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Chapter Objectives

1. Review the history of bariatric surgery and the problems that led to a need for quality assurance to improve patient safety.
2. Review quality standards, accreditation, and data collection requirements among various bariatric surgery programs.
3. Identify the key elements of quality healthcare.

Introduction

Quality is not an act, it is a habit.

– Aristotle

The movement to reduce variation in outcomes of surgical procedures has become a critical component of the efforts to improve the value of healthcare. Throughout the history of surgical intervention, surgeons have been keenly interested in improving patient safety, and in almost every surgical field improvements have been made. Metabolic and bariatric surgeons, criticized for offering operations to patients who suffer from the “lifestyle” disease of obesity, have by necessity embraced accreditation as a pathway to provide a structure of programmed longitudinal care. Collecting data, reporting of outcomes, and using outcomes for improvement within the structure of accreditation serve to garner the support of hospitals, staff, and colleagues for these efforts and provide an economic context for the inclusion of integrated health staff in the longitudinal pathway of care. In the history of surgery, there may not have been a more focused or successful

effort, resulting in a reduction of mortality from 0.5 % (1/200) patients in 2004 [1] to 0.06 % (1/1,750) patients in 2013 in programs doing more than 50 laparoscopic stapled cases in accredited centers [2].

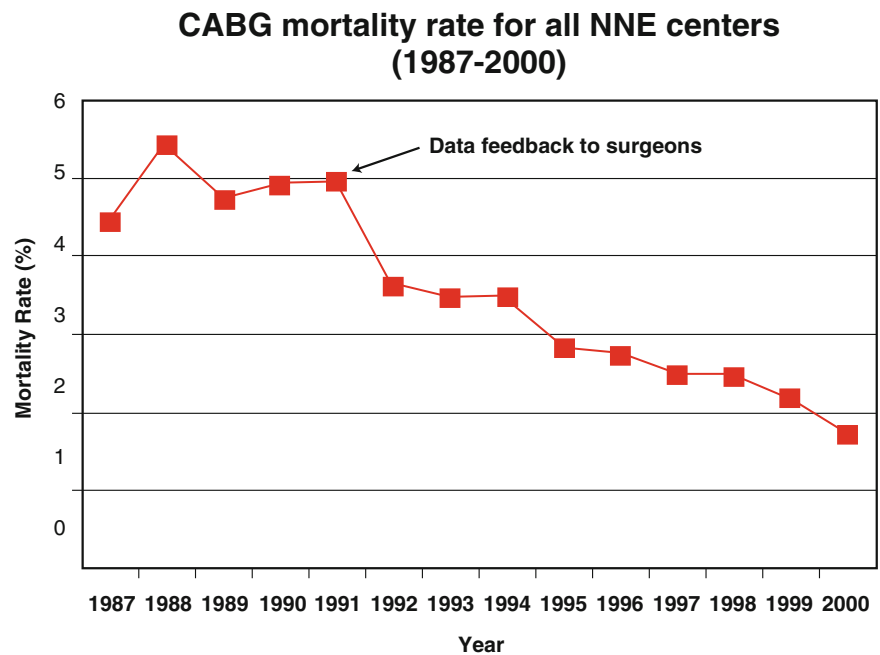
The hallmark of quality in surgery is reduction in variation. Sometimes it falls to outside agencies to point out that we have a problem. A pivotal early example involved cardiothoracic surgery. In 1986, the United States Department of Health and Human Services Health Care Financing Administration (HCFA) released a report pointing to wide variation in the mortality of cardiothoracic surgery. Cardiothoracic surgeons in the Northeast, who disbelieved the administrative data used by HCFA, formed the Northern New England Cardiovascular Disease Study Group in 1987. They were sure if they could provide clinically rich data that it would dispute the government’s claim. To their surprise, the data confirmed the findings. Their findings included all consecutive coronary artery bypass grafts (isolated) within all centers and by all surgeons in Vermont, Maine, and New Hampshire from 1987 to 1989. Reported in 1991, the hospital mortality varied from 3.1 to 6.3 % (4.3 % average) and surgeon-specific mortality from 1.9 to 9.2 % [3]. After the announcement of these findings, a decline occurred in the variation; the first inflection was in just making the programs and centers aware of the results (Hawthorne effect) [4]. Sharing of best practice and structured improvement process led to further gains, driving the mortality to its lowest level of under 2 % by 2001 (Fig. 14.1) [5].

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 way. First, they do not believe the information; then, they question whether it is adjusted for the level of risk of the patient; and finally, they accept it and immediately begin to try and figure out how to improve. While data collection has always been the hallmark

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Fig. 14.1 Coronary artery bypass graft (CABG) mortality rates for Vermont, Maine, and New Hampshire from 1987 to 2000. Data from Northern New England (NNE) Cardiovascular Disease Study Group



of the academic surgeon, because of the strong effect that knowing outcomes has on surgeon behavior, in 2013 it has become required for all surgeons in practice as part of maintenance of certification part IV [6]. In addition, accumulating high-quality data through well-designed prospective, randomized studies that includes strict study design, data collection, and publication occurs in such a long cycle of time that it may become irrelevant to some degree in terms of the use of data to impact quality immediately and improve care for individual patients at the local level of care in real time and on an ongoing basis. In addition, once results of these trials are published, the individual surgeon/program has to know of the data and be able to integrate it into their own course of care—a daunting task for busy clinical practitioners. While level 1 data remains the gold standard, questions about cost and applicability to community practice have been raised leading to a movement led by the Institute of Medicine to define and revise the clinical trial infrastructure [7].

Initial efforts were made to establish a voluntary bariatric registry by Edward Mason, MD. He writes:

We began the International Bariatric Surgery Registry (NBSR/IBSR) in 1985 with Kathleen Renquist as Manager. The goal was to assist in continuing improvement of results. IBSR was run in the Department of Surgery. We had full financial support from one of the staple companies for the first two years. Subsequent support was to come from participating surgeons who were voluntary members and had the additional expense of their satellite program of data collection and reporting. We had a computer programmer, who worked full time or part time as needed. A graduate student from the College of Preventive Medicine assisted the Manager. There was a full-time secretary for a few

years. A professor from Preventive Medicine provided advice regarding statistical work and consultation for the graduate student. I functioned as director. We used the University Computer Center for storage of data and our own computers in the IBSR office for preparing reports of results, publishing the Newsletter and papers for journals. IBSR provided software, training and instruction manuals for collecting, storing, and preparing reports of local data for comparison with the total data reported. Reports of local results for lectures or publication could be prepared using the IBSR software, which was provided to each satellite for data collection. Special reports from IBSR pooled data were provided when requested for cost of preparation. Direct access to the Registry data was limited to those working in the central office. The manager published quarterly reports to each satellite surgical practice, which provided comparison of the contributed results with total IBSR results. A newsletter containing two sections was published twice a year. I wrote a section for surgeons and Kathleen wrote a section for the people who were collecting and reporting data. The ultimate closure of IBSR resulted mainly from inadequate financing. There is no access now to the data collected or reports and publications.

At this early stage, 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 Clarke, MD, and Alan Wittgrove, MD, documented performance of a gastric bypass with laparoscopic access. This one controversial change in approach to the procedure heralded the acceleration of adoption by patients who were seeking help for obesity—in part because of the publicity that surrounded the laparoscopic gastric bypass of Carnie Wilson,

