PCORI Funded Projects: Sample Engagement Plans

June 11, 2015

About PCORI
PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work.

Our Mission: PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Our History: PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI's purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by "advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions."

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research and the support of new research.

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Introduction

PCORI seeks to support research that includes meaningful involvement of patients and other stakeholders in all the steps of research. From time to time, PCORI is asked for information about patient and stakeholder engagement plans. PCORI recognizes that patient and stakeholder engagement plans can take multiple forms and will vary depending on the nature of the research, including the hypotheses, design, conduct, and dissemination of the research.

To enhance understanding of different models of patient and stakeholder engagement, we have selected sample engagement plans taken from actual funded projects. The actual names of patient and stakeholder partners have been removed. However, in the August 2015 funding cycle we are instituting a new requirement during the application process that will allow us to publicly recognize, by name, the contributions of patient and other stakeholder partners in our funded projects.

These engagement plans are provided solely as examples for educational purposes; they do not reflect all engagement and stakeholder plan models, and do not reflect PCORI's endorsement. Incorporation of similar engagement plans in a research proposal will not guarantee funding of the proposal. PCORI may update this resource from time to time.

—PCORI Engagement Team June 29, 2015

Engagement Plan A: Effect of Glucose Monitoring on Patient and Provider Outcomes in Non-Insulin Treated Diabetes

Patient and Stakeholder Engagement Plan

This section describes our key stakeholder groups, the ways in which their guidance has already shaped our work, and how we will continue to utilize their expertise and unique perspectives to insure that the resulting study is highly relevant and useful to patients with NIT DM and their caregivers.

Identification of key stakeholders

The stakeholders who play a critical role in providing care, advocacy, and education for persons with diabetes include patient groups, community members/at risk individuals, policy makers, providers, industry, and professional organizations. To obtain a broad yet appropriately sized swath of this community, we have chosen eight key stakeholder groups (see Figure 1). These include a state-based Diabetes Advisory Council, a state-based family medicine patient advisory board, a state-based Physicians Network, a regional Community Advisory Board, the a diabetes advocacy organization, the a national diabetes education program, a state-based diabetes patient registry and representatives from two glucose monitor manufacturers. Detailed descriptions of each group are provided below. Named individuals in **Figure 1** and described below under Completed and Planned Stakeholder and Engagement meetings have provided a letter of support.

Figure 1: Key Stakeholder groups and Stakeholders

1. State Organizations

The state based advisory council is an advisory group to the state's diabetes program that develops epidemiological reports on diabetes incidence, prevalence, morbidity, and mortality. They also increase advocacy by policy makers and stakeholders in securing reimbursement for self-management of diabetes and enhance diabetes prevention efforts through legislation.

The council coordinates many diabetes stakeholders in the state. Several of their core responsibilities are applicable to this proposal, including, 1) educating and publicly validating self-management training for diabetes control as a health priority, 2) providing scientific credibility and public validity for interventions based on evolving clinical and epidemiological studies and technology, and 3) evaluating strategies for the control of diabetes in terms of assessed need, estimated costs, potential benefits and

probability of success. Additionally, they work in advocacy and legislative issues with policy makers to secure reimbursement supporting the self-management of diabetes.

2. Patient Groups

a) *A state-based patient advisory board*: Established in 2011, this board arose during the development of a patient centered medical home and is made up of 10-12 patients and/or family members and 5-7 representatives of a medical school's family medicine faculty, residents and staff. Patient members represent a variety of patient care experiences, diagnoses, ages, geographical locations, cultures and life experiences. Staff representatives also come from divergent areas of work and expertise throughout family medicine.

b) A diabetes registry. Created in 2009 this group is comprised of 2,300 people living with diabetes who have expressed an interest in participating in diabetes-related clinical research. The medical school's diabetes center engages in a variety of community outreach projects to recruit a diverse group of registry participants.

3. Providers

A physician's network: The network provides primary and specialty outpatient care in multiple communities. It encompasses 34 practices and is actively growing; the majority (93%) of these practices focus on primary care including internal medicine, family medicine and pediatrics. Practices see approximately 2,750 patients per day across the network, and in total over 800,000 people are cared for at medical center practices annually. The leadership of both the network and the affiliated health care providers and staff have expressed strong support of using pragmatically designed trials to address practical clinical questions such as the effectiveness of SMBG testing in routine clinical practice.

