Cost-effective Care Delivery Models in Ambulatory Surgery: Expedited Discharge and Virtual Care

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science

Institute of Health Policy, Management and Evaluation

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Abstract

Cost-effective Care Delivery Models in Ambulatory Surgery: Expedited Discharge and Virtual Care

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My Master’s thesis applies the Value Agenda framework to the ambulatory breast reconstruction population.

The first study uses patient level quality of recovery (QoR) data to determine if autologous breast reconstruction is suitably performed in an ambulatory facility. We found that QoR scores approach baseline by postoperative day 7; and are comparable to other ambulatory surgery patient populations\(^1\). In keeping with the Value Agenda, this study uses patient outcome data to support autologous breast reconstruction in more cost-effective, ambulatory facilities.

The second study models the cost-effectiveness of replacing in-person follow-up care with mobile app follow-up care during the first month following ambulatory breast reconstruction. We found a societal incremental net benefit of $245 CAD between mobile app and in-person follow-up care. Mobile app follow-up care expands the geographical reach of breast reconstruction by reducing the burden of physical patient travel and its associated costs after surgery.
Acknowledgements

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To John Semple: Thank you for your sharing your virtual care dream and your tireless efforts to push our projects forward. I remember receiving the advice as a medical student that you “know you’ve found your specialty when you find the people you aspire to become”. You are that person to me. Beyond my Master's, you continue to teach me how to balance the roles of a respected clinician, investigator and a stand-up guy who values friends, family, and life.

Thank you to Dr. Sacha Bhatia for including me in all of your great initiatives at Women’s College Hospital Institute for Health System Solutions and Virtual Care. You have opened my eyes to the policy side of health care.

Health all the special individuals at the Institute of Health Policy, Management and Evaluation: Dr. Audrey Laporte, for always looking out for my best interest; Dr. Claire D'Olivieria, for advice regarding econometric models used in the first paper; and Dr. Jeffrey Hoch for your awesome class and guidance regarding person-level cost-effectiveness data.

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Funding Acknowledgements

Finally, I gratefully acknowledge salary and tuition funding from the (1) Ministry of Health and Long Term Care, Clinical Investigator Program, (2) the Department of Surgery, Surgeon Scientist Program, (3) the Canadian Breast Cancer Foundation, (4) the Mentor Medical Systems Canada Graduate Scholarship, (5) the Michael Decter Scholarship for Health Leadership and Policy Studies from the St. Elizabeth Foundation.

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**List of Abbreviations**

- **ABIM**: American Board of Internal Medicine
- **ASA**: American Society for Anesthesiologists
- **ASC**: Ambulatory Surgery Centre
- **BMI**: body mass index
- **eGFR**: estimated glomerular filtration rate
- **HTA**: health technology assessment
- **ICER**: incremental cost-effectiveness ratio
- **INB**: incremental net benefit
- **IPU**: Integrated Practice Units
- **IT**: information technology
- **OHIP**: Ontario Health Insurance Plan
- **PACU**: post-anesthesia care unit
- **QALY**: quality adjusted life year
- **QoR**: quality of recovery
- **QoR-9**: Quality of Recovery-9
- **QoR-27**: Quality of Recovery-27
- **TRAM**: transverse rectus abdominis muscle
- **VAS**: visual analog scale
- **WCH**: Women’s College Hospital
- **WTP**: willingness-to-pay
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Chapter 1 – Background: Strategies in Health care

1.1 Climate of Health care in Canada

Canada’s publicly funded health care system faces fiscal challenges associated with a growing older demographic apt to develop expensive, chronic diseases and a dispersed national population. Canada’s $211-billion annual health care spending has swelled to 11.2% of its gross domestic product. Though the rate of growth has slowed; Canada remains in the top quartile of OECD countries in terms of per person health care spending. Canada has 35 million people and just over half of the population has one or more chronic conditions such as diabetes, chronic kidney disease, and high blood pressure. Canada’s population and health care resources are unevenly spread across 10 million square kilometers. It is within this milieu that we search for strategies to address our health care challenges.

1.2 Economics in Health care

There are grounding economic principles that guide health care strategy. The first is that of opportunity costs. In health care, this concept acknowledges the fact that we are dealing with finite resources. In order to invest in one way, we must give up the value of the next best alternative. Therefore, a strategy must measure or weigh out the costs and benefits of doing one thing vis-à-vis another.

The other key principle is that of the margin. Marginal analysis requires an assessment of the relative costs and benefits of each marginal addition or reduction in production. At the margin, we can shift or change the resource mix to improve efficiency. This is a decision between alternatives depending only on factors that change. There are many ways to allocate a health care budget. We strive to achieve productive efficiency. This is a concept, intuitive to most, that seeks the lowest cost
for a given output or outcome. However, we must also strive to achieve allocative
efficiency. This means that the cost of production of the last unit is no greater than
the benefit derived from that unit. In health care, this means finding a mix of
resource allocation that maximizes the welfare of the community.

In Canada, we face a fixed, if not a diminishing, health care budget. This warrants us
to ask whether resources should be re-allocated (with some areas cut back so that
others can expand) so as to improve the benefit of the overall population being
served. This type of analysis highlights trade-offs and can help decision makers
weigh the costs and benefits of alternative options. With a fixed budget (cost), if we
wish to invest more in preventative care then we must disinvest in some other
program and still generate a marginal benefit. Finding this balance becomes
increasingly important when you consider diminishing returns. As you invest more
and more into one program there comes a point where you experience diminishing
returns. For example, the return on investment in a vaccination program is greatest
when you target the population at risk. If the vaccination program grows larger than
the population at risk, then you experience a diminished return for your investment
in vaccination. This is because you are now vaccinating individual at high, medium,
and possibly low risk. However, these medium and low risk individuals still face the
same potential harm of the intervention as the high risk individuals who have more
to gain. Avedis Donabedian coined the term “point of optimality” to describe the
sweet spot of maximal benefit when you consider both the benefits and harms of an
intervention (Figure 1).
Figure 1: The Point of Optimality

![Diagram showing the point of optimality with axes for Investment of resources and Harms vs. Benefits - harm.]


Any health care strategy should consider these economic principles in order to ensure that resource allocation is optimized.

1.3 Strategy in Health care

These grounding economic principles help us understand the Value Agenda\textsuperscript{10}, which seeks to maximize value for patients by achieving the best outcome at the lowest cost. This agenda permeates the core of all current provincial, national and international health care strategies. Ontario’s Health System Funding Reform labels it “smarter use of limited resources”\textsuperscript{11}, the Health Council of Canada calls it “Better health, better care, better value for all”\textsuperscript{12}; and the Institute for Healthcare
Improvement (IHI) captures this same sentiment in its “Triple Aim”\textsuperscript{13}.

Internationally, the American Board of Internal Medicine (ABIM) Foundation brands it “Choosing Wisely”\textsuperscript{14}.

Some of the core strategies identified in the Value Agenda include:

1. **Measure Outcomes and Costs for Every Patient**: Capturing outcomes that matter to patients. Time driven, activity based costing is the best way to measure costs. It allows providers to identify opportunities such as better capacity utilization, more-standardized processes, locating care in the most cost-effective type of facility, etc\textsuperscript{10}.

2. **Move to Bundled Payments for Care Cycles**: This payment model best aligns with value by encouraging teamwork and high-value care throughout the continuum of the care cycle\textsuperscript{10}.

3. **Expand Excellent Services Across Geography**: Health care delivery remains heavily local. Superior providers for a particular medical condition need to serve more patients and extend their geographic reach through strategic expansion and partnership\textsuperscript{10}.

4. **Build an Enabling Information Technology Platform**: The preceding components are powerfully enabled by an IT system that supports integrated, multidisciplinary care\textsuperscript{10}.

These core strategies will inform both research papers (chapter 2 and chapter 3); as well, they will guide the policy implications outlined in the conclusion.

**1.4 Tying it All Together**

In the first study entitled *Shifting Autologous Breast Reconstruction into an Ambulatory Setting*, I describe a shifting model of delivering autologous breast reconstruction.
Prior to this study, a multidisciplinary team developed a perioperative protocol that facilitated expedited discharge (<24hrs) of autologous breast reconstruction in an ambulatory setting. This type of procedure uses a patient’s own tissue instead of, or in conjunction with, an implant. From previous work, we know that it is safe, feasible and generates a societal savings of $2,015 CAD per episode of patient care when autologous breast reconstruction is performed in an ambulatory versus in-patient setting (unpublished work). Still the majority of providers perform autologous breast reconstruction in an inpatient setting. This represents a missed opportunity for value transformation. In accordance with the Value Agenda strategy we used patient outcomes to demonstrate the acceptability of autologous breast reconstruction in an ambulatory setting. A common criticism of performance or outcome measurement is that we rarely go beyond tracking a few areas, such as mortality and safety. These are Tier 1 measurements that are not relevant to the majority of processes or procedures experienced by patients (see Figure 2). Therefore the public remains largely indifferent to measurement.

Figure 2: The Outcome Measures Hierarchy

Tier 1: Health status achieved or retained
• Survival
• Degree of health or recovery

Tier 2: Process of recovery
• Time to recovery
• Disutility of care or treatment process

Tier 3: Sustainability of health
• Nature of recurrences
• Long-term consequences of therapy

For this study we chose patient-reported quality of recovery as our outcome measure. This was captured using the quality of recovery-27 questionnaire\(^1\). It is a Tier 2 measurement which is more appropriate for a low morbidity procedures, such as breast reconstruction, and more likely to resonate as an important outcome or indicator with our patient population\(^16\).

In the second study entitled **Replacing Ambulatory Surgical Follow-up Visits with Mobile App Home Monitoring: Modeling Cost-Effective Scenarios**, an enabling information technology platform is used to provide postoperative care to patients undergoing ambulatory breast reconstruction.

We know that the breast reconstruction patient population is dispersed throughout Ontario but the care is typically only available in metropolitan centers. At Women’s College Hospital, the average patient travels 76 km from home for a clinic visit. From the previous literature, we also know that women from more rural locations in Ontario are less likely to undergo breast reconstruction. In accordance with the Value Agenda, we identified breast reconstruction patients as a low-risk population that could benefit from enabling information technology platforms that expand geographical reach and limit costs. Limiting costs without negatively affecting outcomes transforms the postoperative process into a higher value activity.

This study models the cost-effectiveness of replacing in-person follow-up care with mobile app follow-up care over the first 30 days following surgery. Mobile app follow-up care helps expand the geographical reach of breast reconstruction by reducing the burden of physical patient travel and its associated costs after surgery. Cost-effective strategies become increasingly important as we move towards bundled payment models.
Chapter 2 – Shifting Autologous Breast Reconstruction into an Ambulatory Setting: Patient Reported Quality of Recovery

2.1 Abstract

**Background:** As bundled payment models gain popularity, it is imperative that providers use patient outcomes and patient experience to define evidence-based pathways of care. The purpose of this study was to evaluate the quality of recovery (QoR) experienced by women undergoing early discharge (<24 hours) after autologous breast reconstruction with a pedicled flap and determine predictors of QoR and postoperative pain.

**Methods:** A prospective cohort study was performed on all women undergoing autologous breast reconstruction at Women’s College Hospital between September 2011 and July 2013 that met study inclusion criteria. Patient-reported QoR and pain scores were measured on postoperative days (POD) 1, 2, 4 and 7. Panel regression analysis was used to assess postoperative QoR over time while controlling for American Society for Anesthesiologists (ASA) classification and body mass index (BMI). Secondary analyses of delayed discharge (>24 hours) and complications were also undertaken.

**Results:** Forty women (28-69 years) were included in this study. There was a statistically significant improvement in the total QoR-27 over POD 1 to 7. The mean and standard deviations of the POD 7 dimensional and total QoR-27 scores were similar to that reported in other ambulatory surgical patient populations. Poor total QoR-27 scores were associated with the extremes of BMI and higher ASA classification.

**Conclusions:** Patients undergoing an ambulatory pathway of care for autologous breast reconstruction demonstrate acceptable quality of recovery. Standardizing the
delivery of autologous breast reconstruction using an ambulatory pathway of care is in keeping with the Value Agenda.

2.2 Introduction

Bundled payment models are growing in popularity across the United States and Canada\(^ {17}\). This model pays a set (bundled) price for an episode of care. It is meant to encourage health care services to adopt best practice standards, re-engineer clinical processes to improve patient outcomes, and develop innovative care delivery pathways to enhance patient experience. Surgical specialties will be amongst the first to experience the institution of bundled payments, as “episodes of care” are more easily defined within these fields\(^ {17}\). As physicians, it is important that we participate in defining these pathways from preoperative assessment to postoperative care and beyond.

