Quality in Bariatric Surgery

40

Robin P. Blackstone, Thomas P. Petrick, and Anthony T. Petrick

Chapter Objectives

1. Review the challenges that led to development of accreditation and quality collaboratives in metabolic and bariatric surgery.
2. Review current initiatives and programs facilitating quality in bariatric surgery.
3. Identify future trends toward quality improvement in bariatric surgery.

Introduction

Quality is not an act, it is a habit. – Aristotle

The history of quality in American medicine is a history of surgical leadership. Ernest Codman, MD, first proposed the "end-result" system of hospital standardization in 1910 which led to the American College of Surgeons (ACS) developing the Minimum Standard for Hospitals incorporating on-site inspections between 1917 and 1918. This initiative was officially transferred from the ACS to the Joint Commission on Accreditation of Hospitals (JCAH) in 1952 [1].

While diseases related to obesity have been a focus of American healthcare, obesity has long been viewed by both physicians and the public as failing of personal choice with little recognition of its related diseases. Only in the last two decades has obesity come to be recognized as a disease and metabolic and bariatric surgery as an effective treatment. Obesity was classified as a disease by the American Association of Clinical Endocrinologists in 2012 [2] and by the American Medical Association in 2013 [3]. Initial surgical attempts to treat obesity were criticized as primarily cosmetic in high-risk patients with unacceptable complications. It was not until 2011 that medical societies such as the American Heart Association (AHA) [4] and the American Diabetes Association (ADA) [5, 6] endorsed bariatric surgery for the treatment of obesity-related disease. The history of both public and professional skepticism as to the goals and benefits of metabolic and bariatric surgery necessitated a commitment to the highest standards of quality just to ensure the survival of surgery as a treatment option for patients suffering from obesity.

A detailed history of the forces and people who founded quality programs in metabolic and bariatric surgery is provided in Part I of this textbook. Our purpose in this chapter is to provide a brief overview of the history as a means of providing context toward understanding accreditation and other current initiatives and programs facilitating quality in the surgical treatment of obesity.

The History of Quality in Bariatric Surgery

One of the most critical elements of quality seems self-evident, but it is to know your own outcomes. Most surgeons respond to their data in a forthright and predictable way. First, they doubt the data; then, they question whether it is adjusted for the level of risk of their patients; and finally, they accept it and commence efforts to improve. Creating a mechanism by which data can be translated into quality improvement initiatives benefiting patients has long been a challenge. The time required to design, implement, analyze, and publish high-quality studies precludes rapid application to patient care problems. In addition, once results of these trials are published, individual surgeons must access the findings and design processes to integrate them into their own practice setting. This is a daunting task for busy clinical practitioners

R. P. Blackstone
Metabolic and Bariatric Surgery, Banner University Medical Center – Phoenix, Phoenix, AZ, USA

T. P. Petrick
Department of Surgery, Chinle Comprehensive Health Care Facility, Chinle, AZ, USA

A. T. Petrick (✉)
Geisinger Medical Center, Danville, PA, USA
e-mail: atpetrick@geisinger.edu

© Springer Nature Switzerland AG 2020

N. T. Nguyen et al. (eds.), *The ASMBS Textbook of Bariatric Surgery*, https://doi.org/10.1007/978-3-030-27021-6_40

and often limited by facilities, costs, and human resources. These limitations have led the Institute of Medicine to define and revise the clinical trial infrastructure [7].

In the early years of bariatric surgery, community surgeons may not have seen a clear need to participate in data collection. However, a confluence of events forced bariatric surgery into the glare of public opinion, accelerating the need for a national approach to quality.

One pivotal event came in 1999 when Wesley Clark, MD, and Alan Wittgrove, MD, documented performance of a gastric bypass with laparoscopic access. This controversial change in approach to the procedure significantly accelerated the adoption of bariatric surgery by patients who were seeking help for obesity. The number of bariatric cases increased rapidly from 1999 to 2004 (Fig. 40.1) [8]. What had been heralded as a step forward quickly led to high-profile reports of complications and deaths that threatened to tarnish the emerging specialty and restrict or even eliminate access to care. Payers, employers, and others began to drop the procedure as the cost of surgery mounted. The number of cases nationally dropped for the next 3 years [8].

In response to the crisis, the leadership of the American Society for Bariatric Surgery (ASBS) developed a unique and controversial solution – an accreditation program. The impact was significant with approximately 1/3 of programs leaving the field as insurance carriers began to limit their networks to just the programs within a Bariatric Surgery Center of Excellence (BSCOE). There was a contraction in access to bariatric surgery, particularly in rural areas where the number of cases nationally dropped from 2004 to 2007 [8]. In 2006, a landmark national coverage decision by the Centers for Medicare and Medicaid Services (CMS) required accreditation by the ACS or ASMBS for centers performing bariatric procedures [9].

American Society for Metabolic and Bariatric Surgery Bariatric Surgery Center of Excellence (ASMBS BSCOE) Program

When the BSCOE program was developed in 2004, the ASMBS established ten standards by which facilities and surgeons would be evaluated to ensure quality of care in bariatric surgery.

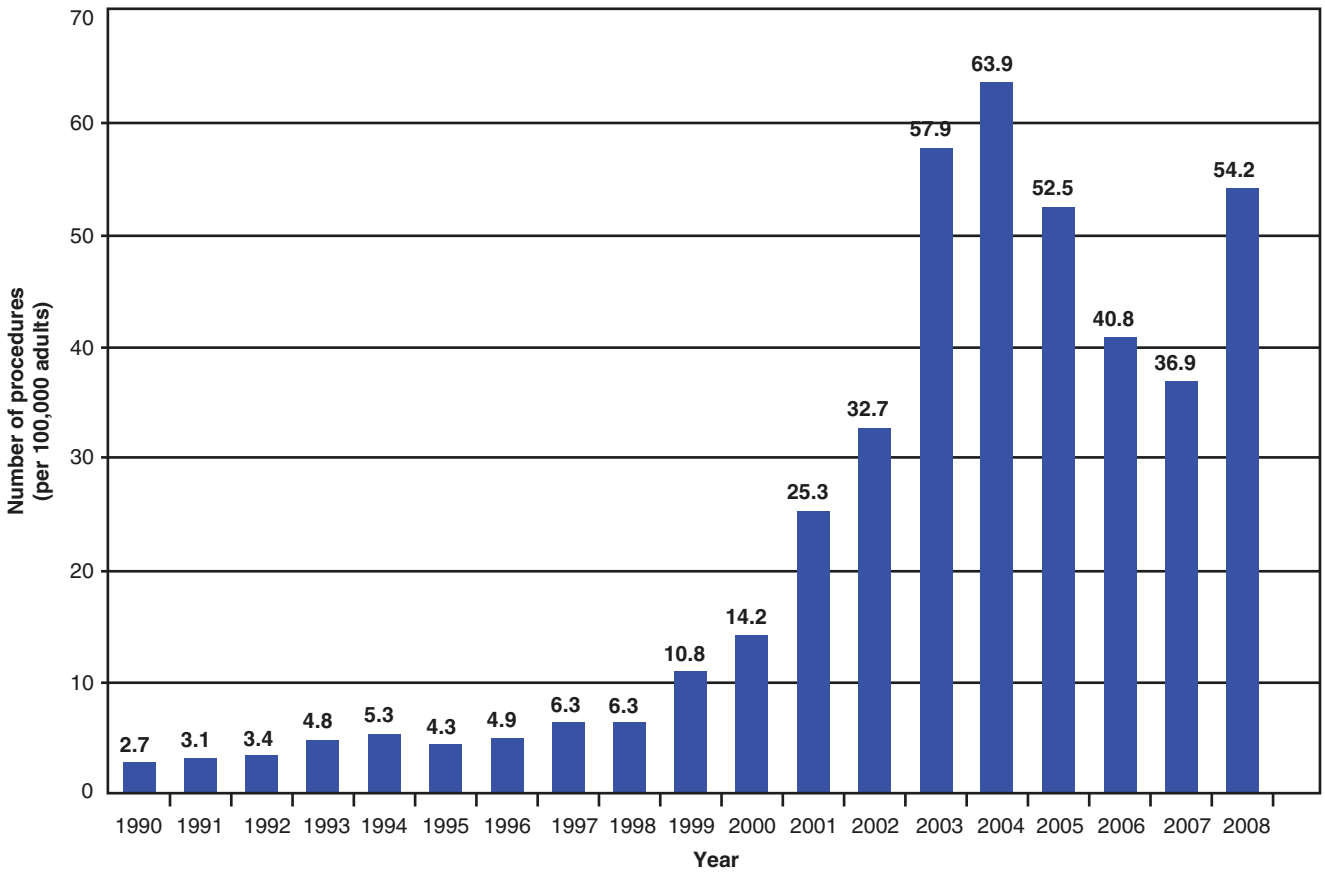

Fig. 40.1 Growth in bariatric surgery procedures from 1990 to 2008

Table 40.1 Total number of 2011 ASMBS BSCOE programs before transition to MBSAQIP

	Hospitals	Surgeons
Full approval	458	849
Provisional approval	143	260
Provisional in process	83	147
Total participants	684	1256

The Ten Original Requirements for an ASMBS BSCOE

1. Institutional commitment to excellence
2. Surgical experience and volume
3. Designated medical director
4. Responsive critical care support
5. Appropriate equipment and instruments
6. Surgeon dedication and qualified call coverage
7. Clinical pathways and standardized operating procedure
8. Bariatric nurses, physicians, extenders, and program coordinators
9. Patient support groups
10. Long-term patient follow-up

A nonprofit company, the Surgical Review Corporation (SRC), was established by ASMBS and contracted to administer the program in 2004. A data registry, Bariatric Outcomes Longitudinal Database (BOLD), was established in 2006 and became a requirement for SRC membership in 2008–2009. ASMBS felt it was important that the SRC remain independent from the business interests of ASMBS. The program was widely supported by ASMBS members and played an important role in providing safe access to bariatric surgery across the United States (Table 40.1).

American College of Surgeons Bariatric Surgery Center Network (ACS BSCN)

The ACS established their own Bariatric Surgery Center Network (BSCN) with similar standards and reporting requirements. The ACS initiative in bariatric surgery was part of a broad strategy to promote quality across all disciplines in surgery through the National Surgical Quality Improvement Program (NSQIP). This effort in bariatric surgery by the ACS was parallel rather than collaborative, primarily due to a disagreement between ASMBS and ACS regarding the use of a third party (SRC) to administer the program. An examination of the ACS BSN program demonstrated some philosophical and practical differences between ACS and ASMBS:

Table 40.2 Total number of 2011 ACS BSCN programs before transition to MBSAQIP

ACS BSN type	Total number	Comments
Level 1	98	12 converted from level 2
Level 2 and 2 new	31	
Outpatient and outpatient new	8	

1. The control and direction of the program by ACS rested *solely* with ACS – without a third party (ASMBS/SRC).
2. The ACS program required certification of the hospital and had no requirement regarding individual surgeon volume or certification (ASMBS).
3. Surgeons instead of nurses (ASMBS) performed the site visits.
4. The burden and financial obligation for data collection in the ACS program rested with the hospital and not the individual surgeon/practice (ASMBS).
5. Data collection was made by an independent clinical reviewer and not by someone who participates in the bariatric program (ASMBS).
6. The ACS had a level 2 designation for programs with lower volumes of cases within a specific window of risk-adjustment requirements.

By October 2011, the ACS BSCN reported a total of 137 programs (Table 40.2). All payers, including Medicare, accepted the ACS program despite the absence of a third-party administrator such as the SRC [10].

The Michagan Bariatric Surgical Collaborative (MiBSC)

The MiBSC (2006) is a voluntary group of hospitals and surgeons performing bariatric surgery in Michigan organized with a goal to decrease complications from bariatric surgery. The Northern New England Cardiovascular Disease Study Group (detailed previously) pioneered the model that was adapted in Michigan. The model has four major components:

1. A clinical registry with enough detail to allow for risk adjustment
2. A mechanism to provide hospitals and physicians risk-adjusted, confidential reports
3. A requirement for hospitals and surgeons to review and interpret the data at regular intervals
4. A requirement for hospitals and surgeons to utilize risk-adjusted reports for designing and implementation of best practices and quality improvement initiatives

This model was adopted in the state of Michigan in partnership with Blue Cross Blue Shield (BCBS) of Michigan. At the time BCBS covered 47% of patient lives in Michigan and funded the central administration of the program. BCBS also reimbursed surgeons or facilities to enter the data. The data was collected and managed through a central staff using third-party abstractors. Data was audited annually and not accessible to BCBS. As of 2011, 6000–8000 patients per year participated in the program which included all but one bariatric program/surgeon in Michigan [11]. The mission of the MiBSC was to improve the care and outcomes of all participating programs/surgeons – aka "a rising tide lifts all boats" [12]. This objective stood in contrast to the exclusionary philosophy initially adopted by the ASMBS of choosing only the best programs.

