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# How A Regional Collaborative Of Hospitals And Physicians In Michigan Cut Costs And Improved The Quality Of Care

**ABSTRACT** There is evidence that collaborations between hospitals and physicians in particular regions of the country have led to improvements in the quality of care. Even so, there have not been many of these collaborations. We review one, the Michigan regional collaborative improvement program, which was paid for by a large private insurer, has yielded improvements for a range of clinical conditions, and has reduced costs in several important areas. In general and vascular surgery alone, complications from surgery dropped almost 2.5 percent among participating Michigan hospitals—a change that translates into 2,500 fewer Michigan patients with surgical complications each year. Estimated annual savings from this one collaborative are approximately \$20 million, far exceeding the cost of administering the program. Regional collaborative improvement programs should become increasingly attractive to hospitals and physicians, as well as to national policy makers, as they seek to improve health care quality and reduce costs.

**T**he need to improve quality of care in US hospitals is widely recognized. Potentially avoidable adverse events are common among hospitalized patients, and wide variation in hospital performance outcomes suggests that there is ample room for improvement.<sup>1-4</sup> The business case for improving hospital quality is also apparent. In surgery, for example, the true cost associated with treating complications exceeds \$10,000 per patient, the large majority of which is passed on to payers and purchasers.<sup>5</sup> Additional payments for complicated hospital stays (outlier payments), unplanned readmissions, and care following discharge for patients with complications account for approximately 20 percent of the total costs associated with many inpatient procedures, according to national Medicare data.<sup>6</sup>

## Background On Hospital Quality Improvement

Despite increasing attention from payers, policy makers, and professional organizations, large-scale efforts to improve hospital quality have had little effect on patient outcomes. Public reporting of performance data may motivate hospitals to improve.<sup>7</sup> However, there remain doubts that programs such as the Centers for Medicare and Medicaid Services' Hospital Compare website or the Leapfrog Group's selective referral initiative will be successful in redirecting large numbers of patients to hospitals that have demonstrated superior results.<sup>8-10</sup> Simply put, it hasn't been demonstrated that patients will actually stop going to hospitals that achieve poor results and start going to hospitals that achieve far better ones. Even if practical barriers to changing these referral patterns could be addressed—such as efficient transfer of patients' medical

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records—these initiatives are limited by a lack of good data and measures for identifying truly superior hospitals.

**VARIED APPROACHES** In addition to not paying for so-called never events, such as surgical procedures on the wrong site or when foreign objects are left inside a patient after surgery, both public and private insurers have implemented pay-for-performance programs aimed at increasing the use of specific, evidence-based practices. An example is ensuring that a patient is taking a beta-blocker when discharged from the hospital after a myocardial infarction, or heart attack.<sup>11,12</sup> Hospitals have generally improved their performance with these process-of-care measures, which are distinct from outcome measures that indicate how the health status of patients has changed. But whether such programs have conferred clinically meaningful improvements in patient outcomes is debatable.<sup>13–17</sup>

**REGIONAL COLLABORATIONS** Regional collaborations between hospitals and physicians may be more effective than either selective referral or pay-for-performance in improving the quality of health care at the population level. Pioneered by the Northern New England Cardiovascular Disease Study Group, regional collaborative improvement programs are based upon clinical registries containing detailed information about patients' risk status, processes of care, and outcomes.<sup>18</sup> Hospitals and physicians receive regular and (usually) confidential feedback on their performance from their registry coordinating center—for example, risk-adjusted mortality rates for cardiac surgery. Hospital officials and physicians convene regularly to review and interpret their data, often focusing on areas of variation in practice or outcomes. Best practices are then identified and implemented across the region, which may be an area within a large state or a group of one or more states.

Despite the conceptual appeal of this model and its success in northern New England, it has not been widely adopted in other parts of the United States. However, an ambitious program in Michigan now provides the first opportunity to assess the value and practicality of regional collaborative improvement programs on a much larger scale.

After early success with a program focusing on percutaneous coronary interventions—commonly known as heart angioplasties—Blue Cross and Blue Shield of Michigan/Blue Care Network decided to make regional collaborative improvement a major component of its statewide Value Partnership program. Then, in 2004, the insurer began implementing similar programs in other clinical areas.<sup>19,20</sup> This insurer currently invests almost \$30 million annually in nine programs,

which collectively focus on the care of almost 200,000 Michigan patients annually.

Five of the programs—in breast cancer, cardiac computed tomography, peripheral vascular interventions, trauma care, and hospital-based medical care—have not been established long enough to enable the judging of results. However, results from the other four, more mature regional collaborative improvement programs—targeting percutaneous coronary interventions, cardiac surgery, bariatric surgery for obesity, and other types of general and vascular surgery—are now emerging.

**FOCUS ON MICHIGAN** We review the Michigan regional collaborative improvement program and its success to date in improving clinical outcomes. Given the substantial cost of these improvement programs, we also consider savings accrued to payers as a result of fewer adverse outcomes or other efficiency gains and thus the return on investment from the payer perspective. Finally, we review lessons learned from the first five years of the Michigan program and potential challenges associated with scaling up this model nationwide.

## Overview Of The Program

**PARTICIPANTS** Blue Cross and Blue Shield of Michigan/Blue Care Network is the dominant private insurer in Michigan, insuring approximately 47 percent of the ten million residents of the state. Based on the assessment of the lead author of this article, David Share, approximately 5 percent of its total reimbursements to hospitals (\$160 million annually) are currently reserved for its Participating Hospital Agreement Incentive Program. This program includes elements of traditional pay-for-performance plans. However, 20 percent of the program's overall budget is devoted to nine regional collaborative improvement programs, whose annual costs range from \$1.2 million to more than \$5 million each, according to financial documents from fiscal year 2010.

Each regional collaborative improvement program is administered by a coordinating center staffed by one of the participating hospitals (mostly university-based), not by Blue Cross and Blue Shield of Michigan/Blue Care Network. Although staff composition varies by program, most coordinating centers have a physician-director, program epidemiologist or statistician, data analyst, data auditor, quality improvement nurse, and administrative support.

**COSTS AND PAYMENTS** Based on financial reports from fiscal year 2010, payments to hospitals account for most of the costs of the regional collaborative improvement programs. Hospitals

are compensated for each improvement program in which they participate, regardless of their performance relative to other centers. Payment formulas were originally designed to cover the direct costs of participation, but they are now based on a fixed percentage of each hospital's total payments from Blue Cross and Blue Shield of Michigan/Blue Care Network. In 2007 these payments to hospitals ranged from \$11,000 to more than \$1 million across the forty-four hospitals participating in at least one regional collaborative improvement program.

For most hospitals, payments exceed the true costs of participation, according to a financial analysis conducted by John Birkmeyer, one of this paper's authors. Participating hospitals are expected to collect and submit data to the program registries on a timely basis and allow regular site visits from data auditors. To receive payments, hospitals must send at least one physician-representative and a program coordinator to the quarterly meetings of each regional collaborative improvement program and participate actively in statewide and hospital-specific quality improvement interventions.

**TARGETED CONDITIONS** The improvement programs target clinical conditions and procedures that are relatively common and that are associated with high costs per episode. They also tend to focus on procedures that are technically complex, evolving rapidly, and associated with wide variation in hospital practice and outcomes.

Although the programs all administer detailed clinical registries, they vary in several aspects of data collection and measurement (Exhibit 1). Outcomes are measured using established national registries administered by professional organizations, locally developed databases, or some combination of the two.

**DATA** To help hospitals target and monitor

their local improvement activities, all of the regional collaborative improvement programs provide participating hospitals with hospital- and physician-specific outcome data, relative to Michigan and (in some cases) national benchmarks. These data are confidential and not accessible by Blue Cross and Blue Shield of Michigan/Blue Care Network. Although most of the programs focus on short-term morbidity and mortality, some track longer-term measures of effectiveness, such as weight loss and patients' functional status after bariatric surgery. Several of the programs link to the insurer's claims data to track use of health care services and spending.

