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**Introduction**

Severe obesity has increased more rapidly than less extreme levels of excess body weight in the US. In 2009-2010, 15% of US adults had a BMI ≥35 kg/m², while 6% had BMI ≥40 kg/m². Bariatric surgery is an important treatment for severe obesity, with consensus guidelines recommending consideration of surgery for patients with severe obesity (BMI ≥40 kg/m²) or BMI ≥35 kg/m² plus a comorbidity. Among adolescents (age 12-19 years), 20.5% have obesity, and severe obesity prevalence appears to be rising. While still controversial, bariatric surgery has emerged as a treatment option in this population. Weight loss surgery increased dramatically in the US between 1998-2003, then plateaued or declined slightly over the next five years. A better understanding of expected risks, benefits, and patient perceptions of the experience of bariatric surgery would assist patients, families and clinicians in making informed decisions about whether or not to pursue bariatric surgery or which procedure to choose.

**Patient-centeredness**

To what extent is the proposed research focused on questions and outcomes of specific interest to patients, their caregivers, and clinicians? For many individuals who undergo bariatric surgery, it is a weight loss option “of last resort” after multiple failed weight loss efforts. Patients planning to undergo bariatric surgery appear to value weight loss highly, with 73% in one sample reporting that they were willing to risk death to achieve a weight loss of 20% of their weight. The main reason for patients to undergo bariatric surgery is to improve health. These findings emphasize the importance of providing patients (and parents, for pediatric patients) with the information they need to make informed decisions. Recent publications, whose authors included clinicians and health system stakeholders, have identified critical topics for further research that are consistent with the aims of this topic brief. Furthermore, although limited, data suggest that primary care providers (PCPs) lack high quality evidence for clinical management decisions for patients after bariatric surgery. In one study, although approximately 85% of PCPs treated patients who had undergone bariatric surgery, 35% felt unprepared to provide good quality long-term medical care for these patients.

**Burden on Society**

Based on consensus guidelines, 6.4% of Americans are eligible for bariatric surgery because they have a BMI ≥40 kg/m². Substantial ethnic/racial disparities exist with 16.4% of non-Hispanic Black women and 7.6% of Hispanic women meeting this threshold. Another 8.1% of Americans have BMI ≥35 kg/m² and would qualify for bariatric surgery if they have a co-morbidity; more than 60% of people with a BMI ≥35-40 kg/m² likely have a qualifying co-morbidity. Guidelines regarding which adolescents may qualify for bariatric surgery are less clear, but at least 5% of youth have severe obesity.

Severe obesity entails a significant health burden for affected individuals and for the US health care system, including premature mortality; elevated rates of CHD, diabetes, and hypertension; and impaired quality of life. Compared with people who have normal BMI, people with a BMI of 30-35 have about 25% higher health care expenditures, those with a BMI of 35-40 with about 50% higher and those with a BMI ≥ 40 with about 100% higher. Severe obesity in childhood is unlikely to reverse and is linked with early-onset of cardiovascular risk factors, gallstone disease, fatigue and diminished mobility.

**Assessment of Current Options**

In several long-term observation studies, bariatric surgery has been associated with long term weight loss, diabetes remission, decreased diabetes incidence, decreased cardiovascular risk, lower cancer incidence, and decreased mortality. Randomized clinical trials have found robust short term benefits of adjustable gastric banding and...
Roux-en-Y gastric bypass/sleeve gastrectomy[^7-^9] for weight loss and diabetes remission. Systematic reviews and meta-analyses have confirmed that bariatric surgery can lead to dramatic weight loss and improvements in weight-related health problems such as obstructive sleep apnea, hypertension, dyslipidemia, and type 2 diabetes – including resolution of diabetes and improvement in other cardiovascular risk factors.[^40-^45] Qualitative data indicate that bariatric surgery can result in more energy, mobility and confidence.[^46]

