THE IMPACT OF ONTARIO’S BARIATRIC NETWORK ON HEALTH SERVICES UTILIZATION FOLLOWING BARIATRIC SURGERY

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science in Clinical Epidemiology & Health Care Research

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University of Toronto

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Abstract

In 2009, the Ontario Bariatric Network (OBN) was created to address the increasing demand for out-of-country bariatric services. This study evaluated the impact of the OBN on postoperative hospital services use among Ontario residents who received bariatric surgery. A retrospective, before-and-after study was conducted. All Ontario residents who underwent funded first-time bariatric surgery were included. Hospital services use within one year following surgery was compared between the 3-year periods before (2007-2009) and after (2010-2012) the OBN. A total of 5,617 and 6,896 patients received bariatric surgery before and after the OBN, respectively. After adjustment, the OBN was associated with fewer postoperative hospital services (RR 0.83, 95%CI 0.78-0.89, P<0.001) and a lower 1-year mortality (OR 0.44, 95%CI 0.23-0.82, P=0.01). The physician visit rate was significantly higher (RR 3.50, 95%CI 3.19-3.84, P<0.001). A comprehensive province-wide multidisciplinary bariatric program appears to provide a better model of care when compared to outsourcing bariatric surgery.
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Chapter 1

1 Introduction

1.1 Obesity in Canada

Over recent decades, there has been a dramatic increase in the prevalence of obesity within Canada. In 2009, 24% of Canadians were considered obese, up from just 6% in 1985.\textsuperscript{1,2} Approximately, 31% of women and 21% of men in Canada are diagnosed with abdominal obesity, which can lead to significant health risks.\textsuperscript{3} Obesity, in general, is known to be a major risk factor for several chronic conditions including type II diabetes, hypertension, obstructive sleep apnea, cardiovascular disease, cancer, gallbladder disease, hyperlipidemia and osteoarthritis.\textsuperscript{4} The prevalence of these comorbidities has increased steadily alongside the growing prevalence of obesity.\textsuperscript{5} In addition, the considerable number of obesity-related comorbidities has resulted in a reduced life expectancy for obese individuals. A morbidly obese man in his twenties can have up to a 22% reduction in his expected remaining life span, losing 13 years of his life to obesity.\textsuperscript{5} In fact, some authors have argued that obesity should be considered the leading cause of death in North America.\textsuperscript{6} Furthermore, the adverse effects of obesity can appreciably diminish a person’s quality of life, with many patients experiencing psychosocial problems, functional limitations, disabilities, decreased productivity, and difficulty finding work.\textsuperscript{7,8}

The growing number of obese Canadians has been attributed to multiple factors. As a result, there have been several significant changes in Canadian health care policy with respect to the prevention of obesity and its related comorbidities. An important consideration in the management of the “obesity epidemic” has been improving access to surgical interventions.

1.2 Surgical Management of Morbid Obesity

Surgical management has emerged in recent years as an effective treatment for morbid obesity. Current surgical options for the treatment of morbid obesity include the laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric band (AGB) and laparoscopic sleeve gastrectomy (SG). The RYGB procedure consists of a horizontal division of the upper stomach to create a small gastric pouch with a 20-30 mL capacity.\textsuperscript{9} Gastrointestinal continuity is then
reestablished with a Roux en-Y reconstruction. The biliopancreatic limb extends from the ligament of Treitz to the jejunojejunostomy and is typically 30-60 cm in length, while the Roux limb extends from the gastrojejunostomy to the jejunojejunostomy and is typically 75-150 cm.\textsuperscript{9} The common channel is the remainder of the small intestine from the jejunojejunostomy distally to the ileocecal valve and usually constitutes the majority of the small intestine. In a LAGB procedure, a band or collar is placed around the upper stomach 1-2 cm below the gastroesophageal junction in order to create an upper gastric pouch of approximately 30 mL.\textsuperscript{9} Constriction of the pouch may be adjusted by modifying the amount of saline injected into a subcutaneous port, which is linked to a balloon within the confines of the band.\textsuperscript{9} Finally, the LSG involves a longitudinal resection of the stomach on the greater curvature from the antrum to the angle of His.\textsuperscript{10} Firstly, the vascular supply of the greater curvature of the stomach is divided followed by a longitudinal gastrectomy that “sleeves” the stomach to reduce it to a narrow tube between 60 and 200 mL in size.\textsuperscript{10}

### 1.3 Efficacy of Bariatric Surgery

Previous studies have demonstrated that bariatric surgery is the only treatment modality to produce significant and sustained weight loss for morbidly obese individuals.\textsuperscript{11,12} Lifestyle modification and medical therapies have shown limited effectiveness due to sub-optimal adherence, risk of relapse and a lack of reliable long-term weight loss.\textsuperscript{13,14} Bariatric surgery results in substantial weight reduction and far outperforms other therapeutic approaches on both the short- and long-term markers of health.\textsuperscript{13} The overall percentage of excess weight lost for 10,172 bariatric surgery patients included in a recent meta-analysis was 61.2%.\textsuperscript{15} A recent prospective, controlled study from Sweden demonstrated that bariatric surgery was associated with significant long-term weight loss and a 39% reduction in relative risk of death when compared to controls.\textsuperscript{16} The study also found that RYGB surgery is the most effective type of operation when compared to other bariatric procedures, producing a mean weight loss of 25% after 10 years.\textsuperscript{16} The results of this landmark study has been substantiated in other long term studies.\textsuperscript{17,18} Recently, a large multi-centre randomized controlled trial has demonstrated that the LSG is an effective and safe alternative to the current standard procedure, the laparoscopic RYGB.\textsuperscript{19} Both procedures were found to be almost equally efficient with respect to weight loss, improvement of comorbidities, and quality of life one year after surgery.\textsuperscript{19}
The sustained weight loss following bariatric surgery also improves obesity-related comorbidities. Three quarters of operated patients experience complete resolution of type II diabetes, and more than half of the remaining patients experience significant improvement in their glycemic control. After two years from surgery, 83% of patients previously presenting with diabetes would no longer require their diabetic medication. Bariatric surgery has also led to significant improvement or remission in conditions such as hypertension, hyperlipidemias, and obstructive sleep apnea. Studies have demonstrated that surgery is associated with reduced all-cause, coronary artery disease-related, and cancer-related mortality. In addition, surgical treatment has been shown to enhance quality of life, productivity, social relations and employment opportunity. As a result, the impact of bariatric surgery on both obesity-related comorbidities and overall quality of life has been significant.

In 2009, a review of all published economic evaluations was performed to evaluate the cost-effectiveness of bariatric surgery. Bariatric surgery was found to be cost-effective relative to non-surgical treatment and produced better clinical outcomes for patients. In the management of type II diabetes, bariatric surgery provided net health benefits and cost savings compared to non-surgical interventions. With respect to quality of life, a Canadian study reported that the incremental cost-effectiveness ratios for bariatric surgery can range from $5000 to $35,000 per quality-adjusted life-year.

1.4 Bariatric Surgery in Canada

Given the growing prevalence of obesity and popularity of bariatric surgery, it is not surprising that the demand for weight loss procedures has grown significantly in recent years. In the late 1980’s, only 5,000 bariatric procedures were performed worldwide, however up to 350,000 procedures were documented in 2009. Approximately, 63% of these procedures were performed in North America alone.

In 2005, Ontario’s Ministry of Health (MOH) decided to conduct an evidence-based review on bariatric surgery to determine its effectiveness on morbid obesity. Their findings led to a recommendation that bariatric surgery be considered as an effective treatment for morbid obesity. However, at the time, the average wait period for urgent bariatric surgery in the country was about five years and one of the longest of any surgically treated condition. Some estimates predicted that only 0.1% of potentially eligible Canadian patients were accessing
surgery, and in Ontario, the demand for surgery was estimated to be 7-fold greater than supply.\textsuperscript{29} It was evident that the Canadian publically funded health care system was unable to accommodate the growing demand for bariatric surgery.\textsuperscript{30}

The lack of public provision for bariatric surgery would ultimately foster the development of private surgical markets within Canada that offered uninsured services such as the laparoscopic AGB. Furthermore, some Ontario residents were encouraged to travel out-of-country (OOC) for treatment after their requests for coverage were denied by the MOH since bariatric procedures such as the RYGB, SG and the vertical band gastroplasty were already available health services in the province.\textsuperscript{31} As a result, patients increasingly processed appeals to the Health Services Appeal & Review Board (HSARB) arguing that the long wait times had, in reality, made the service inaccessible. Research studies were also suggesting that prolonged waits for bariatric surgery could contribute to death secondary to unresolved obesity-related diseases.\textsuperscript{32,33} When the HSARB began ruling in favour of patients, the province decided to classify bariatric surgery as one of the eligible “OOC Health Services”. Under the recommendation of the Ontario Health Technology Advisory Committee, contracts were established with bariatric centres in the United States for OOC referrals.\textsuperscript{34} Figure 1 presents the MOH annual summary of Ontario patients who underwent funded bariatric surgery from 2002 to 2009.\textsuperscript{29} The red line represents the cost of services for the provincial government over time, while the bars compares the number of patients treated at in-province and OOC centres each year.
In 2008, limited bariatric surgery capacity within Ontario prompted the MOH to accept over 1660 OOC applications for bariatric surgery that year at a cost of around 50 million dollars. Given such a high influx of OOC services, the MOH decided to commit $75 million in 2009 to increase the number of bariatric operations offered in Ontario. As a result of this initiative, the number of OOC surgeries scheduled and funded for Ontario residents began to rapidly decline.

1.5 Ontario Bariatric Services Strategy

In 2009, the MOH announced a $75 million investment to increase bariatric surgery capacity in Ontario, as part of a $741 million strategy for the management of diabetes. The objective of the Ontario Bariatric Services Strategy was to facilitate the development of an Ontario Bariatric Network (OBN) program that would centralize and standardize referrals for bariatric surgery. The OBN would provide a chronic disease management model that was more suitable for the care of bariatric patients. Furthermore, the program would recognize the complexity and
multidisciplinary issues surrounding obesity and its comorbidities. Once fully established, the province would no longer fund patients to receive bariatric surgery abroad. Accordingly, family doctors would refer eligible patients exclusively to one of four provincial Bariatric Centres of Excellence (COE). At these centres, patients would undergo a formal assessment and proceed with surgery once they met specific eligibility criteria. All patients would have access to a specialized bariatric surgeon along with a dedicated multidisciplinary team that included an internist, psychologist and dietician. As well, patients would receive formal surgical follow-up with established medical, psychological or dietary supervision.

1.6 Out-of-Country Surgery

The number of bariatric surgical procedures performed OOC peaked in 2009 because of long wait times and limited capacity within the province. Little information is available regarding the clinical outcomes, patient experiences and indirect costs related to OOC bariatric surgery. It is known that on average, the direct cost of each OOC procedure was at least US$19,000, which was $10,000 more than it would cost to perform the surgery in Ontario. Since 2002, the direct cost of OOC surgeries for the province has been estimated to be just over $172 million dollars. Indirect expenses could further inflate the total costs if OOC patients demonstrate an increased level of health services utilization.