4. Community members

The local community advisory board: The CAB was established in 2005 through a partnership between the community core within a local CTSA and a local health education center. The CAB meets quarterly and consists of fourteen members representing non-profit organizations and agencies, clinicians, health care providers and advocates, faith-based groups, and at-large community members. They provide recommendations and guidance to researchers and others on the development and implementation of research and research-related activities. They specifically focus on reviewing research proposals and related materials intended to address health priorities relevant to state citizens through clinical, translational, and community-based research.

5. National organizations

A national patient advocacy organization: It is the pre-eminent national diabetes stakeholder organization leading the fight against the deadly consequences of diabetes and supporting all those affected by diabetes. They fund diabetes related research, deliver services to hundreds of communities, provide credible diabetes information, and give a voice to persons with diabetes.

A national diabetes education program: Founded in 1997, is a partnership of federal health agencies and more than 200 public and private organizations. One of its goals is to reduce the burden of diabetes by facilitating the adoption of proven approaches to prevent or delay complications and to facilitate the incorporation of evidenced-based research findings into health care practices. The chair of this program will chair the Key Stakeholders Group.

6. Manufacturers of Glucose Meters

a) First is the creator of the world's first cellular-enabled glucose meter, with embedded cellular technology; It leads the glucose meter market in innovative product design. The meter is an FDA-regulated class II medical device that pairs with a back-end clinical server.

Second is the maker of a wide range of blood glucose monitoring products to both hospitals and patients, their integrated systems help healthcare professionals and patients better monitor and control blood glucose levels.

Completed and Planned Stakeholder Engagement Meetings

Two primary methods are planned for continuing our collaboration with these stakeholder groups. First, the two PIs and the Stakeholder Engagement Leader will attend regularly scheduled meetings of organizations on a pre-stipulated basis (twice yearly). Finally, we will hold Key Stakeholder Teleconferences with a small group of representative stakeholders (ten), with one in-person meeting in years 1 and 3 of the study. These primarily phone-based and web-ex supported meetings will begin with a three-hour kick off meeting, followed by 8 meetings in year 1, 4 in year 2, and 8 in year 3. In year 3 there will also be a three-hour in-person meeting for close-out and review of the results. Budgeting for these meetings and teleconferences is outlined in the resources sharing section of our Dissemination and Implementation section. In the following, we describe our current contacts to date with each of the stakeholder groups described above and the plans for continued contact. This is followed by a table outlining the ways in which our collaborations thus far have improved the current application.

State council: In October of 2012, we began meeting with key members of the council. We also met with the full council board on November 2nd, 2012. The board was unanimously supportive of our proposal and provided useful feedback on our aims and outcomes. We plan to present to the entire council board annually and to include two of its representatives in our regular Key Stakeholder Teleconferences.

State Family Medicine Advisory Board: We met with the patient advisory board on September 24, 2012. We presented our study plans and sought feedback on our study design and outcome measures. The board invited us to return annually to provide updates. They are also open to providing feedback on the content and scope of the tailored patient messages that will accompany the glucometer feedback.

Local Medical School's Diabetes Center Patient Registry. In preparation for this grant application, we surveyed the non-insulin treated T2DM population in the registry to learn about current practices with regard to SMBG and outcomes important to patients. In terms of outcomes, over half felt it was important to test blood sugars. This was despite the fact that over two-thirds of respondents reported that providers 'never' or 'only sometimes' review test results with them. Patients also confirmed the research literature showing little consistency in recommendations regarding SMBG for patients with non-insulin treated T2DM. Thirty-nine patients were willing to be part of a stakeholder advisory group, of which we have secured the commitment of, a middle aged African-American female living with non-insulin treated T2DM, to participate in the Key Stakeholder Teleconferences.

Medical School Physician's Network. During a March 2012 meeting with the medical directors, providers, staff, and administrators were pleased to take part in the proposed pragmatic trial of SMBG in NIT DM patients. They validated our approach and the importance of the question addressed. A representative from the network, will take part in Key Stakeholder Teleconferences.