Data on outcomes of adolescent bariatric surgery are more limited and include mostly studies of short duration. However, outcomes and adverse events appear similar to those seen for adults, with over 30% of baseline body weight lost at 1 year, following Roux-en-Y gastric bypass surgery[6] and lower amounts of weight loss resulting from adjustable gastric banding.[^36] One study with 14 years of follow-up found that 5 of 33 adolescents regained all weight lost after bariatric surgery, but the majority of participants were able to achieve sustained weight loss with resolution of comorbidities.[^47]

**What are the limitations of current literature for which new research could contribute to achieving better patient-centered outcomes?**

Among adults, limited long-term data are available to compare outcomes and adverse events by surgical type (Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding). Further, prior studies have not been large enough to sufficiently parse outcomes by subgroups or to examine pre-operative and post-operative predictors of outcomes after surgery. Furthermore, long term data of the effect of bariatric surgery among adolescents are limited.

**What recent innovations made research on this topic especially compelling?**

Several factors make this topic compelling and timely: (a) the availability of PCORNet, which provides a large, diverse population across the US; (b) escalating rates of severe obesity in US adults and youth, with substantial long-term health risks, emphasizing the timeliness of addressing this problem; (c) the increasing utilization of bariatric surgery in the adolescent population; and (d) the emergence of newer bariatric surgical procedures, such as the sleeve gastrectomy.[^48]

**What is the added value of performing this research in PCORNet over doing it in more limited settings, eg a single CDRN?**

PCORNet provides the ability to (a) determine estimates of the effect of bariatric surgery stratified by important subgroups (e.g., patient age, race/ethnicity, smoking history, starting BMI); (b) evaluate a sufficient number of patients to quantify less-common adverse outcomes; (c) include a real-world spectrum of surgeons and patients[^49] from different regions and with variation in surgical volumes and (d) combine data collected in the routine delivery of clinical care with data on patient perspectives.

### Potential for New Information to Improve Care and Patient-Centered Outcomes

**How likely is it that new CER on this topic would provide better information to guide clinical decision making?**

Knowing long-term results of bariatric surgery in different subgroups would provide information to help patients, families and providers make informed decisions about whether to pursue surgery and which surgical procedure may be best for them. PCORNet could also facilitate overcoming certain deficits in the current literature, such as the need for large sample sizes to evaluate adverse outcomes.[^18]

**How likely is it that the results of new research on this topic would be implemented in practice right away?**

The findings can immediately be integrated into discussions between patients and their health care teams, to reach the study goal of helping patients and clinicians make informed, patient-centered decisions about bariatric surgery.

**How would findings be disseminated?**

With the participation of all CDRNs and 8 PPRNs, the PCORNet Obesity Task Force (OTF) is a key dissemination resource. OTF members will be asked to draw attention to the study’s findings within their CDRNs or PPRNs, and to their relevant other affiliate organizations (i.e., via annual meetings, print and online publications). For example, OTF participants include members of The Obesity Society (TOS), the American Society of Metabolic and Bariatric Surgery (ASMBS), and the HMO Research Network (HMORN). TOS and ASMBS have large networks of obesity researchers and clinicians while the HMORN is comprised of 18 member organizations across the US, mostly large health maintenance organizations.

### Feasibility of the Study within Health Systems

**Does this study meet the requisite technical, governance and regulatory constraints described below?**

Outcomes are drawn primarily from CDM1 and CDM2, mitigating the technical concerns.
### Study Design Aspects

#### Conceptual/ causal model

Bariatric surgery results in both health improvements and adverse outcomes, with different results expected depending on which bariatric surgical procedure is performed. How patient characteristics, pre-operative factors, and post-operative factors influence these outcomes are critically important for patients, their family members, providers, and payers and could help guide decisions about surgery and the care leading up to and following it. Identifying expectations regarding surgery, directly from patients, will also help elucidate what questions are most important to address prior to and following surgery. Other factors clearly affect outcomes, but we will be unable to capture them in the data available for this study. These include diet, physical activity, and prior experience with behavioral weight loss. Further, other outcomes are important to examine, such as diabetes remission, cardiovascular risk, and resolution of obstructive sleep apnea. As the CDM evolves, more of these outcomes may be accessible as will more patient reported outcomes.