A major concern with OOC surgery is the lack of continuity in care to monitor for postoperative complications and nutritional deficiencies. The importance of follow-up care is further apparent in this context given that bariatric surgery has protracted effects, with weight reduction and correlated changes in comorbidities continuing for months or even years after the procedure. Unlike other types of surgical procedures, the successful long-term treatment of morbid obesity and its associated comorbidities requires a lifelong process of care that includes a comprehensive program of surgical, medical, psychological, and dietary care. Furthermore, without specialized follow-up, patients cannot be considered for revisional procedures that could enhance their clinical outcome. In fact, a recent position statement put forth by the American Society of Metabolic and Bariatric Surgery (ASMBS) on global bariatric healthcare opposes the “referral across international borders or long distances for patients requesting bariatric surgery if a high-quality bariatric program is available locally”. 


The reality of OOC surgery is that many patients experience difficulty trying to find local bariatric surgeons willing to deal with their follow-up concerns. Currently, the proportion of bariatric surgeons accepting these select patients with complex postoperative issues remains unknown. These patients are likely to make emergency room visits and/or urgent referrals to Canadian bariatric centres for complications arising from their surgery. They may also experience severe psychological problems that could have been avoided by proper preoperative evaluation and patient education.

In Alberta, their provincial bariatric program reported that medical services for postoperative issues following OOC bariatric surgery cost their province $162,000 annually at one centre alone. From the Ontario experience, the OOC bariatric surgery program has proven to be costly for the MOH but more research is needed to fully understand the indirect expenses incurred through the health services utilization of OOC patients.

1.7 Outsourcing Health Services

The Ontario MOH has been approving reimbursement of OOC health care services since the 1990s. Various health services have been outsourced in the past mainly because of poor domestic accessibility as opposed to achieving higher quality care. For example, some Canadians have received treatment for substance abuse at various facilities located in the United States. Most of the cost for this strategy was borne by the various provincial health insurance plans. Canadians crossing the border to receive fertility services has also been an increasingly common practice. The restrictive regulation and limited availability in Canada has prompted the migration of some patients but often without clear lines of communication. Although fertility services are not insured by the MOH, it has demonstrated the challenges of ensuring appropriate continuity, quality and ethics of OOC care. Another example of outsourced health services was the referral of cancer patients from Ontario to the United States for radiation treatment. Since April 1999, the MOH was increasingly arranging cross-border referrals to the United States due to significant delays in treatment. As a result, the Canadian Radiation Oncology Services (CROS) was developed in January 2001 and contracted to improve access to publicly funded radiation therapy in Ontario.
1.8 Study Rationale

In 2010, the cost of healthcare was 42% of the Ontario government budget and is projected to increase.\textsuperscript{41} It will be necessary to evaluate the long-term effects of the province’s change in policy surrounding bariatric surgery and care. Understanding the impact of the OBN on health services use can better inform Ontario’s future health care spending strategies.

Along with a lack of understanding regarding the short-term clinical outcomes and safety of outsourcing bariatric services, the extent of health services utilization incurred by these patients remains unexplored. Before implementation of the OBN, there was little to no surgical follow-up for bariatric recipients and a deficiency in medical, dietary and psychological supervision. However, most patients that undergo bariatric surgery undoubtedly require the expertise and care of a dedicated bariatric team at some point in their lives.\textsuperscript{35} This potentially inadequate follow-up care could have delayed the diagnosis and treatment of postoperative complications, leading to unnecessary hospitalizations or emergency room visits. The findings from this study may demonstrate a longer-term advantage for government policies that foster clinical programs within Ontario as opposed to outsourcing costly health services.

1.9 Objectives

The primary objective of this study was to evaluate the impact of the OBN on the postoperative hospital services utilization among Ontario residents who received bariatric surgery.

The secondary objective was to compare the physician visit, mortality and abdominal reoperation rates before and after implementation of the OBN.

The study hypothesis was that Ontario residents who received bariatric surgery after the implementation of the OBN were less likely to utilize the provincial health care system than earlier recipients because they were more likely to receive the appropriate postoperative follow-up care.
Chapter 2

2 Methods

2.1 Study Design

This is a retrospective, uncontrolled “before-and-after” study using administrative data held at the Institute for Clinical Evaluate Sciences (ICES).

2.2 Overview

The one-year postoperative health services utilization of Ontario residents receiving bariatric surgery during the 3-year periods before and after establishment of the OBN was compared in this study. Prior to the OBN, most bariatric surgery was performed OOC with approval by Ontario’s Ministry of Health and Long Term Care.

2.3 Data Sources

2.3.1 Institute for Clinical Evaluate Sciences (ICES)

ICES is an independent, non-profit organization that evaluates health care delivery and outcomes in the province of Ontario. ICES is funded by the Ontario Ministry of Health and Long-Term Care and receives peer-reviewed grants from federal and provincial agencies. ICES research is used to guide decision-making and inform changes in health care policy and delivery.

In order to conduct analyses and compile statistics about the management and effectiveness of health care in Ontario, ICES has received approval by the Information and Privacy Commissioner (IPC) under section 45 of Ontario’s Personal Health Information Protection Act (PHIPA, 2004). Information is protected through privacy policies and practices, such as controlled access, secure zones within ICES facilities, complex passwords and encryption.

Personal health information collected at ICES from Ontario’s administrative systems is linked using unique, encoded identifiers. Each person in Ontario is assigned a unique, encrypted ICES key number (IKN) based on their Ontario health card number that permits successful linkage across the ICES data inventory.
This study cohort was linked to individual-level records from several administrative databases held at ICES. These data sources included the Ministry of Health and Long-term Care Out-of-Country Service (MOHLTC OOC) database, the Ontario Health Insurance Plan (OHIP) physician claims database, the Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD), the National Ambulatory Care Reporting System (NACRS) and the Registered Persons Database (RPDB).

2.3.2 Ministry of Health and Long-term Care Out-of-Country (MOHLTC OOC) Service Database

The MOHLTC OOC database contains data collected on all Ontario residents that received OOC bariatric surgery funded by Ontario’s Ministry of Health and Long Term Care. The purpose of this registry was to allow the MOH to keep close track of OOC payments for all bariatric operations. The appropriate data-sharing agreement was drafted and accepted between ICES and the MOH to permit linkage with the rest of the administrative data held at ICES. The database captures information relating to the diagnosis and type of treatment. Data on the date, facility, city and state of surgery were all included. There was also information on total cost for the procedure. There is no information on the reliability or validity of information in this database. However, it should be reasonably accurate for the provision of health services since the MOH was closely monitoring payments for approved OOC services in an effort to control the total expenditure.

2.3.3 Ontario Health Insurance Plan (OHIP) Database

The OHIP database provides details on all claims paid by OHIP to physicians, groups, laboratories, and out-of-province providers since 1991. Important exclusions include fees paid under Worker’s Compensation claims and services provided by physicians participating in Alternate Funding Plans (AFPs), which account for 5% of total physician expenditures in Ontario. The OHIP database is updated bi-monthly as records are received from the MOHLTC. Information extracted from OHIP claims includes encrypted patient and physician identifiers, date of service, fee codes for service, fee suffix for service, main diagnosis and fee paid by OHIP. The MOHLTC Schedule of Benefits for physician services reports all eligible claims and describes each fee code along with its associated reimbursement fee. The fee suffix label specifies the physician role with respect to surgical procedure claims.
There have been no previous studies evaluating the validity of OHIP fee coding to identify bariatric surgical patients. However, the reliability of coding surgical procedures in the Ontario health databases is good, with studies demonstrating the concordance between OHIP claims and discharge summaries to be as high as 94% for procedures such as hysterectomy and cholecystectomy.44

2.3.4 Canadian Institute for Health Information - Discharge Abstract Database (CIHI-DAD)

The Canadian Institute for Health Information (CIHI) is an independent, not-for-profit organization that collects and analyzes data on Canadian patients and the Canadian health system.45 The organization is federally funded and mainly responsible for capturing information and maintaining databases in order to present the spectrum of health care services in Canada.45

In this study, the CIHI’s discharge abstract database (DAD) was used to identify several relevant variables. This database contains demographic, administrative and clinical information on all discharges from acute care facilities for Ontario residents dating from 1988. Relevant clinical information is collected from the chart by trained medical records coders and includes codes for main diagnosis, procedures and discharge status. The database is updated annually and contains information on all hospitalizations that ended in discharge, transfer or death during each fiscal year. The major data elements include patient demographics (sex, date of birth, postal code, county and residence code), clinical information (discharge diagnoses, inpatient procedures/interventions, physician/provider identification), and hospital administrative data (institution number, admission category, length of stay, discharge disposition). The first diagnosis code represents the diagnosis that was most responsible for the length of stay (LOS). Patients may have up to 25 different types of diagnosis to describe their hospital stay, as well as up to 20 different procedure/intervention codes. A recent CIHI validation study has demonstrated that agreement on demographic data within the CIHI DAD is uniformly excellent when compared to medical chart abstraction (i.e. >99.9%).46

Before 2002, diagnostic coding in the DAD was performed using the International Statistical Classification of Diseases, Injuries, and Causes of Death, Ninth Revision (ICD-9) and procedural coding was in accordance to the Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures (CCP). Currently, the International Statistical Classification of Diseases and
Health Related Problems, Tenth Revision, Canada (ICD-10-CA) is used for diagnostic coding classification. In addition, the Canadian Classification of Health Interventions (CCI) was introduced to replace the previous CCP classification system for procedural coding.

2.3.5 National Ambulatory Care Reporting System (NACRS)

The NACRS database captures information of patient visits to hospital and community based ambulatory care, including day surgery, and emergency departments. Data holdings are nearly complete beginning in the fiscal year 2002-2003.47

2.3.6 Registered Persons Database (RPDB)

The RPDB contains demographic information (i.e. birthdate, sex, residence) on all individuals who have ever received an Ontario health card number starting from 1990. The database is maintained by the MOHLTC and includes information on death from a variety of sources. Dates of health card issuance, last contact and death are also provided.

2.4 Participants

2.4.1 Study Population

Ontario residents who received funded, first-time bariatric surgery between January 1\textsuperscript{st}, 2007 and July 31\textsuperscript{st}, 2012 were eligible for the study.

2.4.2 Cohort selection

The OOC patient cohort was identified using the MOHLTC OOC database, which contained all OOC surgery recipients tracked by the MOH. Patients who received in-province bariatric surgery covered by OHIP were identified using specified OHIP fee codes for bariatric surgery. Fee codes included S120 for gastric bypass with Roux-en-Y anastomosis and S114 for sleeve gastrectomy. Each patient IKN was then used to link the patient cohort across databases. To prevent inclusion of duplicated subjects, the “feesuff” OHIP variable was used to select only the claims made by the primary surgeon as indicated with an “A” suffix. For patients who had more than one bariatric procedure identified during the study period, the first surgery was selected. Patients who underwent private/uninsured surgical procedures (i.e AGB) were not included in this study.
2.4.3 Study Timeline

The timeline for accrual and follow-up period for the study population is depicted in Figure 2.

**Figure 2: Study design and follow-up for cohorts**

Study patients underwent surgery between January 1st, 2007 and July 31st, 2012. The comparison groups were selected based on the year of surgery. Postoperative health services use was measured for one full year (i.e. 365 days) after the date of surgery for each cohort. The start of the follow-up period was the discharge date of the principal operation. For patients who received OOC surgery, the discharge date was unavailable and therefore the start of the follow-up period was replaced with the date of surgery. It is reasonable to assume that the day of surgery and discharge in OOC patients would usually be a few days apart.

