter 1

1 Early Post-Operative Readmissions following Colorectal Surgery

1.1 Introduction

Initiatives incentivizing the delivery of high-quality care at reduced costs are of great interest because all health systems have limited resources with which to provide care for patients. Within the field of colorectal surgery, early post-operative readmission rates are increasingly used as a quality of care metric to which healthcare funding is tied. For example, the Hospital Readmissions Reduction Program (HRRP) was implemented as part of the Affordable Care Act (ACA) in the United States and functioned to penalize hospitals with higher readmissions rates for prespecified diagnoses by reducing Medicare payments.¹⁷ In Ontario, funding for Quality Based Procedures (QBP), such as cancer surgery, is linked to institutional adherence with evidence-based care bundles.¹⁸ In addition, Cancer Care Ontario (CCO) is actively exploring the 30-day unplanned hospital visit rate as a measure of quality and integration of provided services.¹⁸ These policies target readmissions as a significant and preventable cause of healthcare expenditure. They are designed to simultaneously encourage improvements in the delivery of care and reduce costs.

In Ontario, policies targeting early readmission following colorectal surgery occur in the context of established best practice recommendations for length of stay following

colorectal resection. CCO targets for length of stay are 4 days for laparoscopic colorectal resection, 6 days for open colon resection and 7 days following open rectal resection. These targets may serve to incentivize physicians to discharge patients earlier and perhaps are at odds with readmission quality metrics – patients may be discharged home prior to being medically fit or before adequate home supports can be arranged, increasing their risk of readmission.

In addition to being utilized as a quality of care metric by governmental agencies, early post-operative readmissions among colorectal surgery patients are pervasive, often avoidable, financially burdensome and reflect patient morbidity. Readmissions are common following colorectal surgery, with rates varying between 4.5% to 32.9% in the literature.^{4,19–23} Colorectal surgery readmissions are expensive, costing approximately \$8715 CAD per admission in Ontario.²⁴ They represent a significant, and to an extent, avoidable cause of increased health care utilization and spending; as many as 39% of readmissions are preventable in this patient population.²⁵ Importantly, early-postoperative readmissions are a marker of patient morbidity among colorectal surgery patients and are associated with both post-operative complications^{5,21,26–28} and reduced long-term survival in patients with colorectal cancer.²⁹

It would be beneficial to target early-postoperative readmissions among the colorectal surgery population to decrease healthcare expenditure and improve patient outcomes. However, the literature pertaining to hospital readmissions following colorectal surgery must be critically evaluated prior to the development of feasible readmission reduction strategies. This chapter will aim to provide a general overview of the existing literature on early-postoperative readmissions following colorectal surgery,

defined as colon and/or rectal resection. Throughout the chapter, early post-operative readmissions will be defined as a readmission to hospital and/or an emergency department visit within 30 days of discharge from the index surgical admission, unless otherwise specified. Data pertaining to readmission following colonic and rectal resections, emergent and elective procedures, and all operative indications will be considered. The risk factors predisposing patients to readmission, subgroups in greatest need of intervention and causes of readmission will be discussed.

1.2 Risk Factors for Readmission Following Colorectal Surgery

1.2.1 The Role of Patient Demographics on Risk of Readmission

The relationship between chronologic age and readmission is of great interest. Life expectancy of the average Canadian has increased substantially over the last several decades³⁰ and age itself is a major risk factor for the development of colorectal cancer.³¹ Unsurprisingly, the age of patients undergoing colorectal surgery has increased correspondingly.²⁹ The elderly fair worse following colorectal surgery and have higher 30 day and 1 year mortality in comparison to younger patients.³² They have increased comorbidity and are more likely to present urgently or emergently when undergoing colorectal resection.³³ This in turn is associated with poorer oncologic outcomes, increased mortality and morbidity.³⁴ It is natural to suspect that the elderly are at

increased risk for readmission given their predisposition to post-operative complications, which are major drivers of readmission.

Schneider *et al.* utilized the 1986-2005 Surveillance, Epidemiology and End Results (SEER)-Medicare database to investigate readmissions among Medicare beneficiaries (age >65) undergoing colorectal surgery in the United States.²⁹ 11.2% were readmitted to hospital within 30 days of discharge.²⁹ This is similar to readmission rates among the average colorectal population. Among Medicare beneficiaries, those over the age of 75 years were found to be at slightly increased risk of readmission (OR 1.05, 95% CI 1.01 - 1.09) when sex, discharge year, length of stay, Charlson comorbidity score, postsurgical complications, transfusions during the index admission and rectal resection were controlled for.²⁹

Chaudhary *et al.* conducted a small retrospective review of 173 octogenarians and nonagenarians who underwent laparoscopic colorectal resections between 2000 and 2009 in the United Kingdom.³⁵ Mortality (1.7%), complication rate (12%) and readmission rate (5.8%) were also comparable to that of the average colorectal population. Post-operative readmissions were predominantly caused by surgical site infections (SSIs) and gastrointestinal complications,³⁵ similar to colorectal patients as a whole. This suggests that perhaps operative and readmission risks among the elderly are comparable to those of younger age in a controlled, elective environment and when the laparoscopic approach is used. Of note, no direct comparison was made between groups based on age in this study and the results could simply be due to selection bias – elderly patients with higher functional status and fewer comorbidities were more likely to be offered surgery.

Multiple studies have included age as a predictor when exploring risk of readmission following colorectal surgery. The results are variable, with some reporting no difference^{19,27,28,36,37}, reduced risk^{24,26,38,39} and increased risk^{29,40-42} of readmission with increasing age. This likely stems from variable modelling of age, adjustment for confounding, and selection bias. Many studies model the relationship between age and readmission linearly, but this may not be an accurate representation. For example, Pucciarelli *et al.* found that individuals between age of 50 and 70 undergoing surgery for colorectal cancer had reduced readmission risk in comparison to those below the age of 50 and over the age of 70.⁴² Lucas *et al.* observed that only those patients over the age of 80 had significant increased risk of readmission when compared to patients in their 60s.⁴⁰ These studies suggest that perhaps there is a cut-off after which readmission risk increases. Additionally, elderly comorbid individuals are less likely to be operated on and may be less likely to survive an in-hospital complication. Thus, those elderly individuals who survive to discharge following colorectal surgery may truly not be at increased risk of readmission, as they represent an overall healthier subpopulation. Currently, no study has directly investigated this hypothesis.

Several studies have also aimed to investigate the impact of race on readmission following colorectal surgery. These studies are largely conducted using data from the United States where information on race is routinely collected and disparities in healthcare coverage, provision and utilization in relation to race are well established. All such studies show increased readmission risk among black individuals (OR 1.16-1.6).^{36,40,43-46} This association persists regardless of data source used and after controlling

for comorbidities, illness severity on presentation, procedure type, post-operative complications, insurance status and socioeconomic status (SES).^{43,45,46}

There is some evidence to suggest that the relationship between race and readmission may reflect a disparity in access to higher quality of care. Girotti *et al.* noted that hospitals with a higher proportion of black patients had higher readmission rates for all patients regardless of race.⁴⁴ Visible minority patients are also more likely to undergo colorectal surgery by low volume surgeons in comparison to white patients,⁴³ and reduced surgeon volume has previously been shown to be associated with poorer outcomes after colorectal surgery in several studies.⁴⁷ Hospital and surgeon volume, however, do not fully explain the association between race and early post-operative readmission; black individuals are at increased risk of readmission, even when surgeon and hospital volume are controlled for.⁴³ It is also unclear how the association between race and readmission among colorectal patients translates to the Canadian single-payer healthcare system. There are no studies exploring the impact of race or distance from a tertiary academic centre on colorectal surgery readmissions in the Canadian setting.

1.2.2 Patient Comorbidities Are Associated with Readmission

In general, more comorbid individuals are at increased risk for readmission following colorectal resections. The American Society of Anesthesiologists (ASA) classification,²⁶ Charlson score,^{42,46} elevated body mass index (BMI),^{5,26} hypertension,²⁶ pulmonary disease,^{26,48} diabetes,⁴ disseminated cancer,^{26,46} pre-operative steroid

use,^{5,26,27,48} chronic opioid use,⁴⁹ and smoking history⁴ have all been independently associated with increased risk of early post-operative readmission following colorectal surgery. The use of diuretics has also been identified as a predictor of early post-operative readmission secondary to dehydration among patients with ileostomies (OR 2.44, 95% CI 1.5–3.8, p=0.0001).²⁸ These are all potential targets for pre-operative optimization and post-operative patient education to reduce readmissions after colorectal surgery.

The relationship between frailty and surgical outcomes is currently an area of great interest in the surgical literature. Frailty is a state of decreased physiologic reserve which predisposes patients to negative outcomes, such as increased length of stay, post-operative complications, institutionalization and mortality.⁵⁰ The negative impact of frailty extends to other measures of post-operative recovery, including early post-operative readmission. Chen *et al.* utilized the National Surgical Quality Improvement Program (NSQIP) database to investigate the association between frailty (defined by a modified frailty index ≥ 3), functional status (dependent or independent) and post-operative outcomes following gastrointestinal surgery. They found that both frailty and dependent functional status were predictive of post-operative unplanned readmissions.⁵¹ Al-Khamis *et al.* similarly found frailty to correspond with worse post-operative outcomes, including hospital readmission, among colorectal surgery patients.⁵²

The concept of frailty as a risk factor for readmission also allows for potential risk reduction through prehabilitation programs. In addition to baseline frailty, major abdominal surgery has been shown to further reduce functional reserve in elderly patients. On average, it takes 6 weeks following surgery for elderly patients to return to

baseline activities of daily living (ADLs) and 3 months to return to baseline instrumental activities of daily living (iADLs).⁵³ Six months following major abdominal surgery, 39% of elderly patients have not regained preoperative Timed Up and Go speeds, 58% have not regained preoperative functional reach and 52% have not regained preoperative grip strength.⁵³ There is some evidence to suggest that multimodal prehabilitation programs can help improve physiologic reserve preoperatively, facilitating post-operative recovery and return to independence following surgery.⁵⁴ However, it is still unknown whether these benefits of prehabilitation translate to reduced readmissions in the colorectal population.

1.2.3 The Effect of Operative Indication and Urgency on Early Post-Operative Readmissions

The indication for colorectal resection may be an important factor related to risk of readmission. Patients undergoing colorectal resection for inflammatory bowel disease (IBD) appear to have higher risk of readmission than those undergoing resection for a neoplasm,^{26,36,55} while those undergoing resection for diverticular disease may be at lower risk.^{26,36} The methodologic limitations of the studies suggesting an association between operative indication and readmission risk need to be considered when interpreting this relationship. It is critical to note that none of these studies were designed to specifically evaluate operative indication as a risk factor for readmission. For example, the study by Bartlett *et al.* was primarily designed to investigate the effect of post-discharge complications on early readmission.²⁶ They utilized the NSQIP database for this purpose, which captures readmissions occurring within 30 days of surgery, not discharge. For this

reason, they excluded all patients with index hospital admissions greater than 2 weeks. This inevitably also excludes patients with complicated hospital trajectories. Additionally, they did not control for urgency of the procedure or severity of illness upon admission in their multivariate analysis. Therefore, their results are subject to significant bias and confounding. For example, those discharged within 2 weeks of diverticular resection may represent a healthier subpopulation, potentially explaining the reduced risk observed.

Damle *et al.* conducted a retrospective study investigating risk factors for early post-operative readmission and similarly found that those with diverticular disease were at reduced risk (OR 0.89, 95% CI 0.82-0.98), compared to those undergoing surgery for a benign neoplasm.³⁶ Patients with IBD were found to be at higher risk of readmission (OR 1.32, 95% CI 1.19-1.46) and cancer patients at an intermediate risk (OR 1.00, 95% CI 0.92-1.10). Unlike Bartlett *et al.*, they did measure 30-day readmission from discharge and corrected for illness severity and procedural urgency in their analysis.³⁶ However, their study is still subject to confounding.

Surgery for inflammatory bowel disease, in comparison to colorectal cancer, has been associated with a higher risk of readmission in the literature.^{26,36,55} This is a population that has many predisposing factors, such as emergent presentation, malnutrition and weight loss leading up to surgery, chronic pain, immunosuppression, chronic steroid use, and mental health issues, which are all independently associated with post-operative complications and readmission risk.⁵⁶⁻⁵⁹

Multiple studies have investigated early post-operative readmissions specifically among patients with ulcerative colitis (UC) undergoing proctocolectomies and ileal pouch anal anastomoses (IPAA). 30 day readmission rates are uniformly high (12% to 32.9% in various studies).^{20,37,60-63} The cause of this elevated readmission risk is likely multi-factorial. These are long, complex, invasive, low volume operations. As previously discussed, surgical volume has been implicated in post-operative outcomes⁴⁷ and many centres perform less than 15 IPAA per year.⁶² Furthermore, these staged procedures usually require the creation of an end ileostomy or diverting loop ileostomy, which independently increases the risk of early post-operative readmission.^{4,24,36,42,45}

Several investigators have considered urgency of colorectal resection when modelling risk of readmission in multivariate analyses.^{4,5,19,28,36,42,64} Some have found an increased risk of readmission among those patients who have had non-elective colorectal procedures. Others have reported no significant difference between those patients who underwent their surgeries emergently, urgently or electively. In general, we know that emergent surgical procedures are associated with increased mortality and morbidity in comparison to elective procedures.⁶⁵ To illustrate this, one study found that 32.80% of patients undergoing emergent procedures had a major complication in comparison to 12.74% of patients undergoing non-emergent procedures ($p < 0.0001$) upon reviewing NSQIP data for a variety of common general surgery and vascular procedures.⁶⁵ Additionally, there is a strong association between complications and early post-operative readmissions.^{5,19,24,26,29,36,48} A higher risk of early post-operative readmission is thus expected among those patients who have undergone emergent colorectal resection in comparison to elective. The lack of association between urgency of surgery and

readmission in some studies likely is the cause of residual confounding and chance, rather than truly no association between these variables.

1.2.4 The Influence of Treatment Factors on Readmission Rates

Treatment factors throughout the patient's course of care and variables related to the healthcare system impact early post-operative readmission risk following colorectal surgery. This includes neoadjuvant chemoradiotherapy, hospital and surgeon case load, type of surgical procedure performed and surgical approach utilized.

Many patients undergoing colorectal resections for rectal cancer have undergone neoadjuvant chemotherapy and radiotherapy treatments prior to surgery. Several studies have explored the effect of neoadjuvant therapy on early readmission risk, with variable results. Neoadjuvant therapy is associated with an increased risk of anastomotic leak,⁶⁶ and therefore, may be related to increased risk of readmission. A retrospective study conducted in the United Kingdom found that neoadjuvant therapy increased the odds of readmission 4.48 times among patients undergoing elective laparoscopic colorectal resection in the context of an Enhanced Recovery After Surgery (ERAS) program.⁶⁷ An Australian study similarly found that neoadjuvant therapy increased the odds of readmission by 1.65 times among patients who underwent colorectal resection for colorectal cancer.¹⁹ Although the second study controlled for important confounders, such as rectal versus colon resection and creation of a stoma, the UK study did not.^{19,67}

Therefore, an odds ratio of 4.48 likely is an overestimate of the true effect size if one does indeed exist.

Additionally, both hospital and surgeon caseloads have been implicated in surgical outcomes, including readmission rates. High volume surgeons and hospitals have significantly reduced risk of patient mortality, morbidity and anastomotic leak following colorectal surgery.⁶⁸ Among patients undergoing IPAA, increased hospital volume and improved patient outcomes translate to a reduced readmission risk.⁶² The effect of hospital and surgeon volume on readmission risk among other colorectal patients is not as clear. Burns *et al.* conducted a hierarchical multilevel regression analysis, accounting for common infrastructure and resources available to surgeons within a hospital, to examine the effect of surgeon volume on readmission risk using administrative data from the National Health Services (NHS) in the United Kingdom.³⁸ They found no difference in 28-day readmission rates between low, medium and high volume surgeons and hospitals, nor was there a statistically significant increase in risk of readmission when case volume was considered as a continuous variable.³⁸ This result may truly represent no effect, but as with any retrospective study, residual confounding and type II errors need to be considered.

Procedure type may also impact early post-operative readmission risk following colorectal surgery. The uniformly high risk of readmission among patients undergoing IPAA was previously discussed. Among colorectal cancer patients, it appears that those patients undergoing rectal resections are at increased risk of readmission as well.^{29,38,42} Rectal resections, in general, are longer and more complex surgeries than colonic resections. Pucciarelli *et al.* showed that this relationship was independent from stoma

creation.⁴² However, they did not consider neoadjuvant chemoradiotherapy in their multivariate regression analyses.⁴²

Doumouras *et al.* used a Canadian cohort of colorectal patients to compare readmission risk between those undergoing rectal and colonic resection.²⁴ Readmission rates were significantly higher among rectal resection patients (10.7% vs 7.1%, $p < 0.001$). They additionally found that risk factors for readmission differed between patients undergoing rectal and colon resection. Diabetes, age and discharge to long-term care were more predictive of readmission among rectal patients in comparison to colon patients.²⁴ Causes for readmission were also more likely to be related to complications secondary to the creation of a diverting loop ileostomy among patients undergoing rectal resections. For example, renal and ostomy-related causes for readmission were more common following rectal resection, whereas cardiac complications were more common among patients undergoing colonic resection.²⁴

Ileostomy creation has also been theorized to increase readmission risk as it predisposes patients to dehydration and obstruction secondary to parastomal hernias. Several studies have examined the association between the presence of a stoma and readmission risk^{4,19,24,36,42,45,55}; most have found an increased risk of readmission with creation of a stoma, with the odds of readmission being as high as 2.6 times higher when a stoma is present.^{4,24,36,42,45} Specifically, ileostomies seem to confer increased risk of readmission in comparison to no stoma.⁴ Readmissions in this subpopulation are particularly driven by an increased risk of dehydration; one study found that 43.1% of patients readmitted within 60 days following colorectal surgery who had a diverting loop ileostomy were readmitted for dehydration.²⁸

Laparoscopic surgery has numerous benefits for patients in comparison to open procedures, including improved pain, length of stay and recovery of bowel function,^{69,70} however, it is unclear how the surgical approach impacts early post-operative readmission risk. Overall morbidity and mortality among patients with laparoscopic surgery have been comparable to those undergoing open resection for colorectal cancer in randomized controlled trials, but readmission risk has not been specifically reported.^{69,70} A meta-analysis of randomized controlled trials comparing laparoscopic and open approaches among adults undergoing colorectal surgery for resection of benign or malignant neoplasms showed no significant difference in readmission risk between the two surgical approaches in the context of an ERAS program.⁷¹

However, it does appear that in certain subpopulations and contexts, readmission risks may vary between the two approaches. Several retrospective studies have shown a reduced risk of readmission among patients undergoing colonic resection with laparoscopic surgery,^{24,26} while simultaneously showing no benefit regarding readmissions among rectal resection patients.²⁴ Conversion from a laparoscopic to an open procedure has been associated with increased risk of readmission.²² Also, multiple studies have shown an almost 2-fold increased risk of readmission with laparoscopic surgery among patients with diverting loop ileostomies²⁸ and among patients undergoing procedures that are higher risk for creation of a diverting ileostomy, such as rectal resections⁵⁵ and IPAAAs.³⁹ It is unknown whether this is a true effect due to an inherent risk of the procedural approach, reduced time for patient education regarding stoma management because of shortened length of stays or simply due to residual confounding.

1.2.5 The Effect of Timing of Discharge on Early Post-Operative Readmission Risk

With the advent of Enhanced Recovery After Surgery (ERAS) programs, length of stay has been explored as risk factor for readmission among colorectal patients due to concerns of a trade-off between early discharge and readmission risk. This concern has not panned out in the literature. Studies examining length of stay show an increased risk of readmission with prolonged length of stay, even when patient comorbidities and post-operative complications are controlled for.^{2,29,72} Guidelines outlining best practice targets for length of stay, such as those proposed by CCO, may thus not impact early post-operative readmission rates.

It is important to acknowledge that length of stays at the extreme short end of the spectrum may also confer greater risk of readmission. For instance, Zhang *et al.* performed sensitivity analyses in their study which revealed that hospitals with a very short median length of stay (≤ 4 days) have higher readmission rates among colorectal patients on an institutional level.⁷² This may reflect decision making and acceptance of higher readmission rates for the achievement of reduced length of stays at those particular institutions.

Timing of discharge in relation to the day of the week has also been explored. It was hypothesized that perhaps risk of readmission was higher among those patients discharged over the weekend due to fewer available resources and the absence of allied health professionals to aid in the coordination of discharge planning and care. Two large retrospective studies examining this relationship were conducted using state and national

databases in the United States and found that weekend discharges were unexpectedly associated with lower readmission risk than weekday discharges overall.^{73,74} Importantly, among those patients who required home support services, those discharged on the weekend had higher readmission rates than those who were discharged during the week.⁷⁴ Authors postulated that this pattern was related to (1) physicians intentionally avoiding discharge of medically complex patients over the weekend and (2) the unavailability of ancillary staff to coordinate home services for patients discharged over the weekend if needed.^{43,73} Notably, it is also more difficult to schedule outpatient follow-up appointments prior to discharge for patients sent home over the weekend as offices are closed. The lack of a scheduled follow-up appointment prior to discharge has been found to be an independent predictor for readmission among the colorectal population, increasing the odds of readmission over 2-fold.⁴

1.2.6 Post-Operative Complications as a Cause of Readmission

Post-operative complications are perhaps the strongest predictor of early post-operative readmission, increasing readmission risk up to 13-fold.^{5,19,24,26,29,36,48} Post-operative complications following colorectal surgery are common, with rates upwards of 50% quoted in the literature.²⁶ Reoperation, percutaneous drain placement, intensive care unit admission, blood loss, surgical site infections, respiratory complications, urinary tract infections, renal insufficiency, venous thromboembolism, cerebrovascular accidents (CVA), clostridium difficile infection, ileus, anastomotic leak and high stoma output have all been implicated in readmissions risk among colorectal surgery patients.^{22,27,29,36,45,75}

Hendren et al. analyzed readmission risk by type of complication following colorectal surgery, and found that CVA, post-operative venous thrombotic events (VTE) and organ-space surgical site infections (SSI) were associated with the highest risk of readmission (OR 10.0, 6.51, 5.63, respectively),²⁷ while ileus, deep and superficial SSI, sepsis and anastomotic leak were the most common complications to occur.²⁷ Bartlett *et al.* also looked at readmission risk by complication type. Similarly, the most common post-discharge complications were wound complications, organ space infections and sepsis. Although the frequency of readmission following wound complication was lower than that of organ space infection or sepsis (38%, 92% and 95%, respectively), the high prevalence of wound complications, such as SSI, among the population resulted in more absolute readmissions than any other complication.