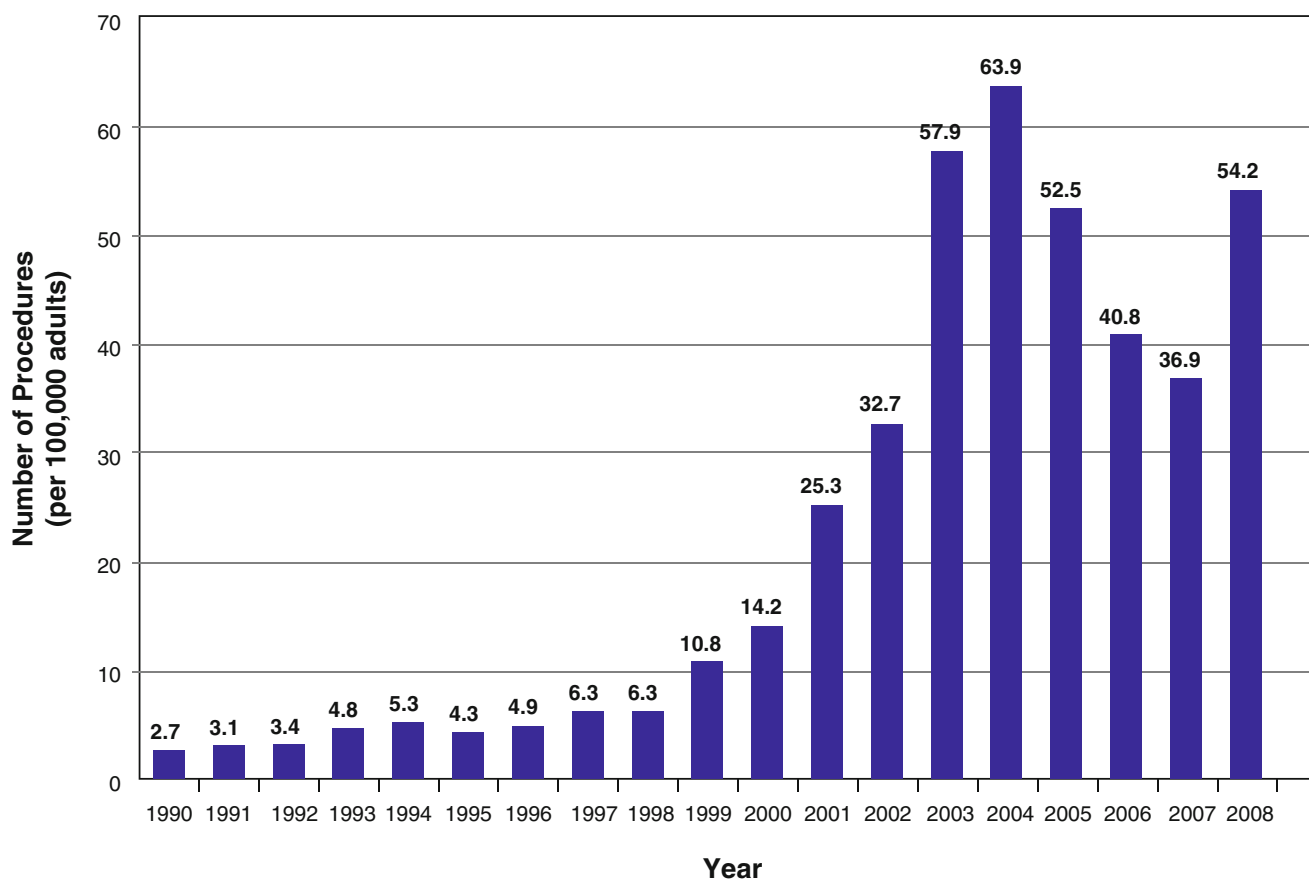


Fig. 14.2 Growth in bariatric surgery procedures from 1990 to 2008

a popular singer who told her story in *People* magazine. In the early part of that decade, general surgeons—many of whom had never practiced bariatric surgery—took a weekend course and, with little training or program structure, started offering the procedure. The number of bariatric cases increased rapidly to a peak in 2009 (Fig. 14.2) [8]. What had been heralded as a step forward quickly led to a host of complications and deaths that threatened to swamp the nascent specialty and close down access to care. Payers, employers, and others began to drop the procedure as the cost of surgery mounted. In one single year (2005), the entire State of Florida lost all effective access to care unless a patient was able to self-pay for a procedure. Malpractice claims jumped, causing insurance to become extremely expensive if it was available. Bariatric surgery, and the patients who need surgical therapy for obesity and related disease, was in crisis and patients were on the verge of losing all access to the procedures.

Payers were not pleased with the red ink they saw from the increase in complications. Faced with increasing demand by employers and patients, they stepped up to manage the situation. Payers had experience in managing high-risk specialties, having had to manage transplantation networks for

many years. In conjunction with employers, they began designing similar systems to try and control access to bariatric surgery. In Las Vegas, several unions and employers expressed concerns regarding data indicating expensive complications for an elective surgical procedure. However, people suffering from obesity who worked for Caesar's Entertainment group were unrelenting in their applications for coverage to the management of Caesar's. Finally, a junior executive, Mr. Scott Haverlock, partnered with First Health and designed a request for application (RFA) to participate in a small, exclusive network in order to provide bariatric surgery to employees of Caesar's Entertainment group. Their consultant identified 11 programs in the Southwest that had outcomes/program structure that he thought was acceptable and the RFA was sent out to those programs. Nine programs responded and three were invited to come to Las Vegas to meet with Mr. Haverlock and the First Health team at Caesar's to determine if they could provide safe care and be good business partners. Two programs were selected and then the negotiation of the actual contracts took place. By early 2005, this prototype of the payer/employer-driven center of excellence was in place and patients were being referred only into this network.

In response to the crisis, the leadership of the American Society for Bariatric Surgery (ASBS) stepped up to put in place a unique and controversial solution: accreditation for programs in bariatric surgery with a qualifying volume of 125 cases per year. This vote for the program occurred during the annual business meeting chaired by President Alan Wittgrove, MD. Walter Pories, MD, delineated a description of the concept to the surgeons at the business meeting. Discussion ensued with respect to the idea of stratification put forth by invited guest Thomas Russell, MD, president of the American College of Surgeons (ACS). Finally, the motion to approve the concept of Bariatric Surgery Centers of Excellence (BSCOE) without stratification was approved by an overwhelming majority of the surgeons present. When the program was implemented, the impact was severe with approximately 1/3 of programs leaving the field as insurance carriers began to limit their networks to just the programs within the BSCOE. There was a contraction in access to bariatric surgery, particularly in rural areas. In a landmark national coverage decision on bariatric surgery in 2006, the Centers for Medicare and Medicaid Services (CMS) chose to allow procedures only at centers accredited by the ACS or ASMBS [9]. Gradually access rebounded to pre-NCD levels [10].

The original goals of the ASMBS BSCOE program are stated in an article authored by Ken Champion, MD, and Walter Pories, MD, published in *Surgery for Obesity and Related Diseases* (SOARD) in 2005: “The purpose of a COE program is to provide the means for the public and interested parties to identify programs in bariatric surgery that provide a comprehensive and standardized program of surgical care and long-term follow-up and management of the morbidly obese patient. The routine reporting and compiling of outcomes from bariatric surgical patients will provide an opportunity to assess and verify risks and benefits of therapy, which can potentially resolve many of the conflicts over the role of surgery in severe obesity. In addition, the COE program may challenge inadequate programs to improve their standards, education, and training to meet the guidelines” [11].

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

When the BSCOE program was developed in 2004, the ASMBS established ten standards by which facilities and surgeons would be evaluated as providing excellent quality of care in bariatric surgery (Table 14.1). The BSCOE designation became a commercially valuable designation, with some insurance payers, including the Centers for Medicare and Medicaid Services (CMS) requiring the designation in order to participate in their network of care.

Table 14.1 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

The society established an outside not-for-profit company, called the Surgical Review Corporation (SRC), to administer the program. The ASMBS and SRC entered into an initial 6-year contract in 2004. The registry, Bariatric Outcomes Longitudinal Database (BOLD), was established in 2006 and fully subscribed to as a requirement for members to participate in 2008/2009. At the time the SRC was established, the leadership of ASMBS believed that establishing a separate not-for-profit company to remain at arm’s length from the actual designation of programs would protect the integrity of that process. The result, however, was that as the terms of office of the original board members expired, they were rotated off. The board began to reflect less involvement of the current leadership of ASMBS, weakening communication. The leadership of ASMBS believed that they had no direct control of the program that granted accreditation under its name through the contract that had been executed. Although bariatric surgeons who were ASMBS members populated the committees at SRC, ASMBS leadership believed there was no control through the Executive Council of decisions made by SRC and that impacted the program or the membership. This included the use of funds for development of the program, the strategy of the programs development, and contracting for release of data to outside parties. Most importantly, the program was growing organically through decisions made by the SRC committees. These decisions had secondary consequences to programs that were outside the oversight of the society. Throughout time, these difficulties in communication, direction, and oversight led to frustration on the part of ASMBS leadership. This began during the presidency of Phil Schauer, MD, when SRC established the International Centers of Excellence program (not sanctioned or supported by ASMBS), apparently with funds generated by the fees that had been paid to SRC through the accreditation of programs by the ASMBS. This distraction in the business model diverted time, money, and attention away from SRC’s primary service to the society. Difficulties continued through the presidencies of Kelvin Higa, MD, and Scott Shikora, MD. Finally, during the presidency of John Baker, MD, a new 5-year contract was negotiated in an

Table 14.2 Total number of 2011 ASMBS BSCOPE programs before transition to MBSAQIP

	Hospitals	Surgeons
Full approval	458	849
Provisional approval	143	260
Provisional in process	83	147
Total participants	684	1,256

attempt to address the concerns. It was executed in June 2010. This new contract sought to establish a clear relationship between the ASMBS and SRC in terms of control of the program. SRC was designated to manage the application process, site visits, and the collection of data in BOLD. ASMBS was responsible for establishing the guidelines and direction of the program as well as directing the use of BOLD data through the ASMBS Research, Data Access, and Data Dissemination Committees. All proposals for the use or release of data from BOLD were required to come through ASMBS committees and leadership. Income generated from any release of BOLD data was to come to ASMBS. The SRC had by this time established other programs, including the International Center of Excellence (ICE) program and the American Association of Gynecologic Laparoscopists (AAGL) Center of Excellence program. SRC had the contractual authority to develop other programs, although the resources of the ASMBS BSCOPE program were contractually segregated financially from the use in other programs. The ASMBS also was assured of SRC's ability to establish new BSCOPE programs. Of note, the SRC was contractually prohibited from interacting with payers on behalf of the ASMBS BSCOPE. The support of the program by members of the society was robust (Table 14.2).

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

In a parallel effort, the ACS established their own Bariatric Surgery Center Network (BSCN), with somewhat similar standards and reporting requirements. The ACS had established twin missions of education and quality and had partnered with societies on programs in trauma—established the Committee on Trauma in February 1976 in collaboration between the ACS and the AAST (the American Association for the Surgery of Trauma)—and cancer. This equivalent effort in bariatric surgery by ACS, rather than a collaborative one, resulted largely from a disagreement between ASMBS and ACS regarding the need for outside stakeholders to participate in the executive direction of the program by being part of the SRC board and the use of a third-party (SRC) to administer the program instead of partnering directly with the ACS. It was the position of the ACS that the specialty society (ASMBS) is best able to deter-

Table 14.3 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	

mine what constitutes quality in our field and that arm's length relationships were not necessary. The ACS also was concerned that some interests by individuals involved in SRC might not be in alignment with the mission of the college. An examination of the ACS BSN program demonstrated some philosophical and practical differences between ASMBS and ACS:

1. The control and direction of the program by ACS rested solely with ACS without involvement of a third party.
2. The ACS program required certification of the hospital and had no requirement regarding individual surgeon volume or certification of surgeons individually.
3. Surgeons instead of nurses as in the ASMBS program performed the site visits.
4. The burden and financial obligation to pay for data collection in the ACS program rested with the hospital instead of being placed on the individual surgeon/practice.
5. Data collection was made by an independent clinical reviewer and not by someone who participates in the bariatric program.

Finally, in an effort to provide a solution for low-volume programs, the ACS BSCN had evolved to include a level 2 designation for programs with lower volumes of cases within a specific window of risk-adjustment requirements. Data began to accumulate on these centers that showed similar outcomes at lower volumes within the context of an accreditation program.