### Clinical Improvements

The regional collaborative improvement programs vary widely with respect to their primary outcome measures, risk-adjustment models and statistical techniques, and use of external benchmarks for assessing comparative improvements. In general, however, the success of the programs is judged by trends in statewide rates of use and adverse outcomes, which are assessed for both clinical and statistical significance. The latter is determined by regression-based time-series analyses, which adjust for any measurable changes in patient characteristics over time.

**GENERAL AND VASCULAR SURGERY** The largest of the regional collaborative improvement programs is the Michigan Surgical Quality Collaborative, which targets general and vascular surgery. Given the broad range of procedures included in this program, it tends to focus its quality improvement efforts on aspects of perioperative care—care before, during, and after surgery that is common to almost any type of inpatient surgery, including practices aimed at preventing common complications such as sur-

#### EXHIBIT 1

##### Overview Of Four Regional Collaborative Improvement Programs In Michigan

Characteristic	Percutaneous coronary interventions	Cardiac surgery	Bariatric surgery	Major general and vascular surgery
Program start	1998	2006	2006	2005
Current number of hospitals (percent eligible)	31 (100%)	33 (100%)	27 (96%)	34 (94%)
Approximate number of patients per year <sup>a</sup>	32,000	10,000	7,000	50,000
Cost to BCBSM/BCN per year	\$3.2 million	\$3.0 million	\$2.7 million	\$5.0 million
Registry	Locally developed	STS registry with local enhancements	Locally developed	ACS-NSQIP with local enhancements

**SOURCE** Blue Cross and Blue Shield of Michigan. **NOTES** BCBSM/BCN is Blue Cross and Blue Shield of Michigan/Blue Care Network. STS is Society of Thoracic Surgeons. ACS-NSQIP is American College of Surgeons National Surgical Quality Improvement Program. Although approximately 100,000 Michigan patients each year undergo general and vascular procedures targeted by ACS-NSQIP, this registry collects data on a random subset. <sup>a</sup>Patients per most recent year (2010).

gical site infection or venous thromboembolism (a blood clot forming in a vein).

The Michigan Surgical Quality Collaborative shares the same measurement platform as the American College of Surgeons National Surgical Quality Improvement Program. It collects additional data on selected procedures, including colorectal surgery and lower-extremity revascularization. The National Surgical Quality Improvement Program collects very detailed clinical information about patient characteristics (for purposes of risk adjustment) and postoperative complications. Between 2005 and 2009 the national program included approximately 200 hospitals nationwide, a group in which large academic centers tend to be overrepresented. Although it hosts an annual national meeting where hospitals share their experiences and improvement work, the program does not itself direct improvement interventions or coordinate collaborations across hospitals.

To assess the added value of the regional collaborative improvement model, we used the National Surgical Quality Improvement Program registry to compare surgical outcomes in hospitals within Michigan to those outside the state. For the entire study period, Michigan patients could be identified directly using the Michigan Surgical Quality Collaborative database. Other patients undergoing surgery between 2005 and 2007 could be identified directly from the National Surgical Quality Improvement Program public-use database.

In 2008–09, however, the public-use file no longer contained hospital identifiers. For this reason, we identified patients outside of Michigan by using a matching algorithm based on patient characteristics, primary procedure code, and other variables. This algorithm matched more than 95 percent of patients.

When comparing the performance of hospitals in and outside of Michigan, we focused on thirty-day morbidity rates, which is the primary outcome measure of the National Surgical Quality Improvement Program. To ensure fair comparisons between the two groups, morbidity rates were adjusted for patients' risk factors, including preoperative albumin, creatinine, functional status, sepsis, inpatient and emergency surgery status, illness severity (using the American Society of Anesthesiologists score), work relative value units, and surgical specialty (peripheral vascular versus general surgery).

In addition to cross-sectional comparisons, we used logistic regression to assess time trends in morbidity rates in both groups of hospitals after adjusting for the above covariates. Relative improvements in outcomes between the Michigan hospitals and the others were formally compared

## Although hospital-specific morbidity rates are less precise, some Michigan hospitals improved more than others.

using a likelihood ratio test for interaction between time and site (in Michigan versus not in Michigan) based on the logistic regression model. In essence, this analysis examined whether the slopes in morbidity rate trends over time were significantly different between hospitals in Michigan and those not in Michigan.

As seen in Exhibit 2, risk-adjusted morbidity rates in Michigan hospitals fell from 13.1 percent in 2005 to 10.5 percent in 2009 ( $p < 0.001$ ). In contrast, morbidity rates in hospitals outside of Michigan participating in the National Surgical Quality Improvement Program remained essentially flat between 2005 and 2008, before dipping slightly in 2009. Although trends toward improvement in the two populations were both statistically significant, improvement occurred at a faster rate in Michigan hospitals ( $p < 0.001$ ). In 2009 (the latest year for which complete data were available), overall morbidity in Michigan hospitals was significantly lower than in the other hospitals (10.5 percent versus 11.5 percent,  $p < 0.001$ ).

Although hospital-specific morbidity rates are less precise, some Michigan hospitals improved more than others. Of the thirty-two hospitals participating by the end of 2008, eight hospitals (25 percent) showed statistically significant ( $p < 0.05$ ) reductions in their morbidity rates by the end of 2009. Another eight hospitals (25 percent) had achieved trends toward declining morbidity ( $p < 0.20$ ). There were no significant improvements in morbidity rates at the remaining hospitals.

**BARITRIC SURGERY** The Michigan Bariatric Surgery Collaborative, which enrolls more than 95 percent of patients undergoing bariatric surgery in the state, has to date focused its improvement activities on reducing technical complications and rates of venous thromboembolism. Overall complication rates declined from 8.7 percent to 6.6 percent between 2007 (the first year for which complete data were available) and



2009.

Because the Michigan Bariatric Surgery Collaborative and the National Surgical Quality Improvement Program rely on separate registries with different outcome measures and definitions, improvements in complication rates in Michigan cannot be assessed against that national benchmark. However, we did compare surgical mortality in our two hospital populations, adjusting for variables common to both registries, including age, sex, body mass index, and procedure type.

As seen in Exhibit 3, risk-adjusted thirty-day mortality with bariatric surgery in Michigan hospitals dropped significantly from 2007 to 2009 ( $p = 0.004$ ). Bariatric surgery mortality at hospitals outside of Michigan participating in the National Surgical Quality Improvement Program also declined during the same time period, although this improvement was not statistically significant. Based on analysis of interaction terms in the mortality model, the rate of improvement at Michigan hospitals exceeded that of the other hospitals ( $p = 0.045$ ).

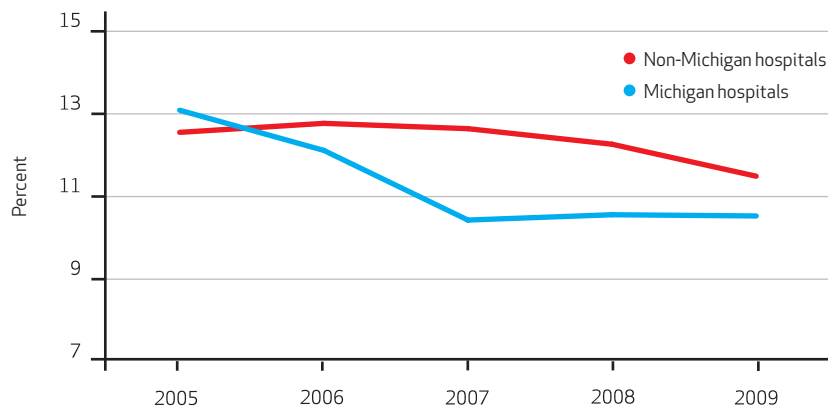
**INTERVENTIONAL CARDIOLOGY** The main outcome measure of the percutaneous coronary intervention program is not a single endpoint, such as whether or not the patient dies, but rather a so-called composite endpoint of serious complications, including emergency coronary artery bypass graft surgery, repeat of the procedure, stroke, and death. Between 1998 and 2002, serious complications fell from 3.8 percent to 2.3 percent among Michigan hospitals participating in the regional collaborative improvement program ( $p < 0.001$ ).<sup>21</sup> In 2002, participating hospitals had substantially fewer serious complications than Michigan hospitals not participating at that time (2.3 percent versus 3.2 percent,  $p < 0.001$ ), according to our analysis. Those latter hospitals joined the program shortly thereafter, and their outcomes have since caught up to those of the original cohort.