Local Community Advisory Board. We met with the CAB on September 28, 2012, engaging in group discussion of our planned research. We received valuable feedback on the project's goals, aims and outcomes. This group invited our team back to present to them twice yearly.

National patient advocacy group. Our research team has a longstanding relationship with the group. The executive director of a local chapter, will meet with our group as a key stakeholder monthly and provide a liaison to their stakeholders on a regional and national level as well as the potential role of the group and the non-profit sector dissemination of our findings at the state and national level. Furthermore, the representative had a prior role in leadership with the group and has substantial contact and access to the national organization.

National Diabetes Education Program. The chairman of this initiative is a co-investigator on this proposal, and our Research Leader for Stakeholder Engagement. He will Chair Key Stakeholder meetings.

Manufacturer. The President and COO of the manufacturing company will attend key stakeholder meetings. He has over twenty years of experience in healthcare information technology and healthcare services. He has his finger on the pulse of the current state of the science in blood glucose monitoring and has a firm understanding of need to produce products that are patient-centered and support enhanced patient care.

Manufacturer. The CMO and world-wide Vice President of Clinical Affairs, an endocrinologist by training with a long-standing investigative career in academia before moving to the pharmaceutical and more recently the device industry and a person living with diabetes. He will provide input from all perspectives, but uniquely from the perspective of industry. That later perspective will be particularly important vis-à-vis dissemination.

Description of Planned Ongoing Engagement

The Key stakeholder meetings will occur beginning after a three hour kick off meeting, with 8 meetings in year 1, 4 meetings in year 2 and 8 meetings in year 3. Additionally, in year 3 there will be a three-hour in-person meeting for stakeholders for final review of results. Key Stakeholder Teleconferences will occur monthly for the first 6 months of the project and taper to quarterly till month 18 then monthly for the last 6 months of the project. Follow-ups with the other Stakeholder groups will occur twice yearly.

Input and Study Design Changes Resulting from Collaborative Work with Key Stakeholders

Stakeholders can be instrumental in formulating research questions; defining essential characteristics of study participants, comparators, and outcomes; monitoring study conduct and progress; and disseminating research results. Our stakeholder groups, the primary input they have provided thus far and how that input shaped our study design are listed in Table 4 below.

Table 1. Stakeholders and Their Input in the Study Design

Stakeholders	Input provided	How it shaped our design
State advisory council	• Consider patient health literacy • Policy subgroup would be useful to engage for this work	• Engaged the Center for Diabetes Translation and Research literacy core to join our team and assist with message tailoring • Tailoring algorithm that could be used in office
State family medicine board	• Emphasize quality of life questions (e.g., Can I feel better or improve my ADLs?)	• Added quality of life to outcomes
Local advisory board	• Important outcomes: Quality of life, hypoglycemia, health care service use, and patient empowerment. • CMEs for providers important • Query patient/provider community care	• Hypoglycemia added as an outcome • CME added for providers • Added survey questions about patient-provider communication

Table 1. Stakeholders and Their Input in the Study Design		
Stakeholders	**Input provided**	**How it shaped our design**
Registry	• A1C is important in addition to Quality of Life. • Patients willing to be randomized to no SMBG or daily SMBG.	• A1C designated as a primary outcome • Overall recruitment plan feasibility confirmed
Medical school directors	• Testing is quite variable in real world clinical settings	• Designed three-armed plan to address this reality and better respond to pragmatic patient issues.

Barriers Assessment

We expect our continuing collaborations with these stakeholder groups to be especially valuable for identifying and addressing barriers to implementation of study results and incorporation into practice. For example, there are currently numerous approaches to blood glucose monitoring in NIT DM and making sure our implementation is feasible in real life as well as the results credible regardless of which way the findings direct care. As our Stakeholder Engagement leader and investigator, the leader will guide our key stakeholder meetings to make sure we are addressing barriers throughout the project so results are credible and easily disseminated by stakeholder groups. For example, we will work to make the intervention efficient and feasible in practice based on stakeholder feedback. We will also have focus groups of providers and patients to explore how the intervention went and feasibility issues.

