Stakeholder Engagement Plan

PCORnet Bariatric Study

Submitted to PCORI	*April 29, 2016*
Revised	*May 27, 2016*

TABLE OF CONTENTS

ENGAGEMENT PLAN

A. GOALS OF THE PCORNET BARIATRIC STUDY ENGAGEMENT PLAN

- To provide a voice equal to the scientific investigators in the study design, implementation, and dissemination for the following stakeholder groups: patients and their families, providers and surgeons, community and advocacy organizations, and healthcare policy makers and professional organizations.

- To create, test, institutionalize, and promote access to a national network of bariatric patient and family engagement platforms where patients and their families are free to exchange information and share experiences, learn about bariatric surgery, and communicate with providers, policy makers, advocacy groups, and research scientists in a neutral commercial-free environment.

- To understand how payer and insurance groups make decisions about coverage for bariatric surgery and design and implement the study to provide the evidence necessary for them to make equitable decisions.

- To understand the bariatric patient and surgeon experience to design and implement future research studies that are directly relevant to their concerns.

B. CORE PRINCIPALS OF ENGAGEMENT

In addition to the PCORI Engagement Rubric,[1] we will use two theoretical frameworks to help us implement the PCOR Engagement Principles for all of our stakeholder groups. The first is Community Based Participatory Research (CBPR)[2,3] for patients and their families and community and advocacy groups and the second is the Veteran's Affairs Quality Enhancement Research Initiative (VA QUERI) framework for providers and surgeons, healthcare policy makers and professional organizations, and the PCORnet Bariatric Study principal investigators.[4,5] We have chosen to use these two frameworks because CBPR is the most widely used (considered the "gold" standard) of models for community-engaged research where community members have the same status in a research study as the investigators and the VA QUERI approach is one of the only organized, clearly outlined strategies for the engagement of health care professionals in research studies where they also hold the same status as investigators in the planning, implementation, and dissemination of study findings.

CBPR is distinct from community-based research in that although both are conducted in community settings, the former involves the stakeholders in all important decisions about the research project. There is a particular emphasis on community assets rather than what communities lack when developing research questions. We will embrace the principles of CBPR by doing the following: recognizing our patient partners and their families as a unit of identity, valuing and acknowledging the expertise patient stakeholders possess, involving them in all phases of the research project, promote co-learning and empowerment among our patient and family partners (i.e. we have as much to learn from them as they do from us), using an iterative process in developing the project, creating a shared dissemination strategy, and building a relationship with our patient partners and their families and the community and advocacy groups who will help us engage patients and their families that will extend beyond the grant to maintain the study cohort for future work.[2] This approach is also consistent with the PCORI Engagement Rubric[1] and its core principals of reciprocal relationships, co-learning, partnership, and truth/transparency/honesty.

Key pillars in the VA QUERI framework are the engagement of clinical stakeholders and organizational leaders during the development phase of any project as well as the recognition that the research team is in itself a stakeholder group.[3,4] Engagement with the VA QUERI framework will address 1) what are the most important clinical issues related to bariatric surgery, 2) how we might address these clinical issues given the limitations of existing medical record data, 3) how can the information we learn be used to impact clinical practice, and 4) how can we provide a meaningful role for the PCORnet Bariatric Study principal investigators and leaders of the Clinical Data and Patient-Powered Research Networks that can address their professional needs (i.e. publications and other scholarly activities).

Using these frameworks, the following will be the core principles of engagement for the PCORnet Bariatric Study. The methods for how we will implement these core principals are detailed in the remainder of the engagement plan:

1. *Reciprocal Relationships*: All stakeholders will contribute in a meaningful way to study design and execution, as well as to assist with dissemination of our results to a wider audience. While we do not expect our stakeholders to be expert researchers, we do expect them to be "expert patients/professionals/leaders", helping us understand their points of view and experiences to better inform the research methods and dissemination strategies.

2. *Co-Learning*: All stakeholders (including the investigators at the Clinical Data Research Network sites) will serve as experts on the bariatric experience from a number of viewpoints. They will provide direction on the best methods to engage this patient population and the professionals who care for them, the outcomes that are important to them, and how best to communicate our findings to a wide variety of audiences. In addition, we have made a specific effort to involve health system leaders, bariatric surgeons, and individual investigators within the Clinical Data Research Networks and broader professional societies that serve these groups to make sure that their voices are heard and that they can play a meaningful role in our study design, implementation, and dissemination.

3. *Partnership*: The engagement strategy is designed to reflect the voice of the different stakeholder groups in bariatric research. All stakeholder groups provide the same value to the proposal. Without our stakeholders we could not hope to design a study that was meaningful and had any chance to inform treatment and policy guidelines, discourse, and provider-family decisions regarding the choice to have bariatric surgery for weight loss and remission of diabetes.

   Monetary compensation will be provided to the Executive Bariatric Stakeholder Advisory Group members for their time and effort in the development of the research plan and dissemination strategies for the study, and recognition of the research networks' leadership in a way that is meaningful to them will be a primary goal of this partnership. This was budgeted at $1,500/per year, but each CDRN is then able to dispense payments in accordance with their local stakeholder engagement policies. We will also be sensitive to the needs of the various stakeholder groups and hold conference calls at times that work for their schedules. Though this often means evening calls for the members of the Stakeholder and Secondary Aim Leadership Core, this is planned to accommodate their needs.