**CARDIAC SURGERY** For coronary artery bypass graft surgery, the regional collaborative improvement program rates hospital performance in terms of an eleven-item composite quality measure, which includes risk-adjusted mortality; complications; use of a section of the internal mammary artery that serves the chest wall and breasts as a graft; and several other important processes of care, as defined by the Adult Cardiac Surgery Registry of the Society of Thoracic Surgeons.<sup>22</sup> The Society of Thoracic Surgeons coordinating center conducts most of the analyses for the Michigan program and provides it with regular reports on hospital-specific and statewide performance.

During its initial reporting periods (2006–07

## EXHIBIT 2

### Risk-Adjusted Morbidity With General And Vascular Surgery: Hospitals In Michigan Versus Hospitals Outside Of Michigan, 2005–09

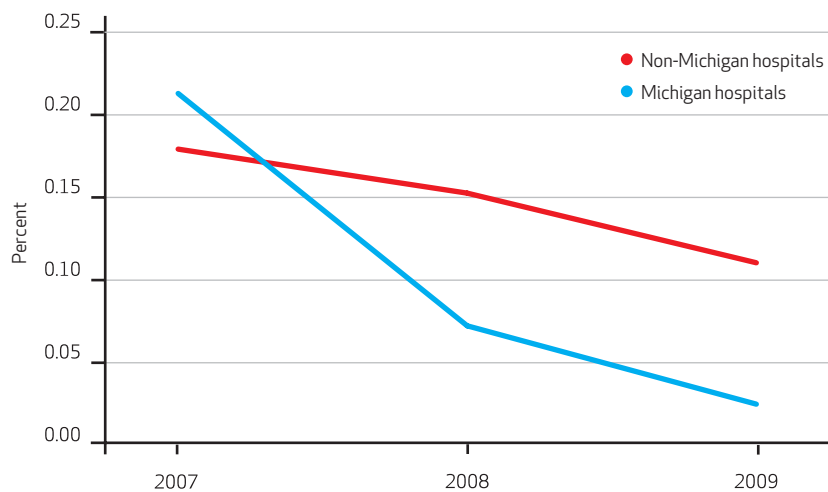


**SOURCE** Michigan Surgical Quality Collaborative and National Surgical Quality Improvement Program registries, 2005–09. **NOTES** Morbidity rates declined faster in Michigan hospitals ( $p < 0.001$ ) and, by 2009, were lower than in other hospitals participating in the National Surgical Quality Improvement Program ( $p < 0.001$ ).

and 2007–08), composite quality scores for Michigan hospitals as a whole were statistically indistinguishable from national benchmarks, according to reports provided by the Society of Thoracic Surgeons. By 2008–09, however, Michigan hospitals as a whole had achieved a three-star rating from the society, indicating that their aggregate performance exceeded national norms (with 99 percent probability) and fell

## EXHIBIT 3

### Thirty-Day Mortality After Bariatric Surgery: Hospitals In Michigan Versus Hospitals Outside Of Michigan, 2007–09



**SOURCE** Michigan Surgical Quality Collaborative and National Surgical Quality Improvement Program registries, 2007–09. **NOTES** Thirty-day mortality rates declined faster in Michigan hospitals than in other hospitals participating in the National Surgical Quality Improvement Program ( $p = 0.045$ ).

within the top tenth percentile of hospitals nationwide.

### Return On Investment

The most persuasive return-on-investment analysis of the regional collaborative improvement programs would require linking the clinical outcome registries to claims databases and demonstrating the extent to which measured improvements lead directly to less cost to insurers. Although this work is ongoing, there is reason to believe that the programs more than pay for themselves.

For example, in general and vascular surgery alone, the approximately 2.5 percent drop in surgical morbidity rates observed by the Michigan Surgical Quality Collaborative translates to 2,500 fewer Michigan patients with surgical complications each year, based on our analyses. One study—which used resource-based cost accounting methods—found that the average cost of such complications is \$11,000, of which 75 percent is passed along to insurers.<sup>5</sup> If these estimates are correct, the Michigan Surgical Quality Collaborative reduces payments associated with adverse outcomes by approximately \$20 million annually—far exceeding the \$5 million annual cost of administering the program.

The business case for the regional collaborative improvement programs can be made with far less extrapolation. For example, in 2007 almost 10 percent of patients in Michigan hospitals undergoing gastric bypass surgery received inferior vena cava filters to prevent postoperative pulmonary embolism. In this procedure, a filter is placed in the large abdominal vein that returns blood to the heart, in order to trap clot fragments and prevent them from traveling through the vein to the heart and lungs and causing blockage of circulation.

The use of these filters varied widely across hospitals, from 0 percent to more than 40 percent.<sup>23</sup> Six of the twenty-four hospitals were placing the large majority of the filters being placed statewide. Analysis of outcome data from the Michigan Bariatric Surgery Collaborative revealed that the use of inferior vena cava filters was not protective, but instead was associated with markedly higher risks of serious complications, many of which were directly related to complications from the filter itself. Following feedback of this information to surgeons and implementation of statewide guidelines, the use of the filters dropped to fewer than 2 percent of patients in a one-year period, according to Michigan Bariatric Surgery Collaborative data.

The average payment associated with placing the filter is \$13,000 (in 2007 dollars), so this

single change in practice saves payers more than \$4 million annually—considerably more than the cost of administering the regional collaborative improvement program in bariatric surgery.

Several other specific quality improvement interventions have also generated substantial savings. The use of two very expensive therapies in cardiac surgery—intra-aortic balloon pumps and prolonged mechanical ventilation—has fallen substantially.<sup>22,24</sup> Implementation of risk-prediction tools and practice guidelines has reduced the incidence of contrast-induced nephropathy (acute kidney failure triggered by the use of contrast dye in the procedure) and the need for dialysis after percutaneous coronary intervention.<sup>21</sup> Between 2007 and 2009, rates of thirty-day emergency department visits after bariatric surgery fell from 8 percent to 5 percent, with associated savings approaching \$1 million annually.

### Lessons Learned And Challenges For Dissemination

Hospitals have options for improving quality and efficiency that do not require them to collaborate with competing hospitals and physicians. Internal quality improvement activities can include the implementation of protocols and clinical pathways that reduce unwanted variation and incorporate evidence-based practices and guidelines. Hospitals can also establish checklists to minimize mistakes and improve communication and teamwork among providers and staff.<sup>25,26</sup>

Unfortunately, although protocols and checklists help ensure that processes known to be effective (for example, timely administration of perioperative antibiotics) are implemented, such evidence-based practices represent only a small proportion of the overall care delivered to hospitalized patients. Such efforts do not teach hospitals and physicians how to improve other aspects of care.

**BENEFITS OF REGIONAL COLLABORATION** Results from the Michigan initiative suggest that hospitals participating in regional collaborative improvement programs improve far more quickly than they can on their own. Practice variation across hospitals and surgeons creates innumerable “natural experiments” for identifying what works and what doesn’t.

The large sample sizes and statistical power associated with regional collaborative improvement program registries allow for more robust, rapid assessment of relationships between process and outcomes and of the effects of quality improvement interventions than can be achieved by hospitals examining their own prac-

# The insurer had the confidence that benefits would accrue primarily to its beneficiaries and purchasers.

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tice in isolation. Although identification and implementation of best practices are cornerstones of the regional collaborative improvement model, we believe that these programs also have salutary but immeasurable effects on the local safety culture. In our experience, participating hospitals and physicians simply start paying more attention to their practices and how to improve them.

