

# The impact of a standardized program on short and long-term outcomes in bariatric surgery

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**Abstract** The purpose of this study was to determine whether there has been an improvement in short- and long-term clinical outcomes since 2010, when the Ontario Bariatric Network led a province-wide initiative to establish a standardized system of care for bariatric patients. The system includes nine bariatric centers, a centralized referral system, and a research registry. Standardization of procedures has progressed yearly, including guidelines for pre-operative assessment and perioperative care.

**Methods and procedures** Analysis of the OBN registry data was performed by fiscal year between April 2010 and March 2015. Three-month overall postoperative complication rates and 30 day postoperative mortality were calculated. The mean percentage of weight loss at 1, 2, and 3 years postoperative, and regression of obesity-related diseases were calculated. The analysis of continuous and nominal data was performed using ANOVA, Chi-square, and McNemar's testing. A multiple logistic regression

analysis was performed for factors affecting postoperative complication rate.

**Results** Eight thousand and forty-three patients were included in the bariatric registry between April 2010 and March 2015. Thirty-day mortality was rare (<0.075 %) and showed no significant difference between years. Three-month overall postoperative complication rates significantly decreased with standardization ( $p < 0.001$ ), as did intra-operative complication rates ( $p < -0.001$ ). Regression analysis demonstrated increasing standardization to be a predictor of 3 month complication rate OR of 0.59 (95 %CI 0.41–0.85,  $p = 0.00385$ ). The mean percentage of weight loss at 1, 2, and 3 years postoperative showed stability at 33.2 % (9.0 SD), 34.1 % (10.1 SD), and 32.7 % (10.1 SD), respectively. Sustained regression in obesity-related comorbidities was demonstrated at 1, 2, and 3 years postoperative.

**Conclusion** Evidence indicates the implementation of a standardized system of bariatric care has contributed to improvements in complication rates and supported prolonged weight loss and regression of obesity-related diseases in patients undergoing bariatric surgery in Ontario.

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The rate of obesity is increasing in developed countries, including Canada [1, 2]. Perhaps most alarming is this trend has yet to show signs of abating, presenting a major challenge in health policy [1]. The health implications of the obesity epidemic are vast, as the relationship between obesity and coronary artery disease, diabetes (DM), cancer, and mortality is well established [3–9]. Overwhelming data now demonstrates the unparalleled efficacy of bariatric

surgery in helping patients achieve sustainable weight loss, a reduction in obesity-related comorbidities, and improved survival [10–13]. The development of bariatric surgery programs has become of paramount importance in the interest of public health; however, many challenges have arisen in the establishment of quality care in this relatively new area of surgery. Evidence has supported the development of bariatric surgical centers of excellence [14–17], minimum bariatric case volumes [18, 19], in addition to targeted strategies in quality of care [20].

Ontario, the largest of the Canadian provinces, holds almost 40 % of the Canadian population [21]. In 2010, the Ontario Bariatric Network (OBN) began implementing a province-wide strategy to provide centralized bariatric surgery in a systematic and standardized manner. The OBN administers Bariatric Centers of Excellence (BCoE), which is distributed across the province and share a common organizational structure and process of referral, assessment, and treatment of bariatric patients. The process of standardization has occurred over time and has been dynamic to respond to quality improvement initiatives.

The purpose of this study is to determine whether there has been a measurable improvement in clinical outcomes including morbidity and mortality with the implementation of a standardized structure and process by the OBN in 2010. Our hypothesis is that advancements in process and structure in the delivery of bariatric surgery have resulted in a significant improvement in clinical outcomes and a reduction in postoperative complications for patients in Ontario.

## Materials and methods

This was a retrospective cohort study of the Ontario bariatric registry database between April 2010 and March 2015. The database is an observational, multi-center, and prospectively gathered resource, which tracks postsurgical outcomes of Ontario bariatric patients. The registry project has secured research ethics board approval at each site, and written informed consent was obtained from all patients prior to inclusion in the registry.