In September 2010, Women’s College Hospital (WCH) was incentivized to develop an innovative care delivery pathway when it transformed from an inpatient to an ambulatory care facility. In this system, all surgical patients had to be prepared for discharge within 24 hours postoperatively. This included breast cancer patients undergoing postmastectomy breast reconstruction with pedicled flaps. There are two common methods of breast reconstruction in which the transverse rectus abdominus or latissimus dorsi are dissected and mobilized on their blood supply and then rotated into the position of the mastectomy defect to reconstruct the breast, respectively (see Figure 3).
Figure 3: A visual representation of the pedicled TRAM (top) and latissimus dorsi (bottom) flap breast reconstruction

Source: myhealth.alberta.ca
This was a dramatic shift given that such patients would have previously stayed in hospital for several days following surgery and had access to patient controlled analgesia (PCA) infusion pumps. Although this type of reconstruction requires minimal postoperative flap monitoring, it does involve the dissection and transposition of muscle leading to significant postoperative pain. Pain management was therefore the primary factor limiting early discharge in this patient population.

Several strategies have been proposed to safely improve postoperative pain management in ambulatory surgery. Multimodal analgesia has been effectively utilized to decrease postoperative pain, limit opioid use, and improve recovery following ablative and reconstructive surgery for breast cancer\textsuperscript{18,19}. In an effort to improve patient recovery following autologous breast reconstruction, a multidisciplinary team at WCH developed a perioperative protocol including the use of multimodal analgesia based on the literature and clinical expertise. A previous study from our institution demonstrated that use of multimodal analgesia was a significant predictor of earlier discharge time\textsuperscript{15}. Following implementation of the perioperative protocol, 83\% of patients undergoing a pedicled transverse rectus abdominis muscle (TRAM) flap reconstruction were discharged in less than 24 hours\textsuperscript{15}. However, quality of recovery under this new protocol had not been formally assessed.

There is a deficiency in the patient experience literature following ambulatory surgery\textsuperscript{20}. Specifically, patient-reported quality of recovery is an important indicator of successful process and planning in surgery and anesthesia. Poor quality of recovery can prolong duration of stay in the post-anesthesia care unit (PACU), delay discharge from hospital, and result in additional clinic calls, visits, and readmissions\textsuperscript{21}. This creates inefficiency in the episode of care. Markers of poor quality of recovery, such as persistent nausea and pain, and consequence of poor quality of recovery, such as longer lengths of stay and readmissions, are associated
with incomplete patient satisfaction\textsuperscript{22,23}. Quality of recovery data can also help identify patients at risk of poor postoperative recovery and be used to improve perioperative management. This information can help us optimize the patient’s experience following autologous breast reconstruction. Knowledge surrounding patient-experienced quality of recovery is necessary to judge the care delivery pathways used following autologous breast reconstruction.

The primary objective of this study was to prospectively evaluate the quality of recovery experienced by women undergoing early discharge (<24 hours) following postmastectomy breast reconstruction with pedicled flaps. Secondary objectives were to 1) examine delays in discharge and 2) evaluate postoperative complications and need for readmission.

\subsection{2.3 Methods}

A prospective cohort study was performed to assess quality of recovery of women undergoing autologous breast reconstruction using either a pedicled TRAM or pedicled latissimus dorsi muscle flap in an ambulatory setting. Of note, all latissimus dorsi muscle flaps were performed in conjunction with tissue expander insertion. All women selected for autologous breast reconstruction at WCH between September 2011 and July 2013 (one year and nine months) were screened for inclusion. To meet standard eligibility, patients had to be less than 75 years old, non-smokers (defined as lifetime non-smokers and ex-smokers who quit >1 year prior to surgery), and have a body mass index (BMI) less than 35. Patients were further excluded from this study if they had a history of chronic pain, chronic use of opioid medications, and/or were unable to complete study questionnaires due to a language barrier. One of two plastic surgeons, and one of six anesthesiologists performed all surgical procedures. A sample of 40 patients with 4 cluster observations (on POD 1, 2, 4 and 7) and an estimated correlation within cluster of 0.5 allows for 6 independent variables to be included within the panel analysis\textsuperscript{24}. 


Forty out of the sixty-one women that were consecutively approached agreed to participate. Study approval by the WCH Research Ethics Board was obtained.

**Perioperative Protocol to Facilitate Expedited Discharge**

In 2010, a multidisciplinary team of experts in breast reconstruction and anesthesia at WCH developed a perioperative protocol for patients undergoing breast reconstruction with pedicled TRAM flaps or pedicled latissimus dorsi muscle flaps\(^\text{15}\). This protocol is outlined as follows, and was applied to all study patients:

Prior to surgery all women attended preadmission clinic at WCH, as is routine practice at our institution. The preadmission nurse arranges consultations with physiotherapy, occupational therapy, and the Community Access Care Centre (CCAC). A consultation with Anaesthesia was also arranged. Patients received information about the recovery period and the pain medications received on discharge.

One hour preoperatively, patients receive: Oxycodone CR 10 mg po (per os or by mouth), Celecoxib 400 mg po, Gabapentin 300 mg po, and Acetaminophen 1000 mg po with sips of water. All patients will receive a standardized general anaesthetic to include prophylactic antiemetic medication (including 4 mg of intravenous dexamethasone) and intraoperative opioids as needed.

Perioperative thromboprophylaxis will consist of: 1) preoperative administration of 5000 units of subcutaneous low-molecular weight heparin (LWMH) and a second dose of LMWH 12 hours later; 2) intraoperative application of thromboembolic stockings, to remain in place until hospital discharge; and, 3) intraoperative
application of sequential compressive devices on patients’ legs, to remain in place until discharge from the recovery room.

Pedicled TRAM and latissimus dorsi flap procedures were performed according to standard practices by one of 2 expert surgeons in breast reconstruction. Abdominal reconstruction following TRAM flap harvest was performed using an interpositional polypropylene mesh to avoid excessive tightening of the abdominal fascia and prevent lateral displacement of the umbilicus. Prior to abdominal closure, lateral segmental nerve blocks will be performed by the surgeon using 0.25% Bupivacaine with 1:200,000 epinephrine. Postoperative pain and nausea will be treated appropriately, as needed, in the recovery room. Postoperatively on the ward, patients will receive Oxycodone CR® 5-10 mg po q3h prn, Acetaminophen 1000 mg po q6h, Gabapentin 200 mg po q8h and Celecoxib 200 mg po q12h for pain.

All patients were targeted for discharge within 24 hours postoperatively, provided they met discharge criteria. Discharge pain medications will include Acetaminophen 1000 mg po qid, Celecoxib 200 mg po bid, Oxycodone 5-10 mg po q3h prn, and Gabapentin 200 mg po q8h for 1 week. Please see Figure 4 for a step by step illustration of the perioperative protocol.
Figure 4: Perioperative protocol for patients undergoing autologous breast reconstruction with a pedicled TRAM or pedicled latissimus dorsi flap

Preadmission
- RN arranged consultation with physiotherapy, occupational therapy and the Community Care Access Center (CCAC)
- Patients receive information about the recovery period and pain medications received on discharge
- Anesthesia consultation

Pre-op
- Celecoxib 400 mg po, Gabapentin 300 mg po, Acetaminophen 1000 mg po, Oxycodone CR® 10mg po with sip of water 1 hour preoperatively
- Thromboprophylaxis: 5000 units of subcutaneous low-molecular weight heparin (LWMH) every 12 hours

Intra-op
- General anesthesia, opioids, and minimum of 2 prophylactic antiemetics
- Thromboembolic stockings and sequential compressive device applied
- TRAM patients receive lateral segmental nerve blocks with 20 cc 0.25% bupivacaine with 1:200,000 epinephrine; abdominal closure with mesh

Post-op
- Acetaminophen 1000 mg po qid, Celecoxib 200 mg po bid, Oxycodone 5-10 mg po q3h prn, and Gabapentin 200 mg po q8h for 1 week.
- Thromboembolic stockings removed upon discharge

Primary Outcome: Postoperative Quality of Recovery and Pain:

Patient-reported quality of recovery was evaluated preoperatively and on postoperative day (POD) 1, 2, 4 and 7 using the Quality of Recovery-27 (QoR-27). The QoR-27 is a validated 27-item patient questionnaire. It is a modified version of the QoR-40. It is appropriate and feasible to use as it was specifically developed in adult patients undergoing a wide range of day surgery procedures under general anesthesia. It measures the same 4 dimensions of quality of recovery that are...
captured in the QoR-40 including emotional state, physical comfort, psychological support, and physical independence (see Table 1). Based on expert opinion, certain questions were deleted from each dimension because they were less relevant or redundant in the context of ambulatory surgery. For instance, questions regarding “retching” and “shivering” within the physical comfort dimension were deleted due to overlap with other questions such as “nausea and vomiting” and “frozenness”, respectively\(^1\). Each item is scored on a 5-point Likert scale ranging from 1 (none of the time) to 5 (all of the time) providing adequate tool precision\(^20\). Total QoR-27 scores are calculated by summating all 4-dimensional scores. Similar to a previous study, the QoR-27 was combined with 10-point pain and general health score\(^1\). The pain score ranges from 1 (severe pain) to 10 (no pain), and the general health score ranges from 1 (very bad health) to 10 (very good health). Psychometric testing performed on the QoR-27 using over 800 multi-site ambulatory (day) surgery patients revealed good internal consistency, convergent validity, and responsiveness\(^1\). The physical comfort and physical independence dimension were found to be the most sensitive to change in the immediate postoperative period\(^1\). Emotional state was found to be least sensitive to change in the immediate postoperative period. It was hypothesized that this may be because e.g. feeling depressed or anxious (1) is not dependent on surgery or (2) takes longer to recover from if dependent on surgery\(^1\). This questionnaire has been used to assess quality of recovery after orthopedic surgery when compared to other types of day surgical procedures\(^25\); and the relationship between quality of recovery and health related quality of life. A Cronbach’s alpha coefficient of 0.88 is reported on the first postoperative day\(^1\).
### Table 1: Total Quality of Recovery-27 questionnaire

<table>
<thead>
<tr>
<th>Emotional State</th>
<th>1-None of the time; 2-Some of the time; 3-Usually; 4-Most of the time; 5-All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Having a feeling of general well-being:</td>
<td></td>
</tr>
<tr>
<td>Feeling in control:</td>
<td></td>
</tr>
<tr>
<td>Feeling comfortable:</td>
<td></td>
</tr>
<tr>
<td>Had bad dreams:</td>
<td></td>
</tr>
<tr>
<td>Feeling anxious:</td>
<td></td>
</tr>
<tr>
<td>Feeling depressed:</td>
<td></td>
</tr>
<tr>
<td>Feeling alone:</td>
<td></td>
</tr>
<tr>
<td>Had difficulty falling asleep:</td>
<td></td>
</tr>
<tr>
<td><strong>Total of Emotional State (/40)</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Comfort</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to breathe easily:</td>
<td></td>
</tr>
<tr>
<td>Had a good sleep:</td>
<td></td>
</tr>
<tr>
<td>Been able to enjoy food:</td>
<td></td>
</tr>
<tr>
<td>Feel rested:</td>
<td></td>
</tr>
<tr>
<td>Nausea:</td>
<td></td>
</tr>
<tr>
<td>Vomiting:</td>
<td></td>
</tr>
<tr>
<td>Feeling restless:</td>
<td></td>
</tr>
<tr>
<td>Shaking or twitching:</td>
<td></td>
</tr>
<tr>
<td>Feeling too cold:</td>
<td></td>
</tr>
<tr>
<td>Feeling dizzy:</td>
<td></td>
</tr>
<tr>
<td><strong>Total of Physical Comfort (/50)</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Psychological Support</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to communicate with family or friends:</td>
<td></td>
</tr>
<tr>
<td>Getting support from hospital doctors</td>
<td></td>
</tr>
<tr>
<td>Having support from family or friends:</td>
<td></td>
</tr>
<tr>
<td>Able to understand instructions and</td>
<td></td>
</tr>
<tr>
<td><strong>Total of Support (/20)</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Independence</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Have normal speech:</td>
<td></td>
</tr>
<tr>
<td>Able to wash, brush teeth or shave:</td>
<td></td>
</tr>
<tr>
<td>Ability to look after your own</td>
<td></td>
</tr>
<tr>
<td>Able to write:</td>
<td></td>
</tr>
<tr>
<td>Able to return to work or usual home</td>
<td></td>
</tr>
<tr>
<td><strong>Total of Physical Independence (25)</strong></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL QoR-27 (/135)**
**Multivariate Random Effects Panel Analysis**

Postoperative QoR-27 scores were assessed using panel analysis. Predictors of postoperative QoR-27 were chosen a priori based on the current literature and clinical experience. Idvall et al. found that the QoR-27 score was highly correlated with pain\(^1\). The remaining literature surrounding predictors of quality of recovery is sparse. It is known that quality of recovery is associated with health related quality of life (HRQoL) following ambulatory surgery\(^25\). There has been documentation in the literature of an association between HRQoL and American Society for Anesthesiologists (ASA) classification I, II and III defined as patients in good health, with mild systemic disease, or severe systemic disease, respectively. However, the direction of the relationship is unclear\(^25\). As well, there is a well-documented relationship between low HRQoL scores and low and high BMI\(^26\). The final list of predictors of postoperative total QoR-27 scores included pain, ASA classification, BMI, and BMI\(^227-29\). Patients are classified as ASA class I, II or III if they are considered healthy, with mild systemic disease, or with severe systemic disease, respectively\(^30\). BMI\(^2\) is a common transformation in the econometric literature\(^31\). It has been previously used to capture the relationship between low and high BMI and low quality of life scores (HRQoL)\(^26\).