**DIFFERENCES AMONG PROGRAMS** It is difficult to identify which specific components of the regional collaborative improvement model are most important. Each program involves numerous, concurrent interventions including performance feedback, site visits, collaborative learning, and targeted interventions aimed at specific clinical problems. Their cumulative effects are not readily disentangled.

The programs also use different approaches to identifying and disseminating best practices. Some are more evidence based than others, relying primarily on empirical analyses that link specific processes of care to clinical outcomes data. Others place a greater emphasis on hospital site visits and benchmarking, examining organizational factors and safety culture as well as specific processes of care. The comparative effectiveness of these different strategies is difficult to assess.

We believe that improvements in Michigan hospitals are largely attributable to the programs themselves, not to trends toward improvement occurring everywhere. First, many of the improvements in overall outcome measures can be directly attributed to specific interventions initiated by the programs. For example, our analysis indicates that mortality rates associated with bariatric surgery fell in large part because of declining rates of fatal pulmonary embolism, which were temporally related to statewide implementation of a protocol for increased prevention of this complication. Similar examples include the effects of comprehensive interventions

targeting surgical site infection in the Michigan Surgical Quality Collaborative and contrast-related nephropathy in percutaneous coronary intervention.

Second, as described earlier, Michigan hospitals had more substantial improvements in rates of morbidity and mortality than other hospitals participating in national data feedback programs administered by the Society of Thoracic Surgeons and the American College of Surgeons. Such data suggest that results in Michigan cannot be attributed simply to secular trends toward improving technical quality. Because most of the regional collaborative improvement programs are based on clinically detailed, well-validated national outcomes registries, results in Michigan cannot be attributed to differences in data collection techniques or outcomes definitions.

It is also important to note that hospitals participating in the Adult Cardiac Surgery Registry of the Society of Thoracic Surgeons or the American College of Surgeons National Surgical Quality Improvement Program may represent a “high bar” for purposes of benchmarking. These programs are voluntary and may attract hospitals most committed to quality improvement. At least with the National Surgical Quality Improvement Program, large teaching centers are overrepresented among participating hospitals and, based on our own (unpublished) analyses of national Medicare data, have notably lower surgical mortality rates than nonparticipating US hospitals.

As currently implemented, the Michigan regional collaborative improvement programs are evaluated for their effect on cost and outcomes in specific, clinically defined patient populations, not for their cumulative effect on the health of the entire population. Nonetheless, because these programs target clinical conditions and procedures that are common, expensive, and associated with substantial morbidity, we believe that their benefits at the population level would compare favorably to weaker interventions aimed at much broader populations, such as employee wellness programs and other preventive strategies.

**ROLE OF DOMINANT INSURER** Although successful regional collaborative improvement programs do not necessarily require payer involvement, the programs in Michigan would not have occurred had the state’s largest private insurer not underwritten their substantial costs, offered additional financial incentives for hospitals to participate, and provided a neutral meeting ground for collaborating hospitals and physicians. Although large private insurers are obvious candidates for leading the dissemination of regional collaborative improvement programs nationwide, this model has challenges.

Given its dominant share of the private insurance market in Michigan, Blue Cross and Blue Shield of Michigan/Blue Care Network had the leverage to urge hospitals to participate in the programs and the confidence that benefits would accrue primarily to its beneficiaries and purchasers. Other states are similarly dominated by one large insurer;<sup>27</sup> several, including Tennessee and Florida, are implementing similar regional collaborative improvement programs. Although private insurers have taken the lead so far, regional collaborative improvement programs could be similarly fostered by public payers or regional coalitions of private payers, purchasers, and provider systems.

**RELEVANCE FOR NATIONAL EFFORTS** Evidence that regional collaborative improvement programs can simultaneously improve quality and reduce costs at the population level comes at an opportune time. The regional collaborative improvement model is particularly relevant to the interests of the Centers for Medicare and Medicaid Services as it begins to enact provisions of the Affordable Care Act, including accountable care organizations.<sup>28</sup> In that context, such programs provide a robust data infrastructure for monitoring quality as health systems work toward constraining their costs.

More important, such programs provide a framework for facilitating improvement with regard to both cost and quality domains. Regional collaborative improvement programs should also become increasingly attractive to hospitals and physicians as they seek to improve quality and reduce costs. As the Centers for Medicare and Medicaid Services and other payers move

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toward episode-based bundled payments for inpatient surgery and other types of hospital-based care,<sup>29</sup> providers will increasingly bear the financial risk associated with complications and unnecessary services.

**CONCLUSION** As other stakeholders consider the value of the regional collaborative improvement model, Blue Cross and Blue Shield of Michigan/Blue Care Network and clinical leaders in Michigan are already fully persuaded of the benefits, and they continue to expand the scope of these programs. New programs focused on total joint replacement and interventions for atrial fibrillation are being added in 2011. If early results from the Michigan initiative hold up, such programs may represent a rare triple win: professional satisfaction and preserved autonomy for physicians; lower costs for payers; and better outcomes for patients. ■

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**David A. Share** is the executive medical director at Blue Cross and Blue Shield of Michigan.

In this issue of *Health Affairs*, David Share, John Birkmeyer, and their coauthors make the case for regional collaborations between hospitals and doctors as a way to

reduce health costs and improve the quality of care. The authors describe a Michigan-based project, financed by Blue Cross and Blue Shield of Michigan, that prevented surgical complications in an estimated 2,500 patients and saved \$20 million annually.

The researchers say that they long ago realized that traditional approaches to improving quality and efficiency—such as pay-for-performance and outside reviews of proposed treatments—didn't work well, for various reasons. Efforts to

find another way brought them together on this project.

Share says that this paper's findings show that data-centered, regional collaborations "can empower hospitals and doctors to transform care in both community and academic settings."

Share is the executive medical director for health care quality at Blue Cross Blue Shield of Michigan and an adjunct clinical assistant professor in the University of Michigan's Departments of Family Medicine and Pediatrics. He

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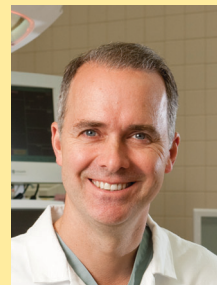
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# Hospital Complication Rates With Bariatric Surgery in Michigan

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**W**ITH RATES INCREASING over the last decade,<sup>1</sup> bariatric surgery has become the second most common abdominal operation in the United States. Despite trends toward declining mortality rates,<sup>2</sup> payers and patient advocacy groups remain concerned about the safety of bariatric surgery and uneven quality across hospitals. In response, 2 major professional organizations—the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery—have implemented programs for accrediting hospitals as centers of excellence (COE) in bariatric surgery. Standards for COE accreditation vary somewhat between the programs, but they generally include minimum procedure volume standards, availability of specific protocols and resources for managing morbidly obese patients, and submission of outcomes data to a central registry.

**Context** Despite the growing popularity of bariatric surgery, there remain concerns about perioperative safety and variation in outcomes across hospitals.

**Objective** To assess complication rates of different bariatric procedures and variability in rates of serious complications across hospitals and according to procedure volume and center of excellence (COE) status.

**Design, Setting, and Patients** Involving 25 hospitals and 62 surgeons statewide, the Michigan Bariatric Surgery Collaborative (MBSC) administers an externally audited, prospective clinical registry. We evaluated short-term morbidity in 15 275 Michigan patients undergoing 1 of 3 common bariatric procedures between 2006 and 2009. We used multilevel regression models to assess variation in risk-adjusted complication rates across hospitals and the effects of procedure volume and COE designation (by the American College of Surgeons or American Society for Metabolic and Bariatric Surgery) status.