### Study population

Patients aged 18 years of age and older and who met criteria for bariatric surgery according to the National Institute of Health [22] were eligible for referral to the Ontario Bariatric Program and inclusion in the bariatric registry. Patients were excluded if they were unable to provide informed consent or suffer from current drug or alcohol dependency, a recent life threatening cancer (<2 years in remission), or untreated or inadequately treated psychiatric illness.

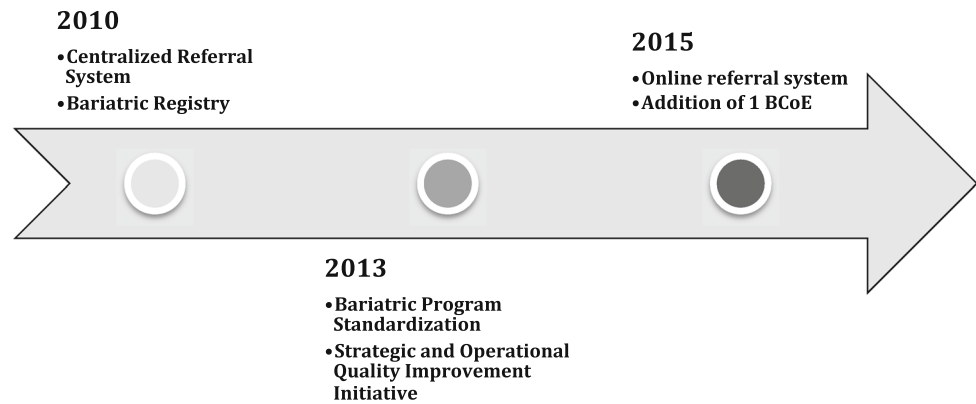
## Program standardization

In April of 2010, the OBN began to standardize the structure and process by which bariatric surgery was delivered in Ontario. These initiatives have occurred over time, and they are summarized in Fig. 1. Key initiatives included:

1. A centralized referral system that allocates patients based upon geographic location and wait times at their closest bariatric centers. This system is now online, which increases access and efficiency for referring physicians.
2. The creation of the bariatric registry research database for the purpose of research and quality care metrics.
3. The establishment of BCoE with multidisciplinary teams, experienced surgeons and minimum requirements, including ICU availability, postoperative oximetry beds, and a minimum 120 bariatric cases per site per year. The BCoEs are the only surgical centers authorized by the Ministry of Health to perform bariatric surgery for the purpose of weight loss in Ontario. Laparoscopic adjustable gastric banding is not covered by the ministry and is exclusively performed in private clinics.
4. Healthcare teams at the BCoE follow recommendations for preoperative, perioperative, and postoperative care, which are evidence-based. Patients currently have an intensive 5-year follow-up schedule, which includes regular meetings with a nurse practitioner and dietitian. Procedure selection is based upon program guidelines, which recommends laparoscopic Roux-en-Y gastric bypass for the majority of patients. Laparoscopic sleeve gastrectomies (LSG) may be recommended in cases where BMI >60, there is excessive intra-abdominal adhesions, or there is an anticipated staged duodenal switch procedure. DVT prophylaxis is recommended; however, the specific drug and treatment length are not yet standardized. Recommendations regarding perioperative antibiotics use have not yet been standardized.
5. The program has evolved with time and newer elements include a strategic and operational quality improvement initiative, which provides focused institutional and surgeons feedback regarding clinical outcomes and quality improvement.

