


Conducting Full-Spectrum Translational Research: Big Data Meets Embedded Mechanistic Studies

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Translational Science 2019

Session Goals

1. Describe the RU-CDN Full-Spectrum Translational Research Team Science Model

2. Discuss CTSA-PBRN Engagement & Collaboration Process: Partnerships and Priorities

3. Illustrate the RU-CDN Full-Spectrum Translational Research Team Science Model with a case study of the “Bariatric Metabolic Outcomes Project” (BMOP)

4. Provide personal reflections on each of our experiences with this collaboration

The Rockefeller University 1901 — Scientia Pro Bono Humani Generis

NYU Lutheran — NYU Langone Health System

CDN — Clinical Directors Network

BUILDING COMMUNITY-ACADEMIC TRANSLATIONAL RESEARCH PARTNERSHIPS

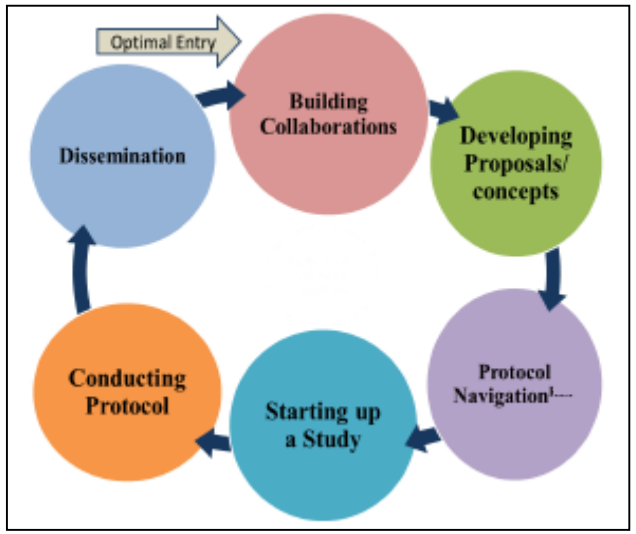
CDN/N² = PBRN INFRASTRUCTURE[1]

- Quality Improvement
- Clinical Outcomes
- Comparative Effectiveness Research Patient Centered Outcomes Research (CER/PCOR)
- Training Clinician Investigators
- Implementation Science
- Disseminating Methods & Clinical Outcomes Results

+

ROCKEFELLER = CTSA INFRASTRUCTURE[2]

- Laboratory Investigation
- Mechanistic Questions
- Protocol Navigation
- Clinical Scholars
- Bioinformatics/Phenotyping
- Disseminating Translational Research Methods



CEnR-Navigation Process (CEnR-Nav)[2]
[Investigators and partners may enter at any stage]

=

CEnR

CER/PCOR
+
Embedded Mechanistic Studies

[1] N²- Building a Network of Safety Net PBRNS, https://www.pbrn.ahrq.gov/sites/default/files/docs/page/N2.pdf ; [2] Kost, et al. Academic Medicine. 2017;92(3):374.

The Rockefeller University

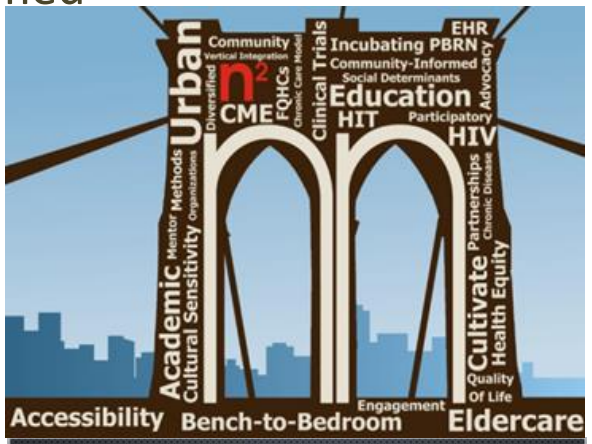
- Unique structure
  - 82 heads of labs
  - 25 Nobel prizes, 22 Lasker Awards, 20 National Medals of Science
  - 100+ year tradition of translational research
  - 40 bed JCAHO-accredited research-only hospital
  - AAHRPP-accredited
- 250 protocols
  - 80% investigator - initiated
  - 20% phase I, II, III or device trials
- Center for Clinical Translational Science, 2006 -
  - Community Engaged Research Core

Clinical Directors Network, Inc. (CDN)

CDN N²: Building a Network of Safety Net PBRNs

AHRQ Center of Excellence for Practice-based Research and Learning

- **A Practice-based Research Network (PBRN)** that works with Federally Qualified Health Centers (FQHCs) and other Primary Health Care Safety-net Practices
- **Research Infrastructure to build a Learning Healthcare System**
- **A collaboration among:**
  - Access Community Health Network (ACCESS)
  - Alliance of Chicago (ALLIANCE)
  - Association of Asian Pacific Community Health Organization (AAPCHO)
  - Center for Community Health Education Research and Service (CCHERS)
  - **Clinical Directors Network (CDN) [LEAD PBRN]**
  - Community Health Applied Research Network (CHARN)
  - Fenway Institute (FENWAY)
  - New York City Research and Improvement Group (NYCRING)
  - Oregon Community Health Information Network (OCHIN)
  - South Texas Ambulatory Research Network (STARNet)
  - One Florida



Funded by AHRQ Grant: P30 HS 021667
Principal Investigator: Jonathan N. Tobin, PhD (CDN)

AHRQ N² PBRN

www.CDNetwork.org

NYU Langone Hospital—Brooklyn

View All Locations (2)

150 55th Street
Brooklyn, NY 11220

718-630-7000

View All Contact Info

NYU Langone Health

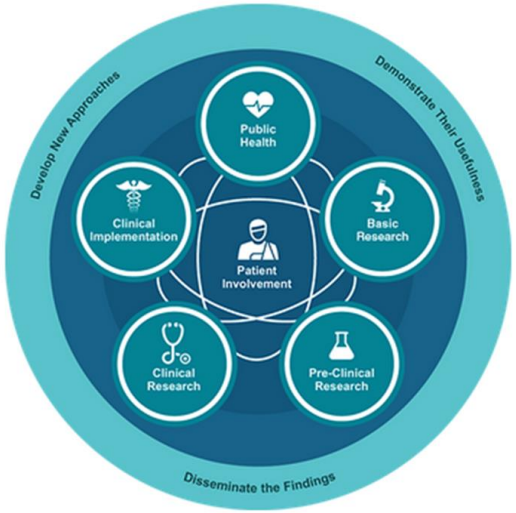
Bariatric Surgery for Obesity

Doctors at NYU Langone's Weight Management Program and Weight Management Program at NYU Langone Hospital—Brooklyn may recommend bariatric, or weight loss, surgery for people with severe obesity—defined as having a body mass index (BMI) of 40 or greater—who are having trouble losing weight after trying other treatments for at least six months. Surgery may also be recommended for people who have a BMI of 35 to 39 and an obesity-related condition, such as type 2 diabetes, hypertension, coronary artery disease, severe osteoarthritis, or obstructive sleep apnea.

Formerly:
Sunset Park Family Health Center Network
and
Lutheran Medical Center

Key Attributes of the RU-CDN Translational Research Model

- Conducting rigorous practice-based comparative effectiveness/health outcomes research in collaboration with academic investigators, community-based clinicians and staff, patients, and other stakeholders
- Engaging FQHCs and Primary Care Clinicians as investigators
- Embedding basic science & mechanistic questions into clinical studies conducted in practice-based settings

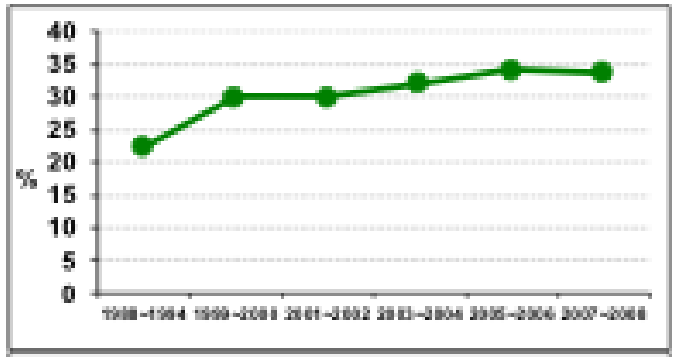


https://ncats.nih.gov/translation/spectrum

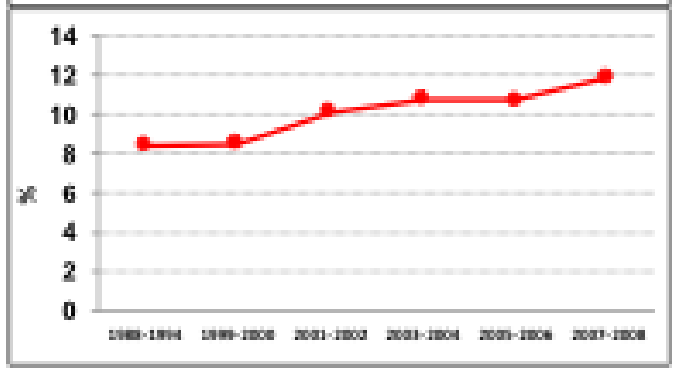
The Deadly Trio

HEALTH 2014

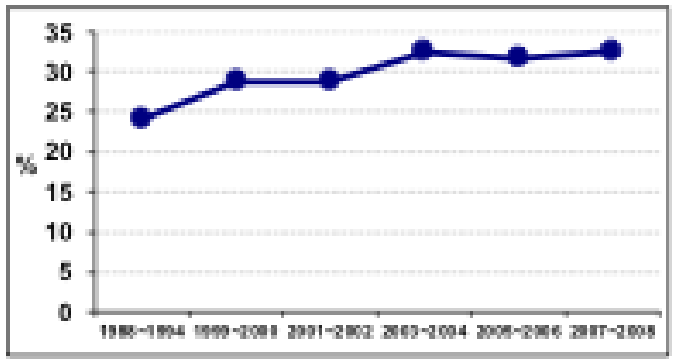
Obesity



Diabetes



Hypertension

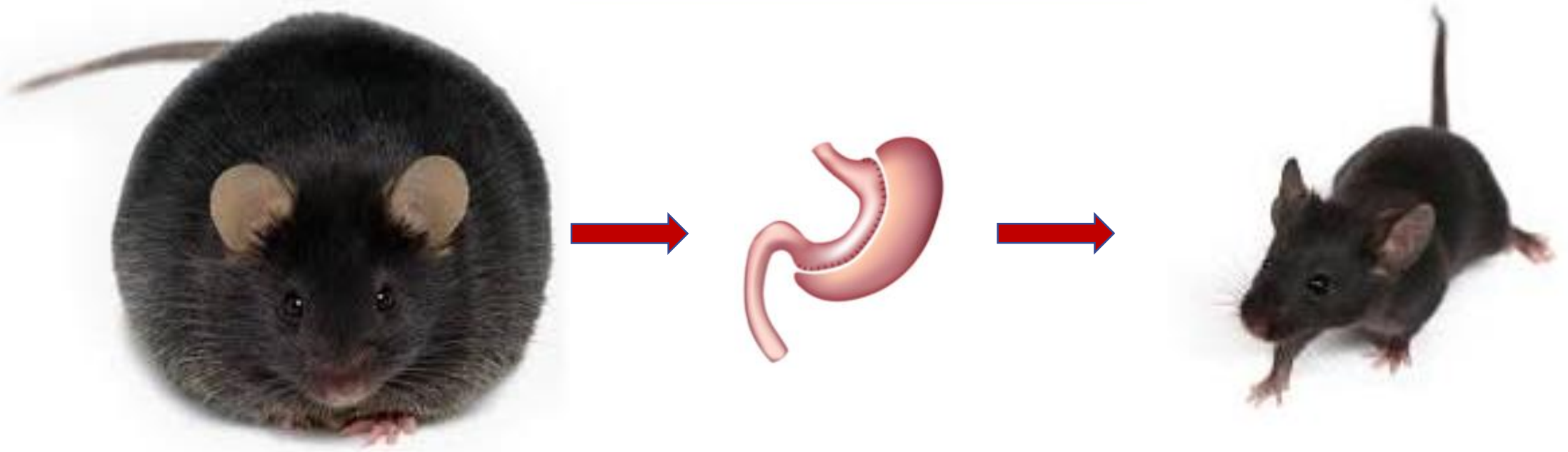


Source: CDC, 2016

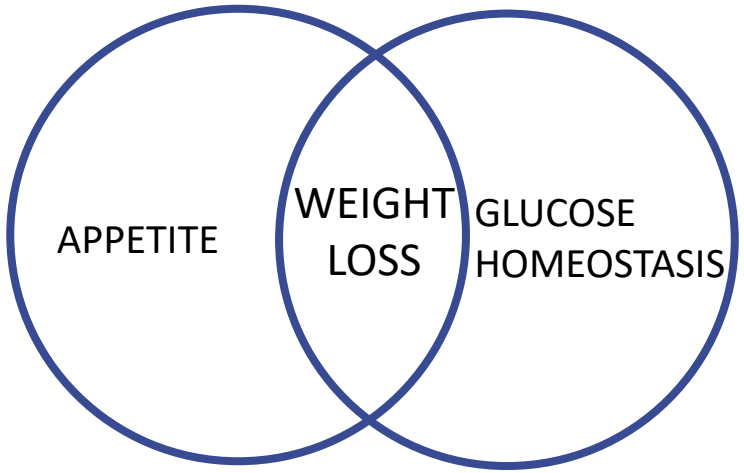
The Process

- Team Meetings with NYU-Lutheran Family Health Center and Hospital primary care physicians, medical and surgical specialists, social workers, nutritionists, psychologists and IT experts serving bariatric patients
  - Collaborated on the:
    - Bariatric Metabolic Outcomes Project (BMOP)
    - NYC-CDRN Obesity Pilot Project
    - PCORnet Bariatric Surgery (PBS) Project

