ASMBS American Society for Metabolic & Bariatric Surgery

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CONTACT: Amber Hamilton
(212) 266-0062

NEW STUDY FINDS MORTALITY RATES SIGNIFICANTLY LESS AT ACCREDITED BARIATRIC CENTERS

Study Comes as Medicare Considers Discontinuation of Bariatric Surgery Facility Certification

GAINESVILLE, FL -- July 22, 2013 -- A new study found non-accredited bariatric centers had an in-hospital mortality rate that was more than three times higher than accredited centers (0.22% vs. 0.06%, respectively) with similar volume.

The study, in press for publication in the journal *Surgical Endoscopy,* provides new insights into the positive impact accreditation and certification can have on the safety and effectiveness of bariatric surgery as the Centers for Medicare & Medicaid Services (CMS) considers reversing its 2006 decision requiring certification for facilities that perform bariatric surgery on Medicare beneficiaries.

“The risk of dying from stapling bariatric procedures was significantly higher at non-accredited facilities even after adjusting for volume," said Ninh T. Nguyen, MD, FACS, study co-author, vice-chair of the department of surgery at UC Irvine School of Medicine and American Society for Metabolic and Bariatric Surgery (ASMBS) President-elect. "These findings suggest that the standards required for accreditation provide important pre-operative and post-operative life-saving safeguards for patients, particularly to those at high risk for complications."

Dr. Nguyen urges CMS to reconsider its proposed decision to drop the facility certification requirement "as it may lead to unnecessary deaths." Dr. Nguyen along with University of California Irvine Department of Surgery researchers analyzed 277,760 laparoscopic gastric stapling procedures performed between 2006 and 2010 using the Nationwide Inpatient Database.

Previous studies have also supported facility accreditation, including a study published in the *Journal of the American College of Surgeons* (*JACS*) last year that showed almost identical differences in mortality between non- accredited and accredited academic bariatric centers (0.21% vs. 0.06%, respectively).

“These large studies further substantiate that there is a difference in mortality between accredited and non-accredited centers as the finding is reproducible using completely different database information,” added Dr. Nguyen, co-author of the *JACS* study of 35,284 bariatric procedures performed between 2007 and 2009 that used the University HealthSystem Consortium, a database of academic centers.

On June 27, 2013, in its proposed decision memo, CMS said "there is little evidence that the requirement for facility certification/COE (center of excellence) designation for coverage of approved bariatric surgery procedures impacts outcomes for Medicare beneficiaries."

"Facility certification, which has been in place for Medicare patients since 2006, has clearly worked. It has saved lives, improved patient outcomes, reduced costs and expanded access to quality care," said Jaime Ponce, MD, President of the ASMBS. "We have deep concerns and new evidence that removal of the certification provision would be a major step backwards and unnecessarily lead to reduced safety and effectiveness and higher mortality rates among Medicare beneficiaries undergoing bariatric surgery."

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The ASMBS will submit the new study on accreditation along with other supporting evidence for CMS to review as the agency considers a final ruling on the need for bariatric certification, which is expected by September 25, 2013.

The public may post comments on the proposed decision at the CMS website by July 27, 2013. When CMS first announced it was opening a national coverage analysis (NCA) in January 2013, it received 214 comments, the vast majority supporting continuation of the certification requirement.

"We strongly encourage CMS to reject the proposal to eliminate the bariatric surgery facility certification requirement. Elimination of bariatric surgery facility certification is a radical departure from previous CMS policy supporting patient safety and puts at risk the very people whom CMS is trying to protect and serve," said John Morton, MD, ASMBS Secretary-Treasurer and Associate Professor of Surgery at Stanford University. "Substantial gains have been made in bariatric surgery, but quality care and patient safety are enduring goals that best take place in an accredited facility setting. Let's not turn back the clock."

Several surgical and medical organizations have joined the ASMBS in requesting that CMS maintain its certification requirement. They include American College of Surgeons (ACS), The Obesity Society, Academy of Nutrition and Dietetics, American Society of Bariatric Physicians and SAGES.

Dr. Morton notes that if CMS eliminates facility certification for bariatric surgery, it will be the only major insurer that does not require it. Anthem, Aetna, Cigna and United Healthcare have each embraced and continue to support bariatric surgery facility accreditation.

While facility certification remains a question for CMS, bariatric surgery itself does not. The agency states that "the evidence continues to support that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) continue to be reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity." It further states that under the existing policy, local Medicare Administrative Contractors have the authority to make coverage decisions for any bariatric surgery procedures not specifically identified as covered or non-covered by an NCD, like the laparoscopic sleeve gastrectomy.

About the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)
On April 1, 2012, the American College of Surgeons (ACS) and the American Society for Metabolic and the Bariatric Surgery (ASMBS) combined their respective national bariatric surgery accreditation programs into a single unified program to achieve one national accreditation standard for bariatric surgery centers, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). The program accredits inpatient and outpatient bariatric surgery centers in the United States and Canada that have undergone an independent, voluntary, and rigorous peer evaluation in accordance with nationally recognized bariatric surgical standards. Bariatric surgery accreditation not only promotes uniform standard benchmarks, but also supports continuous quality improvement.

About Obesity and Morbid Obesity
Obesity is one of the greatest public health and economic threats facing the United States. The Centers for Disease Control and Prevention (CDC) reports more than 72 million Americans have obesity and, according to the ASMBS, about 24 million have morbid obesity. Obese individuals with a BMI greater than 30 have a 50 to 100 percent increased risk of premature death compared to healthy weight individuals, as well as an increased risk of developing more than 30 obesity-related diseases and conditions including Type 2 diabetes, heart disease and certain cancers.[i,ii] The federal government estimated that in 2008, annual obesity-related health spending reached $147 billion,[iii] double what it was a decade ago. Spending on obesity related issues is projected to rise to $344 billion each year by 2018.[iv]

About Metabolic and Bariatric Surgery

Metabolic and bariatric surgery has been shown to be the most effective and long lasting treatment for morbid obesity and many related conditions including type 2 diabetes, and results in significant weight loss.[v,vi,vii] The Agency for Healthcare Research and Quality (AHRQ) reported significant improvements in the safety of metabolic and bariatric surgery due in large part to improved laparoscopic techniques.[viii] The ASMBS reports the benefits of metabolic and bariatric surgery outweigh the risks for many individuals with severe obesity. The risk of death from metabolic and bariatric surgery is equivalent to that associated with hip replacement surgery[ix] and the overall likelihood of major complications is about four percent.[x]

About the ASMBS

The ASMBS is the largest organization for bariatric and metabolic surgeons and integrated health professionals in the world. It is a non-profit organization that works to advance the art and science of bariatric surgery and is committed to educating medical professionals and the lay public about bariatric surgery as an option for the treatment of morbid obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in bariatric surgery, while maintaining a steady exchange of experiences and ideas that may lead to improved surgical outcomes for morbidly obese patients. For more information, visit www.asmbs.org

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