Engagement Plan B: Sustainable Methods, Algorithms, and Research Tools for Delivering Optimal Care Study (SMART DOCS)

Identification of Key Stakeholders

The team will include authentic, feasible, sustainable, novel partnerships with patients, patient support groups, providers, and other appropriate stakeholders. We will involve multiple stakeholders, comprised of patients, providers from various disciplines and diverse practice settings, professional organizations, and medical device and pharmaceutical manufacturers/suppliers, to help refine the management methods, tools, and algorithms in this project. We will plan frequent meetings and encourage active participation from the stakeholders toward three primary goals: (1) review and provide feedback on the patient-centered outcomes and coordinated-care management (PCCM) approach during the progress of the study; (2) determine the best structure and communication pathways to ensure success and sustainability of this multi-stakeholder involvement model; and (3) establish plans to expand and export the PCCM approach to other medical disciplines and practice settings.

The following 20 consultants will be contributing to the study as members of the Stakeholder Team; the asterisks (*) indicate if they are members of more than one of the categories listed below. The stakeholder team has reviewed their expected goals, and this team is comprised of the following representatives *(Section 2.10 - Letters of Support):*

Patients and Patient Support Groups. Three patients from our current patient population and representatives from a local patient support group and national patient advocacy groups will actively participate. These patient representatives are important in ensuring that the patient always has access to his/her data and control of care with our approach.

Providers from Various Disciplines. Provider representatives from other disciplines including pulmonary, critical care, sleep medicine, endocrinology, and internal medicine will participate 8 since it is critical to ensure the successful repurposing of these approaches to other areas of medicine.

Providers from Diverse Practice Settings. We will engage multiple physician representatives from academic institutions (multiple individuals named)

Professional Organizations. The leadership from professional organizations relevant to sleep medicine will participate in this project, including the current president of a sleep medicine organization, two former presidents of another sleep medicine organization, one of whom is also chair of a sleep medicine task force, and a past president of a sleep research group.

Industry - Medical Device and Pharmaceutical Manufacturers/Suppliers. The leadership from medical manufacturers of diagnostic/therapeutic devices, a durable medical equipment company, and pharmaceutical products will be important stakeholders in this project.

In order to have a sustainable impact on an entire discipline of medicine, we believe it is critical to have involvement of stakeholders who can have a broad influence on practitioners of the field and patient populations. The proposed stakeholder team includes the leaders of our field's major medical and research professional organizations that also establish national standards of clinical and research practice, and management representatives from medical device and pharmaceutical manufacturers/suppliers. In discussions with these stakeholder representatives, whom had involvement in the preparation of this application, we recognize that all the missions and needs of these specific stakeholders may not necessarily align, but we believe there is consensus on the need to revise the outpatient medical care experience of patients to one that incorporates patient-centered care to a higher degree. Lastly, sleep medicine is a multidisciplinary specialty and this diversity is reflected in our team; a key goal of this study is to enable the approach to be expanded to other medical disciplines and the broader health care community by discussions and publication of this approach through conferences and journals focused on the aforementioned specialties.

Description of Engagement Frequency

The stakeholders will be engaged from the date of the notice of the award. There will be initial meetings on a weekly basis for the first 2 months, and every 2 weeks thereafter. The meetings will be held at a university, and the engagement of the stakeholders will be prioritized based on the need for their particular expertise during specific periods of the study *(Table 1).* The meetings will last at least 3 hours and will be scheduled at dates/times to allow the most participation from the stakeholders, and stakeholders far from the meeting site will be able to call into the meeting. Meeting materials will be displayed through a secure Adobe Connect website. The stakeholder team will be chaired by the director of a sleep research alliance, which is comprised of key sleep researchers at four universities. He has also served as president of the two main academic sleep organizations.. In all of these roles, he has many years of experience in stakeholder engagement, and this experience, combined with his background, and extensive clinical research knowledge will enable him to provide his leadership and management expertise in chairing the Stakeholder Team. He will be assisted by an individual, who has worked with him for close to a decade and has experience coordinating various industry and NIH-supported trials. She will assist him in scheduling the stakeholder team conference calls and meetings, developing the call or meeting agendas and minutes, and ensuring that the objectives of the team's participation are met.