4. *Trust, Transparency, Honesty*: All of our stakeholders will be included in ongoing discussions of study methods as well as the interpretation and dissemination of the findings. There will always be a safe and open environment for discussion where all stakeholders can honestly share their opinions and feel that their contributions are of value to the project. Meeting minutes will be distributed across all stakeholder groups so that they might understand the evolving

perspectives and concerns of all of our partners involved in the planning, implementation, and dissemination of our proposed study. This will be done using the meeting management website provided by the coordinating center for the PCORnet obesity studies (pcornet.imeetcentral.com). Decisions will be made with the bariatric patient principal investigator's input (Mrs. Neely Williams) equal to the other PCORnet Bariatric Study principal investigators. The Executive Bariatric Stakeholder Advisory Board will be critical to this decision-making process and all recommendations will be taken into consideration during each point of the study period.

C. OVERVIEW OF STAKEHOLDER ENGAGEMENT

The overarching structure of the PCORnet Bariatric Study stakeholder engagement strategy is shown in Figure 1. Through our work with the core scientific leadership team we have identified five key stakeholder groups that would be critical to the success of our project:

1. *Patients and Families*: these are post-bariatric patients, patients who are preparing to have/considering surgery, patients who are eligible for surgery, and/or their family members.
2. *Providers and Surgeons*: these include bariatric surgeons and healthcare providers who are involved in either the preparation of patients for surgery or their post-operative care. These providers will include bariatricians, support group facilitators, social workers, mental health professionals, and health educators who prepare patients for surgery and provide support for them afterwards. We will include at least one healthcare system leader in this stakeholder group. This person will likely be a physician with some say in decisions about bariatric care or obesity management in health care organizations.
3. *Community and Advocacy Groups*: these will be representatives from organizations that are outside of healthcare systems that bring communities' perspectives on bariatric surgery and will include organizations such as Smart Patients and the Obesity Action Coalition. Our efforts to engage the Patient-Powered Research Networks will be included in our efforts to engage community and advocacy groups.
4. *Healthcare Policy Makers and Professional Organizations*: Healthcare policy maker will be members of national organizations, such as Blue Cross/Blue Shield, the Centers for Medicare and Medicaid, and the America's Health Insurance Plans, who make decisions about insurance coverage and benefits for bariatric surgery. Professional organizations will be those that provide a forum for providers, surgeons, and patients in the area of bariatric surgery to gather and share knowledge about this topic. These include the American Society for Metabolic and Bariatric Surgery, the Obesity Society, and the Obesity Medicine Association.
5. *PCORnet Bariatric Study Clinical Data Research Network Principal Investigators*: These are the bariatric study principal investigators of the Clinical Data Research Networks who have some involvement in the PCORnet obesity demonstration projects.

The engagement of these five stakeholder groups will be overseen by two groups within the PCORnet Bariatric Study: 1) the Stakeholder Engagement and Secondary Aim Leadership Core and (leadership core) and 2) the Executive Bariatric Stakeholder Advisory Group (executive stakeholders). The leadership core will consist of the three Principal Investigators for the PCORnet Bariatric Study (Dr. Arterburn [research scientist and clinician], Dr. McTigue [research scientist and clinician], and Mrs. Neely

Williams [bariatric patient and advocate]), Dr. Courcoulas (Co-investigator for the study and bariatric surgeon), and Ms. Cheri Janning (Co-investigator for the study and bariatric patient). The executive stakeholder group will consist of members from stakeholder groups 1 – 3 above. Details for the selection of these executive stakeholders and which stakeholder group they represent are provided in the next section. The activities for both the leadership core and the executive stakeholders will be overseen and coordinated by Dr. Karen J. Coleman (Co-investigator for the study).

Critical to the study engagement plan will be a process for reflection and connection to the overarching work of the PCORnet Engagement Committee and PCORnet Council. These "big picture" engagement groups provide a tremendous opportunity to serve as a feedback loop and ensure that all study processes immediately impact the overall network and other emerging demonstration projects. Dr. Coleman and Mrs. Williams will participate in monthly meetings with Andrea Goodman, Sharon Terry, and Doug Lunsford to discuss the larger network and antibiotic obesity study engagement processes throughout the PCORnet Bariatric Study. Learnings will be transmitted back to the executive stakeholders and the broader stakeholder groups that have been identified for the study (see Figure 1).

We are aware of several existing challenges and limitations to this work. Whenever possible, the engagement and secondary aim leadership core will be focused on finding resolutions to these issues, both within the current study as well as identified best practices for adoption in the future. Currently we propose the following processes to assist us with some of the challenges we have already identified in communication with our stakeholders:

1. Lay versions of the protocols and scientific reports are essential for a successful communication strategy. We have begun piloting this process by creating a lay executive summary of the PCORnet Bariatric Study analytic plan (provided in the appendix). We will continue to create this kind of summary of any technical information we produce and distribute. We will also test these summaries within the patient stakeholder engagement work group among the networks of patient stakeholders we form for the study.
2. All protocols, reports, presentations and the lay summaries of these materials will be compiled in a stakeholder member toolkit for each stage of the project: study design, data collection, analysis, and dissemination.
3. Comprehensive stakeholder training documents and will be created in collaboration with the PCORnet Engagement Committee, Council, and leadership from the PCORnet Antibiotics Study and these will be used to provide templates that can be used across PCORnet studies.