**Main Outcome Measure** Complications occurring within 30 days of surgery.

**Results** Overall, 7.3% of patients experienced perioperative complications, most of which were wound problems and other minor complications. Serious complications were most common after gastric bypass (3.6%; 95% confidence interval [CI], 3.2%-4.0%), followed by sleeve gastrectomy (2.2%; 95% CI, 1.2%-3.2%), and laparoscopic adjustable gastric band (0.9%; 95% CI, 0.6%-1.1%) procedures ( $P < .001$ ). Mortality occurred in 0.04% (95% CI, 0.001%-0.13%) of laparoscopic adjustable gastric band, 0 sleeve gastrectomy, and 0.14% (95% CI, 0.08%-0.25%) of the gastric bypass patients. After adjustment for patient characteristics and procedure mix, rates of serious complications varied from 1.6% (95% CI, 1.3-2.0) to 3.5% (95% CI, 2.4-5.0) (risk difference, 1.9; 95% CI, 0.08-3.7) across hospitals. Average annual procedure volume was inversely associated with rates of serious complications at both the hospital level ( $<150$  cases, 4.1%; 95% CI, 3.0%-5.1%; 150-299 cases, 2.7%; 95% CI, 2.2-3.2; and  $\geq 300$  cases, 2.3%; 95% CI, 2.0%-2.6%;  $P = .003$ ) and surgeon level ( $<100$  cases, 3.8%; 95% CI, 3.2%-4.5%; 100-249 cases, 2.4%; 95% CI, 2.1%-2.8%;  $\geq 250$  cases, 1.9%; 95% CI, 1.4%-2.3%;  $P = .001$ ). Adjusted rates of serious complications were similar in COE and non-COE hospitals (COE, 2.7%; 95% CI, 2.5%-3.1%; non-COE, 2.0%; 95% CI, 1.5%-2.4%;  $P = .41$ ).

**Conclusions** The frequency of serious complications among patients undergoing bariatric surgery in Michigan was relatively low. Rates of serious complications are inversely associated with hospital and surgeon procedure volume, but unrelated to COE accreditation by professional organizations.

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Whether COE accreditation helps patients and payers identify safer hospitals for bariatric surgery remains a matter of debate. Hospital procedure volume, a core component of accreditation, has been linked to perioperative mortality with bariatric surgery.<sup>3-8</sup> However, many of these studies are outdated. As bariatric surgery has been more commonplace and mortality has declined, previous hospital volume benchmarks (125 per year for COEs) may be less important now than in the past. To date, only 1 published study has directly compared the outcomes of bariatric surgery at COE and non-COE hospitals, noting higher mortality and equivalent morbidity at the former.<sup>6</sup> Because this study was based on administrative data, however, its reliability in capturing hospital complication rates is questionable. It also included data from only 1 year, 2005, when COE programs were just beginning to be implemented.

In this context, we studied perioperative outcomes at 25 hospitals participating in the Michigan Bariatric Surgery Collaborative (MBSC), a payer-funded quality improvement program that administers a prospective, externally audited clinical outcomes registry. In addition to comparing complication rates by procedure and among hospitals, we examined relationships between procedure volume, COE accreditation, and hospital safety.

## METHODS

### Study Sample

This study is based on analysis of data from the MBSC. As described in greater detail elsewhere, the MBSC is a regional consortium of hospitals and surgeons performing bariatric surgery in Michigan.<sup>9,10</sup> Participation in the MBSC is voluntary and any hospital that performs a minimum of 25 bariatric procedures per year is eligible to participate. The MBSC now enrolls approximately 6000 patients per year from 25 hospitals in its clinical registry. Participating hospitals submit data for all of their bariatric surgery patients including those undergoing gastric by-

pass, laparoscopic gastric banding, biliopancreatic diversion with or without duodenal switch, and sleeve gastrectomy procedures. Procedures done on an outpatient basis are included in the MBSC registry and are subject to the same data collection requirements.

In the MBSC, data for the clinical registry is collected via medical record review for each patient at the end of the 30-day perioperative period. Information collected includes demographic variables, preoperative clinical characteristics and conditions, as well as perioperative process of care and outcomes. Patient readmissions to other hospitals are captured if it is recorded in the medical records of the hospital performing the bariatric surgery. The medical record reviews are performed by centrally trained nurse data abstractors using a standardized and validated instrument. Each participating hospital is visited annually by the project data quality coordinator to verify the accuracy and completeness of its MBSC clinical registry data. The collection of data for the purposes of participation in the MBSC has been approved by the institutional review boards of all member sites.

For this study, we identified all patients undergoing bariatric surgery between June 2006 and September 2009, which includes 15 275 patients from 25 hospitals. We excluded patients undergoing revisional surgery from this analysis because of the heterogeneity of the patient population and surgical procedures as well as inherently higher rates of complications for patients undergoing revisional surgery. We also excluded patients undergoing duodenal switch ( $n=245$ ) for confidentiality reasons since most of these procedures were performed by 1 surgeon in the state. We combined patients undergoing open and laparoscopic gastric bypass procedures as there was no difference in the rates of major complications with the 2 procedures following adjustment for patient case mix and because open gastric bypass is now performed so rarely (<5% of patients during the study period).

### Outcomes

Data were collected on 12 different types of bariatric surgery-related complications. Complications were grouped according to severity as non-life-threatening, potentially life-threatening, or life-threatening complications associated with residual and permanent disability or death. Potentially life-threatening complications included abdominal abscess (requiring percutaneous drainage or reoperation), bowel obstruction (requiring reoperation), leak (requiring percutaneous drainage or reoperation), bleeding (requiring transfusion >4 units, endoscopy, reoperation, or splenectomy), respiratory failure (requiring 2-7 days intubation), renal failure (requiring dialysis while patient is hospitalized during the perioperative period), wound infection/dehiscence (requiring reoperation), and venous thromboembolism (deep vein thrombosis or pulmonary embolism). Complications resulting in permanent disability included myocardial infarction or cardiac arrest, renal failure requiring long-term dialysis, respiratory failure requiring more than 7 days of intubation, or tracheostomy. The MBSC end points committee grades the severity of any perioperative complications not falling unambiguously into one of these categories. Our primary outcome measure for this study was the occurrence of a serious complication defined as potentially life threatening or resulting in death or disability.

### Independent Variables

Data on patient characteristics include patient demographics, weight and medical history, and weight-related and other comorbidities listed in TABLE 1. In general, MBSC comorbidity definitions include clinical documentation of the condition, its treatment, or both in the medical record. Lung disease includes asthma, other obstructive/restrictive lung disease, and home oxygen use. Cardiovascular disease includes coronary artery disease, heart rhythm disorder, congestive heart failure, or peripheral vascular disease. Patients with nonalcoholic fatty liver, clinical or subclinical cir-

rhosis, or liver transplant are considered to have liver disorders.

Annual hospital and surgeon volume categories (TABLE 2) were determined using a combination of generally accepted volume cut points and empirical derivation based on the distribution of patients, hospitals, and surgeons. Sites were deemed centers of excellence if they were designated as such by the American College of Surgeons or the American Society of Metabolic and Bariatric Surgeons at any point during our study period. Two sites held Blue Cross and Blue Shield Centers of Distinction status, which has similar criteria to the other COE accreditation programs in addition to COE accreditation from the American College of Surgeons or American Society of Metabolic and Bariatric Surgeons.

### Statistical Analyses

Pearson  $\chi^2$  test for categorical variables and the Kruskal-Wallis test for continuous variables were used to compare patient characteristics and rates of 30-day complications among patients undergoing the different types of bariatric procedures. Multilevel mixed-effects logistic regression models were used to evaluate risk factors for serious complications, with the log (odds) of the outcome modeled as a linear function of baseline covariates. The final models included all patient risk factors that were significant in multivariate analyses (age, body mass index [calculated as weight in kilograms divided by height in meters squared], male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass) as fixed effects, and hospital identifier as a random effect to adjust for clustering of patients within hospitals.

Because hospital and surgeon complication rates can vary due to chance alone, we adjusted our estimates for reliability. This technique adjusts hospital and surgeon outcomes for random variation, ensuring that performance is not overestimated or underestimated due to statistical noise.<sup>11</sup> Empirical Bayes methods shrink the observed complica-

tion rate at each hospital or for each surgeon toward the overall average, depending on its reliability. Reliability is measured on a scale of 0 (completely unreliable) to 1 (perfectly reliable) and is largely a function of sample size. For this analysis, we used the random effects from the mixed-effects models to calculate risk- and reliability-adjusted complications rates for each hospital. For this calculation, we add the overall average log (odds) of serious complications to the random effect (since the mean is 0 by definition) and then take the inverse logit of this sum. All reported *P* values are 2-sided, and *P* < .05 was considered statistically significant. All statistical analyses were performed using Stata version 10.1 (StataCorp, College Station, Texas).