The timing of complications in relation to index admission also appears to play a role in readmission. While intra-operative, in-hospital and post-discharge complications all increase the risk of early post-operative readmission,^{26,48} complications diagnosed following discharge are associated with a significantly increased odds of readmission in comparison to complications diagnosed during the index admission.²⁶ Intuitively this is expected as complications diagnosed in hospital can be managed prior to discharge.

1.3 Timing and Cause of Readmission

Both an understanding of the timing of readmission in relation to discharge and appreciation of the indications for readmission are needed to effectively develop strategies for readmission reduction. Multiple studies have aimed to evaluate the

occurrence of readmission in relation to discharge date. Reasons for readmission in relation to time, complication, length of stay and indication for surgery have also been explored.

Post-operative readmissions occur early; 2 out of 5 readmissions occur within the first week of discharge.²⁹ Al-Mazrou *et al.* utilized the ACS-NSQIP database to identify 69 222 patients who had undergone elective colorectal resections between 2012-2013 and found that 43.8% of unplanned readmissions occurred within the first five days post-discharge.²¹ Moreover, half of these patients present to hospital within 3 days of being sent home.²¹ Davids *et al.* also analyzed timing of readmissions and similarly found that the median time to readmission was 7 days among their colorectal cohort.³⁶ Notably, the timing of readmission corresponds to the timing of post-operative complications; half of post-discharge complications also occur within 8 days of discharge (IQR 4–13 days).²⁶ Within 2 weeks of discharge, 79.2% of wound complications, 74.3% of organ space infections, and 81.1% of sepsis complications have occurred.²⁶

The most common causes for readmission are gastrointestinal disorders and SSI.^{4,5,36,42,76} One large retrospective study utilizing the NSQIP database found that the ten most common causes of readmission following colorectal surgery were SSI (25.8%), ileus or obstruction (18.1%), dehydration (6.7%), bleeding (4.1%), VTE (3.2%), sepsis (3.1%), acute kidney injury (AKI) (3.0%), pain (2.9%), other surgical concerns (2.1%) and urinary tract infections (UTI) (2.0%).⁷⁷

Additionally, the distribution of the causes of readmission may differ by timing of representation to hospital. Al-Mazrou *et al.* compared the causes of readmission between

those readmitted early (0 to 5 days following discharge) and late (6 to 29 days following discharge).²¹ They found that the most common reasons for early hospital readmission were GI problems (19%) (predominantly driven by anastomotic, obstruction or hepatic complications, nausea or vomiting, and GI bleeds), obstruction or ileus (16.7%) and intra-abdominal infection (14.3%). The most common reasons for late hospital readmissions were intra-abdominal infection (18.7%), wound complications (14.8%) and GI problems (13.7%). However, these results need to be interpreted in the context of missing data; the cause of readmission was missing for 19% of patients identified in the study.²¹

The type of surgery performed may also result in variable causes for readmission. For example, Doumouras *et al.* compared reasons for readmission between those patients undergoing colonic and rectal resections. The most common causes of readmission for both patient groups were infectious complications, obstruction and other gastrointestinal causes. They, however, found that the rectal patients were more likely to be readmitted to hospital for ostomy or renal related issues, while the colectomy patients were more likely to be admitted for cardiac causes.²⁴

Dehydration is a significant cause of readmission among patients with ileostomies. Messaris *et al.* found that 43.1% of colorectal patients readmitted to hospital within 60 days of discharge with diverting ileostomies were readmitted due to dehydration.²⁸ Paquette *et al.* also investigated readmissions for dehydration among a cohort of patients who underwent colorectal procedures with an ileostomy. 17% were readmitted within 30 days for dehydration.⁷⁸ Notably, readmission did not positively correlate with in-hospital ostomy output; the mean ileostomy output at discharge was 713 ml/day in the readmission group vs 857 ml/day in the patients who were not readmitted

($p = 0.18$).⁷⁸ Perhaps this reflects a difference in the quality of education the patients received regarding management of their ileostomy outputs; those with lower ileostomy output may have been perceived to be at reduced risk of dehydration and thus may not have received adequately thorough teaching.

Finally, index length of stay may influence the reason for readmission as well. Kelly *et al.* found that in comparison to an index length of stay of 6-7 days, patients discharge before post-operative day (POD) 5 were more likely to be readmitted for pain, those discharged prior to POD3 were more likely to readmitted for ileus or obstruction, and those discharge after POD8 were more likely to be readmitted for a wound complication.² These risks are likely related to the normal post-operative course of recovery following colorectal surgery.

1.4 Readmissions Are Not Inevitable

It is important to consider that many readmissions may be preventable. Hyde *et al.* performed an in-depth chart review of all colorectal readmissions occurring within 30 days of surgery between 2013 and 2016 at their institution. They assessed whether the readmissions were preventable based on evidence of the complication causing readmission being present on discharge, the possibility of avoidance with education or anticipatory guidance or a medical error contributing to the readmission, such as incorrect medication reconciliation leading to readmission. It is worth noting that they did not even consider SSIs as preventable in their study because their patients were on a standardized post-operative pathway. SSIs accounted for 20% of all readmissions, but they still found

that 39% of all readmissions could be avoided.²⁵ Common reasons for preventable readmissions in their analysis were dehydration or AKI, pain and ostomy related complications.²⁵ These are important targets for intervention in order to improve patient outcomes and reduce health care costs.

Studies examining the impact of failure to cope, social supports and patient proximity to health care services on readmission rates in the colorectal surgery population are currently lacking. In light of the preventable nature of many readmissions, improved patient access to healthcare resources and physician services would presumably reduce early post-operative hospital readmission, however, this has not been examined in the colorectal population.

1.5 Conclusion

In summary, the epidemiology of early post-operative readmissions following colorectal surgery is quite complex. There are many risk factors contributing to a patient's readmission risk, which include patient demographics, comorbidities, treatment modalities, surgical procedures, as well as institutional practices. Readmissions are common, and often are due to infective complications or gastrointestinal concerns. Those with ileostomies additionally are at an added risk of dehydration. Finally, readmissions are expensive and many are potentially preventable. Armed with this knowledge, we can create targeted interventions to improve patient outcomes and reduce health care costs.

Chapter 2

2 Early Post-Operative Readmissions following Colorectal Surgery at the London Health Sciences Centre: A Retrospective Study

2.1 Introduction

Early post-operative readmissions following elective colorectal surgery represent a significant source of preventable healthcare resource utilization. Readmissions are common following colorectal surgery, with rates up to 32.9% in the literature.^{4,19–23} Early post-operative readmissions are costly²⁴, and as many as 39% are potentially avoidable in this patient population.²⁵ The identification of patients at increased risk of readmission, and delineation of reasons for readmission, are thus necessary to inform the design of targeted readmission-reducing interventions.

With the advent and ubiquity of mobile technologies in our society, mobile health (mHealth) applications have become attractive tools for advancing patient care. These applications can increase patient involvement in their own recovery, connect patients with their health care providers and flag patients at risk for readmission, facilitating outpatient intervention.

To aid in the design of a remote monitoring health application for readmission reduction, we conducted a retrospective review of early post-operative readmissions at our institution. Currently, there is a paucity of published studies exploring early post-operative colorectal readmissions in the single-payer setting, which can influence

healthcare utilization. We therefore aimed to characterize local risk factors for readmission, timing of readmission and causes of readmission among a Canadian elective colorectal surgery population.

2.2 Methods

Reporting of this study was conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.⁷⁹ Approval was obtained from the Human Research Ethics Board at Western University prior to conduction of the study.

This was a nested case-control study evaluating risk factors for early post-operative readmission risk following colorectal surgery. Patients who underwent elective colorectal surgery at London Health Sciences Centre (LHSC) for management of benign or malignant colorectal neoplasms between January 1, 2016 and December 31, 2016 were included in this study. LHSC is an academic tertiary care centre encompassing 2 university affiliated hospitals in London, Ontario and receives referrals from the wider regions of southwestern and northern Ontario. The electronic medical record (EMR) utilized by LHSC is directly linked with 9 community hospitals which service the majority of the referral base, providing a unique opportunity to study post-operative readmission rates at both index and community hospitals.

All adult (≥ 18 years) patients who had undergone (1) elective full or partial resection of the colon or rectum with and without an ostomy created, (2) elective

ileostomy or colostomy creation for diversion prior to neoadjuvant chemoradiotherapy in the setting of a near-obstructing colon or rectal tumour, or (3) elective ileostomy or colostomy reversal following elective resection of a colorectal neoplasm during the study period were considered for inclusion. Patients who had an ileostomy or colostomy created for palliation in the setting of unresectable colorectal cancer were excluded. Patients with colorectal cancer resection with synchronous liver resections were also excluded. Elective surgery was defined as a planned operation for which the patient specifically presented to hospital from home to undergo surgery. Only surgeries performed by general surgeons or colorectal surgeons were included. An enhanced recovery after surgery (ERAS) program was established for colorectal surgery patients during the study period. The final study population was determined by the number of eligible cases performed at LHSC within the study period.

Patients were identified using operating room (OR) booking lists for the Division of General Surgery at Western University and the Ontario Quality Based Procedures (QBP) dataset. The QBP program in Ontario collects administrative data to evaluate adherence to best-practice care bundles and outcomes following colorectal cancer surgery (including resection of both malignant and benign neoplasms) to allocate funds and monitor providers and hospitals to improve care.¹⁸ In addition to utilizing this administrative dataset for patient identification, all operative cases booked as an abdominal perineal resection, anterior resection, left colectomy, right colectomy, sigmoid colectomy, subtotal colectomy, total colectomy, Hartmann's procedure, low anterior resection, proctectomy, proctocolectomy, bowel resection, laparoscopy, laparotomy, colostomy, colostomy closure, Hartmann's reversal, ileostomy, and ileostomy closure

during the study period were screened for inclusion to ensure complete capture of all appropriate cases.

Data regarding outcome and covariates were collected from electronic patient charts by study investigators using standardized collection procedures. These were described a priori in a data collection handbook created specifically for study purposes (Appendix 1). Patients were considered to have the primary outcome of interest (early post-operative hospital readmission) if they had a documented emergency room encounter or unplanned inpatient hospital admission within 30 days of discharge from the index hospital admission during which their colorectal surgery occurred. Covariates included age at the time of surgery (<75 years and ≥ 75 years), gender (male or female), American Society of Anesthesiology (ASA) classification (<3 or ≥ 3), body-mass index (BMI) (kg/m^2), current smoking status (smoker or non-smoker), indication for surgery (malignant or benign), preoperative chemotherapy (yes or no), preoperative radiotherapy (yes or no), presence of an ostomy (ileostomy, colostomy or none), procedure type, minimally invasive approach (laparoscopic/robotic or open/converted to open), length of stay (days), discharge location (home, home with community nursing, long-term care facility or hospital) and in-hospital complication (yes or no). In-hospital complications included mortality, intra-abdominal infection, anastomotic leak, superficial surgical site infection, urinary tract infection, ileus, bowel obstruction, dehydration, acute kidney injury, high stoma output, deep vein thrombosis, pulmonary embolism, gastrointestinal bleeding, enterocutaneous fistula, myocardial infarction, fascial dehiscence and respiratory tract infection. This information was collected from imaging, laboratory results, procedural records and consultation notes occurring at the time of admission.

Documentation of in-hospital complications in discharge summaries was also utilized for data abstraction. Data regarding the timing of readmission, location of readmission, reason(s) for readmission and interventions performed during readmission were also collected.

Descriptive statistics were performed for all study variables. Measures of central tendency (mean and median) and spread (standard deviation and interquartile range) were used for quantitative variables. Observed frequencies were calculated for categorical variables. These were compared between those who were readmitted in the early post-operative period and those who were not using the Student's t-test, chi-squared test and the Wilcoxon rank sum test as appropriate. All statistical analyses were performed using Stata software (Version 15.1, StataCorp, College Station, TX).

2.3 Results

332 adult patients underwent elective colorectal surgery without liver resection from January 1, 2016 to December 31, 2016 at LHSC. Six (1.8%) patients died during their index admission. Causes of death included intrabdominal septic complications directly related to surgery (n=2), decompensation following gastrointestinal bleeding (n=1) and postoperative cardiorespiratory complications (n=3). The remaining 326 patients were at risk for early-postoperative readmission and included in subsequent analyses. All remaining patients survived 30 days following discharge and had complete follow-up.

82 (25.2%) patients were readmitted at least once within 30 days of discharge. On univariate analysis, patients who were readmitted were more likely to be diagnosed with a wound infection during their index admission, have undergone a second operation during their index admission, and discharged with community care supports than those who were not readmitted ($p=0.04$). Although not statistically significant, readmitted patients were also more likely to be male, current smokers, obese, ASA 3 or greater, have a diagnosis of a colorectal malignancy, neoadjuvant chemoradiotherapy, left-sided resections, stoma creation, complications in hospital and discharge with community nursing support (Table 2-1).

Of the 112 readmission encounters, 51 (45.6%) resulted in admission to hospital and 61 (54.5%) patients were discharged from the emergency department without admission to hospital. 91/112 readmissions (81.3%) were encounters in which patients presented to LHSC or were ultimately transferred to LHSC from a community hospital. 5 encounters led to surgical intervention and 10 encounters necessitated interventional radiology procedures. Median time to first readmission was 8 days (IQR 5-13) (Figure 2-1). Among first readmissions resulting in inpatient stays, median length of readmission was 4 days (IQR 2-6).

17 patients had 2 readmissions, 5 patients had 3 readmissions and 1 patient had 4 readmissions within 30 days of discharge. 11 (45.8%), 3 (50.0%) and 0 of second, third and fourth readmissions resulted in inpatient stays, respectively.

Table 2-1 Baseline Characteristics by Readmission Status

| | Not Readmitted (n=244) | Readmitted (n=82) | p-value |
|---|---------------------------|----------------------|---------|
| Age, years (SD) | 66.3 (12.4) | 65.8 (11.8) | 0.75 |
| Male (%) | 131 (53.7) | 52 (63.4) | 0.13 |
| Current Smoker (%) | 30 (12.3) | 14 (17.1) | 0.27 |
| BMI, kg/m ² (%) | | | |
| <18.5 | 5 (2.1) | 0 | 0.51 |
| ≥18.5 to <25 | 61 (25.0) | 21 (25.6) | |
| ≥25 to <30 | 83 (34.0) | 24 (29.3) | |
| ≥30 to <35 | 58 (23.8) | 20 (24.4) | |
| ≥35 | 37 (15.2) | 17 (20.7) | |
| ASA ≤2 (%) | 76 (31.2) | 22 (26.8) | 0.46 |
| Colorectal Malignancy (%) | 211 (86.5) | 76 (92.7) | 0.13 |
| Pre-operative chemotherapy (%) | 65 (26.6) | 28 (34.2) | 0.19 |
| Pre-operative radiation (%) | 65 (26.6) | 28 (34.2) | 0.19 |
| Surgery Type (%) | | | |
| Right hemicolectomy/ ileocolic resection | 90 (36.9) | 23 (28.1) | 0.15 |
| Left hemicolectomy/ sigmoid resection | 41 (16.8) | 15 (18.3) | 0.76 |
| Proctectomy | 51 (20.9) | 22 (26.8) | 0.27 |
| APR | 20 (8.2) | 11 (13.4) | 0.16 |
| Ileostomy/ colostomy reversal | 38 (15.6) | 9 (11.0) | 0.31 |
| Other | 10 (4.1) | 3 (3.7) | 0.86 |
| MIS (%) | 115 (47.1) | 39 (47.6) | 0.95 |
| Stoma (%) | | | |
| None | 177 (72.5) | 49 (59.8) | 0.08 |
| Ileostomy | 41 (16.8) | 22 (26.8) | |
| Colostomy | 26 (10.7) | 11 (13.4) | |
| Median Post-operative LOS in Days (IQR) | 5 (4-8) | 6 (4-9) | 0.09 |
| Complication During Index Admission (%) | 91 (37.3) | 37 (45.1) | 0.21 |
| Ileus/ Obstruction | 47 (19.3) | 21 (25.6) | 0.22 |
| Dehydration/ AKI | 24 (9.8) | 9 (11.0) | 0.77 |
| GI Bleed | 22 (9.0) | 6 (7.3) | 0.64 |
| Wound Infection | 13 (5.3) | 10 (12.2) | 0.04 |
| UTI | 16 (6.6) | 6 (7.3) | 0.81 |
| Pneumonia | 6 (2.5) | 4 (4.9) | 0.27 |
| Intraabdominal Infection | 4 (1.6) | 3 (3.7) | 0.28 |
| Anastomotic Leak | 3 (1.2) | 2 (2.4) | 0.44 |
| Fistula | 0 | 1 (1.2) | 0.08 |
| DVT/PE | 1 (0.4) | 0 | 0.56 |
| Fascial Dehiscence | 0 | 1 (1.2) | 0.08 |
| MI | 0 | 0 | n/a |
| Second Surgery During Index Admission (%) | 2 (0.8) | 4 (4.9) | 0.02 |
| Disposition | | | |
| Home | 138 (56.6) | 32 (39.0) | 0.04 |
| Home with community nursing | 94 (38.5) | 45 (54.9) | |
| LTC | 5 (2.1) | 3 (3.7) | |

| | | | |
|---|---------|--------|--|
| Community Hospital | 7 (2.9) | 2(2.4) | |
| SD = standard deviation, BMI = body mass index, ASA = American Society of Anesthesiology Physical Status Class, MIS = minimally invasive surgery, LOS = length of stay, IQR = interquartile range, AKI = acute kidney injury, GI = gastrointestinal, UTI = urinary tract infection, DVT = deep vein thrombosis, PE = pulmonary embolism, MI = myocardial infarction, LTC = long-term care | | | |

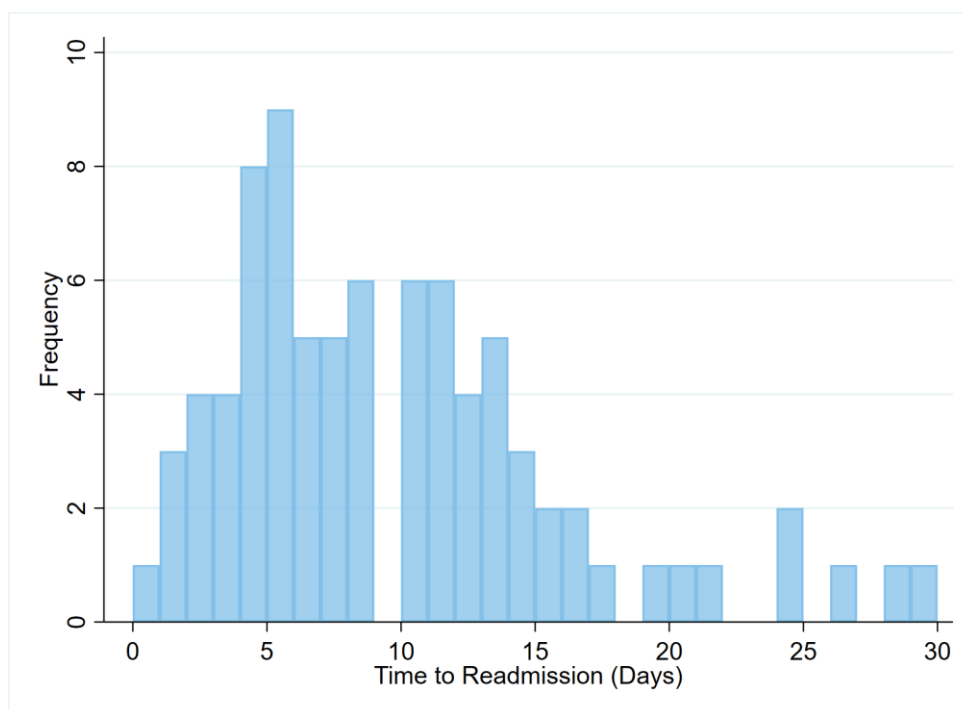


Figure 2-1 Time to First Readmission

Overall, the most common causes for presentation to hospital were superficial surgical site infection (17.9%), ileus or bowel obstruction (14.8%), intra-abdominal infection (10.7%), dehydration or AKI (9.8%), non-infectious concerns with the wound or ostomy (8.9%), UTI (7.1%), pain (5.4%) and anastomotic leak (4.5%) (Table 2-2). Among patients presenting to hospital for the first time with a surgical site infection, median time to readmission was 6.5 days (IQR 5-11) and 72.2% were managed on an outpatient basis in the emergency department.

Table 2-2 Common Causes of Early Post-Operative Readmission

| | N (%) |
|---|-----------|
| Total Readmissions | 112 |
| Wound infection (%) | 20 (17.9) |
| Ileus/ obstruction (%) | 18 (14.8) |
| Intra-abdominal infection (%) | 12 (10.7) |
| Dehydration/ AKI (%) | 11 (9.8) |
| Wound or stoma concern other than infection (%) | 10 (8.9) |
| Urinary tract infection (%) | 8 (7.1) |
| Pain (%) | 6 (5.4) |
| Anastomotic Leak (%) | 5 (4.5) |

2.4 Discussion

We found that early post-operative readmissions were common in our patient population, occurred early and were driven by surgical site infections. 25.2% of elective colorectal patients were readmitted to hospital or presented to the emergency department within 30 days of discharge. About half of these encounters resulted in inpatient stays. This is in keeping with the published literature, where readmission rates among colorectal

patients are quoted up to 32.9%.^{4,19-23} We have thus identified a need for readmission reduction strategies in our local colorectal surgery population.

Clear predictors of readmission were not identified in our study. Readmitted patients were more likely to have wound infections ($p=0.04$), reoperations during the index admission ($p=0.02$) and discharged with community supports ($p=0.04$), however, these associations need to be interpreted in the context of multiple testing and may be the result of type I errors. Additionally, readmitted patients were more likely (although not significantly so) to be male, current smokers, obese, ASA 3 or greater, diagnosed with a colorectal malignancy, recipients of neoadjuvant chemoradiotherapy, left-sided resections, stoma creation, or have had complications in hospital. Many of these risk factors have been positively associated with readmission risk in the literature (previously discussed in Chapter 1). Therefore, the lack of statistical significance in the association of these variables with early post-operative readmission may have been due to a lack of power in our study resulting in type II error, rather than true non-effect. Nevertheless, the overall lack of strong predictors suggests that all colorectal patients are at risk of readmission and should be considered for readmission-reducing strategies.