How the collaboration began



Central Nervous System → Peripheral Nervous System →



Early glycemic effects of bariatric surgery in humans

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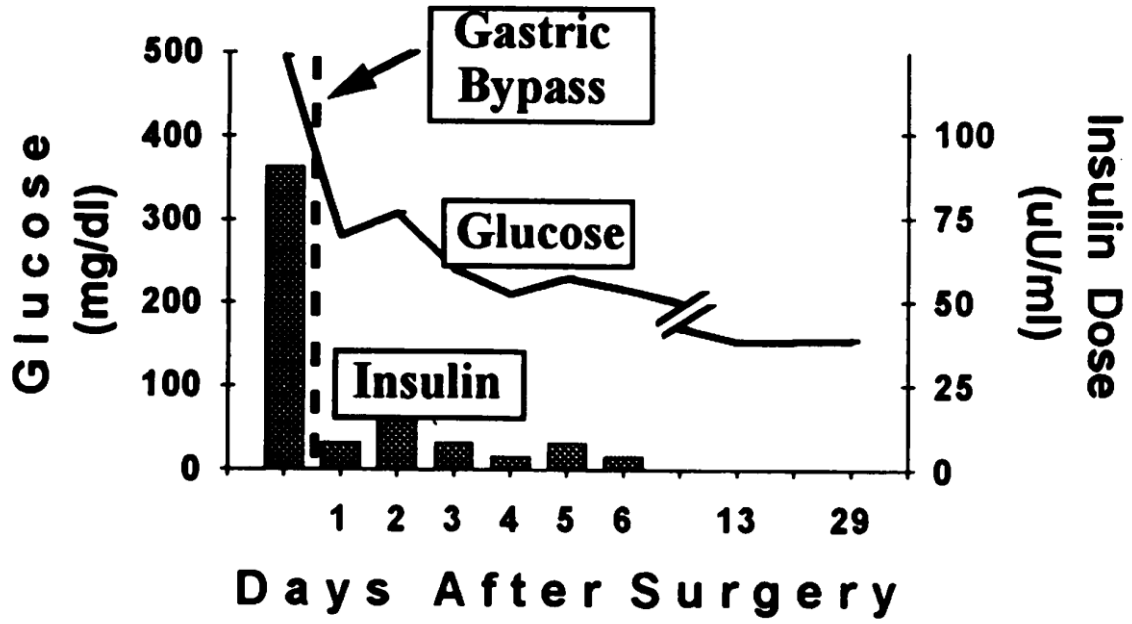
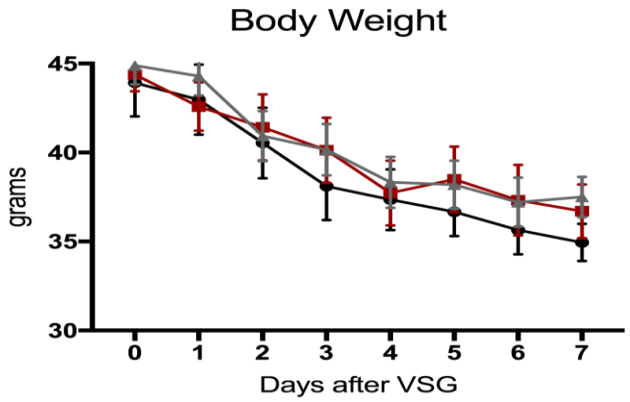
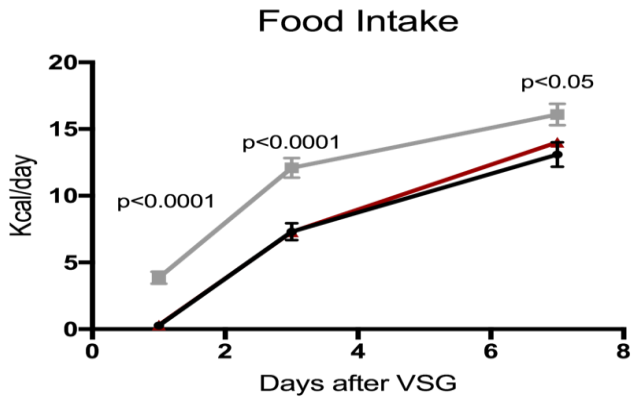


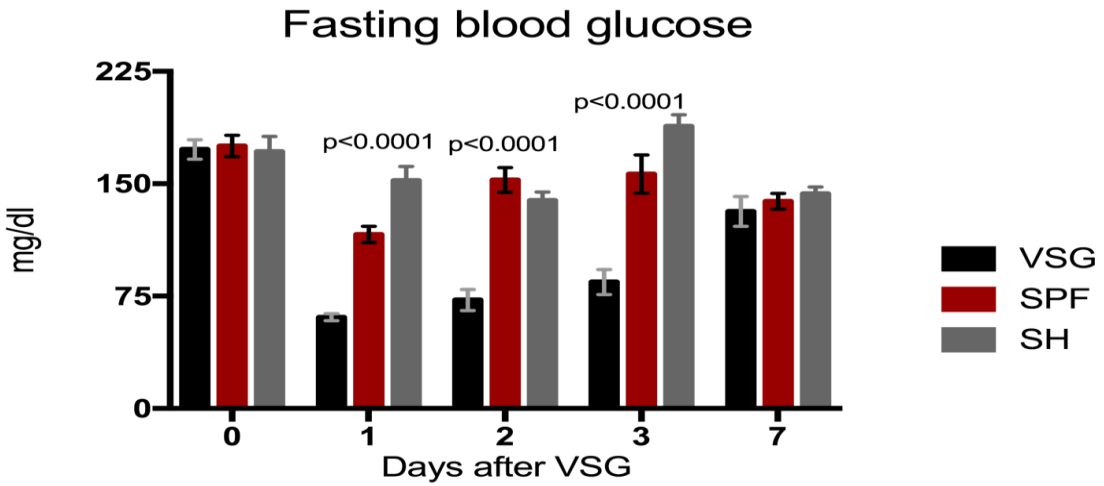
Pories et al, 1995

Early glycemic effects of bariatric surgery in rodents

Early Findings after VSG

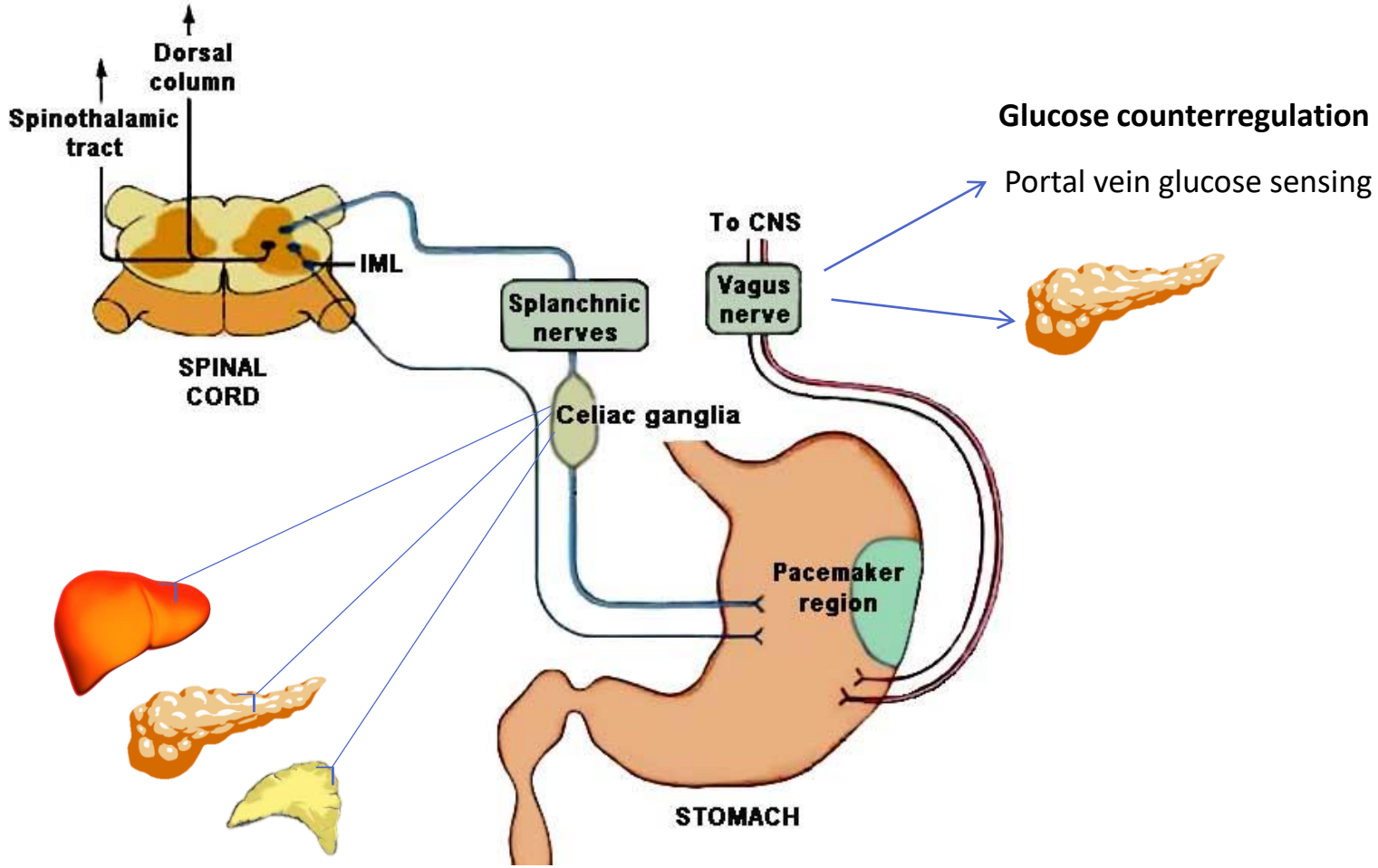






Emiliano et al, manuscript in preparation

Gastric innervation and glucose homeostasis



Glucose counterregulation:
sympathoadrenal response and increased hepatic glucose output

Fujita & Donovan, 2005; Kumukara, 2013; Taborsky, 2015
Image adapted from Clinicalgate.com, chapter by Kenneth Koch

Primary goal of starting community engagement project

- Goal was to test hypothesis that bariatric surgery led to a defect in glucose counter-regulation
- Identify bariatric patients in the community that would be eligible for a hypoglycemic clamp study at baseline and 6 months after the surgery
- Strategy of collaboration involved meeting with group at community health center to present our ideas and listen to their own ideas of what should be studied.

Bariatric Metabolic Outcomes Project (BMOP)

- Interdisciplinary group, including gastroenterologists, surgeons, internists, family medicine practitioners, endocrinologists, nutritionists, psychologists, IT professionals
- Lively discussion about obesity and its management
- Discussions led to hypothesis generation on outcomes, as well project ideas involving:
  - sleep apnea
  - joint mobility early after surgery in rheumatoid arthritis
  - body image after bariatric surgery
  - diabetes
  - renal function
  - stress associated with voluntary food restriction/dieting

Clinical Observations Proposed by NYU/Lutheran Bariatric Program Clinicians

Medical Specialty	Variables of Interest (Hypotheses)
Pulmonary	Changes in continuous positive airway pressure (CPAP) ?
Rheumatology	Improvement in joint symptoms ? Increased mobility ?
Endocrinology	Hypoglycemia?
Mental Health	Depression and suicide?

Study Proposal - Feasibility

The group hypothesized that patient baseline clinical and laboratory characteristics may accurately inform who will respond to bariatric surgery with significant and sustained metabolic improvement.