## Study outcomes

Patient demographics, including age, gender, BMI, type of surgery, and comorbidities (hypertension (HTN), diabetes mellitus (DM), and hyperlipidemia), were collected for the study group. Primary outcomes included 3-month overall postoperative complication rate and 30-day postoperative

**Fig. 1** Timeline for OBN standardization initiatives

mortality. Secondary outcomes included the rates of specific complications within the 3-month postoperative period, including anastomotic leak, bowel obstruction, hemorrhage, wound infection, deep vein thrombosis/pulmonary embolism (DVT/PE), anastomotic stricture, and ulceration. Medical complications occurring within 3 months postoperative were also collected, including cardiac and pulmonary complications and nutritional deficiency. Data on intra-operative complications, defined by inadvertent severe organ injury or hemorrhage requiring transfusion, were also extracted. Specific data on surgeon case volumes and hospital case volumes were also gathered. Clinical outcomes for patients, including mean percentage weight loss at 1, 2, and 3 years postoperative, were collected, and regression of obesity-related comorbidities (HTN, DM, OSA, and hyperlipidemia) was also measured at 1, 2, and 3 years postoperative.

### Statistical analysis

Analysis was performed based upon the timeline of standardization initiatives, which occurred by fiscal year between April 2010 and March 2015. The first year of the OBN (2010/2011) served as the control group for the purpose of statistical analysis. The Chi-square test and the McNemar's test were used to compare unpaired and paired nominal data, and analysis of variance (ANOVA) was used for continuous variables. A multiple logistic regression was performed for factors affecting postoperative complications. Odds ratios with 95 % confidence intervals (CIs) were reported, and statistical significance was set at  $p < 0.05$ . Data were analyzed using RStudio (version 0.99.484, RStudio Inc).

### Results

Of the 12,777 patients undergoing OBN-administered bariatric surgery, a total of 8043 patients consented to participation in the bariatric registry between April 2010

and March 2015. The total number of surgeries per year grew from 1870 in 2010 to over 2800 by 2015. The baseline demographics of the patients have remained stable between fiscal years, with the majority of patients being female (82.5–89.9 %), with a mean age of 45.3–45.7 years, and a mean BMI of 49.0–49.7 kg/m<sup>2</sup> (Table 1). Comorbid diseases including HTN, DM, and hyperlipidemia affected greater than one-third of the study patients and were not significantly different between fiscal years.

The number of bariatric surgeries rapidly increased after the establishment of the OBN (Fig. 2). There was rapid increase in case volumes at multiple surgical sites, and the creation of new surgical centers to accommodate the geographically distributed demands of the study population. The surgical volumes have stabilized over the past 3 years, with the majority of hospitals averaging >200 cases per year.

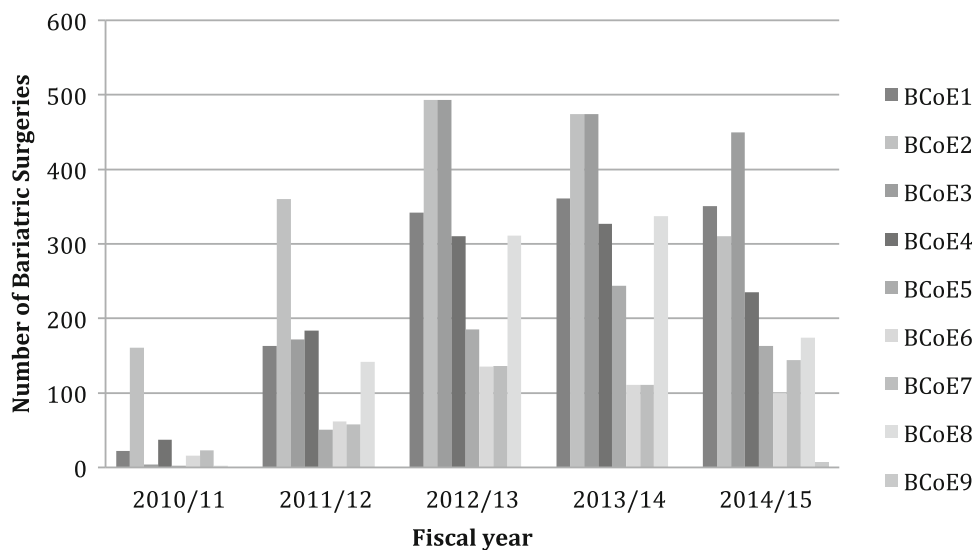
The surgical procedure performed remained relatively constant during the study period, with RYGB being the most commonly performed operation, accounting for 89.2 % of cases at the inception of the registry in 2010/2011 and 83.5 % of surgeries in 2014–2015 (Fig. 3). There has been a slight increase in LSG, which has risen from 9.7 to 14.3 % of bariatric procedures. As expected, the number of revisional surgeries has increased from just 1 case in 2010/2011 to 29 in 2014/2015, as the cohort of existing bariatric patients has grown with time. Duodenal switch procedures remain uncommon, with fewer than 10 performed in 2014/2015.