2.5 Exposures

2.5.1 Primary Exposure (Program Implementation)

Patients who underwent bariatric surgery after the OBN was implemented from 2010 to 2012 were considered the exposure group, while those who had surgery before the OBN from 2007 to 2009 were considered the control group. Program implementation was chosen as the study exposure in order to determine an estimate of the program’s effect on the study outcome. Although, the OBN was established at the start of the 2009/10 fiscal year, OBN funded procedures were performed at the start of the 2010 calendar year (Figure 3). Given that the study control group underwent either OOC or in-province surgery without formal follow-up before 2010, surgical period rather than location was used to provide a better evaluation of the
OBN effect on the study outcomes. Simply comparing OOC with in-province surgical recipients would introduce a selection bias since bariatric patients accepted for OOC services may have been systematically different than patients who received surgery in Ontario. In addition, patients who received their surgery at Ontario hospitals outside the OBN after 2010 were not excluded from the study population since they were still eligible to participate in the program.

Figure 3: Bariatric referral trends (April 2009 – March 2010)

2.5.2 Demographic Information

Demographic variables captured from data sources included age, sex, socioeconomic status (income quintile) and rurality. Data on patient age and sex was obtained from the RPDB. Age was analyzed as a continuous variable. The above demographic variables were considered potential confounders in the analysis. Older aged patients and male patients may be at higher risk for postoperative complications. Socioeconomic status may influence access to health care. As
well, patients from rural areas may experience longer travel distances to hospitals, which may affect their likelihood of accessing health care services.

2.5.2.1 Rurality

Information on rurality was provided by the “rural” variable in the OHIP database. Patient rurality was captured using census information and applied to any individuals living outside urban areas. Urban was defined as “a minimum population concentration of 1,000 persons and a population density of at least 400 persons per square kilometre, based on the current census population count”. The residential location of individuals was determined by linking patient postal code information from the RPDB with the Postal Code Conversion File (PCCF) from Statistics Canada.

2.5.2.2 Socioeconomic Status

The income quintile “incquint” variable was used as a measure of socioeconomic status. This information was also obtained from the PCCF, by linking the residential postal code to the corresponding Dissemination Area (DA). A DA is defined by Statistics Canada as “a small, relatively stable geographic unit composed of one or more neighbouring dissemination blocks, with a population of 400 to 700 persons”. All of Canada is divided into these areas, which are the smallest standard geographic unit in census data. After the average income per person equivalent (IPPE) is calculated for each DA, the areas are ranked and divided into quintiles. The lowest neighbourhood income quintile is coded as 1, and the highest income quintile is coded as 5.

2.5.3 Type of Bariatric Procedure (RYGB vs. Other)

The RYGB is the most commonly performed bariatric surgical procedure in the United States and Canada. The application of laparoscopic surgery and the development of improved stapling devices have simultaneously facilitated the advancement of this operation. Among bariatric surgeries, previous studies have demonstrated that the RYGB is associated with the greatest readmission rate. However, higher surgeon and hospital volume in bariatric surgery has managed to improve clinical outcomes for postoperative RYGB patients.
2.5.4 Adjusted Clinical Groups (ACG) Comorbidity Score

The Adjusted Clinical Groups (ACG) is a patient case-mix adjustment system that was developed to provide a relative measure of an individual’s expected or actual consumption of healthcare resources. The ACG system is able to quantify morbidity by categorizing individuals based on their demographic information and medical diagnoses that were captured over a certain period of time. In order to accomplish this task, the system identifies International Classification of Diseases (ICD) diagnostic coding recorded in several administrative datasets, such as physician claims and hospital discharge abstract records. Furthermore, the ACG system has been extensively validated in Canada and the United States.

In contrast to other comorbidity scoring systems, the ACG does not rely solely on patient hospitalization records. Therefore, the main advantage of this index is its applicability to both ambulatory and hospitalized patients. The ACG system can automatically classify a patient’s morbidity into one of six categories termed Resource Utilization Bands (RUB) using existing ICES data sources. These levels range from non-users to very high users of health services. Accounting for patient morbidity across cohorts will be a necessary component in the primary analysis.

2.6 Outcomes

2.6.1 Primary Outcome

2.6.1.1 Days requiring Hospital Services

The primary outcome of this study was the number of postoperative days requiring hospital services. This endpoint was a composite count of the number of emergency room visits and total days spent in hospital.

The “edvisit” variable from the NACRS database provides information on whether a patient has visited an emergency department. This indicator was used to determine the number of postoperative emergency room visits within the follow-up period. The length of stay for each postoperative hospitalization was added to determine the number of days spent in hospital after surgical discharge. The admission and discharge date variables were used to calculate the total number of inpatient days.
The number of days requiring hospital services provides a measure of the intensity of hospital resource utilization. Hospital care in the form of emergency visits and inpatient stay is a very important component of health services use in the postoperative bariatric population.

2.6.2 Secondary Outcomes

2.6.2.1 Hospitalizations

The number of hospitalizations was determined by counting the different admission dates recorded for each patient in the CIHI discharge abstract database within the follow-up period. The efficiency and ability to promptly manage postoperative complications can be described in part by the frequency of postoperative hospitalizations.

2.6.2.2 Intensive Care Unit (ICU) Stay

The number of days requiring an ICU stay was based on enumerating the daily OHIP fee claims for the physician-in-charge in an ICU setting. Claims for either critical care services, ventilator support or comprehensive care captured by the OHIP database “feecode” variable was included. Using administrative data to identify ICU stay has been previously validated.56 The following is a list of eligible fee codes: G400, G401, G402, G405, G406, G407, G557, G558, G559. Since ICU stay for post surgical patients can be quite resource intensive, capturing the length of stay allows for a more comprehensive understanding of health services use in this select population.

2.6.2.3 Ventilatory Support

The number of days requiring ventilation in the ICU was determined by counting daily fee codes for ventilatory care or comprehensive care in the ICU setting. The following is a list of eligible fee codes: G405, G406, G407, G557, G558, G559. Similar to intensive care, the need for ventilator support requires a substantial amount of time and commitment from several hospital services. The extent that postoperative patients require ventilation may also influence the length of their recovery and future requirement of other hospital services.

2.6.2.4 Physician Visits

All physician visits were identified based on the “A” prefix in the OHIP assessment fee code. All claims with this identifier were counted to determine the total number of physician visits within the follow-up period. Physician visits included both primary care and specialist visits. Unlike
other outcomes in this study, the utilization of postoperative physician services may deliver more value to the Ontario health care system by improving the quality and continuity of care. The opportunity to address concerns and complications in an outpatient setting can also translate to a reduced need for hospital services.

2.6.2.5  Reoperations

Postoperative abdominal procedures were identified using the “S” prefix identifier in the OHIP claims database, which usually indicates a digestive system surgical procedure. Only certain abdominal gastrointestinal operations were considered clinically relevant and included in the count. Relevance was based on the common interventions required to manage bariatric surgical complications such as abscess drainage, bowel obstructions/resections, and feeding tube placements. The following is a list of eligible fee codes: S083, S090, S091, S092, S095, S096, S117, S118, S122, S123, S125, S128, S129, S131, S132, S138, S140, S151, S161, S162, S164, S165, S166, S175, S176, S177, S180, S184, S187, S312, S313, S314. Any of the above procedures claimed within the follow-up period was counted as a reoperation.

2.6.2.6  Mortality

Vital status was obtained using information from the RPDB using the “dthdate” variable. Death within 30 days and one year of the surgery date was captured. With respect to bariatric surgery, mortality is considered a very important marker of surgical quality and care.

2.7  Statistical Analysis

2.7.1  Sample Size and Power

There were 12,513 Ontario residents identified from the datasets who received bariatric surgery. Based on Power Analysis and Sample Size software (PASS), a two-tailed Poisson regression of the primary outcome achieves a power of 0.80 at an alpha of 0.05 to detect a response rate ratio of at least 0.97 or a true difference of at least 3%.\(^57\) Since a 15% difference in the rate of hospital services would be considered clinically significant, this study appears to be adequately powered to analyze the primary outcome. Although this power calculation assumes a Poisson rather than a negative binomial regression, it should be acceptable for providing an approximated estimate.
2.7.2 Descriptive Statistics

Descriptive statistics were computed to compare patient characteristics between the two cohorts. Continuous data were expressed as both means with standard deviations and medians with the interquartile range. Categorical variables were expressed as frequencies (counts) and percentages.

2.7.3 Tests of Association

The following tests of association were used to compare baseline patient characteristics. For all continuous data, a Wilcoxon rank sum test was used to compare median values. A t-test was also performed for continuous variables to compare mean values. A chi-square test was used to compare categorical data across groups.

2.7.4 Measurement of Count Data

Count data are characterized by discrete, non-negative values. Several models have been proposed in order to accommodate the nature of count data. The degree of dispersion and the proportion of excess zero counts in the count distribution are considered when choosing the model that could provide the best fit for the data. Possible models for count data distribution include simple Poisson and negative binomial regression models, zero-inflated models and two-part hurdle models.

2.7.4.1 The Poisson Model

A Poisson distribution expresses the probability of a given number of events occurring in a fixed interval of time.\(^{58}\) The classic example of a Poisson distribution is data consisting of mostly low values and less frequently of higher values. Therefore, a model with Poisson distribution would be more appropriate to apply for non-negative count outcomes than an ordinary least-squares linear model.\(^{59}\)

2.7.4.2 The Negative Binomial Model

With respect to count data for health services use, it is common to encounter distributions characterized by a high number of low counts and a very small number of high counts. As a result, this may create “over-dispersion” in the distribution and violate the assumption of a Poisson distribution that the variance is equal to the mean. In this case, the negative binomial
(NB) distribution is an alternative to the Poisson model and is especially useful for count data where the sample variance exceeds the sample mean (i.e. data with over-dispersion).

2.7.4.3 The “Zero-inflated” Model

One model to consider for health services use data is the “zero-inflated” model, which accounts for a much larger than expected number of observed zeros than assumed by the Poisson and negative binomial distribution. This model assumes that zero counts are from two separate processes or origins: “structural” and “sampling”. The sampling zeros are due to the usual Poisson (or negative binomial) distribution, which assumes that those zero observations happened by chance. The structural zeros are observed due to a known partition within the data between zero and positive counts. This model can be applied to health services utilization data when zero counts can either occur as a result of the disparity of an individual’s health within the sample population (i.e. sampling) or recognizing that some individuals do not have access to services altogether (i.e. structural).

2.7.4.4 The “Hurdle” Model

The “hurdle” model is another approach to measure health services utilization data. This model assumes that all zero counts are due to a single “structural” source that is fundamentally different from the process that creates positive counts. The positive data belongs to the “sampling” process, which follows either a zero-truncated Poisson or negative binomial distribution. For example, health services data can be conceptually divided into two categories where zero counts are taken to represent all the “non-users” of health services and positive counts are regarded to represent all the “users” of health services. An advantage of this model is that it can characterize the initiation and intensity of health services separately. The decision to initiate services (which represents the hurdle) is usually ascribed to patient-level factors, however the decision to receive further medical attention usually relies on the health care provider’s continual assessment of the patient. Therefore, compared to the “zero-inflated” model, this distinctive framework may yield different results and interpretations of the same data.