#### Aims

**Aim 1: To what extent does weight loss and weight regain differ across bariatric surgical procedures (Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding)?**

*Sub-aim 1:* Examine average loss at 1, 3, and 5 years, weight nadir, frequency of return to within 5% and 10% of initial body weight at 1, 3, and 5 years, as well as variability in these outcomes and trajectories of weight change over time.

*Sub-aim 2:* Examine heterogeneity in weight outcomes by patient factors (age, race/ethnicity, starting BMI, smoking history, comorbidities)

**Aim 2: To what extent do pre-operative and post-operative factors influence weight loss and weight regain after bariatric surgery?**

Pre-operative predictors: number of ambulatory visits to any provider, number of visits to a primary care physician, weight change during the 6 month period prior to surgery, duration of time from first bariatric visit to surgery

Post-operative predictors: number of ambulatory visits to any provider, number of visits to a primary care physician, use of plastic surgery (i.e., body contouring)

*Sub-aim 1:* Examine heterogeneity in these relationships by the patient factors described in Aim 1.

**Aim 3: In a subset of patients who have had bariatric surgery, to determine patient expectations prior to and following surgery and patient perspectives on factors that shaped their use of the health care system following surgery.**

*Sub aim:* Identify patient expectations for recommended post-surgery care, how those expectations were communicated and reasons why post-surgical patients did or did not follow-up with that care

**Aim 4: To what extent do different bariatric surgical procedures lead to adverse outcomes?**

CDM 1: hospitalizations, re-operations (revisions, removal/reversal, incisional or internal hernia repair), fractures

CDM2: Anemia (defined as a hemoglobin < 13 g/dl for men and < 12 g/dl for women)

*Sub-aim:* What factors moderate the incidence of adverse outcomes following bariatric surgery (focusing on the patient factors as described in Aim 1)?

#### Inclusion/exclusion criteria

(a) All ages, adults and children; (b) CPT code for a primary bariatric surgical procedure, excluding reoperation; (c) 1 height, 1+ weight measures in the 12 months before surgery, 2+ weight measurements in the 12 months after surgery
Please note: The topic brief work group tried to develop aims that align with the elements of CDM1 and CDM2. If there will be extensions to the CDMs before a study takes place, additional variables that could add value to these analyses would include:

- a) Mortality (an additional adverse outcome)
- b) Other laboratory values that guidelines recommend be monitored following bariatric surgery and that could help determine whether patients experience additional adverse outcomes (e.g., hypocalcemia, vitamin d deficiency) or resolution of pre-existing health problems (e.g., diabetes)
- c) Health system factors (e.g., procedure volume, academic affiliation, rural vs. urban vs. suburban) as additional measures by which to examine heterogeneity in findings

### Key variables & data sources

<table>
<thead>
<tr>
<th>Key variables &amp; data sources</th>
<th>Exposure(s)</th>
<th>Outcome(s)</th>
<th>Covariates</th>
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<tbody>
<tr>
<td><strong>Aim</strong></td>
<td><strong>Procedure type</strong></td>
<td><strong>Anthropometric measures</strong></td>
<td><strong>Patient age, Race/ ethnicity, Starting BMI, Smoking history and comorbidities</strong></td>
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<td>1</td>
<td>Procedure type</td>
<td>Anthropometric measures, Factors perceived by patients as shaping pre-op &amp; post-op use of the health system</td>
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<tr>
<td>2</td>
<td># of pre-op &amp; post-op surgical, primary care, and nutrition visits; selected pre-operative labs; pre-op weight change; time from first visit to surgery; number &amp; type of plastic surgery procedures</td>
<td>Anthropometric measures, Factors perceived by patients as shaping pre-op &amp; post-op use of the health system</td>
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</tr>
<tr>
<td>3</td>
<td>Procedure type</td>
<td>Hospitalizations, Re-operations, Fractures, Hypoglycemia episodes, Suicide attempts, Drug overdoses, Hemoglobin</td>
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</tbody>
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1. Procedure codes; 2. Height, weight; 3. Demographics; 4. Diagnosis codes; 5. Health services utilization; 6. Patient reported outcomes; 7. Procedure codes; 8. Laboratory values

### Approach to analyses

In Aim 1, we will compare weight loss across bariatric surgery types (Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding) by using longitudinal analytic techniques such as random effects models and generalized estimating equations. To ensure comparability of patients across surgical types, we will control for a range of covariates and will consider propensity score matching. Aim 2 will utilize similar techniques. For adverse effects (Aim 4), we will use survival analyses for categorical outcomes and linear regression for continuous.