## RESULTS

### Patient Characteristics

There were significant differences across the procedure types with regard to all potential risk factors for complications, including demographics, medical history, and obesity-related comorbidity (Table 1). In general, patients receiving laparoscopic adjustable gastric bands were lower risk than patients receiving gastric bypass or sleeve gastrectomy. Specifically, patients receiving laparoscopic adjustable gastric bands had significantly lower body mass index at baseline and lower rates of associated comorbid conditions. The predicted risk of serious complications based on a logistic regression model including significant multivar-

**Table 1.** Patient Characteristics and Predicted and Adjusted Rates of Serious Complications According to Bariatric Procedure Type

Characteristic	Procedures, %				<i>P</i> Value <sup>a</sup>
	Overall (N=15 275)	Laparoscopic Adjustable Gastric Band (n=5380)	Sleeve Gastrectomy (n=854)	Gastric Bypass (n=9041)	
Demographics					
BMI, median (IQR) <sup>b</sup>	46 (42-52)	43 (40-49)	50 (44-56)	47 (43-56)	<.001
Age, median (IQR), y	46 (37-54)	47 (38-56)	47 (37-55)	45 (37-54)	<.001
Male sex	21	20	30	20	<.001
Private insurance	72	76	80	69	<.001
Medical history					
Musculoskeletal disorder	76	70	68	79	<.001
Cardiovascular disease	56	55	59	56	<.001
Hyperlipidemia	50	46	50	51	<.001
Gastroesophageal reflux disease	47	46	43	48	<.001
Psychological	46	44	43	48	<.001
Sleep apnea	44	38	56	47	<.001
Current or past smoking	39	36	41	40	<.001
Diabetes	34	30	36	36	<.001
Total No. comorbidities >5	29	24	31	32	<.001
Cholelithiasis	27	24	29	28	<.001
Lung disease	26	23	20	27	<.001
Urinary incontinence	20	19	23	20	<.001
Mobility problems	5	5	10	5	<.001
Liver disorder	4	3	3	4	.001
Prior venous thromboembolism	4	3	5	4	<.001
Peptic ulcer disease	3	2	4	3	<.001
History of hernia repair	3	2	5	3	<.001
Predicted risk of serious complications <sup>c</sup>	2.7	2.4	3.0	2.8	<.001

Abbreviations: BMI, body mass index; IQR, interquartile range.

<sup>a</sup>*P* values for medians calculated using a nonparametric k-sample test on the equality of medians and *P* values for categorical variables calculated using  $\chi^2$  tests.

<sup>b</sup>BMI was calculated as weight in kilograms divided by height in meters squared.

<sup>c</sup>Based on a multivariate logistic regression model including all significant patient risk factors for serious complications (age, body mass index, male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions).

iate predictors (age, body mass index, male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) was 2.4% for laparoscopic adjustable gastric band, 3.0% for sleeve gastrectomy, and 2.8% for gastric bypass.

**Incidence of Specific Complications**

Overall, 7.3% (95% confidence interval [CI], 6.9%-7.7%) of patients experienced 1 or more perioperative complications. Rates of potentially life-threatening complications (TABLE 3) were highest for patients undergoing gastric bypass (3.1%; 95% CI, 2.8%-3.5%), followed by sleeve gastrectomy (2.2%; 95% CI, 1.3%-3.5%), and laparoscopic adjustable gastric band (0.78%; 95% CI, 0.56%-1.1%) procedures ( $P < .001$ ). Fatal complications occurred in 2 patients receiving laparoscopic adjustable gastric band (0.04%; 95% CI, 0.01%-0.13%), 0 patients receiving sleeve gastrectomy, and 13 patients receiving gastric bypass (0.14%; 95% CI, 0.08%-0.25%). Complications that were not fatal but that resulted in permanent disability occurred in 2 patients receiving

laparoscopic adjustable gastric band (0.04%; 95% CI, 0.01%-0.13%) and 30 patients receiving gastric bypass (0.33%; 95% CI, 0.22%-0.47%).

Complications at the surgical site occurred in 5.9% of patients (95% CI, 5.6%-6.3%) and were highest in patients undergoing gastric bypass (8.7%; 95% CI, 8.1%-9.3%), followed by patients receiving sleeve gastrectomy (3.6%; 95% CI, 2.5%-5.1%), and laparoscopic adjustable gastric band (1.7%; 1.4%-2.1%). Infection was the most frequent type of complication (3.2%; 95% CI, 2.9%-3.5%) and was most common among patients undergoing gastric bypass (4.4%; 95% CI, 4.0%-4.8%) and sleeve gastrectomy (2.5%; 95% CI, 1.5%-3.7%) procedures (Table 3). The subcategory of medical complications (including venous thromboembolism, cardiac, renal failure, and respiratory) occurred in 1.5% of patients overall (95% CI, 1.3%-1.7%), with the incidence varying from 0.58% (95% CI, 0.39%-0.82%) in patients with laparoscopic adjustable gastric band to 2.1% (95% CI, 1.8%-2.4%) in patients who received gastric bypass.

Rates of reoperation ranged from 0.59% (95% CI, 0.19%-1.4%) for sleeve gastrectomy to 2.5% (95% CI, 2.2%-2.8%) for gastric bypass procedures (Table 3). Transfers to other medical facilities (0.14%; 95% CI, 0.09%-0.22%) occurred infrequently. Hospital readmission and emergency department visits occurred in 4% (95% CI, 3.7%-4.3%) and 6.8% (95% CI, 6.4%-7.2%) of patients overall, respectively. Rates of both readmission and emergency department visits were lowest in patients who received laparoscopic adjustable gastric band and highest in those receiving gastric bypass. Median hospital length of stay (days) was 1 (range, 0-96), 2 (range, 0-63), and 2 (range, 0-148) for patients receiving laparoscopic adjustable gastric band, sleeve gastrectomy, and gastric bypass, respectively.

**Variation in Serious Complication Rates**

Risk- and reliability-adjusted rates of serious complications varied from 1.6% (95% CI, 1.3%-2.0%) to 3.5% (95% CI,

**Table 2.** Distribution of Patients, Hospitals, and Surgeons and Predicted and Adjusted Rates of Serious Complications by Mean Annual Bariatric Procedure Volume Category

	No. (%) <sup>a</sup>		
	Low	Medium	High
Annual bariatric procedures by surgeon, mean	<100	100-249	≥250
Patients	3664 (24)	7542 (49)	4069 (27)
Surgeons	33 (53)	22 (36)	7 (11)
Predicted risk of serious complications, % (95% CI) <sup>b</sup>	2.5 (2.4-2.6)	2.7 (2.6-2.8)	2.6 (2.5-2.7)
Adjusted serious complication rate, % (95% CI)	3.8 (3.2-4.5)	2.4 (2.1-2.8)	1.9 (1.4-2.3)
Annual bariatric procedures by hospital, mean	<150	150-299	≥300
Patients	1346 (9)	4338 (28)	9591 (63)
Hospitals	10 (40)	9 (36)	6 (24)
COE hospitals	6 (32)	8 (42)	5 (26)
Predicted risk of serious complications, % (95% CI) <sup>b</sup>	2.7 (2.6-2.8)	2.7 (2.6-2.8)	2.6 (2.6-2.6)
Adjusted serious complication rate, % (95% CI)	4.1 (3.0-5.1)	2.7 (2.2-3.2)	2.3 (2.0-2.6)
Adjusted serious complication rates by surgeon, % (95% CI)			
Low-volume surgeons	4.0 (2.8-5.3)	4.4 (3.2-5.6)	3.3 (2.3-4.2)
Medium-volume surgeons	6.1 (2.2-10.0)	2.2 (1.7-2.7)	2.4 (1.9-2.9)
High-volume surgeons	<sup>c</sup>	<sup>c</sup>	1.9 (1.4-2.3)
Adjusted serious complication rate, % (95% CI) by COE status			
Non-COE	3.7 (2.1-5.2)	2.2 (0.8-3.6)	1.6 (1.2-2.1)
COE	4.4 (3.0-5.8)	2.7 (2.2-3.3)	2.6 (2.2-3.0)

Abbreviations: CI, confidence interval; COE, center of excellence.