Readmissions also occurred early among our study population. 50% of initial readmissions occurred within 8 days of discharge. 75% of readmissions occurred within 13 days. This is similar to the findings reported by Davids *et al.*³⁶ who found that the median time to readmission was 7 days among their colorectal cohort. Post-operative monitoring strategies for readmission reduction, therefore, would be most efficacious in the first 2 weeks following discharge.

The most common causes for readmission were superficial surgical site infection (17.9%), ileus or bowel obstruction (14.8%), intra-abdominal infection (10.7%), dehydration or AKI (9.8%), non-infectious concerns with the wound or ostomy (8.9%), UTI (7.1%), pain (5.4%) and anastomotic leak (4.5%) among our study population. Once again, this is in keeping with the literature where gastrointestinal disorders and SSI have been described as the most common causes of early post-operative readmission among the colorectal population.^{4,5,36,42,76}

Superficial surgical site infections and other wound related complications were significant contributors to hospital readmission among our study population, of which a subset represent avoidable emergency department encounters. Strategies for surgical site infection prevention and early detection, clearer patient instruction regarding acuity of care and improving access to outpatient assessment by the surgical team or wound care nurses may help reduce readmissions of this nature.

We have explored early post-operative readmission risk following colorectal surgery in the context of the Canadian single-payer health care system. While not our primary goal, these results may be generalizable to other institutions within Canada with similar colorectal surgery populations and practices, but they are likely not applicable to settings where patients are responsible for point-of-care cost-sharing. Point-of-care costs can alter utilization and influence healthcare-seeking behaviour. The frequency of readmission and reasons for readmission may differ in other funding models. This study nonetheless fills an important gap in knowledge given the paucity of published single-payer studies exploring early post-operative colorectal readmissions.

We have previously discussed the predisposition of our analysis of risk factors for readmission to both Type I and Type II errors. This analysis is not without significant other limitations. It is an unrandomized, retrospective study and we cannot exclude confounding contributing to the results. We are also limited by the quality of available data in electronic patient records. Finally, the possibility of patients presenting to institutions other than LHSC or the 9 regional hospitals linked to the LHSC EMR in the post-operative period cannot be excluded. Capture of hospital inpatient admissions and emergency department encounters may therefore not be complete and the true early post-operative readmission rate may be higher than our estimate.

2.5 Conclusion

Local early post-operative readmissions among elective colorectal patients are common, occur early and are driven by potentially preventable causes, such as SSI. mHealth interventions aiming to reduce readmissions among this population should target patients particularly in the first 2 weeks following discharge and screen for common preventable causes for readmission, such as SSI.

Chapter 3

3 Post-Operative Mobile Health Monitoring in Colorectal Surgery Patients: A Systematic Review

3.1 Introduction

The popularity of digital technologies, such as cellphones and tablets, has surged over the last decade. 90% of Canadians owned two or more digital devices and 76% owned a smartphone in 2016.⁸⁰ Increased accessibility to digital devices has been accompanied by gains in internet usage, particularly among the elderly. Between 2013 and 2016 internet usage rose from 65% to 81% among those aged 65 to 74 years and from 35% to 50% among those 75 years of age and older.⁸⁰

Growth in the technology sector has made the use of mobile health (mHealth) applications for the advancement of patient care increasingly enticing. mHealth applications have the potential to encourage patient engagement in their own recovery, improve access to health care providers from home and enable remote patient monitoring. Theoretically, this has many benefits such as the early identification of complications, patient rescue, and delivery of more efficient and convenient care.

The utility of these applications in the post-operative period is currently under study. mHealth technologies have been trialed in a variety of surgical populations, including cardiac, orthopedic, vascular, neurosurgery and general surgery patients.⁸¹⁻⁸⁵ A wide range of remote monitoring functionalities have been explored, including digital

activity tracking, vital sign monitoring, wound monitoring and automated surveys to track post-operative recovery.^{81,83,84,86} Other studies have examined the delivery of educational tools through digital technologies^{82,87-89} or have aimed to improve efficiency by replacing standard surgical follow-up appointments with mHealth interventions.⁹⁰⁻⁹² While these technologies are promising, it is unclear if their applications are feasible in all surgical populations or efficacious at improving meaningful post-operative outcomes, such as earlier selfcare, readmissions or complication rates.

Colorectal surgery patients have unique needs due to their predisposition to early post-operative readmissions. This predominantly results from an elevated risk of surgical site infections (SSIs), dehydration (in the subset of patients who have a new ostomy), ileus and altered bowel function after surgery.^{28,77,78} The colorectal cancer population, in particular, is older. In 2018, Cancer Care Ontario projected 77.9% of new colorectal cancer diagnoses to occur among those 60 years and older, and 24.5% over the age of 80.¹ Colorectal patients may benefit from extended post-discharge monitoring and educational interventions delivered via a digital platform, but the utility of these interventions may also be limited older patients do not buy in to available new technologies.

There is currently no summary of the use of post-operative mHealth interventions among the colorectal surgery population. This information would guide further implementation and study of mHealth technologies among these patients. A systematic review of the post-operative application of digital mHealth technologies among patients who have undergone colorectal surgery was performed. The aim of this study was to (1) identify mHealth technologies that have been trialed in the post-operative colorectal

surgery population, (2) summarize data regarding the feasibility of mHealth application in this population, and (3) summarize data regarding the efficacy of mHealth interventions among colorectal surgery patients. All outcome measures and digital mHealth interventions delivered via mobile phone, tablet or computer were considered.

3.2 Methods

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.⁹³ The study was not registered and a protocol for this study has not been previously published.

3.2.1 Eligibility

A comprehensive literature search of the Medline and EMBASE databases was performed from inception to July 8, 2019, to identify all randomized controlled trials, cohort studies and single-armed pilot studies investigating the use of mobile health technologies post-operatively in the colorectal surgery population. For the purposes of this review, studies utilizing text messaging, mobile applications or digital communication tools delivered via cellphones, tablets, computers and/or internet webpages were considered mHealth technologies. Wearable activity trackers or remote vital sign monitors syncing with digital applications were also considered mHealth technologies. Interventions applied between the time of surgery to within 30 days after surgery were considered post-operative. Interventions initiated prior to surgery were also

included if they had a post-operative component. Adult (≥ 18 years) patients undergoing colon or rectal resection, with or without stoma creation, were considered colorectal patients. Published abstracts and conference proceedings were considered for inclusion. Publications in all languages were included. Studies that merely reported on stages of software or hardware development were excluded. Purely qualitative studies were also excluded.

3.2.2 Search Strategy

Search terms included: ["mHealth" OR "eHealth" OR "mobile Health" OR "cellphone" OR "smartphone" OR "mobile phone" OR "tablet" OR "iPad" OR "app" OR "mobile application" OR "internet" OR "computer" OR "laptop" OR "technology" OR "website" OR "text" OR "text messaging"] AND ["postoperative" OR "postop"] AND ["colorectal" OR "ileostomy"]. No restrictions were placed.

3.2.3 Study Selection

Duplicate records were removed prior to review. All titles and abstracts were screened independently by two reviewers (TK and SS) and data was abstracted in duplicate using standardized forms. Disagreements were resolved by a third reviewer (NC). Remaining articles were fully reviewed by study investigators (TK and SS) and eligibility based on predetermined inclusion and exclusion criteria was determined by consensus amongst all reviewers (TK, SS and NC).

3.2.4 Data Extraction and Analysis

The following data were collected from the selected publications: authors' names, year of publication, study location, study design, sample size, inclusion and exclusion criteria, average age of study population, measures of computer literacy or use, intervention details, control details, primary outcome measure(s) and reported results.

Individual study bias in randomized control trials (RCTs) was assessed using the Cochrane Collaboration's tool.⁹⁴ Bias in non-randomized cohort studies was assessed using the ROBINS-I tool, which has been endorsed by the Cochrane Collaboration.⁹⁵ The selection of study participants, measurement of exposure and outcome, design-specific sources of bias, confounding control and statistical analysis were independently considered for studies with no control group. These domains were adapted from a systematic review by Sanderson *et al.*, who utilized these key factors to evaluate tools for bias assessment.⁹⁶

Due to the anticipated heterogeneity of included studies, a narrative synthesis of results was performed. Studies examining mHealth interventions designed for stoma education and monitoring of the nature of ileostomy output were considered separately from those applied to the general colorectal population. Bias in randomized controlled trials and cohort studies were also summarized separately.

Interobserver agreement following screening of titles and abstracts was assessed using Cohen's kappa statistic.⁹⁷ Strength of agreement was defined using accepted

benchmarks: poor ($\kappa < 0.00$), slight ($0.00 < \kappa < 0.20$), fair ($0.21 < \kappa < 0.40$), moderate ($0.41 < \kappa < 0.60$), substantial ($0.61 < \kappa < 0.80$), and almost perfect ($0.81 < \kappa < 1.00$).⁹⁸ All statistical analyses were performed using Stata software (version 15.1, StataCorp, College Station, TX).

3.3 Results

3.3.1 Summary of Included Studies

The search yielded 1432 results. 1364 studies remained after removal of duplicates. Titles and abstracts were screened for eligibility and 19 studies were selected for full review (Figure 1). Interobserver agreement was substantial (percent agreement 99.4%; $\kappa = 0.77$). Of the studies assessed for full review, 1 was not conducted among the colorectal population, 1 did not intervene in the early post-operative period, 1 utilized daily phone calls for post-operative surveillance and did not meet our definition of an mHealth intervention, 1 was a qualitative study and 2 were descriptions of mHealth development. Thirteen studies remained and are summarized in Table 1.

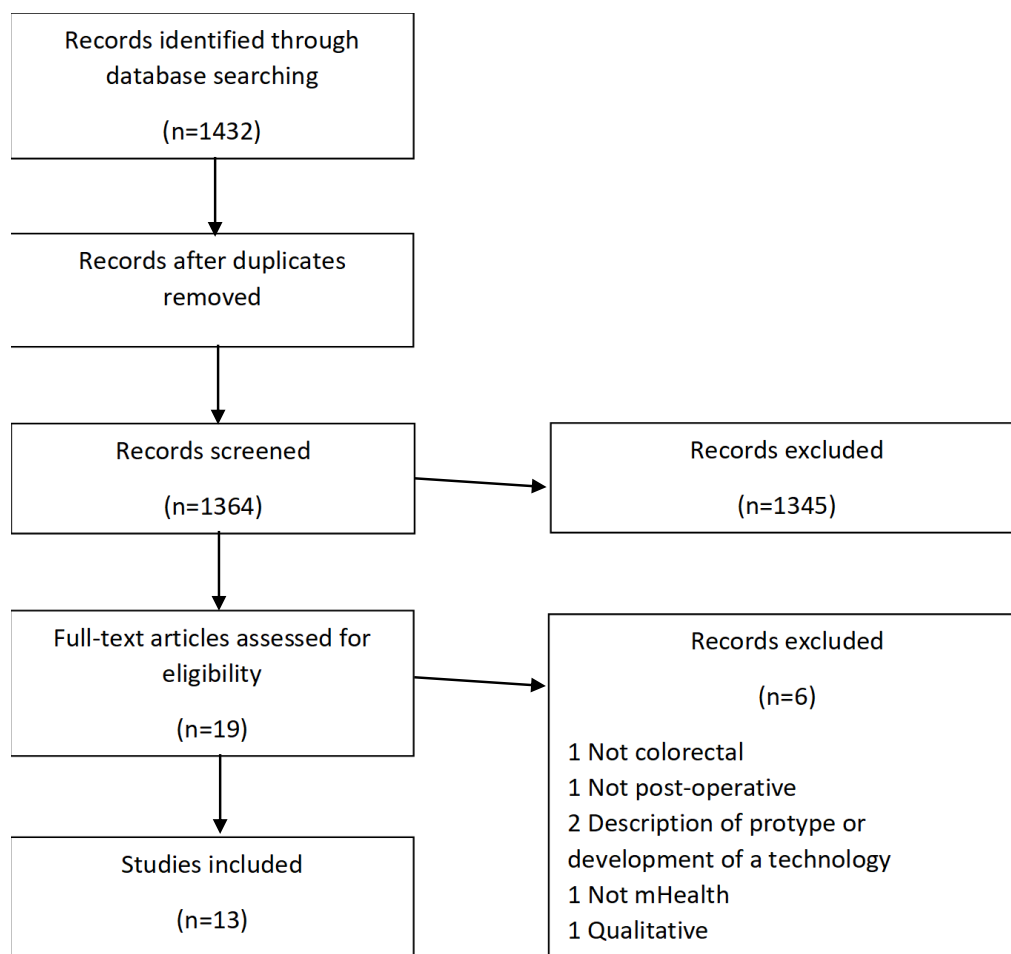


Figure 3-1 PRISMA flow diagram of study selection.

Four studies were published between 2000-2015,^{13,99-101} 1 in 2016,¹⁶ 2 in 2017,^{15,102} 2 in 2018,^{103,104} and 4 in 2019.¹⁰⁵⁻¹⁰⁷ Nine studies were conducted in the United States,^{13,15,100-103,105,106} 1 in Taiwan,⁹⁹ 1 in France,¹⁶ 1 in the United Kingdom¹⁰⁴ and 1 in Canada.¹⁰⁷ Three publications were conferences proceedings.^{101,105} Two randomized control trials^{99,107} and 2 non-randomized cohort studies^{105,106} were included. The remaining 9 studies did not have a comparison group.^{13,16,100-105,108} Seven studies had

fewer than 50 enrolled patients,^{13,15,16,100,102-104} 5 studies had greater than 50 patients^{99,105-107} and 1 did not report the sample size.¹⁰¹

Several studies excluded patients who did not own a mobile phone or smartphone^{15,16,102} or patients who reported poor proficiency with computer use.^{13,16} Of the studies not requiring baseline ownership of a mobile device, only 1 study by Mata *et al.*¹⁰⁷ assessed prevalence of ownership among their study population. In this study, 79% of patients in the control group and 86% of patients in the intervention group were owners of a smartphone, tablet or personal computer. Of the studies not requiring baseline proficiency of mobile device use, only the study by Bedra *et al.*¹⁰⁰ assessed prevalence of mobile use among their study population. In this study, 94% of patients reported daily computer use and 50% of patients reported daily tablet or e-reader use. Median and average ages of the included study populations ranged from 39.8 years to 60.9 years among studies reporting these values (Table 1).

Interventions varied across all studies, but were grouped into four broad categories: (1) primarily educational, (2) post-operative monitoring utilizing automated daily prompts, (3) technologies for the assessment of ileostomy output and (4) virtual clinical encounters. Many studies combined elements of multiple intervention types (Table 1).

Outcome measures also varied across studies and included change in knowledge and selfcare efficacy following educational interventions, patient compliance with use, number of hospital readmissions, number of emergency department visits, concordance

between virtual and in-person assessments and application usability (Table 1). In general, results in all studies were prone to bias and confounding (Table 2).

Table 3-1 Characteristics of Included Studies

| Author/ Year/ Country | Characteristic | Description |
|--|---|---|
| Lo <i>et al.</i> ⁹⁹ 2010/ Taiwan | Study Design | RCT |
| | Number of Patients | 102 |
| | Study Population | Adult patients with a stoma admitted post-operatively to the surgical unit who were able to speak and read Chinese. Patients were excluded if they had poor levels of consciousness, a serious co-existing medical condition or comorbidity that might interfere with the intervention (including depression), or poor post-op pain relief. |
| | Average Age | Overall: 60.9 years (SD 16.6) Control: 62 years (SD 15.8) Intervention: 59.7 years (SD 17.6) |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Multimedia education program consisting of (1) information about the process of stoma formation, including anatomy, physiology and clinical indications (2) elements of stoma care, using flash, 2D animation, film and illustration to convey that information |
| | Control | Standard information brochure detailing stoma care |
| | Outcome | Change in self-care knowledge, attitudes towards self-care and self-care behaviour from baseline as measured by an investigator created questionnaire administered at baseline and 1 week following intervention (which was administered on POD1). |
| Results | Multimedia education program resulted in greater improvement in self-care knowledge ($p<0.001$), attitudes towards self-care ($p<0.001$) and self-care behaviour ($p<0.001$) in comparison to the information brochure. | |
| Bedra <i>et al.</i> ¹⁰⁰ 2013/ United States | Study Design | Single-arm study |
| | Number of Patients | 15 |
| | Study Population | Hospitalized patients with new ileostomies following colorectal resection |
| | Average Age | 51 years |
| | Baseline Computer Literacy | 94% of patient reported daily computer use. 50% of patients reported daily tablet of e-reader use. |
| | Intervention | Interactive ostomy education program delivered via tablet in hospital. |
| | Control | None |
| Outcome | Knowledge assessment via questionnaire. Evaluated prior to and after educational intervention. Semi-structured qualitative interview to assess patient experience and areas for improvement. | |

| | | |
|---|---|---|
| | Results | Improved ileostomy knowledge score (27.8 to 31.3, $p<0.002$). Improved stoma care self-efficacy (78.4 to 92.7, $p<0.05$). 100% of patients expressed ease of use, 80% of patients reported that tablet-based education was a good supplement to ostomy nurse teaching, 80% reported good or excellent learning experience |
| Bennett <i>et al.</i> ¹⁰¹ 2013/ United States (abstract only) | Study Design | Single-arm study |
| | Number of Patients | Not reported |
| | Study Population | Colorectal surgery patients with new ileostomies |
| | Average Age | Not reported |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Interactive, tablet-based ileostomy educational program used over a 24h period |
| | Control | None |
| | Outcome | Difference in scores on an ileostomy knowledge survey and ileostomy self-efficacy scale administered prior to and following table use |
| Results | Improvement in patient knowledge scores (+12.12%), communication and attitudinal efficacy (+23.68%) and stoma care and social self-efficacy (+33.93%) | |
| Dawes <i>et al.</i> ¹³ 2015/ United States | Study Design | Single-arm study |
| | Number of Patients | 20 |
| | Study Population | Convenience sample comprised of patients undergoing elective colorectal surgery for any indication. Those who did not speak English or reported poor proficiency with electronic devices were excluded. |
| | Average Age | Median age: 57.5 years (IQR 15.5) |
| | Baseline Computer Literacy | Those who reported poor proficiency with electronic devices were excluded. |
| | Intervention | Daily survey regarding post-op recovery delivered via tablet beginning on POD1-3 and ending at the time of the patient's first clinic visit. Daily wound photos were also prompted via the application. |
| | Control | None |
| | Outcome | Compliance with the application, calculated as a percentage = number of days with a completed survey or photo divided by the total number of days the patient had the device. |
| Results | Data was submitted during 166/ 265 monitored days (63%). Compliance rates were higher during inpatient time periods than outpatient (72% vs 53%) | |
| Carrier <i>et al.</i> ¹⁶ 2016/ France | Study Design | Single-arm study |
| | Number of Patients | 11 |
| | Study Population | Patients who had undergone colorectal surgery for cancer, IBD, endometriosis or diverticulitis and had access to a mobile phone/ were familiar with text messaging. |
| | Average Age | Median age: 57 years (range 25-82) |
| | Baseline Computer Literacy | Access to a mobile phone and familiarity with text messaging were required for study inclusion. |
| | Intervention | Patients were provided with written and oral follow-up instructions on the day of discharge. Five standardized questions regarding recovery were texted to the patients on post-discharge days 1, 3 and 5. Alerts with predetermined thresholds for each question were sent to the |

| | | |
|--|----------------------------|--|
| | | surgeon when indicated, who phoned the patient and managed as necessary. |
| | Control | None |
| | Outcome | Number of alerts, rapidity of response, pertinence of alerts, number of readmissions, number of surgical reoperations, visits to the emergency department |
| | Results | Non-response was 10% on day 1, 7% on day 3 and 10% on day 5. Median time to response was 12min on day 1, 5 min on day 3, 4 min on day 5. 48 patient alerts were generated; of these, 27 were due to pain and 19 were due to no response. 2 alerts resulted in reoperation, 3 in rehospitalization. None of the patients that did not trigger an alert were re-hospitalized or re-operated on. |
| Scott <i>et al.</i> ¹⁵ 2017/ United States | Study Design | Mixed-methods |
| | Number of Patients | 20 |
| | Study Population | Post-operative, English or Spanish speaking, adult patients who had undergone colorectal surgery at a large urban county hospital. Patients required their own mobile device. |
| | Average Age | 6 patients were 29 years or younger, 8 patients were 30-44 years, 6 patients were 45-64 years |
| | Baseline Computer Literacy | Patients required their own mobile phone for inclusion in the study. |
| | Intervention | Seamless MD app, which facilitates daily post-operative symptom reporting through standardized questions. Patients are additionally able to take photos of their wounds and record their daily temperatures. The app gives automatic responses, guiding patients to seek further medical attention as needed. The app was used daily for at least 2 weeks after discharge. |
| | Control | None |
| | Outcome | Rating of the app on the System Usability Scale (SUS), semi-structured interviews conducted regarding app use, 30-day readmissions, ER visits and phone calls |
| | Results | Median SUS score (of 100) following initial use: 95 (IQR 86-98) Median SUS score (of 100) at follow-up among patients who used app at least once after discharge: 95 (IQR 83-98) 67% felt the app fit into their daily routines Many patients did not use the app daily as instructed: 30% did not use the app after discharge, 10% only used the app once 8/ 20 patients had unplanned ER visits; 5 of these patients presented with symptoms that could be addressed by the app if they had used it Many patients trusted the app (11/15 = 73%), however, did not follow the recommendations (only 4/10 patients who were told to contact the surgical team did so) Most patients did not take photos of their wounds (median 0% (IQR 0-54)) |
| Symer <i>et al.</i> ¹⁰² 2017/ United States | Study Design | Single-arm study |
| | Number of Patients | 31 |
| | Study Population | Adults undergoing colorectal surgery at the New York Presbyterian Hospital between Sep 2015 and January 2017. Patients who did own or could not use an Android or iOS smartphone were excluded. Patients who could not speak English were excluded. |
| | Average Age | 51.7 years (range 21 - 75) |
| | Baseline Computer | Patients who did not own or use an Android or iOS smartphone were excluded. |