2.7.4.5 Rationale for Standard Negative Binomial Regression

When regressing on count data with excessive zero counts, zero-inflated Poisson (ZIP) models typically fit better than a standard Poisson model. However, when compared to a standard
negative binomial regression, ZIP models do not provide a better fit.\textsuperscript{61} Although a zero-inflated negative binomial (ZINB) model can handle data with excessive zero counts better than a conventional NB regression model, the interpretation of the estimates can be quite difficult.\textsuperscript{61} Furthermore, because the difference in fit is usually trivial, this study used the simpler conventional NB model over the ZINB model to regress the count data.

Although the degree of access may vary among Ontario residents in this study, all health cardholders have the ability to access medically necessary health care in Ontario. Zero counts could be considered as part of the sampling distribution and therefore a Hurdle model was not employed.

2.7.5 Multivariable Analysis

The final multivariable NB model included various demographic variables such as age, sex, income quintile, and rurality. The type of bariatric procedure was also included as an independent variable. For risk adjustment, the Johns Hopkins Adjusted Clinical Groups (ACG) method for characterizing study participant comorbidity was incorporated into the regression model. All the above independent variables were chosen \textit{a priori} based on clinical relevance. As well, given the large study sample size, all covariates could be used in the model without compromising fit. Multicolinearity was examined among the independent variables and there was no correlation in the models based on a variance inflation factor (VIF) threshold of four.\textsuperscript{62}

The over-dispersion factor (ODF) for each study outcome was examined using a Poisson regression model. The values were greater than one, which suggested the data was over-dispersed. A LaGrange Multiplier (LM) test was performed after using a negative binomial model with a dispersion factor forced to zero. The test was significant and therefore the null hypothesis, which implied the Poisson model was adequate, was rejected. This result was expected since the distribution of the outcome was positively (right) skewed due to a low number of high counts. Although, there was an excess of zero counts, a conventional NB model was chosen over a ZINB model based on ease of interpretation and trivial difference in model fit.

A \textit{P} value of less than 0.05 was considered statistically significant and provided for all tests. Negative binomial regression results were presented as rate ratios (RR) and logistic regression
results as odds ratios (OR) with corresponding 95% confidence intervals (CI). All programming and analyses were conducted using SAS v9.3 for Unix (SAS Institute Inc, Cary, NC).

2.7.6 Trend Analysis

In order to illustrate the trend of hospital services use over time, the mean value of all model covariates for each successive three-month interval in the study period was determined. The mean number of days requiring hospital services was then regressed on the mean value of each predictor variable for each three-month interval. Similarly, the one-year postoperative mortality rate was also determined for each successive three-month interval. Using data points from before the OBN, a line-of-fit was extrapolated to the period after the OBN and compared with a line-of-fit developed from data points after the OBN was established.

2.7.7 Ethics and Confidentiality

Data from several administrative databases were used to conduct this study. Policies and practices are in place at ICES to protect privacy, maintain confidentiality, and secure information from available data sources. All the study results are reported using grouped data without any individual-level identifiers. Both the University of Toronto and University Health Network Research Ethics Boards provided administrative approval of the study methodology (see Appendix).
Chapter 3

3 Results

3.1 Description of Study Cohorts

A total of 12,513 Ontario residents underwent first-time, funded bariatric surgery between January 1, 2007 and July 31, 2012. The number of patients that underwent surgery after implementation of the OBN was 6,896, while the number of patients before implementation was 5,617. Table 1 describes the baseline patient characteristics between the two defined cohorts. The results demonstrate that both groups were generally comparable with respect to demographic and clinical variables. Although the P value was statistically significant after comparing patient age and rurality, the corresponding mean and risk differences were minimal. Furthermore, difference in ACG comorbidity score was statistically significant but the histogram distribution of scores was quite similar.

The mean age before the OBN was 43 compared to 45 after implementation (P<.001). Females made up approximately 82% of the patient population. More than 80% of patients in both groups resided in an urban location at the time of surgery. In addition, the distribution of neighbourhood income quintile appeared even across groups. Interestingly, the proportion of RYGB operations was lower after the OBN was implemented (93% vs. 96%, P<.001). This can be attributed to the higher number of SG performed in recent years.

Table 1: Characteristics of the Ontario Bariatric Surgery Cohort before and after establishment of the OBNa

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Before OBN (n = 5,617)</th>
<th>After OBN (n = 6,896)</th>
<th>Mean &amp; Risk Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean [SD]</td>
<td>43.3 [10.3]</td>
<td>44.8 [10.4]</td>
<td>-1.5 (-1.9, 1.2)</td>
<td>&lt;.001b</td>
</tr>
<tr>
<td>Median [IQR]</td>
<td>43.0 [15.0]</td>
<td>45.0 [15.0]</td>
<td></td>
<td>&lt;.001c</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4551 (81.5)</td>
<td>5633 (81.8)</td>
<td>-0.003 (-0.017, 0.011)</td>
<td>0.68d</td>
</tr>
<tr>
<td>Male</td>
<td>1031 (18.5)</td>
<td>1252 (18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACG Comorbidity Score ≤2</td>
<td>135 (2.4)</td>
<td>101 (1.5)</td>
<td>N/A</td>
<td>&lt;.001d</td>
</tr>
</tbody>
</table>
Table 2: Location of bariatric surgery before and after program implementation

<table>
<thead>
<tr>
<th>Year</th>
<th>Out-of-Country</th>
<th>In-Province</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>OBN Centre</td>
<td>Other</td>
</tr>
<tr>
<td>2007</td>
<td>791</td>
<td>165</td>
<td>31</td>
</tr>
<tr>
<td>2008</td>
<td>1447</td>
<td>354</td>
<td>17</td>
</tr>
<tr>
<td>2009</td>
<td>2146</td>
<td>645</td>
<td>21</td>
</tr>
<tr>
<td>Total (%)</td>
<td>4384 (78.1)</td>
<td>1164 (20.7)</td>
<td>69 (1.2)</td>
</tr>
</tbody>
</table>

**PROGRAM IMPLEMENTATION**

<table>
<thead>
<tr>
<th>Year</th>
<th>Out-of-Country</th>
<th>In-Province</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>OBN Centre</td>
<td>Other</td>
</tr>
<tr>
<td>2010</td>
<td>467</td>
<td>1461</td>
<td>71</td>
</tr>
<tr>
<td>2011</td>
<td>*</td>
<td>2256</td>
<td>77</td>
</tr>
<tr>
<td>2012</td>
<td>*</td>
<td>2499</td>
<td>64</td>
</tr>
<tr>
<td>Total (%)</td>
<td>- (6.8)</td>
<td>6216 (90.1)</td>
<td>212 (3.1)</td>
</tr>
</tbody>
</table>
Figure 4 illustrates the number of cases performed in the study period by year and centre location. The stark decline of OOC cases after the implementation of the OBN in 2009 followed by the sharp increase in cases performed at OBN centres can be appreciated. There were a small number of cases performed in Ontario institutions outside the OBN, which remain unchanged throughout the study period. With respect to OOC cases, the three most common surgical sites were Michigan (63.0%), New York (27.5%), and Minnesota (5.8%) (Table 3).

Table 3: Volume of bariatric cases based on centre location

<table>
<thead>
<tr>
<th>Out-of-Country Locations</th>
<th>Number of Cases (%)</th>
<th>In-Province Locations</th>
<th>Number of Cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>*</td>
<td>Guelph</td>
<td>1153 (15.1)</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>*</td>
<td>Hamilton</td>
<td>1214 (15.8)</td>
</tr>
<tr>
<td>Florida</td>
<td>*</td>
<td>Ottawa</td>
<td>932 (12.2)</td>
</tr>
<tr>
<td>Illinois</td>
<td>*</td>
<td>Toronto</td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td>*</td>
<td>Humber River</td>
<td>2178 (28.4)</td>
</tr>
<tr>
<td>Maine</td>
<td>*</td>
<td>Scarborough</td>
<td>187 (2.4)</td>
</tr>
<tr>
<td>Michigan</td>
<td>3052 (63.0)</td>
<td>St. Joseph’s</td>
<td>514 (6.7)</td>
</tr>
<tr>
<td>Minnesota</td>
<td>282 (5.8)</td>
<td>St. Michael’s</td>
<td>304 (4.0)</td>
</tr>
<tr>
<td>North Carolina</td>
<td>118 (2.4)</td>
<td>Toronto East</td>
<td>126 (1.6)</td>
</tr>
<tr>
<td>New Jersey</td>
<td>*</td>
<td>Toronto Western</td>
<td>703 (9.2)</td>
</tr>
<tr>
<td>New York</td>
<td>1333 (27.5)</td>
<td>Other</td>
<td>350 (4.6)</td>
</tr>
<tr>
<td>Ohio</td>
<td>24 (0.5)</td>
<td>TOTAL</td>
<td>7661</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Texas</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td>17 (0.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>11 (0.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>4852</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* cell size < 6
3.3 Summary of Outcomes

Table 4: One-year postoperative health services utilization before and after program implementation

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Before OBN (n = 5,617)</th>
<th>After OBN (n = 6,896)</th>
<th>Mean Difference (95% CI)</th>
<th>P value&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any hospital services&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3033 (54.0)</td>
<td>3510 (50.1)</td>
<td></td>
<td>0.001</td>
</tr>
<tr>
<td>Number of days requiring hospital services among persons with ≥ 1 day</td>
<td>5.7 [14.1]</td>
<td>4.8 [9.5]</td>
<td>0.8 (0.2, 1.4)</td>
<td></td>
</tr>
<tr>
<td>Mean [SD]</td>
<td>6.0 [7.0]</td>
<td>5.0 [7.0]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median [IQR]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any emergency room visit</td>
<td>2778 (49.5)</td>
<td>3244 (47.0)</td>
<td></td>
<td>0.007</td>
</tr>
<tr>
<td>Number of emergency room visits among persons with ≥</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
<td>-------------</td>
<td>---------------------</td>
<td>-----------</td>
</tr>
<tr>
<td></td>
<td>2.5 [2.7]</td>
<td>2.0 [2.0]</td>
<td>2.3 [2.3]</td>
<td>0.2 (0.1, 0.3)</td>
</tr>
<tr>
<td></td>
<td>1.7 [1.4]</td>
<td>1.0 [1.0]</td>
<td>1.7 [1.3]</td>
<td>-0.02 (-0.11, 0.08)</td>
</tr>
<tr>
<td></td>
<td>9.3 [21.0]</td>
<td>4.0 [6.0]</td>
<td>6.8 [12.6]</td>
<td>2.5 (1.2, 3.8)</td>
</tr>
<tr>
<td></td>
<td>11.1 [20.8]</td>
<td>5.0 [10.0]</td>
<td>4.4 [9.4]</td>
<td>6.7 (3.1, 10.3)</td>
</tr>
<tr>
<td></td>
<td>13.1 [24.2]</td>
<td>5.0 [11.0]</td>
<td>4.3 [6.2]</td>
<td>8.8 (2.8, 14.7)</td>
</tr>
<tr>
<td></td>
<td>429 (7.6)</td>
<td>2218 (32.2)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td>144 (2.6)</td>
<td>300 (4.4)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.0 [1.6]</td>
<td>1.5 [1.0]</td>
<td>1.3 [0.7]</td>
<td>0.6 (0.4, 0.8)</td>
</tr>
<tr>
<td></td>
<td>11 (0.2)</td>
<td>9 (0.1)</td>
<td>0.0007 (-0.0008, 0.002)</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>26 (0.5)</td>
<td>16 (0.2)</td>
<td>0.002 (0.0002, 0.004)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