The Evolution of the ASMBS BSCOE

In 2010, an article was published in the *Journal of the American Medical Association* (JAMA) by John Birkmeyer, MD, and members of the MiBSC that concluded that the incidence of serious complications after bariatric surgery was unrelated to a program accreditation by ASMBS BSCOE [13]. In response, Michigan BCBS promptly removed the requirement for ASMBS BSCOE accreditation. Other studies raised concerns about the limitation of access to care created when Medicare restricted bariatric surgery to the BSCOE and BSCN networks [14]. In the summer of 2013, Medicare decided to eliminate the accreditation requirement for CMS patients. While the BSCOE program undoubtedly was instrumental in protecting patients during the rapid growth phase of bariatric surgery, there were clear opportunities for refinement of the initial BSCOE accredited programs:

1. They were based on structural and process elements and not outcomes:
   - There was no mechanism for data-driven quality improvement.
   - This was an important factor when payers, like Blue Cross Blue Shield (BCBS) of Michigan and Leapfrog, removed requirements for program accreditation through ASMBS. These costly process and structural requirements expanded with little peer-reviewed data validating their contribution to quality.
2. The volume requirement (125 cases annually) was onerous with unintended consequences.
   - It effectively excluded many surgeons and hospitals.
   - It precluded programs and surgeons from utilizing the BSCOE best practices during the formative stages of their bariatric program.
   - Volume was not transferrable, making it difficult for experienced surgeons to move to new locations.
   - During the 2008 recession, bariatric volumes decreased across the country, making it difficult for many experienced programs to maintain BSCOE accreditation. Estimates were that more than 35% of programs risked losing accreditation.
   - It precluded collection of data to understand safety in lower-volume centers.
3. There was no mechanism to stratify programs by procedure despite a significantly different risk profile for common bariatric procedures.
4. They created confusion for ASMBS membership, surgeons, facilities, and payers relative to:
   - The complex and changing relationship between ASMBS and the SRC
   - The existence of two quality programs (ASMBS BSCOE and ACS BSCN) and one state-based collaborative (MiBSC) all with different standards
5. There were numerous inadequacies with the BOLD data registry:
   - It collected a large volume of data but was plagued by burdensome variables, vague definitions, and reporting bias.
   - Data was inaccessible to surgeons and hospitals.
   - It lacked a clear mission (i.e., accreditation versus research).
   - It was unable to provide risk-adjusted data to programs.
6. In the absence of clinical data from BSCOE:
   - Pay-for-performance linking outcomes to reimbursement were emerging, and the BSCOE program provided no mechanism for measurement of outcomes.
   - Risk-adjusted and reliability-adjusted composite quality measures were being adopted as the preferred data source by payers [15].
   - Public sources of information like Healthgrades and CMS used administrative data lacking risk-adjustment capability and flawed by over- and underreporting of complications [16].
7. Surgeon credentialing at variance with BSCOE had been developed by multiple societies with different recommendations.

Expectations by patients, hospital administrators, government, and private payers to improve the value (quality/cost) and patient experience of care were fast becoming a reality. The ASMBS BSCOE program had reached a tipping point wherein, without significant change, it was becoming irrelevant.

These concerns provided the basis for the ASMBS to conduct a thorough reevaluation of its own accreditation program. In February of 2011, Bruce Wolfe, MD, and the Executive Council of ASMBS established the ASMBS Quality and Standards Committee, to provide oversight of the BSCOE program and to undertake a complete evaluation

of the program. The objective of the ASMBS Quality and Standards Committee was to facilitate collaboration between all stakeholders on a future integrated program that would eventually improve on the earlier accreditation programs to correct deficiencies and facilitate patient safety.

The ASMBS leadership met with the SRC in March 2011, resulting in a unanimous decision to transfer management of the data to the ASMBS. In September, the ASMBS Executive Council unanimously endorsed creation of an integrated program in collaboration with the ACS. Both the ACS Board of Regents and the ASMBS Executive Council voted unanimously to support a combined program. These decisions required resolution of the complex legal and financial relationships between the ASMBS and SRC. On April 1, 2012, the ASMBS and ACS integrated their two quality programs into the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) (Fig. 40.2). By agreement, MBSAQIP utilized the BSCN registry, while the BOLD data was retained by the ASMBS Research Committee with the charge to produce a public use file and to return data to the programs that had entered it.

Fig. 40.2 Logo of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). (Reprinted by permission of the American College of Surgeons)

The most important and challenging task for MBSAQIP was integrating a common culture of quality. This required rigorous examination of every aspect of the current quality paradigm in both societies in order to propose a patient-centric system of quality. The new program standard *Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2014: MBSAQIP Standards and Pathways Manual* was published on January 28, 2014 [17].

Key elements of the new standards were:

1. Hospital-based designation and accreditation
2. Creation of local committees in metabolic and bariatric surgery to evaluate and use the data for process improvement
3. Continuation of support for the role of integrated health in providing education and support in a program structure
4. Requirement of at least one verified bariatric surgeon in the facility
5. Requirement for entry of all cases in the data registry with abstraction by independent clinical reviewers
6. Requirement for quality improvement initiative annually
7. Adolescent accreditation standards

Administration of MBSAQIP was intentionally structured as a collaborative effort between the ACS and ASMBS. The reporting structure of the administrative staff based in the ACS headquarters in Chicago is depicted in Fig. 40.3. Surgeon oversight of the program is provided by the Committee for Metabolic and Bariatric Surgery (CMBS), initially co-chaired by Drs. Ronald Clements and John Morton. CMBS was initially comprised of three subcommittees – Data and Reporting, Standards, and Verification. Two co-chairs led each subcommittee. The subcommittees have since been

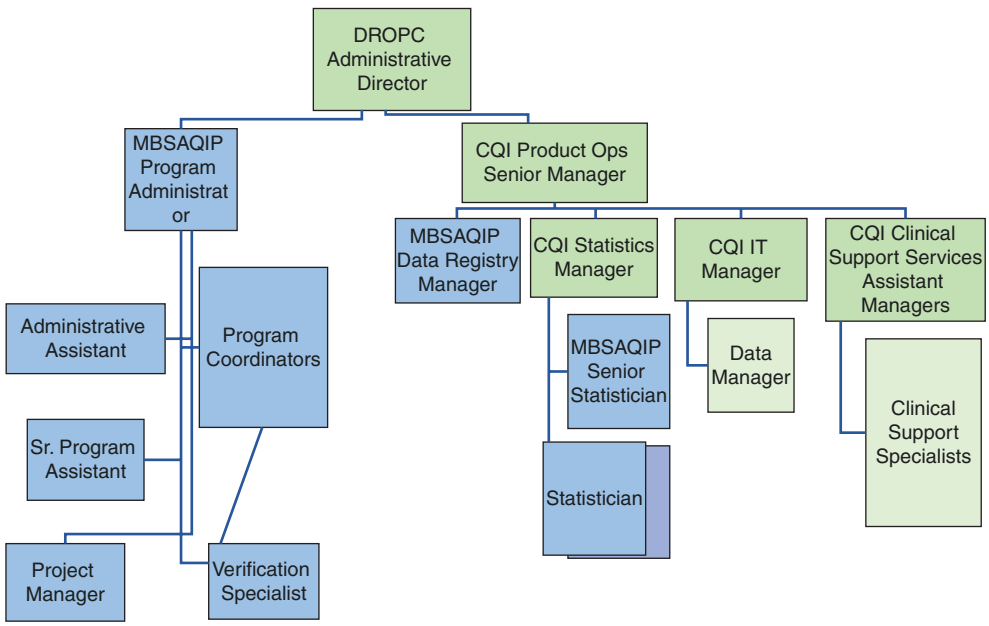

Fig. 40.3 MBSAQIP staff reporting structure

consolidated into (1) Data and Quality and (2) Standards and Verification. The ASMBS president, president-elect, and secretary/treasurer are standing committee members of CMBS.

The Maturation of MBSAQIP

After release of the inaugural Standards Manual in 2014, MBSAQIP embarked on the monumental task of accreditation and reaccreditation of all bariatric centers under the guidance of the Verification Committee.

The problems associated with volume and stratification of procedures were addressed using five center designations [17]:

1. Low Acuity – minimum of 25 stapled cases annually
2. Comprehensive – minimum of 50 stapled cases annually
3. Comprehensive with Adolescent Qualifications
4. Band
5. Adolescent

Low-acuity centers were provided a pathway to comprehensive designation, and new centers seeking accreditation were invited to participate in data collection only. This provided centers with a mechanism to accumulate their data and utilize best practices early in the learning curve of their bariatric program.

The first site visit was conducted in September 2014 in Marquette, MI. In January 2015, St. Joseph's Hospital in Syracuse, NY, became the first MBSAQIP center to receive an official final report and accreditation under the new program. By the first anniversary of MBSAQIP in September 2015, 335 site visits had been completed. MBSAQIP sponsored educational courses and tutorials to assist centers in preparing for accreditation. The first such course was sponsored in November 2015 at Obesity Week. Accredited centers were featured and reported their experiences implementing MBSAQIP standards.

Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016 was published in March 2016 with the effective date of implementation in October 2016. The Standards Manual Version 2.0 eliminated the band center designation and created an ambulatory center designation. Ambulatory centers were required to perform a minimum of 25 cases annually and were approved for all primary stapled procedures in "low-acuity" patients. Another change was a more specific definition of the quality improvement process. Centers with "high-outlier" designation on the semiannual report (SAR) were required to develop a quality improvement initiative focused on their "high-outlier" metric [18].

As of 2018, there were 836 participating MBSAQIP centers, of which 792 were fully accredited. There are accredited sites in all 50 states, Canada and Puerto Rico (Fig. 40.4). There were 60 new center initial applica-

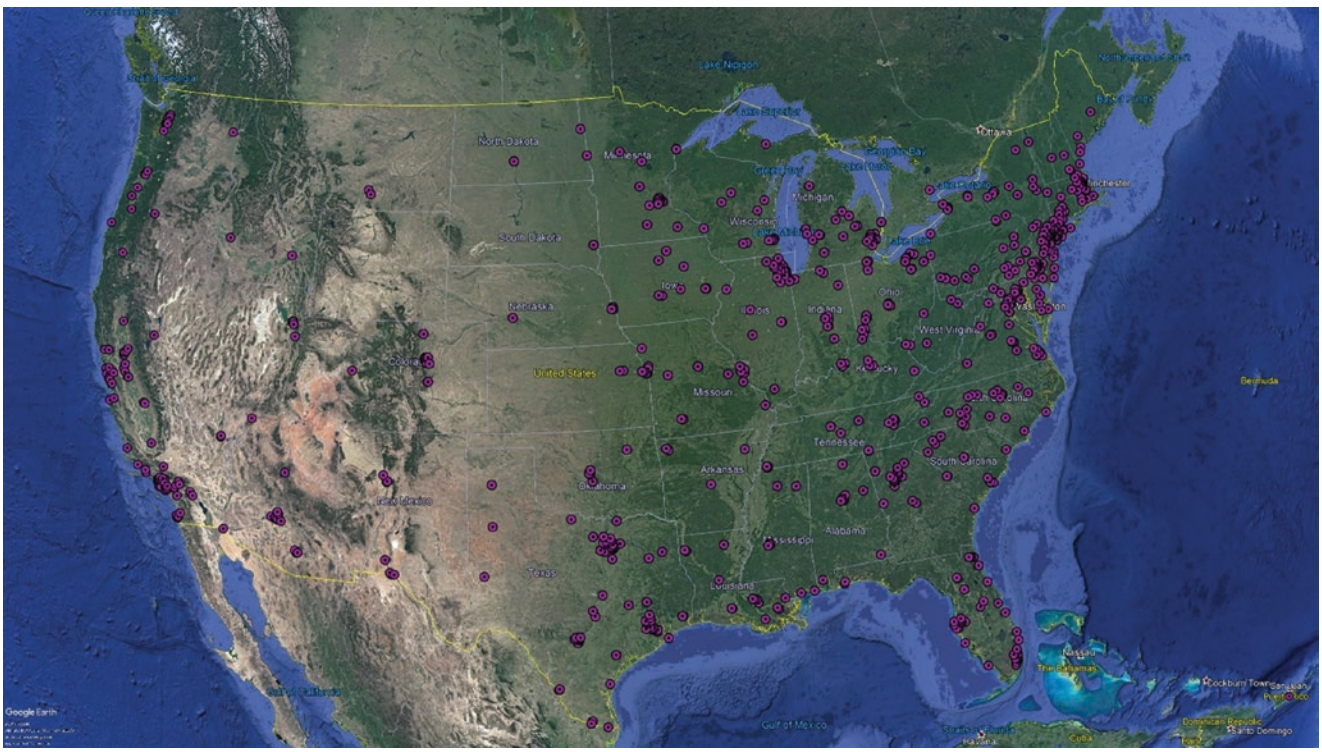

Fig. 40.4 2018 map of MBSAQIP centers

tions in 2018 and 28 accredited data collection centers. The option for international centers to participate as data collection-only centers was added in March 2017. The first three accredited international centers were Lebanon, Jordan, and the United Arab Emirates in 2018.