EHR Study

Inclusion Criteria

EHR data from November 2010- to December 2014

One of the following procedures:

- RYGB - 43644
- VSG - 43775
- LAGB - 43770

Baseline evaluation:

- With pre-surgical (within 3 months prior to surgery) evaluation
- With at least two clinical evaluations post-surgery (within 6 months post surgery)
- Follow-up could be in Surgery, Primary Care, Cardiology, Endocrinology, Nephrology

Diagnosis:

- Obesity – 278.00
- T2DM – 250.00

Variables Extracted from EHRs

- **Demographics**: age, gender, ethnicity, insurance, zip code
- **Medical**: hypertension, diabetes, diabetes duration, dyslipidemia, OSA, use of CPAP, diagnosis of RA, depression
- **Clinical characteristics**: weight, BMI
- **Prescription drugs**: anti-hypertensives, anti-diabetics, statins, fibrates, niacin, weight loss, aspirin, steroids
- **Laboratory parameters**: hemoglobin A1C, fasting blood glucose, CBC, CMP, cholesterol, triglycerides, PHQ2/9

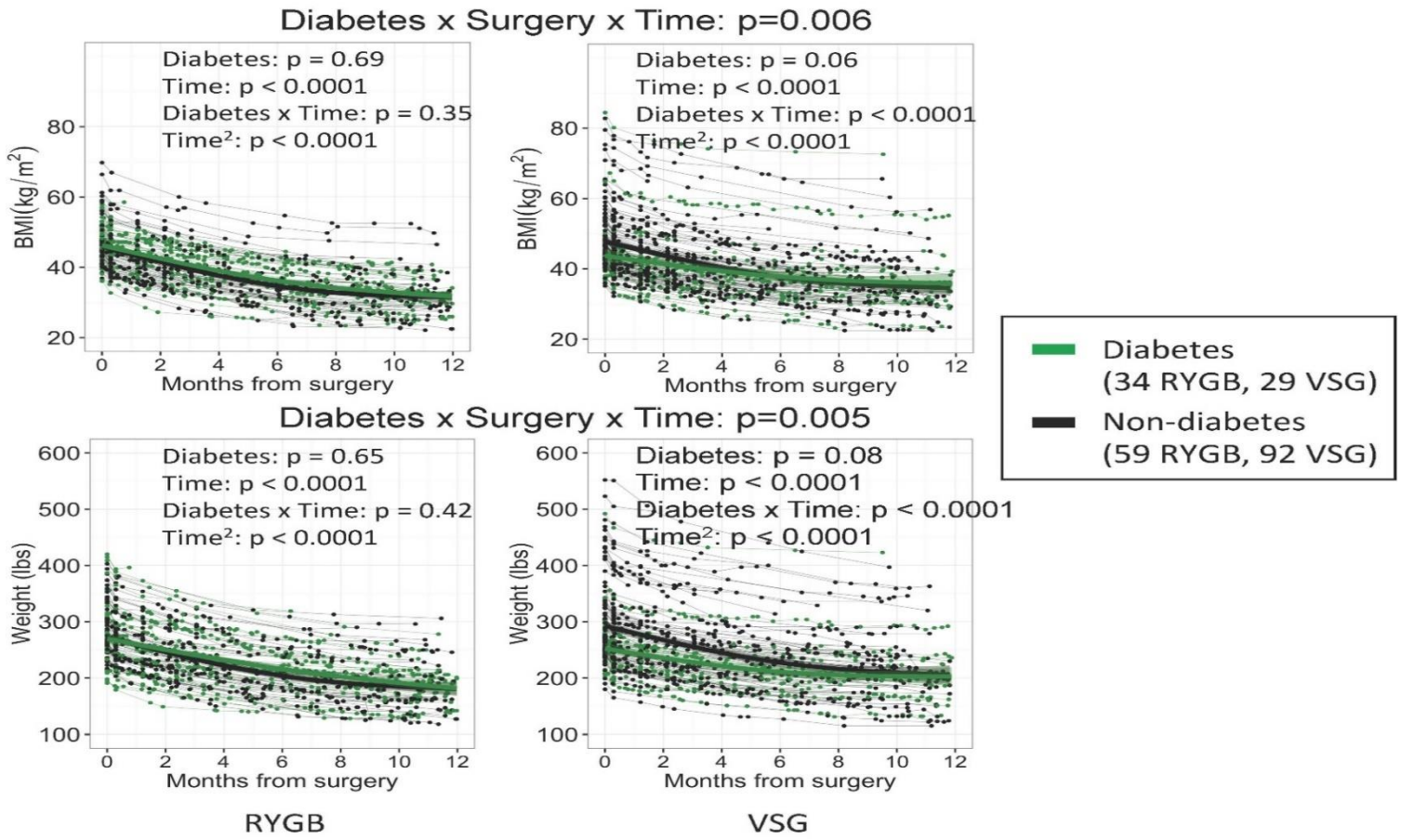
BMOP Results – proof of principle

Table 1. Clinical Characteristics of the Patients at Baseline

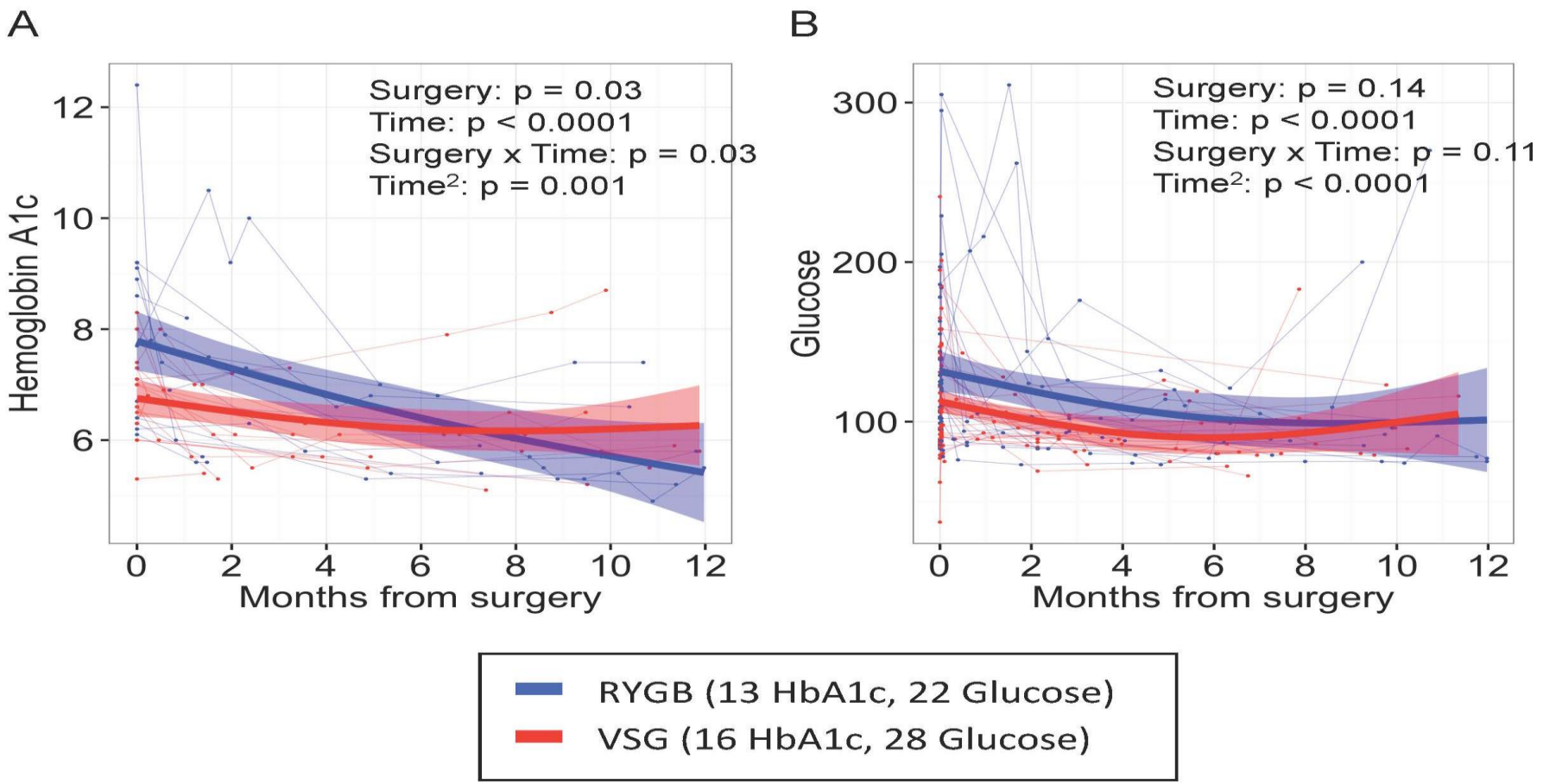
Characteristic	RYGB (n = 93)	VSG (n = 121)	P-value
Demographics, Vitals, and Labs			
Age (years)	42·2 ± 10·5	38·9 ± 11·4	**0·03**
Female	83 (89·2%)	99 (81·8%)	0·13
Hispanic ethnicity	50 (53·8%)	57 (47·1%)	0·57
BMI (kg/m^2)	47·8 ± 6·6	48·4 ± 9·4	0·58
Weight (lbs)	283·3 ± 54·1	293·8 ± 73·4	0·25
Systolic BP (mm Hg)	124·2 ± 15·5	124·1 ± 16·3	0·98
Diastolic BP (mm Hg)	77·4 ± 8·4	77·1 ± 8·5	0·80
Hemoglobin A1c (%)	8·0 ± 1·8	6·9 ± 0·8	**0·04**
Glucose	126·7 ± 34·4	111·5 ± 42·5	0·18
Comorbid Conditions			
Depression	17 (18·3%)	22 (18·2%)	0·99
Diabetes	34 (36·6%)	29 (24·0%)	**0·05**
Hyperlipidemia	29 (31·2%)	28 (23·1%)	0·19
Hypertension	46 (49·5%)	52 (43·0%)	0·35
Hypertriglyceridemia	3 (3·2%)	3 (2·5%)	1·00
Sleep apnea	51 (54·8%)	73 (60·3%)	0·42

Data are presented as mean ± SD for continuous variables or n and percentage for categorical variables. Abbreviations: RYGB, Roux-en-Y gastric bypass; VSG, vertical sleeve gastrectomy; BMI, body mass index; BP, blood pressure.

BMOP Results – proof of principle



BMOP Results – proof of principle

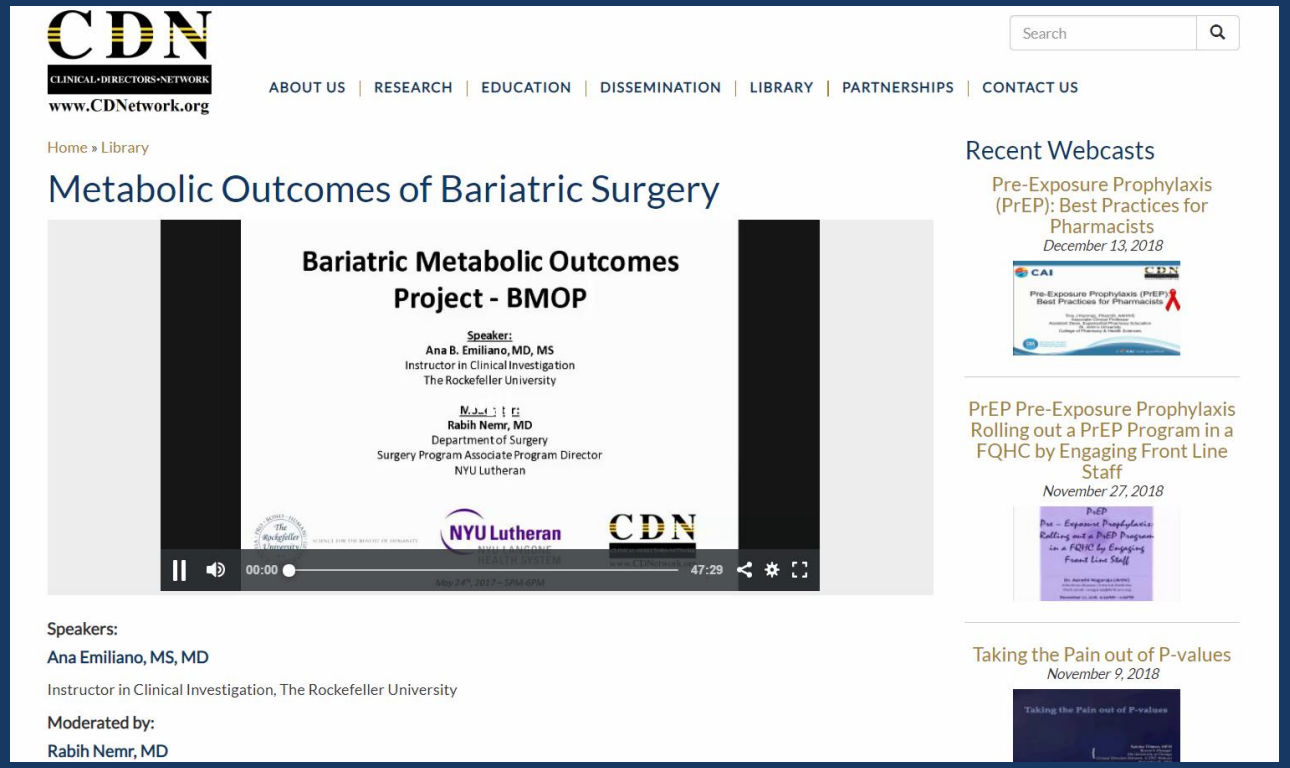


Bariatric Metabolic Outcomes Project Dissemination:
Live CME at NYU Lutheran & Webinar