As of October 2011, the ACS BSCN reported a total of 137 programs at the October Bariatric Surgery Committee meeting (Table 14.3). There was no evidence that an arm's length relationship was necessary to establish credibility with outside stakeholders. In fact, all payers similar to the ASMBS program including Medicare accepted the ACS program. The effort in bariatric surgery was part of a strategy to promote quality across all disciplines in surgery through the National Surgery Quality Improvement Program (NSQIP) [12]

The Michigan Bariatric Surgery Collaborative (MBSC)

The MBSC (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 three major components:

1. A clinical registry with rich-enough detail to allow for risk adjustment.
2. Hospitals and physicians receive risk-adjusted and confidential feedback.
3. Hospitals and surgeons convene to review and interpret the data, identify best practices, and implement them across the region. The actual process for implementation is done on the local level based on the resources available.

This model was adopted in the state of Michigan in partnership with Blue Cross Blue Shield (BCBS) of Michigan (representing 47 % of covered lives in Michigan) that funds the central administration of the program and reimburses surgeons/facilities to enter the data. The data are confidential and not accessible to BCBS. The data is collected through a central data management center with independent third-party abstractors. There is an annual audit of the data reported by the hospitals. Approximately 6,000–8,000 patients per year participate in the program, and all but one bariatric program/surgeon in Michigan participates [13].

The serious complication rate in Michigan has declined from approximately 5 to 2.5 % in the most recent publications, a result that is directly related to the program's Collaborative Quality Initiatives (CQI) [14]. Gradually in Michigan, even surgeons who were initially skeptical or reluctant have come around to be supportive. One surgeon said, "quality and performance are going to drive our collective future, it is nice to have guidance and ownership in the process." The strength of the program revolves around the integrity and quality of the data and the leadership of the collaborative effort. The Michigan program was organized around the idea of improving all programs/surgeons who cared to join, a rising tide lifts all boats [15]—a marked difference in philosophy from choosing only the best programs (exclusionary philosophy) invoked by the ASMBS in its first BSCOE effort.

Ideally, the model for statewide collaboration could be adopted by state chapters within ASMBS, as in all but five states the top one or two insurers have market shares of more than 50 % and in 18 states they have shares higher than 75 % [16].

Why Did the ASMBS BSCOE Need to Evolve?

In 2010, an article was published in the *Journal of the American Medical Association* (JAMA) by John Birkmeyer, MD, and members of the MSBC that illustrated that the incidence of serious complications was unrelated to whether a program was an ASMBS BSCOE or not [17].

This prompted BCBS to remove the requirement that programs in Michigan had to be a part of the ASMBS BSCOE in order to operate on BCBS patients. In addition, some questions had been raised about access to care after Medicare limited bariatric surgery to the BSCOE and BSCN networks [18]. Although both papers were widely viewed by society leadership as flawed (outlined in the commentary of the paper by Bruce Wolfe, MD), they raised questions about the differences between the accreditation program and the collaborative effort based on evaluation of outcomes in Michigan. A critical evaluation of the BSCOE program revealed the following opportunities to evolve:

- The BSCOE accreditation process was not able to discriminate between those programs that were excellent and those that were not. Using the initial quality matrix, programs were accredited based on structural and process elements only, not on outcomes. Centers who achieved national accreditation might not have good outcomes or excluded programs might have excellent outcomes. Those programs with poor outcomes were not required to have a mechanism to examine the data and improve. Although still overwhelmingly supported by commercial insurance and CMS (at that time), some payers, like Blue Cross Blue Shield (BCBS) of Michigan and Leapfrog, had moved away from requiring that a program have accreditation through ASMBS to qualify as a provider in their network. These were possible early signs of what was to come with other payers. This has come full circle with the Medicare decision to drop the accreditation requirement for CMS patients in the summer of 2013.
- The BOLD registry, despite having a large volume of data collected, was plagued by numerous issues including nonspecific definitions, bias of reporting, inadequate long-term follow-up, the requirement for high numbers of entered variables, lack of specificity of purpose (accreditation versus research), and inability to generate reports on outcomes that could be used for quality improvement. The database had not provided any risk-adjusted data in feedback back to the programs that entered the data since its implementation in 2007.
- The volume requirement had the effect of "exclusion" of many surgeons/hospitals. In addition, it was difficult for new programs to get started and they went through their entire learning process before they entered the program rather than being able to utilize the best practices of the program from the beginning. This also kept good surgeons from being able to transfer to new locations. The volume requirement became difficult to maintain in many programs as the economy worsened. In fact, as the volumes started to come down around the country in response to the recession, more than 35 % of programs were not going to qualify in the next round of accreditation. SRC had arbitrarily lowered the volume standard by allowing

programs to average volumes throughout a 3-year period in partial response to this problem to accommodate the volume issue, but this change contravened the intention of the standards because no examination of lower volumes had been made that justified the change. Finally, because of the volume requirement very little, if any, data existed on safety with lower volumes.

- Process and structural requirements expanded. They were established in an era where expert opinion rather than peer-reviewed data was used to justify them. These had not been systematically reexamined for relevancy and were often expensive additions to program structure, especially for rural and smaller hospitals. The extent to which these requirements impact quality and patient safety was unknown.
- Technology (better stapling technology), new procedures (gastric sleeve), and new techniques (laparoscopic access) contributed to an improvement of mortality, but serious complication rates still remained high for stapled procedures. All procedures were thrown equally into the mix for accreditation, although the adjustable gastric band had a much lower complication rate. So accreditation was considered equal even if one surgeon was doing 100 % adjustable gastric band, and another had a more complex case mix.
- Members of ASMBS did not clearly understand the role and responsibility of ASMBS versus SRC in the program. It was difficult for the society to achieve accountability with a third-party administrator. Only one bariatric surgeon remained on the board of SRC at the time of the eventual transition to partnership with the American College of Surgeons.
- The existence of two quality programs (ASMBS BSCOE and ACS BSCN), and one state-based collaborative all with different standards, created confusion for surgeons, facilities, and payers and duplication of effort.
- Medicine was changing. Better outcomes are being linked to pay for performance through the National Quality Forum. Future reimbursement through a pay-for-performance system of care would require the ability to predict quality and control costs associated with care and thereby improve value. There was no mechanism in the BSCOE program to achieve this because the data was not accessible. Ideally, the effort being expended by programs and surgeons to report outcomes could be used to meet these requirements and improve their reimbursement.
- Data was published that indicated that measuring outcomes using risk-adjusted and reliability-adjusted composite quality measures might be more efficient at predicting quality than volume or risk adjustment alone—a technique ripe for adoption by payers [19]. Payers (insurance companies and employers) are interested in identifying and sending their insured/employees to

programs that will perform operations with the best outcomes and the lowest complication rates for the best price. Surgeons and programs did not have accessible data through BOLD. They did not know how they performed in comparison with their peers and had no data to use to improve their quality and value to payers, patients, and peers. In lieu of clinical data, public sources of information like HealthGrades and CMS use administrative data reported by the hospital to state agencies as their source of information. These data have poor risk adjustment capability and are flawed by over- and underreporting of complications [20].

- The move to transparency, where patients use the Internet to participate to a greater extent in choosing their surgeons/programs based on public reported data, was becoming a reality.
- Surgeon credentialing had been developed by multiple societies with different recommendations.

In this changing environment, questions arose for the leadership: What is the ASMBS goal in identifying centers of excellence? Are we establishing a threshold of quality that is an acceptable minimum standard? Are we trying to determine which programs offer the best care? Are we providing a template for new programs to begin and practice safely at all times? Are we trying to provide a platform for the study of outcomes and process improvement?

Expectations by patients, hospital administrators, government, and private payers to improve the value (quality/cost) and patient experience of care are fast becoming a reality. The ASMBS BSCOE program had to be updated or it would have become irrelevant, a dangerous problem for patients if access improved and the number of surgeons doing these procedures once again expanded rapidly.

The Process of Evolution

It was this analysis and these questions that provided the basis for the society to begin a reevaluation of its own accreditation program in order to meet the challenges of the future. In February of 2011, Bruce Wolfe, MD, and the Executive Council of ASMBS established a new committee, the ASMBS Quality and Standards Committee, to provide oversight of the BSCOE program and to undertake a complete evaluation of the program in the context of the current science of quality. This committee was made up of a wide group of stakeholders representing different constituencies in the society and the SRC, and also included stakeholders that represented the other groups in the United States who developed quality programs in bariatric surgery (ACS and the Michigan Bariatric Surgery Collaborative) (Table 14.4). This effort was designed to facilitate collaboration between all groups on a future integrated program that would eventually

Table 14.4 ASMBS Quality and Standards Committee (QSC)

<i>Chair/Cochair</i>	Robin Blackstone, MD	Barry Inabnet, MD	Dr. Inabnet also chairs the subcommittee to align surgeon credentialing guidelines (ASMBS, ACS, SAGES)
<i>Representing ASMBS committees</i>	State and local chapter	Lloyd Stegemann, MD	
	Research	Ranjan Sudan, MD	
	Bariatric training	Samer Mattar, MD	
	Insurance	Jaime Ponce, MD	
	Pediatric	Marc Michalsky, MD	Kirk Reichard, MD
	Access to care	John Morton, MD	
	Integrated health	Karen Schulz, RN	
	Rural subcommittee	Wayne English, MD	
	International	Raul Rosenthal, MD	
<i>Representing ACS</i>	Ninh Nguyen, MD	Matt Hutter, MD	
	Chair of ACS Bariatric Committee	Bariatric NSQIP Database Expert	
<i>Representing MBSC</i>	John Birkmeyer, MD	Justin Dimick, MD	Nancy Birkmeyer, MD
<i>Representing SRC</i>	David Provost, MD	Debbie Winegar, PhD	Lynne Thompson, RN
	Chair of the Bariatric Surgery Center Review Committee	BOLD Database Expert	Representing Site Inspectors/Process of Certification
<i>At large members</i>	David Flum, MD	Joe Nadglowski	
	Quality expert	Executive Director, ASMBS Foundation, CEO of Obesity Action Coalition	

replace the initial adoption of accreditation by ASMBS and ACS and seek to correct deficiencies in the current programs to facilitate improved patient safety and further the culture of safety by surgeons and program teams.