Another opportunity addressed by the new MBSAQIP was the problem of data reporting and access. The MBSAQIP Data Registry was developed with a clear objective to facilitate quality improvement. Toward this end, an idealized model of objectives has developed as a compass for ongoing refinement and enhancements (Fig. 40.5). Standard 6.1 requires both the MBS director and MBS clinical reviewer to confirm and attest that data from *all* metabolic and bariatric operations and interventions be submitted to the MBSAQIP Data Registry Platform. Standard 6.2 requires that the data be accessed and monitored and that the semiannual reports (SARs) be reviewed [18]. The SARs show risk-adjusted outcomes data for initial bariatric procedures. The first SARs were released to centers in June 2014.

One factor driving accreditation in bariatric surgery was the pressure from both the Centers for Medicare and Medicaid Services (CMS) and commercial entities (payers, Healthgrades®, Leapfrog®, etc.) to link reimbursement to quality. These initiatives were most prominent in the Michigan Bariatric Collaborative with Blue Cross Blue Shield as described earlier in the chapter. The passage of the Patient Protection and Affordable Care Act of 2010 (P.L. 111–148) accelerated the efforts of CMS to incentivize quality. CMS sought to identify Qualified Clinical Data Registries for implementation of the Physician Quality Reporting System (PQRS). At Obesity Week in November 2014, members were informed that the MBSAQIP Data Registry was approved as ACS's first Qualified Clinical Data Registry (QCDR). CMS quality reporting names and definitions have changed several times since initial passage of the Affordable Care Act with the current evolution of the program now called the Merit-based Incentive Payment Program System (MIPS). MIPS created a new mechanism for payment adjustments to Medicare Part B payments 2 years after the performance year. Payment adjustments may be bonuses or penalties and begin in 2019, based on 2017 performance. 2017 and 2018 MIPS components include:

1. Quality (formerly PQRS).
2. Advancing Care Information (ACI) – this was formerly EHR meaningful use but was renamed to Promoting Interoperability for 2018.
3. Improvement Activities (IA) – started in 2017.
4. Cost

The 2018 MBSAQIP QCDR measures are outlined in Table 40.3. By 2018, about 2400 surgeons in MBSAQIP-accredited centers were eligible for participation in

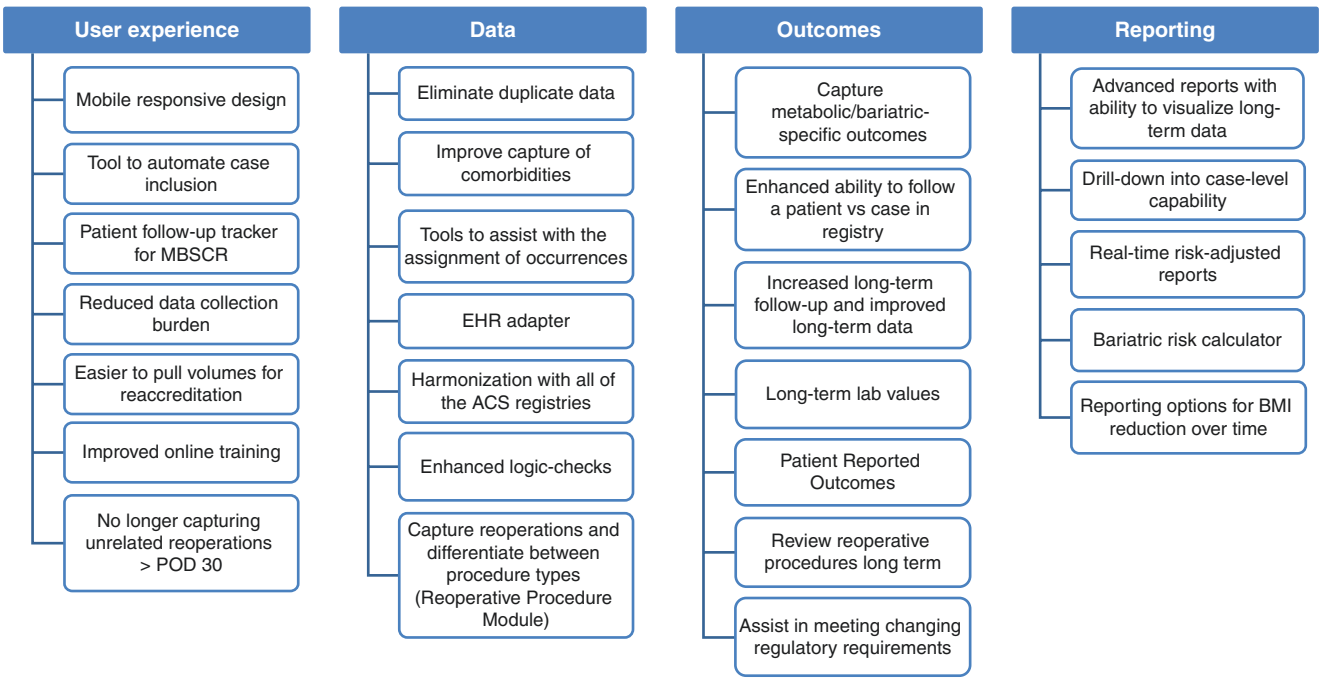

Fig. 40.5 Objectives of the MBSAQIP Data Registry

Table 40.3 MBSAQIP QCDR measures

Non-MIPS measures developed by MBSAQIP and approved by the CMS for the 2018 reporting year
1. Risk standardized rate of patients who experienced a postoperative complication within 30 days (*NEW* in 2018)
(a) Blood transfusion within 72 h of surgery start time
(b) Surgical site infection (SSI) within 30 days of surgery
(c) Urinary tract infection (UTI) within 30 days of surgery
2. Risk standardized rate of patients who experienced a postoperative escalation in care event (*NEW* in 2018)
(a) Readmission within 30 days of surgery
(b) Reoperation within 30 days of surgery
(c) Intervention within 30 days of surgery
(d) Admission to ICU within 30 days of surgery
3. Risk standardized rate of patients who experienced a pulmonary complication (*NEW* in 2018)
(a) Pneumonia within 30 days of surgery
(b) Unplanned intubation within 30 days of surgery
(c) Pulmonary embolism within 30 days of surgery
(d) On ventilator >48 h within 30 days of surgery
4. Risk standardized rate of patients who experienced extended length of stay (>3 days) (changed from >7 days)
5. Risk standardized rate of patients who experienced postoperative nausea, vomiting, or fluid/electrolyte/nutritional depletion within 30 days
MIPS measures
6. Quality ID # 354 anastomotic leak intervention
7. Quality ID # 356 unplanned hospital readmission within 30 days of the principal procedure

MIPS. Surgeon participation by QCDR cycle year is listed below (Source: MBSAQIP).

PQRS:

2014 $n = 85$
2015 $n = 115$
2016 $n = 137$

MIPS:

2017 $n = 115$

The MBSAQIP modeled the MBSC philosophy of "a rising tide lifts all boats" when developing the data registry to facilitate quality improvement not only at participating centers but in metabolic and bariatric surgery centers that were not participating. The first Participant Use Data File (PUF) of outcomes data for all centers was released in January 2017. The July 2017 ACS Quality and Safety Meeting (formerly the ACS NSQIP Conference) introduced the bariatric track aimed at MBSAQIP participants. Educational courses directed at implementing MBSAQIP standards were offered for MBS directors, MBS coordinators, and MBS clinical reviewers. Scientific presentations focused on outcomes trends and quality improvement opportunities utilizing unadjusted center data and SARs. The PUF data was also presented.

To further the quality mission, the Quality Committee designed and launched the first MBSAQIP national quality improvement project in 2014. MBSAQIP data identified centers that were high outliers for readmissions with 140 MBSAQIP centers identified and invited to participate in Decreasing Readmissions through Opportunities Provided (DROP). The program focused on education and communication as tools to improve readmission rates after bariatric surgery. Some unique interventions in DROP included the distribution of a "HELP" card to all patients. This card includes a list of signs and symptoms that would prompt a patient to call their provider. The back of the card lists names and phone numbers for contact with the bariatric program (Fig. 40.6). DROP also required centers to make a post-discharge phone call to patients. The program interventions by phase of care are described in Fig. 40.7. Custom data fields were utilized in the MBSAQIP Data Registry to track adherence to protocol elements, and monthly webinars were held to address frequently asked questions. The DROP project was initiated with a pilot group of centers on January 8, 2015, and concluded on March 31, 2016. Results were presented as a Top Ten Paper at Obesity Week 2016 by then ASMBS President-Elect Dr. John Morton. He reported that hospital readmission rates dropped in analysis of all procedures and that protocol adherence was associated with a shorter length of stay and improved readmission rates.

MBSAQIP launched the second national collaborative quality improvement project – *E*mploying *N*ew *E*nhanced *R*ecovery *G*oals to Bariatric Surger*Y* (ENERGY) in November 2016. The project was led by ASMBS President Dr. Stacy Brethauer. The MBSAQIP Data Registry was again utilized, to identify those centers that were high outliers for length of stay greater than 4 days. Seventy-four sites were

