

The PCORnet Bariatric Study – Engaging patients and other stakeholders across the US to improve bariatric care

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About the Study

The PCORnet Bariatric Study will compare the effectiveness of the three most common US bariatric procedures, using real-world health data from over 60,000 patients (adult and adolescent). It aims to demonstrate the utility of PCORnet, the National Patient-Centered Clinical Research Network. A secondary aim will examine patient and provider perspectives on key decisions related to surgery.

Engagement Strategies

Multiple engagement strategies help ensure a patient-centered approach. Patients and surgeons were active participants of the team that shaped the initial study concept and aims. The study leadership includes a patient co-Principal Investigator and other patient study team members. During the proposal writing process, patient partners affiliated with each of 11 participating clinical data research networks expanded study engagement, as did a nation-wide advisory group including patient advocates, surgeons, and caregivers (see Figure). Their input shaped the study’s design and dissemination plans.

Minimizing Jargon & Inviting Shared Ownership & Decision-Making

This study aims to exemplify a model for engaging patients and community in the research process to maximize the benefits for all stakeholders:

- The team has focused on minimizing jargon and inviting shared ownership and decision-making during study conference calls and in planning analyses (see Table)
- When documents are circulated, key areas are highlighted to focus attention on topics in most need of patient input & to minimize readers’ burden.
- Spoken feedback is a welcomed alternative to written comments
- Conference calls are scheduled with options to accommodate different schedules.
- An in-person meeting kicked off the research after funding; feedback from attendees suggests that it helped team members contribute and feel valued
- Social media will further expand community engagement moving forward

LAY EXECUTIVE SUMMARY OF PCORNET BARIATRIC STUDY ANALYTIC STRATEGY

The PCORnet Bariatric Study (“the study”) team has prepared a detailed analysis plan for accomplishing the main study aims. This plan was developed by the Methods Core with feedback from the Scientific Core, Executive Bariatric Stakeholder Advisory Group, and the Clinical Data Research Network (CDRN) Bariatric Principal Investigators.

The study seeks to answer three main scientific questions:

Aim 1: To what extent does weight loss and weight regain differ across the three most common bariatric surgical procedures in the United States – Roux-en-Y Gastric Bypass (RYGB), Adjustable Gastric Banding (AGB), and Sleeve Gastrectomy (SG) – at 1, 3, and 5 years after surgery?

Aim 2: To what extent do the three most common bariatric procedures in the United States differ with respect to diabetes status at 1, 3, and 5 years after surgery?

Aim 3: What is the frequency of major adverse events for the three most common bariatric procedures in the United States at 1, 3, and 5 years?

PCORnet Bariatric Surgery - HTE Analyses

PBS HTE Analyses

We know that different types of people respond to medical and surgical treatments in different ways: some individuals may get great benefit; some very little benefit; and others may be harmed. The technical term for such different responses is called “heterogeneity of treatment effects (HTE)”. Our study will use statistics to understand how different groups of people respond to bariatric surgery. We need your help to rank the characteristics listed below, so that we can decide how to prioritize our HTE analyses. This prioritization exercise is important because it will take a lot of analytic resources for our team to explore each one of these – and we don’t have the time or money to explore them all. So, your ranking of what’s important to you is important to us and will help us decide what to focus our efforts on.

Structure of Stakeholder Engagement

