

Bariatric Surgery

Draft Evidence Report: Comment & Response

February 4, 2015

Health Technology Assessment Program (HTA)

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Bariatric Surgery

Draft Report Public Comment and Response

April 10, 2015

Response to Public Comments

The Institute for Clinical and Economic Review (ICER) is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment period are included in this response document. Comments related to program decisions, process, or other matters not pertaining specifically to the draft key questions, project scope, or evidence assessment are acknowledged through inclusion only.

This document responds to comments from the following parties:

Draft Report

- Robert Michaelson, MD, PhD, FACS, FASMBS
President, Washington Chapter of the American Society for Metabolic and Bariatric Surgery (ASMBS)
Diplomate, American Board of Obesity Medicine

	Comment	Response
Robert Michaelson, MD, PhD, FACS, FASMBS <i>President, Washington Chapter ASMBS</i>		
1	“[...] the authors have chosen not to include any of the Swedish Obese Subjects (SOS) reports – as the most commonly used intervention in that study, the vertical banded is no longer performed in the United States.”	<p><i>The SOS study was not included as a primary study because over two-thirds of the patients received gastropasty, a procedure no longer performed in the U.S.</i></p> <p><i>We nevertheless summarized the mortality findings of the SOS study on page 30 given its import as a large, long-term cohort study. We have now expanded this discussion to include other key clinical outcomes of interest, and the SOS study remains a key source of long-term data for our economic model.</i></p>
2	“The other large longitudinal study in a reasonably generalizable population (Adams, 2007) has been excluded due to lack of information on the baseline health status of the control patients.”	<p><i>No changes made. We did not include this study because it did not meet our entry criteria. The control group did not feature an active comparator (i.e., applicants for driver’s licenses); in addition, there was no information on the health status of controls, making it impossible to rule out the effects of systematic differences in the clinical profile of surgical patients vs. controls on the outcomes of interest in this study.</i></p>
3	Referring to Maciejewski (2011): “The Veteran’s database, however, has been re-analyzed and reported over the same interval of time (JAMA 2015; 31391):62-70). The second report from the Veteran’s experience is that there is a definite survival benefit associated with bariatric surgery, suggesting a methodologic difference between the two reports.”	<p><i>No changes made. Arterburn, 2015 was included in the draft report, and the same discussion can be viewed on page 31 of the final report: “However, a more recent VA-based evaluation examined all-cause mortality at multiple timepoints during up to 14 years of follow-up in 2,500 surgical patients matched on a 1:3 basis to nonsurgical controls (demographics for matched cohorts: mean age 53, 74% male, mean BMI 46) (Arterburn, 2015). No significant differences between groups in all-cause mortality were observed at one year of follow-up. At 1-5 years, however, surgical patients experienced significantly lower rates of mortality (HR: 0.45; 95% CI: 0.36, 0.56); findings were similar at 5-14 years of follow-up.”</i></p>