Fig. 40.6 Geisinger Bariatric HELP Card

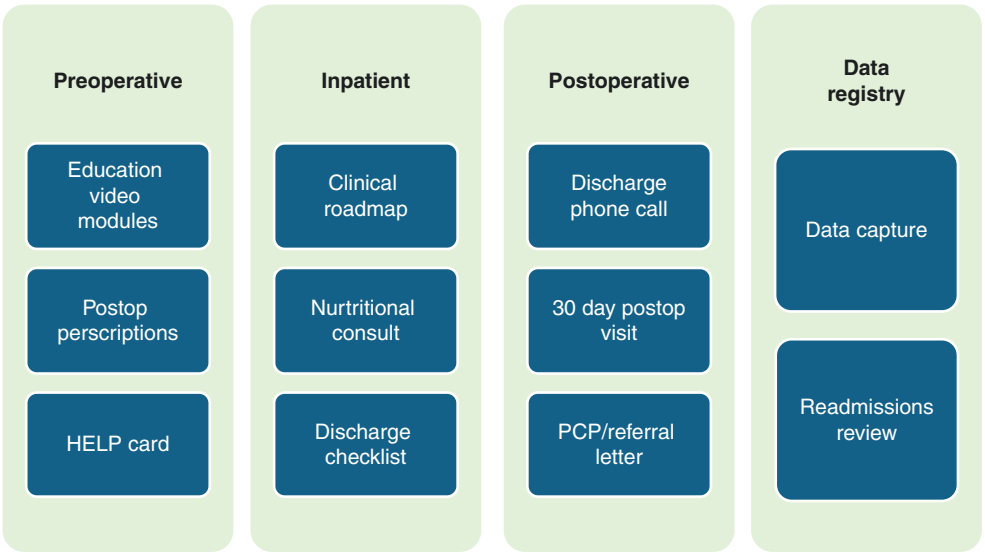

Fig. 40.7 DROP care interventions

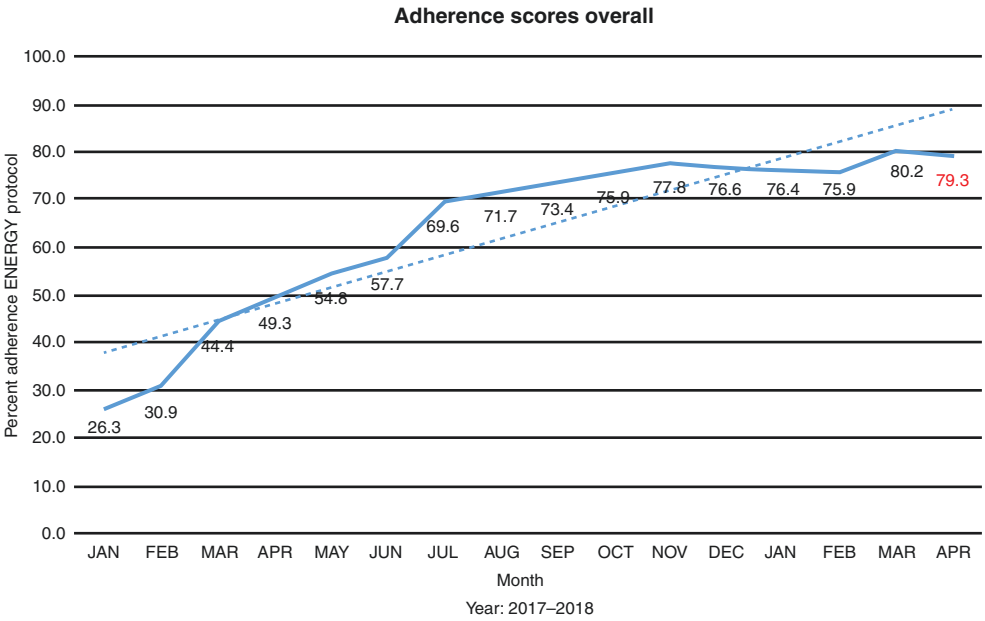

Fig. 40.8 ENERGY adherence to protocol

invited to participate, and 36 sites accepted. This project expanded on lessons learned from the DROP project incorporating many of the care elements. ENERGY incorporated many of the care processes utilized in other clinical enhanced recovery programs as well [19]. These included prehabilitation, skin prep prior to surgery, tight glucose control, regional anesthesia, and minimizing fluids, tubes, drains, and reduction of opioid use in the perioperative period. Elements unique to bariatric surgery were the use of high protein liquid nutritional supplements rather than arginine-enriched supplements prior to surgery and the utilization of the HELP card for patient communication.

The project was administered using center mentors and monthly webinars. Implementation began with a "run-up" period from January through June 2017. This gave centers an opportunity to imbed process elements into their practice and electronic health records as well as training the MBSCRs in the use of custom data fields in the registry. Time was also needed for engagement of the anesthesia services responsible for many of the intraoperative protocol elements. Overall adherence scores reached the target of 70% in July 2017 just as the project reached the "Go Live" phase (Fig. 40.8). Dr. Brethauer reported the results in a Top Ten Paper at Obesity Week 2018. A reduction in extended length of stay (greater than 4 days) was seen overall in centers participating in the ENERGY quality improvement initiative. Complete outcomes data are currently undergoing final analysis.

Additional ASMBS Quality Initiatives

The ASMBS is committed to providing members resources to promote quality care in metabolic and bariatric surgery above and beyond participation in MBSAQIP. Many of these are covered in more detail in other chapters. Educational opportunities are available at ASMBS Weekend and Obesity Week for member and nonmember bariatric surgeons and integrated health personnel. After several years of partnership with The Obesity Society (TOS), ASMBS and TOS created Obesity Week in 2013 under the presidency of Dr. Jaime Ponce. This is the most comprehensive meeting in the world focused on the basic science, clinical application, surgical intervention, and prevention of obesity and related diseases. ASMBS provides Patient Safety Vignettes, Position and Consensus Statements to members and patients to educate and facilitate the care of bariatric patients.

There are currently 25 ASMBS committees and 7 Integrated Health committees all of which contribute to quality in bariatric surgery. Specifically, the Quality Improvement and Patient Safety (QIPS) Committee supports the mission and values of ASMBS by promoting continuous improvement in patient safety and risk reduction. These goals are achieved by the integration and coordination of patient safety initiatives of member surgeons. The Committee teaches that the most effective manner to decrease surgeon exposure to liability is through improving patient safety. The QIPS Committee is committed to working with members to identify malpractice trends, professional liability insurance costs and availability, and gaps in risk management. Toward that end, bariatric patient care and expert witness guidelines have been published. Among numerous quality initiatives, the committee is currently working toward the creation of a comprehensive library of patient care pathways as a resource for membership [20].

The MBSAQIP Approach to Accreditation

Introduction

The most important element in a bariatric program is establishing a culture of quality and safety leadership. A leader sets direction, aligns people around common goals, and motivates and inspires the team to reach them. The core value of the MBSAQIP program is that oversight of the program resides with the local Metabolic and Bariatric Surgery Committee (MBSC). The leader of the MBSC is the surgical director. The MBSC is comprised of the surgeons and integrated health professionals who work together to establish the elements of a quality MBS program. All surgeons who operate within the program must participate in the MBSC. The goal is to ensure high-quality perioperative outcomes, long-term effectiveness, and an outstanding patient experience for *all* patients in the program. The MBS committee is charged with developing *value* within the program which is defined as quality over cost. Value goes up as quality goes up or as cost decreases while maintaining quality.

MBS committee members are responsible for establishing this ethos under the leadership of the MBS director. This culture should encourage surgeons to continuously evaluate their outcomes in collaboration with the integrated care team using the SAR as well as the unadjusted data registry in real time. This permits comparison both locally and nationally. Analysis of outcomes can lead to evaluation of technical, structural, and process aspects of the program and drive changes that improve care. The director is responsible for creating a "nonpunitive" culture that encourages transparent discussions of outcomes toward the purpose of quality improvement. The committee is purposefully positioned to meet the challenges of the new medical environment: improved patient safety, enhanced patient experience, growing access, and maximizing revenue while minimizing cost.

While an exceptional program requires both management and leadership, they are not one in the same. While the leader sets the direction and culture, a manager plans and develops a budget, organizes staffing, controls activity, and solves problems [21]. To implement the MBSAQIP standards within your current program or use them to start a new program, both leadership and management are required.

Understanding the Key Elements of Quality

Key elements of a quality program are as follows:

- Credentialing of surgeons and integrated health
- Understanding risk
- Consideration of volume and its impact on quality
- Program process and structure
- Data registry and outcomes reporting
- Collaboration to design and implement process improvement

Quality Basics

In the classic Donabedian paradigm for assessing quality of care, three measures prevail as indicators of quality: structure, process of care, and direct outcomes (Fig. 40.9) [22]. There are strengths and weaknesses of each measure as outlined in Table 40.4 [23].

Once accurate data is collected, it can be analyzed to provide information that can be turned into improvement in quality. The science of measuring variability and predicting the future performance of a facility or hospital has advanced.

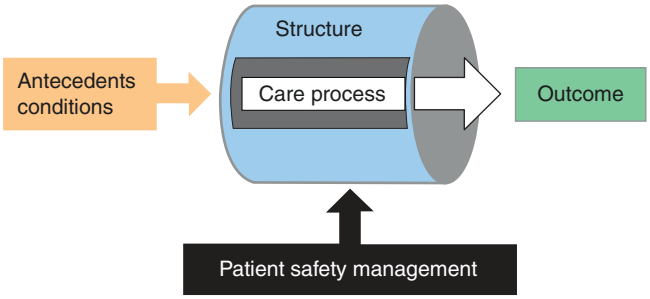

Fig. 40.9 Donabedian's model for assessing quality of healthcare based on structure, process, and outcomes [24]

Table 40.4 Primary strengths and limitations of structural, process, and outcome measures

Types of measure	Examples	Strengths	Limitations
Structural	Volume of procedures	Expedient and inexpensive	The number of measures is limited
	ICU managed by intensivists	Efficient (a single measure may generate several outcomes)	Measures usually are not actionable
		Sometimes structural measures predict subsequent performance better than process or outcome measures do	Measures do not reflect individual performance; can be considered unfair by providers
Process of care	Prophylactic antibiotics used appropriately	Reflects care that patients actually receive, therefore resulting in greater support from providers	Many measures are hard to define with existing databases
		Measures are directly actionable for quality improvement activities	Extent of linkage is variable between measures and important patient outcomes
		Risk adjustment is often unnecessary	Lacks high-leverage, procedure-specific measures
Direct outcome	Risk-adjusted mortalities for CAGB from state or national registries	Face validity	Limited sample sizes
		Measurement may improve outcomes in and of itself (i.e., Hawthorne effect)	Expensive to collect clinical data
			Concerns regarding risk adjustment using administrative data

Adapted from Birkmeyer and Dimick [25]

The important question is explaining what in a given process produces the variation. Iezzoni attributes variation to her "algebra of effectiveness," meaning variation in outcomes is attributed to one of three factors: chance, case mix, and quality of care [24]. This model has evolved as the understanding of contributory processes has evolved. A more current concept is presented in Fig. 40.10 [26].

Credentialing of Metabolic and Bariatric Surgeons

MBSAQIP Standard 2.6 outlines credentialing requirements for metabolic and bariatric surgeons. It is recommended that both hospitals and surgeons participate in MBSAQIP to achieve participation in the necessary program structures. This recommendation is also fulfilled by participation in an equivalent approved statewide or national bariatric quality improvement program. The guidelines are intentionally flexible enough to enable the local MBS committee to utilize the standard to develop specific surgeon credentials. Once approved, the MBS committee should act as a resource for the credentialing committee to ensure that these credentialing guidelines be adopted within the official credentialing requirements of the hospital or health system.

Expertise and Risk Adjustment (Comorbid Medical Conditions)

A key element in reducing variation is to understand the risk of the population and determine the case mix. The program will need to decide what level of risk the group is willing to accept. Decisions made on these issues will direct the structure and process parts of the quality paradigm. Risk considerations include four questions for the program:

1. Does the surgeon have the experience and expertise to perform the procedures, and does the integrated health staff have the expertise to manage the patient?
2. What is the risk associated with the procedures that will be performed, and which ones should the program provide to patients?
3. What is the level of support that the program must have for special groups (adolescent patients, elderly, super morbid obese patients, transplant patients, etc.), and will surgery be offered to them?
4. What is the risk the patient brings with them, and how can you manage that risk during the perioperative period?

MBSAQIP provides risk-adjusted outcomes data to each program in the semiannual reports (SARs). The limitation is that enough procedures must be performed nationally and in

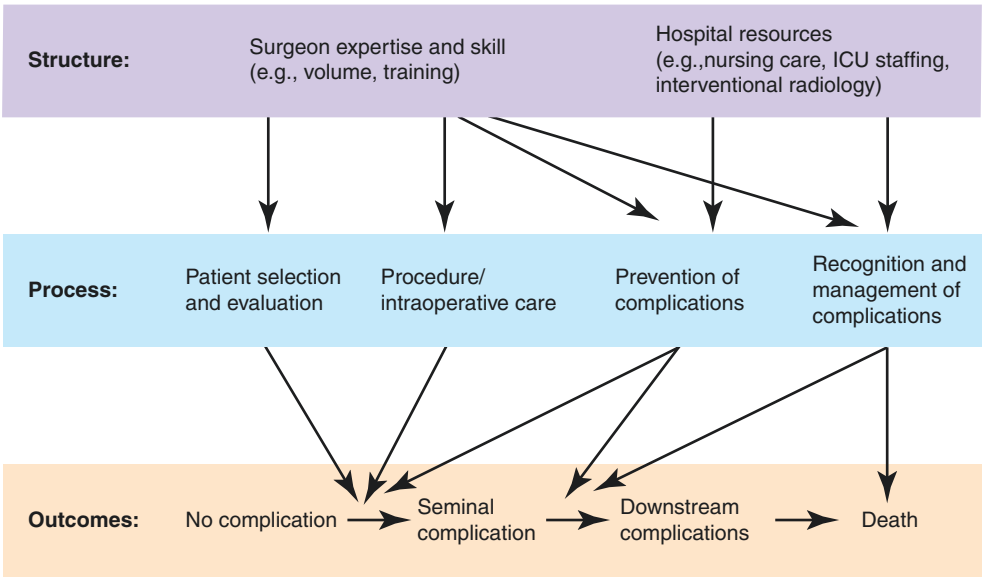

Fig. 40.10 Conceptual framework of modern quality showing relationships between structure, process of care, complications, and mortality after surgery [26]

the program to provide adequate power for risk adjustment. For help with these questions, the integrated health leadership and committees of ASMBS have developed recommendations. Networking with other programs will also help the program define these roles and the proper credentials for them.

