MBSAQIP Data Collection Program:

PROs

Post Market Surveillance and Performance Metrics (QCDR)

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Disclosures

None.

I am a metabolic and bariatric surgeon.
Increased Number of WLS operations

**Figure 1.** Estimated Number of Bariatric Operations Performed in the United States, 1992–2003.
Data are from the American Society for Bariatric Surgery.

*NEJM 2004; 350:1076*
Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures

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Context Case series demonstrate that bariatric surgery can be performed with a low rate of perioperative mortality (0.5%), but the rate among high-risk patients and the community at large is unknown.

“Mortality rates were greater for those aged 65 years or older compared with younger patients (4.8% VS 1.7% at 90 days, and 11.1% vs 3.9% at 1 year, P<0.001).”

• MCAC. November 4, 2004.


For patients 65 years or older
• **Period for Discussion** (30 days)

• **National Coverage Determination** February 15, 2006.
  - Cover for age greater than 65.
  - Cover Bypass and LapBand.
  - Cover BMI 35 and over, with comorbidity.
  - Cover if accredited by ASBS or ACS.
Unification of Bariatric Programs and Data Collection Systems
MBSAQIP Data Collection System

- 100% of cases.
- Data collected by trained surgical clinical reviewers.
- Does NOT require a center to have NSQIP (but it was designed to integrate with the NSQIP).
- Bariatric specific data points:
  -Leaks, strictures, internal hernias etc.
  -Risk-adjusted.
  -Weight.
  -Weight related illnesses.
- Long term follow-up.
  
  30 days, 6 months, one-year........Annually... Forever?

- Captures 95% of all bariatric procedures done in the US.
MBSAQIP has high quality data:

- Data is prospective, clinically rich, risk adjusted and benchmarked.
- Data collectors at each site, trained and audited.
- Data collectors are not involved directly in patient care (third party).
- Data points have discreet standardized definitions, and are derived from objective information.
- Data collection is audited, including site reviews.
## CMS PQRS QCDR and VBM

<table>
<thead>
<tr>
<th>CMS</th>
<th>Centers for Medicare and Medicaid Services</th>
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<tbody>
<tr>
<td>PQRS</td>
<td>Physician Quality Reporting System</td>
</tr>
<tr>
<td>QCDR</td>
<td>Qualified Clinical Data Registry</td>
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<tr>
<td>VBM</td>
<td>Value Based (Payment) Modifier</td>
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### Penalties:

<table>
<thead>
<tr>
<th>Year</th>
<th>PQRS</th>
<th>VBM</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>0.5% bonus on Part B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>-1.5% (penalty)</td>
<td>-1.0%</td>
<td>-2.5%</td>
</tr>
<tr>
<td>2016</td>
<td>-2.0% (penalty)</td>
<td>-2.0%</td>
<td>-4.0%</td>
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</table>
1. Risk Stratified Overall Complication Rate.
2. Risk Stratified 30 Day Readmission Rate.
3. Risk Stratified 30 Day Reoperation Rate.
4. Risk Stratified 30 Day Anastomotic/Staple Line Leak Rate.
5. Risk Stratified Perioperative Bleeding Rate.
6. Risk Stratified Postoperative Surgical Site Infection Rate.
7. Risk Stratified Postoperative Nausea, Vomiting or Fluid, Electrolyte, Nutritional Depletion Rate.
8. Postoperative Extended Length Of Stay. (>7 days)
9. 30-Day Postoperative Follow-Up Rate.

- Effective Clinical Care
- Efficiency and Cost Reduction
- Patient Safety
- Communication and Care Coordination
QPP: Quality Payment Program

Zero sum game.

$ from Losers goes to Winners.

(Up to 10% can go to winners....)

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>2019</td>
<td>4%</td>
</tr>
<tr>
<td>2020</td>
<td>5%</td>
</tr>
<tr>
<td>2021</td>
<td>7%</td>
</tr>
<tr>
<td>2022 and after</td>
<td>9%</td>
</tr>
</tbody>
</table>
Patient Reported Outcomes

Congratulations!
The tests were negative, everything is perfectly alright!

My whole life is affected!
I cannot sleep
I cannot bend over or exercise
I cannot eat and drink whatever I like
“LOBSTER PROMs”

Long-term Outcomes of Bariatric Surgical Techniques and their Effect on Related Patient Reported Outcome Metrics

Preop and annually postop.
The Impact of Different Surgical Techniques on Outcomes in Laparoscopic Sleeve Gastrectomies

The First Report from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)

Elizabeth R Berger, MD,*§ Ronald H. Clements, MD, FACS,† John M. Morton, MD, MPH, FACS,‡ Kristopher M. Huffman, MS,§ Bruce M. Wolfe, MD, FACS,¶ Ninh T. Nguyen, MD, FACS,*¶ Clifford Y. Ko, MD, MS, MSHS, FACS,# and Matthew M. Hutter, MD, MPH, FACS**

Annals of Surgery, epub ahead of print, 7/26/16.

190,000 Laparoscopic Sleeve Gastrectomies
• 80% of surgeons use Staple line reinforcement
Staple line reinforcement is associated with increased leak rates.

SLR cases were associated with:
higher leak rates (0.96% vs 0.65%, OR 1.20 (1.00–1.43) and lower bleed rates (0.75% vs 1.00%, OR 0.74 (0.63–0.86)

At the surgeon level, leak rates remained significant, but bleeding events became nonsignificant.
New Data Variables

Intragastric Balloons

“Interventional Therapies for Metabolic and Bariatric Diseases”

Elipse™ (Allurion Technologies)
Obalon™ (Obalon Therapeutics)
Orbera™ (Apollo Endosurgery)
ReShape™ (ReShape Medical)
AspireAssist
Spatz™ (Spatz)
Vbloc
AspireAssist

New Standards (effective 10/1/16)

▪ ALL interventional therapeutic procedures done at your center, need to be included for data collection.
▪ Regardless of who does them and where.
Proposal:
To use the MBSAQIP for Post Market Analyses

- **Already have experience:**
  - FDA Project in 2009 with the American College of Surgeons.
  - Analyzed Adjustable Gastric Bands when second band ("Realize") was introduced. LapBand vs. Realize.

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**Intragastric Balloons:**

- Discussions with President/Senior leadership at Orbera and ReShape. Both are interested to do this.
- Balloon brands and balloon specific variables have been added. Complications, effectiveness, and reasons for premature or delayed/non removal.
- High quality, standardized data with comparative effectiveness to other procedures.
- Data from 95% of hospitals doing bariatric surgery. Real world, generalizable, lots of power.
- Cost savings for companies.
Proposal: To use the MBSAQIP for Post Market Analyses

To partner with the FDA, the ACS and industry.

- FDA acts as broker:
  - Industry gives funds to do post market analyses.
  - ACS has contract with FDA to do analyses.
  - Avoids conflicts of interest, maintains objectivity.