While we continue to identify solutions and build tools, we will access our partnerships with other organizations that engage stakeholders in their work such as the Health Care Research Network's Patient Engagement in Research Special Interest Group (http://www.hcsrn.org/en/).

D. THE EXECUTIVE BARIATRIC STAKEHOLDER ADVISORY GROUP

1. Purpose of the Executive Stakeholders

The Executive Bariatric Stakeholder Advisory Group (executive stakeholders) was formed to facilitate the engagement of the broader stakeholder groups identified in the previous section (and shown in Figure 1) and create a more nimble body of professionals who could contribute to the study with the same importance as the leadership core. They will be instrumental in developing the research plan, dissemination of study methods and findings, and will assist the core leadership team with designing, implementing, and interpreting the secondary aim for the study which seeks to understand patients' and surgeons' perspectives on weight loss treatment and bariatric surgery.

2. Process for Selecting the Executive Bariatric Stakeholder Advisory Group Members

The executive stakeholders were chosen during proposal development using a nomination process. Each Clinical Data Research Network bariatric study principal investigator and leaders of the Patient-Powered Research Networks who had an interest in obesity treatment were asked to nominate at least one stakeholder they had worked with during their PCORnet infrastructure development that fit into at least one of the first three stakeholder groups (patients, healthcare system, and community) listed above. They were also asked to provide a brief 1 – 2 sentence reason for their nomination. These nominations were sent to Dr. Coleman and she processed them to obtain a broadly representative group of executive stakeholders. If a network nominated only one stakeholder then that stakeholder was added to the advisory group regardless of the stakeholder group they represented. If a network nominated more than one stakeholder, one individual was chosen based upon the least well-represented stakeholder group. For example, if a bariatric surgeon and a bariatric patient were nominated from a single network, and there were already six patients but only one surgeon nominated as executive stakeholders, then the surgeon was chosen.

3. Representation of Expertise and Constituencies among Executive Stakeholders

The membership of the Executive Bariatric Stakeholder Advisory Group and the research network and stakeholder group they represent are shown in Table 1. Many of our executive stakeholders are members of multiple stakeholder groups. The primary group for which they were chosen is noted, followed by the other groups they represent. This intersection of multiple perspectives provides the PCORnet Bariatric Study a unique opportunity to fully understand the perspectives of all of its stakeholders.

4. Criteria for Membership

The criteria for membership on the Executive Bariatric Stakeholder Advisory Group are as follows: 1) being a member of one or more of the stakeholder groups we wish to engage; 2) being involved with a Clinical Data or Patient-Powered Research Network; 3) being nominated and approved by the PCORnet Bariatric Study principal investigator or leader of the Clinical Data or Patient-Powered Research Network; and 4) willing to meet the responsibilities and commitments outlined below. Should a stakeholder have to step down from the advisory group, the bariatric study principal investigator or leader for that network will be asked to nominate a replacement, preferably in the same stakeholder category.

5. Member Responsibilities and Commitments

Each executive stakeholder will have the following responsibilities and be asked to make the following commitments:

a) Attend an in person meeting once per year for 2 - 3 days (total of two annual meetings);
b) Meet once per month by web or telephone conference for one hour throughout the two years of the project and spend an additional hour per month reading materials/thinking about study-related issues;
c) Help brainstorm how to better involve the larger membership of our major stakeholder groups and assist us in making these connections;
d) Engage in the Executive Bariatric Stakeholder Advisory Group (attend meetings, provide feedback, contribute ideas, make connections);
e) Learn about and discuss the PCORnet Bariatric Study, obesity–related research, and other research studies;
f) Provide feedback on all phases of the study;

g) Contribute to communications about engaging diverse communities (racial/ethnic minorities, patients with different gender identities (LGBTQ), patients with disabilities, and other groups of patients whose voice is often not heard in this work);
h) Engage in an ongoing feedback loop to the core scientific leadership and bring information back to communities and professional societies when applicable.

6. Conflicts of Interest

Executive stakeholders must fully disclose potential conflicts of interest, or the appearance of conflict of interest, as a consequence of involvement in commercial, private, or government entities that compete with or might appear to benefit from the PCORnet Bariatric Study. Conflicts of interest will be explained to the executive stakeholders and they will be provided a process for disclosing the conflicts they do have or develop throughout the length of the study. This process will follow any guidelines created by the PCORnet.

7. Length of Term

Executive stakeholders are asked to serve for two years. Stakeholders who are absent without reasonable cause from at least 50% of all meetings or are unable to provide meaningful contributions to tasks required by the study (i.e. review analytic and stakeholder engagement plans and provide input) will be considered to have resigned their seat and a replacement will be sought as described above.