Procedure choices represent a challenging decision for many bariatric programs. How and when will new types of procedures be added to the program? What is the required educational/training/proctoring or certification process to add more difficult procedures or new technology? Reoperative surgery for inadequate weight loss or weight regain, the use of new or "off-label" medical devices, robotic-assisted techniques, or high-risk procedures may require additional consideration by the committee and/or program. The most important risk factor remains the procedure itself. MBSAQIP has designed the MBS committee to facilitate program leadership, mentorship, and communication to consider surgeons' experience and program experience in the creation of a thoughtful approach to the treatment of high-risk patients or the introduction of new and complex procedures. Failure of effective MBS committee oversight may significantly affect a program's reputation and cause the program to become financially insolvent.

Another concern the MBS committee and surgeon director must address is the impact of volume on quality and surgical outcomes. In 2011, gastric bands made up 35% of the volume in the MBSAQIP Data Registry. That decreased to 2.7% by 2017 while sleeve gastrectomy increased from 17.8% to nearly 60%. With many centers now performing sleeve gastrectomy in nearly 100% of their bariatric patients, consideration must be given to the management of patients for whom this procedure may not be appropriate [27]. Programs must continuously monitor outcomes as the volume of procedures fluctuates.

Special Groups of Patients

Against the backdrop of established structure and process of care is the provision of surgical care to special groups of people: patients seeking revisions of previous bariatric procedures, adolescent and elderly patients, extremely large patients, patients with high metabolic acuity, transplant patients, patients with high psychological acuity (schizophrenic/bipolar or severe personality disorders), patients paying cash, patients who become pregnant after surgery, and research patients seeking new procedures. Each of these special groups of patients should be reviewed in the context of the program structure and process to see what protocols and processes need to be put in place for their optimal management if surgery will be offered to them. Early in a program's experience, it may not be appropriate to offer procedures to any of these groups of people. The recently published standards provide for programs doing as few as 25 stapled cases per year to restrict operations to a lower-risk patient group and still participate in the program. The solutions for each patient group will differ from program to program, but having a specific plan for these groups and adhering to it will provide an opportunity to link best practices with others providing similar care.

Patient Risk

For risk adjustment to accurately predict future adverse events, complications must occur with sufficient frequency to be analyzed statistically. In addition, the complications need to occur in a predictable pattern. No single patient-derived risk factor has emerged as a predictor of complications, including BMI. The incidence of serious complications is a J-shaped curve. The variability of these analyses also speaks to the low

frequency of serious complications, the lack of consistent correlation of specific risk factors with these complications, and, to some extent, variable statistical analyses and approaches. One of the great successes of metabolic and bariatric surgery of this century has been the reduction in mortality risk. Despite the data quality and with case entry now exceeding 200,000 annually, MBSAQIP data cannot adequately model mortality due the low frequency of events (Table 40.5). In 2018, MBSAQIP added a new "Serious Event" data field. This is a field represents a composite of both death and serious events and is risk adjusted. The MBSAQIP Data Registry provides a rich data source for modeling risk (Table 40.6) [26–31].

Table 40.5 2017 MBSAQIP 30-day mortality by procedure

Procedure	Number of cases[a]	30-day mortality (%)
BPDDS	1540	0.19
Band	1868	0
LRYGB	40,872	0.15
LSG	117,620	0.05
Total	161,900	0.08

[a]Cases performed in calendar year 2017

The type of bariatric surgery procedure performed is the most important predictor of perioperative risk; however, the surgical approach to any bariatric procedure is an independent predictor of risk. Older trials that have completed a correlation analysis to identify risk factors associated with mortality or other complications in bariatric surgery used primarily an open cohort or mixed patient cohort. These may no longer be relevant since almost no initial bariatric procedures are performed open. The effect on mortality of the open approach is so profound [29] that when these surgical approaches are mixed, a more significant perioperative risk profile emerges than when a solely laparoscopic cohort is used. While open cases have nearly disappeared, the number of bariatric procedures done by means of a robotic approach is increasing. A similar risk/benefit and cost analysis should be utilized for new surgical approaches as for open approaches. Bariatric patients realized a clear benefit once laparoscopic procedure were deemed safe and effective because of the evolution from open to closed procedures. The reduction in hernia and wound complications was dramatic, and the physiologic benefits of closed

Table 40.6 Summary of risk-adjustment publications

Author/date	Description of study	Risk factor	Adjusted odds ratio (95% CI)
El Chaar et al. (2018) [26]	MBSAQIP Public Use File 2015 (Initial SG and RYGB) 101,599 patients Endpoint: 19 serious adverse events within 30 days or surgery	H/O pulmonary embolism	2.81 (2.34–3.38)
		Type of surgery	2.08 (1.96–1.22)
		Limited mobility	1.48 (1.24–1.77)
		Cardiovascular disease	1.43 (1.24–1.64)
		Steroid use	1.40 (1.14–1.72)
		Hypertension	1.17 (1.09–1.26)
		Diabetes	1.15 (1.07–1.23)
		Sleep apnea	1.12 (1.05–1.19)
		BMI	1.07 (1.05–1.09)
Gupta et al. (2011) [27]	Bariatric NSQIP (all bariatric procedures including revisions) 11,023 patients Endpoint: selected 17 postoperative complications	MI/angina	3.65: CI 1.23–10.8
		Dependent functional status	3.48: CI 1.78–6.80
		Stroke	3.01: CI 1.09–7.67
		Bleeding disorder	2.37: CI 1.47–3.38
		Hypertension	1.34: CI 1.10–1.63
		BMI 35 <45	0.9: CI 0.67–1.21
		BMI 45–60	0.69: CI 0.52–0.91
		Procedure type:	
		BPD/DS	2.04: CI 0.51–8.08
		OGBP	1.13: CI 0.34–3.74
		LGBP	0.57: CI 0.17–1.86
		LAGB	0.17: CI 0.05–0.57
Nguyen et al. (2011) [28]	Nationwide inpatient sample 304,515 patients 2006–2008Endpoint: in-hospital mortality; overall 0.12%	Male gender	1.7: CI 1.2–2.2
		Age >50	3.8: CI 2.8–5.0
		Congestive heart failure	9.5: CI 6.8–13.2
		Peripheral vascular disease	7.4: CI 4.5–12.2
		Chronic renal failure	2.7: CI 1.6–4.5
		Open procedure	5.5: CI 4.4–7.2
		GBP	1.6: CI 1.2–2.4

(continued)

Table 40.6 (continued)

Author/date	Description of study	Risk factor	Adjusted odds ratio (95% CI)
Finks et al. (2011) [29]	MBSC 25,469 patientsAll procedures June 2006–December 2010 Endpoint: grade 2 or 3 complications	Most significant risk factor was procedure type:	
		Duodenal switch	9.68: CI 6.05–15.5
		Laparoscopic gastric bypass	3.58: CI 2.79–4.64
		Open gastric bypass	3.51: CI 2.38–5.22
		Sleeve gastrectomy	2.46: CI 1.73–3.50
		Patient factors:	
		Previous history VTE	1.90: CI 1.41–2.54
		Mobility limitations	1.61: CI 1.23–2.13
		Coronary artery disease	1.53: CI 1.17–2.02
		Age over 50	1.38: CI 1.18–1.61
		Pulmonary disease	1.37: CI 1.15–1.64
		Male gender	1.26: CI 1.06–1.50
		Smoking history	1.20: CI 1.02–1.40
DeMaria et al. (2007) [30]	University	BMI >50	3.60: CI 1.44–8.99
DeMaria et al. (2007) [31]	Retrospective 2075 patients Validated, multicenter retrospective 4431 patients Procedure: gastric bypass Endpoint: mortality 0.7%	Male gender	2.80: CI 1.32–5.92
		Hypertension	2.78: CI 1.11–7.00
		Pulmonary embolus risk[a]	2.62: CI 1,12–6.12
		Age >45	1.62: CI 0.78–3.48

MI myocardial infarction, *OGB* open gastric bypass, *LGBP* laparoscopic gastric bypass, *LAGB* laparoscopic adjustable gastric band, *BPD/DS* biliopancreatic diversion/duodenal switch, *BMI* body mass index, *GBP* gastric bypass

[a]Pulmonary embolus risk = history of previous venous thrombosis, pulmonary embolus, inferior vena cava filter, right heart failure, and obesity hypoventilation

abdominal procedures have been well established. The benefits of robotic-assisted closed bariatric procedures are currently less clear. Robotic-assisted abdominal procedures have commonly resulted in higher costs and longer operative times [32, 33]. With laparoscopy, adverse outcomes were offset by the benefits of evolving from open to closed abdominal approaches. No such benefit exists in bariatric surgery where laparoscopic techniques have almost universal adoption. Another current concern with robotic-assisted approaches is the increased procedural costs. Questions to be answered when considering the robotic approach are as follows: (1) What is the value to patients? Given the overall low risk of morbidity and mortality in all bariatric procedures, it does not seem possible to power a study that demonstrates a clinical outcome benefit for robotic procedures compared to laparoscopic should one exist. (2) Is it reasonable to subject patients to the risk of a "learning curve" given the current clinical outcomes of laparoscopic bariatric surgery? (3) Is there a role for robotic-assisted bariatric surgery in revisional procedures? (4) Will robotic technology facilitate the evolution of natural orifice bariatric surgery? (5) What are the health benefits of robotic surgery for the surgeon? All these questions need to be answered by current and future generations of metabolic and bariatric surgeons.

In any quality paradigm addressing outcomes, risk adjustment is imperative; however, for the purposes of "improvement" of care, unadjusted outcomes will yield the richest data for use at the local hospital/surgeon level. The inaccessibility of BOLD data restricted this opportunity for programs operating under the ASMBS BSCOE. The MBSAQIP Data Registry provides unadjusted reports to accredited centers on demand. Review and analysis of this data is invaluable in the design of quality improvement (QI) initiatives. Communicating the level of patient risk to the wider team including clinic staff, OR, and hospital staff allows for quick identification of the higher-acuity patient. Specific pathways of care can be designed to address these patients with specific attention to their comorbid medical problems. These care pathways should include identification of complex psychological problems with a tailored psychiatric follow-up plan.

Volume and Failure to Rescue

As described in the historical review of ASMBS BSCOE initiative, the volume requirement of 50 cases and 125 for facilities created many unforeseen problems with patient access and maintenance of accreditation after implementa-

tion. There are many reports supporting the use of volume as a surrogate for quality [34]. In the early days of the ASMBS BSCOE program, reports of the importance of volume to quality were cited to justify its use as the primary quality indicator in the program [35].

The Longitudinal Assessment of Bariatric Surgery (LABS) attempted to answer the volume question in bariatric surgery using a composite event (CE) score for serious adverse events. Mortality is so rare an event in bariatric surgery that its use is precluded as a single endpoint. Risk adjustment was based on patient body mass index (BMI), functional status, history of deep vein thrombosis, and history of obstructive sleep apnea. After adjusting for patient risk, the effect of surgeon volume on outcomes for Roux-en-Y gastric bypass (RYGB) procedures in LABS showed that for each increase by ten cases per year in surgeon volume, the rate of risk of a CE was reduced by 10%. No significant differences were observed in mortality between low- and high-volume surgeons, but the study was not sufficiently powered to detect small differences. The study also found a higher risk of a CE in high-risk patients treated by low-volume surgeons. The observed relationship between surgeon RYGB volume and CE rates was continuous, illustrating that there was no satisfactory level of annual case volume that could act as a threshold for surgeon credentialing within the BSCOE [36].

Numerous statewide reports have demonstrated an inverse correlation between volume and adverse events. In Pennsylvania, Courcoulas et al. reported that surgeons performing <50 RYGB cases annually had a significantly increased rate of complications with even worse performance for low-volume surgeons in low-volume facilities [37]. A New York state study found that both low surgeon volume and low facility volume were associated with increased risk of complications [38], and the Michigan collaborative data found a similar inverse relationship between volume and complication rates [39]. Morton et al. used MBSAQIP PUF data reported at Obesity Week 2018, in an analysis that found that surgeon volume has a greater influence on morbidity than hospital volume.

Increasingly, the value of volume alone as the determinate of quality has been questioned, especially in procedures in which the mortality rate is low. The ACS NSQIP clinical data registry was used to study patients undergoing general surgery and vascular procedures. Mortality rates were lower at high-volume versus low-volume centers (3.5% versus 6.9%). However, major complication rates were similar in the high-mortality (24.6%) and low-mortality hospitals (26.9%) [40]. These findings have focused quality leaders on the problem of "failure to rescue" as a potential cause of the increased mortality in lower-volume centers. Dr. Ninh Nguyen examined this problem in bariatric patients. His group reviewed 35,000 bariatric operations. Mortality at accredited centers was 0.06% compared with 0.21% at nonaccredited centers. Complication rates were similar, but mortality was significantly associated with the ability of accredited centers to rescue patients with complications rather than with the volume of cases [41].