Thirty-day mortality was rare during the study period with only six reported mortalities among over 8000 surgeries performed (Table 2), and no significant difference between years was appreciated. Three-month postoperative complication rates significantly decreased with time from 20.2 % in 2010/2011 to 13.2 % in 2014/2015 (Table 2). The rate of specific complication rates at 3 months postoperative was low, and only postoperative stricture ( $p = 0.00202$ ) and rates of nutritional deficiency

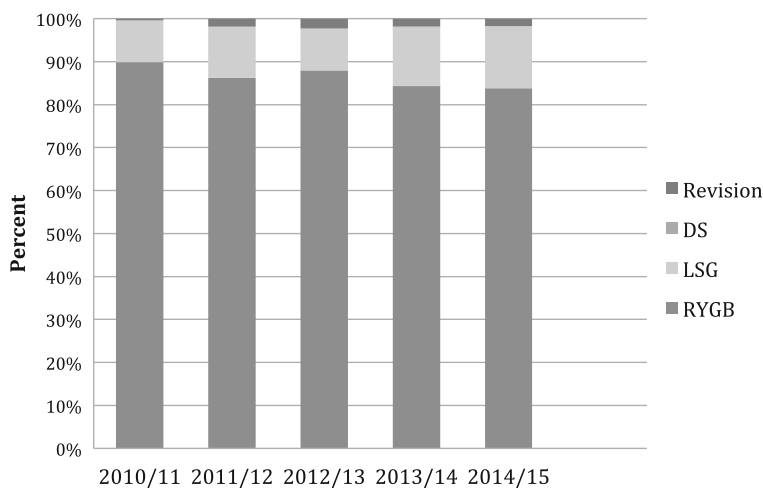
**Table 1** Baseline demographics of patients at first assessment undergoing bariatric surgery by fiscal year

	2010/2011 (N = 268)	2011/2012 (N = 1192)	2012/2013 (N = 2405)	2013/2014 (N = 2439)	2014/2015 (N = 1739)	p value
Mean age in years (±SD)	45.3 (±10.1)	45.3 (±10.1)	45.4 (±10.5)	45.7 (±10.6)	45.5 (±10.6)	0.472
Male (%)	29 (10.7)	204 (17.3)	386 (16.4)	420 (17.5)	323 (16.6)	0.0768
Mean BMI kg/m <sup>2</sup> (±SD)	49.0 (±7.1)	49.7 (±7.8)	49.4 (±7.7)	49.7 (±8.2)	49.1 (±7.9)	0.0963
Comorbidities						
HTN (%)	118 (43.7)	570 (48.5)	1090 (46.3)	1118 (46.6)	902 (46.3)	0.593
DM (%)	89 (33.0)	373 (31.3)	717 (30.4)	734 (30.6)	622 (31.9)	0.730
Hyperlipidemia (%)	87 (32.2)	403 (34.3)	777 (33.0)	776 (32.4)	605 (31.1)	0.509

**Fig. 2** Volume of bariatric surgeries by bariatric center of excellence (BCoE) pre fiscal year



**Fig. 3** Trends in bariatric surgery procedure type by fiscal year. *DS* Duodenal switch, *LSG* Laparoscopic sleeve gastrectomy, and *RYGB* Laparoscopic Roux-en-Y gastric bypass