	Comment	Response
4	<p>"The results of [...] landmark studies should be reconsidered with regard to the long-term value and efficacy of bariatric surgery. In so doing, the authors might consider revising the phrase 'shorter-term' (ES-55 under section entitled 'Rationale for ICER Ratings'), and reconsider that impact on their conclusions."</p>	<p><i>No changes made. As is the case with many other systematic reviews, we are unable to draw definitive conclusions about long-term effects of bariatric surgery due to a paucity of available studies, significant patient attrition in those studies that are available, lack of suitable analytic methods (e.g., survival analysis), and other concerns described in our report.</i></p>
5	<p>"Question 1a, under the section entitled "Impact of Bariatric Surgery on Resolution of Comorbidities" (ES-18 and p33) the relapse rate is reported to be '38 percent and 46 percent for RYGB and VSG, [sic: vertical sleeve gastrectomy] respectively'. However the actual rates reported in Schauer, 2014 – are 24 percent RYGB and 50 percent VSG. More disturbing however is the omission of the diabetes relapse rate in the [...] medically treated group."</p>	<p><i>We have added "[...] discontinuing anti-diabetic medications [...]" to the definition on page 34. Table 1 of Schauer, 2014 reports <u>relapse of glycemic control</u> (24% RYGB and 50% VSG), defined as HbA1c of 6% or less at one year but not at three years. The same table reports <u>relapse of diabetes remission</u> (38% RYGB and 46% VSG), which was defined as HbA1c of 6% or less at one year with <u>use of no anti-diabetic medications</u> but not at three years. Relapse could not be calculated among medically-treated patients because none of these patients achieved remission at one year. The report has been revised to make this point more clear.</i></p>
6	<p>"The review is potentially misleading as it fails to distinguish between perioperative (30 days) complications and longer-term complications. In addition, the severity or magnitude of complications is not taken into account."</p>	<p><i>No changes made. The studies varied considerably in the way in which complication rates were reported. It was not possible to differentiate between perioperative and longer-term complications in many studies; many other reviews have faced the same difficulty. Similarly, the severity and magnitude of complications were rarely reported, and when they were, standardized scales (e.g., Clavien) were rarely employed.</i></p>
7	<p>"[...] Question 4 [...] requires updating within the study interval as the establishment of the Metabolic and Bariatric Surgery Accreditation & Quality Improvement Program (MBSAQIP) and recent references regarding further analysis of the question of the benefits of center accreditation are not included."</p>	<p><i>MBSAQIP is now mentioned on page 57: "In April 2012, the ASMBS and the ACS formed the Metabolic Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). This unified national accreditation program [...]"</i></p> <p><i>We also updated the report on page 10 and page 57 to reflect changes in CMS's former coverage requirement: "[...] CMS removed the requirement that bariatric surgical procedures be performed at</i></p>

Comment		Response
		<p><i>an accredited facility [...] (p. 57)”</i></p> <p><i>One additional reference was found (Jafari et al., Surg Endosc (2013) 27:4539-4546) which compared RYGB and VSG outcomes for accredited versus non-accredited high-volume centers (≥ 50 cases annually). The authors’ findings have been added to the certification discussion on page 57.</i></p>

Washington State Chapter American Society for Metabolic & Bariatric Surgery

March 13, 2014

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Dear Committee Members:

The American Society for Metabolic and Bariatric Surgery (ASMBS) and the Washington State Chapter of the ASMBS (WA-ASMBS) are pleased to provide the following comments in response to the Draft Evidence Report on Bariatric Surgery (the report) developed by the Institute for Clinical and Economic Review (ICER) for the Washington State Healthcare Authority. We found the report to be a comprehensive assessment of the current status of the field and the authors should be commended for their attention to detail of the vast body of literature examined. However, we believe there are significant areas that require clarification.

There needs to be an awareness that an RCT in a surgical discipline is vastly different from an RCT in a pharmacologic or study. It is much less difficult to find study participants willing to take a sugar pill if randomized to a control group than it is to find subjects willing to undergo major surgery as a control subject. Nonetheless, many high quality RCTs have been conducted in bariatric surgery. The peer review process has evolved to critically analyze studies within these constraints. However, the authors dismiss and criticize benchmark studies from the most highly respected peer reviewed journals with data gathered for over 15 years. Further, it should be noted that these benchmark studies were not published in the surgical literature (which could be construed as self-serving to the surgical community) but rather the *New England Journal of Medicine (NEJM)* - one of the most highly regarded peer reviewed medical journals.

Specifically, the authors have chosen not to include any of the Swedish Obese Subjects (SOS) reports - as the most commonly used intervention in that study, the vertical banded is no longer performed in the United States. This exclusion is inappropriate for the following reasons: the weight loss (approximately 15% long-term) achieved is in the range seen with the adjustable gastric banding reports that are emerging at the present time. The 15% weight loss, while less than that associated with other procedures, still greatly exceeds the weight loss for all non-surgical comparative groups, particularly at two years and beyond. Thus, the SOS trial does give an opportunity to examine the benefits of greater weight loss on long-term outcomes than can be achieved by non-surgical interventions. While it is true that there was not discriminatory power in the analysis to relate the extent of weight loss to mortality specifically, there is no basis in this trial to ascribe the outcome differences between the surgical and medical arms of this trial to any factor other than weight loss. The number of RYGB's (13%) is presumed to be insufficient to permit attribution of the improved mortality and other outcomes reported by the SOS to the special effects which may occur as the result of RYGB. The fact that the individual weight loss data does not have discriminatory power regarding mortality does not mean that the improved survival was due to any effect other than weight loss.