* Data reported as Number (%) unless otherwise indicated
* Hospital services = total number of emergency room visits + days in hospital
* Based on a chi-square test
* OBN (Ontario Bariatric Network)
* CI (Confidence Interval)

Table 4 summarizes all components of the health services use incurred in the year following surgery for each cohort, including 30-day and 1-year mortality. The proportion of patients who
required at least one day of hospital services before the OBN was 54.0% compared to 50.1% after the OBN (P=0.001). The proportion of patients requiring at least one postoperative hospitalization before and after the OBN was 26.8% and 28.4%, respectively (P=0.01). The mean length of stay in the before group was 9.3 days, while the after group had a mean stay of 6.8 days (mean difference 2.5, 95% CI 1.2-3.8). In both groups, just over 2% of patients needed a stay in the ICU and about 1% required ventilator support. However, the mean number of days in the ICU among persons requiring an ICU stay was 11.1 and 4.4 in the before and after group, respectively (mean difference 6.7, 95% CI 3.1-10.3). With respect to physician visits, only 7.6% of patients before the OBN visited a physician within one year following surgery compared to 32.2% after the OBN (P<.001). Although, more patients had abdominal reoperations in the after group (4.4% vs. 2.6%, P<.001), the mean number of operations was higher in the before group (2.0 vs. 1.3). The 30-day mortality was also higher in the before group (0.2% vs. 0.1%, P=0.36), while the 1-year mortality was 0.5% and 0.2% in the before and after group, respectively (P=0.03).

3.4 Unadjusted Analyses

Table 5: The impact of program implementation on one-year health services utilization

<table>
<thead>
<tr>
<th>Outcome</th>
<th>RR(^a) (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital services</td>
<td>0.78 (0.72, 0.84)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Emergency room visits</td>
<td>0.88 (0.83, 0.93)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Days in hospital</td>
<td>0.76 (0.66, 0.87)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>1.07 (0.99, 1.15)</td>
<td>0.07</td>
</tr>
<tr>
<td>Intensive care stay</td>
<td>0.44 (0.29, 0.67)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Ventilatory support</td>
<td>0.31 (0.17, 0.58)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Physician visits</td>
<td>3.49 (3.19, 3.83)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Reoperations</td>
<td>1.16 (0.93, 1.45)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

\(^a\)Estimated using an unadjusted negative binomial regression model
OBN (Ontario Bariatric Network)
RR (Rate Ratio)
CI (Confidence Interval)

Table 5 summarizes the unadjusted analyses on the effect of program implementation on each component of one-year health services utilization. The rate of hospital services (RR 0.78, 95% CI 0.72-0.84), ICU days (RR 0.44, 95% CI 0.29-0.67), and days on ventilation (RR 0.31, 95% CI 0.17-0.58) were significantly less after the OBN. There was no significant difference with respect to hospitalization (1.07, 95% CI 0.99-1.15) or reoperation rates (RR 1.16, 95% CI 0.93-
However, physician visits was about 3.5 times higher after the establishment of the OBN (95% CI 3.19-3.83, P <.001).

### 3.5 Adjusted Analyses

#### 3.5.1 Hospital Services

**Table 6: The impact of program implementation on days requiring hospital services during the year following bariatric surgery**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>0.83 (0.78, 0.89)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age</td>
<td>1.00 (0.99, 1.00)</td>
<td>0.55</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>1.05 (0.96, 1.14)</td>
<td>0.34</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>0.60 (0.52, 0.69)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>1.24 (1.13, 1.36)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1b (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.92 (0.83, 1.01)</td>
<td>0.09</td>
</tr>
<tr>
<td>3</td>
<td>0.89 (0.80, 0.98)</td>
<td>0.02</td>
</tr>
<tr>
<td>4</td>
<td>0.92 (0.83, 1.01)</td>
<td>0.09</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.78 (0.69, 0.87)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ACG comorbidity score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2c (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>1.48 (1.15, 1.92)</td>
<td>0.003</td>
</tr>
<tr>
<td>4</td>
<td>2.45 (1.89, 3.17)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>4.44 (3.38, 5.83)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*a Estimated using an adjusted negative binomial regression model

*b Income quintile reference category

*c ACG comorbidity reference category

*HS (Hospital Services) = number of emergency room visits + number of days in hospital

*ACG (Adjusted Clinical Groups)

*RR (Rate Ratio)

*CI (Confidence Interval)

Table 6 presents the adjusted effect of program implementation on the number of days requiring hospital services using a standard negative binomial regression model. The RR after program implementation was 0.83 (95% CI 0.78-0.89, P <.001). In other words, after program implementation, there was approximately a 17% reduction in the rate of hospital services use. Other significant variables in the model that predicted less hospital services included receipt of a RYGB and a higher income quintile. On the other hand, a rural residence and higher ACG comorbidity score were associated with more days requiring hospital services. Figure 5 illustrates the mean number of days requiring hospital services for each 3-month interval in the study period.
Figure 5: Trend in mean number of days requiring postoperative hospital services within one year from 2007 to 2012

![Trend in Hospital Services Use Following Bariatric Surgery: 2007-2012](image)

3.5.2 Emergency Room Visits

Table 7: The impact of program implementation on emergency room visits during the year following bariatric surgery

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR &lt;sup&gt;a&lt;/sup&gt; (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>0.92 (0.87, 0.97)</td>
<td>0.004</td>
</tr>
<tr>
<td>Age</td>
<td>0.98 (0.97, 0.98)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>1.00 (0.93, 1.07)</td>
<td>0.96</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>1.00 (0.89, 1.13)</td>
<td>0.98</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>1.46 (1.36, 1.57)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1&lt;sup&gt;b&lt;/sup&gt; (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.92 (0.85, 0.99)</td>
<td>0.04</td>
</tr>
<tr>
<td>3</td>
<td>0.88 (0.82, 0.96)</td>
<td>0.003</td>
</tr>
<tr>
<td>4</td>
<td>0.86 (0.79, 0.93)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.81 (0.74, 0.89)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Table 7 presents the adjusted effect of program implementation on the number of emergency room visits using a standard negative binomial regression model. The RR after program implementation was 0.92 (95% CI 0.87-0.97, P=0.004). Other significant variables in the model that predicted less emergency room visits included age and a higher income quintile. However, a rural residence and higher ACG comorbidity score were associated with more visits.

### 3.5.3 Days in Hospital

**Table 8: The impact of program implementation on days in hospital during the year following bariatric surgery**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR(^a) (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>0.80 (0.70, 0.92)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age</td>
<td>1.02 (1.01, 1.02)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>1.08 (0.91, 1.29)</td>
<td>0.36</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>0.44 (0.33, 0.59)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>1.06 (0.89, 1.27)</td>
<td>0.53</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1(^b) (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.90 (0.74, 1.09)</td>
<td>0.27</td>
</tr>
<tr>
<td>3</td>
<td>0.90 (0.79, 1.02)</td>
<td>0.11</td>
</tr>
<tr>
<td>4</td>
<td>1.02 (0.89, 1.16)</td>
<td>0.80</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.88 (0.76, 1.02)</td>
<td>0.09</td>
</tr>
<tr>
<td>ACG comorbidity score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(\leq2)^c (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>1.33 (0.81, 2.20)</td>
<td>0.26</td>
</tr>
<tr>
<td>4</td>
<td>2.41 (1.45, 3.99)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>4.81 (2.82, 8.19)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

\(^a\) Estimated using an adjusted negative binomial regression model  
\(^b\) Income quintile reference category  
\(^c\) ACG comorbidity reference category  
ACG (Adjusted Clinical Groups)  
RR (Rate Ratio)  
CI (Confidence Interval)
Table 8 presents the adjusted effect of program implementation on the number of inpatient days using a standard negative binomial regression model. The RR after program implementation was 0.80 (95% CI 0.70-0.92, P<.001). Patients who underwent a gastric bypass also had significantly less inpatient days. Older patients and those with higher ACG comorbidity scores had significantly more days in hospital.

3.5.4 Hospitalizations

Table 9: The impact of program implementation on hospitalizations during the year following bariatric surgery

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>1.05 (0.98, 1.13)</td>
<td>0.16</td>
</tr>
<tr>
<td>Age</td>
<td>1.00 (1.00, 1.01)</td>
<td>0.007</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>1.01 (0.92, 1.11)</td>
<td>0.88</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>0.96 (0.83, 1.13)</td>
<td>0.65</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>0.94 (0.85, 1.04)</td>
<td>0.25</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.92 (0.83, 1.03)</td>
<td>0.13</td>
</tr>
<tr>
<td>3</td>
<td>0.98 (0.88, 1.09)</td>
<td>0.67</td>
</tr>
<tr>
<td>4</td>
<td>0.95 (0.85, 1.06)</td>
<td>0.36</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.90 (0.80, 1.02)</td>
<td>0.11</td>
</tr>
<tr>
<td>ACG comorbidity score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2 (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>1.67 (1.19, 2.33)</td>
<td>0.003</td>
</tr>
<tr>
<td>4</td>
<td>2.50 (1.79, 3.50)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>3.21 (2.27, 4.53)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*a* Estimated using an adjusted negative binomial regression model  
*b* Income quintile reference category  
*c* ACG comorbidity reference category  
ACG (Adjusted Clinical Groups)  
RR (Rate Ratio)  
CI (Confidence Interval)

Table 9 presents the adjusted effect of program implementation on the number of hospitalization episodes using a standard negative binomial regression model. The RR after program implementation was 1.05 (95% CI 0.98-1.13, P=0.16). The single significant predictor of hospitalization was higher ACG comorbidity scores.

3.5.5 Days in Intensive Care Unit

Table 10: The impact of program implementation on days in ICU during the year following bariatric surgery
Table 10 presents the adjusted effect of program implementation on the number of days in the ICU using a standard negative binomial regression model. The RR after program implementation was 0.53 (95% CI 0.35-0.81, P=0.003). In addition, older patients and males spent significantly more days in the ICU following surgery.

### 3.5.6 Ventilated Days

Table 11: The impact of program implementation on ventilated days during the year following bariatric surgery

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR(^a) (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>0.37 (0.19, 0.71)</td>
<td>0.003</td>
</tr>
<tr>
<td>Age</td>
<td>1.06 (1.03, 1.09)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>2.66 (1.18, 5.99)</td>
<td>0.02</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>0.43 (0.12, 1.54)</td>
<td>0.19</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>1.57 (0.66, 3.78)</td>
<td>0.31</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1(^b) (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.82 (0.33, 2.03)</td>
<td>0.67</td>
</tr>
<tr>
<td>3</td>
<td>0.36 (0.14, 0.94)</td>
<td>0.04</td>
</tr>
<tr>
<td>4</td>
<td>0.94 (0.37, 2.38)</td>
<td>0.89</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.34 (0.12, 1.01)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

\(^a\) Estimated using an adjusted negative binomial regression model
\(^b\) Income quintile reference category
\(^c\) ACG comorbidity reference category

ICU (Intensive care unit)
ACG (Adjusted Clinical Groups)
RR (Rate Ratio)
CI (Confidence Interval)
Table 11 presents the adjusted effect of program implementation on the number of days on ventilation using a standard negative binomial regression model. The RR after program implementation was 0.37 (95% CI 0.19-0.71, P=0.003). Similar to the predictors of ICU stay, older patients and males required more time on postoperative ventilation.