Speaker:
Ana B. Emiliano, MD MS
Instructor in Clinical Investigation
The Rockefeller University

Moderator:
Rabih Nemr, MD FACS
Department of Surgery
Associate Program Director
Surgery Program
NYU Lutheran

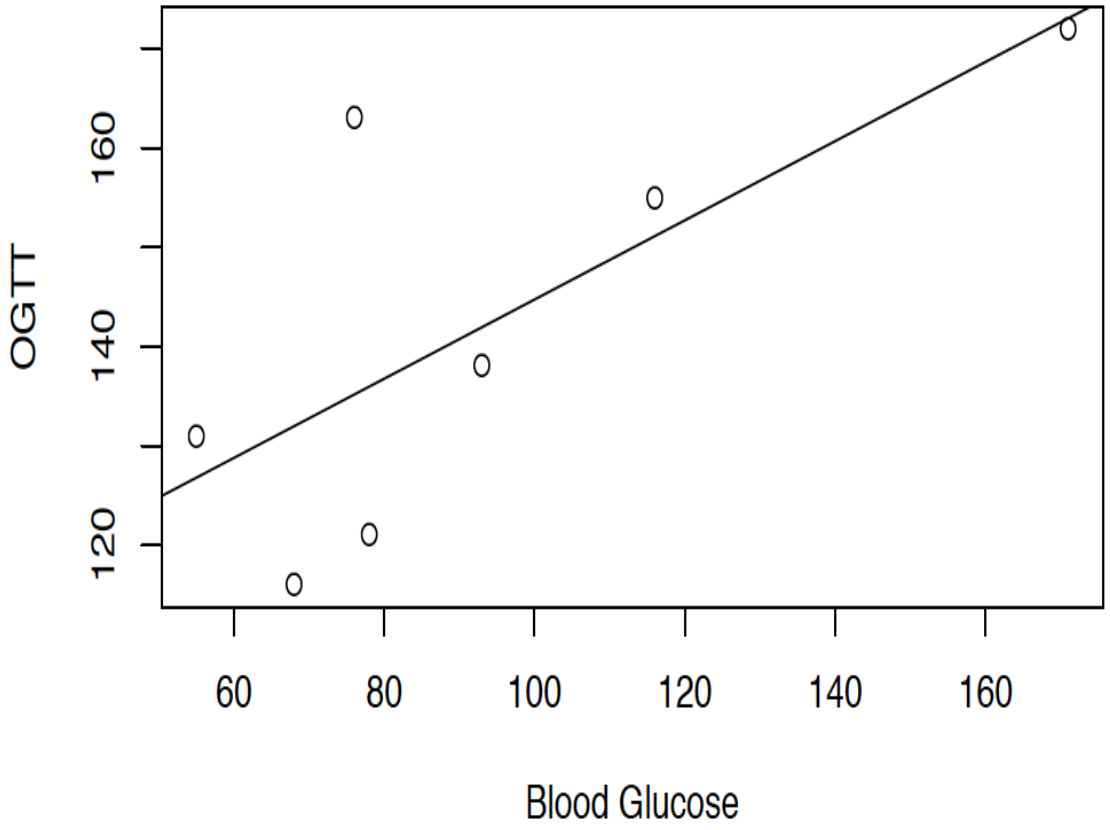
May 24, 2017 – 5PM-6PM



https://www.CDNetwork.org/library/metabolic-outcomes-of-bariatric-surgery

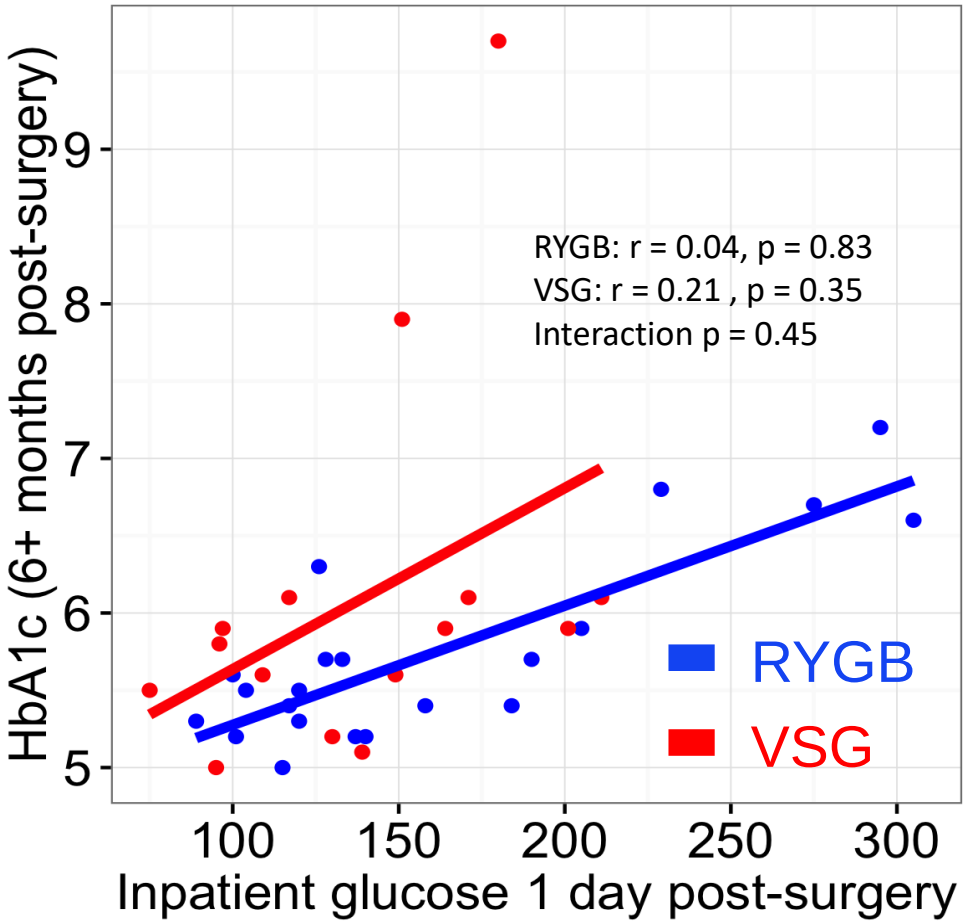
Integrative Translational Science

Mouse Model Results



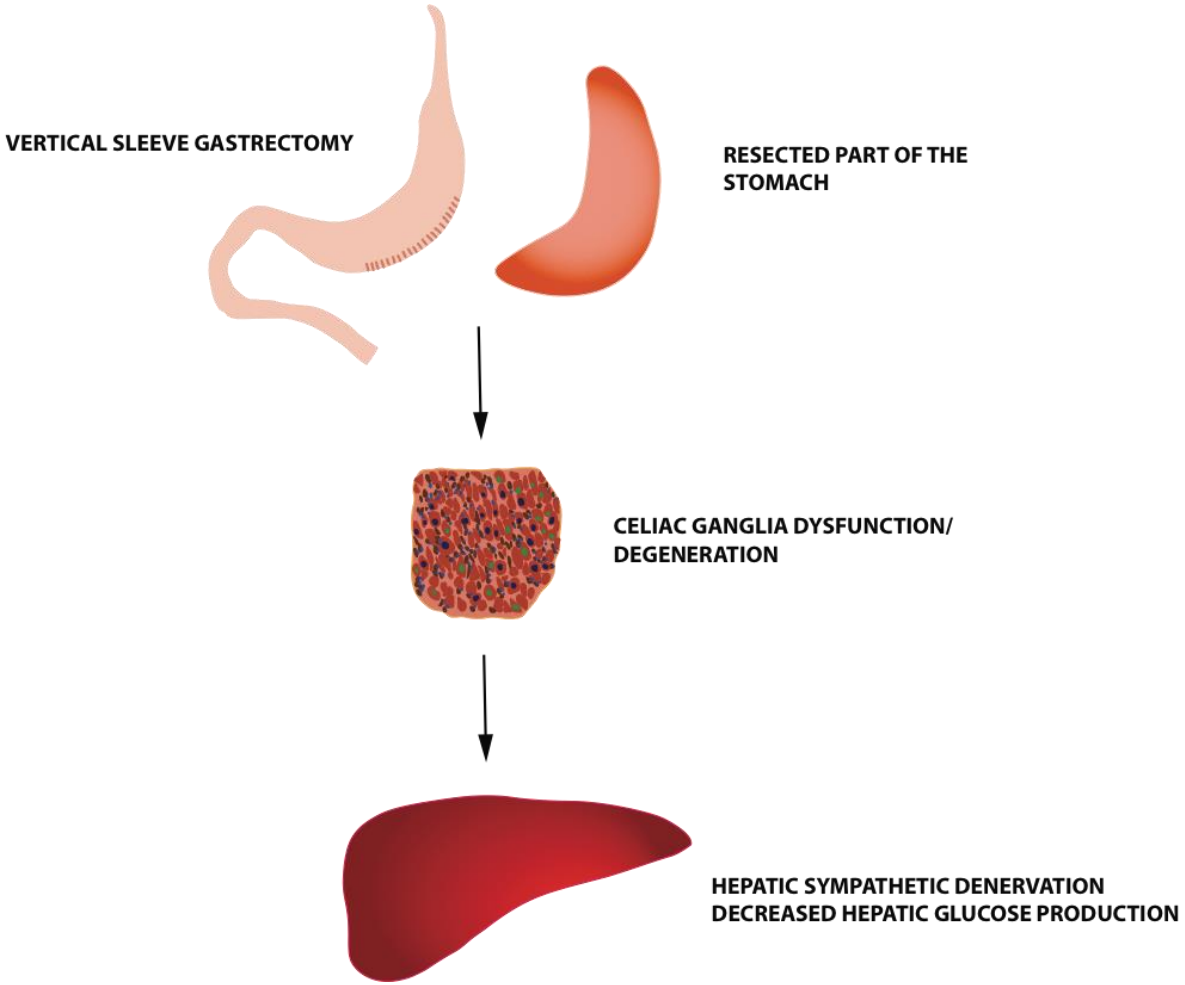
Correlation between blood glucose on the first post-operative day after sleeve gastrectomy in DIO mice and the 120 minute-time point of the OGTT on post-operative day 35. Correlation 72%, p=0.06.

Human Results (CDN/NYU Lutheran EHR)