Failure to rescue initiatives represents a significant opportunity to improve mortality and major complications. Processes designed to identify the early warning signs of adverse events after bariatric surgery should be considered for quality improvement initiatives. The electronic health record provides a highly effective platform for these initiatives. Many hospitals and health systems have adopted the use of a modified early warning score (MEWS) to facilitate early identification of clinical deterioration [42]. An example of an early warning scoring system and nursing response algorithm used in the Geisinger Health System is demonstrated in Fig. 40.11. Reliable early warning systems for identification of adverse events present an opportunity to expand access to bariatric care. MBSAQIP standards require centers that do not have comprehensive specialty services and full-time critical care to have a signed transfer agreement (Standard 4.3) to receive accreditation. These systems may enable smaller community centers to ensure timely and safe transfer to tertiary centers to lessen the sequela of adverse events.

Several additional issues merit discussion around the question of volume. The first is that of case mix. The volume requirements in the first iteration of the quality program did not discriminate between procedure types and counted all procedures as equal. In the years following the launch of the ASMBS BSCOE, a unique risk profile emerged for different bariatric procedures. Mixing low-risk gastric band patient outcomes with stapled procedures such as RYGB and duodenal switch was not a useful measure for patients or surgeons. This recognition was incorporated into the new MBSAQIP standards requirement of 50 stapled cases annually in comprehensive centers. The requirement was lowered to 25 stapled cases per year for low-acuity centers, and a band-only designation was created. The band center designation was removed in Version 2.0 2016 and replaced with an ambulatory center designation.

Volume remains an important concern to bariatric surgeons entering practice immediately after training. Those that do not join an established bariatric practice must develop the resources within their hospital to support their program. It is important for these surgeons to determine their commitment to bariatric surgery as well as the level of support from

Fig. 40.11 Modified early warning score (MEWS) and response algorithm

MEWS Score								
	3	2	1	0	1	2	3	4
HR		< 41	41-50	51-99		100-109	110-119	> 120
SBP	< 71	71-80	81-100	101-200	> 200			
RR		< 9		9 -14	15-20	21-29	> 29	
Temp		< 35.1		35.1–38.4	> 38.5			
O_2 Sat (2L NC while awake)	< 90%			> 90%				
Pain Score					8-9	10		

Score	Nursing Action Algorithm
0-2	Continue routine monitoring
3	Increase VS q 1/2 hr X 4, continue Q2h monitoring, 02 PRN, pulse ox with vitals Inform charge nurse Inform surgeon on call
4	In addition to all of the above, Obtain second IV access Inform charge nurse and surgeon on call of change in MEWS Score Consider more intensive nursing care.
5	In addition to all of the above ... Inform charge nurse and surgeon on call of change in MEWS Score Consider informing the Quick Response Team* Consider transfer to higher level of care
6 and higher	In addition to all of the above... Inform charge nurse and surgeon on call of change in MEWS Score Likely requires informing the Quick Response Team* Likely requires transfer to higher level of care
* Follow Institutional Policy for Notification of Quick Response Team	

both their hospital and administration prior committing to a position. Once the personal and institutional commitments have been validated, the surgeon can utilize a wide array of resources provided by MBSAQIP to implement a quality bariatric program. While establishing appropriate volume in a practice is important, consideration must be given to limiting the choice of procedures and acuity of patients to provide the best chance of early success. The reputation of the surgeons is a personal brand and since the patients are socially connected in the digital world, problems with patients or with the program will quickly become public knowledge. Use of the MBS committee to plan for volume expansion, procedure selection, and growth of resources are effective means to ensure long-term success.

Volume, Reliability, and Composite Measures

Statistical modeling predicts that outcomes reported by facilities may occur due to chance depending on the volume. For instance, a hospital with an annual volume of 1000 cases reporting mortality of 2 in 1000 patients is probably a better representation of the true risk of death than a small hospital reporting 1 death in 80 patients. To reduce this statistical "noise" in the data, a technique called "reliability adjustment" has been developed. Reliability is a measure representative of the impact of hospital sample size on true variation across hospitals. The overall observed effect shrinks toward the mean of facilities with similar volume (not the overall mean), thereby correcting the observed risk-adjusted rate for

volume of the facility. This allows for all hospital volumes within the sample to be assigned a reliability adjustment factor (from 0 to 1.0), and using empirical Bayes techniques, the observed-to-expected (O/E) ratio is adjusted to reduce the statistical "noise" in the sample size [43].

It is important that surgeons have tools to compare their performance to that of their peers. One method is to develop a composite measure of quality. This analytical tool allows different quality "signals" including reliability and risk-adjusted volume, risk-adjusted mortality, and risk-adjusted potentially serious complications to be combined into a single composite measure of quality [44]. The composite measure is unique in that it can predict with reasonable accuracy how a center will perform in the future based on its past performance and provides multiple targets for quality improvement. While the most important use of data is to provide regular feedback for process improvement, programs and surgeons can measure themselves against their peers regionally and nationally. This analysis can lead to efforts that will improve patient safety using evidence-based risk-adjusted results [11].

The data in Fig. 40.12 illustrates the predictive value of composite measures in bariatric surgery. When composite measures were used to compare the variability rankings of hospitals to their subsequent performance, hospital volume was the worst predictor.

Toward this end, MBSAQIP modified the SAR in 2018 to include a composite measure of serious events. Many adverse outcomes after bariatric surgery occur with such low frequency that they cannot be modeled for risk adjustment. Payers utilizing center MBSAQIP data were left with few quality measures to determine center performance resulting in the use of less meaningful outcomes such as superficial site infections by default. MBSAQIP has responded by creating the Serious Event Composite Measure. Centers can now utilize the SAR and their unadjusted "real-time" data to provide patients and payers reassurance that their program provides value, safety, and an exceptional patient experience of care.

MBSAQIP Serious Event Composite Measures
30-day occurrences

- Organ/space SSI
- Wound disruption
- Pneumonia
- Unplanned intubation
- Pulmonary embolism

	Hospital volume	Serious complications	Composite measure
Odds ratio (95% CI) 1-star vs. 3-star	0.85 (0.43–1.68)	1.56 (0.84–2.91)	1.99 (1.14–3.47)
% Variation explained	0%	28%	89%

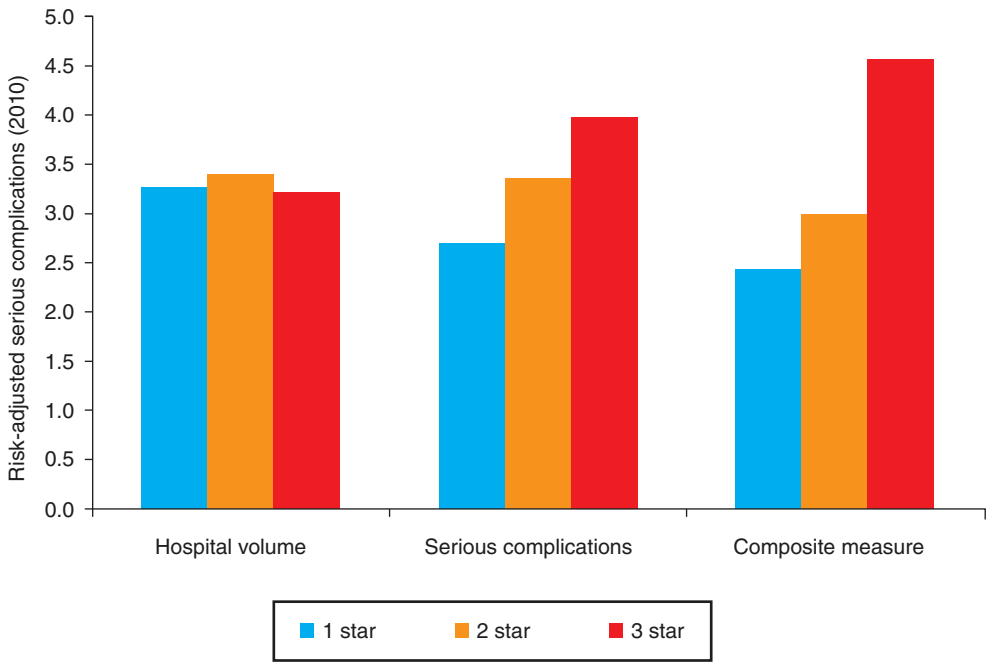

Fig. 40.12 Prediction of performance of bariatric surgery programs in Michigan using three measures: (1) hospital volume, (2) risk-adjusted serious complications, and (3) composite measure [11]. Composite measures are the best predictors of quality to use for accreditation

- On ventilator >48 H
- Progressive renal insufficiency
- Acute renal failure
- Stroke/cerebral vascular accident
- Coma >24 H
- Cardiac arrest requiring CPR
- Myocardial infarction
- Transfusion
- Vein thrombosis requiring therapy
- Sepsis
- Septic shock

Death

- Admission to ICU within 30 days

Reoperation

- Related
- Unplanned

Source: MBSAQIP

Program Process and Structure

The continuum of care requirements for metabolic and bariatric surgical patients (Standard 5.0) [18] was developed to address the costly process and structural requirements that had come to characterize the ASMBS BSCOE program. The standards provide a structured template for key programmatic elements that centers can develop based on their specific program needs and resources. These elements include patient education, care pathways, long-term follow-up, and support groups. Care pathways should include the following core elements:

1. Defined selection criteria process based on the resources, including equipment weight limits and expertise of the center
2. Psychosocial-behavioral evaluation
3. Algorithms for preoperative system clearances
4. Preoperative and postoperative nutrition regimen

Implementation of care pathways must be through standardized order sets which are specific to metabolic and bariatric procedures which must address each of the following care elements:

1. Dietary progression
2. Deep vein thrombosis prophylaxis
3. Respiratory care
4. Physical activity
5. Pain management
6. Parameters for notifying the attending surgeon

Individual centers can develop their care pathways based on available resources to optimally utilize personnel and minimize costs to both the program and patients. If your program is already established, doing this type of patient flow diagram and time-driven activity-based costing (TDAC) allows you to identify opportunities for improvement in value between surgeons and within the structure of the program. A goal of every program is continuous improvement of their care pathways and proficiency in capturing long-term follow-up data elements.

ProvenCare® Bariatric is an example of one such program developed by the Geisinger Health System in 2008. This project leveraged the unique structure of Geisinger in which the facilities, providers, and payer report through a single leadership. The program represents an effort to optimize "value" (quality, patient experience, and cost) in a bariatric program through adherence to the following core principles:

1. Create a culture that expects and insists on elimination of unwarranted variation as a patient-safety issue.
2. Clearly describe the organizational outcomes goals.
3. Set process expectations at a minimum >90% level of reliability.
4. Variation in protocols is to be driven by patients rather than individual providers.
5. Require clinicians to communicate and document exceptions.
6. Provide resources to measure the outcomes and reasons for noncompliance.

Clinical specialists teamed in the development of 34 best-practice elements (BPEs) for the care of patient undergoing initial RYGB. They were supported by statisticians and clinical-effectiveness and information-technology specialists who developed electronic medical record (EMR) workflows to facilitate compliance and reporting. Best-practice elements were designed to be both actionable and measurable. Reliable delivery of BPEs was only 40% during the 1st year of implementation but increased to 95% in subsequent years.

Data analysis confirmed the value of the comprehensive care pathways. After adjusting for sex, age, BMI, comorbidity count, medication count, and surgical approach (open vs. laparoscopic) in logistic regression analysis, a significant decrease in odds of extended LOS was noted for the reliable group (odds ratio [OR] 0.51; $p < 0.0001$), but not for the unreliable group (OR 0.90; $p = 0.494$). The same was found for complications with a significant decrease in odds of complication noted for the reliable group (OR 0.57; $p = 0.0005$),

but not for unreliable group (OR 0.78; $p = 0.147$) [45]. This program was implemented in partnership with the Geisinger Health Plan® as a "bundled-care" product stipulating a single clinic and professional reimbursement for all bariatric care for 90 days after the procedure. Even with the cost increases, revenues in 2016 were 92% of baseline, and contribution margins were 78% of baseline.