8. Honorarium

Executive Stakeholders' travel expenses will be provided by the grant and they will be paid for their time. Executive stakeholders will not be paid for their time while attending the in person meetings, although their travel expenses will be reimbursed. $1,500/year per CDRN was allocated to stakeholder honoraria. Each CDRN was then able to dispense payments in accordance with their local stakeholder engagement policies.

9. Procedures for Engagement

The primary method for engaging our executive stakeholders is through meetings, emails, and individual phone calls as needed. Meetings will be done through web conference and in person. A schedule for the web conference meetings is shown in Table 2. Because of the difficulty in having one meeting per month that fit everyone's schedules, we created two meetings per month and executive stakeholders could choose which one to attend. Whenever possible the same information will be presented at each of these meetings, however, because there will be different attendants, the meetings will differ. We will record both meetings each month and distribute action items across the two meetings as well as both recordings to all executive stakeholders using email. In person meetings will be held once a year for 2-3 days. There will be a total of two annual meetings.

Executive stakeholders may be engaged outside of these regular meetings when necessary to help the PCORnet Bariatric Study with engagement of the larger stakeholder groups that they represent. We will be mindful of the time devoted by our executive stakeholders and have frequent "check ins" with them about the workload for this study. Executive stakeholders will be invited to attend any working subgroups that are formed for the implementation of the study as their time allows. Currently we propose two working subgroups: patient engagement and secondary aim implementation.

E. OTHER KEY STAKEHOLDER GROUPS

1. Patients and Families

a. Overview

A working subgroup will be formed to work solely on patient engagement. The membership of this workgroup will be made up of members of the executive stakeholders, the leadership core, representatives from select Clinical Data and Patient-Powered Research Networks, and a web-based community that engages patients around a variety of health-related topics called Smart Patients© (www.smartpatients.com). Dr. Roni Zeiger, who leads Smart Patients©, is also one of our executive stakeholders. Smart Patients© is a web-based platform that facilitates online conversations among an unlimited number of patients and their families regarding issues that matter to them. For the proposed study, Smart Patients© will work with the patient engagement work group to engage patients through this platform to identify bariatric outcomes of importance to them, to understand privacy concerns (both for data collected through the routine delivery of care and in clinical trials or other prospective studies), to elicit thoughts about participating in clinical research, to provide topics to explore as part of the proposed secondary study aim (i.e. What should we ask bariatric patients about in our focus groups? What would you like to know about how your surgeon decides what surgery is right for you?), and to brainstorm ideas regarding how to disseminate study-related information to patient and caregiver audiences.

We recognize that not all patients and families can be engaged through web-based methods. As part of our patient engagement process (see procedures in next section) we will work with our Clinical Data and Patient-Powered Research Network partners to create a method for engaging patients at a local level through work they have already done as part of the infrastructure development of PCORnet. Any web-based conferencing will include options for participation by phone only.

b. Procedures for Engagement

To choose the Clinical Data Research Network representatives for the patient engagement workgroup (and the secondary aim implementation work group), an online survey will be sent to all of the PCORnet Bariatric Study principal investigators and directors of our network partners. This survey will ask about their current patient engagement strategies specific to their healthy weight/obese/overweight cohort including methods of engagement, specific populations engaged (i.e. bariatric patients), and expertise they might have for qualitative methods and social media. They will also be asked specifics regarding the questionnaire they administered to the healthy weight/obese/overweight cohort as part of their PCORnet infrastructure work (i.e. content, target population, findings if available).

From this online survey for patient engagement, approximately 3 - 5 networks demonstrating well-developed engagement strategies with bariatric patients and/or patients who might be eligible for surgery will be approached to contribute patients and/or professionals to our patient engagement work group. To obtain membership on this work group from the Patient-Powered Research Networks we have identified those networks that have some relevance to obesity-related research questions including those devoted to arthritis, cardiovascular health, mental health, Lesbian/Gay/Bisexual/Transgender/Queer (LGBTQ), and Chronic Obstructive Pulmonary Disease (COPD). We will work with one of our executive stakeholders, Elisha Malanga who leads the Patient-Powered Research Network for COPD, to identify key contacts in each of these pre-identified Patient-Powered Research Networks and how best to approach them. This will consist of having an initial web conference with these representatives to present an overview of the study and obtain their opinions about how they could contribute to both patient engagement and implementation of our secondary aim.

The patient engagement workgroup will also meet monthly throughout the entire period of the study and will determine the specifics of our patient engagement strategy. At this time there are no plans to provide compensation to these workgroup members. However, if compensation becomes a barrier to participation, then we will reconsider this decision.

c. Smart Patients©

The Smart Patients© platform will have a specialized area for bariatric patients to interact around health issues and questions/concerns that they raise for discussion, and thus we will be able to tell when bariatric patients register for and use the Smart Patients© site. We will obtain quarterly statistics for use of the website by bariatric patients and use these to evaluate any efforts we make to engage bariatric patients by promoting their use of the site. We will also survey the bariatric patient population who uses Smart Patients© and ask about their satisfaction with the platform and their desire for features such as interactions with different types of physicians (bariatric and plastic surgeons, psychiatrists, primary care physicians, bariatricians, etc.) and research scientists or content areas. We will conduct the survey at six month intervals once we have worked with Smart Patients© to engage bariatric patients across the PCORnet Bariatric Study participating organizations (reporting on survey at month 12, 18, and 24).