**Secondary Outcomes**

A delay in discharge was defined as any time exceeding 24 hours from the time of admission to the PACU to the time of discharge. All postoperative complications, readmissions, or reoperations occurring within the first postoperative year were extracted from a patient chart review.

**Statistical Analysis**

Descriptive statistics (frequencies, means, standard deviations) were calculated for all clinical and outcome variables. Mean postoperative QoR-27 dimensions, pain, and general health scores were calculated at each time point. Initially, a Wilcoxon Rank Sum test was used to evaluate for a difference in the median preoperative and
POD 7 scores without controlling for confounding variables. Arguable pedicled TRAM and pedicled latissimus dorsi flap breast reconstruction are very different procedures. We performed a simple Wilcoxon Rank Sum test on POD 7 dimensional and total QoR-27 scores to determine if there was a significant difference between groups.

Then a panel model was used to evaluate postoperative QoR-27 over time while controlling for confounding variables including pain scores, ASA classification, BMI and BMI$^2$. The appropriateness of the model was assessed and regression diagnostics were performed. A LaGrange Multiplier test was used to assess for the presence of random effects in the underlying pooled ordinary least squares. A Hausman specification test was used to compare fixed versus random effect model under the null hypothesis that the individual effects are uncorrelated with the other regressors in the model. A Likelihood Ratio test and Wooldridge test were used to assess for heteroskedasticity and autocorrelation, respectively. All explanatory variables were included in the model. As a result of missing data points on the QoR-27 (41/160), the panel regression analysis was also repeated using multiple imputations to evaluate the robustness of our findings. All analyses were conducted using Stata 13.1 (2014, StataCorp, TX).

### 2.4 Results

Forty women undergoing autologous breast reconstruction were included in the study, with an age range of 28 – 69 years. Patient demographics are shown in Table 2.
Table 2: Descriptive characteristics of patients undergoing autologous breast reconstruction in an ambulatory setting

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>N=40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (SD)</td>
<td>50.5 (8.2)</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>26.7 (3.5)</td>
</tr>
</tbody>
</table>

**Household Income**

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$40,000</td>
<td>7 (17.5%)</td>
</tr>
<tr>
<td>$41,000 - $60,000</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>$61,000 - $80,000</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>$81,000 - 100,000</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>&gt;$100,000</td>
<td>12 (30%)</td>
</tr>
<tr>
<td>Not answered</td>
<td>4 (10%)</td>
</tr>
</tbody>
</table>

**Education**

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not complete high school</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>High school</td>
<td>8 (20%)</td>
</tr>
<tr>
<td>College certificate or diploma</td>
<td>15 (37.5%)</td>
</tr>
<tr>
<td>University</td>
<td>15 (37.5%)</td>
</tr>
</tbody>
</table>

**ASA Classification**

<table>
<thead>
<tr>
<th>ASA Classification</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (%)</td>
<td>11 (27.5%)</td>
</tr>
<tr>
<td>II (%)</td>
<td>25 (62.5%)</td>
</tr>
<tr>
<td>III (%)</td>
<td>4 (27.5%)</td>
</tr>
</tbody>
</table>

**Type of Reconstruction**

<table>
<thead>
<tr>
<th>Type of Reconstruction</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral TRAM Flap (%)</td>
<td>25 (62.5%)</td>
</tr>
<tr>
<td>Bilateral TRAM Flap (%)</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Unilateral Lat. Dorsi Flap (%)</td>
<td>13 (32.5%)</td>
</tr>
</tbody>
</table>

**Timing of Reconstruction**

<table>
<thead>
<tr>
<th>Timing of Reconstruction</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed</td>
<td>37 (92.5%)</td>
</tr>
<tr>
<td>Immediate</td>
<td>3 (7.5%)</td>
</tr>
</tbody>
</table>
The most common reconstructive method was the pedicled TRAM flap (n=27, 67.5%), and most reconstructions were unilateral (n=38, 95%) and delayed (n=37, 92.5%) relative to the timing of mastectomy. Thirty-three patients (82.5%) received the full perioperative protocol including multimodal analgesia. Two patients (5%) received no premedication due to allergy. One patient did not receive celecoxib, two patients did not receive oxycodone and two patients did not receive gabapentin preoperatively. No reason was provided for this variation; however, this was likely a result of the preoperative team becoming familiar with the introduction of this protocol. The average intraoperative opioid consumption was 27.4 ± 7.6 mg of morphine equivalents (range, 15 – 45.5 mg).

**Primary Outcome: Postoperative Quality of Recovery and Pain**

The mean total and dimensional scores for the QoR-27 score are presented in Table 3. When a Wilcoxon Rank Sum test was used to evaluate the difference in the median preoperative and POD 7 scores, there was no statistically significant difference in the emotional support, psychological support, physical comfort, and total QoR-27 scores. There was a statistically significant difference in physical independence, pain and general health scores (p<0.001, p<0.001, and p=0.001, respectively).
Table 3: Total and dimension QoR-27 scores in the first 7 days following autologous breast reconstruction in an ambulatory setting

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Max Score</th>
<th>Pre-Op Mean (SD)</th>
<th>POD 1 Mean (SD)</th>
<th>POD 2 Mean (SD)</th>
<th>POD 4 Mean (SD)</th>
<th>POD 7 Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional state /40</td>
<td>40</td>
<td>35.7 (4.9)</td>
<td>36.9 (4.0)</td>
<td>35.1 (4.4)</td>
<td>35.2 (4.6)</td>
<td>35.5 (4.6)</td>
</tr>
<tr>
<td>Physical comfort n/40</td>
<td>50</td>
<td>46.9 (3.1)</td>
<td>43.2 (4.9)</td>
<td>43.5 (4.3)</td>
<td>44.6 (5.0)</td>
<td>46.3 (4.5)</td>
</tr>
<tr>
<td>Psychological support n/40</td>
<td>20</td>
<td>19.6 (0.9)</td>
<td>19.6 (1.3)</td>
<td>18.9 (1.9)</td>
<td>19.2 (1.6)</td>
<td>19.2 (1.6)</td>
</tr>
<tr>
<td>Physical independence* n/40</td>
<td>25</td>
<td>24.7 (1.2)</td>
<td>19.2 (3.4)</td>
<td>20.0 (3.2)</td>
<td>21.5 (2.4)</td>
<td>22.2 (2.1)</td>
</tr>
<tr>
<td>Total QoR-27 Score n/40</td>
<td>135</td>
<td>126.8 (9.0)</td>
<td>118.8 (11.5)</td>
<td>118.3 (10.9)</td>
<td>120.5 (11.7)</td>
<td>124.0 (10.3)</td>
</tr>
<tr>
<td>Pain* n/40</td>
<td>10</td>
<td>0.35 (0.8)</td>
<td>2.8 (2.2)</td>
<td>3.0 (2.4)</td>
<td>2.4 (1.6)</td>
<td>1.5 (1.2)</td>
</tr>
<tr>
<td>General health* n/40</td>
<td>10</td>
<td>9.2 (1.4)</td>
<td>8.5 (1.5)</td>
<td>7.9 (1.9)</td>
<td>8.3 (1.4)</td>
<td>8.2 (1.6)</td>
</tr>
</tbody>
</table>

* p < 0.01 between pre-op and POD 7 scores

All POD 7 dimensional and total QoR-27 scores were similar for patients undergoing pedicled TRAM and pedicled latissimus dorsi flap breast reconstruction, except within the physical comfort dimension (see Table 4).
Table 4: A comparison of pedicled TRAM and pedicled latissimus dorsi flap breast reconstruction postoperative day 7 scores

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Max Score</th>
<th>Pedicled TRAM Mean (SD)</th>
<th>Pedicled latissimus dorsi Mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional state</td>
<td>40</td>
<td>36.4 (4.0)</td>
<td>33.6 (5.3)</td>
<td>0.08 α</td>
</tr>
<tr>
<td>Physical comfort</td>
<td>50</td>
<td>47.5 (3.2)</td>
<td>44 (5.7)</td>
<td>0.05 α</td>
</tr>
<tr>
<td>Psychological support</td>
<td>20</td>
<td>19.3 (1.4)</td>
<td>18.8 (2.0)</td>
<td>0.35 α</td>
</tr>
<tr>
<td>Physical independence</td>
<td>25</td>
<td>22.6 (1.7)</td>
<td>21.3 (2.5)</td>
<td>0.12 α</td>
</tr>
<tr>
<td>Total QoR-27 Score</td>
<td>135</td>
<td>126.5 (7.8)</td>
<td>118.9 (13.2)</td>
<td>0.10 α</td>
</tr>
<tr>
<td>Pain</td>
<td>10</td>
<td>1.3 (1.0)</td>
<td>1.9 (1.4)</td>
<td>0.23 α</td>
</tr>
<tr>
<td>General health</td>
<td>10</td>
<td>8.5 (1.3)</td>
<td>7.6 (1.9)</td>
<td>0.14 α</td>
</tr>
</tbody>
</table>

α assessed using a Wilcoxon Rank Sum test

**Multivariate Random Effects Panel Analysis**

Secondarily, changes in the postoperative total QoR-40 over time were examined when controlling for confounding variables using multivariate random effect panel analysis. The Lagrange Multiplier test rejected the null hypothesis, favouring a random effect model. The Hausman specification test did not reject the null hypothesis, again favouring a random effect model. We can use iterated and non-iterated generalized least squares to generate models with and without heteroskedasticity, respectively. We can then use a Likelihood Ratio Test. The null hypothesis for this test is homoskedasticity, which we reject (p = 0.024). Wooldridge derived a simple test for autocorrelation in panel data models. Drukker wrote the program, xtserial, to perform this test in Stata and provides simulation results showing that the test has good size and power properties in reasonably sized samples\(^{32}\). The null hypothesis for this test is that there is no autocorrelation, which we reject (p = 0.007). The findings of these diagnostics favour a feasible generalized least squares model that allows for heteroskedasticity and autocorrelation while maintaining efficiency\(^{33,34}\). See appendix 1 and 2 for the estimates derived from the
pooled OLS and random effects model not accounting for heteroskedasticity and autocorrelation, respectively. Only thirty-one of the 40 patients had two or more QoR-27 data points necessary to be included in the panel analysis (see Table 5). Patients with only one QoR-27 are automatically dropped from analysis when accounting for autocorrelation, as a correlation coefficient cannot be calculated with only one score.

**Table 5: Multivariate Random Effect Panel Analysis**

<table>
<thead>
<tr>
<th>TOTAL QoR-27</th>
<th>Coefficient</th>
<th>Standard Error</th>
<th>p-value</th>
<th>95% Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>-2.51</td>
<td>1.10</td>
<td>0.023</td>
<td>-4.68</td>
</tr>
<tr>
<td>BMI</td>
<td>8.01</td>
<td>3.56</td>
<td>0.024</td>
<td>1.03</td>
</tr>
<tr>
<td>BMI²</td>
<td>-0.13</td>
<td>0.07</td>
<td>0.044</td>
<td>-0.26</td>
</tr>
<tr>
<td>Pain</td>
<td>-2.04</td>
<td>0.40</td>
<td>0.000</td>
<td>-2.82</td>
</tr>
<tr>
<td>constant</td>
<td>13.52</td>
<td>47.97</td>
<td>0.778</td>
<td>-80.50</td>
</tr>
</tbody>
</table>

119 observations, 31 groups, 0.40 common AR(1) coefficient, $R^2 = 0.33$

The postoperative total QoR-27 scores were negatively correlated with ASA ($p=0.023$), positively correlated with BMI ($p=0.001$) and inversely correlated with BMI² ($p=0.002$). This reflects a negative quadratic relationship between the postoperative total QoR-27 score and BMI, in which the highs and lows of BMI are associated with lower total QoR-27 scores (Figure 5). The postoperative total QoR-27 score was also negatively correlated with pain ($p=0.005$).
As previously stated, only thirty-one of the 40 patients had two or more QoR-27 scores necessary to be included in the panel analysis. This was because 9 patients failed to answer all questions necessary to calculate the QoR-27. In most cases, only one question was missed (see Appendix 3). The missing questions were assessed using multiple imputations. The main questions that were missing were “Been able to enjoy food” (9 missing responses between POD 0-7) and “Getting support from hospital and doctors” (4 missing responses between POD 0-7). If we impute values for these missing questions, all 40 patients are included in the multivariate random effect panel model. The response to “been able to enjoy food” was positively correlated with “nausea”. The response to “getting support from hospital and doctors” was positively correlated with “having support from family or friends”. Therefore, we used an univariate poisson regression of “been able to enjoy food”
dependent on “nausea” and an univartiate poisson regression of “getting support from hospital and doctors” dependent on “having support from family or friends” to generate imputed values. In total, five imputed data sets were generated based on recommendations from the literature. When the multivariate random effect panel model was re-run with the multiple imputation estimates and pooled results were generated, the negative correlation with ASA and total Q0R-27 score was no longer significant at the 5% level. All other findings did not change (see Table 6).