**Table 2** Mortality and 3-month complication rate and intra-operative complication rate by year of surgery

	2010/2011 (N = 268)	2011/2012 (N = 1192)	2012/2013 (N = 2405)	2013/2014 (N = 2439)	2014/2015 (N = 1739)	p value
30 day mortality (%)	0 (0.0)	0 (0.0)	4 (0.2)	2 (0.1)	0 (0.0)	0.287
3 month overall complication rate (%)	51 (20.2)	258 (23.5)	394 (18.6)	359 (17.1)	184 (13.2)	<0.001*
Anastomotic leak	2 (0.8)	13 (1.2)	11 (0.5)	18 (0.9)	12 (0.9)	0.428
Bowel obstruction	1 (0.4)	10 (0.9)	20 (0.9)	12 (0.6)	7 (0.5)	0.585
Wound infection	1 (0.4)	24 (2.2)	58 (2.7)	44 (2.1)	19 (1.4)	0.0507
Hemorrhage	7 (2.8)	24 (2.2)	56 (2.6)	41 (2.0)	33 (2.4)	0.641
Ulceration	5 (2.0)	22 (2.0)	32 (1.5)	26 (1.2)	15 (1.1)	0.224
Stricture	3 (1.2)	28 (2.6)	34 (1.6)	24 (1.1)	12 (0.9)	0.00202*
DVT/PE	0	1 (0.1)	5 (0.2)	5 (0.2)	1 (0.1)	0.556
Nutritional	4 (1.4)	32 (2.7)	45 (1.8)	64 (2.6)	23 (1.3)	0.0123*
Pulmonary	1 (0.4)	5 (0.4)	9 (0.4)	6 (0.2)	7 (0.4)	0.916
Cardiac	0 (0)	1 (0.1)	1 (0.04)	1 (0.04)	2 (0.1)	0.868
Intra-operative complications (%)	11 (4.1)	37 (3.1)	48 (2.0)	46 (1.9)	11 (0.6)	<0.001*

\* Chi-square test ( $p < 0.05$ )

( $p = 0.0123$ ) were identified as significantly changed over time (Table 2). Although none of the other surgical complications were significantly different, a trend toward improvement was appreciated in the category of bowel obstruction, wound infection, ulceration, and DVT/PE. Finally, the rate of intra-operative complications significantly decreased from 4.1 % in 2010/2011 to 0.6 % in 2014/2015 ( $p < 0.001$ ).

A multiple logistic regression analysis of factors potentially affecting overall 3-month postoperative complication rate was performed (Table 3). Factors examined included the fiscal year of surgery reflecting the degree of standardization, surgeon case volume per year, hospital volume per year, surgical procedure type (RYGB vs. LSG), gender, age, BMI, and the presence of comorbid diseases including DM, HTN, hyperlipidemia, and OSA. The year of surgery (our proxy for degree of standardization) was a significant factor in 2014/2015, with an OR of 0.59 (95 % CI 0.41–0.85,  $p = 0.00385$ ). The other years were not identified as significant factors in our analysis; however, there was a trend toward reduction in OR of 3-month overall complication rate with time, with the exception of 2010/2011 which had a low OR of 0.56 (95 % CI 0.29–1.06,  $p = 0.0752$ ). Three other factors were found to significantly affect overall 3-month complications rates age, BMI, and hyperlipidemia. Although significant, the affect of age on complication rate was small with an OR of only 0.99 (95 % CI 0.99–1.00,  $p = 0.0356$ ). Similarly, BMI was identified as significant, but the affect size was small with an OR of 0.99 (95 % CI 0.98–1.00,