After the formation of the committee, the leadership met with the SRC in March 2011 to discuss the committee and ensure their participation as the long-standing vendor of the program. At that meeting, it was decided that the responsibility for management of the data would be transferred to the ASMBS under the leadership of the Research Committee as had been outlined in the contract. Ranjan Sudan, MD, the ASMBS Research Committee Chair, and Debbie Winegar, PhD, from SRC developed an organizational document regarding the transfer of responsibility. In addition, Dr. Provost, Dr. Winegar, and Lynne Thompson, RN, were designated by the SRC to participate in the committee as official representatives. Dr. Blackstone; past-President Bruce Wolfe, MD; and SRC BOLD database expert Debbie Winegar, PhD, met with John Birkmeyer, MD; Nancy Birkmeyer, MD; and Justin Dimick, MD, of the Michigan Bariatric Surgery Collaborative in August 2012 to understand the strengths of the Michigan Collaborative. Following that meeting, Dr. Blackstone met with the SRC—including Neil Hatcher, MD, Medical Director for SRC; Michael Hartney, ESQ, in-house council for SRC; David Provost, MD; Wayne English, MD; Debbie Winegar, PhD; Lynne Thompson, RN; and Georgeann Mallory, RD, Executive Director ASMBS, in Raleigh, NC—to discuss the future direction of the program. There was unanimous consensus to move forward with this

process. In late August, a white paper laying out the scientific arguments for change was developed by the president of ASMBS Robin P. Blackstone, MD; this was widely circulated for comment and input to the leadership of the QSC, SRC and Executive Council, and those comments adopted into the document. In September, the ASMBS Executive Council unanimously endorsed moving forward with the evolution of the quality program based on the evidence provided in the white paper in September of 2011. A specific process was outlined including possible collaboration on an integrated program with ACS. Senior Past ASMBS President John Baker, MD, in December 2010, had initiated initial contact with ACS. David Hoyt, MD, the Executive Director of ACS, gave the Mason lecture at the annual ASMBS meeting in 2011. In late September 2011, a pivotal meeting took place with David Hoyt, MD; Clifford Ko, MD; and Matt Hutter, MD, representing the ACS in Chicago. Robin Blackstone, MD, President; Jaime Ponce, MD, President-Elect; and Ninh Nguyen, MD, Secretary/Treasurer with the results reported to the Executive Council, represented ASMBS leadership. After that meeting, initial interest in possible collaboration was confirmed by both parties. A subsequent meeting was held with the Board of Regents Committee on Research and Optimal Patient Care in October 2012. Based on the recommendation by the Committee, the Board of Regents during that annual clinical congress in 2012 voted unanimously to endorse the process of integration of the two programs. In November and December, an extensive series of webinar town halls were presented to a

large segment of the leadership with broad consensus that the society was moving in the correct direction. To quote our founder, Ed Mason, MD, after attending one of the town hall meetings, “it is easy to gain consensus with the truth.” During this time, a selected group of almost 40 members of ASMBS including members of the QSC and other member surgeons of ASMBS representing a broad spectrum of practice settings within bariatric surgery practice were reworking the white paper to establish the interlocking set of initial proposals that were presented to the membership for public comment in December 2012.

One of the most important aspects of understanding and evaluating the BSCOE quality system was to evaluate the registry. The QSC reviewed all the available data registries including BOLD, BCSN (ACS), and MBSC registries. A contract for an outside evaluation of the BOLD database for strengths and weaknesses was executed. The aggregate data was taken from BOLD as of September 30, 2011, and sent for an outside third-party analysis (ArborMetrix) where the weakness and strengths of the data were evaluated. The data was used to provide initial information to the Committee and Executive Council about the relative strength of volume as compared to a composite measure for judging the safety record or a program that participated in the network.

In December, the white paper was published to the membership in five separate segments, which included the proposals for integration of the ASMBS and ACS programs and initial proposals of mechanisms for integrating the standards of both programs. In early January of 2012, a meeting was held in Dallas with multiple surgeons and integrated health members representing diverse practice settings, MBSC and ACS representatives, and data experts to discuss the proposals made in the five-segment publication and determine a future process.

The ASMBS has embarked on an evaluation of our current BSCOE program. Throughout the last 10 months, many of our colleagues have been working in ASMBS committees and sub-committees evaluating different parts of the current program and making proposals for an evolution of the program. Those proposals are now ready for member comment and input. Once you have reviewed this information, we would appreciate your comments. December 2012, Robin Blackstone, MD, President of ASMBS.

Meanwhile, in the background of this effort to evolve the ASMBS BSCOE program, difficulty in the relationship with SRC continued. The perception by the ASMBS leadership was that SRC continued to show evidence that they were unwilling to accept the leadership of the ASMBS and Executive Council and QSC in regards to the program and, in addition, ASMBS was concerned that the contract between the two parties had been breached. The ASMBS attorney and accounting firm conducted a careful analysis of the situation and presented those findings to the Executive Council. In addition, with the publication of the five segments outlining a future relationship of collaboration rather than conflict



Fig. 14.3 Logo of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) (Reprinted by permission of the American College of Surgeons)

with the ACS, the SRC sent a letter indicating they would not collaborate or participate and plans were made by the SRC leadership and board to provide their own independent COE program in bariatric surgery. It was in this environment that the society sought an injunction against such action by SRC and terminated their contract effective April 1, 2012.

In January 2012, a business plan was developed that examined whether it was financial feasible for ASMBS to establish their own BSCOE program. A proposal was also developed to partner with the ACS. In January, at the Executive Council retreat, these proposals were evaluated in detail. The ASMBS, at this time, had a total endowment of just under \$4 million. Based on the business proposal, ASMBS would not have been able to fund the program alone. In addition, excluding the ACS from partnership isolated ASMBS from the mainstream work going on in surgical quality. After careful consideration of all aspects of the opportunities that were presented, the Executive Council voted unanimously to support integration with the ACS into a combined program. The Board of Regents of ACS ratified this decision in a unanimous vote in February 2012. On April 1, 2012, the ASMBS and ACS integrated their two quality programs into one program: the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) (Fig. 14.3). The programs migrated to use of the BCSN registry. All programs began entering data beginning on March 1, 2012. The data that had been captured in BOLD was able to be retained and was entrusted to the Research Committee to clean and produce a public use file and to return data to the programs who had entered it.

The most important task ahead was integration of the culture of the two partners in quality. In order to do this, it was essential that the teams for integration start out small and members whether appointed by ASMBS or ACS is equal in authority. They had to be able to rigorously examine every aspect of the current quality paradigm in both societies in order to propose a system of quality. There could be no “sacred cows” and each aspect of the previous programs had to be examined. In other words, the beginning of the acculturation could not be political and it had to be patient centric. This step would include change for both groups and change is perhaps on a large scale one of the most difficult integrations to manage.

Table 14.5 The Original MBSAQIP Standards Committee

Wayne English, MD	Cochair ASMBS Appointment
Karen Schulz, ANP	ASMBS
Marc Michalsky, MD	ASMBS
Barry Inabnet, MD	ASMBS
Ronnie Clements, MD	Cochair ACS Appointment
Ramsey Dallal, MD	ACS
Ed Felix, MD	ACS
Tim Jackson, MD	ACS

Four initial committees were formed, with each society nominating one-half of the committee members and with a shared cochairmanship. Robin Blackstone, MD, and Ninh Nguyen, MD, chaired the oversight committee for MBSAQIP. Three working committees—standards, verification, and data—were chaired by Wayne English, MD, and Ronald Clements, MD; David Provost, MD, and Dan Jones, MD; and Bruce Wolfe, MD, and Matt Hutter, MD, respectively. The Standards Committee was charged with the development of new standards. This small group of eight people, working with experienced ACS staff members (Table 14.5), met weekly to coalesce the two sets of standards into one document and did a critical analysis of each to determine its validity. In addition, they took the input from the Dallas meeting as well as the considerable experience of the ASMBS and ACS that they brought from many years working with the programs to the table. Once an initial draft was made, critical issues were identified and the larger committee met repeatedly over the next 4 months to work through pivotal issues like minimum qualifying volumes. The amount of work, meetings, and careful consideration was a monumental effort. Ninh Nguyen, MD, examined the issues involved with volume and presented that data in September of 2012. Each step of the process was examined and voted on by both the Standards Committee members and members of the oversight committee prior to being changed within the document. The qualifying minimal volume issue was one of the most discussed with a final agreement that 50 cases per year was adequate to ensure sufficient experience for accreditation in all patients regardless of acuity. Programs were able to become part of the system for low-acuity patients at 25 cases per year. In addition, new programs could enter the registry as a data collection center, allowing them to accumulate their data and taking advantage of best practice available within the system from the first case forward. Other difficult issues, including individual surgeon verification, were discussed at length. By mid-December 2012, an initial draft of the new standards had been finished and reviewed by the legal department at ACS and presented to the Executive Council. The council voted to send it for public comment but did not endorse it, waiting instead for

the public comments and revisions that would ensue based on those comments. This was an essential and planned step in the process. More than 1,300 public comments were received and the input sorted into categories. At this point, additional members of the Executive Council were added to each committee to include a broader representation, and each area of input from the membership was carefully considered and amendments were made to the initial draft. The membership of ASMBS was passionate about the requirement to have at least one ASMBS verified surgeon working within a program and this was incorporated into the final standards. It was also during this time that the standards for adolescent bariatric surgery were worked out with significant input from the ASMBS Pediatric/Adolescent Bariatric Surgery Committee so that the next draft could include an accreditation process for adolescent bariatric surgery. Once all the input was considered and incorporated into the standards, members of ASMBS had an opportunity to comment and make suggestions to the second draft over the summer of 2013. The response to this draft was less robust, as expected when many of the issues raised by the first draft had been clarified. The Executive Council of ASMBS, the MBSAQIP committees, and the Board of Regents gave unanimous consent to the new integrated program standards for accreditation. The new program standards “Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2014: MBSAQIP Standards and Pathways Manual” was published on January 28, 2014 [21]. Key elements of the new standards were:

- Creation of local committees in metabolic and bariatric surgery to evaluate and use the data for process improvement
- Continuation of support for the role of integrated health in providing education and support in a program structure
- Requirement of at least one verified bariatric surgeon in the facility
- Data abstraction by independent clinical reviewers
- Adolescent accreditation standards

Currently, the MBSAQIP has more than 700 participant programs and it is anticipated that number will grow significantly throughout the next few years as demand for surgical therapy increases and is increasingly covered by employers and payers.