Table 1. Stakeholder Engagement Prioritization by Study Stage

	Patient/Patient Support Groups	Providers (Various Disciplines)	Providers (Diverse Practice Settings)	Professional Organizations	Industry
Stage 1 (4/5/13-8/31/13)	X	X	X	X	X
Stage 2 (9/1/13-10/31/15)	X	X	X	O	O
Stage 3 (11/1/15-4/30/16)	X	X	X	X	O

X = high priority, O = optional

Description of Engagement Type

The stakeholders will be engaged throughout the entire study period, but their contributions to the group will be prioritized *(Table 1)* based on the timeline of the study *(Project Plan and Timeline Section).*

Stage 1: During this period of organization, training, and study initiation, the stakeholders will be requested to provide review and provide feedback on the PCCM approach. Additionally, the stakeholders will be requested to comment on the structure, frequency, and communication pathways of our multi-stakeholder engagement model to ensure success and sustainability of this model during the study.

Stage 2: This period is the conduct of the clinical trial with patient participation and evaluation. During this period, input from the patient and patient support groups and the providers from various disciplines and diverse practice settings are most critical.

Stage 3: This period consists of data analysis, study expansion, and dissemination of results, and the input from the stakeholders is important for discussions and planning of the sustainability of the model and the expansion and exportation of the PCCM approach to other medical disciplines and practice settings.

Stakeholders will be emailed the agenda for the meeting (and minutes from the prior meetings) at least one week in advance of the meeting so that they will be informed of the topics to be discussed. The agenda will highlight the key questions to be asked the stakeholders and it is expected that, based on the above stages, the input from the stakeholders belonging to the groups (i.e., patients/patient support groups, providers from various disciplines, providers from diverse practice settings, professional organizations, and industry) will be more relevant during certain stages of the project. For example, input from providers from various disciplines/practice settings and representatives from professional organizations will be especially important in Stage 3, when

exportation of the PCCM approach to other medical disciplines and practice settings and dissemination of results are critical. With this in mind, if the stakeholders who belong to one or more of the groups listed above are unable to participate at a given meeting, the PI and our core team will ensure that their feedback is solicited before the meeting so that it can be discussed at the meeting. Efforts will be made to ensure that topics relevant especially to certain stakeholders will also be scheduled at specific times during the agenda, so that these stakeholders can be present or call in at those times to maximize efficient use of their participation. We are especially sensitive to a potential concern of the patient voice not being heard in meetings of the stakeholder team, so the PI and our leadership team will ensure that the patients and patient support group representatives, who comprise 30% (6 of 20 members) of the team will have ample opportunity and priority in voicing their opinions and suggestions.

Barriers Assessment

The facilitators to dissemination and implementation of study results and their incorporation into practice are the stakeholders themselves who are influential leaders who can assist in these goals. In particular, we will be relying on the leadership of the professional organizations and patient support groups within the stakeholder team who can help disseminate the results of this study within their respective fields. Members of the core team and stakeholder team also participate in other alliances and networks: these networks can also assist in the translating the study results into practice. The primary barriers and solutions to dissemination and incorporation of the study results into practice are the following:

Communication. This is critical, particularly with respect to the disseminating information early in the decision-making process of the study, so that all stakeholders are provided with data and information that are both meaningful and accessible. As part of our AHRQ-supported Comparative Outcomes Management with Electronic Data Technology (COMET) Study, we have developed and implemented an electronic informatics infrastructure through the Microsoft SharePoint platform that allows permissioned access to data and information relevant to a given participant or stakeholder.

Trust. In any engagement model, this is always a concern. We believe that devoting adequate time for discussion and scheduling frequent meetings at the start of the study will help to establish trust; it is important that the stakeholders understand and respect the perspectives of the other participants and why they are brought together so that there is mutual understanding.

Concerns and Grievances. It is important that the stakeholders feel that they can have a free and open exchange of ideas, including expressing concerns and grievances. The key personnel of the study have many years of experience in managing large-scale multicenter studies, so they recognize the importance of soliciting, identifying, and addressing concerns and grievances of everyone participating in the study.

Feedback and Reporting. The stakeholders need to have a process by which their feedback is captured and recorded. The study leadership will ensure that stakeholder feedback is accurately recorded and stored, and will be accessible to the stakeholders and the rest of the team through the electronic informatics infrastructure developed through the AHRQ-supported COMET Study.