Data Collection/Integrity

Data integrity and fidelity are paramount. While the MBS clinical reviewers (MBSCRs) are charged with the collection and input of data, this culture is the responsibility of the MBS director as surgical leader. The demand for data continues to grow as payers, and outside healthcare rating organizations expand their use of quality metrics. Data can be used to improve care through quality improvement, enhance or detract from reimbursement, and is increasingly available to patients. Surgeons and hospital administration need to confirm that their quality efforts are based on high-quality data.

To obtain high-quality data and prevent bias, it is important to utilize an independent third-party clinical reviewer who has medical knowledge but no personal stake in the outcomes. Toward this end, the MBSCRs are not approved to provide direct patient care. In addition, the MBSCR must be trained and certified to determine when adverse events have taken place based on strict definitions of the data collection points. The ACS and ASMBS offer training symposia for MBSCRs both online and at national meetings.

Two types of data are reported and used by a variety of outside stakeholders: administrative data and clinical data. Administrative data is derived from hospital charts that are processed after discharge by coders. Data is abstracted by hospital coding teams reviewing provider documentation (or the absence of documentation). These teams often focus on maximizing the charges for the episode of care rather than clinical accuracy since there are many "gray" areas. This situation is exemplified in a patient requiring oxygen after gastric bypass who is sent for a chest X-ray. If the report diagnoses atelectasis, there must be documentation that this is expected based on laparoscopy, BMI, and sleep apnea. Otherwise, it may be coded as "pulmonary collapse," to maximize reimbursement. This code represents a complication in administrative databases.

There is nothing fraudulent about this practice. It reflects the obligation of hospitals and health systems to maximize revenues in a "perverse" payment system that has always provided better reimbursement for complications. Reimbursement penalties implemented by CMS, payer bundled care and clinical specialty designations, and the public reporting of quality rating systems, including CMS Five Star, have resulted in the recognition that coding complications to maximize revenue now carries a significant cost – both financial and reputational. The clear definitions provided to MBSCRs by MBSAQIP are a valuable resource for programs to educate all clinical providers in negotiating these dual objectives – and to ensure accurate reporting of administrative data. A valuable exercise is for programs to analyze differences between coding and the clinical record in a test group of cases. Their goal is to balance coding with clinical data to accurately reflect patient outcomes in public reporting. These efforts will require discussion and coordination with hospital leadership and finance as they will undoubtedly result in diminished revenue from payers that continue to reimburse complications. The ability of MBS leaders to understand and articulate the implications of reimbursement penalties for poor-quality care as well as the opportunities presented by bundled-care reimbursement is critical to maintaining their reputation as a quality program.

Clinically derived data is collected within the ACS National Surgical Quality Improvement Program (NSQIP) and MBSAQIP registries. It is regarded as the highest-quality data available due to standardized definitions and trained, impartial third-party clinical reviewers. In a comparison of the NSQIP clinical data with CMS Compare website data, a significant difference was noted between the two data sources. CMS Compare data has a high error rate due to coding inaccuracies. As outlined earlier in the chapter, the MBSAQIP Data Registry was approved as ACS's first Qualified Clinical Data Registry (QCDR) by CMS. The Affordable Care Act requirement for "meaningful use" of electronic health records (now called Advancing Clinical Information) creates an opportunity for large repositories of data ("big data") that have the potential to answer complex care questions. Several of the larger EMR vendors currently have steering committees working to develop tools to extract EMR data into NSQIP and MBSAQIP registries.

There is no doubt that the collection of high-quality data is costly. This up-front cost for the most part is borne by the accredited hospital. However, hidden costs include the time and work effort of surgeons to guarantee that the data being collected is accurate. The ABS maintenance of certification requirement implemented in 2013 made this work effort mandatory for board certification. Participation in the MBSAQIP registry assists surgeons in maintaining ABS certification because it is recognized by the ABS. Each surgeon who participates in MBSAQIP or MBSC has the opportunity to examine his or her own data and participate in collaborative process to improve care. The data collection standard was designed to address the changing landscape of American healthcare. Participation has the potential to optimize clinical care, cost of care, and reimbursement. Currently, Dr. Matthew Hutter is leading a project to collect patient-centered outcomes data with funding from the

Patient-Centered Research Institute (PCORI). In collaboration with the ACS and MBSAQIP, this project is currently enrolling beta-sites to participate in a project to better understand the outcomes valued by patients with the objective of improving both care and patient experience.

Collaboration for Quality Improvement

Accreditation is a tool to enhance safety. The surgeon and integrated health team, through the local MBSC, can use the standards manual as a blueprint for the development of a safe program. In order to get significant resources for the program, many hospital systems will require a business plan. In the contemporary era of surgery, surgeons are expected to work collaboratively with the hospital system to provide effective care to patients. Gaining a commitment from the system to collect high-quality data that allows the team to do continuous quality improvement, compare their results, and share best practice through collaboration is a significant step. Clinically rich data provides ample targets for process improvement. A Michigan collaborative project targeted variation in the use of IVC filters. Data suggested eliminating routine IVC filter placement would improve safety with a cost savings of about $2.6 million per year. Both a reduction in complications and a cost savings were realized. Remarkably, the savings from this QI project paid the administrative costs of the Michigan collaborative program [46].

QI also drives both program focus and collaboration, even when surgeons are part of different private practices. While the primary goal of safety is paramount, improving value is a direct result of decreasing complications which are the major driver of variation in cost of care. Also, poor patient experience now results in reimbursement penalties as well as directly impacts provider and patient referrals. Increasingly providing *value* has become the primary target for healthcare reform.

How to Implement QI

The design and implementation of quality improvement (QI) projects consistently rates as one of the most concerning standards in polls of symposia participants. To address these concerns, MBSAQIP provides an online library of educational resources for both potential and participating programs. A webinar entitled 11/10/16: Deep Dive into Standard 7.2 Quality Improvement Process provides step-by-step instructions as a resource to assist centers in the design and implementation of quality improvement projects [47]. Resources for many QI tools are available from both industry and healthcare. MBSAQIP has adopted the DMAIC (define, measure, analyze, improve, control) methodology to educate centers and implement quality improvement projects under Standard 7.2 [48].

The key steps are outlined below:

1. Define:
   - Use the MBS committee as a framework to organize and launch QI projects.
   - MBSAQIP QI projects must be led by the MBS director but design projects to include participation from all providers (surgical and nonsurgical) influencing the targeted care elements.
2. Measure:
   - Review all potential data sources. MBSAQIP semiannual report elements that are identified as "high outliers" require quality improvement initiatives focused on those elements.
   - Non-risk-adjusted reports from the MBSAQIP registry provide an important means to identify quality improvement opportunities in the absence of "high-outlier" elements.
   - Hospital and health system level data may be available to identify targets or benchmarks for QI. Choose an initial target to focus on improvement and assign responsibility for the process.
3. Analyze:
   - Conduct data analysis and choose a timeframe for implementation and review of the ongoing data.
   - Reference benchmark data.
   - Process targets may be most appropriate as early projects.
   - A root cause analysis using the "5 Whys" methodology may be used.
   - Write a problem statement. Example of a QI problem statement:

> Our predicted (adjusted) observed rate for All Cause Readmission for LSG was X% in the 2015 calendar year, which makes us a high outlier in this model. Our goal is to lower our LSG All Cause Readmission rate to the expected rate of Y% by December 31, 2016.

   - Propose a clearly defined intervention.
4. Improve:
   - Implement an intervention to achieve the objective identified in the problem statement.
5. Control:
   - Documentation and data should be presented to the MBS committee at the annual QI meeting (Standard 2.1).

- Documentation of all QI projects is a requirement for accreditation.
- One of the greatest challenges of QI is sustainability. "Hard-wire" processes.

Continuing Education

MBSAQIP Standard 2.7 requires that verified surgeons complete a minimum of 24 AMA PA Category 1 continuing education credit hours over a 3-year cycle. There are many avenues through which members of the local program (both verified surgeons and integrated health members) can seek to improve their knowledge base and satisfy this requirement. As the care standard for patients suffering from obesity and metabolic disease continues to prioritize multidisciplinary collaboration, the importance of understanding the science of obesity becomes paramount. This includes an understanding of the pathophysiology of obesity as well as behavioral and pharmacologic therapies. Bariatric surgical quality and QI educational opportunities abound. The most focused of these is the ACS Quality and Safety Conference which now includes a bariatric track. Others for bariatric providers to consider include Obesity Week, ASMBS Weekend, and the Clinical Congress of the American College of Surgeons.

The Future of Quality in Bariatric Surgery

The future of quality in bariatric surgery remains a high priority for both ASMBS and the ACS. MBSAQIP will launch its third national quality improvement project in 2019. This project will focus on reducing opioid use after bariatric surgery. Studies suggest that about 6% of opioid-naïve patients develop opioid dependence after surgical procedures [49]. The LABS study found similar results in opioid-naïve bariatric surgical patients at 6 months post-op, and the number of opioid-dependent bariatric surgical patients increased to over 14% 7 years post-op [50]. MBSAQIP is committed to assist in national efforts to address the current opioid crisis which may disproportionately impact bariatric surgical patients.

MBSAQIP continues to release the risk-adjusted Participant Use File (PUF) annually and is working toward the development of on-demand risk-adjusted reports. The development of a risk calculator is complex, but the robust data registry provides a resource to develop a bariatric-specific risk calculator as complement to the ACS surgical risk calculator. Resources for the Optimal Care of the Metabolic and Bariatric Surgical Patient: Standards Manual V3.0 are near release as of 2019, and work on the release of refined data registry platform continues as does the ongoing development of education and support infrastructure for MBS directors.

Several key gaps remain in the understanding of surgical interventions treating obesity. The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) convened a public hearing in 2017 to review the available evidence for the "Health Outcomes After Bariatric Surgical Therapies in the Medicare Population." The purpose was to obtain public comment on the findings of an Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program study of evidence for "Short- and Long-Term Outcomes after Bariatric Surgery in the Medicare Population." The conclusion of the AHRQ study was that "very few studies exist that address clinically relevant outcomes in Medicare-eligible patients who undergo surgical or endoscopic bariatric procedures" [51]. The MEDCAC panel reported a low level of confidence in "the predictors of success (of bariatric surgery) in the Medicare population." Their conclusion was largely predicated on the AHRQ assessment, the poor quality of long-term follow-up, and a dearth of studies reporting the outcomes of metabolic and bariatric surgery specifically in Medicare patients younger than 65. MSAQIP is committed to addressing this knowledge gap. The Standard Manual V3.0 will capture payer data including Medicare. It will include new standards, refinement of data fields, and educational initiatives. All are focused on improving the difficult task of long-term follow-up.

Obesity has been identified by healthcare providers, policy-makers, and the public as one of the highest priority healthcare problems in the United States and most other economically developed countries. The number of people who qualify for surgical management of obesity and related disease is growing while access to care continues to improve too slowly. In this environment, increasing numbers of those affected will seek the only durable solution: surgical therapy.

The goals of the current quality effort in bariatric surgery are embodied within the structure of MBSAQIP accreditation: to provide a common framework of best practice to yield safe and effective care to all patients in every setting, to participate in a high-quality registry, and to use the data to improve care at the locally, regionally, nationally, and now internationally. With nearly 900 MBSAQIP-accredited centers, it is clear that bariatric surgeons have embraced both collaboration and quality. MBSAQIP has become a paradigm of a national healthcare culture that demands quality and safety for all patients. The ACS quality programs are becoming this benchmark for all surgical procedures.

The evolution from initial accreditation programs to MBSAQIP has facilitated the ability of surgeons and programs to meet the requirements of the current healthcare environment in a way that improves *value* and long-term effectiveness and decreases cost. The program enables collaboration between providers based on clinically rich,

risk-adjusted data from the MBSAQIP registry rather than administratively derived data. This transparency has proven to be invaluable in a new healthcare environment. Reporting of outcomes is now unavoidable, and in the absence of high-quality clinical data, the use of less reliable administrative data sources carries at a high price. Currently, metabolic and bariatric surgery is utilized by only a small percentage of eligible patients. It is critical that a framework of safety be maintained around which the delivery of bariatric interventions can expand in a way that continues to offer outstanding value – improved quality and lower cost.