| | | |
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| | Literacy | |
| | Intervention | Patients were provided with a mobile application that surveys post-operative recovery, alerts patients and clinicians when survey responses are concerning, allows patients to upload photos of their surgical site, ostomy and urine, syncs with a Fitbit for step-counting, and delivers a single-item visual measure of affect. 2 days of preoperative FitBit data were collected and a research assistant helped patients install the app. The app was used from discharge to POD30. Submitted wound photos were reviewed on a daily basis by a surgeon. |
| | Control | None |
| | Outcome | Feasibility, defined as the percent of patients who completed a daily survey-related task. A priori definition of feasibility was >75% of patients completing at least one component of the app greater than 70% of the time |
| | Results | 26 patients interacted with the app by completing a survey or taking a photo at least 70% of the time (83.9%) |
| Bednarski <i>et al.</i> ¹⁰³ 2018/ United States | Study Design | Single-arm study |
| | Number of Patients | 49 |
| | Study Population | Adults undergoing colorectal surgery with the possibility of ileostomy creation |
| | Average Age | Median age: 51.1 years (range 22.3 - 75.1) |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Ileostomy output assessment via FaceTime on an iPad in hospital |
| | Control | In-person assessment of ostomy output by same attending physician for each patient |
| | Outcome | Agreement between telemedicine and in-person assessment of need for antimotility agents. This information was obtained from a chart review if in-person assessment could not be performed. |
| | Results | 43/ 44 encounters among 27 individuals were concordant between telemedicine and in-person/ chart review assessment for initiation of anti-motility agents. |
| Kontovounisios <i>et al.</i> ¹⁰⁴ 2018/ United Kingdom | Study Design | Single-arm study |
| | Number of Patients | 9 |
| | Study Population | Adults who had undergone abdominal surgery with a ileostomy created |
| | Average Age | 52 years (range 26 - 76) |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Ostomi-i alert sensor, which clips to the lower portion of a stoma bag and relays information about the bag filling and output volumes via a smart phone application |
| | Control | None |
| | Outcome | Usability/ acceptability of the device |
| | Results | Descriptive: patients were able to understand instructions easily and pair the device with their smartphones |
| Bidwell <i>et al.</i> ¹⁰⁵ | Study Design | Single-arm study |

| | | |
|---|--|---|
| 2019/ United States (abstract only) | Number of Patients | 185 |
| | Study Population | Adults undergoing elective colorectal operation between Oct 2017-Sep 2018 |
| | Average Age | Not reported |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Web-based perioperative program accessible via smartphone, tablet and desktop which provided reminders of pre-operative instructions and post-operative expectations, surveys of patient reported outcomes and patient self-efficacy and information about colorectal operations |
| | Control | None |
| | Outcome | Comparison of self-efficacy as measured by a survey administered pre-op and 30 days post-op. Patient reported impact of frequency of clinical encounters. |
| | Results | Increased knowledge of preparation for surgery ($p=0.018$) and decrease in anxiety ($p<0.001$). 68% of patients who completed the program reported that it prevented 1 or more outpatient phone calls. 30% reported that the program prevented one or more return visits to the emergency department. |
| Borsuk <i>et al.</i> ¹⁰⁶ 2019/ United States | Study Design | Cohort Study |
| | Number of Patients | 281 |
| | Study Population | Adult patients who underwent an elective right hemicolectomy, subtotal colectomy, total colectomy, low anterior resection by 4 colorectal surgeons at a single institution between Mar 2015 and Feb 2018. Those who had a hospital stay greater longer than 30 days or who were transferred to hospice or an extended care facility rather than home were excluded. |
| | Average Age | Control: 63.4 years (range 22-90) Intervention (excluding non-compliers): 60.3 years (range 18-93) |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Active post-discharge surveillance (APDS) was implemented and offered to all colorectal patients in addition to the standard institutional ERAS protocol. APDS employs automated protocols defined by the care team delivered via a mobile phone app, computer, email or standard telephone. The app initiates pre- and post-op patient-provider communication in the form of text alerts, video demonstrations and recovery surveillance (wound photos and well-being questionnaires). Patient alerts were triaged via a registered nurse and were escalated to surgeons via the app as appropriate. |
| | Control | Pre-APDS cohort of colorectal patients from the same institution |
| | Outcome | Frequency of ED visits and hospital readmissions occurring by POD30. |
| Results | No difference in ED visits between patients with and without APDS (OR 0.493, 95% CI 0.218-1.113), $p=0.0887$). No difference in readmission (OR 0.429, 95%CI 0.184-1.002, $p=0.0504$). | |
| Chang <i>et al.</i> ¹⁰⁵ 2019/ United States | Study Design | Cohort study |
| | Number of Patients | 153 |
| | Study Population | Colorectal surgery patients with colorectal adenocarcinoma |
| | Average Age | App group: 64.7 years (SD 13.4) |

| | | |
|---|----------------------------|---|
| (abstract only) | | Standard care group: 65.0 years (SD 13.1) |
| | Baseline Computer Literacy | No measure reported |
| | Intervention | Mobile application used for pre-op surgery preparation and post-operative monitoring via patient responses to post-op care questions on preventable readmission complications |
| | Control | Pre-mobile application implementation cohort at the same institution |
| | Outcome | Readmissions rates and emergency department visits |
| | Results | No statistically significant difference in readmissions and ED visits in the app group vs standard care group |
| Mata <i>et al.</i> ¹⁰⁷ 2019/ Canada | Study Design | RCT |
| | Number of Patients | 97 |
| | Study Population | Adult patients with colonic or rectal diseases planned for surgical resection. Patients unable to follow the ERAS pathway or use a tablet due to medical comorbidities were excluded. Those unable to understand English or French were excluded. |
| | Average Age | Control: 56.6 years (95% CI 53.2-60) Intervention: 63.3 years (95% CI 60-66) |
| | Baseline Computer Literacy | 79% of patients in the control and 86% of patients in the intervention group were owners of a smartphone, tablet or personal computer. |
| | Intervention | <p>Patients received standard pre-operative education and written materials. Post-operatively patients received a tablet pre-loaded with a mobile application (SeamlessMD) customized to institutional ERAS pathway. This contained:</p> <p>(1) Milestones checklist listing the day's recovery goals, completed by the patient and always visible on the app's dashboard</p> <p>(2) Daily clinical questionnaire about the previous day's milestones, with a brief phrase of encouragement for achieved goals and advise for unachieved goals</p> <p>(3) Educational material available through the app's homepage</p> |
| | Control | Patients received standard pre-operative education and written materials. Post-operatively patients received a tablet with internet access but no SeamlessMD mobile app. |
| | Outcome | Overall adherence to a bundle of 5 post-op ERAS elements dependent on patient participation on POD1 and POD2. This included early mobilization, gum chewing, consumption of oral liquids, breathing exercises, consumption of nutritional drinks. |
| | Results | No difference in adherence to 5-element post-operative bundle on POD1 and POD2. The mean overall adherence was 62% (95% CI 56-68%) in the control group and 59% (95% CI 52-66%) in the intervention group. Mean difference was 2.4% (95% CI -5-10, p=0.53) |
| RTC= randomized controlled trial, SD = standard deviation, CI = confidence interval, POD = post-operative day | | |

3.3.2 Studies Assessing Feasibility of Ileostomy Monitoring

Two of the included studies examined the feasibility of applying mHealth technologies for monitoring ileostomy outputs in patients with new stomas. Bednarski *et al.*¹⁰³ measured concordance between the determination of the need for initiation of antimotility medications during virtual ileostomy output assessments via FaceTime and in-person assessments. They found that 43/44 clinical encounters included in the study to be concordant.

Kontovounisios *et al.*¹⁰⁴ examined the usability of the Ostom-i device among a cohort of 9 patients. This is an electronic device that clips onto a stoma bag, electronically determines ostomy output through sensory detectors, and relays measurement of ileostomy output to a mobile application. They described that patients were able to pair the device and remove and re-attach the device without difficulty. However, they did experience network problems when patients were moved to different wards or discharged. Details regarding the nature of these network errors, teaching required to use the device, length of time patients used the device, and accuracy of the device readings were not described.

3.3.3 Studies Assessing Efficacy of Ileostomy Education

Three studies evaluated electronic educational interventions targeting patients with new stomas.⁹⁹⁻¹⁰¹ All evaluated a change in ileostomy knowledge and self-care efficacy from baseline. It is unclear whether similar questionnaires were used for this

purpose and whether these measurement tools were validated. All assessed knowledge at different time intervals. Bedra *et al.*¹⁰⁰ and Bennett *et al.*¹⁰¹ were both single-arm studies with no comparison groups. Both reported improvement in baseline knowledge and care self-efficacy following use of their respective ileostomy educational interventions.

Lo *et al.*⁹⁹ conducted a randomized control trial comparing the difference in the change in ileostomy knowledge and self-care attitudes between those who received an in hospital multi-media education program and those who received a standard educational brochure. They found that the multimedia education program resulted in greater improvement in self-care knowledge ($p < 0.001$), attitudes towards self-care ($p < 0.001$) and self-care behaviour ($p < 0.001$) when compared to an information brochure.

3.3.4 Studies Assessing Feasibility of Extended Monitoring Using mHealth Technologies

Four studies assessed patient compliance with automated surveys delivered via mobile applications or text messaging.^{13,15,16,102} Initiation of monitoring and follow-up time varied among all these studies (Table 1). The specific components of the study intervention and the definition of compliance also differed (Table 1). Compliance was low in two studies. Dawes *et al.*¹³ observed that patients submitted responses to their survey or uploaded a wound photo on only 53% of the days during which the app was available. Scott *et al.*¹⁵ found that 30% of enrolled patients did not use their app to answer survey questions following discharge and 10% used their app only once. The other two studies reported higher compliance rates. Symer *et al.*¹⁰² found that 83.9% of patients in

their cohort were compliant with their intervention, which they defined as the percent of patients who completed at least one daily app-related task at least 70% of the time. In the study by Carrier et al.,¹⁶ only 10%, 7% and 10% of the study population did not respond to survey questions delivered via text messaging on post-discharge days 1, 3 and 5, respectively. Longer term monitoring through text messaging was not investigated.

Scott *et al.*¹⁵ additionally assessed the usability and patient satisfaction of the SeamlessMD mobile application for post-operative monitoring and communication in their study. This was done via semi-structured interviews with the patients and the use of the System Usability Scale (SUS), a validated survey using Likert-type question to evaluate usability of technological tools on a scale of 0 to 100.¹⁰⁹ Usability was rated high (median SUS 95 (IQR 83-98) following post-discharge use. Additionally, 67% of patients reported that the app fit into their daily routines and 73% reported that they trusted the alerts generated by the application. However, this did not translate into action taken by the patients. Only 4/10 patients who were advised to contact the surgical team by the application did so. Reasons for non-compliance included patient uncertainty about the significance of their symptoms, patient judgement (they thought they knew better than the app) and recent evaluation by a physician.

3.3.5 Studies Assessing the Efficacy of Extended Monitoring Using mHealth Technologies

Bidwell *et al.*¹⁰⁵ designed a web-based perioperative program accessible via smartphone, tablet and desktop for patients undergoing colorectal surgery. This platform

(1) provided patient reminders of pre-operative instructions and post-operative expectations, (2) surveyed patients about their post-operative recovery and selfcare efficacy and (3) contained information about colorectal operations. No control arm was included. The authors found an improvement in knowledge and anxiety from baseline (prior to surgery) after exposure to this intervention.

Two non-randomized cohort studies were conducted to evaluate the effect of active post-discharge surveillance on hospital readmission rates and emergency department visits.^{105,106} Both studies utilized a pre-/ post-study design, in which they offered the mobile application to all colorectal patients at their institution following a certain date and compared readmission rates to a historical cohort. Additionally, both studies included a 9 to 10 month “ramp-up” period during which the mobile application was introduced and troubleshooted. Readmissions were measured up to 30 days post-operatively in the study by Borsuk *et al.*¹⁰⁶; it is unclear what timeframe Chang *et al.*¹⁰⁵ used to identify post-operative readmissions. Patient responses were triaged by a registered nurse in the study by Borsuk *et al.*¹⁰⁶; triage details were not provided in the abstract by Chang *et al.*¹⁰⁵ Neither study identified a statistically significant difference in hospital readmissions or emergency department visits following the implementation of their intervention.

A randomized controlled trial was performed by Mata *et al.*¹⁰⁷ to evaluate the effect of an electronic Enhanced Recovery After Surgery (ERAS) patient checklist and provision of digital education materials on overall adherence to a bundle of 5 post-operative ERAS elements that are dependent on patient participation. This intervention was delivered on a tablet in-hospital via the SeamlessMD mobile application and was

compared to use of a “sham” tablet (tablet with no SeamlessMD application) and standard preoperative education. Adherence to the bundle was evaluated on POD1 and POD2 by blinded outcome assessors. No difference in adherence to the 5-element post-operative bundle on POD1 and POD2 was found ($p=0.53$).

Table 3-2 Assessment of within study bias using the Cochrane Collaboration Tool and ROBINS-I Tool.

| Randomized Controlled Trials | | |
|--|--|---|
| Author/ Year/ Country | Domain | Assessment of Bias |
| Mata <i>et al.</i> ¹⁰⁷ 2019/ Canada | Random Sequence Generation | <i>Quote:</i> “Randomization was conducted centrally using a web-based randomization system provided by an independent contractor... Randomization was stratified by surgery with formation of a new stoma versus surgery without a stoma, as patients with a stoma are treated within a slightly modified ERP and used a modified version of the app” <i>Judgement:</i> Low risk |
| | Allocation Concealment | <i>Quote:</i> “To ensure concealment of allocation, patients were randomized once they arrived at the surgical ward after surgery. To ensure balance in treatment allocation, patients were randomized in blocks with block sizes randomly assigned (2, 4, or 6)” <i>Judgement:</i> Low risk |
| | Blinding of Participants and Personnel | <i>Quote:</i> “A researcher blinded to the participants’ treatment allocation recorded all outcome measures... To ensure blinding, participants in the control group had a tablet computer in their room during hospital stay (sham intervention). Participants were asked not to discuss information about their group allocation with the assessor. The codes for group allocation were not revealed until data collection was completed. Any inadvertent unblinding was reported. Due to the nature of the intervention it was not possible to blind the participants to their group assignment.” <i>Comment:</i> Personnel were blinded to the study intervention, but patients were not. <i>Judgement:</i> High risk |
| | Blinding of Outcome Assessment | <i>Quote:</i> “A researcher blinded to the participants’ treatment allocation recorded all outcome measures... To ensure blinding, participants in the control group had a tablet computer in their room during hospital stay (sham intervention). Participants were asked not to discuss information about their group allocation with the assessor. The codes for group allocation were not revealed until data collection was completed. Any inadvertent unblinding was reported.” <i>Judgement:</i> Low risk |
| | Incomplete Outcome Data | <i>Support:</i> Of the 100 patients randomized, 97 completed the study. 2 patients in the control group were admitted to the intensive care unit and 1 patient in the control group had post-operative delirium. 2 patients (1 in each study arm) declined assessment on POD1. Data is missing for 32 patients for adherence on POD2 because they were discharged prior to assessment on the morning of POD3 (15 in the app group and 17 in the control group). Analysis was conducted using the intention to treat principle. <i>Judgement:</i> High risk <i>Comment:</i> Although missing data is significant in comparison to the sample size, it is missing due to early discharge. The utility of adherence to the post-operative bundle needs to be considered in this context. |
| | Selective Reporting | <i>Support:</i> Study registered on clinicaltrials.gov and all pre-specified outcomes are reported <i>Judgement:</i> Low risk |
| Lo <i>et al.</i> ⁹⁹ 2010/ Taiwan | Random Sequence Generation | <i>Quote:</i> “Participants were randomized using a computer-developed random list that assigned them into either the experimental or the control group” <i>Judgement:</i> Low risk |

| | Allocation Concealment | <i>Quote:</i> "Allocation was concealed from the recruiting research assistant" <i>Judgement:</i> Low risk |
|---|--|---|
| | Blinding of Participants and Personnel | <i>Support:</i> No mention of participant or study personnel blinding. Participant blinding would not be possible due to the nature of the intervention. Study personnel administered the intervention and were present to answer questions following administration, therefore, they were unlikely blinded. <i>Judgement:</i> High risk |
| | Blinding of Outcome Assessment | <i>Support:</i> Outcomes were assessed via a patient questionnaire delivered at baseline and 1 week following the intervention. The patient answering the questionnaire was not blinded to the intervention. It is unclear whether the research assistant delivering the questionnaire was blinded. <i>Judgement:</i> High risk |
| | Incomplete Outcome Data | <i>Support:</i> Of the 50 patients randomized to the intervention, 4 were lost to follow-up and were excluded from the analysis. Of the 57 patients randomized to the control, 1 was lost to follow-up and was excluded from the analysis. <i>Comment:</i> Most randomized patients were included in the final analysis and only 8% of patients randomized to the intervention group and 1.8% of patients randomized to the control group were lost to follow-up. <i>Judgement:</i> Low risk |
| | Selective Reporting | <i>Support:</i> Prior registration of study protocol is not specified. <i>Judgement:</i> High risk |
| Non-Randomized Cohort Studies | | |
| Author/ Year/ Country | Domain | Assessment of Bias |
| Borsuk <i>et al.</i> ¹⁰⁶ 2019/ United States | Bias due to confounding | There is potential for confounding. The authors utilized logistic regression to control for confounding in the effect of APDS on ED visits in readmission. Only tobacco use, procedure type and ostomy status were controlled for in the model investigating effect on ED visits. Only tobacco use and procedure type were controlled for in the model investigating effect on readmissions. These were chosen due to significant difference in these factors identified on bivariate analyses. Inclusion of confounders based on a priori knowledge would have been preferable. For example, age, surgical approach, comorbidities and ostomy formation varied between APDS and non-APDS patients and independently are associated with early post-operative readmission and ED visits. Other confounders, such as ERAS adherence, SES, sex, race, insurance status were also not considered. Of those variables controlled for, there was no differentiation between type of stoma (ileostomies have greater risk of readmission). Covariate data was obtained from chart review, which may not be accurate or complete. Missing data was not reported. It is unclear if APDS may have also altered patient education during time of admission and physician practices over time. |
| | Bias in selection of participants | All patients with qualifying surgery after December 2016 were offered the intervention. This was compared to a cohort prior to initiation of the intervention. Selection for the intervention was based on time. Bias could be introduced due to other care changes occurring over this period. |
| | Bias in classification of interventions | Intervention groups were clearly defined and were time-based. However, the degree of individual use of the app was not outlined. Time cut-offs were determined by the initiation of APDS at the institution and end of the app adjustment phase. These are discrete time-points that were determined prior to initiation of the study, but theoretically other time cut-offs could have been applied and altered based on knowledge of the risk of the outcome. |
| | Bias due to deviations from intended interventions | Measures of ERAS adherence pre and post APDS were not recorded. Changes in other care practices that occurred concurrently were not outlined, however, are possible. Of the 168 patients eligible for APDS, 38 never enrolled in the program and 7 enrolled and never interacted with the program (45/168 = 26.8%). Both an intention-to-treat and as-treated analysis were performed. Deviations likely bias the effect of APDS away from the null. Significant differences in readmission and ED visits were identified between patients using APDS and those who were not |

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| | | on as-treated analyses, but not intention-to-treat. |
| | Bias due to missing data | Outcome data were available for all patients. Patients were not excluded due to missing data on intervention status or other variables needed for the analysis. |
| | Bias in measurement outcomes | The primary outcome measures (admission or no admission, ED visit or no ED visit) could not have been influenced by knowledge of the intervention received. This information was obtained via a chart review for all patients. Subjective secondary outcomes (whether an admission was avoidable, whether an interaction via the app prevented an ED visit) were assessed by 3 evaluators blinded to the intervention. Systematic errors in measurement of the outcome are unlikely to be related to the intervention received. |
| | Bias in the selection of reported results | Bias due to multiple comparisons and selected reporting is unlikely. |
| Chang <i>et al.</i> ¹⁰⁵ 2019/ United States (abstract only) | Bias due to confounding | There is potential for confounding due to a non-randomized design. The authors made no attempt to control for confounding. Comparisons of the primary outcomes between study arms were made using the chi-squared test and t-test. |
| | Bias in selection of participants | All patients undergoing colorectal surgery for colorectal adenocarcinoma during the study period were considered for inclusion in this retrospective cohort study. Patients who had their surgery between January – September 2018 were included in the intervention group. Patients who had their surgery between June 2016 – Feb 2017 were included in the control arm. Selection for the intervention was based on time. Bias could be introduced due to other care changes occurring over this period. |
| | Bias in classification of interventions | Details regarding the mobile application and patient interaction with the application are not provided. Comparison groups were defined by time, which may be a poor proxy for mobile application use. Compliance with aspects of the application was not outlined. Chosen time-points for inclusion of patients in each arm of the study are not well justified and theoretically other time cut-offs could have been applied and altered based on knowledge of the risk of the outcome. |
| | Bias due to deviations from intended interventions | 34/93 patients offered the mobile application did not sign up for the intervention. These patients were more likely to be older, female and minorities. On sensitivity analyses utilizing only patients who signed up for the application in the intervention arm, still no difference was seen in ED visits and admissions between those who used the app and did not. It is unclear whether any other educational interventions or care changes were put in place over the study period that could bias results. Of those who enrolled to use the application, it is unclear how compliant the patients were with various features of the application. |
| | Bias due to missing data | It is unclear if outcome data was complete and whether this resulted in exclusion of patients from the analysis. |
| | Bias in measurement outcomes | It is unlikely that the primary outcome measures (admission or no admission, ED visit or no ED visit) were influenced by knowledge of the intervention received. This information was obtained via a chart review for all patients. Systematic errors in measurement of the outcome are unlikely to be related to the intervention received. |
| | Bias in the selection of reported results | Bias due to multiple comparisons and selected reporting is unlikely. |
| Other Studies | | |
| Bedra <i>et al.</i> ¹⁰⁰ 2013/ United States | Selection of participants | 15 consecutive patients hospitalized patients with new ileostomies after colon and rectal resection were chosen at a single institution. A power calculation was not reported. Overall, these patients were younger than the typical colorectal population (51 years). Age distribution was not reported. Frequency of baseline computer use was high (94% reported daily computer use, 50% reported daily tablet or e-reader use). 44% were male. No other baseline participant characteristics were reported. Given the lack of reporting on baseline characteristics, generalizability is difficult to assess. Results may not be applicable to older, colorectal patients or those with poor computer literacy. |