Engagement Plan C: Peer-Driven Intervention as an Alternative Model of Care Delivery and Coordination for Sleep Apnea

5. DEMONSTRATE THE COMMITMENT TO PATIENT AND STAKEHOLDER ENGAGEMENT (*CRITERION 5*): Identification of stakeholders: Over the past many years, input from all key stakeholders (**8 Ps**; see figure 4 below) has gone into the development of this proposal. By placing experienced patients – "peer-buddies" – with sleep apnea at the focal point of our intervention, and by embedding them in the research team, we have made our proposal highly patient-centric and have raised the level of engagement with the patient stakeholder at many levels. Our previous nation-wide cross-sectional survey, now published manual pilot study, and the new IVR-based pilot studies and focus groups helped us identify the key stakeholders; the research questions; comparators and patient-centric outcomes; and will continue to identify both potential current and anticipated barriers to the conduct, dissemination, and implementation of our study findings (see section 2(c) & 2(d)5).

1. Patients: Peer-buddies and current patients (excluding active subjects) will serve as members of the biannual stakeholder committee. All peer-buddies in the study will be invited to serve on the stakeholder meetings to provide input on new obstacles that they identify during the course of the study. Such an open invitation will serve as a "***continuous improvement process***" that will continually update the content of PDI-IVR interactions. **2. Providers:** Involvement of community sleep physician, behavioral therapist, primary care physicians, clinical psychologist, nurses, durable medical equipment (DME; homecare) company, sleep technician, and respiratory therapists. We will engage only those providers who are caring for patients in the intervention group in the stakeholder meetings to prevent cross-contamination. **3. Purchaser:** An area medical center. **4. Public:** Executive Director of a national patient advocacy group who has worked with PI on educational efforts in the past. **5. Payer:** The Chief Medical Officer of an area health plan. **6. Product maker:** Director of Clinical Research for a leading CPAP device manufacturer with whom the PI has conducted pre-FDA trials of CPAP devices (6 years). He provided input regarding industry server related issues for monitoring adherence. **7. Policymaker:** The president of a premier professional sleep organization that develops practice guidelines and sleep-center accreditation standards, has provided letter of support indicating that they will send a representative to the biannual stakeholder meetings. The PI served as Chair of a research committee for this organization for the past 3 years and the co-investigator is a past president of the organization and have served on taskforces and guidelines[85-88]. **8. Principal Investigators:** The PI and

other researchers have all served as PIs in funded research studies that involved health services and education research with impact on health policies[66,67,89,90].

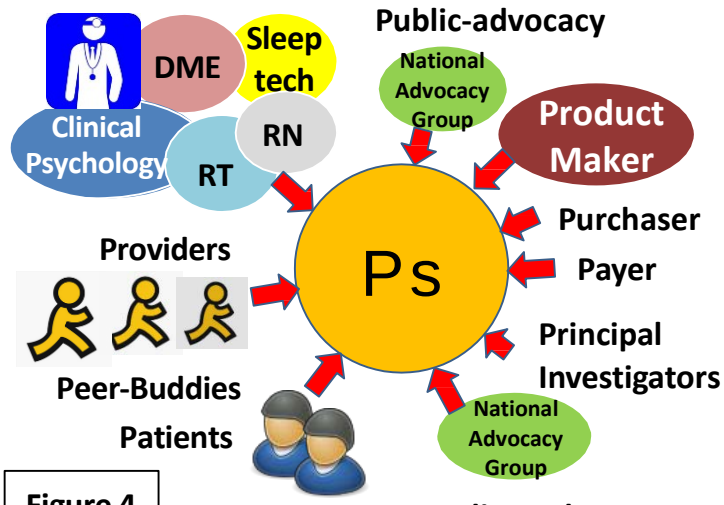

Figure 4

Additionally, one of them is a researcher with expertise in community outreach programs for preventative efforts and experience in cultivating *Promotores* (Latino community health promoters) and another has similar experience in outreach in Native American and other minorities will engage the Native American community through a well-established community-based network. The previously engaged stakeholders have recently contributed with greater specificity to the pilot studies and the current proposal.

Between meetings, at any given point in time, all stakeholders will be encouraged to be able to communicate with PI and research staff with any additional suggestions or concerns. **BARRIERS ASSESSMENT:** The table below provides information regarding the individual stakeholder and important barriers that they have already assessed with practical solutions for overcoming such barriers

Table 4: Barrier assessment and facilitation.