Table 6: Multivariate Random Effect Panel Analysis Using Multiple Imputations (Pooled)

<table>
<thead>
<tr>
<th>TOTAL QoR-27</th>
<th>Coefficient</th>
<th>Standard Error</th>
<th>p-value</th>
<th>95% Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>-1.83</td>
<td>1.13</td>
<td>0.106</td>
<td>-4.04 0.39</td>
</tr>
<tr>
<td>BMI</td>
<td>9.60</td>
<td>3.16</td>
<td>0.002</td>
<td>3.42 15.79</td>
</tr>
<tr>
<td>BMI²</td>
<td>-0.17</td>
<td>0.06</td>
<td>0.005</td>
<td>-0.28 -0.05</td>
</tr>
<tr>
<td>Pain</td>
<td>-2.11</td>
<td>0.34</td>
<td>0.000</td>
<td>-2.79 -1.43</td>
</tr>
<tr>
<td>constant</td>
<td>-5.23</td>
<td>41.69</td>
<td>0.900</td>
<td>-86.94 76.48</td>
</tr>
</tbody>
</table>

5 imputations, 156 observations, 40 groups

Secondary Outcomes

Twenty-four patients (60%) were successfully discharged within 24 hours postoperatively. The remaining 16 (40%) patients were discharged between 24.1 and 28.3 hours postoperatively. No patients remained in hospital for longer than 28.3 hours post completion of surgery. A simple Wilcoxon rank sum or Chi square tests was performed to identify statistically significant differences between the patients that were discharged within 24 hours and those that were discharged beyond 24 hours. Women who were successfully discharged within 24 hours tended to have a lower ASA classification (p=0.01, see Table 7). The 30-day readmission rate was 0 percent.
Table 7: A comparison of patient characteristics between groups meeting and not meeting the discharge target of ≤ 24 hours

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>≤24 hours (N=24)</th>
<th>&gt;24 hours (N=16)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (SD)</td>
<td>49.9 (8.7)</td>
<td>51.4 (7.9)</td>
<td>0.96α</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>27.1 (3.3)</td>
<td>26.2 (4.0)</td>
<td>0.47α</td>
</tr>
<tr>
<td>ASA I (%)</td>
<td>9 (82%)</td>
<td>2 (18%)</td>
<td>0.01β</td>
</tr>
<tr>
<td>ASA II (%)</td>
<td>15 (60%)</td>
<td>10 (40%)</td>
<td></td>
</tr>
<tr>
<td>ASA III (%)</td>
<td>0</td>
<td>4 (100%)</td>
<td></td>
</tr>
<tr>
<td>Immediate Reconstruction (%)</td>
<td>2 (66%)</td>
<td>1 (33%)</td>
<td>0.81α</td>
</tr>
<tr>
<td>Bilateral Reconstruction (%)</td>
<td>2 (100%)</td>
<td>0 (0%)</td>
<td>0.24α</td>
</tr>
</tbody>
</table>

α – Wilcoxon rank sum test  
β – Chi square test

Three patients (7.5%) developed a postoperative complication, all of which occurred later than 2 weeks postoperatively. Two patients, one who underwent a delayed bilateral TRAM flap procedure and another who underwent a delayed unilateral TRAM flap procedure, developed a superficial skin infection characterized by clinical symptoms including redness at the recipient site on POD 14 and 17, respectively. Both were successfully treated on an outpatient basis with oral antibiotics. A third patient who underwent a breast reconstruction revision with a delayed latissimus dorsi flap developed a seroma necessitating ultrasound-guided drainage at the recipient site on POD 38. This same patient went on to experience tissue expander loss due to infection requiring operative revision on POD 73.

### 2.5 Discussion

As bundled payment models gain popularity in the United States and Canada, it is imperative that providers define evidence-based pathways of care (also known as quality based procedures) that will be funded under this model in terms of best practice standards, patient outcomes and patient experience. Minimally invasive surgical approaches, multimodal analgesia and regional analgesia limiting opioid
intake make ambulatory surgery safe and feasible. However, the success of all medical interventions, including ambulatory surgery, is increasingly judged based on patient experience\textsuperscript{1,36}. This ambulatory model of care has been successfully instituted at WCH since 2010, with approximately 50 autologous breast reconstructions performed per year. We have previously reported on its success in terms of safety and feasibility\textsuperscript{15}. In this prospective study, the success of this approach is again documented. All patients were discharged on POD 1 without incidence of readmission and with surgical complication rate (7.5\%) well in keeping with rates previously reported in the literature\textsuperscript{27,36,37}. It is also important to note that all complications occurred at POD 14 and beyond and would not have been ameliorated by a longer hospital stay.

It is difficult to determine what defines “good” quality of recovery. There is no cut-off score to guide our decision. Therefore, in this study we chose to define good quality of recovery in two ways. Firstly, we know from the literature that postoperative quality of recovery scores should approach their preoperative baseline by POD 7\textsuperscript{20}. In this study, we demonstrate that there is no statistically significant difference in our preoperative and POD 7 total QoR-27 score, suggesting that our patients have approached their baseline level. Secondly, we look to QoR-27 scores reported in other ambulatory surgery patient populations and determine how our patients compare. We compared the mean and standard deviation of the dimensional scores on POD 7 generated in this study to those generated in the 800+ ambulatory surgery patient study by Idvall et al\textsuperscript{1}. All dimensional, pain and general health scores were comparable with the exception of mean psychological support score which was better in our patient population (19.2 versus 15.9, respectively). This difference may in part reflect the nature of postmastectomy breast reconstruction, which in and of itself can have a positive impact on psychological well-being, especially when reconstruction is delayed as in 93\% of our patients\textsuperscript{36}. This difference could also be reflective of the more continuous follow-up afforded by
the telephone calls to administer the questionnaire. In our study, we completed the QoR-27 by telephone; whereas, Idvall et al. mailed out their survey for completion.

Similar to the study by Idvall et al., the physical independence, pain, and general health scores demonstrated a delay in returning to preoperative levels. This is an anticipated finding. Patients are unlikely to be pain free by POD 7; and therefore, are also unlikely to report a baseline value when simply commenting on their general health. Of note, a persistently low “return to work” score drove down the mean physical independence score. Again, this is anticipated as most physicians recommend that patients return to work 4-6 weeks following ambulatory breast reconstruction.

This is the first study to demonstrate an association between high and low BMIs and higher ASA classification with a worse postoperative quality of recovery score. The previous literature has only demonstrated a relationship between high and low BMIs and an unclear correlation with ASA and worse HRQoL. However, given that postoperative recovery is significantly associated with HRQoL, it makes sense that BMI and ASA classification are associated with postoperative recovery as they are associated with HRQoL. Similar to the HRQoL studies, a lower QoR-27 score in patients with a low BMI may be due to the components of the score which correlate to the mental components of HRQoL (i.e. emotional and psychological support). Whereas, the lower QoR-27 scores amongst patients with a higher BMI may be due to the components of the score that correlate with the physical components of HRQoL (i.e. physical comfort and support). The significance of association between higher ASA classification and worse postoperative quality of recovery score was not robust when the model was re-run using multiple imputations. In the future, we will further explore the relationship between ASA and postoperative quality of recovery.
and look for ways to optimize perioperative care for these populations at risk of lower quality of recovery scores.

Lower ASA classification also appeared to be related to earlier discharge within the ambulatory framework. Almost all ASA classification I patients (82%) met the discharge goal of 24 hours or less. Further investigation is required to better understand why 40% of patients were discharged between 24.1 – 28.3 hours, as these do not appear to be true failures of the ambulatory system. Additional exploration may help further streamline the episode of care.

**Limitations**

This study is limited by its small sample size; however it is adequately powered to include 6 independent variables based on study design. Bilateral and immediate reconstructions are under-represented in this study. This is due to the nature of the surgical procedures performed at WCH. WCH has an internationally recognized high-risk screening program. For this reason, we tend to provide immediate reconstructions to patients undergoing prophylactic mastectomies. Under these circumstances, most immediate reconstructions are one-stage implant based reconstructions with or without Alloderm. Another limitation of this study is the lack of a direct comparator group. WCH is completely ambulatory. It was impossible to randomize patients to undergo ambulatory or inpatient autologous breast reconstruction; furthermore this type of data is not collected at other facilities where inpatient autologous breast reconstruction may be offered. The study design is strengthened by its prospective nature and multiple time points of measurement. Moreover, data analysis was strengthened by imputation of missing values and panel analysis using generalized least squares regression.
The findings of this study have wide-ranging clinical and health care policy implications. Firstly, it challenges common inpatient delivery models of autologous breast reconstruction and highlights subgroups of patients who may be further optimized via preoperative counseling, additional or extended postoperative home assistance and pain management. From a clinical and health care policy perspective, transitioning additional procedures to an ambulatory setting while ensuring optimal patient experience is an ideal goal. One of the most important determinants of health care costs is the length of stay. Recent studies continue to report average length of stays ranging from 5 to 12.4 days for patients undergoing pedicled TRAM and pedicled latissimus dorsi flap breast reconstruction\textsuperscript{2–4}. To a certain extent, bundled payments will incentivize health care providers to drive down length of stay. However, additional health care policy standardizing and requesting justification of what is defined as an “episode of care” including the postoperative length of stay can help enforce a uniform code of conduct that keeps patients safe and satisfied and promotes efficiency within the system.

2.6 Conclusion

In summary, this study highlights that postmastectomy breast reconstruction with a pedicled flap can be safely offered in an ambulatory setting with good postoperative pain control, favorable quality of recovery, acceptable rates of complication, and a 0% 30-day readmission rate. Our experience suggests that comprehensive perioperative protocols involving patient and health care provider education, appropriate patient selection, precise and atraumatic surgical technique, and multimodal analgesia are central to achieving expedited discharge. Our study further suggests that certain subgroups of patients can be targeted for additional optimization of quality of recovery.
### 2.7 Appendices

Appendix 1: A Pooled OLS Model (not adjusting for heteroskedasticity and autocorrelation)

<table>
<thead>
<tr>
<th>TOTAL QoR27</th>
<th>Coefficient</th>
<th>Standard Error</th>
<th>p-value</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>-0.28</td>
<td>1.47</td>
<td>0.840</td>
<td>-3.20 2.64</td>
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<tr>
<td>BMI</td>
<td>10.85</td>
<td>2.77</td>
<td>0.000</td>
<td>5.36 16.33</td>
</tr>
<tr>
<td>BMI^2</td>
<td>-0.19</td>
<td>0.05</td>
<td>0.000</td>
<td>-0.30 -0.09</td>
</tr>
<tr>
<td>Pain</td>
<td>-2.33</td>
<td>0.44</td>
<td>0.000</td>
<td>-3.20 -1.46</td>
</tr>
<tr>
<td>constant</td>
<td>-22.59</td>
<td>37.11</td>
<td>0.544</td>
<td>-96.04 50.86</td>
</tr>
</tbody>
</table>

128 observations, $R^2 = 0.33$

Appendix 2: A Random Effect Panel Model (not adjusting for autocorrelation)

<table>
<thead>
<tr>
<th>TOTAL QoR27</th>
<th>Coefficient</th>
<th>Standard Error*</th>
<th>p-value</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA</td>
<td>-0.39</td>
<td>2.02</td>
<td>0.845</td>
<td>-4.35 3.56</td>
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<tr>
<td>BMI</td>
<td>11.54</td>
<td>4.28</td>
<td>0.007</td>
<td>3.15 19.93</td>
</tr>
<tr>
<td>BMI^2</td>
<td>-0.21</td>
<td>0.08</td>
<td>0.011</td>
<td>-0.37 -0.04</td>
</tr>
<tr>
<td>Pain</td>
<td>-1.86</td>
<td>0.77</td>
<td>0.015</td>
<td>-3.37 -0.35</td>
</tr>
<tr>
<td>constant</td>
<td>-30.99</td>
<td>56.11</td>
<td>0.581</td>
<td>-140.96 78.98</td>
</tr>
</tbody>
</table>

128 observations, 40 groups, $R^2 = 0.33$, *robust
### Appendix 3: Summary of Missing Data

<table>
<thead>
<tr>
<th>Variable</th>
<th># of Missing Observation</th>
<th># of Complete Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had a bad dream</td>
<td>1</td>
<td>159</td>
</tr>
<tr>
<td>Emotional Support</td>
<td>1</td>
<td>159</td>
</tr>
<tr>
<td>Had a good sleep</td>
<td>1</td>
<td>159</td>
</tr>
<tr>
<td>Been able to enjoy food</td>
<td>26</td>
<td>134</td>
</tr>
<tr>
<td>Feeling too cold</td>
<td>1</td>
<td>159</td>
</tr>
<tr>
<td><strong>Physical Comfort</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>132</td>
</tr>
<tr>
<td>Getting support from the hospital and doctors</td>
<td>4</td>
<td>156</td>
</tr>
<tr>
<td>Able to understand instructions</td>
<td>1</td>
<td>159</td>
</tr>
<tr>
<td><strong>Psychological Support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>155</td>
</tr>
<tr>
<td><strong>Total QoR27</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>128</td>
</tr>
</tbody>
</table>
Chapter 3 - Replacing Ambulatory Surgical Follow-up Visits with Mobile App Home Monitoring: Modeling Cost-Effective Scenarios

3.1 Abstract

Background: Women’s College Hospital (WCH) offers specialized surgical procedures, including ambulatory breast reconstruction in post-mastectomy breast cancer patients. Most patients receiving ambulatory surgery have low rates of postoperative events necessitating clinic visits. Increasingly, mobile monitoring and follow-up care is used to overcome the distance patients must travel to receive specialized care at a reduced cost to society. WCH has completed a feasibility study using a mobile app (QoC Health Inc, Toronto) that suggests high patient satisfaction and adequate detection of postoperative complications.