2. Healthcare System Professionals

a. Overview

As part of the original PCORnet Bariatric Study proposal, we stated that we would create a healthcare system professionals stakeholder group and engage these professionals quarterly. The challenges of coordinating such a diverse, busy group of people will make this very difficult. Thus we are exploring other possibilities. Towards this aim, the PCORnet Bariatric Study team created a preliminary strategy at the first in person meeting in February 2016. In this meeting, we concluded that because many professionals attend national meetings to maintain their accreditation and to remain connected to current practices and clinical guidelines in their fields, we can target professional society meetings as our first attempt at engaging healthcare system professional stakeholders. We have several core scientific team members and executive stakeholders who are in leadership positions with the American Society for Metabolic and Bariatric Surgery and the Obesity Society who have agreed to take a leadership role in establishing a PCORnet Bariatric Study presence in these professional organizations. We have also identified a number of other professional society meetings and other national venues to explore for engagement opportunities.

b. Procedures for Engagement

Initial procedures for engaging this stakeholder group will consist of preparing abstracts for submission to national meetings where bariatric patients and professionals gather. We were able to connect with the leadership team of the American Society for Metabolic and Bariatric Surgery to present our study and ask for their ideas about how we might best engage their group. We will have this leadership group as one of our main healthcare and policy engagement groups for the study and they will provide insight and input into our study design, implementation, and dissemination strategies.

3. Community and Advocacy Groups

a. Overview

We have representatives of three community and advocacy groups as executive stakeholders: Smart Patients, the Obesity Action Coalition, and the COPD Foundation which is also part of a Patient-Powered Research Network for COPD (see Table 1). In addition, as part of our engagement of the Patient-Powered Research Networks in our work groups, we anticipate that we will be able to make connections with and engage community clinics, local advocacy organizations, and local health departments and medical agencies. This work will be critical to patient engagement that is not web-based and to the collection of data for our secondary aim. Arguably the most important role that the community and advocacy stakeholder groups play are in helping us develop a dissemination strategy for our findings, tools, and approaches to engaging such a large, diverse group of stakeholders for bariatric surgery.

b. Procedures for Engagement

Engagement of this stakeholder group will be through the patient engagement and secondary aim work groups.

4. Healthcare Policy and Coverage Decision-Makers

a. Overview

During our in person meeting in February, 2016 it became clear that we had not considered one of the most critical stakeholder groups in determining access to bariatric surgery: the insurers and payers who set coverage standards for these procedures. There is a tremendous disparity in coverage for bariatric surgery among states in the U.S. as well as among healthcare organizations.[6] The PCORnet Bariatric Study team members agreed that we should identify this group of organizations as a key stakeholder group and a plan should be made to engage them in discussion of how the PCORnet Bariatric Study could serve as a resource for their decision-making process.

b. Procedures for Engagement

We will begin to engage their leadership in existing venues where they already interface with professional and community groups. One of these venues is the American Society for Metabolic and Bariatric Surgery leadership meetings, which often have insurers and payers such as the Centers for Medicare and Medicaid attending. We will present the PCORnet Bariatric Study at one of these meetings and begin a conversation about having 1 – 2 90 minute web conference meetings per year with this stakeholder group to discuss how we can design, implement, and present our study findings so that we provide the necessary information these organizations need to make informed, equitable decisions about coverage for bariatric procedures. In addition, many of our core leadership and executive stakeholders have connections to organizations such as America's Health Insurance Plans and the Centers for Medicare and Medicaid and they will work with the study to represent the PCORnet Bariatric Study and bring the study feedback from these organizations.

5. PCORnet Research Network Leadership

a. Overview

We consider the PCORnet Bariatric Study principal investigators of the individual Clinical Data Research Networks and leaders of the Patient-Powered Research Networks critical stakeholders in the success of the study. Arguably they are the most important stakeholders because without their

cooperation and labor we would not be able to conduct the study. Each of these participating networks received very little funding to do the proposed work and thus we need to consider their opinions and concerns during the design, implementation, and dissemination of the study findings. Issues such as demonstrated scientific productivity (i.e. the opportunities for intellectual contribution, publication, and presentation) are important to understand and accommodate if the PCORnet Bariatric Study is to succeed and continue.

b. Procedures for Engagement

All PCORnet Bariatric Study Clinical Data Research Network principal investigators (please see Table 3) meet as a group during two one hour monthly web conferences with the core scientific leadership team. All study related decisions are reviewed and discussed during these meetings for all scientific aims, including the secondary aim, and stakeholder engagement. A short-term publications subcommittee has been created with executive stakeholders, bariatric study Clinical Data Research Network principal investigators, and core scientific leaders to discuss how best to reflect the scientific contributions of all PCORnet Bariatric Study members. This subcommittee will determine the criteria for publication and presentation authorship, public recognition of contributions that do not meet the criteria for authorship, and how to evaluate and consider future study proposals with the PCORnet Bariatric Study patient cohort.