Patient	Identify new barriers to care delivery (e.g., reduction in mask and other supplies due to cut- backs in home care company reimbursements), and identify solutions with other stakeholders as part of ***continuous improvement process***. Patients will improve the availability of peer-buddies and help with dissemination and implementation by training to serve as peer-buddies upon completion of their participation. Identify new needs that may arise from establishment of state insurance exchanges. Assess option of IVR for measurement of outcomes obviating return visits
Public-advocacy group	National advocacy group representative will identify issues with recruitment and training of experienced peer-buddies through the A.W.A.K.E network group. Facilitate identification of experienced peer- buddies and even train them using the peer-buddy training manual and disseminate such information through their **200 plus A.W.A.K.E Network groups[84].**

Providers	(a) Issues pertaining to reimbursement for time spent in providing education, inability or difficulty in retrieving CPAP adherence information, lack of coordination of care, lack of efficient triage of patient phone calls, existent volume of patient panel and number of calls per day. Overcome such barriers by identifying mechanisms for reimbursement of peer-buddy time in the real world, improving IVR-based triage of patient calls to improve efficiency. (b) Competitive bidding in the DME (home care) company market and potential further reduction in time that a DME provider can spend with the patient. This barrier could be overcome by the PDI-IVR system by significant reduction in DME time spent in educating patients or retrieving CPAP adherence information. (c) DME provider can identify and solicit adherent patients to consider participation as peer-buddies thereby addressing the potential barrier of insufficient number of well-trained peer-buddies.
Purchaser	Identify and understand the (a) barriers in running and maintaining a secure HIPAA compliant IVR-system (b) solutions for future program development and maintenance costs as pertaining to IVR-system and reimbursement and training for peer-buddies in other chronic disease conditions. (c) Assess barriers for scale-up and for exporting to other chronic disease conditions. (d) Realize how offset by gains in provider efficiency, patient satisfaction, and patient outcomes.
Payer	(a) Identification of barriers to dissemination and implementation due to concerns regarding privacy and patient confidentiality. Surmounting such a barrier through the IVR system that is HIPAA compliant and behind a secure firewall without the need for exchange of telephone numbers and other personal information between the peer-buddy and the patient. (b) Another barrier may be the payment of peer-buddies' nominal fee. Utilization of a CPT code for phone-based care rendered by a non-MD may be a feasible option but will require coordination and acceptance across all payers and policymakers.
Product maker	Identification of barriers in disseminating and implementing the PDI-IVR model if multiple provider IVR servers attempt to log-on to and overwhelm the industry server that communicates with patients' CPAP devices. A potential solution would be to allow the provider's IVR server to directly communicate with the CPAP device and remove the industry server as an intermediary. This may require sale of server (SQL) software to providers.
Policymaker	A potential barrier is the incorporation of the PDI-IVR in to current practice as a feasible model of care delivery under the current regulatory and economic constraints. Will perform a critical review through various committees and advocate for incorporation into practice by setting guidelines and standards for accreditation of sleep centers.

Principal Investigators	Potential barrier of lack of sufficient time for training peer buddies. Potential solution to have the peer-buddies and A.W.A.K.E network representatives train the peer-buddies with providers responsible for only the mock sessions that are performed to assess competency of the peer- buddy trainees before they are assigned to CPAP naïve patients.

Engagement Plan D: Caring for the Whole Person: A Patient-Centered Assessment of Integrated Care Models in Vulnerable Populations

G. Research Engagement Plan. This research project features an engagement plan that will guarantee that patient and stakeholder involvement is not just token participation, but rather that stakeholders and patients in particular have a formative and meaningful role at most points of the study design. The research team includes three sets of stakeholders. The *Patient Advisory Panel* features 12 patients from different backgrounds who have both a mental health and physical health diagnosis. The *Research Support Team* is made up of clinic staff, and staff at community-based organizations who work with integrated clinics. They are separate from the Patient Advisory Panel because research has shown that patients do not always participate to the full extent when they are on teams that also include health care professionals (74, 75). The *Investigator Team* is made up of investigators, the learning systems manager, and the project manager. Our engagement plan is robust and complete. Highlights are presented here; the full plan is available in Appendix 2.