Objective: The proposed cost-effectiveness study models the replacement of conventional, in-person postoperative follow-up care with mobile app follow-up care following ambulatory breast reconstruction in post-mastectomy breast cancer patients.

Methods: This is a societal perspective cost-effectiveness analysis, wherein all costs are assessed irrespective of the payer. The patient/caregiver, health care system, and externally borne costs are calculated within the first postoperative month based on cost information provided by WCH, QoC Health Inc., and age-sex adjusted estimates. The effectiveness of telemedicine and conventional follow-up care is measured as successful surgical outcomes at 30-days postoperative, and is modeled based on previous clinical trials containing similar patient populations and surgical risks.
Results: This costing assumes that 1,000 patients are enrolled in bring-your-own-device mobile app follow-up per year and that 1.64 in-person follow-up visits per patient occur in the conventional arm within the first month postoperatively. The total cost difference per patient between mobile app and in-person follow-up care is $245 CAD ($223 USD based on the 2014 exchange rate), with in-person follow-up care being more expensive ($381 CAD) than mobile app follow-up care ($136 CAD). This takes into account the total of health care system, patient, and external borne costs. If we were to examine health care system costs alone, in-person follow-up care would be $38 CAD ($35 USD) more expensive than mobile app follow-up care over the first postoperative month. The baseline difference in effect is modeled to be zero based on clinical trials examining the effectiveness of telephone follow-up care in similar patient populations. An incremental cost-effectiveness ratio (ICER) is not reportable in this scenario. An incremental net benefit (INB) is reportable, and reflects merely the cost difference between the two interventions for any willingness-to-pay value (INB=$245 CAD). The cost-effectiveness of mobile app follow-up care even holds in scenarios where all mobile patients attend one in-person follow-up visit.

Conclusions: Mobile app follow-up care is suitably targeted to low-risk postoperative ambulatory patients. It can be cost-effective from a societal and health care system perspective and therefore in keeping with the Value Agenda.

3.2 Introduction

Technology is identified as an opportunity to constrain the growth in health care costs and eliminate barriers due to distance. In Ontario (Canada), specialized surgical services tend to be concentrated within metropolitan areas. This results in many patients having to travel great distances to receive care. Women’s College Hospital (WCH) in Toronto offers specialized ambulatory surgical procedures, including breast reconstruction following mastectomy for breast cancer.
Ambulatory surgery means that the patient goes home within 24 hours of surgery and comes back at a later date for follow-up care. The average ambulatory breast reconstruction patient travels 76 km from home to hospital, with the furthest patient coming from 540 km away (see Figure 6). This situation is not unique to the breast reconstruction patient population. Similarly, in Ontario, 23% of all orthopedic surgery patients leave their local health care catchment to receive care\textsuperscript{39}.

**Figure 6: Geographical Distribution of Patients Receiving Ambulatory Breast Reconstruction at Women’s College Hospital**

Patients not only travel to receive care, they also travel to receive follow-up care. In an ambulatory (or outpatient) surgery patient population, travel for postoperative follow-up seems superfluous as the chance of postoperative complication is
exceedingly low. This is because of advancements in surgery and rigorous patient selection. In general, ambulatory surgery is largely reserved from the treatment of American Society for Anesthesia (ASA) class I and II patients\textsuperscript{40,41}. These patients are considered healthy or with mild systemic disease, respectively. Complication rates in this subset of breast reconstruction patients are approximately 5\%\textsuperscript{15}. If a complication occurs, it is typically a minor skin infection or wound dehiscence. Rarely (<1\%), a hematoma requiring surgical evacuation may occur. These types of complications occur suddenly and present to the emergency department.

Finding solutions to limit unnecessary burden of care associated with travel is a worthwhile goal in any patient population. However, it is particularly important in patient populations where rurality and lower socioeconomic status are known barriers to breast reconstruction\textsuperscript{42,43}.

**Postoperative Monitoring Using a Mobile Application**

For these reasons, began a partnership with QoC Health Inc., Toronto to provide postoperative surgical follow-up using a mobile application. This mobile app raises the bar by combining a validated quality of recovery questionnaire and surgical site photos submitted at the patients’ convenience in an asynchronous manner (see Figure 7 and Table 8). This app conforms to the leading health-care audit and interoperability standards, including the Personal Health Information Protection Act (PHIPA), Health Insurance Portability and Accountability Act (HIPAA) and the standards of Health Level Seven International (HL7), a non-profit organization that develops frameworks for exchanging, integrating, sharing and retrieving electronic health (e-health) information.

There are multiple layers of encryption, including:

- wireless carrier virtual private network (VPN) encapsulation and routing;
• resting-state advanced encryption standard (AES) database encryption; and

• in-transit transport layer security/secure sockets layer (TLS/SSL) protocol encryption.

To date, WCH has completed a feasibility study using the mobile app to support postoperative care in breast reconstruction patients. The study suggests that mobile follow-up care adequately detects postoperative complications and eliminates the need for in-person follow-up care. Eighty-seven percent of patients rated their overall satisfaction with the app as “excellent”. This is concordant with other postoperative telemedicine studies.

Figure 7: The mobile app user interface

Description of the QoC Mobile App: The app contains the QoR-9 questionnaire, a pain visual analogue scale, drain output tracker and the capacity to take surgical site photos.
Table 8: The Quality of Recovery-9 (QoR-9) Questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>1-None of the time; 2-Some of the time; 3-Usually; 4-Most of the time; 5-All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Had a feeling of general well being</td>
<td></td>
</tr>
<tr>
<td>2. Had support from others</td>
<td></td>
</tr>
<tr>
<td>3. Been able to understand instructions and advice. Not being confused</td>
<td></td>
</tr>
<tr>
<td>4. Been able to look after personal toilet and hygiene unaided</td>
<td></td>
</tr>
<tr>
<td>5. Been able to pass urine (&quot;waterworks&quot;) and having not trouble with bowel function</td>
<td></td>
</tr>
<tr>
<td>6. Been able to breathe easily</td>
<td></td>
</tr>
<tr>
<td>7. Been free from headache, backache or muscle pains</td>
<td></td>
</tr>
<tr>
<td>8. Been free from nausea, dry-retching or vomiting</td>
<td></td>
</tr>
<tr>
<td>9. Been free from experiencing severe pain or constant moderate pain</td>
<td></td>
</tr>
</tbody>
</table>

Description of the QoR-9 Questionnaire: Good convergent validity between the QoR-9 score and the visual analog scale score ($\rho=0.55$, $p<0.0001$), discriminant construct validity was supported by comparing patients undergoing day-surgery, minor, and major surgery ($p=0.008$), as well as a negative correlation with duration of hospital stay ($\rho=-0.21$, $p<0.0001$). There was good interrater agreement ($\rho=0.55$, $p>0.0001$), test-retest reliability (median $\rho=0.61$, $p<0.0001$) and internal consistency ($\alpha=0.57$ and 0.90, $p<0.0001$)\textsuperscript{48}.

Previous studies have found that after a tonsillectomy or adenoidectomy, telephone follow-up care with standardized questionnaires is as safe as standard follow-up care and offers considerable cost reduction and patient convenience\textsuperscript{46}. Similar telephone follow-up has also been used successfully in elective open hernia repairs, laparoscopic cholecystectomy, and curative breast cancer surgery\textsuperscript{45,47}. In a prospective study by Hwa et al. patients were assessed over the telephone using a scripted template assessing overall health, pain, fever, incision appearance and activity level. Of those patients who underwent telephone follow-up care, 70.8% of hernia patients and 90.5% of cholecystectomy patients accepted telephone follow-up.
up care as the sole means follow-up\textsuperscript{45}. Others have shown that planned outpatient appointments after uncomplicated surgery are neither necessary nor cost-effective\textsuperscript{49}. A “no planned follow-up” saves money for hospitals and patients\textsuperscript{49}.

Patients are highly satisfied with telephone follow-up. Still, there are some glaring disadvantages when telephone follow-up care is compared to mobile app follow-up care. Telephone follow-up relies on synchronous communications between patients and health care providers. Studies report between 15 and 27\% of patients were unreachable by phone after multiple attempts to reach postoperative patients\textsuperscript{45,50}. It is also heavily dependent on labor costs as a nurse or other health care worker is designated to call, collect, and relay the questionnaire information to the primary surgeon. This makes the questionnaire data more expensive to relay when compared to a mobile app, which transmits directly from patient to surgeon. Similarly, “no planned follow-up” is poorly received by patients and providers who value continuity of care\textsuperscript{49}. In this way, mobile app follow-up care offers a middle ground between conventional in-person follow-up care, telephone follow-up care, and no planned follow-up care.

The proposed project provides breast reconstruction patients with timely contact with their surgeon from the comfort of their home. This technology has the potential to address wait times by freeing up specialty surgeon clinic time so that they may engage in new consultations and attend to patients in the emergency department. The first step in more widespread implementation involves demonstrating cost-effectiveness.
3.3 Methods

This study used methods recommended by international health technology assessment (HTA) agencies for economic evaluations to develop a model for comparing mobile app follow-up care with in-person follow-up visits\textsuperscript{51}. Inputs and outputs were chosen based on relevance to the decision-making perspective of the economic evaluation\textsuperscript{51}. Cost data were derived from WCH breast reconstruction patient administrative data and QoC Health Inc. mobile app billed costs. This is in keeping with HTA agency recommendations\textsuperscript{51}. A societal perspective was adopted wherein all costs were assessed irrespective of the payer. Again, this perspective was chosen based on HTA agency recommendations\textsuperscript{52}. This recommendation is meant to improve comparability and consistency across studies\textsuperscript{53}. The patient/caregiver, health system, and externally borne costs are calculated within the first postoperative month. The results are also presented using a narrower health system perspective that may be of key interest to health administrators and policy decision makers. The effectiveness of mobile app and conventional follow-up care was measured as successful surgical outcomes at 30-days postoperative. Successful surgical outcome was clearly defined as a "surgical patient not requiring medical or surgical intervention related to the original surgery within the first 30-days postoperative"; this evaluation was made by a medical expert upon chart review. It was deemed an important outcome where no meaningful difference in health-related quality of life (HRQL) between mobile app and in-person follow-up care has been demonstrated\textsuperscript{54}. The 30-day time horizon was chosen based on literature surrounding postoperative complications in the first 30-days\textsuperscript{55}. It was felt to be long enough to capture all relevant costs and benefits of mobile app and in-person follow-up care. Effectiveness data were derived from clinical studies from similar ambulatory patient populations. Model parameters were input into TreeAge R1.0 (2014, Treeage Software, MA).
Cost data were collected from a societal perspective using a micro-costing approach advocated for by HTA agencies. All cost data were based on 2013/2014 estimates.

In-person follow-up costs incurred by the health system include employees, compensation, drugs, surgical instruments and supplies, equipment, and other (eg, linens, telephone charges, general supplies), specialized breast center clinical assistant compensation, resident compensation, and physician fee (see Appendix 4; see Table 9). WCH provided per patient clinic costs and Ontario Health Insurance Plan (OHIP) billing codes were used to determine physician fees. Physician payment methods were verified through the hospital to ensure double counting did not occur. In keeping with cost-effectiveness analysis, non-recoupable or sunk costs were not included in the in-person follow-up arm.

Mobile app follow-up costs incurred by the health system include the start-up fixed costs such as: health center setup, design/setup of procedure protocols, and training of hospital staff. The start-up costs were divided over the number of patients served over the useful lifespan of mobile technology, which was conservatively estimated at 5 years. Current e-assessment OHIP physician billing codes are limited. There is currently no OHIP billing code for surgical e-assessments. In the future, we assume that billing codes will exist and so we applied a fee based on actual OHIP telemedicine follow-up fees. The variable costs for mobile follow-up care included software, licensing, and technical support. The bring-your-own-device model variable cost was $3.50 CAD per patient per day. This costing assumes that 1,000 patients are enrolled in bring-your-own-device mobile app follow-up per year based on a QoC Health Inc. business model that enrolls hospitals.
In-person follow-up costs incurred by the patient included foregone patient leisure time, the wage of a caregiver, and travel and parking costs associated with follow-up visits. We determined foregone leisure costs based on labor force participation rates and age-sex adjusted average Ontario wages (see Appendix 5-6). Labor force non-participants were assigned an Ontario homemaker’s wage. We presumed that a caregiver equivalent would be present at the first follow-up visit, and assigned a homemaker wage ($11.28 per hour) to that person. This is considered a conservative estimate of true caregiver costs because most patients bring their partner with them to clinic, and those individuals would earn higher average age/sex adjusted wages. The hourly rates were multiplied by the travel time and length of the clinic visit. The clinic time was assumed to be 1 hour to include time to park, register, and meet with the health care team. Travel time and costs estimates were based on actual breast reconstruction patient distance data from home postal code to WCH. Canadian Automobile Association (CAA) Ontario-based average costs per km driven were used to calculate transportation costs. The number of clinic visits was averaged at 1.64 visits per patient over the first postoperative month based on actual attendance by breast reconstruction patients at WCH.