TABLES

TABLE 1. EXECUTIVE BARIATRIC STAKEHOLDER ADVISORY GROUP

Table 1 shows the Executive Bariatric Stakeholder Advisory Group Members and the stakeholder groups and PCORnet networks they represent (section a). The primary group each member represents is shown in blue. The membership of the Stakeholder Engagement and Secondary Aim Leadership Core who interface with and lead the executive stakeholders is shown in section b.

a) EXECUTIVE BARIATRIC STAKEHOLDER ADVISORY GROUP		
EXECUTIVE STAKEHOLDER	**STAKEHOLDER GROUP**	**NETWORK**
Elisha Malanga	**Community/Advocacy Group (COPD Foundation)** Patient-Powered Research Network	COPD PPRN
Roni Zeiger	**Community/Advocacy Group (Smart Patients)** Healthcare System Professional (Primary Care Provider) Leader of Larger Patient Engagement Strategy	PORTAL - CDRN
Sameer Murali	Healthcare System Professional (Bariatric Program Leadership and Bariatrician)	PORTAL - CDRN
Joseph Vitello	Healthcare System Professional (Bariatric Surgeon)	CAPriCORN - CDRN
Roz Saizan	**Bariatric Patient** Healthcare System Professional (Bariatric Program Coordinator)	REACHnet - CDRN
Tammy St. Clair	Bariatric Patient	NYC - CDRN
Julie Tice	Bariatric Patient	PaTH - CDRN
Elizabeth Doane	**Bariatric Patient** Healthcare System Professional (Bariatric Nurse)	SCILHS - CDRN
Caroline Apovian	**Healthcare System Professional (Pediatrician)** Research Investigator	SCILHS - CDRN
Bryan Sandler	Healthcare System Professional (Bariatric Surgeon)	pSCANNER - CDRN
Nirav Desai	Healthcare System Professional (Pediatrician)	PEDSnet - CDRN
Marc Michalsky	**Healthcare System Professional (Pediatric Bariatric Surgeon)** LABS Research Investigator	PEDSnet - CDRN
Joe Nadglowski	Community/Advocacy Group (Obesity Action Coalition)	OneFlorida - CDRN
Emily A. Eckert	Healthcare System Professional (Bariatric Family Nurse Practioner)	MidSouth - CDRN
Corrigan McBride	**Healthcare System Professional (Bariatric Surgeon)** Bariatric Patient	GPC – CDRN
b) STAKEHOLDER ENGAGEMENT AND SECONDARY AIM LEADERSHIP CORE		
LEADER	**ROLE**	**NETWORK**
Karen Coleman	Overall Lead for Stakeholder and Secondary Aim Leadership Core	PORTAL - CDRN
Neely Williams	Overall Study Co-Principal Investigator; Co-Lead for Stakeholder Engagement	MidSouth CDRN
Anita Courcoulas	Co-Investigator	PaTH - CDRN
David Arterburn	Overall Study Co-Principal Investigator	PORTAL - CDRN
Jane Anau	Overall Project Manager	PORTAL - CDRN
Kathleen McTigue	Overall Study Co-Principal Investigator; Co-Lead for Secondary Aim	PaTH - CDRN
Cheri Janning	Co-Investigator	