**Table 3** Multiple logistic regression of factors associated with 3-month complication

	Odds ratio (95 % CI)	p value
<i>Odds ratio for 3 month complication</i>		
2010/2011	0.56 (0.29–1.06)	0.0752
2011/2012	1.18 (0.84–1.68)	0.339
2012/2013	0.93 (0.65–1.33)	0.674
2013/2014	0.87 (0.61–1.26)	0.465
2014/2015	0.59 (0.41–0.85)	0.00385*
Age at surgery	0.99 (0.99–1.00)	0.0356*
Surgeon case volume/year	1.00 (0.99–1.01)	0.0877
Hospital case volume/year	1.00 (0.99–1.01)	0.716
Surgical procedure type	0.98 (0.79–1.20)	0.838
Female	0.98 (0.83–1.16)	0.795
Average BMI	0.99 (0.98–1.00)	0.0394*
DM	0.91 (0.78–1.07)	0.252
HTN	1.08 (0.94–1.24)	0.281
OSA	1.08 (0.96–1.23)	0.204
Hyperlipidemia	1.19 (1.03–1.23)	0.0217*

$p = 0.0394$ ). Finally, hyperlipidemia increased the risk of postoperative complication at 3 months with an OR of 1.19 (95 % CI 1.03–1.23,  $p = 0.0217$ ). The remaining factors, including surgeon case volume per year, hospital case volume per year, surgical procedure type, gender, DM, HTN, and OSA, were not identified as significant variables in our regression analysis.

The mean percentage of weight loss at 1, 2, and 3 years postoperative showed stability at 33.2 % (9.0 SD), 34.1 % (10.1 SD), and 32.7 % (10.1 SD), respectively. Similarly, sustained regression in obesity-related comorbidities including DM, HTN, hyperlipidemia, and GERD was demonstrated at 1, 2, and 3 years postoperative (Fig. 4). The rate of diabetes decreased sharply from 31.5 % at baseline assessment to 10.9 % at 3-year follow-up. Likewise, HTN rates showed a marked reduction from 47.2 % at 3 years postoperative, and hyperlipidemia showed sustained regression from 32.9 to 11.7 % at 3 years postoperative. Rates of OSA remained stable within the study population and did not show a significant decrease following bariatric surgery.

## Discussion

In this retrospective cohort study, we have examined the effect of establishing a centralized, systematic, and standardized network for bariatric surgery on clinical outcomes. Examination of registry data has illustrated a rapid expansion of bariatric surgery in Ontario, with the creation of nine BCoE and the abrupt increase of overall case volumes over a 5-year period of time. The procedure type remains predominantly RYGB, likely secondary to program guidelines for the selection of LSG. Bariatric revisional surgery remains uncommon with only 29 cases in 2014/2015. Although infrequent, these revisional bariatric cases are increasing in number as the bariatric program continues to expand.

This study found that despite the sudden growth of bariatric surgery in Ontario, there has not been a significant “learning curve”; in fact, 3-month overall postoperative

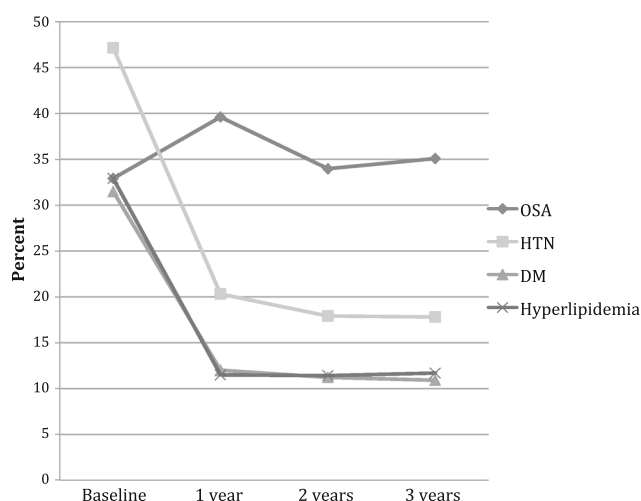
complication rates have decreased significantly during this period of expansion. The complication of stricture and nutritional deficiency showed a significant decrease with increasing standardization. There was also a trend toward reduction in postoperative surgical complications among the majority of subgroups that were measured (ulcer, bowel obstruction, DVT/PE), which likely contributed to achieving significance in the 3-month overall complication rate. This decrease in complication rate can be attributed to the standardized bariatric program initiatives, including preoperative patient education and close postoperative multidisciplinary follow-up. Additionally, program surgical recommendations such as surgical procedure selection guidelines (with RYGB as standard procedure), mandatory auditing of surgeon outcomes, standardized recommendations for the use of proton pump inhibitors [23], minimum bougie size, and DVT prophylaxis may all contribute toward the improvement in intra-operative and postoperative complication rates.