Mobile app follow-up costs incurred by the patient were modeled based on a bring-your-own-device format, in which the patient loads the app on to their own mobile phone. Costs included the foregone leisure time to submit follow-up data and the cost of data submission. Each submission takes approximately 3 minutes to enter and submit. In the feasibility study, patients were asked to submit monitoring information once daily for the first 2 weeks and then once weekly for the next 2 weeks. Leisure time was not interrupted by the submission of a mobile follow-up. Patients submit their data from the comfort of their home. This process typically takes 2 minutes per submission; therefore, there was minimal sacrifice. Each submission (including survey information and photo) used approximately 0.35 MB of data. In Ontario, 2 GB of data can be purchased for $45 CAD; therefore, data
costs were negligible. Patient training sessions were held while patients waited for their preoperative appointment. There were no additional patient costs associated with this time.

This modeling study used telephone follow-up studies to determine the effectiveness of mobile app follow-up when compared to in-person follow-up care. Telephone and mobile app follow-up care are considered to transmit the same questionnaire-based data from patient to provider. HTA agencies recommend conducting a systematic review of the literature on key model inputs including effect data; however, clinical trials and observational studies can be used to obtain effect data if they more appropriately represent the model of interest. A recent article in BMC Health Services Research systematically reviewed telephone consultations in place of face-to-face outpatient consultation for patients discharged from hospital following surgery. It reported low methodological quality and dissimilar outcomes. None of the articles included in the review captured patient populations or outcomes that were comparable to the patient populations and outcomes modeled in this study. From a clinical perspective, type of follow-up care is unlikely to impact chance of complication, which is inherently determined based upon surgical and patient factors (face validity). For this reason, baseline equivalence in effect was modeled between the two groups. This assumption is supported by large observational studies following laparoscopic cholecystectomy, inguinal and paraumbilical hernia repair, other hernia repair, varicose vein surgery, circumcision, excision of subcutaneous lesions, carpal tunnel release, and appendectomies. These studies found that structured postoperative telephone questionnaires conducted between 2 and 6 weeks were a safe alternative to in-person follow-up care. Telephone questionnaire-based follow-up adequately detected patients that required further in-person assessment (5-11% of all patients). These studies contain similar patient populations, procedural variation, and surgical risks when compared to ambulatory breast reconstruction patients.
Three types of sensitivity analyses were performed to determine their effects on costs and outcomes. A scenario analysis was conducted for variations in the number of in-person clinic visits and crossover from mobile follow-up to in-person follow-up. A two-way sensitivity analysis varied patient wage and mobile follow-up effect. Additionally, a probabilistic sensitivity analysis was performed to account for uncertainty in the distribution of patient, caregiver, and clinic costs as well as uncertainty in effects (ie, complication rates).

3.4 Results

Patient Population Description

This retrospective review included the last 100 patients from the only two breast surgeons at WCH. All patients were female, between 29 – 69 years of age. Patients travel from all over Ontario including rural northern communities (3 percent) to undergo breast reconstruction at WCH. Patients underwent breast reconstruction for mastectomy for known breast cancer (81 percent), high familial risk of breast cancer (39 percent), or non-cancer related diagnoses (8 percent) covering reconstruction under OHIP. Types of breast reconstruction included immediate (i.e. at time of mastectomy) or delayed reconstruction using implants or expanders that are later exchanged for implants, immediate or delayed reconstruction using a pedicled flap, breast reduction, and/or fat grafting.

In this patient population, there was a six percent rate of complication including five minor wound infections treated with oral antibiotics and one hematoma requiring surgical exploration and evacuation. Complications were not significantly associated
with smoking or previous radiation, though there was a trend toward significance for increasing BMI and ASA classification.

On average, each patient attended 1.64 visits during the first 30 days postoperative. Minor procedures (including fat grafting and nipple areola complex reconstruction) were associated with less in-person follow-up (p=0.00). Distance from hospital was associated with less in-person follow-up, though not statistically significant (p=0.076).

Cost-effectiveness Analysis

The results of this analysis are summarized in Table 9. The total cost difference between mobile app and in-person follow-up care was $245 CAD ($223 USD based on the 2014 exchange rate), with in-person follow-up being more expensive ($381 CAD) than mobile app follow-up care ($136 CAD). This takes into account the total of health care system, patient, and external borne costs. If we examine health care system costs alone, in-person follow-up was $38 more expensive than mobile follow-up care (see Table 9).
**Table 9: Cost breakdown.**

<table>
<thead>
<tr>
<th>In-person follow-up</th>
<th>Cost (CAD $)</th>
<th>Mobile app follow-up</th>
<th>Cost (CAD $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care system costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fixed costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compensation to shared clinic staff</td>
<td>103.74</td>
<td>Health center setup</td>
<td>1.39</td>
</tr>
<tr>
<td>Equipment</td>
<td>2.16</td>
<td>Design/setup procedure protocol</td>
<td>6.94</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training</td>
<td>0.44</td>
</tr>
<tr>
<td><strong>Variable costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>0.21</td>
<td>Platform licensing, accounts</td>
<td>42.00</td>
</tr>
<tr>
<td>Other (Linens)</td>
<td>3.83</td>
<td>Standard support</td>
<td>43.05</td>
</tr>
<tr>
<td>Clinical assistant (10 min)</td>
<td>10.25</td>
<td>Infrastructure hosting</td>
<td>19.95</td>
</tr>
<tr>
<td>Surgeon fee</td>
<td>43.46</td>
<td>Surgeon fee</td>
<td>22.00</td>
</tr>
<tr>
<td>Resident</td>
<td>10.56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health care system costs subtotal (per patient per 1.64 visits over 30 days)</td>
<td>$174.21</td>
<td>Health care system costs subtotal (per patient per 30 days monitoring)</td>
<td>$135.77</td>
</tr>
<tr>
<td>Patient costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Variable costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient leisure time</td>
<td>102.24</td>
<td>Patient leisure time</td>
<td>negligible</td>
</tr>
<tr>
<td>Caregiver wage</td>
<td>33.84</td>
<td>Data (approx. 350 kB per transmission with photo)</td>
<td>negligible</td>
</tr>
<tr>
<td>Travel (to and from clinic)</td>
<td>38.11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parking</td>
<td>32.80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient costs subtotal (per patient per 1.64 visits)</td>
<td>$206.99</td>
<td>Patient costs subtotal (per patient per 30-day monitoring)</td>
<td>negligible</td>
</tr>
<tr>
<td>Grand total (per patient per 1.64 visits over 30 days)</td>
<td>$381.20</td>
<td>Grand total (per patient per 30-day monitoring period)</td>
<td>$135.77</td>
</tr>
</tbody>
</table>

The baseline difference in effect was modeled to be zero based on the WCH feasibility study, as well as other ambulatory telephone follow-up studies. An incremental cost-effectiveness ratio (ICER) is not reportable in this scenario. An incremental net benefit (INB) is reportable, and reflects merely the cost difference between the two interventions for any willingness-to-pay value (INB=$245 CAD).
**Scenario Analysis**

**Societal Perspective Costs With Varying Number of In-Person Visits in the First Month Postoperative**

The number of in-person follow-up visits was set to a minimum value and compared to the costs of mobile follow-up. This sensitivity analysis demonstrates that even at only 1 in-person visit per patient over the first month postoperative, mobile app follow-up care is less costly from a societal perspective. From a societal perspective, mobile app follow-up care remains cost equivalent to in-person follow-up even when 100 percent of the mobile app follow-up care patients attend 1 in-person visit during the first month.

**Two-Way Sensitivity Analysis**

**Societal Perspective Costs With Varying Foregone Patient Leisure Time and Mobile Effectiveness**

The patient’s wage was set between $11.28 (homemaker) and $26.71 (the highest average age/sex adjusted) per hour wage. The effectiveness of the mobile app was varied between a 90-96% success rate. This is to simulate a scenario where the mobile app may increase the rate of complications when compared to conventional in-person follow-up care. Table 10 demonstrates how an incremental net benefit only favors (i.e., produces a negative value) in-person follow-up care if a 6 percentage point difference in effect exists between the two follow-up groups. In this scenario, the patient must also be limited to making <$19 CAD per hour. This calculation uses a willingness-to-pay (WTP) of $100,000 USD ($109,970 CAD based on the 2014 exchange rate) per quality adjusted life year (QALY), and a 0.04 QALY difference between no complication and minor skin infection. This is a high estimate previously reported in the literature.\(^{60}\)
Table 10: Two-way sensitivity analysis with varying patient lost income and effectiveness of mobile follow-up care.\textsuperscript{a}

<table>
<thead>
<tr>
<th>Mobile Effect</th>
<th>Patient lost leisure time (CAD $)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$33.84</td>
</tr>
<tr>
<td>INB\textsuperscript{b} @ Effect 0.96</td>
<td>198.75</td>
</tr>
<tr>
<td>INB @ Effect 0.94</td>
<td>110.77</td>
</tr>
<tr>
<td>INB @ Effect 0.92</td>
<td>22.80</td>
</tr>
<tr>
<td>INB @ Effect 0.90</td>
<td>−65.18</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Willingness-to-pay (WTP)=\$4398.80 CAD per effect based on \$109,970 CAD per quality adjusted life year (QALY) and 0.04 QALY assigned to one superficial skin infection\textsuperscript{60}.  
\textsuperscript{b}INB: incremental net benefit

**Probabilistic Sensitivity Analysis**

To further explore the robustness of the base case results, a probabilistic sensitivity analysis was performed, based on random re-sampling (Monte Carlo simulation). In the analysis, a uniform distribution was allocated to the clinic cost (by +/- 20%) as this reflects reasonable variability in fixed per patient clinic costs, mobile and in-person follow-up effect (+/- 2 percentage points) as this reflects reasonable variability in complication rates\textsuperscript{27,36,37}. A gamma distribution was applied to the patient wage. In 10,000 simulations, the mean societal cost of mobile app follow-up care was \$135.78 CAD and in-person follow-up care was \$383.55 CAD per patient. The large in-person follow-up care standard deviation (+/- \$211.80 CAD) accurately reflects the variation in wage and travel time among patients. In all scenarios, mobile app follow-up care was cheaper than in-person follow-up care from a societal perspective. In approximately 50% of scenarios, the effectiveness of mobile app follow-up was less than in-person follow-up (see Figure 8). This was imposed by the distributions assigned. It is important to note, scenarios that are less effective and less costly can still be considered cost-effective. Again, using a WTP of \$4398.80 CAD/superficial skin infection, mobile follow-up care is the preferred strategy in 99.1% of scenarios.
Figure 8: Graphical representation of the probabilistic sensitivity analysis demonstrating the Incremental Cost-Effectiveness Ratio (ICER) values for mobile app versus in-person follow-up care.

3.5 Discussion

Principal Findings

Results from modeling cost-effectiveness show that mobile app follow-up care is cost-effective when compared to in-person follow-up care from a societal and health system perspective. A detailed examination demonstrated that in the first month of follow-up care, an average of $136 CAD was spent in the mobile app follow-up care stream whereas $381 CAD was spent in the in-person follow-up care stream. The higher cost of in-person follow-up care is spread between the health care system and patient; however, the patient reaps the majority of the cost-savings from participating in mobile app follow-up care. This is demonstrated by comparing the societal and health care system perspective savings ($245 vs $38, respectively), as the patient savings are only captured in the societal perspective. This is an
important finding as lower socioeconomic status is a known barrier to breast reconstruction. The two-way sensitivity analysis demonstrates how these savings are maintained even when the patient makes a homemaker wage. Decreasing costs incurred to the patient, at least in the postoperative period, may improve access.