TABLE 2. MONTHLY MEETING SCHEDULE FOR EXECUTIVE BARIATRIC STAKEHOLDER ADVISORY BOARD

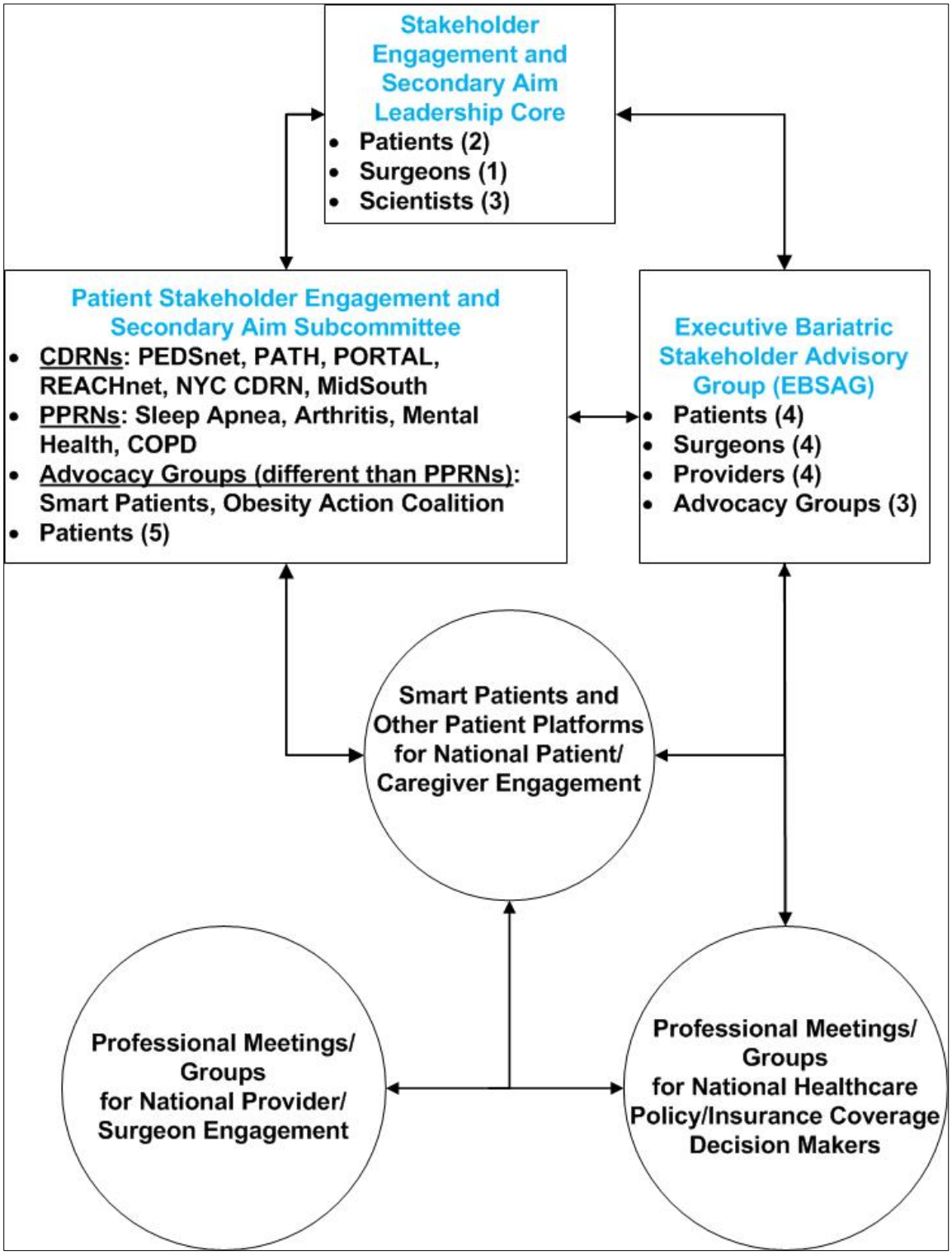
YEAR	TUESDAY MEETINGS *(2nd Tuesday of each month)*		MONDAY MEETINGS *(4th Monday of each month)*
Year 1 (2016)	February 9, 2016 1-2 PM PST/4-5 PM EST	OR	February 22, 2016 9-10 AM PST/12-1 PM EST
	March 8, 2016 1-2 PM PST/4-5 PM EST	OR	March 28, 2016 9-10 AM PST/12-1 PM EST
	April 12, 2016 1-2 PM PST/4-5 PM EST	OR	April 25, 2016 9-10 AM PST/12-1 PM EST
	May 10, 2016 1-2 PM PST/4-5 PM EST	OR	May 23, 2016 9-10 AM PST/12-1 PM EST
	June 14, 2016 1-2 PM PST/4-5 PM EST	OR	June 27, 2016 9-10 AM PST/12-1 PM EST
	July 12, 2016 1-2 PM PST/4-5 PM EST	OR	July 25, 2016 9-10 AM PST/12-1 PM EST
	August 9, 2016 1-2 PM PST/4-5 PM EST	OR	August 22, 2016 9-10 AM PST/12-1 PM EST
	September 13, 2016 1-2 PM PST/4-5 PM EST	OR	September 26, 2016 9-10 AM PST/12-1 PM EST
	October 11, 2016 1-2 PM PST/4-5 PM EST	OR	October 24, 2016 9-10 AM PST/12-1 PM EST
	November 8, 2016 1-2 PM PST/4-5 PM EST	OR	November 28, 2016 9-10 AM PST/12-1 PM EST
	December 13, 2016 1-2 PM PST/4-5 PM EST	OR	December 26, 2016 9-10 AM PST/12-1 PM EST
Year 2 (2017)	January 10, 2017 1-2 PM PST/4-5 PM EST	OR	January 23, 2017 9-10 AM PST/12-1 PM EST
	February 14, 2017 1-2 PM PST/4-5 PM EST	OR	February 27, 2017 9-10 AM PST/12-1 PM EST
	March 14, 2017 1-2 PM PST/4-5 PM EST	OR	March 27, 2017 9-10 AM PST/12-1 PM EST
	April 11, 2017 1-2 PM PST/4-5 PM EST	OR	April 24, 2017 9-10 AM PST/12-1 PM EST
	May 9, 2017 1-2 PM PST/4-5 PM EST	OR	May 22, 2017 9-10 AM PST/12-1 PM EST
	June 13, 2017 1-2 PM PST/4-5 PM EST	OR	June 26, 2017 9-10 AM PST/12-1 PM EST
	July 11, 2017 1-2 PM PST/4-5 PM EST	OR	July 24, 2017 9-10 AM PST/12-1 PM EST
	August 8, 2017 1-2 PM PST/4-5 PM EST	OR	August 28, 2017 9-10 AM PST/12-1 PM EST
	September 12, 2017 1-2 PM PST/4-5 PM EST	OR	September 25, 2017 9-10 AM PST/12-1 PM EST
	October 10, 2017 1-2 PM PST/4-5 PM EST	OR	October 23, 2017 9-10 AM PST/12-1 PM EST
	November 14, 2017 1-2 PM PST/4-5 PM EST	OR	November 27, 2017 9-10 AM PST/12-1 PM EST
	December 12, 2017 1-2 PM PST/4-5 PM EST	OR	December 25, 2017 9-10 AM PST/12-1 PM EST