Emiliano et al, manuscript in preparation

Integrative Translational Science



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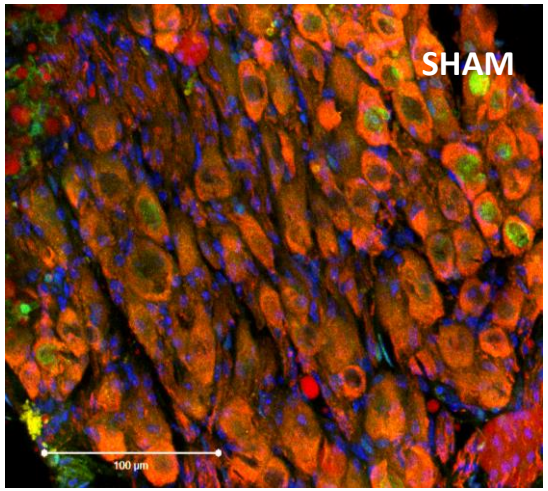
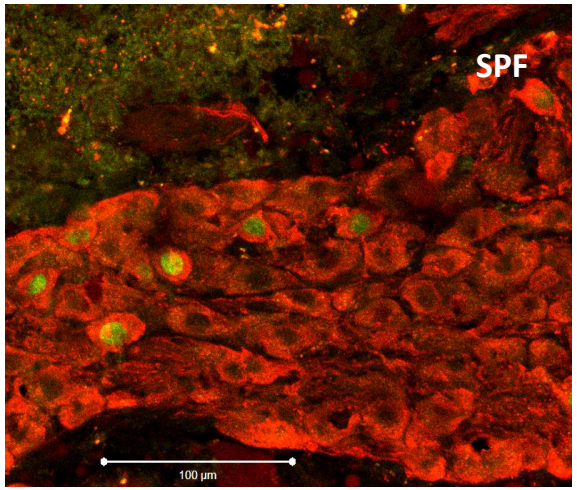
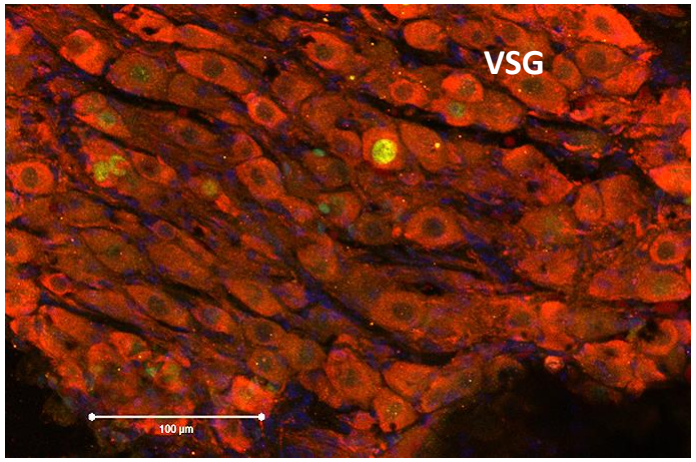
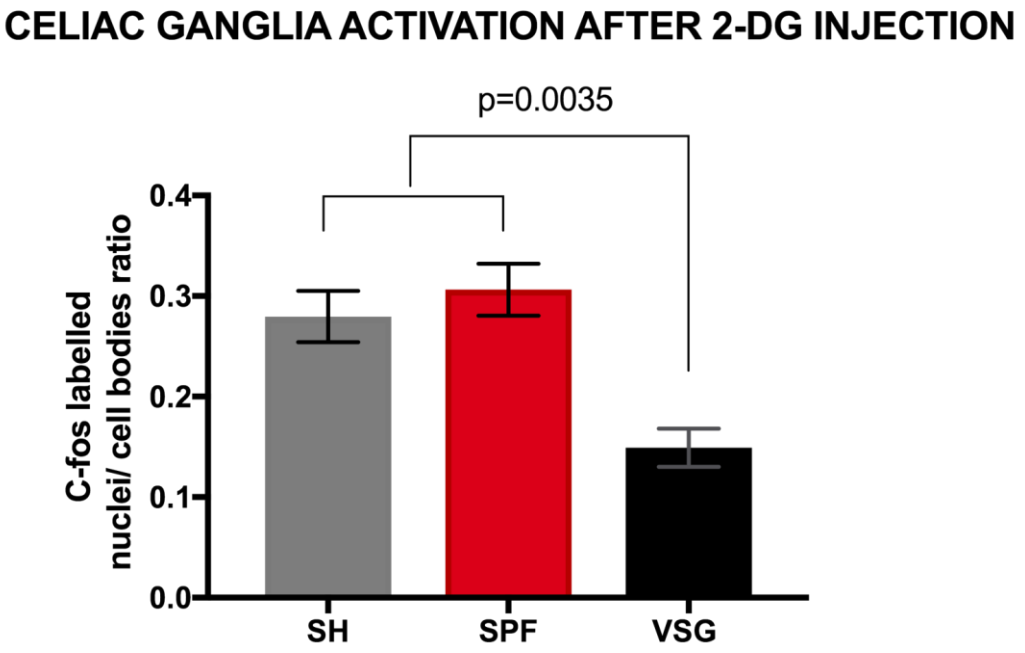
Integrative Translational Science





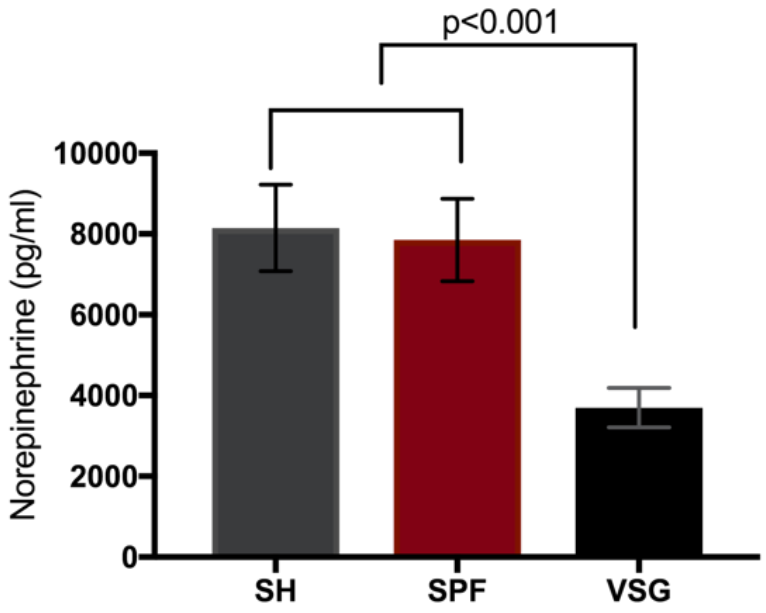


CELIAC GANGLIA AFTER 2-DG INJECTION



Emiliano et al, manuscript in preparation

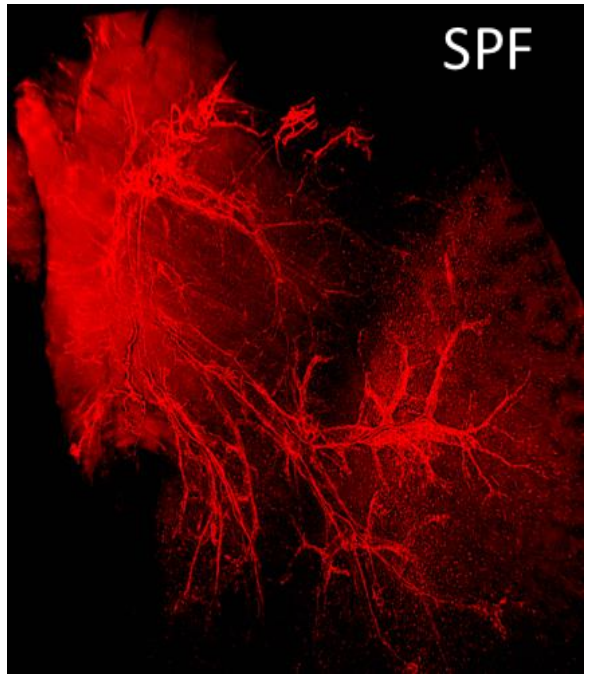
LIVER NOREPINEPHRINE CONTENT

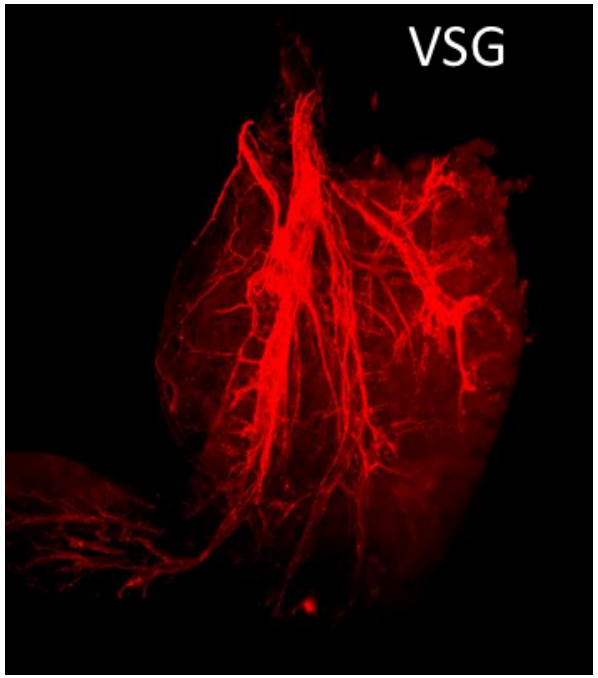


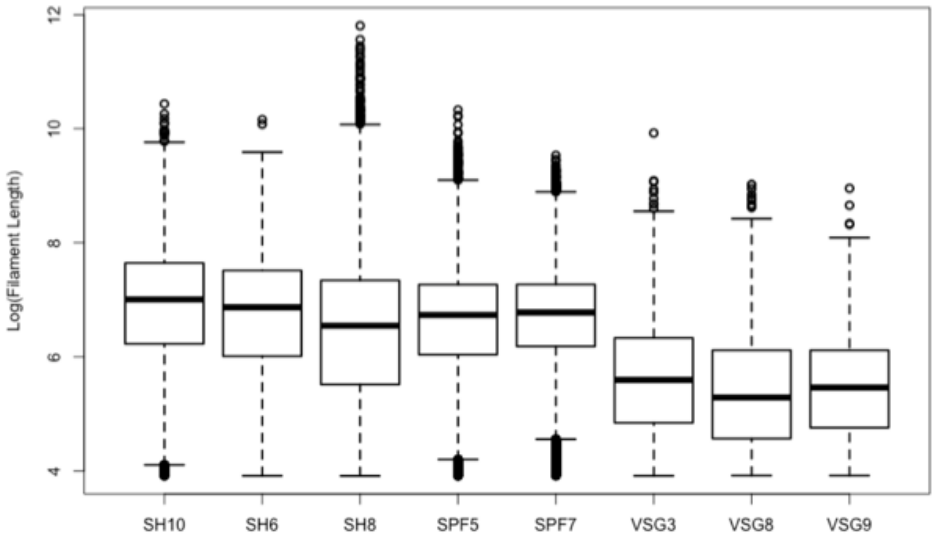
Norepinephrine content by HPLC 30 days after VSG

Emiliano et al, manuscript in preparation

Hepatic tyrosine hydroxylase-labeled fibers







SH vs. SPF: p=0.75
SH vs. VSG: p=0.0002
SPF vs. VSG: p=0.0005

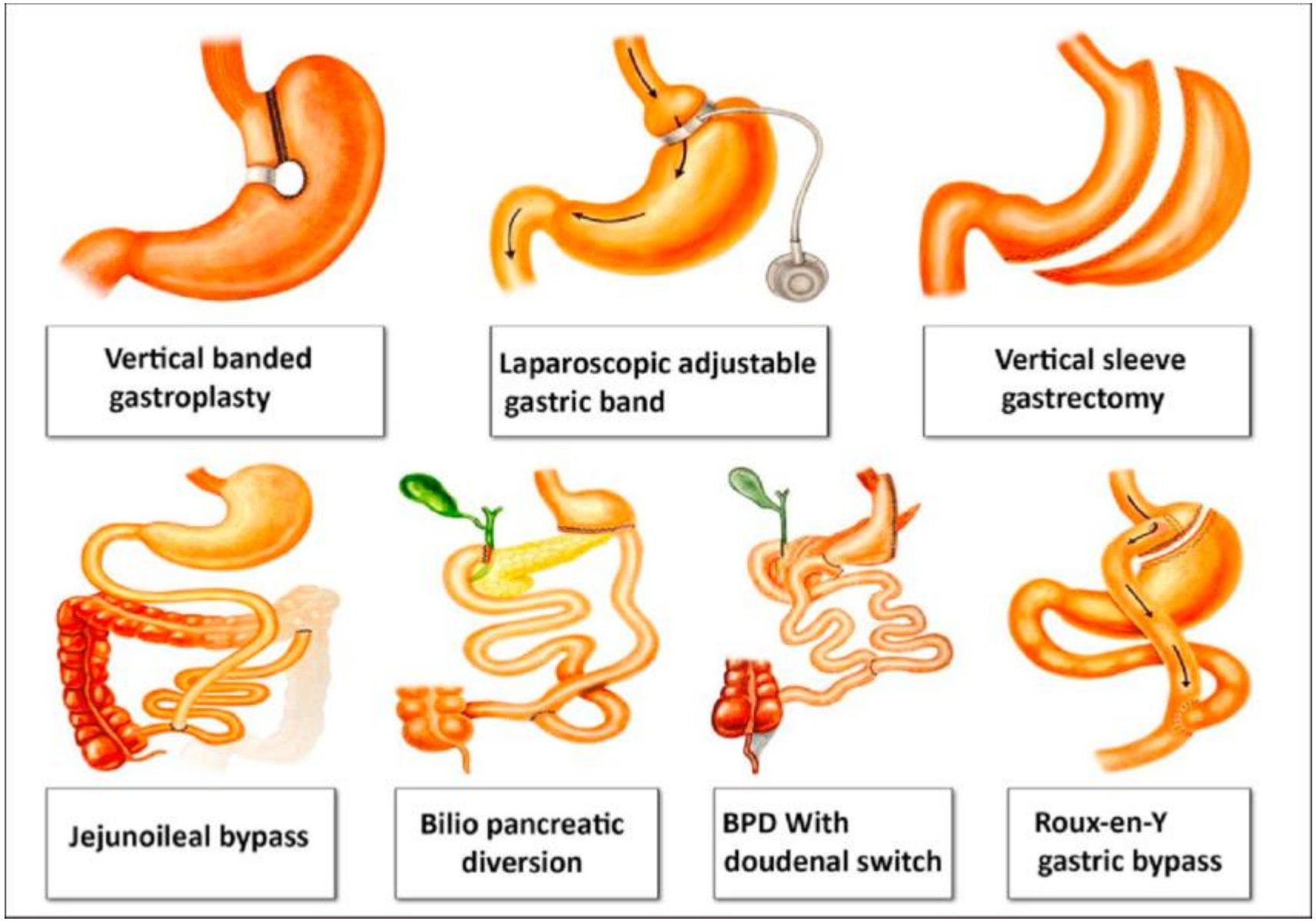
Collaboration outcomes

- It was not possible to directly test my initial hypothesis and perform hypoglycemic clamp before and after bariatric surgery – not financially feasible

