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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality

**Scientific Information Request on Short and Long Term Outcomes
after Bariatric Therapies in the Medicare Population.**

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions to inform our review of *Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation

Scientific Resource Center

ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.):
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
3710 SW U.S. Veterans Hospital Road
Mail Code: R&D 71
Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email:
SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for *Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population*.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population*, including those

that describe adverse events. The entire research protocol, including the key questions, is also available online at:

<http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/bariatric-surgery-protocol.pdf>

This notice is to notify the public that the EPC Program would find the following information on *Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.
 - For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute all Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://subscriptions.ahrq.gov/accounts/USAHRQ/subscriber/new?topic_id=USAHRQ_18.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at:

<http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/bariatric-surgery-protocol.pdf>

KQ 1: What are the theorized mechanisms of action of bariatric procedures on weight loss and on type 2 diabetes in the Medicare population?

KQ 2: In studies that are applicable to the Medicare population and enroll patients who have undergone bariatric therapy, what are

- I. the characteristics and indications of the patients including descriptives of age, BMI, and comorbid conditions
- II. the characteristics of the interventions, including the bariatric procedures themselves as well as pre- and/or post-surgical surgical work-ups (e.g., psychiatric evaluations, behavioral and nutritional counseling)
- III. the outcomes that have been measured, including peri-operative (i.e., 90 days or less after bariatric surgery), short-term (2 years or less from surgery), mid-term (more than 2 but 5 or less years), and long-term (more than 5 years after surgery) outcomes?

KQ 3:

- I. In Medicare-eligible patients, what is the effect of different bariatric therapies (contrasted between them or vs. non-bariatric therapies) on weight outcomes (including failure to achieve at least minimal weight loss)?
- II. What patient- (KQ2 I) and intervention-level characteristics (KQ2 II) modify the effect of bariatric therapies on weight outcomes (including failure to achieve at least minimal weight loss)?

III. In Medicare-eligible patients who have undergone bariatric therapy, what is the frequency and the predictors of failing to achieve at least minimal weight loss?

KQ 4

- I. In Medicare-eligible patients, what is the comparative effectiveness and safety of different bariatric interventions (contrasted between them or vs. non-bariatric interventions) with respect to the outcomes in KQ2 III?
- II. What patient- (KQ2 I) and intervention-level (KQ2 II) characteristics modify the effect of the bariatric therapies on the outcomes in KQ2 III?

KQ 5

- I. In Medicare-eligible patients who have undergone bariatric therapy, what is the association between weight outcomes and eligible short- and long-term outcomes (other than weight outcomes)?
- II. In Medicare-eligible patients, what proportion of the bariatric intervention effect on eligible short- and long-term outcomes (other than weight outcomes) is accounted for by changes in weight outcomes?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Population: Medicare-eligible population to include those age 65 and older and the disabled.

Interventions: Bariatric treatments including anatomic alteration, FDA-approved device placements, open surgical procedures, as well as laparoscopic and endoscopic procedures

I. Surgical bariatric therapies

A. Adjustable gastric banding (AGB)

1. LAP-band, pars flaccida technique
2. LAP-band, perigastric technique
3. Swedish-band (also known as REALIZE-band), pars flaccida technique
4. Swedish-band (also known as REALIZE-band), pars flaccida technique, single bolus filling
5. Gastroplasties

B. Horizontal banded gastroplasty

C. Vertical banded gastroplasty

D. Endoluminal vertical gastroplasty

1. Sleeve gastrectomy
2. Gastric plication (also referred to as gastric greater curvature plication or gastric imbrication)
3. Jejunioileal bypass
4. Biliopancreatic diversion (BPD)

E. Biliopancreatic diversion (BPD) with RYGB (BPD-RYGB)

F. BPD with duodenal switch (BPD-DS)

1. Roux-en-Y Gastric Bypass (RYGB)
2. Mini-gastric bypass
3. Single Anastomosis Duodeno-Ileostomy (SADI)
4. Vagal blockade
5. Omentum removal (omentectomy)
6. Gastric stimulation (also referred to as gastric pacing)
7. Mucosal ablation

II. Endoscopic bariatric therapies

A. Space-occupying endoscopic bariatric therapies

1. Intra-gastric balloons

B. Nonballoon devices

1. Aspiration therapy

2. Endoscopic sleeve gastropasty

3. Endoscopic gastrointestinal bypass devices

C. Duodenojejunal bypass sleeve

D. Gastroduodenojejunal bypass sleeve

1. Duodenal mucosal resurfacing

2. Self-assembling magnets for endoscopy

Comparisons: Comparisons of interest include comparisons between different surgical interventions, or between surgical and non-surgical interventions

Outcomes: Outcomes will be classified as peri-operative (i.e., 90 days or less after bariatric surgery), short-term (2 years or less from surgery), mid-term (more than 2 but 5 or less years), and long-term (more than 5 years after surgery). The following outcome categories are of interest:

I. Mortality

II. Weight loss

III. Reoperations/need for revisional bariatric surgery

IV. Postoperative complications including mortality

V. Metabolic/diabetes-related outcomes

A. Correction of glucose tolerance, including elimination of all medications with Hemoglobin A1c (HbA1c) <6

- B. Diabetes: new onset diabetes; treatment of diabetes; diabetic complications (microvascular disease, kidney disease, retinopathy)
- C. Hypoglycemic-like syndromes such as nesidioblastosis, post-gastric surgery hypoglycemia, and dumping syndrome
- D. Non-alcoholic steatohepatitis (NASH) and/or non-alcoholic fatty liver disease (NAFLD)
- VI. Reflux
- VII. Cardiovascular outcomes
 - A. Myocardial infraction
 - B. Stroke
 - C. Hypertension
- VIII. Respiratory disease
 - A. Asthma
 - B. COPD
- IX. Orthopedic outcomes
 - A. Fractures
 - B. Falls
 - C. Osteoporosis/bone-mineral density (DEXA, DEEG)
- X. Sleep apnea including the discontinuation of CPAP or BiPAP
- XI. Incidence of specific cancers (breast, colorectal cancer, endometrial cancer, esophageal adenocarcinoma, gall bladder cancer, and renal cell cancer)
- XII. Nutritional deficiencies including zinc, iron, thiamine, and vitamin D, and associated disorders such as neuropathy and bone disease
- XIII. Renal function as measured by creatinine clearance or urinary albumin excretion
- XIV. Compliance to follow-up

- XV. Mental health outcomes. Incidence of suicide and suicide attempts
 - A. Incidence of depression
 - B. Alcohol addiction after surgery/Substance abuse
 - C. Psychiatric hospitalizations
 - D. Anxiety
 - E. Panic disorder
 - F. Borderline personality disorder
 - G. PTSD
 - H. Bipolar disorder
- XVI. Function and quality of life (validated measurements only), e.g.,
 - i. Cognitive functioning
 - A. Sexual functioning
 - B. Ability to participate in an exercise program
 - C. Ability to return to work
 - D. Physical performance test pain (joint pain, joint aches)
 - E. Regular daily activities
 - F. Polypharmacy
 - G. Admission to a skilled-nurse facility
- XVII. Access to plastic surgery
- XVIII. Readmissions/rehospitalizations

Timing:

No time limit

Setting:

Any

Sharon B. Arnold,
AHRQ Deputy

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