TABLE 3. PCORnet NETWORK LEADERSHIP MEMBERSHIP

CLINICAL DATA RESEARCH NETWORK	BARIATRIC STUDY PRINCIPAL INVESTIGATOR	EXPERTISE
Mid-South	**David Schlundt, PhD** Vanderbilt University	Behavioral medicine with specific focuses on nutrition and behavior, and racial and ethnic health disparities.
REACHnet	**Lydia Bazzano, MD, PhD** Tulane University	Nutrition and primary prevention; cardiovascular disease; diabetes mellitus
GPC	**James McClay, MD, MS** University of Nebraska	Biomedical Informatics Emergency Medicine
PEDSnet	**Thomas Inge, MD** University of Cincinnati	General Pediatric Surgeon, Adolescent Bariatric Surgeon, Obesity and surgery research
PaTH	**Jeanne Clark, MD** Johns Hopkins University	Obesity research Efficacy of bariatric and lifestyle treatments for obesity
SCILHS	**Ali Tavakkoli, MD** Brigham and Women's Hospital	Bariatric Surgeon, Research on surgical outcomes including diabetes resolution after bariatric surgery
NYC-CDRN	**Ana Emiliano, MD** The Rockefeller University *and* **Rabih Nemr, MD** Lutheran Medical Center	Endocrinology, metabolism, and obesity Bariatric surgery, obesity
CAPriCORN	**Laura Rasmussen-Torvik, PhD, MPH** Northwestern University	Epidemiology, biogenetics, diabetes
PORTAL	**Karen Coleman, PhD**, Kaiser Permanente Southern California	Bariatric surgery outcomes research Behavioral science and community-based research
pSCANNER OneFlorida	**Pietro Gallasetti, MD**, UC Irvine **Steven Smith, MD** Florida Hospital	Obesity, diabetes, and metabolism research Obesity, diabetes, metabolism research, and translational research

FIGURES

FIGURE 1. ORGANIZATION FOR STAKEHOLDER ENGAGEMENT IN THE PCORNET BARIATRIC STUDY



REFERENCES

1. PCORI Engagement Rubric. PCORI (Patient-Centered Outcomes Research Institute) website. http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf. Published February 4, 2014. Updated October 13, 2015. Accessed April 26, 2016.
2. Israel BA, Schulz AJ, Parker EA, Becker AB. Community-based participatory research: policy recommendations for promoting a partnership approach in health research. Education for health (Abingdon, England). 2001;14:182-97.
3. Minkler M. Linking science and policy through community-based participatory research to study and address health disparities. Am J Public Health. 2010;100 Suppl 1:S81-7. PMCID: 2837446.
4. Stetler CB, Mittman BS, Francis J. Overview of the VA Quality Enhancement Research Initiative (QUERI) and QUERI theme articles: QUERI Series. Implementation science : IS. 2008;3:8. PMCID: 2289837.
5. Stetler CB, McQueen L, Demakis J, Mittman BS. An organizational framework and strategic implementation for system-level change to enhance research-based practice: QUERI Series. Implementation science : IS. 2008;3:30. PMCID: 2430586.
6. Consumer Guide to Bariatric Surgery. Weight loss surgery insurance coverage. http://www.yourbariatricsurgeryguide.com/insurance/. Accessed on March 15, 2016.

APPENDIX: 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?

Population: The study will include adults, children, and adolescents less than 80 years old at time of surgery who had one of the three most common procedures in the United States (RYGB, AGB, or SG) during the years 2005 to 2015. To be eligible for the study all patients will also need to have a Body Mass Index (BMI) measurement in the year prior to surgery that is at least 35 kg/m^2.

Data: All data necessary for accomplishing the main scientific aims of this study will be derived from the PCORnet Common Data Model (CDM). In the plan below we have specified each CDM table that will be accessed as well as the key variables that will be examined. Although all of the tables described are necessary to complete the study, of greatest interest are the procedures, diagnosis, vitals, prescribing, dispensing, and death tables. All data for this study will be abstracted from the CDM tables at each participating health care site and then sent using secured file transfer methods to the data coordinating center at Harvard Pilgrim and to Group Health Research Institute for analysis.

Analyses: The "primary analyses" will address the main study questions outlined above using individual-level patient data. There is also a set of "secondary analyses" for each of the main study questions, which will only use aggregate or summary-level data from each participating site. We will conduct three pair-wise comparisons for each study aim – comparing AGB versus RYGB, SG versus RYGB, and AGB vs. SG. To address potential confounding bias in each comparison, we will first use a logistic regression model to estimate the propensity score (PS), which is defined as the probability of receiving a treatment of interest (e.g., RYGB) in each pairwise comparison given the potential confounders variables plus calendar year. We will conduct sensitivity analyses to assess for changes in outcomes by calendar year, and we will use a multiple imputation approach to address missing outcome information. Finally, for each aim, we will seek to identify heterogeneity of treatment effects, with are any differences in the effects of the bariatric procedures across key subgroups (e.g., race/ethnicity).

Methodology Standards: Throughout the document, references are made to PCORI's Methodology Standards (e.g., [RQ-1]). A description of these standards can be found here on the PCORI website.