PCORnet Bariatric Study: Patient-Centered and Policy-Relevant Research on Bariatric Outcomes

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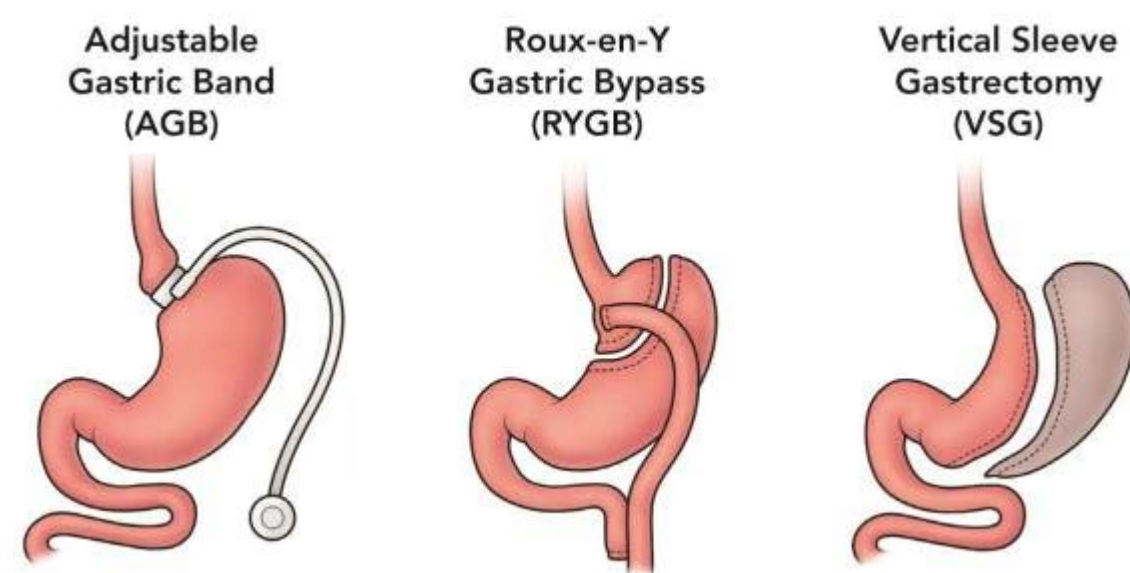
Introduction

Bariatric procedures have changed dramatically in the past decade, with the sleeve gastrectomy now being the most commonly performed procedure worldwide.
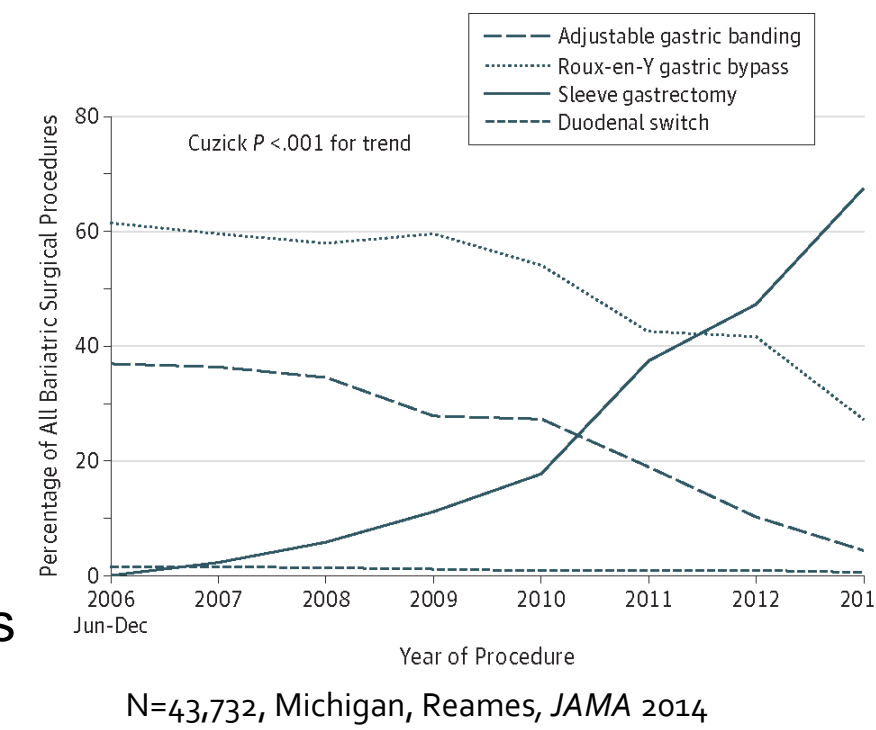
But there are few long-term studies comparing the outcomes of these procedures in large, diverse populations.

N=43,732, Michigan, Reames, *JAMA* 2014

Methods

Goal: Compare 1, 3, and 5 year outcomes of three procedures:

Adjustable Gastric Band (AGB)   Roux-en-Y Gastric Bypass (RYGB)   Vertical Sleeve Gastrectomy (VSG)

Main Outcomes: 1) changes in weight, 2) rates of remission and relapse of diabetes, and 3) rates of major adverse events.

Additional goals:

1. Qualitative Research: Identify patient preferences and opinions about (a) whether to undergo bariatric surgery; (b) which bariatric procedure to utilize; and (c) the delivery of follow-up care after bariatric surgery through focus groups.
2. Infrastructure Development: Develop infrastructure to support future comparative effectiveness studies using the National Patient-Centered Clinical Research Network (PCORnet).

Stakeholder Engagement: Patients and other stakeholders have been engaged in the development of the research questions, the selection of outcomes and the design of the study protocol, and will be engaged in all stages of the research moving forward, including protocol development, monitoring study conduct, and designing and implementing dissemination plans.