There is a deficit in Canadian policy promoting mobile phone communication between patients and providers. Ontarians cannot even renew a prescription over the phone, unless they choose to pay out-of-pocket for a normally insured service, because there is no telemedicine prescription renewal code. This cost-effectiveness study is an important first step in demonstrating to health care administrators and policy decision-makers the benefits of investing in mobile app follow-up care. Mobile app follow-up care generates an incremental net benefit of $38 per patient from the perspective of the health care system. Decreasing the total number of in-person follow-up visits required has the potential to generate efficiency in one of two ways. Hospitals could choose to investment in smaller clinic spaces, decreasing the fixed and variable costs that accompany these spaces. Alternatively, hospitals could serve more patients in a given clinic space, including more new consultations. This is an important finding given the concern with long specialty wait times across Canada. Orthopedic surgery and plastic surgery have the longest wait times. These two specialties perform a significant number of ambulatory surgeries and their patients in particular could benefit from mobile app follow-up care. Moreover, the number of patients that would benefit from mobile app follow-up care is growing yearly. At Women’s College Hospital, over 5,000 elective ambulatory surgeries are performed each year. These numbers are small when you look at other neighboring hospitals, where over 20,000 ambulatory surgeries are performed annually. These numbers will continue to grow as we follow trends in the United States where currently 60 to 70% of the surgical procedures are performed in the ambulatory setting.
Mobile app follow-up transmits the same information as telephone follow-up care, but its obvious advantages include its asynchronous nature and autonomy from health care labor force to call, collect, and relay the patient data. The ease of use allows data to be collected multiple times during the 30-day follow-up period. In our pilot study, patients submitted questionnaire and surgical site photos every day for the first 2 weeks and once a week for the following 2 weeks. This provides richer data than could ever be achieved by telephone or in-person follow-up care. At this point in time, mobile app follow-up makes sense. Usage is ubiquitous throughout North America. Mobile phone penetration is approaching 90% in the United States, and smartphones are now considered the dominant mobile device. As technology is an economy of scale, the potential for cost-savings increases with user uptake.

**Limitations**

There are a few limitations to this study. Equivalency in the effectiveness of mobile app and in-person follow-up care is assumed based on observational studies of telephone questionnaire-based follow-up care from similar ambulatory surgery patient populations. There are no randomized control trials demonstrating equal effectiveness between mobile app and in-person follow-up care. From a clinical perspective, effect equivalence is intuitive because outcomes are dependent on patient and surgical factors (face validity).

This study did not compare the cost-effectiveness of telephone follow-up care to mobile app and in-person follow-up care. This is because most HTA agencies recommend comparing technology to usual care. Mobile app and telephone follow-up care utilize the same standardized questionnaire tool; however, telephone follow-up care has obvious disadvantages including (1) the reliance on synchronous communication between the patient and health care professional, (2) no capacity to submit surgical site photography, and (3) a heavy dependence on human resources leading to higher costs.
This study assumes that 1.67 follow-up visits will be averted with mobile app follow-up care. This is based on informal feedback from the feasibility study\textsuperscript{44}. This may not be possible from multiple reasons including (1) patient comfort level with mobile app follow-up care, (2) health care provider comfort level with mobile app follow-up care, or (3) unavoidable in-person follow-up care due to suture removal, expansion of tissue expanders, etc. We are currently conducting a randomized controlled trial that will determine how many visits are actually averted using mobile app follow-up care.

### 3.6 Conclusions

Mobile app follow-up care is suitably targeted to low-risk postoperative ambulatory patients. It can be cost-effective from a societal and health care system perspective. Mobile phone penetration is approaching 90\% in the United States, and smartphones are now considered the dominant mobile device. Using a ubiquitous technological platform to reduce health care costs for patients and providers in an already large and growing patient population makes sense. Mobile app follow-up care helps expand the geographical reach of breast reconstruction by reducing the burden of physical patient travel and its associated costs after surgery. Again, this is particularly important in patient populations where rurality and lower socioeconomic status are known barriers to breast reconstruction\textsuperscript{42,43}. 
### 3.7 Appendices

**Appendix 4: Breakdown of breast center costs and assumptions for costing.**

**Assumptions:**

- Visit among clinic has same weight.
- Visit among clinic utilize same resources.

**Fact:**

- Breast Centre is located in Hospital environment, in other words certain costs are recorded in Hospital administration (e.g. utilities, insurance, property tax, housekeeping staff).
- If Breast Centre is located in commercial environment, cost per visit is subjected to increase (e.g. office rent, management fee).

Therefore, cost per Face to Face visit is as followed:

<table>
<thead>
<tr>
<th></th>
<th>Apr 2013 - Sep 2013 Actual</th>
<th>Apr 2013 - Sep 2013 Budget</th>
<th>Apr 2012 - Mar 2013 Actual</th>
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<tbody>
<tr>
<td>Expenses</td>
<td>$214,536.39</td>
<td>$244,000.98</td>
<td>$489,886.26</td>
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<tr>
<td>VISITS - FACE TO FACE</td>
<td>3,295.00</td>
<td>4,168.08</td>
<td>7,280.00</td>
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<tr>
<td>Cost per visit Face to Face</td>
<td>$65.11</td>
<td>$58.54</td>
<td>$67.29</td>
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Appendix 8: Ontario Age-Sex Adjusted Hourly Wages

Table 282-0069
Labour force survey estimates (LFS), wages of employees by type of work, National Occupational Classification for Statistics (NOC-8), sex and age group, unadjusted for seasonality
annual (current dollars)

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<th>Manipulate</th>
<th>Download</th>
<th>Related information</th>
<th>Help</th>
</tr>
</thead>
</table>

The data below is a part of CANSIM table 282-0069. Use the Add/Remove data tab to customize your table.

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</tr>
<tr>
<td>Wages: Average hourly wage rate</td>
</tr>
<tr>
<td>Type of work: Total employees</td>
</tr>
<tr>
<td>National Occupational Classification for Statistics (NOC-8): Total employees, all occupations</td>
</tr>
<tr>
<td>Sex: Females</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age group</th>
<th>2013</th>
<th>2014</th>
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</thead>
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<tr>
<td>15 to 24 years</td>
<td></td>
<td>12.91</td>
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<tr>
<td>25 to 54 years</td>
<td>24.90</td>
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<tr>
<td>55 years and over</td>
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<td>24.22</td>
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</table>

Footnotes:

1. Beginning January 1997, information is collected on the usual wages or salary of employees at their main job. Respondents are asked to report their wage/salary before taxes and other deductions, and include tips, commissions and bonuses. Weekly and hourly wages/salary are calculated in conjunction with usual paid work hours per week.
2. Full-time employees are those who usually work 30 hours or more per week at their main or only job. Estimates in thousands, rounded to the nearest hundred.
3. Part-time employees are those who usually work less than 30 hours per week at their main or only job. Estimates in thousands, rounded to the nearest hundred.
4. Occupation estimates are based on the 2006 National Occupational Classification - Statistics (NOC-8). Occupation refers to the kind of work persons 15 years of age and over were doing during the reference week, as determined by the kind of work reported and the description of the most important duties of the job. If the individual did not have a job during the reference week, the data relate to the previous job, if that job was held in the past year. Those unemployed persons who have never worked before, and those persons who last worked more than 1 year ago make up the "undclassified" category in this table.
5. The Labour force survey collection of tables, starting with number 2018, is large with many possible cross-tabulations for the 10 provinces and other geographic regions. To
Appendix 9: Ontario Age-Sex Adjusted Labour Force Participation Rate

**Table 282-0002**

Labour force survey estimates (LFS), by sex and detailed age group annual (persons unless otherwise noted)

<table>
<thead>
<tr>
<th>Labour force characteristics</th>
<th>Age group</th>
<th>2013</th>
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<tr>
<td>Population (x 1,000)$^1$</td>
<td>25 to 44 years</td>
<td>1,863.3</td>
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<tr>
<td></td>
<td>45 to 64 years</td>
<td>1,915.7</td>
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<tr>
<td></td>
<td>65 to 69 years</td>
<td>334.9</td>
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<tr>
<td>Employment (x 1,000)$^3$</td>
<td>25 to 44 years</td>
<td>1,445.8</td>
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<tr>
<td></td>
<td>45 to 64 years</td>
<td>1,707.3</td>
</tr>
<tr>
<td></td>
<td>65 to 69 years</td>
<td>72.1</td>
</tr>
<tr>
<td>Participation rate (rate)$^9$</td>
<td>25 to 44 years</td>
<td>82.7</td>
</tr>
<tr>
<td></td>
<td>45 to 64 years</td>
<td>72.3</td>
</tr>
<tr>
<td></td>
<td>65 to 69 years</td>
<td>22.2</td>
</tr>
</tbody>
</table>

Footnotes:

1. Number of persons of working age. Estimates in thousands, rounded to the nearest hundred.
2. Number of civilian, non-institutionalized persons 15 years of age and over who, during the reference week, were employed or unemployed. Estimates in thousands, rounded to the nearest hundred.
3. Number of persons who, during the reference week, worked for pay or profit, or performed unpaid family work or had a job but were not at work due to own illness or disability personal or family responsibilities, labour dispute, vacation, or other reason. These persons on layoff and persons without work but who had a job to start at a definite date in the future are not considered employed. Estimates in thousands, rounded to the nearest hundred.
4. Full-time employment consists of persons who usually work 30 hours or more per week at their main or only job. Estimates in thousands, rounded to the nearest hundred.
Conclusion

In this thesis I set out to determine how various models of health care delivery within ambulatory breast reconstruction can be redefined and evaluated using principles derived from the Value Agenda. I will conclude by reviewing study findings and policy implications.

4.1 Summary of Study #1

From previous work, we know that it is safe, feasible\(^{15}\) and generates a societal savings of $2,015 CAD per episode of patient care when autologous breast reconstruction is performed in an ambulatory versus in-patient setting (unpublished work). In the first study, I build upon these findings using patient reported outcome measurements. I used patient level panel data to determine if postmastectomy autologous breast reconstruction can achieve satisfactory quality of recovery when performed in an ambulatory setting. Our study demonstrates favorable quality of recovery, acceptable rates of complication, and a 0% 30-day readmission rate. Our study further suggests that certain patient subgroups can be targeted for additional optimization of quality of recovery. Quality of recovery is an important Tier 2 outcome measurement. Our experience suggests that comprehensive perioperative protocols involving patient and health care provider education, appropriate patient selection, precise and atraumatic surgical technique, and multimodal analgesia are central to achieving expedited discharge. Such conditions support value transformation by allowing autologous breast reconstruction to be performed in cost-effective, ambulatory facilities.
4.2 Policy Implications of Study #1

Women’s College Hospital was unique, in that it was encouraged to adopt an expedited discharge model when it became an ambulatory facility. However, policy can be used to promote similar value transformation. Two policy implications arise from this paper and directly relate to the Value Agenda:

1) Increased service provision within ambulatory care facilities;
2) Guidance and legislation for health care providers regarding the use of patient reported outcome measurements.

Increased Service Provision with Ambulatory Surgery Centers

Women’s College Hospital is one of the first hospitals to convert to an ambulatory care facility. This transformation incentivized the transformation of autologous breast reconstruction from an inpatient to an outpatient procedure. Ontario policy should look to promote more Ambulatory Surgery Centres (ASCs). In 2012, it was estimated that only 25 ASCs existed across Ontario. This type of facility is commonplace throughout the United States and most of Europe and should be adopted in Ontario. ASCs promise to save health care dollars and address demand and geographical disparities – these are all concerns in Ontario today.

In the United States, physicians receive the same payment for an outpatient procedure, regardless of whether it occurred in an ASC or a hospital. However, bundled facility payments differ between settings. Typically payments are higher for outpatient procedures performed in a hospital because hospitals must comply with additional regulatory requirements and tend to treat more complex patients. Despite the higher hospital payment, the growth in outpatient volumes was greater in ASCs than in hospitals between 2007-2011 in the United States. This suggests that the incentive structure still favors outpatient surgery in ASCs. This may be due
to the perceived advantages in cost and quality or resource constraints that inhibit hospitals’ ability to meet the growing demand for outpatient surgery\textsuperscript{66}.

Furthermore, patients treated in an ASC spent 31.8 fewer minutes undergoing procedures than patients treated in hospital. This translates to 25\% less time per procedure. This means that ASCs can perform more procedures per day with the same number of staff and operating and recovery rooms. This would help Ontario address service demand while addressing costs, as ASCs generate savings of $363-$1000 per outpatient case. Canada continues to struggle with long specialty wait times\textsuperscript{62}. Orthopedic surgery and plastic surgery have the longest wait times\textsuperscript{62}. These two specialties perform a significant number of ambulatory surgeries and would benefit from more ASCs.

ASCs also have the ability to address geographic disparities because they are smaller and more geographically flexible than inpatient hospitals. Rural ASCs have been shown to be cost-effective and contribute to the profitability of associated rural hospitals\textsuperscript{67}. Rural hospitals with a freestanding ASC in close proximity report relatively higher operating margins and profits, compared to hospitals with ASCs located between one mile and 50 miles away\textsuperscript{67}.

As previously alluded to, wait times for surgical procedures continues to be a hot issue in Ontario. Great strides have been made in reaching wait time targets for cataract surgeries. Now 90\% of the population receives cataract surgery within 182 days\textsuperscript{68}. But why is the target 182 days? There are economic repercussions for waiting; and even within the cataract success story, major cities like Hamilton are waiting more than 200 days for surgery\textsuperscript{68}. 
Current Barriers to Ambulatory Surgery Centers

Currently it is near impossible to establish an ASC in Ontario. The Ministry of Health and Long Term care mandates that all proposed “independent health facilities” undergo a lengthy application process which currently only supporting cataract surgery facilities. As part of this process, facilities must be registered “not for profit”, must seek approval from the Local Health Integration Network (LHIN), and a partner hospital. The partner hospital must agree to re-allocate a portion of their funding to the proposed independent health facility. These conditions limit the ability of independent health facilities to address geographic disparity because they must be near a hospital that is already providing the proposed procedure (i.e. cataract surgery). There is no new population being served so these facilities cannot address demand (i.e. wait times). Hospitals must give up some of their funding while concurrently agreeing to manage any complications that arise at the aligned independent health facility. There is no incentive structure to encourage hospitals to enter into such an agreement. Similarly, there is no additional government funding to support independent health facility start-up costs.