Question Section

1. Which of the following is true about our initial accreditation program – ASMBS Bariatric Surgery Center of Excellence (ASMBS BSCOE)?
   A. Accredited centers were approved to perform bariatric surgery in CMS patients until 2013.
   B. Fifty stapled cases annually were required for center comprehensive designation.
   C. Accredited centers could seek a band-only designation.
   D. BOLD data was used to provide centers with risk-adjusted data semiannually.
2. What is *not* a requirement to achieve high-quality clinical data?
   A. Trained third-party clinical reviewer and abstractor
   B. Strict definitions of adverse events
   C. Adequate documentation in the medical record
   D. Surgeon entering all the data themselves
3. Which of the following is *not* true of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)?
   A. MBS verified surgeons must complete 24 CME credit hours in a 3-year cycle.
   B. MBS clinical reviewers must be directly involved in the clinical care of bariatric patients.
   C. MBS clinical reviewers must be certified and participate in ongoing training.
   D. Accredited centers must perform 50 stapled bariatric cases annually to achieve a comprehensive designation.
4. What finding would ***require*** a program to implement a targeted quality improvement project?
   A. A change in the MBS director
   B. A semiannual report identifying LSG surgical site infections as "needs improvement"
   C. A semiannual report identifying LSG surgical site infections as a "high outlier"
   D. A hospital report identifying LSG surgical site infections as above the health system standard.

References

1. The Joint Commission: Over a Century of Quality and Safety. [Internet] 2018 (cited 2018 Dec 15).Available from: https://jntcm.ae-admin.com/assets/1/6/TJC_history_timeline_through_2018.pdf.
2. Mechanick JI, Garber AJ, Handelsman Y, Garvey WT. American association of endocrinologists position statement on obesity and obesity medicine. Endocr Pract. 2012;18(5):642.
3. Kyle TK, Dhurandhar EJ, Allison DB. Regarding obesity as a disease: evolving policies and their implications. Endocrinol Metab Clin N Am. 2016;45(3):511–20. https://doi.org/10.1016/j.ecl.2016.04.004.
4. Poirier P, Cornier MA, Mazzone T, et al. Bariatric surgery and cardiovascular risk factors. Circ: J Am Heart Assoc. 2011;123:1–19.
5. American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2011 (cited 2018 Dec 18); 32(S1): Available from: http://care.diabetesjournals.org/content/34/Supplement_1/S11.full.pdf.
6. International Diabetes Federation. Bariatric surgical and procedural interventions in the treatment of obese patients with type 2 diabetes. 2011 (cited 2018 Dec 18) Available from: http://www.idf.org/webdata/docs/IDF-Position-Statement-Bariatric-Surgery.pdf.
7. Institute of Medicine. Envisioning a transformed clinical trials enterprise in the United States: establishing an Agenda for 2020-workshop summary. 13 Apr 2012.
8. Nguyen NT, Masoomi H, Magno CP, Nguyen XA, Laugenour K, Lane J. Trends in the use of bariatric surgery, 2003–2008. J Am Coll Surg. 2011;213:261–6.
9. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for bariatric surgery for treatment of morbid obesity (100.1). 2012. 100–3(4).
10. Birkmeyer JD, Shahian DM, Dimick JB, Finlayson SRG, Flum DR, Ko CY, Hall BL. Blueprint for a new American College of Surgeons: National Surgical Quality Improvement Program. J Am Coll Surg. 2008;207(5):777–82.
11. Share DA, Campbell DA, Birkmeyer N, Prager RL, Gurm HS, Moscucci M, Udow-Phillips M, Birkmeyer JD. How a regional collaborative of hospitals and physicians in Michigan cut costs and improved the quality of care. Health Aff. 2011;30(4):636–45.
12. Kennedy JF.. Remarks in Heber Springs, Arkansas, at the dedication of Greers Ferry Dam. The American Presidency Project, 1963. Retrieved 2007-04-07.
13. Birkmeyer NJ, Dimick JB, Share D, Hawasli A, English WJ, Genaw J, Finks JF, Carlin AM, Birkmeyer JD, Michigan Bariatric Surgery Collaborative. Hospital complication rates with bariatric surgery in Michigan. JAMA. 2010;304(4):435–42.
14. Livingston EH, Burchell I. Reduced access to care resulting from centers of excellence initiatives in bariatric surgery. Arch Surg. 2010;145(10):993–7.
15. Staiger DO, Dimick JB, Baser O, Fan Z, Birkmeyer JD. Empirically derived composite measures of surgical performance. Med Care. 2009;47(2):226–33.
16. HealthGrades. 2011. Bariatric surgery trends in American Hospitals. http://www.medicare.gov/hospitalcompare/search.html. Accessed 10 Feb 2014.
17. Resources for the Optimal Care of the Metabolic and Bariatric Surgical Patient: Standards Manual: 2014, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Standards and Pathways Manual [Internet]. 2014 May 1, (cited 10 Sept 2018) Available from: http://www.mbsaqip.org/docs/Resources%20for%20Optimal%20Care%20of%20the%20MBS%20Patient.pdf.
18. Resources for the Optimal Care of the Metabolic and Bariatric Surgical Patient: Standards Manual: 2016, Improving Health and Transforming Lives, Manual [Internet]. 2016, (cited 10 Sept 2018)

Available from: https://www.facs.org/~/media/files/quality%20programs/bariatric/mbsaqip%20standardsmanual.ashx.
19. Grant MC, Galante DJ, Hobson DB, Lavezza A, Friedman M, Wu CL, Wick EC. Optimizing an enhanced recovery pathway program: development of a post implementation audit strategy. Jt Comm J Qual Patient Saf. 2017;43:524–33.
20. ASMBS Quality and Patient Safety Committee. 2019; (cited 2019 Jan 14) Available from: https://asmbs.org/committees/patient-safety.
21. Kotter JP. John Kotter on what leaders really do. Boston: Harvard Business School Press; 1999.
22. Donabedian A. Explorations in quality assessment and monitoring: the definition of quality and approaches to its assessment. Ann Arbor: Health Administration Press; 1980.
23. Birkmeyer JD, Dimick JB. Chapter 2. Performance measures in surgical practice. In: ACS surgery: principles and practice elements of contemporary practice. Hamilton, Ontario, Canada: Decker Publishing Incorporated; 2010. Decker intellectual properties.
24. Iezzoni LI. Risk adjustment for measuring healthcare outcomes. 3rd ed. Chicago: Health Admin Press; 2003.
25. ASMBS, Estimate of Bariatric Surgery Numbers, 2011–2017. 2018. (cited 2019 Jan 14) Available from: https://asmbs.org/resources/estimate-of-bariatric-surgery-numbers.
26. El Chaar M, Stoltzfus J, Gersin K, Thompson K. A novel risk prediction model for 30 day severe adverse events and readmissions following bariatric surgery based on the MBSAQIP database. Surg Obes Relat Dis. 2019. Publication pending Ref: SOARD_2018_194.
27. Gupta PK, Franck C, Miller WJ, Gupta H, Forse RA. Development and validation of a bariatric surgery morbidity risk calculator using the prospective, multicenter NSQIP dataset. J Am Coll Surg. 2011;212:301–9.
28. Nguyen NT, Masoomi H, Laugenour K, Sanaiha Y, Reavis KM, Mills DS, Stamos MF. Predictive factors of mortality in bariatric surgery: data from the Nationwide inpatient sample. Surgery. 2011;150(2):347–51.
29. Finks JF, Kole KL, Yenumula PR, English WJ, Krause KR, Carlin AM, Genaw JA, Banerjee M, Birkmeyer JD, Birkmeyer NJ, for the Michigan Bariatric surgery collaborative from the Center for Healthcare Outcomes and Policy. Predicting risk for serious complications with bariatric surgery. Ann Surg. 2011;254(4):633–40.
30. DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. Surg Obes Relat Dis. 2007;3(2):134–40.
31. DeMaria EJ, Murr M, Bryne TK, Blackstone R, Grant JP, Budak A, Wolfe L. Validation of the obesity surgery mortality risk score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. Ann Surg. 2007;246(4):578–82.. discussion 583–4
32. Tan A, Ashrafian H, Scott AJ, Mason SE, Harling L, Athanasiou T, Darzi A. Robotic surgery: disruptive innovation or unfulfilled promise? A systematic review and meta-analysis of the first 30 years. Surg Endosc. 2016;30:4330–52. https://doi.org/10.1007/s00464-016-4752-x.
33. Schwaitzberg SD. Financial modeling of current surgical robotic system in outpatient laparoscopic cholecystectomy: how should we think about the expense? Surg Endosc. 2016;30:2082–5. https://doi.org/10.1007/s00464-015-4457-6.
34. Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. Ann Intern Med. 2001;137:511–20.
35. Liu JH, Zingmond D, Etzioni DA, et al. Characterizing the performance and outcomes of bariatric surgery. J Gastrointest Surg. 2002;6:855–61.
36. Smith MK, Patterson E, Wahed AS, Belle SH, Bessler M, Courcoulas AP, Flum D, Halpin V, Mitchell JE, Pomp A, Pories WJ, Wolfe B. Relationship between surgeon volume and adverse outcomes after RYGP in Longitudinal Assessment of Bariatric Surgery (LABS) study. Surg Obes Relat Dis. 2010;6:118–25.
37. Courcoulas A, Schuchert M, Gatti G, Luketich J. The relationship of surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. Surgery. 2003;134:613–23.
38. Weller WE, Rosati C, Hannan EL. Relationship between surgeon and hospital volume and readmissions after bariatric operation. J Am Coll Surg. 2007;204:383–91.
39. Birkmeyer NJO, Dimick JB, Share D, Hawasli A, English WJ, Genaw J, Finks JF, Carlin AM, Birkmeyer JD. Hospital complication rates with bariatric surgery in Michigan. JAMA. 2010;304(4):435–42.
40. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. N Engl J Med. 2009;361:1368–75.
41. Nguyen NT, Nguyen B, Nguyen VQ, Ziogas A, Hohmann S, Stamos MJ. Outcomes of bariatric surgery performed at accredited vs. nonaccredited centers. J Am Coll Surg. 2012;215:467–74.
42. Alamab N, Hobbelinka EL, van Tienhovena AJ, van de Venc PM, Jansmad EP, Nanayakkaraab WB. The impact of the use of the Early Warning Score (EWS) on patient outcomes: a systematic review. Resuscitation. 2014;85(5):587–94. https://doi.org/10.1016/j.resuscitation.2014.01.013.
43. Dimick JB, Staiger DO, Birkmeyer JD. Ranking hospitals on surgical mortality: the importance of reliability adjustment. Health Serv Res. 2010;45(6 Part I):1614–29.
44. Dimick JB, Birkmeyer NJ, Finks JF, Share DA, English WJ, Carlin AM, Birkmeyer JD. Composite measures for profiling hospitals on bariatric surgery performance. JAMA Surg. 2014;149(1):10–6.
45. Petrick AT, Still CD, Wood CG, Vitunac MA, Plank M, McGrail L, Strodel WE, Gabrielsen JD, Rogers j, Benotti P. Feasibility and impact of an evidence-based program for gastric bypass surgery. J Am Coll Surg. 2015;220:855–62.
46. Birkmeyer NJO, Share D, Baser O, Carlin AM, Finks JF, Pesta CM, Genaw JA, Birkmeyer JD, for the Michigan Bariatric Surgery Collaborative. Preoperative placement of inferior vena cava filters and outcomes after gastric bypass surgery. Ann Surg. 2010;252(2):313–8.
47. Ask MBSAQIP: Deep Dive into Standard 7.2 Quality Improvement Process | Standard 7.2 QI Process PowerPoint. 2016 Nov 10; (cited 2019 Jan 5): Available from: https://www.facs.org/quality-programs/mbsaqip/ask-mbsaqip.
48. Minnesota Department of Health, Quality Improvement and Performance Management. (cited 2018 Oct 15.): Available from http://www.health.state.mn.us/qi/.
49. Brummett CM, Waljee JF, Goesling J, Moser S, Lin P, Englesbe MJ. New persistent opioid use after minor and major surgical procedures in US adults. JAMA Surg. 2017;152(6):e170504. https://doi.org/10.1001/jamasurg.2017.0504.
50. Raebel MA, Newcomer SR, Reifler LM, Boudreau D, Elliott TE, DeBar L, Ahmed A, Pawloski PA, Fisher D, Donahoo WT, Bayliss EA. Chronic use of opioid medications before and after bariatric surgery. JAMA. 2013;310(13):1369–76.
51. Panagiotou OA, Markozannes G, Kowalski R, Gazula A, Di M, Bond DS, Ryder BA, Adam GP, Trikalinos TA. Short- and long-term outcomes after Bariatric Surgery in the Medicare Population, Technology Assessment Program, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. 2018 Sept 5; (cited 2018 Sept 23) Available from https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/bariatric-surgery/bariatric-surgery-medicare-final-report.pdf.