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| | Measurement of exposure | The study exposure was an interactive educational intervention delivered via a touch-screen tablet over 24 hours. Details regarding individual use of this program over this time were not provided. Details regarding the timing of intervention in relation to surgery or discharge were not provided. Details regarding to the content of the program were not described. |
| | Measurement of outcome | The outcomes measured were change in ileostomy knowledge and care self-efficacy as determined by a questionnaire administered prior to and following the educational program. The elements within the questionnaire are not reported. It is unclear to what extent the questionnaire measures care self-efficacy in practice. |
| | Design-specific sources of bias | Time is a significant source of bias. Patients may have received other forms of ostomy teaching from nurses or physicians over the 24h period during which they had access to the tablet. This can account for the difference in test scores seen. No comparison group with standard care alone makes it difficult to draw conclusions about the efficacy of the intervention. |
| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Details regarding statistical analysis are not reported. |
| Bennett <i>et al.</i> ¹⁰¹ 2013/ United States (abstract only) | Selection of participants | Colorectal surgery patients with new ileostomies were selected. No details regarding the number of patients included, demographics, or patient selection process were provided in the abstract. Therefore, there is a high risk of potential bias. |
| | Measurement of exposure | The exposure was a web-based perioperative program accessible via smartphone, tablet and desktop which provided reminders of pre-operative instructions, post-operative expectations, surveys of patient reported outcomes and patient self-efficacy and information about colorectal surgery. No further details were provided regarding the contents of the program, degree of patient interaction with the program, teaching provided to the patients for use of the program or other educational intervention/ encounters the patient may have had over the 30+ day period during which they had access to the program. |
| | Measurement of outcome | The primary outcome of interest was a difference in scores on an ileostomy knowledge survey and ileostomy self-efficacy scale administered prior to and following table use. Further details regarding the questions included in these surveys and validation of these surveys is not provided. It is unclear whether survey score correlates with self-care in practice. |
| | Design-specific sources of bias | No comparison group with standard care alone makes it difficult to draw conclusions about the efficacy of the intervention. |
| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Details regarding statistical analysis are not reported. |
| Bednarski <i>et al.</i> ¹⁰³ 2018/ United States | Selection of participants | 60 adult patients undergoing colorectal surgery with the possibility of ileostomy creation were enrolled in the study. 11 were removed due to voluntary withdrawal (n=1), no ileostomy at the completion of surgery (n=6) and the patient's decision to defer surgery (n=4). Of the remaining 49 patients, 22 (44.9%) were not evaluated for the primary outcome due to delayed bowel function, weekend discharge and faculty academic and personal obligations impacting assessment opportunities. 44 encounters among 27 patients were used in the final analysis. It is unclear how many of the patients approached opted not to participate in the study. More the 2/5 patients enrolled and eligible for continuation in the study were not evaluated for the primary outcome, therefore, the results are subject to selection bias. Additionally, the study population was younger than the average colorectal population (median age 50.9 years for patients with matched data) and level of computer literacy among the study population is not known. The utility and acceptance of this intervention among older patients is unclear. |
| | Measurement of exposure | The intervention consisted of a FaceTime evaluation of ostomy output, involving a brief introduction and visual assessment of the output. It is unclear whether further details were obtained verbally from the patient at the time of assessment. Surgeons had access to ileostomy output volume via the chart as well. They virtually assessed the consistency of the ileostomy output on a 5-point Likert scale and recorded their impression regarding the need for antimotility agents. Details regarding length of virtual assessment were not provided. |
| | Measurement of outcome | Concordance between virtual and in-person determination for initiation of anti-motility agents was the primary outcome. In-person determination was to be performed after the virtual assessment by the same surgeon. Assessors were not blinded to their initial determination, which predisposes results to measurement bias. Of the 49 patients remaining in the study post-operatively, 22 (44.9%) were not evaluated for the primary outcome due to delayed bowel function, weekend discharge and faculty academic and personal obligations impacting |

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| | | assessment opportunities. 44 encounters among 27 patients were used in the final analysis. Of these encounters, 13 (29.5%) did not have a matched in-person assessment and a chart review was performed to obtain data regarding antimotility agent clinical decision making. More the 2/5 patients enrolled and eligible for continuation in the study were not evaluated for the primary outcome, therefore, the results are subject to significant bias. Moreover, about 1/3 of telemedicine encounters were not compared to the standard of care (inpatient assessment). |
| | Design-specific sources of bias | Decisions regarding the initiation of antimotility agents for high ileostomy output are predominantly based on volume. Therefore, high concordance between virtual and in-person assessment of ileostomy output for the initiation of anti-motility agents is expected because this information was present to surgeons during both modes of assessment. Also, chart review to obtain antimotility initiation data in lieu of inpatient assessment may be inaccurate. |
| | Confounding control | Surgeons and patients were matched for both the virtual and in-person assessment. |
| | Statistical analysis | Only descriptive analyses were performed. |
| Bidwell <i>et al.</i> ¹⁰⁵ 2019/ United States (abstract only) | Selection of participants | 185 adult patients undergoing elective colorectal operations between October 2017 and September 2018 were invited to participate. Of these, only 45 (24%) completed the baseline and 30-day post-operative surveys. Therefore, there is a high risk of selection bias. |
| | Measurement of exposure | The exposure was a web-based perioperative program accessible via smartphone, tablet and desktop which provided reminders of pre-operative instructions and post-operative expectations, surveys of patient reported outcomes and patient self-efficacy, and information about colorectal operations. Degree of patient interaction with the program, teaching provided to the patients for use of the program or other educational intervention/ encounters the patient may have had over the 1 month period during which they had access to the program (which may bias the results away from the null) were not provided. |
| | Measurement of outcome | The primary outcome of interest was the change in self-efficacy as measured by a survey administered pre-op and 30 days post-op. Data regarding patient reported impact on frequency of clinical encounters was also collected via the post-operative survey. Details regarding the questions included in these surveys and survey validation are not provided. It is unclear whether a reported decrease of frequency of clinical encounters correlates with a decrease in healthcare utilization in practice. Self-efficacy measures, such as knowledge and anxiety are expected to improve pre and post-operatively with standard educational practices and interaction with healthcare providers. Improvement in survey measures therefore do not necessarily indicate a benefit of the intervention over standard practice. |
| | Design-specific sources of bias | No comparison group with standard care alone makes it difficult to draw conclusions about the efficacy of the intervention. |
| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Details regarding statistical analysis are not reported. |
| Carrier <i>et al.</i> ¹⁶ 2016/ France | Selection of participants | 111 patients undergoing colorectal surgery at 4 University affiliated hospitals in France between Nov 2014 and Sep 2015. Patients were required to have access to a mobile phone and familiarity with text messaging. It is unclear how many patients who were approached agreed to take part in the study or what "familiarity with text messaging" entailed. Patients selected for the study likely are more technologically adept than the average colorectal population. High risk of selection bias. |
| | Measurement of exposure | The exposure involved written and oral instructions regarding the follow-up at time of discharge and screening questions delivered by text message on post-discharge days 1, 3 and 5. These are 2 separate interventions (education and monitoring) and both may alter outcomes. |
| | Measurement of outcome | Multiple outcomes were assessed, including number of alerts, rapidity of response, pertinence of alerts, number of readmissions, number of surgical reoperations and visits to the emergency department. It is unclear how this data was collected. Blinding of assessors was not described and relevancy/cause of alerts can be a subjective outcome measure. A definition of non-response was not provided; it is unclear whether this refers to a lack of response to all questions presented that day or a select number of questions. The time frame of outcome measures is not defined. The authors report no hospital readmissions or reoperation among those patients who did not generate an alert, but follow-up time is not explicitly described. |
| | Design-specific sources of bias | No comparison group with standard care alone makes it difficult to draw conclusions about the effect of the intervention. Those who were re-hospitalized or re-operated on may have presented to hospital regardless of extended follow-up. |

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| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Only descriptive analyses were performed. No comparisons were made to a non-intervention group |
| Dawes <i>et al.</i> ¹³ 2015/ United States | Selection of participants | A convenience sample of 20 patients was utilized and those with poor proficiency in use of electronic devices were excluded. High risk of selection bias. |
| | Measurement of exposure | The exposure entailed the delivery of mobile application which prompted patients to respond to a 32 question daily survey regarding post-operative recovery and upload wound photos. The timing of initiation of the survey varied (POD1-3) and end of survey varied (first follow-up visit) |
| | Measurement of outcome | Compliance was well defined and compliance rates were separately calculated for inpatient monitoring days and outpatient monitoring days. This study also assessed patient satisfaction by distributing a questionnaire to 5 patients. It is unclear what questions were contained in the questionnaire. Selection bias is also a problem; it is unclear how this subset of patients were chosen. |
| | Design-specific sources of bias | The utility of the mobile application is unclear. No comparison group and no measures of efficacy make it difficult to draw conclusions about the usefulness of the intervention. |
| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Only descriptive analyses were performed. |
| Kontovounisios <i>et al.</i> ¹⁰⁴ 2018/ United Kingdom | Selection of participants | A convenience sample of 9 patients who had undergone abdominal surgery with ileostomy creation was chosen. Further details regarding patient selection and identification were not provided. High risk of selection bias. |
| | Measurement of exposure | The exposure was use of the wearable Ostomi-i device, which measures ileostomy output and transmits this information to a smart phone app. No details regarding how long these patients used this device were provided. No details regarding the patient training process were provided. No details regarding adherence were provided |
| | Measurement of outcome | Outcome measures were poorly defined as usability and acceptability of the device. What is meant by these terms or how they determined whether the device was usable or acceptable is unclear. Difficult to interpret results in this context. |
| | Design-specific sources of bias | The utility of the device is unclear. No comparison group and no measures of efficacy make it difficult to draw conclusions about the usefulness of the intervention. |
| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Regarding usability and acceptability, only a narrative description was provided. |
| Scott <i>et al.</i> ¹⁵ 2017/ United States | Selection of participants | Eligibility criteria included post-operative, English or Spanish speaking, adult patients who had undergone colorectal surgery at a large urban county hospital. Patients required their own mobile device to participate. Over a 1-year period (Dec 2013-Dec 2014), 115 patients were screened, of which 68 patients were eligible. Most patients who were ineligible, did not have a suitable device (n=20) or were not fluent in English or Spanish (n=13). The treating team was unable to introduce the study to 17 patients among those eligible (reason unknown). Of the remaining 51 patients approached by the treatment team for participation, 26 declined. Of the 25 patients enrolled, 2 were unable to have their devices brought to hospital and 3 had devices incompatible with the app. The remaining 20 were include in the study. The selection process is well-outlined, but the study none-the-less does not represent the whole colorectal population. |
| | Measurement of exposure | The exposure was the Seamless MD app, which facilitates daily post-operative symptom reporting through standardized questions. Patients are additionally able to take photos of their wounds and record their daily temperatures. The app gives automatic responses, guiding patients to seek further medical attention as needed. The app was used daily for at least 2 weeks after discharge. Average duration of use was not provided. This was a multimodal intervention, as the app had multiple functionalities. Responses to the system usability scale used to assess the app need to be interpreted in this context. Some details regarding overall adherence and adherence to aspects of the exposure were provided, which were outcome measures of this study. |
| | Measurement of outcome | This study had a mixed-methods design and utilized quantitative and qualitative data to evaluate app use. A validated scoring tool was used to measure usability and semi-structured interviews were used to explore themes related to app use. All interviews were conducted by a |

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| | | single investigator, detailed field notes were taken and authors met to review data, explore themes and determine if data saturation had been achieved. Of the 20 patients enrolled in the study, 3 were lost to follow-up and 2 did not use the app following discharge, therefore, only 15 patients ultimately provided data for the semi-structured interview and follow-up SUS. |
| | Design-specific sources of bias | In general, a well-designed study. However, results are subject to selection bias as only 15/ 68 eligible patients contributed to the final results. |
| | Confounding control | Not applicable |
| | Statistical analysis | Only descriptive analyses were performed. |
| Symer <i>et al.</i> ¹⁰² 2017/ United States | Selection of participants | Eligibility criteria included adults undergoing colorectal surgery at the New York Presbyterian Hospital between Sep 2015 and January 2017. Patients who did own or could not use an Android or iOS smartphone were excluded. Patients who could not speak English were excluded. Patients were recruited from the clinics of 6 colorectal surgeons. It is unclear if patients were identified and approached systematically, which predisposes the study to selection bias. 41 patients were consented, of which 31 participated in the study. 7 withdrew after surgery but prior to app access (unclear why), 1 was lost to follow-up, 1 had emergent surgery at another institution and 1 did not have a compatible device. Demographic information regarding SES, education and computer literacy were not provided. This is expected to be higher, as inclusion was predicated on device ownership. |
| | Measurement of exposure | The exposure was access to a mobile application that surveys post-operative recovery, alerts patients and clinicians when survey responses are concerning, allows patients to upload photos of their surgical site, ostomy and urine, syncs with a Fitbit for step-counting, and delivers a single-item visual measure of affect. The app was used from discharge to POD30. This is a multi-modal exposure as the application has multiple functionalities. The primary outcome of feasibility (defined by adherence to application use) needs to be interpreted in this context. |
| | Measurement of outcome | The primary outcome was feasibility, defined as the percent of patients who completed a daily survey-related task. A priori definition of feasibility was >75% of patients completing at least one component of the app greater than 70% of the time. There are several components of the application, include a daily survey/ alert system, photo uploads, activity tracking and single-item visual measure of affect (PAM). These all have different clinical utility. The authors claim that the app is feasible, as they measured that 83.9% of patients completed a daily task. However, average daily completion rates of Fitbit, PAM, survey and photo uploads varied (84.8%, 72.4%, 68.1%, 51.4%, respectively). Arguable, the survey and photos provide more clinically actionable data, and those had lower completion rates. |
| | Design-specific sources of bias | Feasibility is likely exaggerated as the outcome measure was a composite of compliance with one of several functionalities of the mobile application. |
| | Confounding control | Control of confounding is not reported. |
| | Statistical analysis | Only descriptive analyses were performed. |
| POD = post-operative day, SUS = system usability scale | | |

3.4 Discussion

A variety of mHealth interventions have been trialed post-operatively in the colorectal population over the last 9 years. These have included tools for ileostomy output monitoring, digital education interventions, and technologies facilitating post-

discharge patient monitoring and communication with care providers. The feasibility and efficacy of these interventions is unclear due to variable study design, small sample sizes, poor reporting, inconsistent definitions of study outcomes and methodologic flaws within conducted studies.

Two studies introduced new technologies for ileostomy output monitoring, both with methodologic flaws precluding application of their respective results. The study by Bednarski *et al.*¹⁰³ was prone to selection and measurement bias. Of the 49 patients eligible and agreeable to participation in the study, 22 (44.9%) were not evaluated for the primary outcome. In-person assessors were not blinded to the virtual determination for need of antimotility agents. Surgeons were also aware of the volume of ileostomy output documented by nurses when conducting their virtual clinical assessment. Decisions regarding the initiation of antimotility agents for high ileostomy output are predominantly based on volume. Therefore, the availability of this information in both types of clinical encounters would result in expected high concordance. It is unclear if a virtual video interaction offers benefit over knowledge of output volumes alone.

The second study, conducted by Kontovounisios *et al.*,¹⁰⁴ introduced a novel, wearable device for measurement of ostomy output, however, suffered from poorly defined outcome measures and unsatisfactory reporting of study methods and results. This ultimately undermined the validity of their conclusions. There was no evidence that the usability of the Ostom-i device was determined in systematic fashion. Data regarding key factors for patient use of this device were not reported, such as accuracy of measured ostomy output volumes, frequency of described connectivity issues, patient compliance and device effect on behaviour, medication changes and readmission rates. It is unclear

how this device will ultimately function for colorectal patients, but the concept itself is intriguing and likely warrants further evaluation.

There perhaps is a benefit to delivering pre-operative and post-operative educational materials via a digital platform over paper pamphlets. Lo *et al.*⁹⁹ conducted a randomized control trial comparing the difference in the change in ileostomy knowledge and self-care attitudes between those who received an in hospital multi-media education program and those who received a standard educational brochure. The information presented via both modalities was designed to be as similar as possible. They found that the multimedia education program resulted in greater improvement in self-care knowledge, attitudes towards self-care and self-care behaviour in comparison to an information brochure. However, this may have also been due to unmeasured differences in compliance between the two study arms (information brochures may not have been read) or due to slight differences in the content presented to patients.

Similarly, Bennett *et al.*,¹⁰¹ Bedra *et al.*,¹⁰⁰ and Bidwell *et al.*¹⁰⁵ showed improvement in healthcare knowledge, anxiety and/or selfcare efficacy from baseline following their educational mHealth interventions. However, they utilized study designs that could not establish a causal relationship. None of these studies had a comparison group and all assessed outcomes after at least a 24-hour period from baseline. Knowledge, anxiety and selfcare efficacy are all expected to improve post-operatively with time, standard educational practices and interaction with healthcare providers. Thus, it is unknown whether the observed improvement in these measures was due to the mHealth technology evaluated or standard post-operative recovery and care.

Studies evaluating patient compliance with automated surveys reported variable results. Factors affecting compliance rates across studies are likely multimodal and include differences in study design and definitions of compliance. Carrier *et al.*¹⁶ had a relatively shorter follow-up duration in their study (5 days). Surveys were also short in length (5 questions). A reduced burden of the intervention on study participants perhaps explains the higher compliance rate seen in that study, but does not explain the higher compliance rate seen in the study by Symer *et al.*¹⁰² The latter study's mobile application prompted the widest variety of responses from patients (daily survey, photo uploads, activity tracking, affect assessment) and had the longest follow-up time (30 days). On further examination, this observation is likely due to the composite nature of the definition of compliance used and it appears that measured compliance was primarily driven by patient compliance with activity tracking. The survey was more often left uncompleted and wound photos were more often not uploaded (frequency of task completion was 84.8%, 68.1% and 51.4% for Fitbit tracking, survey and wound photo uploads, respectively).

Of note, the interaction between age, computer literacy and compliance with mHealth interventions has not been explored. Issues with compliance also occurred in the form of patient inaction to automated suggestions made by mobile applications.¹⁵ These are important considerations when designing future studies utilizing algorithmic mHealth interventions for post-operative monitoring.

These studies have not addressed whether patients actually liked or enjoyed utilizing electronic mHealth monitoring or electronic education tools. While health care providers may presume that greater interaction with an electronic interface may provide

more patient confidence with self care or a perceived constant link to their healthcare providers, this may not be the case. The utilization of mHealth technologies, especially in those who are not technologically proficient, may actually be a burden or source of stress. Under or over reporting of symptoms may also be an issue. The studies included in this review did not assess the ideal timing and duration of mHealth interventions, and this warrants further investigation.

Published studies have uniformly shown no change in readmission rates or ED visits following implementation of remote post-operative monitoring via a mobile application on intention-to-treat analyses.^{105,106} However, this is based on 2 cohort studies using a pre-/ post-intervention study design. Neither sufficiently controlled for confounding in their statistical analysis and neither accounted for differences that may have co-occurred with implementation of the mHealth intervention over time. Furthermore, neither study presented a power calculation for determination of sample size. A type II error may have thus occurred.

Additionally, both of these cohort studies offered the mHealth intervention to all patients, who variably enrolled and adhered to daily use. Among those patients who used the mHealth intervention, Borsuk *et al.*¹⁰⁶ actually showed a decline in 30-day readmission and ED visits following implementation on as-treated analyses. The implication of this finding is unclear. It may represent a true signal or may be the result of confounding, as those who opted not to participate in remote monitoring may have been at greater baseline risk for readmission or ED visits following discharge regardless of the study intervention. Additionally, it is possible that efficacy of the intervention depends on

other patient factors, such as age, computer literacy, education or SES. This has yet to be explored.

3.5 Conclusion

In summary, a variety of mHealth interventions have been evaluated for post-operative use in the colorectal population. Published articles contain methodologic flaws and some suffer from inadequate reporting. Studies examining patient experience with mHealth interventions are lacking and feasibility studies have shown mixed results in the colorectal population. Perhaps more questions have been raised than answered, creating an opportunity for further study.

Chapter 4

4 Feasibility of Post-Operative Mobile Health Monitoring Among Colorectal Surgery Patients: A Pilot Study

4.1 Introduction

Mobile health (mHealth) applications are promising tools for the advancement of patient care in the perioperative period. They have the potential to encourage patient engagement in their own recovery, improve access to health care providers and enable remote patient monitoring and communication. This theoretically has many benefits, such as the early identification of complications, patient rescue, and delivery of more efficient and convenient care.

The colorectal surgery population may specifically benefit from extended monitoring in the immediate post-operative period due to their predisposition to early post-operative readmissions. This predominantly is driven from an elevated risk of surgical site infections (SSIs), dehydration (in the subset of patients who have a new ostomy), ileus and altered bowel function after surgery.^{28,77,78} With this in mind, several studies have explored the feasibility of remote monitoring via automated daily surveys delivered through mobile applications.^{13,15,16,102} However, results have been mixed due to variable study design, small sample sizes, poor reporting and methodological flaws within conducted studies resulting in variable patient compliance with study

interventions. Therefore, the utility of these applications for post-operative monitoring among the colorectal population remains unclear.

Moreover, the interaction between age, computer literacy and compliance with mHealth interventions has not been explored. The colorectal cancer population is older. In 2018, Cancer Care Ontario projected 77.9% of new colorectal cancer diagnoses to occur among those 60 years and older, and 24.5% over the age of 80.¹ Therefore, feasibility of extended post-discharge monitoring and educational interventions delivered via a digital platform may be limited if older patients do not buy-in to available new technologies or are not capable of using them due to poor computer literacy. Additionally, patients who have reported poor computer literacy and who personally did not own platforms to run the applications have been excluded from several previous feasibility studies.¹³⁻¹⁶ Therefore, it is unclear as to how remote monitoring via mHealth technologies would be applicable to the colorectal population at large.

Finally, it is not known whether patients actually like or enjoy utilizing electronic mHealth monitoring or electronic education tools. While health care providers may presume that greater interaction with an electronic interface may provide more patient confidence with self-care or a perceived constant link to their healthcare providers, this may not be the case. The utilization of mHealth technologies, especially in those who are not technologically proficient, may be an additional burden or source of stress during surgical recovery. The ideal timing or duration of mHealth interventions is also unknown. These are important considerations when designing future studies utilizing algorithmic mHealth interventions for post-operative monitoring.