- BMOP EHR analysis results validated our approach in the sense that what we found replicated the literature on bariatric surgery outcomes

- Very early glycemic outcomes as predictor of long term glycemic outcomes provides a potential mechanistic link between our laboratory finding and improved glucose homeostasis after bariatric surgery

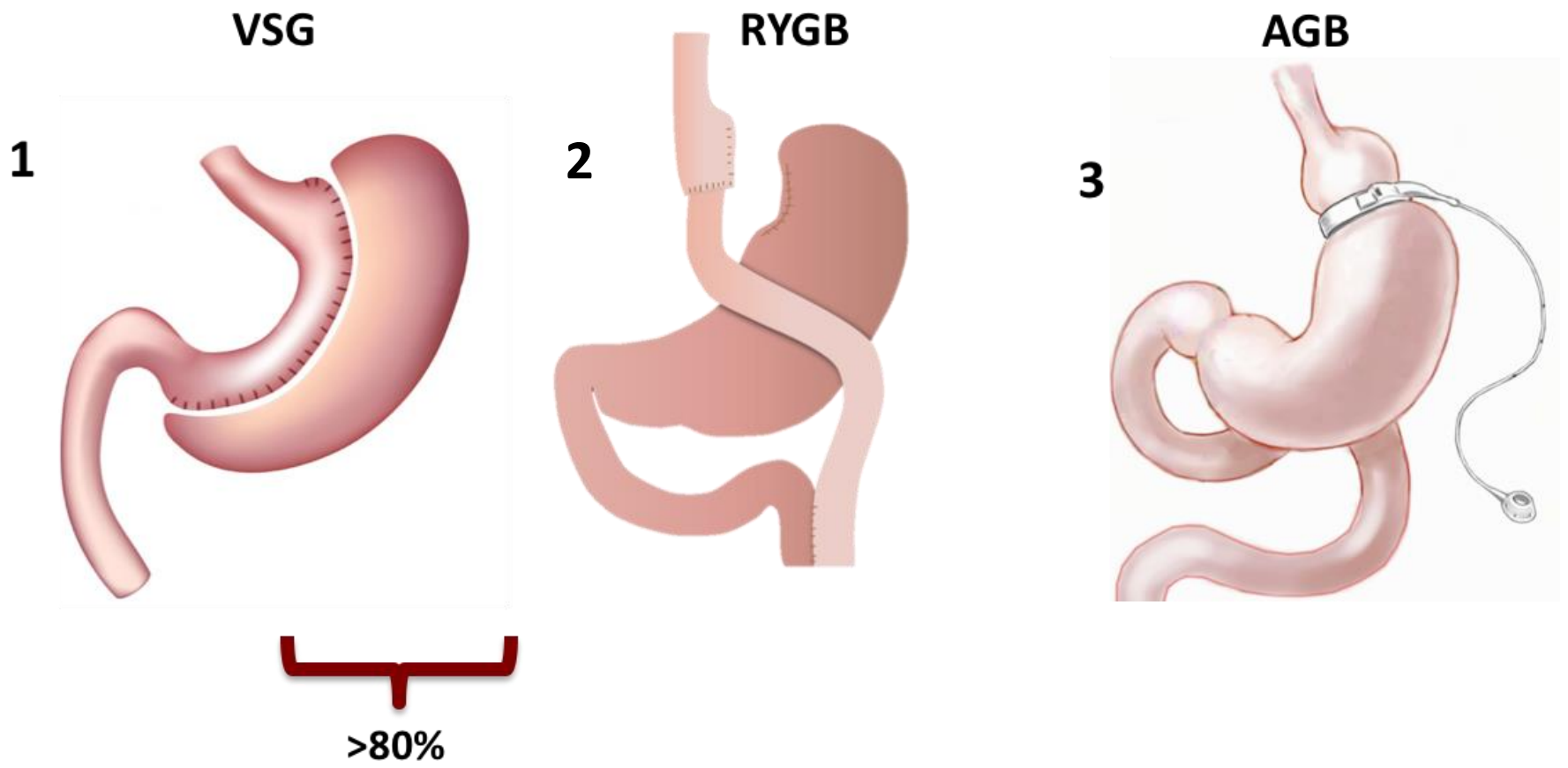
Surgical Treatment of Obesity: Bariatric Surgery



- **Gastric restriction**: volume, stoma size
- **Diversion**: **by-pass** (exclusion), interposition
- **Resection**: sleeve or hemi-gastrectomy

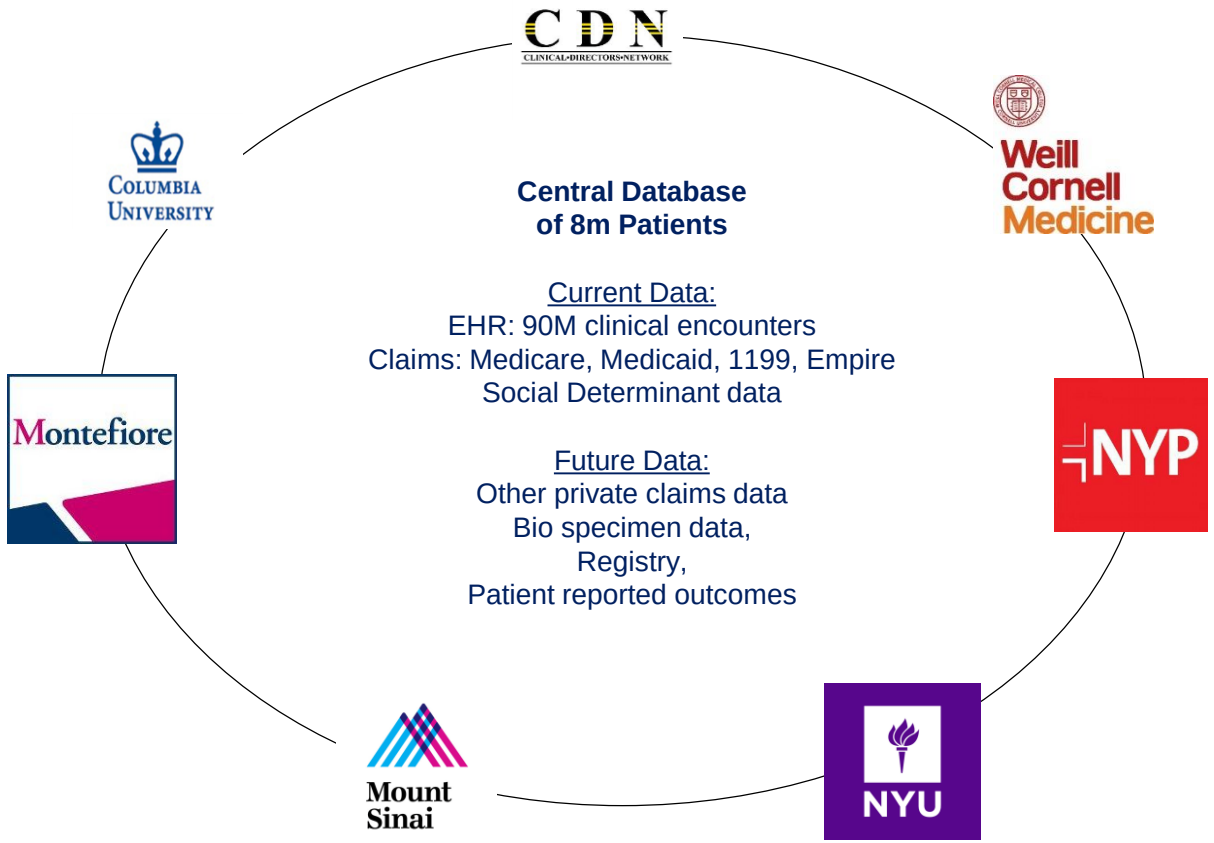
Combinations of above

Most Common Types of Bariatric Surgery in the US



NYC-CDRN
New York City Clinical Data Research Network

(now INSIGHT Network)



Weill Cornell Medicine

PCORNet - NYC-CDRN (PCORI Grant #CDRN-1306-03961)
(PI: Rainu Kaushal, MD MPH, Co-PI: Jonathan N. Tobin, PhD)

CDN
CLINICAL•DIRECTORS•NETWORK

PCORnet NYC-CDRN Obesity Pilot Study

Goals:

1) Learn more about how different factors and experiences come together for people managing weight issues. The project is made up of two components:

- A 10 minute, 25 question survey about managing weight issues and/or undergoing bariatric surgery
- After survey responses have been collected, survey answers are linked to information in patient medical records/EHRs

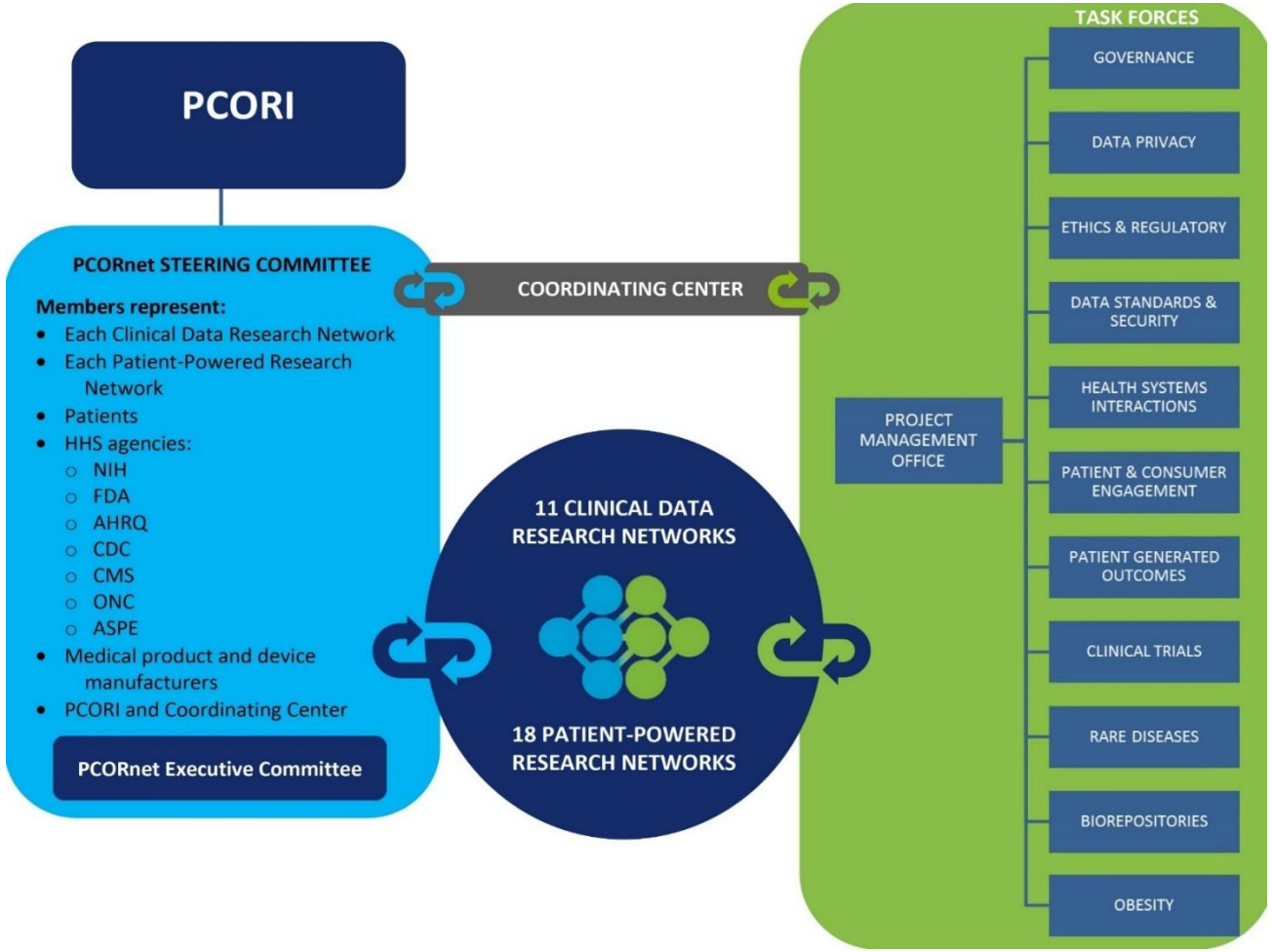
2) Develop and test methodologies to:

- Build a secure, HIPAA-compliant process to combine medical records across multiple NYC institutions and other data sources (eg, health plans) in a way that protects patient privacy
- Integrate individual level data from EHRs with Patient Reported Outcomes collected via surveys

PCORnet NYC-CDRN Obesity Pilot Study- PPRNs and PCOs

Medical Specialty	Variables of Interest (Hypotheses)	PCORnet Patient Powered Research Network (PPRN) Partner	Patient Centered Outcomes (PCO) Measure
Pulmonary	Changes in continuous positive airway pressure (CPAP) ?	Sleep Apnea Patient Centered Outcomes Network **(SAPCON)**	STOP-Bang questionnaire
Rheumatology	Improvement in joint symptoms ? Increased mobility ?	ARthritis Patient Partnership with Comparative Effectiveness Researchers **(AR-PoWER PPRN)**	
Endocrinology	Hypoglycemia?		Hypoglycemia
Mental Health	Depression and suicide?	Mood Patient-Powered Research Network **(MoodNetwork)**	Patient Health Questionnaire (PHQ) 9

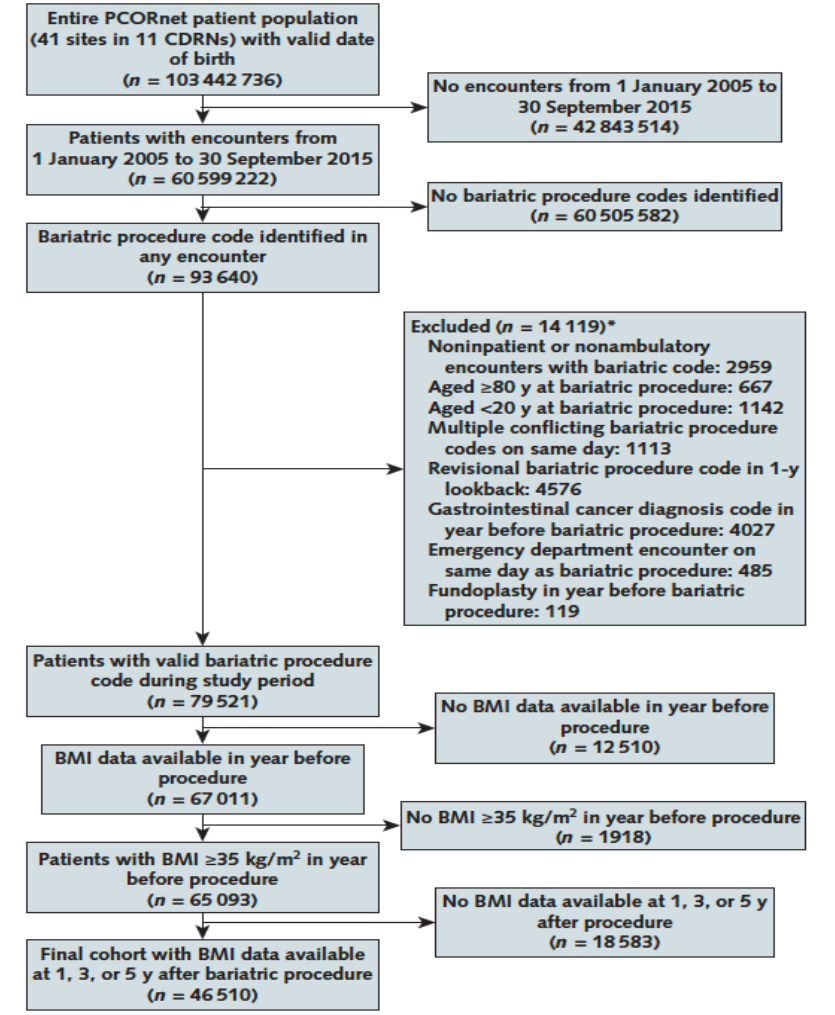
HARNESSING THE POWER OF HEALTHCARE DATA NATIONALLY



- **Large diverse population**
- **Geographic co-location in a fragmented healthcare market**
- **Centralized structure**
- **Largest concentration of AMCs**

PCORnet Bariatric Study

- National PI: David Arterburn, MD
- NYC-CDRN co-PIs: Ana Emiliano, MD and Rabih Nemr, MD



BMI = body mass index; CDRN = Clinical Data Research Network; PCORnet = National Patient-Centered Clinical Research Network.
* Patients could be excluded for >1 reason.

Collaboration with PCORnet Bariatric Study

Observational Comparative Effectiveness

Outcomes Study

Annals of Internal Medicine ORIGINAL RESEARCH

Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss

A PCORnet Cohort Study

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Background: There has been a dramatic shift in use of bariatric procedures, but little is known about their long-term comparative effectiveness.

Objective: To compare weight loss and safety among bariatric procedures.

Design: Retrospective observational cohort study, January 2005 to September 2015. (ClinicalTrials.gov: NCT02741674)

Setting: 41 health systems in the National Patient-Centered Clinical Research Network.

Participants: 65 093 patients aged 20 to 79 years with body mass index (BMI) of 35 kg/m^2 or greater who had bariatric procedures.

Intervention: 32 208 Roux-en-Y gastric bypass (RYGB), 29 693 sleeve gastrectomy (SG), and 3192 adjustable gastric banding (AGB) procedures.

Measurements: Estimated percent total weight loss (TWL) at 1, 3, and 5 years; 30-day rates of major adverse events.

Results: Total numbers of eligible patients with weight measures at 1, 3, and 5 years were 44 978 (84%), 20 783 (68%), and 7159 (69%), respectively. Thirty-day rates of major adverse events were 5.0% for RYGB, 2.6% for SG, and 2.9% for AGB. One-year mean TWLs were 31.2% (95% CI, 31.1% to 31.3%) for RYGB, 25.2% (CI, 25.1% to 25.4%) for SG, and 13.7% (CI, 13.3% to 14.0%) for AGB. At 1 year, RYGB patients lost 5.9 (CI, 5.8 to 6.1) percentage points more weight than SG patients and 17.7 (CI, 17.3 to 18.1) percentage points more than AGB patients, and SG patients lost 12.0 (CI, 11.6 to 12.5) percentage points more than AGB patients. Five-year mean TWLs were 25.5% (CI, 25.1% to 25.9%) for RYGB, 18.8% (CI, 18.0% to 19.6%) for SG, and 11.7% (CI, 10.2% to 13.1%) for AGB. Patients with diabetes, those with BMI less than 50 kg/m^2, those aged 65 years or older, African American patients, and Hispanic patients lost less weight than patients without those characteristics.

Limitation: Potential unobserved confounding due to nonrandomized design; electronic health record databases had missing outcome data.

Conclusion: Adults lost more weight with RYGB than with SG or AGB at 1, 3, and 5 years; however, RYGB had the highest 30-day rate of major adverse events. Small subgroup differences in weight loss outcomes were observed.

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For author affiliations, see end of text.
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* For key investigators and stakeholders in the PCORnet Bariatric Study Collaborative, see the **Appendix** (available at Annals.org).

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Collaboration with PCORnet Bariatric Study

Observational
Comparative
Effectiveness

Outcomes Study

ELSEVIER

Surgery for Obesity and Related Diseases 14 (2018) 1374–1388

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Comparative effectiveness of bariatric procedures among adolescents: the PCORnet bariatric study☆

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Collaboration with PCORnet Bariatric Study

Observational Comparative Effectiveness

Methodological Study

Combining distributed regression and propensity scores: a doubly privacy-protecting analytic method for multicenter research

This article was published in the following Dove Press journal:
Clinical Epidemiology

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Robert Wellman[2]
R Yates Coley[2]
Casie Horgan[1]
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Purpose: Sharing of detailed individual-level data continues to pose challenges in multicenter studies. This issue can be addressed in part by using analytic methods that require only summary-level information to perform the desired multivariable-adjusted analysis. We examined the feasibility and empirical validity of 1) conducting multivariable-adjusted distributed linear regression and 2) combining distributed linear regression with propensity scores, in a large distributed data network.

Patients and methods: We compared percent total weight loss 1-year postsurgery between Roux-en-Y gastric bypass and sleeve gastrectomy procedure among 43,110 patients from 36 health systems in the National Patient-Centered Clinical Research Network. We adjusted for baseline demographic and clinical variables as individual covariates, deciles of propensity scores, or both, in three separate outcome regression models. We used distributed linear regression, a method that requires only summary-level information (specifically, sums of squares and cross products matrix) from sites, to fit the three ordinary least squares linear regression models. A comparison set of analyses that used pooled deidentified individual-level data from sites served as the reference.

Results: Distributed linear regression produced results identical to those from the corresponding pooled individual-level data analysis for all variables in all three models. The maximum numerical difference in the parameter estimate or standard error for all the variables was 3×10^{-11} across three models.

Conclusion: Distributed linear regression analysis is a feasible and valid analytic method in multicenter studies for one-time continuous outcomes. Combining distributed regression with propensity scores via modeling offers more privacy protection and analytic flexibility.

Keywords: distributed regression, propensity score, distributed data networks, privacy-protecting methods

Toh, S., Wellman, R., Coley, R.Y., et al. "Combining Distributed Regression and Propensity Scores: a Doubly Privacy-Protecting Analytic Method for Multicenter Research." Clinical Epidemiology, 2018, 10 :1773-1786. PMID: 30568510

PCORnet Bariatric Study Results that will influence my practice

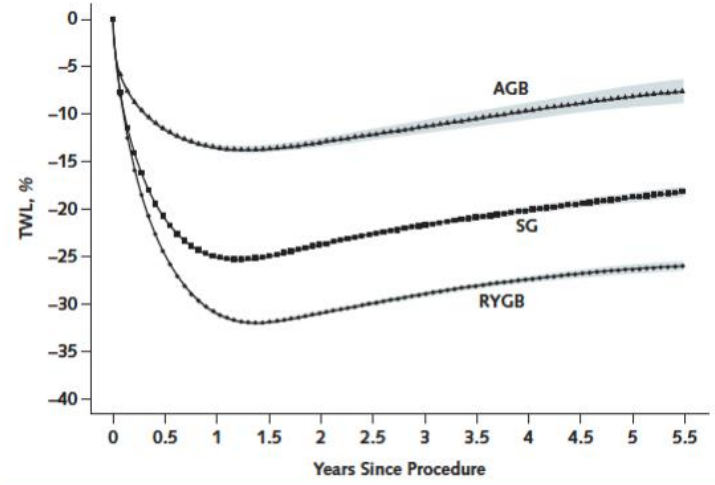


Figure 2. Estimated percentage of TWL through 5 y after bariatric surgery, by procedure type.

This plot shows the estimated percentage of TWL for a patient with the average baseline covariate profile using results from our sensitivity analysis, which included all follow-up weight measurements from 56 156 patients with any postsurgery weight observations. Additional details are provided in the Methods section of the text and the Statistical Appendix section of the **Supplement**. Shaded areas indicate pointwise 95% CIs. AGB = adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; TWL = total weight loss.