### 3.5.7 Physician Visits

**Table 12: The impact of program implementation on physician visits during the year following bariatric surgery**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR$^a$ (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>3.50 (3.19, 3.84)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Age</td>
<td>1.00 (0.99, 1.00)</td>
<td>0.30</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>1.04 (0.94, 1.15)</td>
<td>0.45</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>0.96 (0.83, 1.13)</td>
<td>0.65</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>0.87 (0.77, 0.97)</td>
<td>0.01</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1$^b$ (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>1.06 (0.95, 1.19)</td>
<td>0.30</td>
</tr>
<tr>
<td>3</td>
<td>1.07 (0.95, 1.20)</td>
<td>0.26</td>
</tr>
<tr>
<td>4</td>
<td>1.12 (0.99, 1.26)</td>
<td>0.07</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>1.00 (0.87, 1.14)</td>
<td>0.95</td>
</tr>
<tr>
<td>ACG comorbidity score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\leq 2^c$ (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>1.26 (0.89, 1.78)</td>
<td>0.20</td>
</tr>
<tr>
<td>4</td>
<td>1.61 (1.14, 2.29)</td>
<td>0.007</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>1.89 (1.32, 2.71)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

$^a$ Estimated using an adjusted negative binomial regression model

$^b$ Income quintile reference category

$^c$ ACG comorbidity reference category

ACG (Adjusted Clinical Groups)
RR (Rate Ratio)
CI (Confidence Interval)
Table 12 presents the adjusted effect of program implementation on the number of physician visits using a standard negative binomial regression model. The RR after program implementation was 3.50 (95% CI 3.19-3.84, P<.001). A rural residence was associated with significantly less physician visits, while a higher ACG comorbidity score was associated with more visits.

### 3.5.8 Reoperations

Table 13: The impact of program implementation on reoperations during the year following bariatric surgery

<table>
<thead>
<tr>
<th>Variables</th>
<th>Adjusted RR&lt;sup&gt;a&lt;/sup&gt; (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After program implementation</td>
<td>1.15 (0.92, 1.44)</td>
<td>0.22</td>
</tr>
<tr>
<td>Age</td>
<td>1.00 (0.99, 1.01)</td>
<td>0.53</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>0.97 (0.73, 1.29)</td>
<td>0.83</td>
</tr>
<tr>
<td>Procedure (gastric bypass vs. other)</td>
<td>0.77 (0.49, 1.22)</td>
<td>0.27</td>
</tr>
<tr>
<td>Rurality (rural vs. urban)</td>
<td>0.95 (0.70, 1.29)</td>
<td>0.74</td>
</tr>
<tr>
<td>Income quintile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1&lt;sup&gt;b&lt;/sup&gt; (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>0.90 (0.65, 1.24)</td>
<td>0.52</td>
</tr>
<tr>
<td>3</td>
<td>0.91 (0.65, 1.26)</td>
<td>0.57</td>
</tr>
<tr>
<td>4</td>
<td>0.78 (0.55, 1.10)</td>
<td>0.15</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>0.84 (0.58, 1.21)</td>
<td>0.35</td>
</tr>
<tr>
<td>ACG comorbidity score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2&lt;sup&gt;c&lt;/sup&gt; (lowest)</td>
<td>1.00</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>2.20 (0.76, 6.40)</td>
<td>0.15</td>
</tr>
<tr>
<td>4</td>
<td>2.55 (0.87, 7.47)</td>
<td>0.09</td>
</tr>
<tr>
<td>5 (highest)</td>
<td>3.89 (1.29, 11.71)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

<sup>a</sup> Estimated using an adjusted negative binomial regression model

<sup>b</sup> Income quintile reference category

<sup>c</sup> ACG comorbidity reference category

ACG (Adjusted Clinical Groups)

RR (Rate Ratio)

CI (Confidence Interval)

Table 13 presents the adjusted effect of program implementation on the number of abdominal reoperations using a standard negative binomial regression model. The RR after program implementation was 1.15 (95% CI 0.92-1.44, P=0.22). The single most significant variable associated with a higher rate of reoperations was a higher ACG comorbidity score.

### 3.5.9 Mortality

Table 14: The impact of program implementation on 30-day and 1-year postoperative mortality
Table 14 shows both the unadjusted and adjusted effect of program implementation on the OR for 30-day and 1-year mortality. The adjusted model was estimated using only age and sex as covariates to avoid over-specification. Both the unadjusted and adjusted ORs for 30-day mortality were not significant, yielding an estimate of 0.67 (95% CI 0.28-1.61) and 0.62 (95% CI 0.26-1.50), respectively. However, with respect to 1-year mortality, the unadjusted OR was 0.50 (95% CI 0.27-0.93, P=0.03). When adjusted, the 1-year mortality after program implementation was significantly less likely with an OR of 0.44 (95% CI 0.23-0.82, P=0.01).

Figure 6: Trends in one-year postoperative mortality before and after the OBN
Figure 6 illustrates the percentage of one-year postoperative mortality for each 3-month interval over the entire study period. This figure also shows that the one-year postoperative mortality rate was already declining before the implementation of the OBN. The mortality line-of-fit during the study period after the establishment of the OBN can also be appreciated.

3.6 Subgroup Analysis

Table 15: One-year health services utilization for in-province bariatric surgery recipients outside OBN hospitals after versus before 2010

<table>
<thead>
<tr>
<th>Outcome</th>
<th>RR$^a$ (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital services</td>
<td>1.07 (0.59, 1.93)</td>
<td>0.83</td>
</tr>
<tr>
<td>Emergency room visit</td>
<td>0.70 (0.45, 1.07)</td>
<td>0.10</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>0.89 (0.53, 1.48)</td>
<td>0.65</td>
</tr>
<tr>
<td>Inpatient stay</td>
<td>1.04 (0.55, 1.99)</td>
<td>0.90</td>
</tr>
<tr>
<td>Intensive care stay</td>
<td>0.13 (0.02, 1.14)</td>
<td>0.07</td>
</tr>
<tr>
<td>Ventilatory support</td>
<td>0.13 (0.01, 26.3)</td>
<td>0.45</td>
</tr>
<tr>
<td>Physician visit</td>
<td>4.74 (2.36, 9.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Reoperation</td>
<td>0.81 (0.13, 5.00)</td>
<td>0.82</td>
</tr>
</tbody>
</table>

$^a$Estimated using an adjusted negative binomial regression model
OBN (Ontario Bariatric Network)
RR (Rate Ratio)
CI (Confidence Interval)

Table 15 demonstrates the results of the subgroup analysis including only cases from in-province hospitals outside the OBN. One-year postoperative health services utilization was compared before and after 2010 to determine any significant temporal effect on health services use. The only significant change in this population was the higher number of physician visits (P<.001). All other outcomes showed no significant difference. With respect to the primary outcome, the RR of hospital services in 2010 to 2012 was 1.07 (95% CI 0.59-1.93, P=0.83). This estimate was higher compared to the primary analysis incorporating OBN centres.

3.7 Summary of Results

Table 16: Summary of unadjusted and adjusted estimates

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted RR (95% CI)</th>
<th>P value</th>
<th>Adjusted RR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital services</td>
<td>0.78 (0.72, 0.84)</td>
<td>&lt;.001</td>
<td>0.83 (0.78, 0.89)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ER visits</td>
<td>0.88 (0.83, 0.93)</td>
<td>&lt;.001</td>
<td>0.92 (0.87, 0.97)</td>
<td>0.004</td>
</tr>
<tr>
<td>Days in hospital</td>
<td>0.76 (0.66, 0.87)</td>
<td>&lt;.001</td>
<td>0.80 (0.70, 0.92)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>1.07 (0.99, 1.15)</td>
<td>0.07</td>
<td>1.05 (0.98, 1.13)</td>
<td>0.16</td>
</tr>
<tr>
<td>Outcome</td>
<td>Unadjusted OR (95% CI)</td>
<td>P value</td>
<td>Adjusted OR (95% CI)</td>
<td>P value</td>
</tr>
<tr>
<td>----------------------------</td>
<td>------------------------</td>
<td>---------</td>
<td>----------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Intensive care stay</td>
<td>0.44 (0.29, 0.67)</td>
<td>&lt;.001</td>
<td>0.53 (0.35, 0.81)</td>
<td>0.003</td>
</tr>
<tr>
<td>Ventilatory support</td>
<td>0.31 (0.17, 0.58)</td>
<td>&lt;.001</td>
<td>0.37 (0.19, 0.71)</td>
<td>0.003</td>
</tr>
<tr>
<td>Physician visits</td>
<td>3.49 (3.19, 3.83)</td>
<td>&lt;.001</td>
<td>3.50 (3.19, 3.84)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Reoperations</td>
<td>1.16 (0.93, 1.45)</td>
<td>0.20</td>
<td>1.15 (0.92, 1.44)</td>
<td>0.22</td>
</tr>
</tbody>
</table>

RR (Rate Ratio)
OR (Odds Ratio)

Table 16 provides a brief summary of the main research findings. Both the unadjusted and adjusted estimates are included along with the 95% CI.

**Figure 7: Forest plot of one-year postoperative health services utilization**

Figure 7 is a Forest plot illustrating the changes in postoperative health services utilization following one year from surgery after the implementation of the OBN.
4 Discussion

4.1 Summary of Study Cohort

This study described and evaluated postoperative health services utilization among Ontario bariatric surgical patients. Based on the study data sources, there were a total of 12,513 Ontario residents identified as recipients of first-time funded bariatric surgery between January 1, 2007 and July 31, 2012. Prior to the implementation of the OBN, 5,617 patients received bariatric surgery either in OOC (i.e. United States) or in-province centres. The majority of Ontario residents (78.1%) traveled to the United States to receive an OHIP funded operation. The three most common states to receive OOC surgery applications were Michigan (63.0%), New York (27.5%), and Minnesota (5.8%). In 2010, after the program was established, 6,896 Ontario patients received bariatric surgery. In contrast to the “before” group, the majority of patients (90.1%) had their operation at one of Ontario’s bariatric COE with only 6.8% patients needing to travel to the United States. The small number of patients who received OOC surgery after the program’s implementation likely represented those patients who applied earlier and were awaiting receipt of OOC surgery. This study has also verified that a very limited number of bariatric operations (3.1%) were being performed in Ontario institutions outside OBN centres from 2007 to 2012.