We therefore have conducted a pilot study with several goals in mind. We aim to (1) assess patient satisfaction with the use of a novel mHealth application for post-operative monitoring following colorectal surgery, (2) evaluate the need for electronic patient education materials as perceived by the patient, (3) measure patient compliance with study interventions in relation to time from discharge from hospital, and (4) measure the feasibility of post-operative monitoring through daily automated prompts and wound photo uploads via the Aetonix aTouchAway application. Feasibility as defined in our study is determined not only by patient compliance, but also by the delivery of alerts to healthcare workers that are temporally associated with patient health-seeking behaviour.

4.2 Methods

Reporting of this cohort study was conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.⁷⁹ Approval was obtained from the Human Research Ethics Board at Western University prior to conduction of the study.

4.2.1 Study Setting

This was a prospective single-armed pilot study evaluating patient satisfaction, compliance and feasibility of post-discharge monitoring utilizing a novel mHealth application conducted at University Hospital (UH) at the London Health Sciences Centre (LHSC). UH is an academic tertiary care centre in London, Ontario and receives referrals

from the wider regions of southwestern and northern Ontario. LHSC is a high volume centre for colorectal surgery in the province of Ontario. The electronic medical record (EMR) utilized by LHSC is directly linked with 9 community hospitals which service the majority of the referral base. Patients were operated on by 6 participating surgeons, including 3 colorectal surgeons and 3 general surgeons with minimally invasive surgery (MIS) training. An enhanced recovery after surgery (ERAS) program was established for colorectal surgery patients during the study period and standardized hospital care bundles for perioperative care according to ERAS guidelines were utilized for study patients whenever appropriate.

4.2.2 Patient Recruitment

We aimed to recruit 50 patients for our pilot study over the course of a year, beginning February 1, 2019. All adult (≥ 18 years) patients who had undergone (1) elective full or partial resection of the colon or rectum without an ostomy or (2) elective ileostomy or colostomy reversal were considered for inclusion in the study. Elective surgery was defined as a planned operation for which the patient specifically presented to hospital from home to undergo. Colorectal surgery patients with ostomies were excluded from the study to simplify the design of our post-operative home monitoring intervention. Patients with stomas are known to have different causes of readmission, such as dehydration, in comparison to those without stomas.²⁸ Therefore, they would require unique monitoring elements, such as the reporting of daily ostomy output. Patients with synchronous liver resections were also excluded due to their complex recovery and

potential confounding reasons for readmission. Patients who did not communicate in English and who could not be taught to use the mobile application were also excluded from this study.

Patients were identified using operating room (OR) booking lists and preadmission clinic daily appointment lists on the institutional EMR. Relevant cases were screened for inclusion using these booking lists. Additional patients were identified through direct communication with surgeons and their office staff. Patients were then approached for participation in the study (1) preoperatively at the time of their appointment in preadmission clinic or (2) post-operatively as inpatients during their hospital stay. If patients were enrolled and subsequently had stomas created at their index operation or did not have the planned operation eligible for study participation, they were removed from the study. Informed consent was obtained from all participants prior to inclusion in the study.

4.2.3 Workflow Development

Study investigators partnered with the mobile application developer, Aetonix, to design an automated post-operative monitoring workflow delivered via the application, aTouchAway. aTouchAway is designed to improve connectivity of elderly patients with their healthcare providers and family members via a user-friendly tablet interface. Providers have access to a companion mobile application through which they can access patient responses to workflow prompts. Push notifications are also sent to providers via the companion mobile app to alert providers to critical responses. Both the workflow and

notification triggers are customizable to suit patient and provider needs. The mobile application for this pilot was created in collaboration with developers and study personnel. Input was sought from surgeons and their office staff. This was an extensive process which included testing phases to ensure ease of use for the patient and study monitoring personnel and tailored the application to the local colorectal surgery population.

For the purposes of the study, patients communicated with study members via an automated workflow including four elements. The first was a daily survey comprising of 20 Likert-type questions modeled after the QoR-15 tool,¹¹⁰ which has been validated to measure post-operative recovery. Additional screening questions deemed important in colorectal surgery patients were also added based on study group consensus. Pre-specified thresholds were set, which generated alerts for study investigators via push notifications on a companion smartphone application (Appendix 2). The goal was to flag patients with concerning responses, informing investigators of patients not progressing as expected following discharge.

The second element was an alert prompting patients to upload a photo of their incision for review by the study team. This was programmed to appear every other day for the first 2 weeks following discharge. 2 weeks was chosen after consultation with the wound care and ostomy nurses at our institution, given the common timing of surgical site infections. The majority of wound complications following colorectal surgery have also been shown to occur within this time frame in the literature³⁶ and upon our review of local readmissions (Chapter 2).

The third element was a daily automated prompt to sync an activity tracker (provided by the study group) with the application. The tracker was a Personal Health Information Protection Act (PHIPA) compliant step counter worn around the wrist that uploaded daily steps via Bluetooth to the patient's tablet and mobile application. Unfortunately, our study group encountered difficulties syncing the trackers with the tablets. Connectivity between the trackers and tablets was inconsistent, requiring multiple attempts to sync, and step counts were found to be inaccurate. These issues were troubleshooted with Aetonix, however, persisted. We ultimately decided not to utilize this feature for our analysis given our concerns about the integrity of the data collected.

Finally, patients were also prompted to fill a daily survey regarding pain medication use. All workflow elements were programmed to appear on the application at prespecified times, requiring no patient navigation. The workflow and questions were tested with patients of various ages for clarity and ease of use prior to the start of the pilot study. The application and all study devices were PHIPA compliant.

4.2.4 Study Intervention

All patients participating in the study were provided with data plan enabled tablets pre-loaded with the mHealth application. This was done to not exclude patients without compatible devices or internet connectivity. Patients were trained to use the application prior to leaving the hospital by study investigators. Training consisted of the patient performing a test run of all application elements with a study investigator. A study

investigator was present for the duration of this test run to answer all patient questions about application use and tablet maintenance.

As previously outlined, participants were asked to fill out a daily survey regarding their post-operative recovery, report pain medication use and upload wound photos through automated prompts via the app. Post-discharge monitoring continued until the first of (1) 30 days following discharge, (2) the 1-month post-operative follow-up appointment or (3) readmission to hospital or presentation to the emergency department.

Patient reported outcomes collected via the daily survey were used by research staff, who are practicing general surgeons or surgical residents, to triage patients. Daily survey questions elicited Likert-type responses from patients and thresholds were set by research staff to trigger alerts (Appendix 2). Those patients flagged by pre-determined criteria were contacted by research staff and offered medical advice and intervention as indicated. Patients with evidence of wound infection on uploaded photos were also counselled as appropriate. This included phone consultation, notification of the patient's surgeon or surgical team of patient concerns, booking an earlier follow-up appointment for reassessment and direction to visit the emergency department or family physician for assessment.

Tracking of post-operative recovery of pre-operative activity levels was initially planned. However as previously discussed, the recommended activity trackers did not sync consistently with the mHealth application and measurements were found to be inaccurate. Therefore, this data was ultimately not used for the analysis.

All hardware provided to study participants was returned to study personnel at the patient's first post-operative follow-up visit. At the time of follow-up with their surgeon, patients were also asked to fill out an institutionally developed survey designed to collect demographic data, readmission data and evaluate patient satisfaction with the study intervention and established patient perioperative instructions, including a pre-operative ERAS booklet and perceived post-operative counselling and readiness for discharge (Appendix 3).

Details regarding the surgical procedure, post-operative complications and readmission data were additionally collected from the EMR by study investigators. In-hospital complications included mortality, intra-abdominal infection, anastomotic leak, superficial surgical site infection, urinary tract infection, ileus, bowel obstruction, dehydration, acute kidney injury, high stoma output, deep vein thrombosis, pulmonary embolism, gastrointestinal bleeding, enterocutaneous fistula, myocardial infarction, fascial dehiscence and respiratory tract infection. This information was collected from imaging, laboratory results, procedural records and consultation notes occurring at the time of admission. Documentation of in-hospital complications in discharge summaries was also utilized for data abstraction. Patients were considered to have an early post-operative hospital readmission if they had a documented emergency room encounter or unplanned inpatient hospital admission within 30 days of discharge from the index hospital admission during which their colorectal surgery occurred. Data regarding the timing of readmission and reason(s) for readmission were also collected. Of note, the pilot was not powered to detect a difference in readmission rate from the LHSC baseline data, and focused on patient reported experiences using the mobile application.

4.2.5 Statistical Analysis

Descriptive statistics were performed for all study variables. Measures of central tendency (mean and median) and spread (standard deviation and interquartile range) were used for quantitative variables. Observed frequencies were calculated for categorical variables.

Patient satisfaction with the use of the mobile application for post-operative monitoring and established patient education interventions was assessed using 5-point Likert type scales (Appendix 3). Compliance was assessed via patient response rates to the daily survey and wound photo uploads over the follow-up period. Compliance was defined as the frequency of patients completing study related tasks on each post-discharge day among those patients still being followed in the study. The relationship between (1) compliance with answering daily survey questions and post-discharge day and (2) compliance with wound photo uploads and post-discharge day was explored utilizing univariate linear regression. The number of alerts generated overall and per patient were calculated. The reasons for alerts and temporality of alerts in relation to admission were also explored.

Feasibility of this intervention as a post-operative monitoring tool depended on both patient interaction with the application to generate actionable data and the ability of the resultant alerts to flag at risk patients for healthcare providers to counsel. We therefore defined feasibility of the study intervention a priori by two separate measures. Postoperative monitoring using this mHealth intervention would be deemed feasible if

80% of patients completed a daily survey or wound photo upload 80% of the time (11 out of 14 days) during the first 2 weeks following discharge. 2 weeks was chosen to define feasibility as the majority of hospital readmissions occur within this time period.³⁶ In addition to this criteria, at least 80% of readmissions needed to be preceded by an alert or wound photo on the day of or the day prior to readmission for the study intervention to be deemed feasible.

All statistical analyses were performed using Stata software (Version 15.1, StataCorp, College Station, TX).

4.3 Results

4.3.1 Participant Selection and Demographics

Patient recruitment began on February 1, 2019 and continued until our target population of 50 participants was reached on October 30, 2019. 144 patients were considered for inclusion. Of these, 5 patients were no longer eligible for the study because they had an ostomy created at the time of their surgery, 3 patients had their surgery cancelled, 3 patients ultimately did not have colorectal resection at the time of their surgery and 1 patient was admitted preoperatively at another site and underwent emergency surgery. 40 patients were not approached due to unavailability of study personnel for consent, 21 patients were approached but not interested in study participation, 5 patients were not approached due to technical issues precluding activation of a tablet for the study and 3 were not approached as our target sample size had been

reached. 2 patients had language barriers preventing them from participating, 1 patient did not have access to a phone for follow-up and 1 patient could not provide consent for participation. 6 patients withdrew from the study due to feeling overwhelmed post-operatively and 3 patients did not receive in hospital teaching due to unavailability of study personnel. At the time of submission of this thesis, 4 patients were still awaiting their first follow-up appointment. The remaining 46 patients have completed the study and were included in subsequent analyses (Figure 4-1). Mean patient age was 59.4 years (SD 14.7). Participant ages ranged from 28 years to 82 years. Participant demographic information is summarized in Table 4-1.

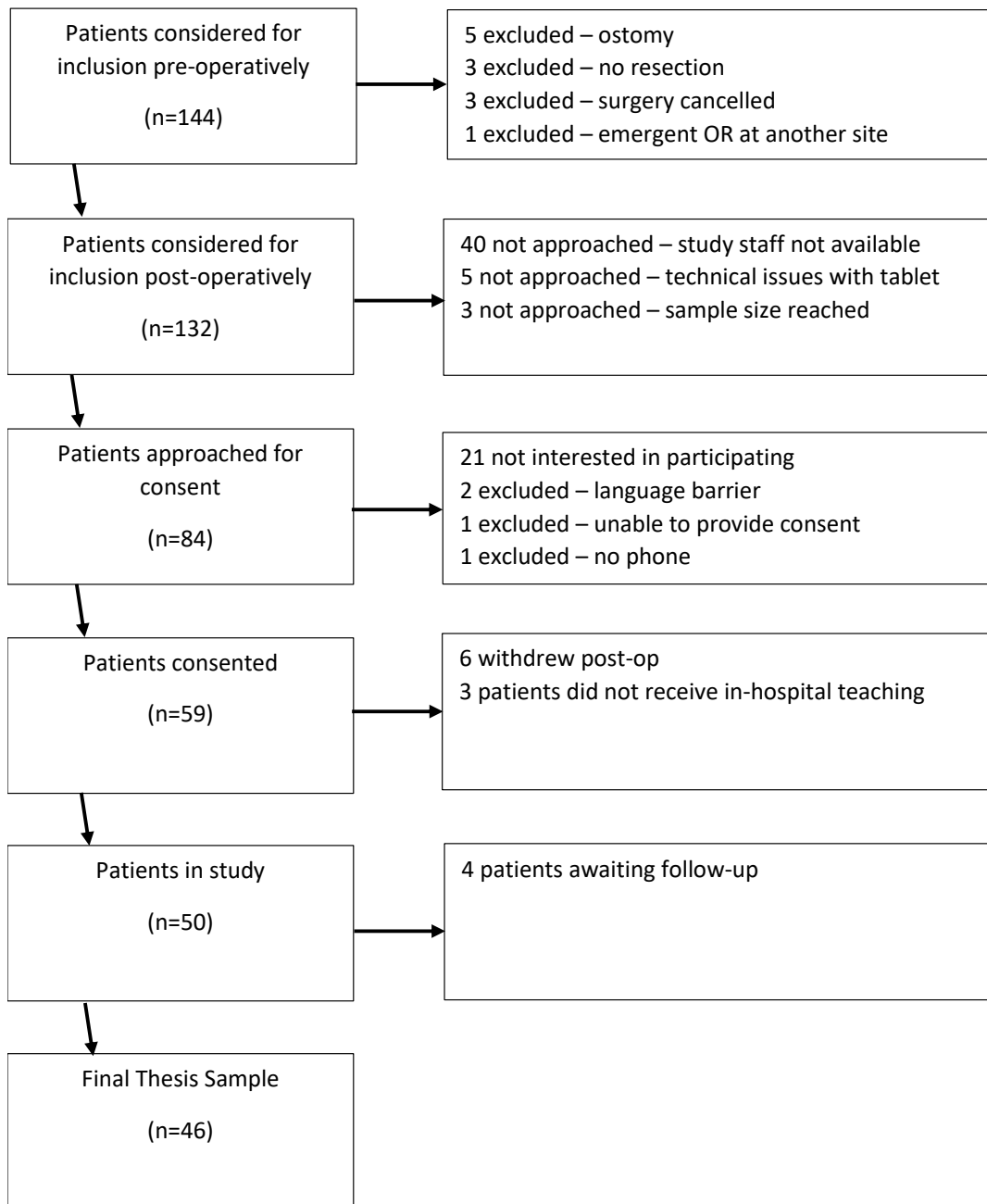


Figure 4-1 Study population selection

Table 4-1 Baseline Participant Characteristics

| | |
|---|-------------|
| | N=46 |
| Age, years (SD) | 59.4 (14.7) |
| Male (%) | 28 (60.9) |
| Highest level of Education (%) | |
| Grade 8 | 2 (4.4) |
| High School Diploma | 18 (40.0) |
| College Diploma or University Bachelor's Degree | 20 (44.4) |
| More than College Diploma or University Bachelor's Degree | 5 (11.1) |
| Smartphone or tablet owner (%) | 39 (86.7) |
| Computer or laptop owner (%) | 38 (84.4) |
| Surgery Type (%) | |
| Right hemicolectomy/ ileocolic resection | 20 (43.5) |
| Left hemicolectomy/ sigmoid resection | 8 (17.4) |
| Ileostomy/ colostomy reversal | 15 (32.6) |
| Other | 3 (6.5) |
| MIS (%) | 20 (43.5) |
| Complication During Index Admission (%) | 14 (30.4) |
| Disposition (%) | |
| Home | 32 (69.6) |
| Home with community nursing | 14 (30.4) |
| SD = standard deviation | |

4.3.2 Prevalence of Device Ownership, Frequency of Use and Patient Perceptions on Ease of Mobile Technology Use

The majority of participants were smartphone/tablet owners (86.7%) and computer/laptop owners (84.4%). 71.1% of participants reported using a smartphone/tablet daily and 48.9% used a computer or laptop daily (Figure 4-2). 100% of patients reported having access to the internet at home, 61.4% reported that they found new applications and computer programs easy to use, while 22.7% reported that they required significant guidance using new applications (Figure 4-3).

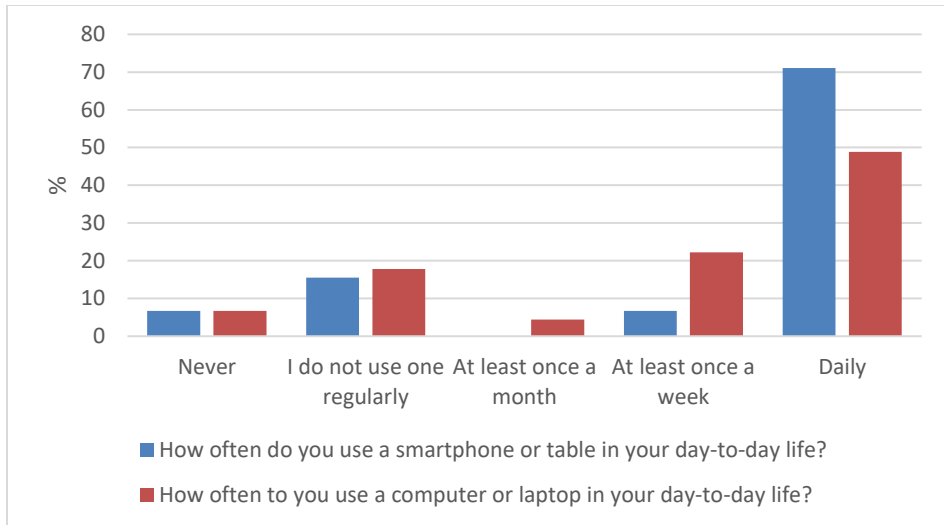


Figure 4-2 Frequency of electronic device use at baseline

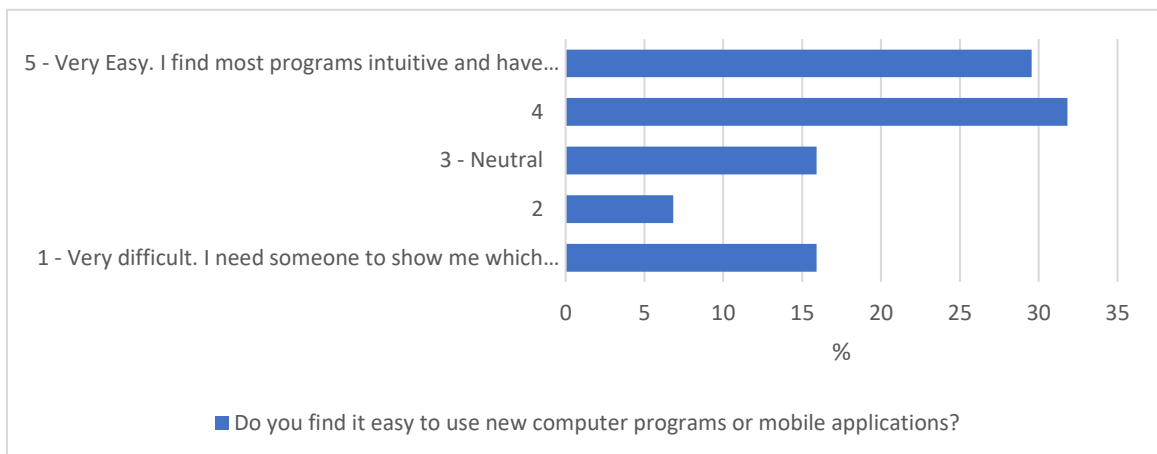


Figure 4-3 Patient perceptions on the ease of learning new program applications

4.3.3 Perceived Need for Digital Medical Education Materials

Patients routinely receive a pre-operative ERAS booklet at University hospital before undergoing colorectal surgery when consent is obtained, providing them

information on what to expect during the perioperative period in hospital and at home. 44/45 (97.8%) of patients responding to the survey reported receiving the booklet. All participants who received the booklet reported reading the information contained within and the majority (90.9%) found the booklet useful for pre-operative preparation.

When asked about their preferred media, most patients voiced that they preferred receiving the information on paper rather than through electronic alternatives such as a mobile application (55.6%) or website (71.1%) (Figure 4). The minority of patients reported that they would be more likely to read instructions that can be accessed on their phones or computer rather than in a written booklet (17.7%) (Figure 4).

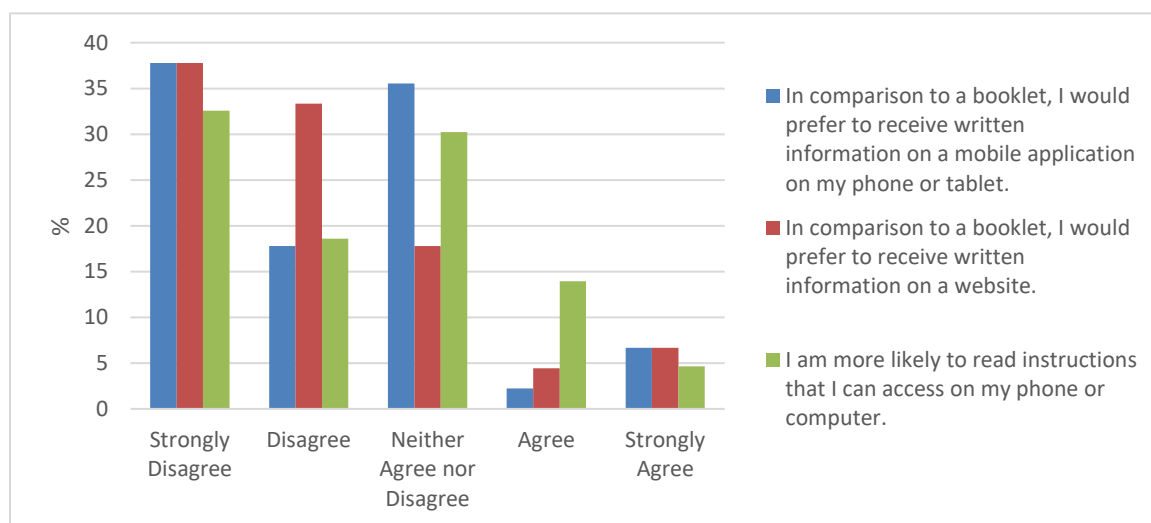


Figure 4-4 Patient media preferences for preoperative instructions

Despite preferring paper booklets for delivery of pre-operative ERAS instructions, most patients (57.8%) have additionally sought medical information from electronic medical resources, with the most popular source being Google™ (55.6%).