How Should I Implement Quality Within my Practice?

Introduction

The most important element in establishing a culture of safety is leadership. Currently, the standard for practice of metabolic and bariatric surgery in the United States is to participate within a nationally accredited program.

The program endorsed by both the ASMBS and ACS is the MBSAQIP program. The core value of the MBSAQIP program is that control of the program resides in the local program Metabolic and Bariatric Surgery Committee (MBSC) comprised of a group of surgeons and integrated health professionals who work together to establish the elements of a quality MBS program at the local hospital. The goal of the local committee is to deliver superior patient experience and safe outcomes with long-term effectiveness in *all* patients in the program who chose metabolic or bariatric surgery. It is this committee that is charged with developing *value* within the program. Each member of the committee not only can contribute their efforts to instill the habits of quality within the program but also has the ability to continuously evaluate their own efforts (through review of their own data in the registry) as well as compare to surgeons 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 committee members embracing the quality process establish a continuing learning community within the program. The committee provides the ideal group to meet the challenges of the new medical environment: improved patient safety, enhanced patient experience, growing access, and maximizing revenue while minimizing cost. There is no substitute for surgeon leadership in this process. A leader sets direction, aligns people around common goals, and motivates and inspires the team to reach them. While a great program requires both, leadership differs from management. A manager plans and sets a budget, organizes staffing, and controls activity and solves problems [22]. In order to implement the MBSAQIP standards within your current program or to use them to start a new program, both leadership and good management will be required. The responsibility for a successful effort is a shared responsibility of the entire committee. Developing leaders among your team will be one of the most important goals. Many opportunities for improvement in safety and patient care will come from the data but also can arise from within the team. All surgeons who operate within the program should optimally participate in every meeting of the local committee.

Understanding the Key Elements of Quality

The key elements of having a quality program are:

- 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 do process improvement

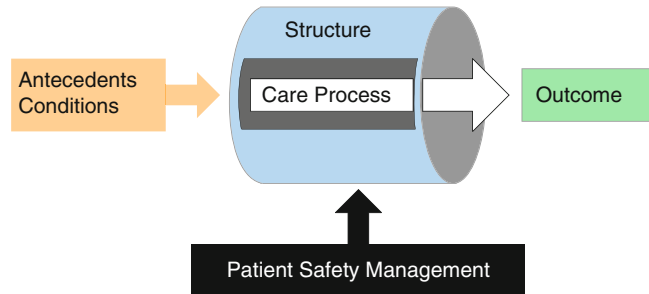


Fig. 14.4 Donabedian's model for assessing quality of healthcare based on structure, process, and outcomes [23]

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. 14.4) [23].

There are strengths and weaknesses of each measure as outlined in Table 14.6 [24].

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. 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 [25]. This model has evolved as the understanding of contributory processes has evolved. A more current concept is presented in Fig. 14.5 [26].

Implementing Credentials in MBS

At the start of any effort in quality is the credentialing of the providers of care. In MBS, four different sets of credentials for practice in surgery within hospitals have been written and published over the years. The ASMBS, ACS, SAGES (Society of American Gastrointestinal and Endoscopic Surgeons), and SSAT (Society for Surgery of the Alimentary Track) all had differing recommendations. As part of the update of the quality program and evolution to MBSAQIP, a joint task force was convened to combine these individual statements into one document. Representatives to the task force were appointed by each society and a combined statement of credentialing recommendations was published under the leadership of William B. Inabnet, MD. It is recommended that both hospitals and surgeons participate in MBSAQIP in order to achieve participation in the necessary program structures (Tables 14.7, 14.8, 14.9, and 14.10) [27] This recommendation could also be fulfilled by participation in an equivalent approved statewide or national bariatric quality

Table 14.6 Primary strengths and limitations of structural, process, and outcomes measures

Type 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) Sometimes structural measures predict subsequent performance better than process or outcomes measures do	Measures usually are not actionable 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 Measures are directly actionable for quality improvement activities Risk adjustment is often unnecessary	Many measures are hard to define with existing databases Extent of linkage is variable between measures and important patient outcomes Lacks high-leverage, procedure-specific measures
Direct outcome	Risk-adjusted mortalities for CAGB from state or national registries	Face validity Measurement may improve outcomes in and of itself (i.e., Hawthorne effect)	Limited sample sizes Expensive to collect clinical data Concerns regarding risk adjustment using administrative data

Adapted from Birkmeyer and Dimick [24]

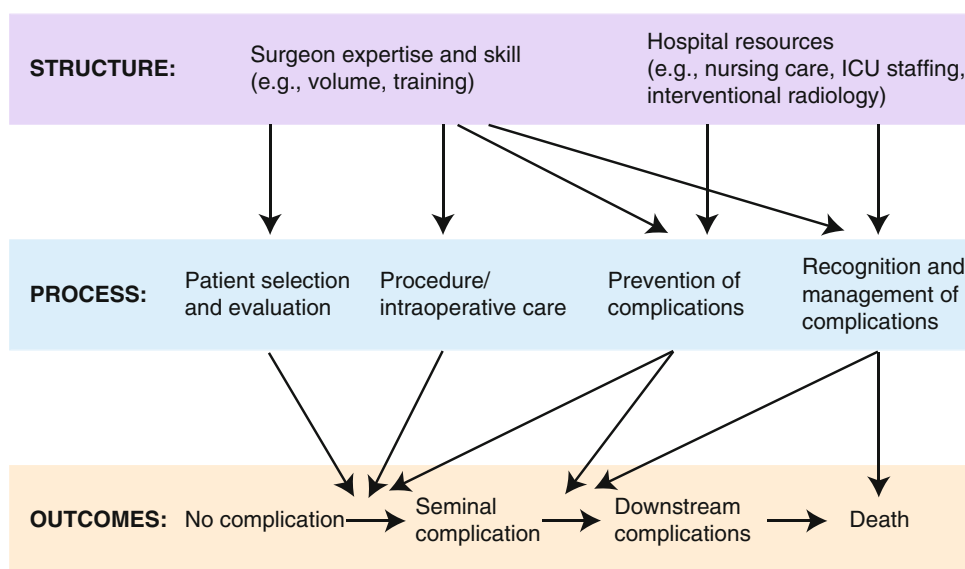


Fig. 14.5 Conceptual framework of modern quality showing relationships between structure, process of care, complications, and mortality after surgery [26]

improvement program. Ideally the local MBSC would review these recommendations and write a set of credentials supported by the document. Once approved, the MBS committee should recommend to the surgical committee of the hospital that these credentialing guidelines be adopted within the official credentialing requirements of the hospital.

Risk Adjustment (Antecedent 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

Table 14.7 Recommendations for bariatric surgeon requirements for practice within a facility [27]

Completion of an accredited general surgery residency
Certified or eligible to be certified by the American Board of Surgery or equivalent (American Osteopathic Board of Surgery, Royal College of Physicians, and Surgeons of Canada). Exceptions to the board certification requirement can be made on a case-by-case basis
State medical licensure in good standing
Completion of an accredited bariatric surgery fellowship. For nonfellowship-trained surgeons, documentation of previous bariatric surgery experience and formal didactic training in bariatric surgery (such as that provided by the ASMBS Fundamentals of Bariatric Surgery Course) is recommended. Supporting documentation, including a case log list or bariatric surgery training certificate, should be provided to allow the credentialing committee to assess the applicant surgeon's bariatric surgery experience
Participation within a structured bariatric program that provides or coordinates comprehensive, interdisciplinary care of the bariatric patient
Commitment to use bariatric surgery clinical pathways
Privileges to perform gastrointestinal surgery
Privileges to perform advanced laparoscopic procedures if laparoscopic bariatric surgery privileges are being requested
The surgeon will actively participate with the MBSAQIP and adhere to its standards by implementing changes in practice in accordance with feedback from the MBSAQIP or an equivalent regional/national quality improvement program

Table 14.8 Recommendations for surgeons with no or limited experience in bariatric surgery or advanced laparoscopic credentials [27]

Applicant surgeon must complete a structured training curriculum in bariatric surgery and advanced laparoscopic surgery as reviewed and approved by the bariatric medical director
The applicant surgeon must have completed a general surgery residency
The applicant surgeon's initial cases should be performed with a co-surgeon who is a fully credentialed bariatric surgeon. The absolute number of proctored cases is left up to the local credentialing committee. However, the local credentialing committees may wish to delineate separate requirements for those procedures that require gastrointestinal stapling versus those that do not
It is advisable that the first cases be of lower technical difficulty with carefully determined lower-risk patients as determined by the bariatric medical director
The surgeon will actively participate with the MBSAQIP program and adhere to its standards by implementing changes in practice in accordance with feedback from the MBSAQIP or an equivalent regional/national quality improvement program

Table 14.9 Types of procedures qualifying under these credentialing guidelines [27]

Adjustable gastric banding
Biliopancreatic diversion with duodenal switch
Biliopancreatic diversion without duodenal switch
Revisional bariatric surgery
Roux-en-Y gastric bypass
Sleeve gastrectomy
Vertical banded gastroplasty
Investigational procedures should be performed under an IRB-approved protocol
Local credentialing committees may wish to delineate separate requirements for those procedures that require gastrointestinal stapling versus those that do not
Endoluminal bariatric procedures are not covered by these guidelines and should be credentialed under endoscopic privileges. It is recommended that practitioners performing endoluminal bariatric procedures should be credentialed to perform bariatric surgery, and if not, they should be an active member of an accredited, structured bariatric surgery program

Table 14.10 Recommendations for maintenance and renewal of privileges [27]

Privileges to perform bariatric surgery should be renewed at a minimum of every 2 years
Maintenance of certification by the American Board of Surgery or its equivalent
Continued active participation within a structured bariatric surgery program. Ongoing participation with the MBSAQIP program or an equivalent regional/national quality improvement program
The surgeon must demonstrate continued critical assessment of his/her outcomes as determined by periodic review of outcomes from an acceptable regional or national outcomes registry
The chief of surgery or his/her designee should verify that these criteria have been met

impact how to address the structure and process parts of the quality paradigm. Risk considerations include four questions for the program:

1. What is the level of expertise of the surgeons and integrated health staff, and what procedures do they have the experience or expertise to perform?
2. What is the risk of 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?