The Ontario bariatric surgical population before and after the implementation of the OBN shared quite similar baseline patient characteristics. There were no major clinically relevant differences between the two cohorts with respect to demographic information, procedure type and comorbidity status. Although the P value was statistically significant after comparing patient age and rurality, the corresponding mean and risk differences were minimal. The demographic composition of the Ontario study cohort also appeared similar to that of American bariatric patients. Results from the United States nationwide inpatient sample showed that bariatric surgery was less likely performed on rural residents, males, older persons and those with higher comorbidity status. In this study, the proportion of RYGB operations were found to be significantly lower after the OBN was implemented, which can be attributed to the increasing popularity of the laparoscopic sleeve gastrectomy (SG) as a primary bariatric procedure in recent years. Furthermore, although the difference in ACG comorbidity score was statistically significant between groups, the differences were small in magnitude.
4.2 Postoperative Health Services Utilization

4.2.1 Hospital Services Use

After both an unadjusted and adjusted analysis, the establishment of the OBN was significantly associated with fewer days requiring postoperative hospital services. The proportion of patients who required at least one day of hospital services before the OBN was 54.0% compared to 50.1% after the OBN. Other significant variables in the model that predicted less hospital services included receipt of a RYGB and a higher income quintile. In contrast, a rural residence and higher ACG comorbidity score were associated with more days requiring hospital services.

There was no significant difference found with respect to the one-year postoperative hospitalization rate between groups. The single significant predictor of hospitalization was found to be a high ACG comorbidity score. The overall 1-year readmission rate in this study was approximately 27%, which is similar to previous literature that reported a RYGB readmission rate of 24.2%. It is important to note that this rate did not distinguish between emergent and elective hospital admissions. Although weight loss after bariatric surgery may allow a patient to receive an elective procedure that was previously high risk, it is reasonable to assume that the majority of hospitalizations were required for urgent medical care.

4.2.1.1 Intensive Care Use

There was a significant decrease in the unadjusted and adjusted rates of ICU and ventilated days following the introduction of the OBN. This may be attributed to managing postoperative complications earlier and preventing clinical deterioration with improved follow-up after the OBN. Of note, older patients and male sex were found to be significant predictors of more days in the ICU following surgery. Similarly, older patients and males were significantly associated with more days on ventilator support.

4.2.2 Physician Visits

The number of physician visits was almost 3.5 times higher after the OBN was introduced. A rural residence was associated with significantly less physician visits, while a higher ACG comorbidity score was associated with more visits. The substantial increase in postoperative physician visits was likely driven by improved access to specialist care within the OBN program. Unlike hospital services, the utilization of outpatient health services may provide a positive
impact on a patient’s postoperative course by preventing or treating complications earlier should they arise. Other research has demonstrated that formal support group and multidisciplinary visits following bariatric surgery not only improves adherence to future clinic visits but may also positively influence long-term clinical outcomes.\textsuperscript{65}

4.2.3 Reoperations

There was no significant difference found with respect to unadjusted and adjusted reoperation rates. The single most significant variable associated with a higher rate of reoperations was a higher ACG comorbidity score. The 1-year reoperation rate in this study was between 2.6 and 4.4%, which is comparable to a 3.7% laparoscopic RYGB reoperation rate for bowel complications reported at a high-volume bariatric surgery center.\textsuperscript{64}

4.2.4 Mortality

With respect to 30-day mortality, the unadjusted and adjusted rates were not significant. However, the 1-year mortality was significantly less after program implementation, with an adjusted OR of 0.44. Postoperative mortality was rare in both groups. The percentage of 30-day mortality before and after the OBN was 0.2% and 0.1%, respectively. The percentage of 1-year mortality was also low at 0.5% before and 0.2% after program implementation. In another study of patients who underwent bariatric surgery, the 1-year crude mortality rate was found to be 1.5%.\textsuperscript{66}

With postoperative mortality decreasing significantly over the years, risk after bariatric surgery is comparable with other frequently recommended and well-accepted procedures such as cholecystectomy and hysterectomy.\textsuperscript{67} In fact, the postoperative mortality risk of bariatric surgery is far lower than that of coronary artery bypass surgery but with significantly greater improvement in long-term mortality.\textsuperscript{67} Much of the improvement in perioperative mortality can be attributed to advances in bariatric surgery such as the introduction of laparoscopic surgery, as well as establishment of a nationwide center of excellence network and required outcome reporting.\textsuperscript{67} Other research has demonstrated that risk factors for 30-day mortality after RYGB can include variables such as increasing BMI, increasing age, male sex, pulmonary hypertension, congestive heart failure, and liver disease.\textsuperscript{68}
4.3 Designated Bariatric Programs

There has been a paucity of literature evaluating the impact of bariatric COEs on postoperative health services utilization. Most previous studies have compared clinical outcomes from bariatric COEs with non-COEs. The results from some of these studies have failed to demonstrate significantly better clinical outcomes after their implementation.\(^69,70\) For example, Livingston et al found no significant differences in outcomes using administrative data from a nationally representative sample of hospitals.\(^70\) The study authors concluded that neither designation as a bariatric surgery COE nor high annual procedure volume ensured better clinical outcomes. Furthermore, the authors stated that the extra expenses associated with COE designation may not be warranted.\(^70\)

Another population-based study by Birkmeyer et al found no difference in the risk-adjusted rates of serious complications between COEs and non-COEs using a high-quality clinical registry database.\(^69\) Although the overall proportion of 30-day serious complications among patients undergoing bariatric surgery in Michigan was relatively low, the study demonstrated that the serious complication rate was inversely associated with hospital and surgeon procedure volume, but unrelated to COE accreditation.\(^69\)

On the other hand, several other studies support the concept of surgical volume in the COE credentialing process. A population-based study based on 14,716 gastric bypass recipients from Pennsylvania hospital between 1999-2003 demonstrated that high volume surgeons and hospitals are associated with decreased 30-day mortality and postoperative LOS.\(^71\) Recently, a perioperative safety evaluation of 32,509 operations based on bariatric procedure-specific data from the 2005-2007 Nationwide Inpatient Sample database found that a definite volume-outcome relationship exists in bariatric surgery.\(^72\) However, the study was unable to detect an inflection point that could justify the specific volume threshold criteria used to determine a COE.\(^72\) In addition, a comprehensive systematic review on volume-outcome association in bariatric surgery was conducted and found that given the strong evidence of improved patient outcomes among high-volume surgeons and centers, COE accreditation is warranted.\(^73\)

In 2004, Nguyen et al conducted a landmark study evaluating the effect of bariatric hospital volume on morbidity, mortality and costs. The study found that bariatric surgery performed at hospitals with more than 100 cases annually was significantly associated with shorter LOS (3.8 vs. 5.1 days), lower overall complications (10.2% vs. 14.5%), mortality (0.3% vs. 1.2%), and
decreased costs ($10,292 vs. $13,908). This volume-outcome relationship was more evident for a subgroup of bariatric patients older than 55 years. In this select population, the in-hospital mortality was 3-fold higher at low-volume compared with high-volume hospitals. The authors suggested that the lower rate of overall postoperative complications in high-volume hospitals may be related in part to formalization of the structures and processes of care.

A subsequent study by Nguyen et al evaluated clinical outcomes 18 months before and after the Centre for Medicare and Medicaid Services (CMS) national coverage determination (NCD) to restrict bariatric surgery to COEs. They concluded that the CMS policy to limit coverage to high-volume centers (i.e. hospitals with >125 procedures per year and a multidisciplinary team) with a low mortality rate and certification by the American College of Surgeons (ACS) or the ASMBS improved outcomes without limiting access to care. In this study, participants included patients who received either RYGB, AGB or biliopancreatic diversion with duodenal switch from October 2004 to September 2007. The University HealthSystem Consortium (UHC) was used to provide administrative and clinical data on individuals with Medicare coverage (i.e. people 65 years or older or younger with a disability and receiving Social Security benefits for at least 24 months from the date of entitlement). A total of 3196 and 3068 patients underwent bariatric surgery before and after the NCD, respectively. The proportion of RYGB recipients in this study cohort was approximately 82%. Patients who underwent bariatric surgery after the NCD had significantly shorter LOS (3.5 vs. 3.1 days) and a lower overall complication rate (12.2% vs. 10.0%). However, there was no significant difference with respect to the in-hospital mortality rates (0.28% vs. 0.20%). Limitations of this study included the lack of clinically relevant information such as BMI that could be incorporated in the risk adjustment of outcomes as well as uncertain validity of coding to identify certain postoperative complications. Since this study was limited to individuals only treated at academic centers and receiving Medicare coverage, the results may not be generalizable to a substantial proportion of the bariatric population.

An updated analysis using the UHC database on 35,284 bariatric operations between 2007 and 2009 was also performed. In this more recent study period, the rate of in-hospital mortality was significantly lower in accredited centres compared with non-accredited centres (0.06% vs. 0.21%). Again, bariatric surgery performed at accredited centers was significantly associated with shorter LOS (mean difference 0.3 days, 95% CI 0.16 to 0.44) and lower cost (mean
difference $3,758, 95% CI, $2,965 to $3,952). The study also suggested a possible association between centre accreditation and decreased in-hospital mortality in those patients who underwent a gastric bypass and had a higher severity of illness. Furthermore, select patients requiring prolonged ICU or hospital stay greater than 7 days had a significantly lower in-hospital mortality within accredited centers. The authors suggested that the lower mortality rate associated with accredited centers may be attributed to their ability to recognize and rescue complications.

In contrast, a large, national study conducted by Dimick et al demonstrated that among Medicare patients undergoing bariatric surgery, there was no significant difference in the rates of complications and reoperation before versus after the CMS policy to restrict coverage to COEs. Unlike previous similar studies, secular trends were accounted for by using a control group of non-Medicare patients and a difference-in-difference analytic approach to evaluate the association between the NCD and clinical outcomes. As a result, the effect of the CMS policy decision was isolated from unrelated factors that could have improved bariatric surgery during the same period (e.g. increased advanced training, use of laparoscopic surgery, and improved surgical technology). Furthermore, improved perioperative outcomes of bariatric surgery may have been attributed to the increased use of laparoscopic AGB procedures, which is a safer but less effective operation. In Ontario, there is no public coverage for AGB and therefore recipients of these procedures were not included among the Ontario bariatric surgery cohort.

In the Dimick study period from 2004 to 2009, bariatric surgery outcomes were already showing improvement in both Medicare and non-Medicare patients before the NCD. As part of the study’s risk adjustment process, the analysis accounted for 29 Elixhauser comorbid diseases as individual covariates, procedure types (open gastric bypass, laparoscopic gastric bypass, laparoscopic gastric banding, and other), along with pre-existing time trends toward improved outcomes. The results revealed no statistically significant improvements in outcomes after versus before implementation of the CMS national coverage decision for any complication (8.0% after vs. 7.0% before; relative risk [RR] 1.14, 95% CI 0.95-1.33), serious complications (3.3% vs. 3.6%, respectively; RR 0.92, 95% CI 0.62-1.22), and reoperation (1.0% vs. 1.1%; RR 0.90, 95% CI 0.64-1.17). In a direct assessment comparing outcomes at hospitals designated as COEs (n = 179) with hospitals without the COE designation (n = 519), the study found no significant differences for any complication (5.5% vs. 6.0%, respectively; RR 0.98, 95% CI 0.90-1.06), serious complications (2.2% vs. 2.5%; RR 0.92, 95% CI 0.84-1.00), and reoperation (0.83% vs.
0.96%; RR 1.00, 95% CI 0.86-1.17). The authors concluded that given the lack of association between COE designation and better bariatric surgery outcomes, restrictive CMS policies may have unintended consequences of reducing access to bariatric surgery.