No significant change in mortality was appreciated during the study period, although the incidence of mortality was very low and the analysis was likely underpowered in this respect. The results of the multiple logistic regression analysis illustrated increasing standardization with time as a positive predictor of reduced complication rates. The year 2014/2015 was identified as the most significant variable in predicting a reduced 3-month overall complication rate; moreover, this factor was found to be more predictive than patient, surgeon, or hospital variables in affecting complication rate.

Finally, the registry data demonstrated sustained weight loss over 3 years postoperative and continued regression of obesity-related diseases in patients undergoing bariatric surgery in Ontario, consistent with those published by respected leaders in the field [12]. These findings support the hypothesis that the standardized system and process administered by the OBN have contributed to significant improvements in short- and long-term outcomes in bariatric surgery, despite the rapid expansion of a new surgical program.

Regression of OSA was not appreciated in the registry data, which is not consistent with the existing literature. Sarkhosh et al. [24] performed a systematic review showing >75 % of patients had resolution of OSA after bariatric surgery. The lack of improvement in OSA in Ontario patients may be secondary to a reporting bias and lack of postoperative sleep studies. Further investigation would be supported.

During the 5-year study period, the OBN has increased standardization in the structure and process of bariatric care delivery in Ontario. Key initiatives have included a centralized referral system, establishment of BCoE with minimum case volumes, evidence-based multidisciplinary



**Fig. 4** Regression of comorbid disease at 1, 2, and 3 years postoperative after bariatric surgery

perioperative care, intensive 5-year follow-up, a bariatric registry research database, and strategic and operational quality improvement initiative. Although there has been limited research examining the role of standardized approaches to bariatric surgery, the findings of this study are consistent with the existing literature supporting the establishment of BCoE and minimum case volumes [14–19]. In 2012, Zevin et al. performed a systematic review supporting the association between high-volume surgeons and high-volume centers in improving patient outcomes. Similarly, Hollenbeak demonstrated significantly lower mortality in Pennsylvania hospitals that were classified as high-volume hospitals (>100 cases/year) or with surgeons who performed >100 cases/year. Finally, accredited Centers of Excellence by the American Society of Metabolic and Bariatric Surgeons and American College of Surgeons were found to have significantly lower complication rates than nonaccredited hospitals by Morton et al.

Similar to other studies examining the effects of institutional changes, interpretation of study results is challenging as several interventions have occurred simultaneously and in a longitudinal fashion. The improvements in bariatric outcomes since the establishment of the OBN can be partially attributed to surgeon and institutional experience, although we have attempted to control for these factors by performing a multiple logistic regression analysis. In addition, although patient participation in the registry database has been good, selection bias cannot be excluded.

In conclusion, evidence indicates the implementation of a standardized preoperative assessment, patient selection, operative approach, perioperative and postoperative care has contributed toward improvements in short- and long-term clinical outcomes in bariatric surgery. Based upon the study findings, the authors recommend standardization of structure and process, strategic operational improvements, and quality care metrics to be encouraged in all bariatric programs.

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#### Compliance with ethical standards

**Disclosures** Dr. Lisa N. F Aird, Dr. Dennis Hong, Dr. Scott Gmora, Ruth Breau, Dr. Mehran Anvari do not have any conflicts of interest or financial ties to disclose.

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