Expertise

Expertise is required not only in surgeons but also in the integrated health staff. Credentialing of surgeons using the recommended requirements discussed earlier will establish a consistent level of surgeon expertise within the program. What is the background and training of integrated health staff specifically in the area of MBS? For help with these questions, the integrated health leadership and committees of ASMBS have developed recommendations. Networking with other programs will also help your program define these roles and the proper credentials for them.

Procedure Choices

Probably the most important choice the group has to make is whether to permit routine open bariatric surgery cases. Laparoscopy has such a profound influence on outcomes that having surgeons performing open cases routinely may change the outcome data and safety profile of the program, perhaps substantially. Other questions to be discussed and answered are as follows: 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 and new medical devices that may not be approved by ASMBS or procedures with extremely high risk (one-stage duodenal switch) may require additional consideration by the committee and/or program. The most influential risk factor is the actual procedure itself, so this consideration is not small. Early on in a surgeon's experience or program's experience, taking on very complex procedures or revisions may cause the program to become financially insolvent or suffer from public reports of complications, both of which can stop a nascent program from fully developing.

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 a previous bariatric procedure, adolescent and elderly patients, extremely large patients, patients with high metabolic acuity, transplant patients, 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

In order 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, as in cardiac surgery. There are several older trials in bariatric surgery that have completed a correlation analysis to identify risk factors associated with mortality or other complications in bariatric surgery using primarily an open cohort or mixed patient cohort. The effect on mortality of the open approach is so profound [28] that when these are mixed, a different picture of risk emerges than when a solely laparoscopic cohort is used. If your program is offering open procedures, then you need to compare the data and think about patient risk in this context. 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. 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 (Table 14.11) [29–33].

The highest odds ratio for risk is the type of bariatric surgery procedure performed. In any quality paradigm that “judges” outcomes, risk adjustment will need to be done; however, for the purposes of “improvement” of care, unadjusted

Table 14.11 Summary of risk-adjustment publications

Author/date	Description of study	Risk factor	Adjusted odds ratio (95 % CI)	
Gupta et al. 2011 [29]	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	
		<i>Procedure type:</i>		
		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 [30]	Nationwide Inpatient Sample 304,515 patients 2006–2008 Endpoint: 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	
		<i>Most significant risk factor was procedure type:</i>		
Finks JF et al. 2011 [31]	MBSC 25,469 patients All procedures June 2006–December 2010 Endpoint: grade 2 or 3 complications	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	
		<i>Patient factors:</i>		
		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 [32]	University	BMI >50	3.60: CI 1.44–8.99	
DeMaria et al. 2007 [33]	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

^aPulmonary embolus risk=history of previous venous thrombosis, pulmonary embolus, inferior vena cava filter, right heart failure, and obesity hypoventilation

outcomes will yield the richest data for use at the local hospital/surgeon level. Through the MBSAQIP registry, unadjusted reports are available to the surgeons and program directors on demand. These data are invaluable in providing feedback for improvement to take place. There is sensitivity around revealing or discussing complications as a group. Many committees have a peer-review session where the surgeon-specific data is available for surgeons and quality experts to evaluate and discuss, and then a larger committee meeting is held the following month or afterward with inte-

grated health staff and hospital administrators where aggregate program-level data is used for discussion around quality improvement projects. Some system of recognizing patient risk and being able to communicate it to the larger group of staff working with the patient is helpful. One way of assigning risk and communicating it to the group is to use some type of scoring system. One published score, the metabolic acuity score (MAS) [34], combines medical acuity with a psychological acuity “score” [35]. Each patient is assigned a combined score. The score is communicated to the OR

during scheduling and used to determine the “acuity” of the schedule for a given day or week. Communicating the level of patient risk to the wider team including clinic staff, OR, and hospital staff allows for quick identification of the patient who is more at risk by nature of their antecedent medical problems. Specific pathways of care can be designed to address these higher-risk patients specific to their individual issues. Patient-specific correlation with the reasons for being in a higher acuity category can provide a strategy to achieve improved perioperative care with specific solutions: CPAP placed in the postanesthesia care unit, pulmonary or cardiology support as needed, close observation for psychological stressors, immobility addressed with plans for preoperative walking to increase mobility, medical weight loss, and plans for the physical therapy team to work with the patient after surgery. MAS 4 patients (highest acuity) may also need weekly follow-up in clinic after surgery (which often can facilitate their recovery) and medication adjustment to spot any problems that may be developing based on their baseline health in the immediate postoperative period. There is a very low threshold to see this group of patients in the clinic between regularly scheduled visits. Identification of a complex psychological component to the care can also facilitate weekly meetings with the patient’s assigned psychologist and allow them to be managed individually enhancing their experience of care.

Volume

There are many reports of volume as a surrogate for quality [36]. In the early days of the ASMBS BSCOE program, reports of the importance of volume to quality were cited to justify using volume as the primary quality indicator in the program [37]. As the standard in regard to surgeon experience, the annual volume requirement for surgeons was set at 50 cases and at 125 for the facility.

One study attempted to determine an appropriate volume requirement by an ASMBS COE surgeon. The Longitudinal Assessment of Bariatric Surgery (LABS) is a multicenter, prospective trial to study 30-day outcome data on patients undergoing bariatric surgery. Mortality is a rare event in

bariatric surgery precluding the use of mortality alone as an endpoint. LABS developed a composite event (CE) endpoint that includes the occurrence of at least one of the following events: death, venous thrombosis, pulmonary embolism, reoperation, non-discharge at 30 days, and repeat hospitalization within 30 days after initial discharge. Risk adjustment in LABS is 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 (RGBP) procedures in LABS showed that for each increase by ten cases per year in surgeon volume, the rate of composite events improved by 10 %. No significant differences were observed in mortality between low- and high-volume surgeons. Unfortunately, the study was not powered sufficiently to detect small differences. An additional contribution of this study is the demonstration that the risk of a serious complication in the hands of a low-volume surgeon is greatly exaggerated in a higher-risk profile patient. 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 [38].

Additional reports in the field of bariatric surgery as well as other specialties validated the volume and outcome relationship, and reports on surgeon volume alone have also been published. In 2003, Courcoulas et al., using an administrative database in Pennsylvania, reported that surgeons performing <50 RYBP cases annually had a significantly increased rate of complications. The effect was worse if a low-volume surgeon was performing in a low-volume facility [39]. A study from New York state using an administrative database looking at RYBP and gastroplasty patients found that both surgeon volume of fewer than 100 cases annually and low-facility volume of less than 150 cases were associated with increased risk of complications [40].

Reports from administrative data focusing primarily on hospital volume have also shown a relationship between procedure volume and outcomes [41]. The Michigan collaborative data found an inverse relationship with volume and complication rates (Table 14.12) [42].

Table 14.12 Annual bariatric surgery complications by surgeon and hospital volumes in MBSC [42]

<i>Annual bariatric surgery complications by surgeon volume in Michigan</i>			
Annual bariatric procedures by surgeon	<100	100–249	≥250
Risk-adjusted serious complication rate	3.8 (3.2–4.5)	2.4 (2.1–2.8)	1.9 (1.4–2.3)
<i>Annual bariatric surgery complications by hospital volume in Michigan</i>			
Annual bariatric procedures by hospital	<150	150–299	≥300
Risk-adjusted serious complication rate	4.1 (3.0–5.1)	2.7 (2.2–3.2)	2.3 (2.0–2.6)

In recent years, the value of volume alone as the determinate of quality has been questioned, especially in procedures in which the mortality rate is low. Coronary artery bypass graft (CABG) is one procedure where more recent data has called volume into question as a surrogate for quality. In a report by Paul Kurlansky, MD, at the annual meeting of the American Association for Thoracic Surgery in 2011, a comparison of low-volume centers (less than 200 cases per year) with high-volume centers (200 cases or more) demonstrated no significant difference in mortality for either surgeon or facility volume. How transferrable this is to bariatric surgery is unknown, as this volume, even at less than 200 cases annually, would be considered high in MBS. The Society for Thoracic Surgeons, always a leader in quality, has adopted a composite score for quality and adopted process measures through the National Quality Forum. Lack of compliance with the NQF measures, in the same data presented by Dr. Kurlansky, was significantly and highly predictive of morbidity regardless of volume even after adjustment for patient risk factors [43].

Another way of looking at volume and mortality is demonstrated in a paper by Ghaferi. Using the ACS NSQIP clinical database, he studied 84,730 patients undergoing general surgery and vascular procedures. Although mortality rates differed from high-volume to low-volume centers (3.5 % versus 6.9 %), major complication rates were similar in the high-mortality (24.6 %) and low-mortality hospitals (26.9 %) [44].