56 Participating Sites from 11 Clinical Data Research Networks
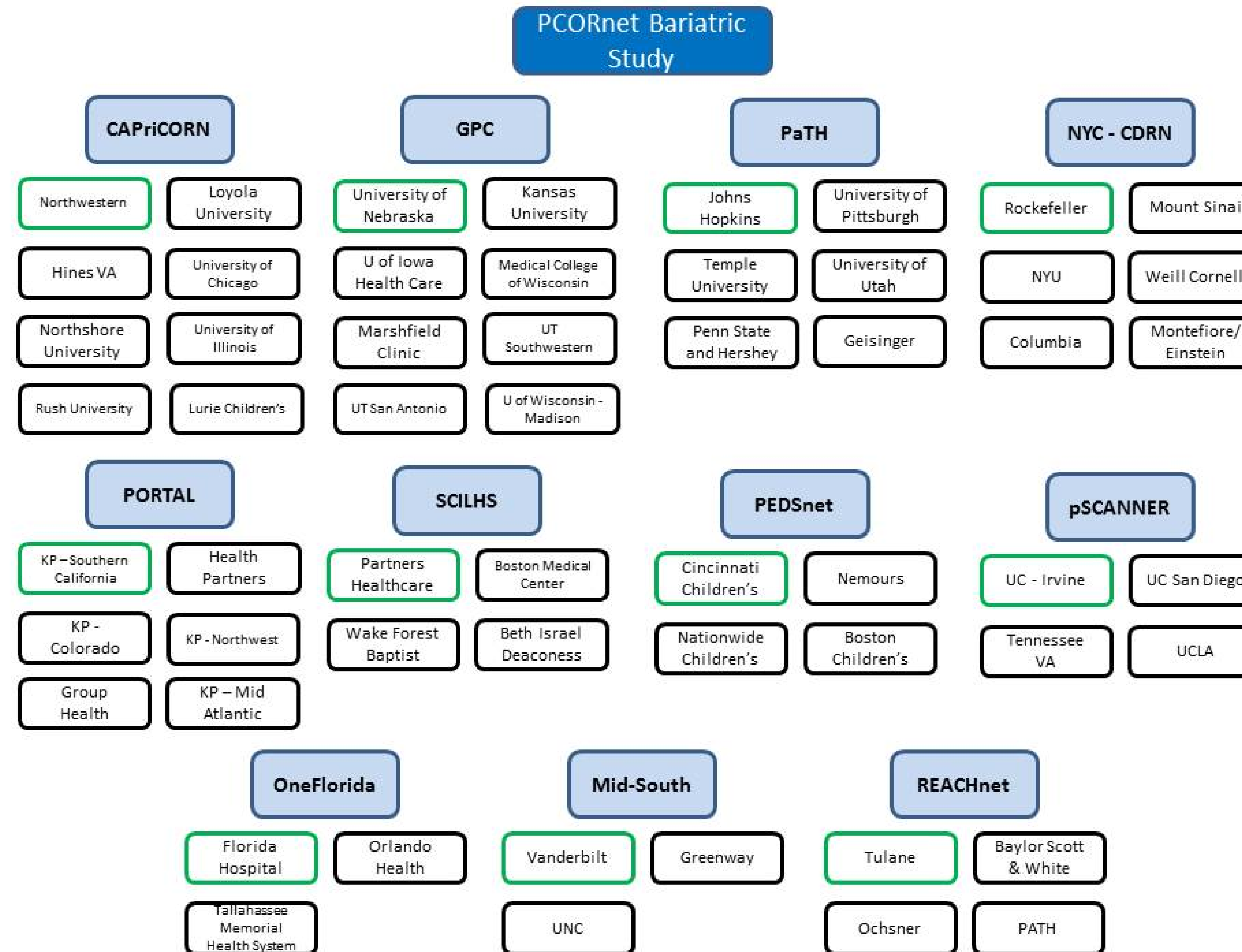
Preliminary Results

Participating Sites: This two-year study involves 11 of PCORnet's Clinical Data Research Networks (CDRNs) including 56 healthcare organizations across the United States

Expected Sample Size: 60,000 patients who have previously undergone bariatric surgery from 2005-2015
- 50 percent gastric bypass,
- 10 percent gastric banding
- 40 percent sleeve gastrectomy

This study includes more than 900 adolescent bariatric patients (<20 years) and more than 17,000 adult patients with diabetes.

Geographic Variability: There is also large geographic variation in the bariatric procedures performed, with some areas dominated by gastric bypass while others are dominated by sleeve gastrectomy.

Timeline: The study will take place in 2016-2017, with final results of Aim 1 (weight loss) in Feb 2017, Aim 2 (diabetes outcomes) in Sept 2017, and Aim 3 (adverse events) and Qualitative Results in Feb 2018.

Conclusion

This study is particularly timely because the sleeve gastrectomy procedure has rapidly grown in popularity in the United States (introduced in the late 2000s as a stand-alone procedure, it currently represents more than 50 percent of all procedures in our 11 PCORnet CDRNs), yet it lacks long-term data comparing its outcomes to the more well-established procedures. Apart from its size and geographic diversity, another key feature of the study is the depth and diversity of its stakeholder involvement, which includes several patients as study team members and executive stakeholder advisors, multiple pediatric and adult bariatric surgeons from different institutions, primary care and specialty physicians, researchers, and leaders of patient-level policy and advocacy organizations. This robust engagement strategy will help insure that the products of this research study are meaningful to patients, clinicians, and policy makers – and will help facilitate the rapid translation of our findings into clinical practice.