### Potential Limitations and approaches to address limitations

1. Some patients may obtain care from >1 health system (especially surgery, and follow-up may differ if they travel some distance to another center for surgery), potentially resulting in incomplete data—health claim data may allow differentiation of missing data from a lack of use of health services
2. Selection factors: (a) Indication—will focus comparison across surgical procedure types rather than comparing patients with- and without-surgery; (b) Differential loss to follow-up—will examine retention across procedures
3. Confounding - will use covariate data to likely generate propensity scores to account for differences across surgical procedures
Additional Information

The vision of PCORI’s National Patient-Centered Clinical Research Network (PCORnet) is to create a large, highly representative electronic data infrastructure that will facilitate efficient, observational research as well as the conduct of pragmatic randomized trials within delivery systems. PCORI has identified a unique early opportunity to support 1 or more weight-related observational studies that answer salient clinical questions and provide use cases for PCORnet. The study should generate evidence that is meaningful to patients, clinicians and the host health systems.

- The study should be one that is better conducted as a multi-network, rather than single-work study. Multi-network studies will emphasize sharing of aggregate data for descriptive and analytic purposes rather than sharing of individual-level data files. Whenever possible, PCORnet analyses will use a distributed model that involves each site or network executing the same analytic program within its own system. PCORnet is not intended to control the CDRNs and PPRNs, and PCORnet will not replace functions that CDRNs and PPRNs currently perform well. Examples of reasons for favoring multiple networks include allowing for more adequate sample size and power, for the ability to address practice variation, to include diverse populations or enable analyses to assess heterogeneity of treatment effect in addition to the primary result. This is consistent with PCORnet’s goal not to compete with individual CDRNs and PPRNs, but rather to provide opportunities to answer questions that may not otherwise be answered as quickly or efficiently in single network studies.

- The study should be characterized by operational simplicity, defined as using elements of the Common Data Model via distributed programs.

Box 1: Criteria for Research Prioritization

**Patient-Centeredness:** Is the proposed research focused on questions and outcomes of specific interest to patients, their caregivers, and clinicians?

**Impact of the Condition on the Health of Individuals and Populations:** Is the condition or disease associated with a significant burden in the US population? Burden of disease may be measured by how many people have the disease (prevalence); how many new cases occur every year (incidence); and other measures such as mortality, morbidity, individual suffering, and loss of productivity. PCORI is also interested in rare diseases.

**Assessment of Current Options:** What current guidance is available on the topic, and is there ongoing research? How does this help determine whether further research in this area would be valuable?

**Likelihood of Implementation in Practice:** Would new information generated by this research be likely to have an impact in practice? Research is valuable when it leads to the use of more beneficial treatments or interventions. Providing new evidence by itself does not ensure that the results of research will be used in clinical practice. Several factors may influence uptake in practice, including the knowledge and behaviors of health professionals, the acceptability to patients and to health systems.

**Feasibility of the study within PCORnet:** Does this study meet the requisite technical, governance and regulatory constraints described above?

**Technical infrastructure constraints:**
- Ability to capture required data elements in standard fashion across systems.
• Required data elements should be captured using standardized terminologies that eliminates or substantially minimize the need for transformations, mappings, or complex data extraction procedures.
• Use of PCORI networking software and standardized querying to facilitate subject identification.

Regulatory and governance constraints:
• The suggestion of a topic by a CDRN should reflect approval and support of the topic by the parent system that hosts the CDRN. A small number of decision makers within each participating health system should be involved in the decision of their systems to participate in the study.
References


