PCORnet Bariatric Study Design: Using health record data from across a nationwide research network to assess bariatric outcomes

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Introduction

- As severe obesity has increased in prevalence, the use of bariatric surgery has expanded considerably over the past 20 years.
- Yet long-term data comparing the effectiveness of different procedures are limited.
- Use of the sleeve gastrectomy procedure has expanded rapidly over the past decade, despite a lack of data comparing its effectiveness to other bariatric procedures.
- The National Patient-Centered Clinical Research Network (PCORnet) enables an evaluation of the comparative effectiveness of these procedures

Methods

The study will analyze electronic health record (EHR) data from health systems participating in PCORnet

- We will estimate the 1-year, 3-year, and 5-year benefits & risks of the most common US bariatric procedures: Roux-en-y gastric bypass (RYGB), adjustable gastric banding (AGB), and sleeve gastrectomy (SG).

Primary comparisons across the 3 procedures:
- Change in weight
- Rates of diabetes remission and relapse
- Incidence of adverse events

Analyses will include:
- Adjustment for potential confounders (e.g., age, sex, race/ethnicity, smoking status, year of surgery, baseline BMI, node site, comorbidity score, also with DM outcomes: HbA1c, insulin use, oral hypoglycemic medication)
- Heterogeneity of treatment effects for important covariates such as race, sex, and age
- Comparison of individual-level & distributed analytic approaches

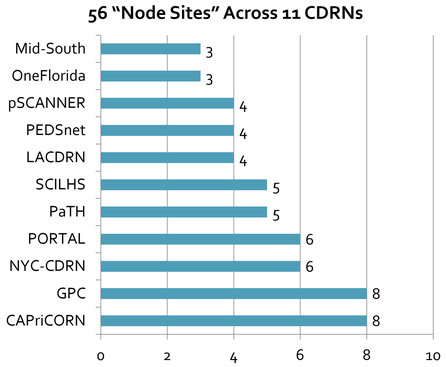
Qualitative work will examine patient perspectives on (a) whether to undergo bariatric surgery; (b) which bariatric procedure to use; and (c) the delivery of follow-up care after bariatric surgery

Patients, surgeons, & other stakeholders have actively contributed to the study design and inform ongoing work

Preliminary Findings

The study has engaged 56 "Node Sites" across 11 Clinical Data Research Networks (CDRNs)

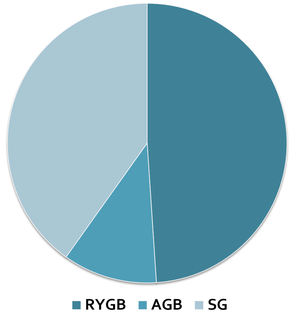
- Each CDRN involves two or more healthcare systems, which include integrated delivery systems, academic medical centers, and safety net clinics.



Over 60,000 patients underwent bariatric surgery between 2004-2014

The sample is expected to include >900 adolescent bariatric patients & over 17,000 patients with diabetes

50% of procedures were gastric bypass; 10% gastric banding, and 40% sleeve gastrectomy.



Conclusions

- The EHR data of PCORnet allows for analysis of a very large sample of bariatric cases
  - Enables comparison of benefits and risks across three bariatric procedures
  - Allows for examination of important demographic sub-groups
- Loss to follow-up is likely to pose analytic challenges
- PCORnet infrastructure will allow for comparison of individual versus distributed analyses

Implications

The PCORnet Bariatric Study will lead to unique insights into the effectiveness of specific bariatric procedures
- Particularly timely given recent changes in procedure frequencies

The findings, reflecting real-world health data and the perspectives of diverse stakeholders, should provide patients and providers with information they need to make informed treatment decisions

The analyses aims to demonstrate the utility of PCORnet as a new national resource for promoting evidence-based and patient-centered health care

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