Surgery is a continually evolving process – a given procedure is rooted in its predecessor with the underlying evidence based assumption that some improvement in the technique or outcome has been made. In fact, each of the four bariatric surgical procedures under consideration, currently employ some form of gastroplasty. Each of the procedures has evolved with their own additions or modifications along with a gastroplasty. Ergo, these contemporary operations should be considered improvements on a gastroplasty. The decision to exclude one of the most highly regarded studies in the bariatric literature, the SOS, (*Sjöström, 2007, 2012, 2013, 2014*) on these grounds is unfounded.

The other large longitudinal study in a reasonably generalizable population (*Adams, 2007*) has been excluded due to lack of information on the baseline health status of the control patients. Adams has been careful to address the issue of inaccurate self-reported weights as well as health of the control population. For example, all subjects were linked to the Utah cancer registry to eliminate of all deaths from cancer occurring within the first five years from baseline. All of the subjects were of sufficient health to be eligible for a driver's license in Utah. Thus it is not clear Adams was excluded for appropriate reason.

Reference to the Veteran's data reported by Maciejewski (2011) speaks to the ever-present limitation of the necessity to have a cut-off date for inclusion of citations. This is important from the standpoint of the mortality benefit of bariatric surgery because the Veteran's population is the only study to date using whatever method to fail to demonstrate a survival benefit associated with bariatric surgery. The Veteran's database, however, has been re-analyzed and reported over the same interval of time (*JAMA 2015; 313(1):62-70*). The second report from the Veteran's experience

is that there is a definite survival benefit associated with bariatric surgery, suggesting a methodologic difference between the two reports.

The results of these landmark studies should be reconsidered with regard to the long-term value and efficacy of bariatric surgery. In so doing, the authors might consider revising the phrase “**shorter-term**” (ES – 55 under section entitled “**Rationale for ICER Ratings**”), and reconsider that impact on their conclusions.

Finally, we would note regarding some of the key questions:

Question 1a, under the section entitled “**Impact of Bariatric Surgery on Resolution of Comorbidities**” (ES-18 and p33) the relapse rate is reported to be “38 percent and 46 percent for RYGB and VSG, [sic: vertical sleeve gastrectomy] respectively”. However, the actual rates reported in *Schauer, 2014* - are 24 percent RYGB and 50 percent VSG. More disturbing however is the omission of the diabetes relapse rate in the third group of Schauer’s study – the medically treated group. This group experienced an 80% relapse rate in diabetes. The distortion and omission of this data is misrepresentative. It gives the impression that the effect of surgery on diabetes is not durable; when in fact, its effect is nearly double that of intense medical therapy (of note, Schauer’s study was also reported in the *NEJM*).

Question 3 discusses complication rates. The review is potentially misleading as it fails to distinguish between perioperative (30 days) complications and longer-term complications. In addition, the severity or magnitude of complications is not taken into account.

Under Question 4, the section regarding the benefit of center accreditation requires updating within the study interval as the establishment of the Metabolic and Bariatric Surgery Accreditation & Quality Improvement Program (MBSAQIP) and recent references regarding further analysis of the question of the benefits of center accreditation are not included.

Again, we appreciate the opportunity to be involved in the development process of the draft evidence report. We look forward to continuing this productive dialogue regarding evidence-based obesity treatment services, such as bariatric surgery, and remain available to you for any assistance or consultation as needed. On behalf of ASMBS and WA-ASMBS, I am

Respectfully,

A black rectangular box redacting the signature of Robert Michaelson.

Robert Michaelson, MD, PhD, FACS, FASMBS
President, Washington Chapter-ASMBS
Diplomate, American Board of Obesity Medicine