<sup>a</sup>Values are reported as No. (%) unless otherwise indicated.

<sup>b</sup>Based on a multivariate logistic regression model including all significant patient risk factors for serious complications (age, body mass index, male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass).

<sup>c</sup>No observation.



**Table 3.** Occurrence of Specific Perioperative Complications and Adverse Events by Procedure Type

Outcome	% (95% CI)				P Value <sup>a</sup>
	Overall (N=15 275)	Laparoscopic Adjustable Gastric Band (n=5380)	Sleeve Gastrectomy (n=854)	Gastric Bypass (n=9041)	
Any complication	7.3 (6.9-7.7)	2.3 (1.9-2.7)	5.9 (1.3-7.4)	10.3 (9.7-11.0)	<.001
Non-life-threatening	4.7 (4.4-5.1)	1.5 (1.2-1.8)	3.6 (2.5-5.1)	6.7 (6.2-7.3)	<.001
Potentially life-threatening	2.3 (2.0-2.5)	0.78 (0.56-1.1)	2.2 (1.3-3.5)	3.1 (2.8-3.5)	<.001
Permanently disabling	0.21 (0.14-0.30)	0.04 (0.01-0.13)	0	0.33 (0.22-0.47)	<.001
Fatal	0.10 (0.6-0.16)	0.04 (0.01-0.13)	0	0.14 (0.08-0.25)	.09
Combined serious complications <sup>b</sup>	2.6 (2.3-2.8)	0.86 (0.61-1.1)	2.2 (1.2-3.2)	3.6 (3.2-4.0)	<.001
Surgical site	5.9 (5.6-6.3)	1.7 (1.4-2.1)	3.6 (2.5-5.1)	8.7 (8.1-9.3)	<.001
Leak/perforation	0.59 (0.47-0.72)	0.07 (0.02-0.19)	0.35 (0.07-1.0)	0.92 (0.73-1.1)	<.001
Anastomotic leak	0.49 (0.36-0.64)	0	0	0.49 (0.36-0.64)	
Perforation/other leak	0.27 (0.20-0.37)	0.07 (0.02-0.19)	0.35 (0.07-1.0)	0.39 (0.27-0.54)	.002
Obstruction	1.5 (1.3-1.7)	0.26 (0.14-0.44)	0.70 (0.26-1.5)	2.4 (2.0-2.7)	<.001
Small bowel obstruction	0.49 (0.38-0.61)	0	0.12 (0.01-0.66)	0.81 (0.63-1.0)	<.001
Stricture/other obstruction	1.1 (0.93-1.3)	0.26 (0.14-4.4)	0.59 (0.19-1.4)	1.6 (1.4-1.9)	<.001
Infection	3.2 (2.9-3.5)	1.3 (1.0-1.6)	2.5 (1.5-3.7)	4.4 (4.0-4.8)	<.001
Abdominal abscess	0.45 (0.35-0.57)	0.07 (0.02-0.19)	0.47 (0.13-1.2)	0.67 (0.52-0.87)	<.001
Wound complication	2.7 (2.5-3.0)	0.84 (0.61-1.1)	2.2 (1.3-3.5)	3.9 (3.5-4.3)	<.001
Port site infection	0.30 (0.32-7.1)	0.30 (0.32-7.1)	0	0	
Hemorrhage	1.5 (1.3-1.7)	0.13 (0.05-0.27)	0.59 (0.19-1.4)	2.3 (2.0-2.7)	<.001
Medical complication	1.5 (1.3-1.7)	0.58 (0.39-0.82)	1.4 (0.73-2.4)	2.1 (1.8-2.4)	<.001
Venous thromboembolism	0.39 (0.30-0.50)	0.11 (0.04-0.24)	0.94 (0.41-1.8)	0.50 (0.36-0.67)	<.001
Cardiac	0.10 (0.06-0.16)	0.04 (0.01-0.13)	0	0.14 (0.08-0.25)	.09
Renal failure	0.31 (0.23-0.41)	0.07 (0.02-0.19)	0	0.48 (0.34-0.61)	<.001
Respiratory	0.99 (0.84-1.2)	0.35 (0.21-0.55)	0.47 (0.13-1.2)	1.4 (1.2-1.7)	<.001
Utilization					
Reoperation	1.7 (1.5-1.9)	0.63 (0.44-0.88)	0.59 (0.19-1.4)	2.5 (2.2-2.8)	<.001
Readmission	4.0 (3.7-4.3)	2.0 (1.6-2.4)	5.5 (4.1-7.3)	5.1 (4.6-5.6)	<.001
Transfer	0.14 (0.09-0.22)	0	0.23 (0.03-0.84)	0.22 (0.14-0.34)	.002
Emergency department visit	6.8 (6.4-7.2)	3.1 (2.7-3.6)	7.5 (5.8-9.5)	8.9 (8.4-9.5)	<.001

Abbreviation: CI, confidence interval.

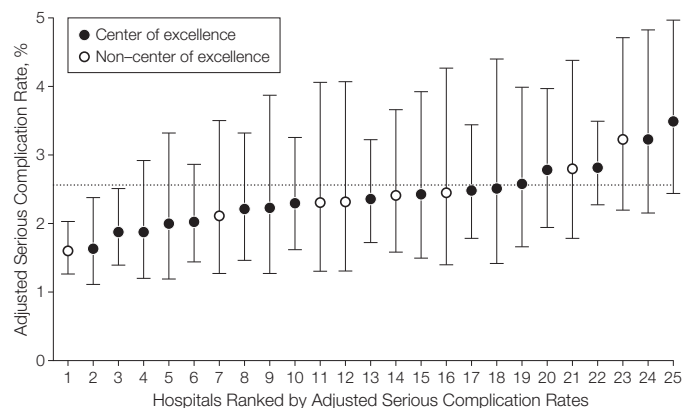
<sup>a</sup>P values were calculated using  $\chi^2$  tests.

<sup>b</sup>Includes potentially life-threatening, permanently disabling, and fatal complications.

2.4%-5.0%) by hospital (FIGURE). Rates were significantly lower than the state-wide average for 3 hospitals. The majority of hospitals (68%) had serious complication rates between 2% and 3%.

Risk of serious complications was inversely associated with average annual bariatric procedure volume (Table 2). For surgeon volume, rates in the low-, medium-, and high-volume categories were 3.8% (95% CI, 3.2%-4.5%), 2.4% (95% CI, 2.1%-2.8%), and 1.9% (95% CI, 1.4%-2.3%), respectively (*P* for trend=.001). For hospital volume, adjusted rates of serious complications were 4.1% (95% CI, 3.0%-5.1%), 2.7% (95% CI, 2.2%-3.2%), and 2.3% (95% CI, 2.0%-2.6%) in low-, medium-, and high-volume hospitals, respectively (*P* for trend <.001). Serious complication rates were about twice as high (4.0%; 95% CI,

**Figure.** Risk- and Reliability-Adjusted Serious Complication Rates by Site



Based on a multivariate logistic regression model including all significant patient risk factors for serious complications (age, body mass index, male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass). Error bars indicate 95% confidence intervals. Dotted line indicates the mean serious complication rate in the Michigan Bariatric Surgery Collaborative.