The failure of the lower volume center to rescue the patient from the complication appears to account for the difference in mortality. At the 2011 ACS Clinical Congress, Dr. Ninh Nguyen reported that looking at 35,000 bariatric operations performed between October 2007 and December 2009 the mortality at accredited centers was 0.06 % compared with 0.21 % at nonaccredited centers; however, the mortality was linked to the ability of accredited centers to rescue the patient rather than associated with the volume of cases since the complication rates were similar [45].

This represents a major opportunity that could be leveraged to improve mortality and major complications. If education could be focused around this issue, and staff and surgeons can identify a patient with a major complication who needs advanced care early and arrange transfer, lives would be saved. This would also allow patients to be treated for their primary procedures within their local area and likely expand access. Setting up specific relationships between smaller community practice centers and tertiary care facilities would enable the early recognition and transfer of patients into a more coordinated opportunity for rescue.

This recently became critical to the discussion of support for accreditation by the Centers for Medicare and Medicaid Services (CMS). CMS initially granted coverage to Medicare beneficiaries in the National Coverage Determination of

2006 and it was reaffirmed in 2009. In 2013, a request to reopen the question of whether accreditation was necessary by John Birkmeyer, MD, was granted. Following a robust public debate, CMS decided not to continue to require national accreditation in order to operate on Medicare and Medicaid patients [46]. This decision was made despite strong protest from surgical societies (ACS, SAGES, and ASMBS), medical societies dedicated to the treatment of patients with obesity (the Obesity Society [TOS] and the American Society for Bariatric Physicians [ASBP]). In addition overwhelming public comment was in favor of maintaining the requirement for accreditation. Part of the data that was presented in favor of abandoning accreditation did not separate out the issue of improvements from laparoscopy versus open cases or case mix (including lower-risk cases like adjustable gastric band) from accreditation [47]. A new analysis separating out the issue of volume based on a purely laparoscopic cohort showed a clear benefit to accreditation alone—outside of volume in a solely laparoscopic cohort showing a decrease in mortality in high-volume centers (HVC) (>50 cases/year) of 0.06 % versus 0.22 % in nonaccredited HVCs. Nonaccredited HVCs performed in a similar manner to low-volume centers (<50 cases/year). The serious morbidity rate was similar in high-volume accredited and nonaccredited centers, suggesting that the difference may be a failure to rescue patients, which points directly to the structure and process implemented as part of accreditation [48]. The other issue that was raised by Justin Dimick, MD, also from the University of Michigan, was a question of whether the policy of limiting surgery to nationally accredited centers limited access of minority patients [49]. A careful analysis by Flum showed an increase in numbers of procedures as well as a decrease in both reoperations and complications in the Medicare population [50].

The impact of the decision by CMS will be monitored but unfortunately, the data required for monitoring lags at least a few years behind real time. By the time the cost in patient morbidity and mortality of this new decision can be demonstrated, many patients may have been harmed. The cost of surgery is directly related to complication rates and mortality, so if these rates increase, so will the cost, but it is the impact on patients' lives that is of greatest concern in the aftermath of this decision. It is the responsibility of each program to decide on the value of accreditation and to establish a program that reflects that value.

Accreditation continues to be endorsed by most payers and an increasing awareness of the value of accreditation is growing among patients who by using the Internet have the ability to learn more about the importance of accreditation and the MBSAQIP program. Regardless of the decision made by CMS, surgeons still have the responsibility of educating prospective patients and providing them with the highest level of quality of care both pre- and postsurgery.

A few additional issues are important in the question of volume. The first is the question 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. It became clear during the analysis of the volume data that device procedures have very low 30-day complication rates and mortality. In addition, the complications, although occasionally of a critical nature, usually are not. It became clear that it was the stapled procedures (making up the majority of the case volume around the country) that were important to analyze for safe practice.

After careful consideration, the ASMBS and ACS have decided that data support accrediting centers at an annual volume of 50 stapled cases per year and that programs/surgeons can enter the program with low-acuity patients at an annual volume of 25 stapled cases per year. Programs/surgeons are encouraged to enter their data prospectively beginning with their first case as a data collection center. Now that Medicare has made a decision to allow surgeons to operate outside of accreditation, coupled with the lack of preauthorization required, Medicare patients will likely make up many of the early cases by a new center. Centers will be able to get onto the database very early, so that cases can be prospectively collected as they work to establish program structure. As the low-volume data accumulates further refinements in the volume requirement can be made.

Many surgeons see MBS procedures as a way to develop their surgical practice, especially when they come out of a fellowship and have obtained certification in MBS. As the new fellow emerges, there are many things on which to focus. Establishing a robust general surgery practice while beginning to develop the infrastructure of a MBS program may be best practice. Unless you join an established MBS practice, you have to develop the resources within your hospital to support the program. An early determinant of the level of support of the hospital and administration is to acquire status as a data collection center within MBSAQIP as well as to locate and coordinate the resources necessary to provide a program structure. Not all volume is good. Putting off high-risk patients and starting with lower-risk patients and procedures with adequate oversight is crucial. The reputation of the surgeons will be a personal brand and since the patients are so socially connected in the digital world, problems with patients or with the program will be publically discussed on the Internet. The impact of this on the ability of a surgeon to grow a great practice depends on having a focus on patient safety and experience with very low complications, readmissions, and reoperations. Volume, in terms of a business model, is problematic and the structure of the program needs to plan for increasing volume increments. Using the MBS committee to plan for volume expansion, procedure selection and grow of resources are ways 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 1,000 cases reporting mortality of two in 1,000 patients is probably a better representation of the true risk of death than a small hospital reporting one death in 80 patients. To reduce this statistical “noise” in the data, a technique has been written about and utilized called “reliability adjustment.” Reliability is a measure of precision and is a function of hospital sample size and the amount of true variation across hospitals. The overall observed effect is shrunk back toward the mean of the facilities with similar volume (not the overall mean) thereby correcting the observed risk-adjusted rate by the 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 [51].

So how do you know where you stand in regards to your peers? One way to determine that 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 life-threatening and life-threatening complications to be combined into a single composite measure of quality [52]. 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. It provides multiple targets for quality improvement. Programs and surgeons can measure themselves against their peers around the nation and in their state. While the most important use of data is to provide regular feedback to programs/surgeons for process improvement, the composite measure gives the program a yardstick that allows them to compare their program to others. This can lead to efforts that will improve patient safety using evidence-based risk-adjusted results [13].

The data in Fig. 14.6 illustrates the strength of the predictive value in bariatric surgery by composite measures. The composite measure explained the variability in comparing the rankings of hospitals to their subsequent performance. Hospital volume was the worst predictor.

Both patients and payers want to direct their care to the “best” hospitals. Patients and payers are looking for value, safety, and a great patient experience of care. Currently, there are some grading systems in use on the Internet that use administrative data. Programs can take a proactive approach by providing higher-quality data (clinical) and risk-adjusted outcomes to the public and payers.

	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%

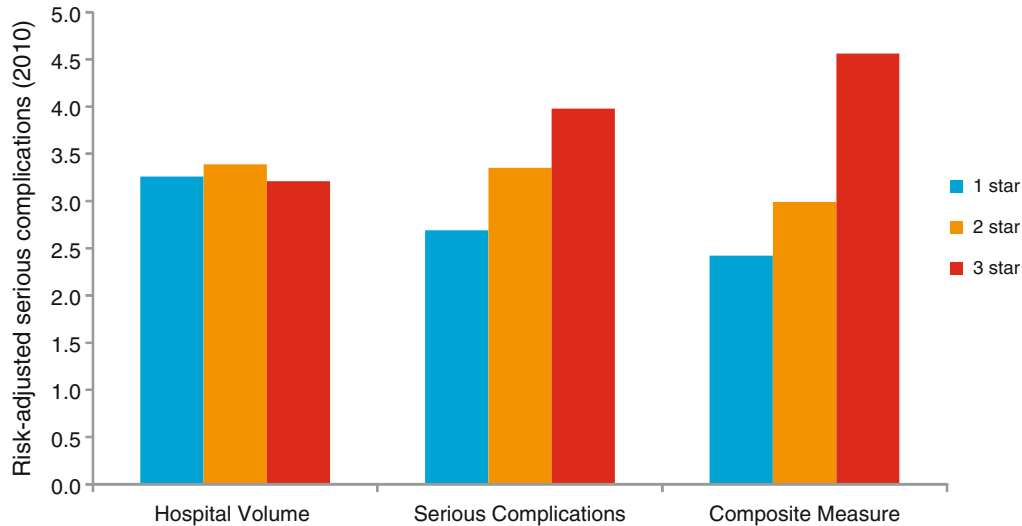


Fig. 14.6 Prediction of performance of bariatric surgery programs in Michigan using three measures: (1) hospital volume, (2) risk-adjusted serious complications, and (3) composite measure [13]. Composite measures are the best predictors of quality to use for accreditation

Program Process and Structure

Each program will need to develop protocols based on the procedures and groups of patients to whom they offer care. If possible, it is helpful to develop a process map so that you can outline each step of the program pathway for patient flow. As you build the program plan, specific protocols, personnel, equipment, and structural items will become apparent. The requirements for a high-quality program are detailed in Chap. 9 of this textbook. You may want to use that as a blueprint to develop your program.

Once the program is developed, you can match the cost of care to each activity allowing you to develop a cost structure based on the actual cost of care. 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. Program structure can directly impact safety and experience of patient care. The integrated health team should establish leadership and management of the process aspects of the program. A goal of every program is to demonstrate improved efficacy of long-term follow-up and programmatic structured care.