In general, patients felt that they were provided clear instructions about changes that were made to their home medications prior to discharge (84.4%), felt that they knew the reason why they were prescribed a new medication prior to discharge (100%), felt that they were appropriately counseled about the signs and symptoms necessitating further medical attention (84.1%) and felt that their follow-up appointments were scheduled in a timely fashion (97.7%).

4.3.4 Patient Satisfaction with Remote Monitoring via a Mobile Application

Patients reported that the daily electronic survey delivered through the tablet took a median time of 5 minutes to complete (IQR 2-5 minutes). In general, most patients found the app easy to use (78.6%), daily survey questions relevant (80.0%), clear (85.0%) and would choose to use the app again for post-operative monitoring (76.2%). Patients felt safer going home knowing that they were monitored via mobile application (80.5%) and believed that surgical patients should be monitored remotely using a mobile app (83.3%). Participants found it more difficult to take photos of their wounds (Table 2), however, believed that patients should be remotely monitored with wound photos post-operatively (78.6%) and would choose to use the app for wound monitoring if they were to have another surgery (76.2%). 1 in 2 patients reported that they would be comfortable going home sooner knowing that they would be monitored by their healthcare team post-discharge after their colorectal surgery (Table 2).

Table 4-2 Patient Satisfaction with Using the Mobile Application

| Daily Survey | | |
|---|--|------------------------------------|
| Question | Strongly Disagree or Disagree (%) | Strongly Agree or Agree (%) |
| I found the mobile application easy to use. | 5 (11.9) | 33 (78.6) |
| I found the daily questions relevant. | 4 (10.0) | 32 (80.0) |
| I found the daily questions clear. | 2 (5.0) | 34 (85.0) |
| If I had another surgery, I would want to use the app again for monitoring through daily surveys. | 4 (9.5) | 32 (76.2) |
| Wound Photos | | |
| Question | Strongly Disagree or Disagree (%) | Strongly Agree or Agree (%) |
| I found it easy to take pictures of my wound through the app. | 9 (23.7) | 24 (63.2) |
| I felt comfortable uploading pictures of my wound onto the app for study doctors to see. | 7 (18.4) | 28 (73.7) |
| I think all surgical patients should have their wounds monitored by uploading photos for their health care team to review. | 5 (11.9) | 33 (78.6) |
| If I had another surgery, I would want to use the app again for wound monitoring | 1 (2.3) | 32 (76.2) |
| Mobile Application (General) | | |
| Question | Strongly Disagree or Disagree (%) | Strongly Agree or Agree (%) |
| I felt safer going home from hospital after my surgery knowing that I would continue to be monitored by study doctors with the application. | 2 (4.9) | 33 (80.5) |
| I would be comfortable going home earlier knowing that hospital staff would check in on me using the application after I went home. | 8 (19.0) | 21 (50.0) |
| I think all surgical patients should be monitored using a mobile application following surgery. | 2 (4.8) | 35 (83.3) |
| *All questions assessed on a Likert type scale of 1 to 5, where 1=strongly disagree and 5=strongly agree | | |

4.3.5 Patient Compliance with Remote Monitoring

40 patients (87.0%) used the app at least once following discharge. 39 participants (84.8%) answered the daily survey at least once during the study period. Within the first 2 weeks post-discharge, only 8 patients (17.4%) responded to the survey every day. 8 patients (17.4%) did not answer the survey at all during this period. The median number of days patients were compliant with answering the survey in the first 2 weeks following discharge was 7.5 days (IQR 2-13). Only 17 patients (37.0%) were compliant with answering the survey 80% of the time or more in the first 2 weeks following discharge.

32 patients (69.6%) uploaded at least 1 wound photo. 14 patients (30.3%) did not upload any photos for review and 8 patients (17.4%) only uploaded 1 photo during the study period. The median number of wound photos uploaded was 2 (IQR 0-4). This corresponds to a median compliance rate of 42.9% (IQR 0-71.4%) for wound photo uploads.

Compliance with answering the daily survey diminished over time (Figure 4-5). Every seven days, compliance was reduced by 5.9% (95% CI 3.4-8.4, $p < 0.001$). There was no significant association between patient compliance with wound photo uploads and post-discharge day ($p = 0.153$) (Figure 4-6).

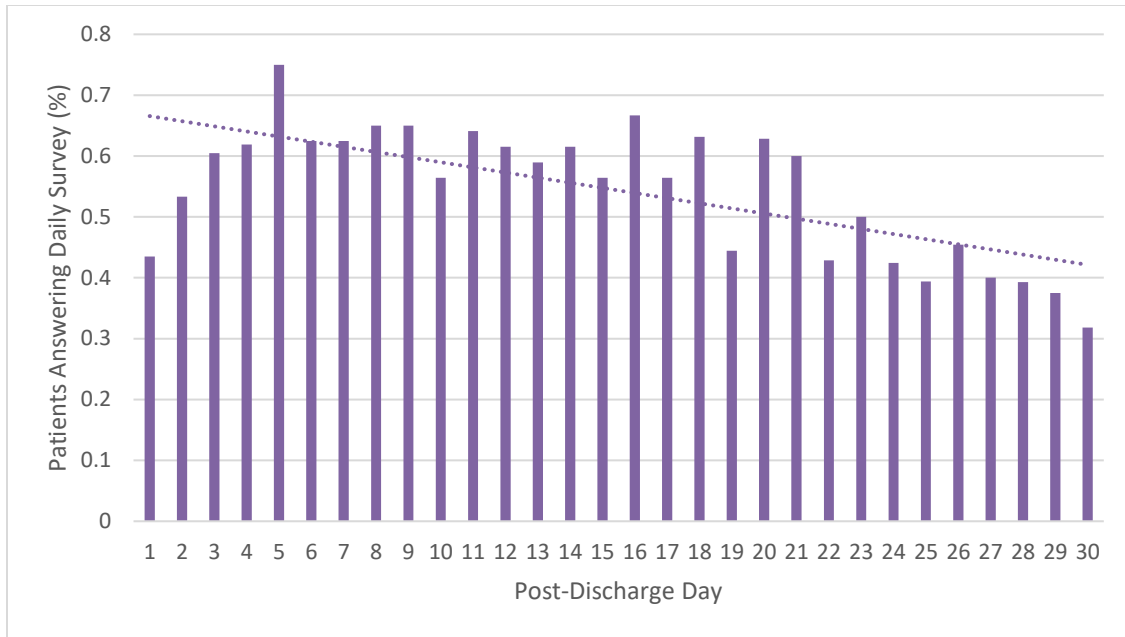


Figure 4-5 Patient Compliance with Answering the Daily Survey

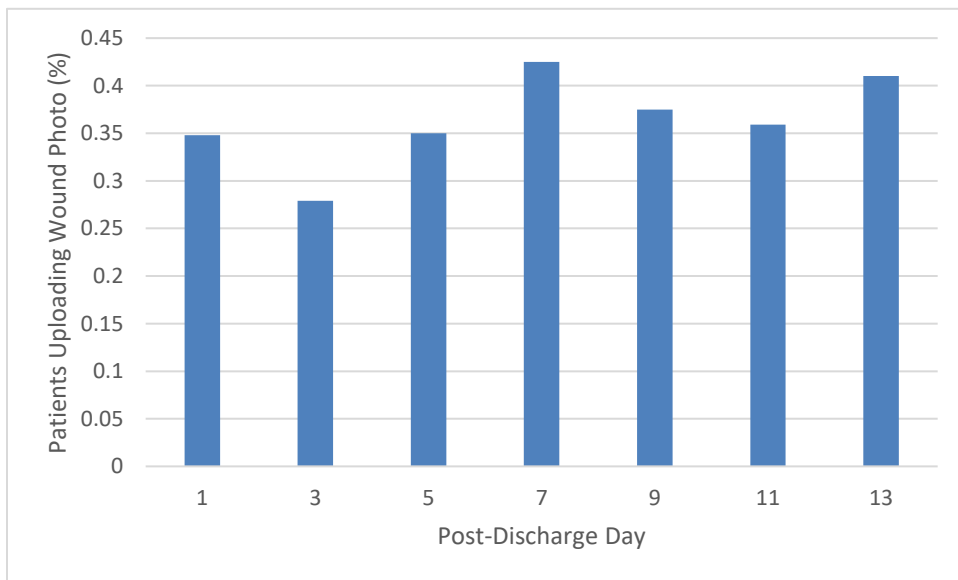


Figure 4-6 Patient Compliance with Wound Photo Uploads

4.3.6 Alerts and Readmissions

40 alerts were generated during the study period from survey results. The median number of alerts per patient was 0 (IQR 0-1). 28 patients (60.9%) generated 0 alerts, 10 patients (21.7%) generated 1 alert and 5 (10.9%) patients generated 2 alerts. The remainder of alerts were generated by 3 patients. 2 wound infections were detected through alerts and managed on an outpatient basis, 1 patient was counselled to return to the emergency department, 4 patients were counselled to follow-up with their family physician and the remaining patients were provided with reassurance.

7 patients (15.2%) presented to hospital following discharge. 1 was readmitted to hospital for a gastrointestinal bleed and 6 were evaluated in the emergency department alone. Reasons for visits to the emergency department included wound infection (2 patients), gastrointestinal complaints (2 patients) and gastrointestinal bleeding (2 patients). 6 of these patients presented to hospital within 4 days of discharge. The seventh patient presented to hospital on post-discharge day 30.

Among these 7 patients who were readmitted to hospital or seen in the emergency department, 4 patients (57.1%) used the app the day of readmission or the day preceding their readmission and 3 (42.9%) had generated alerts. All app interactions prior to admission and all alerts generated were via the daily survey. None of these patients uploaded wound photos prior to presentation to hospital.

Upon review of alerts temporally associated with a presentation to hospital, 1 patient presented with a wound infection to the emergency department shortly following

the alert and was already present in the emergency department at the time of the phone call. 1 patient responded to the survey on the day of presentation to the emergency department for a wound infection, however, the survey that generated the alert was filled following presentation to hospital on that day. The third patient who had generated an alert prior to admission had an infected hematoma during the index admission and had unremitting nausea, vomiting and abdominal pain following discharge. This patient had been counseled over the phone by study investigators to seek further medical attention. The one patient who interacted with the application the day prior to presenting to hospital who was not flagged for risk of readmission presented with an acute onset gastrointestinal bleed.

4.4 Discussion

We performed a single-armed pilot study assessing feasibility of remote post-discharge monitoring among a sample of colorectal patients utilizing patient reported outcomes collected via an automated mobile application. Patient satisfaction with current perioperative educational strategies was also evaluated. In general, patients were satisfied with current preoperative educational materials and post-operative counselling and reported a preference for paper resources in comparison to electronic resources. We found great interest in remote monitoring through daily surveys among the study population, with 80.5% of patients reporting that they felt safer going home knowing that they were monitored via an app, 83.3% of patients reporting that all surgical patients should be monitored post-operatively via a mobile application and 76.2% of patients reporting that they would use the current app for post-operative monitoring again. The

majority of patients (78.6%) also reported an interest in post-operative monitoring via wound photo uploads. This was contrasted by relatively poor compliance with mobile application use; only 17 patients (37.0%) were compliant with answering the survey at least 80% of the time in the first 2 weeks following discharge. Moreover, only 42.9% of readmissions were associated with flags. These seemed to be associated with poor patient compliance with answering the daily survey, resulting in missed opportunities to flag a concern. However, thresholds to alert study personnel may also need adjustment in future use of this technology. Regardless, this intervention did not meet our feasibility criteria in its current format.

It is important to consider patient preferences and needs when developing perioperative strategies for readmission reduction. Optimizing perioperative patient education has been investigated as a potential measure, with several studies evaluating the efficacy of electronic versus paper educational materials among the colorectal surgery population.⁹⁹⁻¹⁰¹ For example, Lo *et al.*⁹⁹ conducted a randomized control trial comparing the change in ileostomy knowledge and self-care attitudes between those who received an in hospital multi-media education program and those who received a standard educational brochure. They found that the multimedia education program resulted in greater improvement in self-care knowledge, attitudes towards self-care, and self-care behaviour when compared to an information brochure.

mHealth applications offering perioperative monitoring also have the capability of delivering electronic educational materials for patients. While it seems that perhaps digital multimedia applications may be more efficacious in educating patients among those who are willing to use them, we found that among our cohort of colorectal patients

there was still a preference for paper educational materials in comparison to digital resources. Patients also reported that they were less likely to access information through a mobile application (55.6%) or website (71.1%) in comparison to paper. Surgeon-provided digital materials, therefore, should be used to supplement current educational written practices rather than replace them. Nonetheless, they likely serve an important role as alternatives to a Google search, which was commonly used by patients in our study as well. The desire to access digital education by patients will likely increase with time given changing patient demographics and the increasingly ubiquitous use of portable electronic devices in daily life.

Despite satisfaction and interest in remote monitoring being high among our patient population, this was not reflected in compliance rates. Similar results have previously been reported in the literature among the colorectal population. Scott *et al.*¹⁵ assessed the usability and patient satisfaction of the SeamlessMD™ mobile application for post-operative monitoring and communication among a cohort of colorectal patients in the United States. Usability was rated high following post-discharge use, with 67% of patients reporting that the app fit into their daily routines and 73% reporting that they trusted the alerts generated by the application. However, this did not translate into action taken by the patients. 30% of enrolled patients did not use the app to answer survey questions following discharge and 10% used the app only once. Only 4/10 patients who were advised to contact the surgical team by the application did so. Reasons for non-compliance included patient uncertainty about the significance of their symptoms, patient judgment (they thought they knew better than the app) and recent evaluation by a physician. Incorporating patient feedback in the design process may serve to improve

patient buy-in by increasing usability and ensuring that the mHealth intervention includes elements valued by both the patient and provider.

Careful patient selection is likely critical to the success of remote mobile monitoring via automated applications because it is dependent on patient participation and trust in the technology. It is also a strategy that is currently inaccessible to a significant proportion of the colorectal population. Of the 84 patients approached for consent, 21 (25.0%) were not interested in participating and 4 (4.8%) were unable to participate due to language barriers, lack of understanding or lack of utilities. This was in the setting of the study team providing participants with a device, software and internet access for participation. Additionally, our study population reported high ownership rates of both smartphones or tablets (86.7%) and computers or laptops (84.4%). However, 14.3% of patients would still not have been able to participate in remote monitoring if a device had not been provided.

Patient satisfaction and compliance likely would have been lower if all colorectal patients were recruited in the study given that patients who were more tech savvy were more likely to self-select, and perhaps be selected, for participation. Of note, our population was relatively young in comparison to the average colorectal cancer population, with a mean age of 59.4 years (SD 14.7). A mean age of 66.4 years (SD 12.3) was found among a cohort of colorectal surgery patients at our institution during our retrospective review of readmissions (Chapter 2).

The cause of the age discrepancy between this pilot study population and the population of our retrospective review is likely multifactorial. The retrospective review of

readmissions only included patients undergoing surgery for neoplasia, while our pilot study also included patients undergoing surgery for inflammatory bowel disease, who are younger. Selection bias likely played a role given the number of patients who declined participation. Age was not collected on patients who declined participation, however, older patients who are less comfortable with using mobile technologies were probably less likely to participate in the study. Finally, a significant number of eligible patients (30.3%) were also not approached due to unavailability of study staff for consent. This may have been another source of selection bias if differential recruitment based on age occurred, and importantly, can be improved upon by using dedicated program staff for patient education and screening.

Ease of application use likely influenced patient compliance with home monitoring as well. This can be seen in the discrepancy between compliance with the daily survey and wound photo uploads. 80.0% of the patients reported that the questions were relevant and 85.0% of patients reported that they were clear. Fewer patients found it easy to take photos of their wound through the app (63.3%). This translated to 37.0% of patients being compliant with answering the survey 80% of the time or more in the first 2 weeks following discharge. Only 10.9% of patients were compliant with wound photo uploads utilizing the same metric. From observations of patients during training sessions, patients particularly struggled with aiming and focusing the tablet camera on their abdominal incisions due to the location of the wound. For this reason, the utility of remote wound monitoring via photo uploads in this patient population may be limited, or require support from a family member, friend, or home care personnel to help with taking

photos. Of note, surgical site infections are the most common reason for readmission among this population, therefore this is a significant limitation.

Remote post-operative monitoring via daily surveys through the mobile application used in this study was also found to not be feasible according to our study criteria due to lack a of compliance. Patient compliance with answering daily surveys within the first 2 weeks following discharge did not meet our predefined threshold for feasibility (80% of patients answering 80% of surveys within the first 2 weeks). Moreover, 80% of readmissions to hospital were not temporally associated with generated alerts. This was also largely due to a lack of compliance; 3 out of 7 patients did not generate an alert on the day of readmission or the day preceding their readmission because they did not interact with the application and 1 patient presented to the emergency department and filled out the survey following their visit which generated an alert.

Compliance decreased with time over the study period by a rate of 5.9% (95% CI 3.4-8.4, $p < 0.001$) per week. All readmissions in our study but one occurred within the first week of discharge. From our review of the literature and own institutional data, the majority of readmissions occur within the first 2 weeks following discharge (Chapter 2). Therefore, focused monitoring limited to the first week following discharge may be used as a potential strategy to increase compliance rates. Moreover, limiting the number of automated prompts to reduce the burden of monitoring on patients may also increase participation. This is corroborated by findings in the study by Carrier et al.,¹⁶ who found a 90%, 93% and 90% response rate to a 5-item post-operative monitoring survey delivered via text messaging on post-discharge days 1, 3 and 5, respectively. In addition, allowing patients the option of reporting problems or giving them the ability to initiate a survey

only if they have a concern may be considered for future use, given high participant satisfaction with the technology in the face of noncompliance with daily screening. Despite the low compliance as defined by the study protocol, useful flags were indeed generated and some readmissions were perhaps avoided through phone conversations with patients, and the potential for impact on readmissions should not be overlooked.

Compliance in our study was also likely affected by the technology used. There were connectivity issues between the activity trackers initially provided to all patients in the study and the tablets. This was a source of frustration for some patients and likely negatively influenced daily participation. Patients were all provided with tablets to run the mobile application, but this perhaps was not the preferred device for all patients. It is possible that compliance may have been higher if the mobile application was downloaded onto participant smartphones for use, as these typically are more portable and accessible during the day and patients are more familiar with their own devices. This can be explored through future uses of this mobile application, as a smartphone application is now available using the program described in the pilot.

Remote monitoring for readmission prevention via automated surveys may also be limited by the acuity of patient concerns and their perceptions of their own medical needs. In our study, one patient presented to the emergency department with a wound infection shortly after they were flagged for review by study staff and were already present in the emergency department at the time of the follow-up phone call. Additionally, it is unclear as to whether more intensive monitoring would ultimately decrease or increase readmissions. For example, we had a patient who was identified as at risk and counseled to present to the emergency department for assessment by study staff.

This patient was subsequently sent home. Unnecessary hospital encounters may be promoted in this fashion. Nonetheless, there were some promising findings. 2 wound infections were detected and treated on an outpatient basis, 4 patients were counselled to seek follow-up with their family physicians and a multitude of patients were provided with reassurance. It is unclear as to how close follow-up with family physicians or surgeons, and reassurance from health care providers ultimately could have impacted readmission rates.

Table 4-3 Lessons Learned

| Strategies to Improve Remote Health Monitoring |
|--|
| <p>Maximize patient engagement</p> <ul style="list-style-type: none"> • Careful patient selection • Incorporate patient feedback in the design process • Include elements valued by patient partners <p>Minimize burden</p> <ul style="list-style-type: none"> • Consider using a screening question prior to the monitoring intervention • Limit the number of survey questions • Limit remote monitoring to one week • Photo monitoring of abdominal incisions likely too cumbersome <p>Improve accessibility</p> <ul style="list-style-type: none"> • Deliver monitoring tool on personal mobile devices • Phone follow-up of nonresponse • Utilize dedicated allied health care workers for patient education, screening and follow-up |

4.5 Conclusion

In summary, we found that patients are very interested in post-discharge monitoring following colorectal surgery via mHealth applications and that monitoring of this nature provides them with a feeling of safety and reassurance. However, monitoring through automated prompts delivered through a mobile application as performed in our study was found to not be feasible due to poor patient compliance. Despite poor compliance, we still detected and acted on several patient concerns, which speaks to the potential of this technology. This is likely an intervention that will not work for all patients. Careful patient selection, minimizing screening questions and perhaps limiting monitoring to the first week following discharge may improve compliance rates and feasibility.

Conclusion

The reasons for early post-operative readmissions following colorectal surgery are complex, with many factors contributing to a patient's readmission risk. Readmissions are common, and often are due to infective complications or gastrointestinal concerns. This is true both in the literature and locally at LHSC. Many readmissions are preventable, creating an opportunity for targeted interventions to improve patient outcomes and reduce health care costs.

A variety of mHealth interventions have been evaluated for post-operative use in the colorectal population. In our pilot study, we found that patients are very interested in post-discharge monitoring following colorectal surgery via mHealth applications. Monitoring of this nature provided them with a feeling of safety and reassurance. However, we did not find patient monitoring through automated prompts delivered via a mobile application as designed in our study to be feasible, largely due to poor patient compliance. Despite this, there likely still is a role for mHealth to bridge the gap between patient desires for added communication with their healthcare providers. Alterations to our protocol may improve compliance and these are areas for future study.

Careful patient selection, minimizing screening questions to ease the burden of remote monitoring and perhaps limiting monitoring to the first week following discharge may improve compliance rates and feasibility. Deploying mobile applications on patient smartphones may also help improve response rates as these devices are more readily accessible to patients during the day. There are new wearable technologies being developed that do not necessitate conscious participation from patients, such as ostomy

output monitors and activity trackers, which can be incorporated into monitoring programs. Finally, perhaps allowing for patient choice and allowing patients to initiate communication with their healthcare providers via mobile applications, rather than pushed surveys, may improve the efficiency of this technology for detection of patient concerns as well.