Health care provider representation, like the Ontario Medical Association or the College of Physicians and Surgeons, should work with the Ministry of Health and Long Term Care to remove unnecessary barriers and improve incentives for establishing new independent health facilities.

Guidance and Legislation for Health care Providers Regarding the Use of Patient Reported Outcome Measurements

In the introduction I outlined a number of Ontario organizations that advocate for the Value Agenda. Most of these group make specific statements promoting the measurement of patient reported outcome. We know that teams improve and excel by tracking progress over time and comparing it to others inside and outside of their organization. From this study, we learned that patients who undergo autologous
breast reconstruction approach their preoperative baseline by postoperative day 7. Understanding level of discomfort during recovery and how long it takes to return to normal activities matters greatly to patients\textsuperscript{10}. This is a more relevant performance indicator for procedures where the risk of morbidity and mortality are rare\textsuperscript{10}. We know that there is widespread international interest in the use of patient reported outcome measures to monitor the effectiveness of health care services and interventions. Yet, the majority rarely go beyond tracking a few areas, such as mortality and safety\textsuperscript{10}. We need to have meaningful conversations regarding what outcomes to measure and how to collect, analyze and report outcomes data.

Porter suggests that outcomes should be measured by medical condition (such as breast cancer) and should cover the full cycle of care\textsuperscript{10}. While this is a worthwhile goal, it also often important to separate the “full cycle of care” into component pieces for the purpose of studying how well those components work and interact to accomplish their purpose (systems analysis). This is why we used the patient-reported Quality of Recovery-27 questionnaire as opposed to breast cancer or breast reconstruction specific patient reported outcome measurements. These later measurements are not meant to capture the quality of recovery data necessary to decide whether ambulatory autologous breast reconstruction is acceptable to patients. As well, comprehensive, “full cycle of care” patient reported outcome measurement tends to be time consuming and expensive to collect. Therefore, a precise purpose and achievable goal should be outlined prior to establishing any patient reported outcome measurement.

Secondly, the collection, analysis and reporting of patient reported outcome measurement data should be incentivized. It should be easy for health care providers and patients to participate in the collection of such measurements. Women’s College Hospital employs 5 full-time personnel that are responsible for
producing and submitting performance measurement data. Yet, the bulk of this data is not composed of patient reported outcomes and there is limited capacity to provide real time feedback to health care providers “on the ground” that may be able to adapt and improve practice based on the information. Technology is one promising facilitator of easy data collection. Though not the purpose of our second study, we are standardizing the collection of quality of recovery data (i.e. QoR-9) using mobile follow-up care. It takes patients less than 2 minutes to complete this survey on their mobile phone. Their results are automatically sent to their health care provider and trended over time (see Figure 9).

**Figure 9: Sparkline for Patient Nausea Scores Over Time**

![Sparkline for Patient Nausea Scores Over Time](image)

It is important to simultaneously limit barriers to collection and analysis while maximizing incentives for health care providers to use data to improve care pathways. Patient reported outcome measures (like quality of recovery) are linked to patient satisfaction including satisfaction with overall reconstruction\(^{22}\). Further, linking payment to outcomes would further incentivize health care providers.
4.3 Future Direction of Study #1

In our 40 patient study, I was able to identify a subset of patients who are at risk of poorer quality of recovery; and therefore, may benefit from targeted perioperative interventions. From this study, we know that pain is highly correlated with quality of recovery. From a secondary analysis, we know that patient reported pain scores vary significantly over the first week postoperatively (Figure 10).

**Figure 10: Postoperative Pain Scores Vary Significantly Between Postoperative Day (POD) 1 and 7.**

This variability is greater than the minimal clinically significant difference in pain scores\(^6^9\). We are currently coordinating with the experts at the Pain Clinic at Toronto General Hospital to perform a secondary analysis of pain scores and to develop strategies to improve pain scores amongst a targeted subgroup of patients. The variables of interest include age, BMI, type of surgery, antidepressant or anxiolytic use, total in-hospital postoperative opioid use and pain score prior to
surgery. We will perform a similar random effects panel analysis as was performed in study 1. We are powered to include 4 variables in our model if we assume a 0.6 correlation coefficient. We will perform a bivariate analysis on all variables of interest and use model fit statistics to inform our final model. The goal of this study is identify patients that may benefit from a higher postoperative quantity of opioid and/or dose of gabapentin, an opioid sparing agent used in this breast reconstruction patient population. Specifically, it is known that gabapentin is eliminated solely by renal clearance via first order elimination. Renal impairment reduces gabapentin excretion and increases plasma gabapentin concentrations in a linear fashion. Age and body mass index are known to impact renal clearance. The estimated glomerular filtration rate (eGFR) was found to be lower in participants with upper normal body weight (BMI, 22.0 to 24.9 kg/m2) or who were overweight or obese (BMI≥25 kg/m2), compared with participants with lower normal body weight (BMI, 18.5 to 21.9 kg/m2). Age was also significantly and independently associated with eGFR. A clinical correlation with age and/or BMI and pain scores may warrant personalized dosing of gabapentin based on these cofactors.

4.4 Summary of Study #2

In the second study, we model the cost-effectiveness of replacing in-person follow-up with mobile app follow-up care in ambulatory breast reconstruction patients over the first 30 days following surgery. We demonstrate an incremental net benefit of $245 CAD ($223 USD based on the current exchange rate) between mobile app and in-person follow-up care, with in-person follow-up being more expensive ($381 CAD) than mobile app follow-up care ($136 CAD). This takes into account the total of health care system, patient, and external borne costs. If we examine health care system costs alone, the incremental net benefit between mobile app and in-person follow-up is $38 CAD ($35 USD) over the first postoperative month. Mobile app follow-up care is a cost-effective care delivery model that helps expand the
geographical reach of breast reconstruction by reducing the burden of physical patient travel and its associated costs after surgery.

4.5 Study #2 Policy Implications

The revolution of consumer electronics has brought powerful mobile devices and wireless high-speed connectivity to the general public. Fixed and mobile broadband are available to over 99% of Canadian households, while smartphone penetration has risen to 56% of the Canadian population. There are now over 97,000 mobile health applications. Consumers are increasingly using online health technologies to self-manage their personal health and wellness goals, access health information, and connect with peer-to-peer health groups. Ninety-six percent of Canadians think it’s important that the health care system make use of digital health tools and capabilities, and 89% feel it is important that they personally have full advantage of digital health tools and capabilities. Additionally, 90% of Canadians who access their own health information online describe the experience as positive.

Despite this growing interest, there are many barriers to uptake of virtual care solutions.

Enabling Information Technology Platforms Through Reimbursement and Improved Privacy and Security Protocols

Right now, there are no signs of government investment in the end-user uptake of other virtual care platforms beyond electronic health or medical records. For those wishing to participate in virtual care, there are no transparent or comprehensive reimbursement models for institutions, physicians, or other members of the allied health care team who provide services via virtual care. Currently there is no way for
surgeons to bill for mobile app follow-up care unless this solution (1) garners the support of the Ontario Telemedicine Network (OTN) or (2) a new e-assessment fee is established. If the virtual solution is OTN approved, surgeons could bill the standard in-person follow-up care fee for the mobile app follow-up care. However, I would argue that failing to differentiate between virtual and in-person follow-up is lost cost-savings opportunity. Mobile app follow-up is faster than in-person follow-up and therefore, a fee reduction may be warranted.

Privacy and security are often cited as a barrier to virtual care. There are multiple layers of national, provincial and hospital level privacy and security policy that hinder the uptake of virtual solutions. Our small 72 patient randomized controlled trial took 1.5 years to receive hospital approval. The mobile app used in this study was compliant with Canada’s Personal Information Protection and Electronic Documents Act and Ontario’s Personal Health Information Protection Act. However, it still underwent a lengthy formal assessment by a lawyer specializing in personal health information privacy and security policy. This, in part, occurred because the virtual care space is new. There is no rulebook regarding how to initiate new virtual care solution at the level of the provider or hospital. The group at Women’s College Hospital Institute for Health Systems Solutions and Virtual Care is attempting to bring together policy makers, administrators and end-users to define a rationale and patient centric approach to privacy and security in virtual care.

Measuring Outcomes and Costs to Ensure Value for Money and Appropriateness

The Canadian College of Physicians and Surgeons have expressed concerns that videoconference visits could become “virtual walk-in clinics” with unsustainable costs on the health care system75. The case study they reference is the recent growth in virtual visits funded by British Columbia health care plan (735% growth in 2013)75. The majority of the growth occurred in online visits between doctors who bill
taxpayer-funded health care programs on a fee for service basis. The British Columbia government paid $336,011 in telemedicine payments in the last fiscal year - or about $41 per virtual visit, according to the Ministry of Health\textsuperscript{75}. The cost of the virtual visit may be reasonable if it is replacing or adequately augmenting services that would not otherwise be provided. In the future, we will directly address these concerns in our randomized controlled trial.

4.6 Future Direction of Study #2

In our cost-effectiveness study, we demonstrate how mobile app follow-up care is potentially cost-effective for society as well as the health care system. This is a purely theoretical analysis. The second part of this study includes a pragmatic, single-centre, open, controlled, 2-arm parallel-group superiority randomized trial comparing mobile app and in-person follow-up care over the first month following surgery. The primary outcome is the total number of physician visits (including specialist, family physician, and emergency department) related to the surgery. This data will be captured at four-weeks after surgery. The secondary outcomes will include: 1) The total number of health care telephone calls and emails (including specialist, family physician, and emergency department) related to the surgery; 2) the number of complications; 3) the societal and health care system costs; and 4) patient satisfaction. We will use a block randomization scheme with variable block size will be generated using STATA ralloc.ado\textsuperscript{76}. This will ensure approximately equal sample size, and that participants and study staff cannot anticipate assignment to either group. Treatments will be allocated in a 1:1 ratio.

A sample of 72 (36 patients per group) will provide an E-test for count data with a power of 95% (p=0.05) to detect a difference of 1 visit between groups, assuming a 10% drop out rate. Descriptive statistics (frequencies, means, standard deviations)
will be calculated for all clinical and outcome variables. We will person level poisson regression to determine if there is a difference in the number of visits attended between patients in the mobile app and in-person follow-up arm. Categorical variables will be tested using a chi-square test. Cost-effectiveness will be analyzed using net benefit regression. We will define cost as all societal costs incurred over the 30-days after surgery. We will define effect as the rate of complication over the 30-days after surgery. We will regress net benefit (dependant variable) on study arm, distance from home to hospital (km), ASA classification, radiation status, and type of procedure (independent variables). Net benefit and distance are continuous variables. ASA classification is a categorical variable. Study arm, radiation status and type procedure (major/minor) are binary variables.

\[ nb = B_0 + B_1(TX) + B_2(km) + B_3(ASA) + B_4(radiation) + B_5(major/minor) \]

We will perform regression diagnostics. We will use these diagnostics to advise on the use of parametric vs. non-parametric generation of 95% confidence intervals. We will use our net benefit regression to generate an incremental net benefit (INB):

\[ INB = WTP \ast (effect_i - effect_c) - (cost_i - cost_c), \] where

- \( effect_i \) = mean effect of the intervention, i.e. rate of complication in the mobile app arm at 30-days
- \( effect_c \) = mean effect of the control, i.e rate of complication in the in-person arm at 30-days
- \( cost_i \) = mean cost of the intervention, i.e. societal costs from baseline to 30-days
- \( cost_c \) = mean cost of the control, i.e. societal costs from baseline to 30-days

In this situation, where willingness to pay is unknown, we assigned numerous values for willingness to pay and generated a cost-effectiveness acceptability curve (CEAC) based on these theoretical values\(^77\). The CEAC illustrates the probability that the intervention is cost-effective by graphing the probability that \( B_1 > 0 \) as a function of WTP \(^77\). We will generate “best” and “worst” case scenarios for the missing data to determine if there is any change in findings.
In keeping with the Value Agenda, we will use this data to inform on value for money (i.e. cost-effectiveness) and appropriateness (i.e. safety and patient satisfaction). This type of research is necessary to push policy that promotes technological solutions in healthcare. Beyond this, there are many potential indirect benefits of mobile app home monitoring. If postoperative patients are attending fewer in-person follow-up care visits, there will be more time to serve new patients. This could potentially reduce wait times in specialty clinic. Secondly, smartphone follow-up care is a more continuous form of monitoring. Patients submit clinical information daily for the first two weeks and weekly for the remaining two weeks. This type of continuous monitoring could help alleviate patient anxiety, catch complications earlier, and reduce the number of non-urgent visits to the emergency department. In order to measure these types of outcomes, a larger multi-center, multi-patient population trial would be required.
References


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