Dimick et al have further suggested that risk-adjusted morbidity can be a much better predictor of safe and successful bariatric surgery than hospital volume and should be considered in COE accreditation. In a 2009 study, they identified 32,381 gastric bypass recipients from 105 hospitals in the New York Inpatient database and showed that hospital risk-adjusted outcomes were better than hospital volume at predicting future hospital morbidity with bariatric surgery. Their results supported the idea that rather than focusing on volume, accreditation of COE programs should focus more directly on measuring outcomes.

### 4.4 Experience with Out-of-Country Health Services for Other Conditions

There have been other studies reporting the impact of outsourcing medical services in the Canadian health care system. Outsourcing for substance abuse treatment at facilities located in the United States has been described by Rush et al. Their report provided a comprehensive analysis of the Ontario experience and compared trends in utilization of American programs with Ontario’s own treatment system. The dramatic increase in utilization of American programs by Ontario residents over the 1980s led to substantial reimbursement costs through OHIP and ultimately influenced a policy decision to restrict OOC treatment for substance abuse. In 2001, the Canadian Radiation Oncology Services (CROS) was awarded a private contract to begin managing radiation treatment in Ontario after long wait times generated a high number of cross-border referrals. Before the implementation of CROS, the MOH was paying about $375,000 per week to refer 20 patients every week to the United States for radiation services. After the implementation of this new program, breast cancer referrals stopped, and within three months, OOC referrals ceased completely. From January 2001 to June 2003, CROS had reported savings of $30 million when compared to prior OOC referrals. These above examples demonstrate that outsourcing health services can lead to considerable financial strain on the government. Ontario’s past experiences may serve as a caution for other provinces when it comes to policy decisions surrounding access to high-demand medical services such as bariatric surgery.
4.5 Study Limitations

This was an observational study based on administrative data and as a result, there are some important limitations to consider. Although the large sample size in this study provided a sufficient power to perform several multivariable analyses, the conclusions are limited to observed associations and cannot ascertain causation.

In this study, all in-province surgery recipients were selected using OHIP procedural fee codes. There have been no previous validation studies on this method for patient selection in administrative data. However, the OHIP fee codes in the schedule of benefits are very explicit for the indication of bariatric surgery. Therefore, the decision to use the OHIP bariatric fee codes was considered appropriate for this study. The reliability of surgical coding has been found to be good in a previous ICES validation study. The concordance between OHIP claims and discharge summaries was around 94% for procedures such as hysterectomies and cholecystectomies. 

Given the before-and-after design of this study, the potential for a secular trend bias was a key limitation. Although the study period is relatively short, spanning over six years, there is a possibility that some of the effect demonstrated by the OBN may be related to temporal factors. A subgroup analysis of in-province centres outside of OBN was performed to evaluate the change of health services use before and after 2010. There was no difference found in most components of health services utilization, including the primary outcome. However, without the inclusion of a control group outside of the Ontario population, it will be difficult to isolate the effect of the OBN from other factors that may have improved health services use over time. Examples of unrelated factors that may have benefited health services utilization include the wider application of laparoscopic surgery, the learning curve of Ontario bariatric surgeons and increased hospital experience with bariatric surgery. In addition, better outcomes may have been associated with a higher percentage of lower risk bariatric procedures, such as the laparoscopic SG and healthier patients undergoing surgery. Patients who received a SG have a lower risk of leaks and are less likely to develop problems such as postoperative internal herniation or nutritional deficiencies. Given that the primary purpose of this study was to evaluate the quality of follow-up care, risk adjustment for comorbidity status and procedure type was appropriately performed in the analysis.
Another limitation to this study was the unavailability of information on discharge dates for OOC recipients. As a result, it was not possible to demonstrate that the postoperative hospital LOS before and after the OBN was comparable. However, there was no reason to believe that surgical stays in the United States and Canada would be substantially different during the study period. The 2012-2013 mean LOS for inpatient bariatric surgery in Ontario has been reported to be approximately three days based on a recent CIHI study.\(^7\) It should be noted that protracted OOC hospital stays would be rare following bariatric surgery. In addition, any shortened follow-up time due to increased time in the United States before returning to Ontario would ultimately favour less utilization by the control group in this study design.

The data used in this study also had limited clinical information with respect to certain relevant bariatric parameters such as BMI, excess weight loss (EWL) and quality of life. As a result, these variables were not considered in the study analysis. As well, there was incomplete data (~12%) on whether a laparoscopic or open approach was used for operations out of country. Better outcomes might have been attributable to the transitioning from open to laparoscopic procedures during the study period. Data from a CIHI study on bariatric surgery in Canada showed that 20% of bariatric operations were performed open in 2007, while only 5% were open in 2012.\(^7\) In fact, an increase in the national utilization of bariatric surgery in the United States was found to correlate with the dissemination of laparoscopic bariatric surgery.\(^8\) Finally, since participants in this study all resided in Ontario and utilized the Ontario health care system, it may be difficult to extrapolate these findings to other regions inside or outside Canada.

### 4.6 Study Significance

This is the largest study to evaluate the initiation and intensity of postoperative health services utilization following bariatric surgery after the implementation of a province-wide bariatric program. The findings from this study suggest that the development of a provincial clinical program may offer a better model of care for Ontario bariatric patients than outsourcing surgical services. Given the lesser extent of hospital services used by patients after the OBN was implemented may encourage other Canadian provinces currently without provincial bariatric programs to consider adopting a system similar to Ontario. Dedicated bariatric programs based on best practices and clinical standards of care can ensure that patients consistently receive the
safest and most effective care possible.\textsuperscript{81} In many ways, the multidisciplinary approach of bariatric programs may prove to be a model for other surgical specialties in the near future.

Bariatric procedures, specifically the laparoscopic RYGB, are complex operations that are sometimes performed on patients with many comorbidities and high surgical risk. This study demonstrates that less utilization of hospital services following surgery is dependent on the presence of a dedicated bariatric team functioning within a formal multidisciplinary program. A bariatric COE should include experienced bariatric surgeons, internists, nutritionists and mental health specialists.\textsuperscript{53} The clinical bariatric nurse specialist is also a vital team member in guiding the education and support for patients and hospital staff. A well-structured program should be based at an institution capable of providing clinical standards of care and evidence-based practices for the management of morbid obesity. It is also important to ensure that along with adequate medical and nursing expertise, that special equipment, supplies, facility resources, and patient support services are in place.\textsuperscript{82}

It is evident from the results of this study that the benefit of a bariatric program is also contingent on the appropriate infrastructure to employ clinical pathways and facilitate long-term follow-up for patients. One of the requirements for the COE program instituted by the ASMBS is to have a system in place to provide comprehensive follow-up care. A recent study showed that the complication rate after bariatric surgery can be up to 39.6\% during the first 180 days after discharge.\textsuperscript{83} However, some research shows that a substantial number of patients will not comply with regular follow-up care after RYGB surgery unless they are prompted to do so by their bariatric clinic.\textsuperscript{84} Inadequate adherence to follow-up care has been recognized as contributory to worse clinical outcomes such as the development of complications, reduced weight loss and nutritional deficiencies.\textsuperscript{83,84} Reports confirm that postoperative RYGB patients who attend all scheduled follow-up appointments experience greater long-term excess weight loss than those with missing visits.\textsuperscript{85} In addition, patients who fail to follow-up with their surgical centre may seek dietary treatment from their primary care physicians or community pharmacists who may not be aware of the various necessary multivitamin and nutritional supplements.\textsuperscript{86} Overall, most research has demonstrated a benefit to the long-term multidisciplinary follow-up care in the postoperative bariatric population.\textsuperscript{85}
The expansion of designated programs for bariatric surgery across North America has become a vehicle for quality improvement in the field. An evaluation of the effect of a bariatric clinical program on quality indicators, such as caseload, average LOS, mortality, readmission, and complication rates showed significant improvement over 6 years.\textsuperscript{87} During this period, a progressive decrease in LOS from 6.7 days in 2001 to 3.2 days in 2006 was observed. As well, a significant reduction in 30-day readmission rates from 15.7\% in 2001 to 8.1\% in 2006, and complication rates from 18.6\% in 2001 to 4.8\% in 2006 was observed. The benefit of dedicated bariatric programs has been considerable and this study further supports its application. Future policy decisions at the MOH should consider this study’s findings with respect to the future direction and funding of the OBN.

\section*{4.7 Future Directions}

There have been several important findings from this study with respect to differences in health services use before and after implementation of the OBN. Future research on this matter should include an economic evaluation that would consider the direct costs associated with Ontario’s policy decision. Specifically, a cost-benefit analysis would be beneficial in comparing the direct cost of OOC versus in-province surgery after implementation of the OBN over a one-year follow-up period. The cost evaluation could also consider differences with respect to long-term health services use following surgery.

Clinical information from the Ontario Obesity Bariatric Registry could also be linked through ICES to complement the study data and analysis. The impact of the OBN on clinical parameters such as surgical complications and EWL would be noteworthy as a measure for future quality control initiatives.
References


47. Data Quality Documentation, National Ambulatory Care Reporting System Ottawa, ON: Canadian Institute for Health Information;2012.


Appendix

Appendix 1: University Health Network Research Ethics Board Approval Letter

Date: November 8th, 2013
To: Dr. David Urbach
Rm 10E214, 10th Floor, Eaton, Toronto General Hospital, 200 Elizabeth St.
Toronto, Ontario, Canada, M5G 2C4

Re: 11-0854-AE
Health Services Utilization After Out-of-Country Bariatric Surgery

REB Review Type: Expedited
REB Initial Approval Date: November 14th, 2011
REB Annual Approval Date: November 14th, 2013
REB Expiry Date: November 14th, 2014

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing.

Furthermore, members of the Research Ethics Board who are named as investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

Best wishes on the successful completion of your project.

Sincerely,

Meenal Mistry, BSc
Research Ethics Coordinator

For Alan Barolet, MD PhD FRCPC
Co-Chair, University Health Network Research Ethics Board
Appendix 2: University of Toronto Administrative Approval of Research Protocol Letter

PROTOCOL REFERENCE # 29957

February 19, 2014

Dr. David Urbach  
DEPT OF SURGERY  
FACULTY OF MEDICINE

Dr. Ahmad Elnahas  
DEPT OF SURGERY  
FACULTY OF MEDICINE

Dear Dr. Urbach and Dr. Ahmad Elnahas,

Re: Administrative Approval of your research protocol entitled, "Comparison of health services utilization among out-of-country and in-province bariatric surgery recipients from Ontario"

We are writing to advise you that the Office of Research Ethics (ORE) has granted administrative approval to the above-named research protocol. The level of approval is based on the following role(s) of the University of Toronto (University), as you have identified with your submission and administered under the terms and conditions of the affiliation agreement between the University and the associated TAHSN hospital:

- Graduate Student research - hospital-based only
- Storage or analysis of De-identified Personal Information (data)

This approval does not substitute for ethics approval, which has been obtained from your hospital Research Ethics Board (REB). Please note that you do not need to submit Annual Renewals, Study Completion Reports or Amendments to the ORE unless the involvement of the University changes so that ethics review is required. Please contact the ORE to determine whether a particular change to the University's involvement requires ethics review.

Best wishes for the successful completion of your research.

Yours sincerely,

Daniel Gyewu  
REB Manager