Given changing patient demographics and the increasing use of portable electronic devices in daily life, the desire to access digital education and monitoring tools by patients will likely continue to rise with time. It is thus important for physicians to partner with developers for the creation efficacious, cost-effective tools that can be used by patients for health education, monitoring and communication with health-care providers.

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Appendices

Appendix 1: Data Collection Instructions for Retrospective Review

Step 1: Confirm case for study

- First make sure that the case is one we would like to include in the study
- We are interested in incident **elective colorectal resections** for malignant or benign neoplasms occurring between January 01 2016 and December 31 2016

Procedure Type

- The best place to find the type of procedure performed is the dictated **OR note**
- I have included the procedure type that was listed in the QBP dataset – some of these look wrong, so double-check
- Please code the procedure type as specified in the column heading; if a procedure doesn't fit within the coding, write it in words and I'll code it later

Elective vs Urgent Cases

- The best place to identify whether or not the surgery was urgent or elective is the dictated **OR note** or **Admission note**
- People admitted emergently/urgently will have an admission note with reason for admission specified. Those who are operated on electively usually do not

If you are unsure whether you need to include/ collect data on a particular case, send me an email and I can double check.

Step 2: Collect Information from OR Note

The following information can also be collected from the **OR note**:

- *Indication for surgery*
 - If unclear, check the last surgical clinic note prior to OR
- *Surgery date*
 - If unclear, check the **nursing intra-op record** (most accurate)
 - Where to find intra-op record?
 - Click “Clinical Documents/Reports” on the left-hand panel
 - Open the folder “Operative/Procedure Records”
 - Open “Perioperative Documents”
 - Open “VC Intraoperative Record”
- *Surgery mode (laparoscopic vs open)*
 - If converted to open, code as an open procedure
- *New stoma*

- Should be listed up top with the procedure, but you may need to read the body of the procedure note to find this information

Step 3: Collect Demographic Information/ Comorbidities

This information can be found in the **panel up top**:

- *Date of birth*
 - We'll convert this to age at the time of surgery once the data is all collected
- *Sex*
- *BMI*
 - Record the height and weight
 - Once these two variables are collected, it's easy to convert to BMI using statistical software

Here's where to find the rest of the demographic information:

- *Distance to hospital*
 - Record the postal code and I'll convert everything to km afterwards using statistical software
 - This information can be found under the "**Patient Information**" tab on the left-sided panel
- *Pre-Op Living Arrangements*
 - Check the social history on the **pre-op surgical consultation, anesthesia consultation and medicine consultation**. If this is not recorded in any of these, leave blank = unknown. If the living arrangements are documented but do not fall nicely into the coding scheme, write it in words and I will code later.
- *Smoker*
 - Also, should be recorded in the social history section of the **pre-op surgical consultation, anesthesia consultation and medicine consultation**. If this is not recorded in any of these, leave blank = unknown.
- *Diabetic*
 - Mark as yes if recorded in the PMHx of the **pre-op surgical consultation, anesthesia consultation or medicine consultation**
- *Pre-op Steroids*
 - Mark as yes if recorded in the Medication sections of the **pre-op surgical consultation, anesthesia consultation or medicine consultation**

Step 4: Collect Information of Neoadjuvant Therapy

This will mostly apply to patients undergoing proctectomy or APRs. That being said, double check to see if there are any **preoperative** notes from radiation oncology or medical oncology for all patients. Read these to see if the patient has received pre-op chemo or radiation therapy.

- *Pre-op chemo*
- *Pre-op radiation*

Step 5: Collect Operative Time and Discharge Date

- *Operative Time (h)*
 - This information can be found in the intra-op record
 - Where to find **intra-op record**?
 - Click “Clinical Documents/Reports” on the left-hand panel
 - Open the folder “Operative/Procedure Records”
 - Open “Perioperative Documents”
 - Open “VC Intraoperative Record”
- *Discharge Date*
 - Click on “**Location**” in the upper panel
 - This will bring up all previous hospital encounters
 - Find the encounter corresponding to the OR and record the listed discharge date
 - Alternative method:
 - Find the **discharge summary** and record this date
- *Post-op length of stay*
 - Don’t worry about filling this in. The computer can calculate based on the day of surgery and discharge date
- *RBC transfusion*
 - There is no easy place to find this info, so leave blank

Step 6: Reoperation during Initial Admission/ Readmission

You’ll be looking for this information in the same place, so might as well collect them at the same time. Best way to identify this is to see if you have any **OR Notes** or **Intra-op records** during your initial admission (based on previously recorded dates) or within 1 month of discharge. If the answer is yes, record the following:

- *Reoperation date during initial admission*
- *Type of surgery (reoperation during initial admission)*
- *Indication for surgery (reoperation during initial admission)*
- *Reoperation date during readmission*
- *Type of surgery (reoperation during readmission)*

- *Indication for surgery (reoperation during readmission)*

Step 7: Inpatient Complications

The following applies to complications occurring during the initial hospital stay as well as readmission. First check the **discharge summary** or **readmission note** if any of the complications are mentioned. This is not always accurate though. You can also check the following locations to look whether a complication happened in hospital. Most of these are located under the left-panel **Results** tab. Ensure that the dates being displayed match up with the admission dates. FYI this is the hardest part in my opinion. If you are unsure, send me a pin and I'll look into it.

- *Intra-abdominal infection*
 - See if a CT scan or US was performed showing an intra-abdominal collection (click Results, then medical imaging)
 - See if an IR drain was inserted (will discuss how to find this below) or see if any fluid cultures were taken (click Results, then microbiology)
 - Record as yes if a fluid collection was identified that was called an abscess by radiology or if the fluid collection was drained
- *Anastomotic leak*
 - See if a CT scan or other imaging was performed suggestive of an anastomotic leak
- *Wound Infection*
 - No good place to find this other than the discharge summary/ admission note for a readmission
 - You can check “microbiology” under results to see if any wound cultures were taken
- *UTI*
 - Urine culture (microbiology) or urine dip (results) suggestive of a UTI
- *Ileus or obstruction*
 - Best place to check is the discharge summary
 - Review any CT scans to see if they are suggestive of an ileus or obstruction (reading the indication for a CT scan can sometimes tell you what the care-team was worried about)
 - Check abdominal x-rays/ chest x-rays for NG tubes... elective colorectal patients typically are fed right away; if an NG tube appears, it usually means they are not progressing as expected and have developed an ileus or obstruction
 - Check to see if there are any OR notes... early post-operative bowel obstruction may be re-operated on
- *Dehydration, AKI, high stoma output*
 - Best place to check is the discharge summary

- You can directly check to see if a patient developed an AKI by looking at what their creatinine was (results) and whether there was a significant elevation
- *DVT/PE*
 - There will be a corresponding US or CTPA or VQ scan (review these)
- *GI bleed*
 - Check the discharge summary
 - Sometimes there will be an Procedure Note from a scope
- *Fistula*
 - CT scan or discharge summary
- *Dehiscence or Evisceration*
 - There will be an OR note
- *MI*
 - There will be a note from cardiology

In summary, you can find most of this information by reviewing the imaging (CT, XR, US), microbiology results (wound culture, fluid culture, urine culture, blood culture), OR notes, Procedure notes, discharge summaries and consultation notes that occurred during the admission.

Step 8: Readmission Data

Before collecting all this info, check to see if they were readmitted within 30 days. The QBP dataset did include some patients who were readmitted, however, we did not capture those patients operated on from Jan 01 to Mar 31 with the QBP dataset. The best place to find out if these patients were readmitted is to click on “**Location**” at the top and see if there are any encounters that fall within 30days of initial discharge. You can also out the discharge date for the readmission here and the service they were admitted to/ whether it was just an ED visit. Disposition following readmission will need to gleaned from the **discharge summary**.

Record the following:

- *Unplanned 30 day readmission*
- *Number of readmission within 30 days*
- *Date of first readmission*
- *ED or Inpatient*
- *Time to readmission – LEAVE BLANK... the compute will calculate*
- *Discharge date*
- *Length of readmission – LEAVE BLANK*
- *Location of readmission*
- *Admitting service*

- *Disposition from readmission* (this is the only variable one on the list that you need to obtain from the discharge summary)

Reason for readmission can be found in the admission note or discharge summary. These, however, are not always accurate or complete. Therefore, review imaging, microbiology, inpatient consults as described above.

Step 9: IR procedure during readmission

Click “Clinical Documents/Reports” on the left-hand panel. Open the “**Medical Imaging**” folder. IR procedures are usually documented here. You can also check the **discharge summary** for the readmission encounter (but this will be less accurate). If an IR procedure was performed, record the following:

- *IR Procedure date*
- *IR procedure type*
- *Indication for procedure*

Appendix 2: Daily Screening Survey Delivered via aTouchAway Application

How have you been feeling in the last 24 hours?

The following questions are assessed on a scale of 1 to 10, where 1 = none of the time and 10 = all of the time. Answering 1 to 4 when responding to underlined questions will trigger a phone call.

1. Able to enjoy food
2. Feel well rested
3. Able to have a good sleep
4. Able to get dressed, wash and use the toilet by myself
5. Able to return to work or my usual home activities
6. Feel well supported by my family and friends
7. Feel well supported by my doctors and nurses
8. Feel comfortable and in control
9. Have a sense of general well-being
10. Feel like I am recovering well following my surgery

Have you had any of the following in the last 24 hours?

The following questions are assessed on a scale of 0 to 10, where 1 = none of the time and 10 = all of the time. Answering 7 to 10 when responding to underlined questions will trigger a phone call.

11. Moderate or severe pain
12. Nausea or vomiting
13. Constipation or bloating
14. Fevers or chills
15. Dry mouth or thirst
16. Shortness of breath
17. Difficulty remembering
18. Difficulty staying awake
19. Feeling worried or anxious
20. Feeling sad or depressed

Appendix 3: End of Study Patient Survey

Date: _____ Study ID: _____

Personal Information:

Please circle the most appropriate response to the following questions:

(1) What is your highest level of education?

- Grade 8
- High School Graduate
- College Diploma or University Bachelor Degree
- More than College Diploma or University Bachelor Degree

(2) Do you own a smartphone or tablet?

- Yes
- No

(3) Do you own a computer?

- Yes
- No

(4) How often do you use a smartphone or tablet in your day-to-day life?

- Daily
- At least once a week
- At least once a month
- I've used a smartphone or tablet before, but I do not use one regularly
- I've never used a smartphone or tablet before

(5) How often to you usually use a computer or laptop in your day-to-day life?

- Daily
- At least once a week
- At least once a month
- I've used a computer or laptop before, but I do not use one regularly
- I've never used a computer or laptop before

(6) Do you typically have access to the internet at home?

- Yes
- No

(7) Do you find it easy to use new computer programs or mobile applications (circle the number)?

| | | |
|---|---|---|
| | Neutral | |
| <p>Very difficult. I need someone to show me which icons to select every step of the way.</p> | <p>_____</p> <p>1 2 3 4 5</p> | <p>Very Easy. I find most programs intuitive and have no trouble navigating them on my own.</p> |

(8) Do you seek medical information online or use electronic medical resources?

- Yes
- No

If you answered yes to the previous question, what electronic medical resources do you use (select all that apply)?

- Google search results
- PubMed or other databases
- Links provided to me by my doctor
- Government sites
- Mobile applications
- FitBit or similar activity tracker
- Other: _____

Pre-operative care:

The following are questions about sources of information available to you before your surgery, including health care workers. Circle the best answer or number that best fits with how much you agree with the statement.

a) I received a booklet with written instructions about my surgery and recovery period *before* my surgery.

- Yes
- No

If you answered yes to the previous question:

a. I read the information in the booklet that was provided to me before my surgery.

- Yes
- No

b. I found the information in the booklet useful.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

b) In comparison to a booklet, I would prefer to receive written information on a mobile application on my phone or tablet.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

c) In comparison to a booklet, I would prefer to receive written information on a website.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- d) I am more likely to read instructions that I can access on my phone or computer.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

Post-operative care:

- (1) The following are questions about how prepared you were for going home after your surgery. Circle the best answer or number that best fits with how much you agree with the statement.

- a) I was given a prescription for at least one new medication after my surgery or changes were made to my home medications following my surgery.

- Yes
 No
 Unsure

If you answered yes above, please answer the following 2 questions:

1. I was provided with clear instructions about changes that were made to my medications during my hospital stay before I left the hospital.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

2. I knew the reason why I was prescribed a new medication after my surgery before I left the hospital.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- b) I was warned about signs and symptoms that would require me to seek medical attention once I was home.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- c) I had a follow-up appointment scheduled with my surgeon in a timely fashion.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

Satisfaction with Study Interventions:

- (1) The following are questions about your experience using the mobile application. Circle the best answer or number that best fits with how much you agree with the statement.

- a) Approximately, how long did it take you to fill out the daily survey? _____ minutes

- b) I found the mobile application easy to use.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- c) I found the daily questions relevant.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- d) I found the daily questions clear

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- e) I felt safer going home from hospital after my surgery knowing that I would continue to be monitored by study doctors with the application.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- f) I would be comfortable going home earlier knowing that hospital staff would check in on me using the application after I went home.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- g) I think all surgical patients should be monitored using a mobile application following surgery.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- h) If I had another surgery, I would want to use the app again for monitoring through daily surveys.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- i) I found it easy to take pictures photos of my wound through the app.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- j) I felt comfortable uploading pictures of my wound onto the app for study doctors to see.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- k) I think all surgical patients should have their wounds monitored by uploading photos for their health care team to review.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- l) If I had another surgery, I would want to use the app again for wound monitoring.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- (2) The following are questions about your experience with the activity tracker. Circle the best answer or number that best fits with how much you agree with the statement.

- a) It was a burden to wear the activity tracker every day.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- b) The information provided by the activity tracker encouraged me to increase my activity level.

Strongly Disagree 1 _____ 2 3 4 5 Strongly Agree

- (3) Do you have any comments regarding the daily survey, wound photo uploads, scheduled phone calls or activity tracker? Is there any study intervention that you really liked or disliked? Which interventions do you think are best to use for patients in the future?

Follow-up:

(1) Did you seek medical attention by phone after you were discharged from the hospital after your surgery?

- Yes
- No
- Cannot remember

If yes, who did you call?

- My surgeon's office
- My family doctor
- Telehealth
- The on-call resident at the hospital
- Other: _____

(2) Did you seek medical attention in person after you were discharged following your surgery?

- Yes
- No
- Cannot remember

If yes, where?

- My surgeon's clinic
- My family doctor's clinic or a walk-in clinic
- The Emergency Department or Urgent Care
- Other: _____

(3) Were you re-admitted to hospital after you were discharged from the hospital following your surgery?

- Yes
- No

If yes, where? (Please name the hospital and city) _____

(4) Do you have any additional comments?

Tanya Kuper

Academic Background and Training

| | |
|---------------------------|---|
| 2016 – 2021 (expected) | General Surgery Residency <i>Schulich School of Medicine & Dentistry, Western University</i> |
| 2018 – 2020 (expected) | Master of Public Health in Epidemiology <i>T.H. Chan School of Public Health, Harvard</i> |
| 2018 – 2019 (expected) | Master of Science in Surgery <i>Schulich School of Medicine & Dentistry, Western University</i> |
| 2012 – 2016 | Doctor of Medicine <i>Schulich School of Medicine & Dentistry, Western University</i> |
| 2008 – 2012 | Honours Bachelor of Science <i>Specialist in Pathobiology, University of Toronto</i> |

Publications

| | |
|------|---|
| 2020 | Mocanu V, Kuper T , Marini W, Assane C, DeGirolamo K, Fathimani K, Baxter N. The Impact of Gender and Ethnicity on General Surgery Training Experiences: Results of a National Canadian Diversity Study. <i>JAMA Surgery</i> [Accepted]. |
| 2020 | Kuper T , Murphy P, Kaur B, Ott M. Prophylactic Negative Pressure Wound Therapy for Closed Laparotomy Incisions: A Meta-Analysis of Randomized Controlled Trials. <i>Annals of Surgery</i> . 2020 Jan;271(1):67-74. doi: 10.1097/SLA.0000000000003435. |
| 2019 | Kuper T , Federman N, Sharieff S, Tejpar S, LeBlanc D, Murphy P, Parry N, Leeper R. Chest Tube Insertion Among Surgical and Non-Surgical Trainees: How Skilled Are Our Residents? <i>Journal of Surgical Research</i> . 2019 Nov 21. pii: S0022-4804(19)30720-6. doi: 10.1016/j.jss.2019.10.010. [Epub ahead of print] |
| 2019 | Murphy P, Kuper T , Ott M. Negative Pressure Wound Therapy for Surgical Site Infection Prevention Requires Further Study Before Widespread Adoption. <i>JAMA Surgery</i> . 2019 Jul 1;154(7):672-673. doi: 10.1001/jamasurg.2019.0428. |

Research Grants

| | |
|------|---|
| 2017 | Co-Investigator , AMOSO Opportunities Fund <i>Academic Medical Organization of Southwestern Ontario</i> <i>Principle Investigator</i> : Dr. Julie Ann Van Koughnett <i>Project</i> : Decreasing Hospital Readmissions Following Colorectal Surgery with Mobile Health Monitoring <i>Award Total</i> : \$32 500 |
| 2017 | Recipient , Department of Surgery Resident Research Grant |

Schulich School of Medicine & Dentistry
Principle Investigator: Dr. Ken Leslie
Project: The Effect of Resection Margin Distance on Survival Following
 Pancreaticoduodenectomy for Pancreatic Ductal Adenocarcinoma
Award Total: \$2000

- 2013 **Recipient,** The American Society of Nephrology Student Scholar Grant
The American Society of Nephrology (ASN)
Principle Investigator: Dr. Joseph Kim
Project: Time-Varying Proteinuria and the Risk of Cardiovascular Disease and
 Graft Failure in Kidney Transplant Recipients
Award Total: \$7000

National and International Presentations

- 2019 **Kuper T,** Malette K, Hirpara D, La J, Assane C, Baker L, Marini W, Spilg E.
 Burnout Among Canadian General Surgery Residents. **Invited speaker** at:
Canadian Surgery Forum. 2019 Sep 5-7; Montreal, QC.
- 2019 **Kuper T,** Murphy P, Kaur B, Ott M. Prophylactic Negative Pressure Wound
 Therapy for Closed Laparotomy Incisions: A Meta-Analysis of Randomized
 Controlled Trials. **Podium presentation** at: *Canadian Surgery Forum.* 2019
 Sep 5-7; Montreal, QC
- 2019 **Kuper T,** Federman N, Tejpar S, LeBlanc D, Murphy P, Parry N, Leeper R.
 Chest Tube Insertion Among Surgical and Non-Surgical Trainees: How
 Entrustable Are Our Residents? **Speaker** at: *Resident Research Retreat,*
Canadian Surgery Forum. 2019 Sep 5 -6; Montreal, QC.
- 2019 **Kuper T,** Federman N, Tejpar S, LeBlanc D, Murphy P, Parry N, Leeper R.
 Chest Tube Insertion Among Surgical and Non-Surgical Trainees: How
 Entrustable Are Our Residents? **Podium presentation** at: *Trauma Association*
of Canada Conference. 2019 Feb 28 – Mar 1; Calgary, AB.
- 2018 **Kuper T,** Mocanu V, Marini W, DeGirolamo K, Assane C, Fathimani K, Baxter
 N. Resident Perceptions on Diversity Within General Surgery. **Invited speaker**
 at: *Canadian Surgery Forum.* 2018 Sept 13-15; St. John's, NF.
- 2017 **Kuper T,** Skaro A, Driman D, Leslie K. The effect of resection margin distance
 on survival following pancreaticoduodenectomy for pancreatic ductal
 adenocarcinoma. How close is too close? **Poster presentation** presented at:
Canadian Surgery Forum. 2017 Sept 14-16; Victoria, BC.
- 2014 **Kuper T,** Famure O, Li Y, Kim SJ. Time-varying proteinuria and the risk of
 cardiovascular disease and graft failure in kidney transplant recipients. **Poster**
presentation presented at: *World Transplant Congress. 2nd Joint Meeting of*
the American Society of Transplant Surgeons, the Transplantation Society and
the American Society of Transplantation; 2014 July 26-31; San Francisco, CA.

Leadership

- 2017 – 2019 **Western University Representative**, CAGS Residents' Committee
Canadian Association of General Surgeons
- 2013 – 2014 **Orientation Coordinator**, Hippocratic (Student) Council
Schulich School of Medicine & Dentistry, London, ON

Teaching and Mentoring

- 2018, 2019 **Instructor**, Surgery Clerkship Orientation
Schulich School of Medicine & Dentistry, London, ON
- 2018, 2019 **Instructor**, PGY1 Surgical Bootcamp
Schulich School of Medicine & Dentistry, London, ON
- 2017 – present **Mentor**, Surgery Interest Group Mentorship Program
Schulich School of Medicine & Dentistry, London, ON
- 2017 – present **Mentor**, Women in Surgery Mentorship Program
Schulich School of Medicine & Dentistry, London, ON
- 2017 Bootcamp for Resident Teachers (Attendance by Nomination)
Schulich School of Medicine & Dentistry, London, ON

Continuing Education

- 2019 SAGES Advanced Laparoscopic Colorectal Surgery Workshop
CSTAR, London, ON
- 2019 SAGES Advanced Laparoscopic Upper GI and Bariatrics Surgery Workshop
CSTAR, London, ON
- 2019 Crucial Conversations
London Health Science Centre, London, ON
- 2017 Bootcamp for Resident Teachers (Attendance by Nomination)
Schulich School of Medicine & Dentistry, London, ON
- 2017 CAGS Postgraduate Course: Ultrasound for the General Surgeon
Canadian Surgery Forum, Victoria, BC
- 2016 Principles and Practice of Clinical Research CME Course
DeGroot School of Business, Burlington, ON

Awards

- 2019 SAGES Pig
SAGES Advanced Laparoscopic Upper GI and Bariatrics Surgery Workshop

- 2019 Best Scientific Paper
General Surgery Research Day, Western University
- 2018 Ontario Graduate Scholarship
Western University
- 2018 Master of Public Health in Epidemiology Funding Scholarship
Harvard T.H. Chan School of Public Health
- 2013 The Rix Family Award for Introduction to Medicine
Schulich School of Medicine & Dentistry
- 2012 St. Michael's College Silver Medal
University of Toronto
- 2009 - 2011 St. Michael's College / C.L. Burton Trust Fund In-Course Scholarship
University of Toronto
- 2008 St. Michael's College Foundation Admission Scholarship
University of Toronto