**Table 4.** Results of Model Fitting

Level	Variable	Coefficient (P Value)				
		Empty Model	Model 1	Model 2	Model 3	Model 4
Fixed effects						
Patient level	Predicted risk <sup>a</sup>		1.02 (<.001)	1.04 (<.001)	1.03 (<.001)	1.02 (<.001)
Surgeon level	Average annual surgeon volume			-0.299 (.003)		
Center level	Average annual hospital volume				0.260 (.02)	
	COE status					0.166 (.50)
Model information criterion						
	Akaike information criterion <sup>b</sup>	3616	3497	3492	3495	3499
Covariance parameter						
Center	Standard deviation of intercepts	0.3895	0.3438	0.1942	0.2501	0.3371
	Reduction in between center variability, %		22	75	59	25

<sup>a</sup>Based on a multivariate logistic regression model including all significant patient risk factors for serious complications (age, body mass index [calculated as weight in kilograms divided by height in meters squared], male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass).

<sup>b</sup>Akaike information criterion is defined as minus twice log likelihood plus 2 degrees of freedom.

2.8%-5.3%) for low-volume surgeons at low-volume hospitals than for high-volume surgeons at high-volume hospitals (1.9%; 95% CI, 1.4%-2.3%). Overall, rates of serious complications were similar among patients undergoing surgery at a COE (2.7%; 95% CI, 2.5%-3.1%) than for patients undergoing surgery at non-COE hospitals (2.0%; 95% CI, 1.5%-2.4%). After adjustment for patient case and procedure mix, there remained no significant difference in rates of serious complications at COE and non-COE hospitals (adjusted odds ratio [OR], 1.27; 95% CI, 0.72-2.25;  $P = .41$ ). There also was no significant difference (adjusted OR, 1.34; 95% CI, 0.88-2.05;  $P = .18$ ) in rates of serious complications in the COE hospitals compared with the non-COE hospitals within hospital procedure volume categories.

In our multivariate models, including patient risk and procedure mix reduced variation in serious complication rates across centers by 22% (TABLE 4). Individually adding surgeon volume, hospital procedure volume, and COE status to this model reduced variation in serious complication rates across centers by 75%, 59%, and 25%, respectively.

## COMMENT

In this study, we report major perioperative adverse outcomes in a large cohort of bariatric surgery patients. Our results provide information about the perioperative risks of the various types

of bariatric procedures in general practice. Overall, 7% of patients experienced perioperative complications. The majority of complications were non-life-threatening with minor wound problems being the most frequent type of complication. Approximately 2.5% of patients had more serious complications with mortality occurring in 0.12% of patients. Complication rates were highest for patients undergoing gastric bypass, followed by sleeve gastrectomy, and laparoscopic adjustable gastric band procedures.

Our study also suggests that the outcomes of bariatric surgery reported from select academic centers are achievable more broadly. Rates of serious complications were similar across providers with rates between 2% and 3% for the majority of hospitals and surgeons. The results of our study are similar to those recently reported by a select group of high-volume bariatric programs participating in the National Institutes of Health-funded Longitudinal Assessment of Bariatric Surgery (LABS) Consortium.<sup>12</sup> Despite similar patient populations, the overall rate of death and major complications are higher in LABS than those reported in our study. Higher complication rates reported in LABS may be attributable to the time periods studied, which included patients undergoing surgery between 2005 and 2007 in LABS and between 2006 and 2009 in Michigan.

Similar to many high-risk surgical procedures, procedure volume has been shown to be an important predictor of adverse outcomes in bariatric surgery.<sup>3-8,13,14</sup> The results of our study are similar to what others have found regarding the magnitude of the procedure volume effect on morbidity with bariatric surgery. For example, a study based on discharge claims data from the state of Florida (1999-2003) found approximate 2-fold differences in adjusted rates of serious complications comparing the lowest to the highest volume strata for both hospitals and surgeons.<sup>7</sup> A limitation of studies based on discharge claims databases is their ability to reliably capture nonfatal complications. Most of these prior volume outcome analyses in bariatric surgery are also quite dated with the most recent cohort including patients from 2005.<sup>6</sup>

Our results support those recently reported by Livingston<sup>6</sup> that COE accreditation is not associated with lower rates of bariatric complications. The prior study used 2005 National Inpatient Survey data to compare morbidity and mortality rates among 19 363 bariatric surgery patients at 24 COE and 229 non-COE centers. Mortality rates were higher at COE centers (0.17%) than non-COE centers (0.09%) and morbidity rates were close to identical (6.3% COE vs 6.4% non-COE). ORs adjusted for procedure volume, patient

risk, and teaching status were 1.76 ( $P = .71$ ) and 1.00 ( $P = .97$ ) for mortality and morbidity, respectively. The study by Livingston<sup>6</sup> differed from ours in that it was based on claims data that captured only in-hospital complications and also included data from only 1 year (2005) when COE programs were just beginning to be implemented.<sup>15-17</sup>

There are a number of reasons why COE accreditation by professional organizations or payers might not necessarily identify safer hospitals with bariatric surgery. First, although COE applications often ask hospitals for rates of specific outcomes (eg, postoperative venous thromboembolism), such outcomes data are generally not audited for accuracy or completeness and are often loosely defined. Second, aside from minimum caseloads, most requirements for bariatric COE accreditation, including the availability of specific protocols and resources for managing morbidly obese patients, are easily met by most hospitals with bariatric programs and likely have little bearing on surgical complication rates. Finally, given the highly competitive marketplace for bariatric surgery, COE accreditation programs may be attracting hospitals motivated as much by marketing advantage as by the desire to demonstrate and improve their quality.

This study has numerous limitations. First, because all but 8 of the 25 hospitals were COE-accredited by the end of the study period, we had suboptimal statistical power for detecting differences in risk between COE and non-COE hospitals. Based on an  $\alpha$  level of .05, our study had only 70% power to detect a relative risk reduction of 25% or more associated with COE accreditation.

Second, we counted as COEs any hospital that had received that designation by the end of the study period. In sensitivity analysis, however, we assessed the outcomes of patients according to whether their hospitals were COEs at the time of their procedures. As in our main analysis, there was no significant difference in rates of serious complications between COE and non-COE hospitals (adjusted OR, 1.15; 95% CI, 0.92-1.43;  $P = .22$ ).

When considering undergoing bariatric surgery, patients should weigh the risks and benefits of the various treatment options. Although we cannot yet report on the relative effectiveness of different bariatric procedures, prior studies suggest that weight loss is greater with procedures that combine both restrictive and malabsorptive elements than in purely restrictive procedures such as the laparoscopic adjustable gastric band.<sup>18-24</sup> In the future, our study will be able to provide information regarding the relative effectiveness of these different procedures with regard to weight loss, weight-related comorbidity resolution, late complications, quality of life, patient satisfaction, and health care resource utilization.

Our study findings may not be generalizable outside of the state of Michigan. These results reflect the outcomes among bariatric surgery centers that participate in a statewide collaborative quality improvement initiative. The extent to which this program, still in its first few years of existence, explains the relatively low rates of serious complications among bariatric hospitals and surgeons in the state is unknown. However, these efforts go beyond data feedback, requiring the active participation of bariatric surgeons in quality improvement initiatives and mandatory attendance at collaborative meetings held 3 times each year. For this reason, we believe that the results reported in this study represent the outcomes of bariatric surgery that are possible, but not necessarily those that are typical in community settings.

In conclusion, the frequency of serious complications among patients after bariatric surgery in Michigan is low. Rates of serious complications are inversely associated with hospital and surgeon procedure volume but not COE status. These data may serve as useful safety performance benchmarks for hospitals performing bariatric surgery. We hope that they might also inform the debate about the effectiveness of various approaches to ensuring high-quality care for bariatric surgery patients.

**Author Contributions:** Dr N. Birkmeyer had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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**Analysis and interpretation of data:** N. Birkmeyer, Dimick.

**Drafting of the manuscript:** N. Birkmeyer, Dimick, J. Birkmeyer.

**Critical revision of the manuscript for important intellectual content:** N. Birkmeyer, Dimick, Share, Hawasli, English, Genaw, Finks, Carlin, J. Birkmeyer.

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**Obtained funding:** N. Birkmeyer.

**Study supervision:** N. Birkmeyer.

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