Data Collection/Integrity

Data integrity and fidelity are paramount. Surgeons need to recognize the importance of this and ensure successful data capture. Although when the first quality program was put in place, the burden of data collection for the community surgeon came as an unwelcome and new burden. Collection of clinical data is required for ongoing maintenance of certification in surgery. The pressure on surgeons regarding collecting data and using it to improve their own outcomes will continue to increase. Data will be used to improve care through quality improvement, enhance or detract from reimbursement, and be increasingly transparent to patients. Surgeons and hospital administration want to ensure that they are investing in quality improvement projects that are based on high-quality data.

What is the most important requirement for high-quality data? An independent third-party clinical reviewer who has medical knowledge but no personal stake in the outcomes so that it is unbiased must collect it. In addition, the clinical reviewer must be trained and certified to determine when adverse events have taken place based on strict definitions for the data collection points.

Two types of data exist and are reported and used by a variety of outside stakeholders: administrative data and clinical data. Currently, administrative data is derived from hospital charts that are processed after discharge by coders. What the provider writes, or does not write in the chart, and all other information in the chart are examined by hospital coding teams that have a goal of maximizing the charges for the episode of care. Some examples are as follows: your patient continues to require oxygen on post-op day one after gastric bypass and you send her for a chest X-ray. The radiologist comments that she has atelectasis. Unless this is explained to be a normal postoperative finding due to use of laparoscopy and the patient's weight and sleep apnea, it gets coded as "pulmonary collapse," which will maximize reimbursement. This is not a fraudulent practice, but it is picked up by the state in their administrative data as a "900 code" complication. Charting of hospitalists, mid-level providers, and others magnifies this problem. Vigilance in documentation is critical to ensure accurate reporting of administrative data. The surgeon and the program will need to invest significant resources to ensure that the data they are using and submitting for public consumption, whether by payers or the public, is of the highest quality. An early valuable project for the group is to analyze the difference between coding and the clinical record in a selected group of cases and work to coordinate the documentation in the medical record with the clinical course in order to ensure accurate public reporting through the coding by the hospital. Some hospitals have noted significant inaccurate coding because the medical record is not adequate for documentation.

Clinical data is the type of data collected within the Longitudinal Assessment of Bariatric Surgery, the Michigan Bariatric Surgery Collaborative, and the ACS National Surgical Quality Improvement Program and MBSAQIP registries. It is regarded as the highest-quality data available. This is due to having standardized and strict definitions, impartial third-party bariatric surgery clinical reviewers, and ongoing training. In a comparison of the NSQIP clinical data with CMS Compare website data, a significant difference was noted between the two data sources. When CMS posts data on the Compare website, it is administrative data and has a high error rate due to coding inaccuracies. CMS is allowing data from NSQIP to be used in some pilots in place of the administrative data that they typically use. This is a tremendous incentive for surgeons and hospitals to participate in a formal data collection system. Eventually, through the use of electronic health records such as EPIC, large repositories of data ("big data") will be available on a myriad of small details that may shed light on process of care that can be implemented and that can matter to overall care.

The major cost of any collaborative network is the cost of collecting high-quality data. This cost for the most part will have to be paid by the hospital that is being accredited, but

the hidden cost is the time for the surgeon to ensure that the data being collected is accurate. In 2013, with maintenance of certification now requiring reporting to a clinical registry, this has become a necessary cost of doing business for the surgeon. The MBSAQIP registry is one of the registries recognized by the Board of Surgery for data collection. 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. Potentially, it can yield significant rewards both in enhanced reimbursement through Patient Centered Research Institute (PCORI) and the patient experience, as well as in decreasing cost of care.

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 to others, and share best practice through collaboration at the local, state, regional, and national level will be a significant step. Clinically rich data provides ample targets for process improvement. In one process improvement project carried out by the MBSC, a variation in the use of IVC filters was noted from 0 to 34 % within the 20 hospitals participating in the collaborative at that time. Further analysis showed that patients with a filter placed preoperatively had a similar rate of VTE and other serious complications including death as patients without a filter. In addition, IVC filters were associated with a high degree of death and complications related to the filter itself. There were no characteristics of any patient in whom placement of a filter improved outcomes. As part of the process improvement initiative throughout the subsequent year, all programs were asked to change their practice patterns voluntarily by eliminating IVC filter placement in future patients. Patient safety was shown to improve significantly and there was a cost savings of approximately \$2.6 million that year. As a result, the cost savings of this single intervention paid for the administrative costs of the Michigan collaborative program [53].

The impact of process improvement is pivotal not only in terms of improving patient safety, but in decreasing cost of care and improving patient experience of care. It has an additional benefit: it builds the focus and collaboration of the team, even where surgeons are part of different private practices. While the primary goal of safety is paramount,

improving value (quality/cost) is impacted to a large extent by the cost of complications as the major driver of cost. In addition, improvement in patient experience has a direct effect on the bottom line of reimbursement. Increasingly providing *value* has become an important target for health-care reform.

How to Implement QI

- Establish the Metabolic and Bariatric Surgery Committee for your program.
- Appoint, by consensus, one surgeon to lead the group for a period of time. However, all surgeons who operate on MBS patients within the hospital should engage in the committee.
- Involve the quality department of the hospital to help evaluate surgeon-specific data and identify targets for QI
- Pull non-risk-adjusted reports from the MBSAQIP registry and review the data.
- Make sure all data reviewed is fair and a discussion of risk takes place.
- Provide aggregate data for the program team that includes integrated health.
- Choose an initial target to focus on improvement and assign responsibility for the process.
- Choose a timeframe for implementation and review of the ongoing data.
- Realize the limitations of using non-risk-adjusted/reliability-adjusted data. You are reviewing a small subset of data. Process targets may be most appropriate as early projects.

Implementation of the Program

The following components should be incorporated in establishing the program:

- Establish the program's Metabolic and Bariatric Surgery Committee as a subcommittee of the surgery committee within the hospital. This step should be formalized to establish the authority of the MBSC within the medical staff process and to get resources from the hospital to support the mechanisms by which the committee will do its work.
- Motivate the group to stay current in their knowledge base about the physiology of obesity. The surgical treatment of obesity seminars and pathways should be updated as frequently as necessary to establish best practice in care.
- Participate in entering all cases, through a third-party independent abstractor, into the MBSAQIP data registry.
- Monitor the data through collaborative meetings of the local Metabolic and Bariatric Surgery Committee to

identify opportunities for improvement. You may want to have a small subset of the committee meet to review surgeon data (surgeons, mid-levels, and quality team) and then have a more inclusive meeting where aggregate data is reviewed and opportunities for improvement as a group are identified and carried out.

- Participate and champion a culture of value—enhance quality and decrease cost.
- Invest in an understanding of the quality improvement process.
- Ensure that coding of your cases is accurately reported.
- Collaborate with others on a local, regional, and national basis to identify targets and participate in finding local solutions to enact change that will improve safety and the patient experience of care and decrease complications and cost.

There are many avenues through which members of the local program (both surgeons and integrated health members) can seek to improve their knowledge base. It will be important, as surgery becomes part of the continuum of care for the patient with obesity and metabolic disease, that the understanding of the science of obesity and the modalities for management—including an understanding of the pathophysiology of obesity and other modalities of therapy (behavioral and medications)—become part of that knowledge base. In addition, staying current in a rapidly evolving field requires at least annual investment in ongoing medical education. In addition to this base of knowledge in the subject area, an investment in understanding quality itself and the process used to improve it will be key. Conferences such as the annual NSQIP conference and Obesity Week offer cross-educational opportunities in medical and surgical science as well as quality.

This year, during Obesity Week, the ASMBS sponsored the first national quality initiative. Led by the ASMBS president-elect Dr. John Morton, the session focused on readmissions. The work was a sharing of best practice, based on a study done at Stanford Hospital where the adoption of a “readmission bundle” that leveraged “common sense care coordination” of patient education, discharge planning, and preoperative procedures. The results of the study showed hospital readmission rates dropped by 75 % (2.5 % compared to the 6 %). Partnering with the hospital quality department will help integrate the MBSAQIP program into the overall quality paradigm at the hospital and establish the bariatric team as leaders for improving value. Fortunately, these investments will pay off for the team as they will improve the experience of care and improve outcomes, all of which will translate into improved value. Members of the local MBS committee will be able to help colleagues within the hospital structure and general surgery to achieve improved care. This will be necessary, as all of the programs of the hospital will be judged in the future

when a health plan, insurer, or employer is contracting and individual programs that bring value will have an influence over that contracting process. Improved quality may also result in higher reimbursement as compared to programs in lower quartiles of quality.

Conclusion

Obesity is an epidemic of historic impact. The number of people who qualify for surgical management of obesity and related disease is growing and access to care is gradually improving. In this environment, many who are 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 local, regional, and national level. Bariatric surgeons have established and embraced the new benchmark of a national culture of safety.

The new strategy articulated in the MBSAQIP accreditation allows MBS surgeons and programs to meet the requirements of the current healthcare environment in a way that improves *value*, long-term effectiveness, and decreased cost and allows for collaboration of surgeons based on clinically rich, risk-adjusted data from the MBSAQIP registry rather than administratively derived data. Transparency of outcomes will be unavoidable in the future and surgeons/programs will be called upon to provide the data. If not, administrative data resources will provide it. The data registry is sufficiently mature for programs to begin this process immediately. As access to care improves and case volume expands, we can expect an influx of new surgeons and programs in MBS. It is critical that a framework of safety be established as a backdrop against which this growth may occur in a safe way. MBSAQIP standards offer just such a framework.

The initial efforts to establish accreditation programs in MBS were exemplary and effective in both the ASMBS and ACS programs and in the MBSC collaborative. Along with technique and technical advances, mortality was decreased dramatically, major complication rates declined substantially, and the culture of safety became the norm for MBS practice. Metabolic and bariatric surgeons have been at the forefront of efforts to establish safe and effective care. Born of necessity and forged by visionary surgeons and integrated health leadership, they have joined and led the national imperative to reduce cost by reducing variation in surgical procedures and will have a major role to play in providing value as medicine moves on to its next frontier.

Question Section

Question

1. 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

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