Significantly lower weight loss observed in:

- Patients with diabetes
- Individuals with BMI less than 50 kg/m2
- Patients aged 65 years or older
- African American patients
- Hispanic patients

Arterburn et al, **Annals of Internal Medicine** 2018

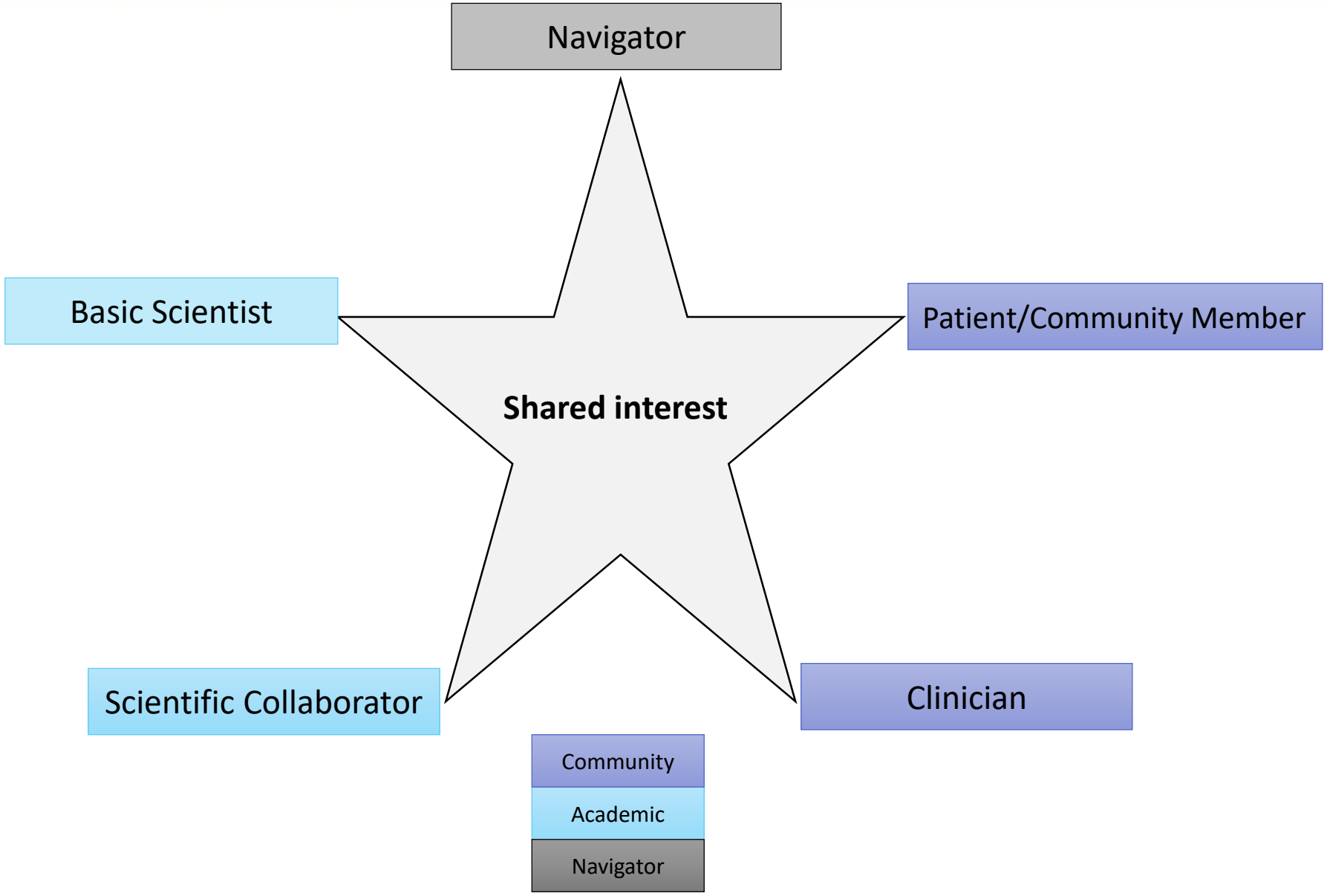
Conclusions

- Engaged community-based clinicians with basic science, translational and health services researchers
- Generated hypotheses from practice-based observations
- Collaborated in local pilot studies to develop and refine methods to extract and combine EHR data with patient-reported outcomes
- Participated in national observational comparative effectiveness studies of bariatric surgical outcomes for adults and adolescents and developed and validated a novel methodology to enhance patient privacy and data security when conducting distributed, multivariable regression analyses

Philosophy

Rather than being polar ends of the translational spectrum, T0 mechanistic research and T3-T4 community/patient-oriented research are powerful synergistic partners

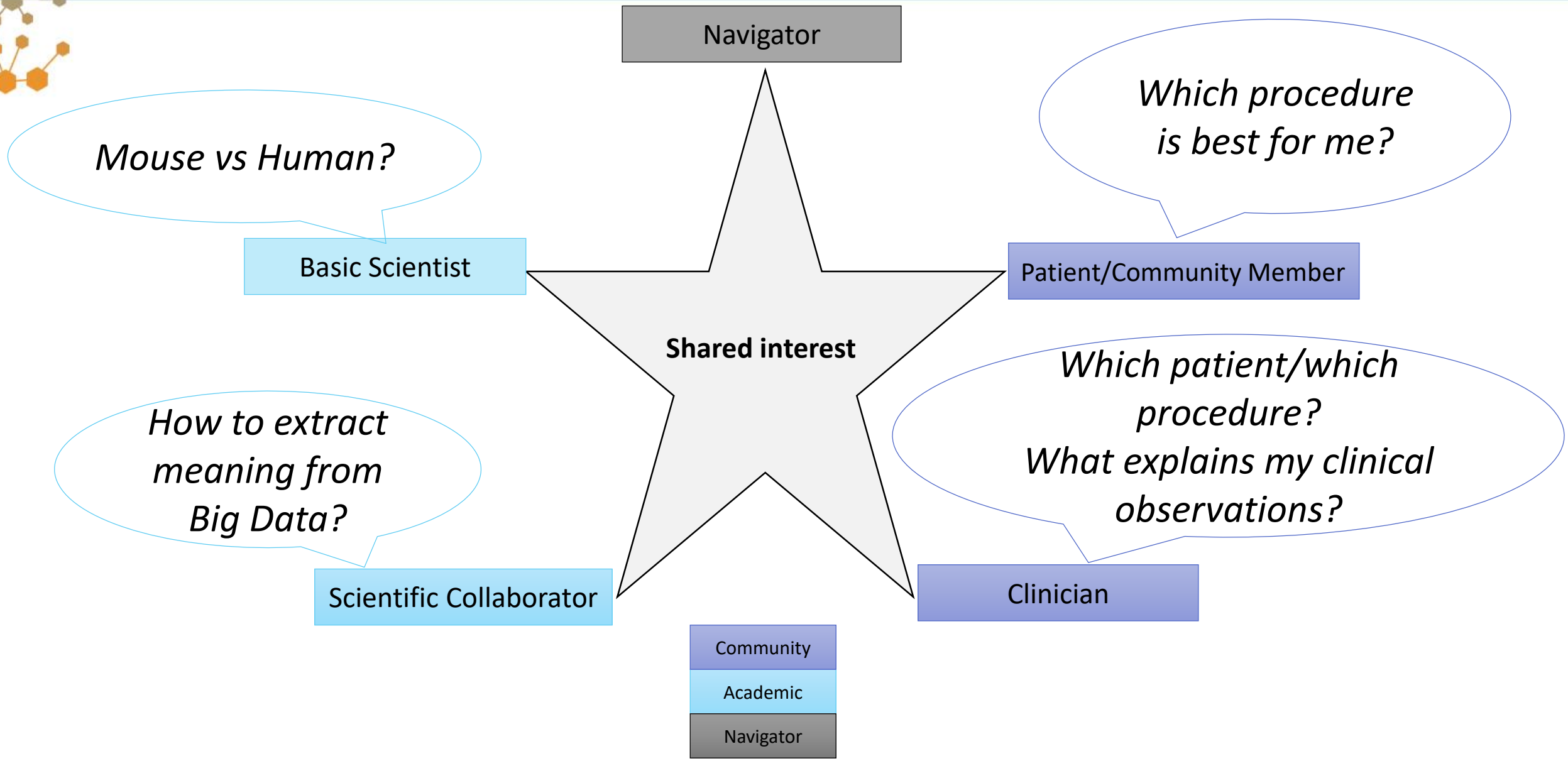
Stakeholders in Community Engaged Research



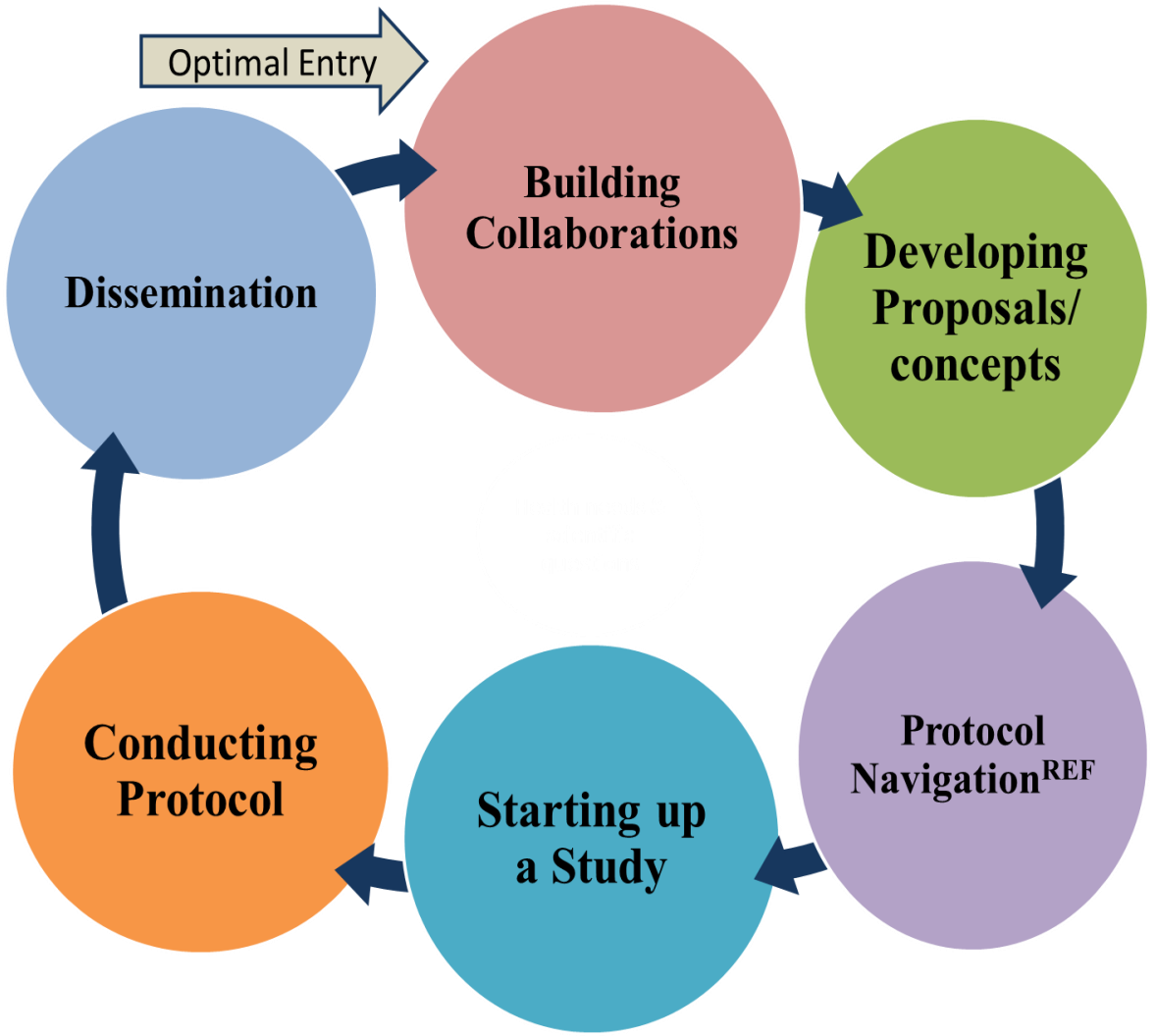
Who Was at the Meeting

FQHC	CDN (PBRN) / RU (CTSA)
Site Principal Investigator (Bariatric Surgery)	Clinical Epidemiologist
Primary Care/Family medicine	Project Manager
Endocrinology	The Rockefeller University Clinical and Translational Science Award Program (CTSA)
Pulmonary	Clinical Scholar – Physician/Scientist
Gastroenterology	Biostatistics
Mental Health Specialist	Bioinformatics
Nutritionist/Dietitian	Pilot Grant Mechanism
Information and Statistician	CEnR/Protocol Navigation

Stakeholders in Community Engaged Research



Community-Engaged Research Navigation



Kost RG, et. al. Acad Med 2017

Outcomes: Something for everyone

Career Stage	Time invested	Protocol Aims, mapped to Translational Continuum					Measure of partnership	External Funding	Publication	Health Impact
		T0	T1	T2	T3	T4				

Adapted from Kost RG, et. al. Helping Basic Scientists Engage Acad Med 2017

Outcomes: Something for everyone

Career Stage	Time invested	Protocol Aims, mapped to Translational Continuum					Measure of partnership	External Funding	Publication	Health Impact
		T0	T1	T2	T3	T4				
Early career	Extended						Time, leadership, co-authorship, dissemination	Clinical scholar Pilot K award	Co-author, Annals Int Med	
Clinicians	Extended						Time, leadership, co-authorship, dissemination		Co-authors Annals Int Med	Evidence based practices
Patients	Limited *& in silico*						PCOs, surveys, EHR data			Evidence based Rx
Collaborators	Extended						Time, Analysis, Dissemination	PCORI	Co-authors Annals Int med	
PBRN & CTSA Navigators	Extended						Time, leadership, co-authorship, grant-writing	CCTS AHRQ PCORI	Co-author, methodology	

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- **PCORNet - NYC-CDRN** (PCORI Grant #CDRN-1306-03961) (PI: Rainu Kaushal, MD MPH, Co-PI: Jonathan N. Tobin, PhD)

- **The PCORnet Bariatric Study - Comparing the Benefits and Harms of Three Types of Weight Loss Surgery -** (PCORI/OBS-1505-30683) (PI: David Arterburn, MD, MPH – NYC-CDRN Co-PIs: Ana Emiliano MD MSC, Rabih Nemr MD FACS)

Reflections on the Collaboration

Discussion

Questions & Answers