Participant Compensation. All research team participants will be compensated for their time. Patient Advisory Panel members and Research Support Team members will receive ***equal*** incentives: an honorarium, a travel stipend, and a childcare stipend. Meetings will be held at times that allow for maximum participation.

Training. Both the Patient Advisory Panel and the Research Support Team will have the opportunity to create a training curriculum in partnership with the Learning Systems Manager to ensure that they have adequate training for participation in research.

The Authority to Make Decisions. This research project features an engagement plan that will guarantee that patient and stakeholder involvement is not just token participation, but rather that stakeholders and patients in particular have a formative and meaningful role at most points of the study design. A cornerstone of our engagement plan is decision-making power. In some engagement plans, patients are consulted but are not given the authority to make decisions about the study. Not so in our project: <u>All stakeholder teams—the Patient Advisory Panel, the Research Support Team, and the Investigator Team— have authority and accountability for different aspects of the project.</u>

Team Meetings. All meetings will be facilitated by CORE's Learning Systems Manager, who is experienced in community engagement, working with low-income and vulnerable populations,

facilitation, group dynamics, and adult learning theory. Stakeholders will participate in a shared project kickoff. They will meet quarterly to complete tasks as outlined in Exhibit 10, below.

Learning Collaboratives. Most research input will be provided separately by each of the three stakeholder teams, allowing peers to work closely with peers and then present to the other groups. However, our project will be bookended by two Learning Collaboratives. These 4-hour events will provide an opportunity for all members of the research team—patients, professional stakeholders, and investigators—to learn from one another, to develop project materials in partnership, and to celebrate success.

Shared Dissemination. All dissemination activities will be led by a group that includes at least one member of the Patient Advisory Panel, the Research Support Team, and the Investigator Team. This process will ensure that all three stakeholder groups have the opportunity to share learnings and successes from their own perspective, and that all three groups get credit for the finished project.

Exhibit 10. Roles and Responsibilities at Every Stage in Research

RESEARCH STAGE	ACCOUNTABLE	CONSULTED	GIVE FINAL APPROVAL
Topic Selection, Formulating Study Question	Investigator Team	Patient Advisory Panel	Patient Advisory Panel
Design of Recruitment and Consent Procedures	Investigator Team	Patient Advisory Panel	Research Support Team
Identifying Outcomes for Measurement	Patient Advisory Panel	Investigator Team Research Support Team	Patient Advisory Panel
Learning Collaborative Agenda Setting	Patient Advisory Panel	Research Support Team Investigator Team	Patient Advisory Panel
Data Collection	Investigator Team	Patient Advisory Panel Research Support Team	Investigator Team
Interpretation of Findings	Investigator Team	Patient Advisory Panel Research Support Team	Investigator Team
Dissemination Plan	Research Support Team	Investigator Team Patient Advisory Panel	Research Support Team
Final Dissemination	ALL PARTICIPATE IN DISSEMINATION		

Shared Roles in Research: A Case Study. Appendix 2 details the ways that our stakeholders will participate in the research project, but the design of the survey is a great example of how we involve patients in research. Patients will be trained in the use of validated measures in survey research. Using the Work-Out methodology and guided by the Learning Systems Manager, the Patient Advisory Council will develop and prioritize a list of constructs to be measured by the survey. The Investigator Team will research validated measures that might measure those constructs, and will create a draft survey. The Research Support Team will review the survey and offer input. The draft survey will go before the Patient Advisory Panel to assess suitability and response burden; the Patient Advisory Panel has the final stamp of approval before the survey goes before the IRB.

This process allows each stakeholder to enter the project at a period that makes the most use of his or her expertise. This study is expected to measure outcomes that matter to patients; therefore, patients will have the final say in terms of outcomes measured. However, it's easiest for the investigator team to acquire potential validated instruments to measure those outcomes; they have ready access to academic literature and have extensive survey design experience. The Research Support Team may be able to offer new perspectives on potential outcomes, and may have measures that they can recommend. This process of co-learning brings all stakeholders together—but in the end, the buck stops at the Patient Advisory Panel.

With this research team and these assets in this particular policy environment, we are confident that we can engage meaningfully with patients and other stakeholders, meet the established project milestones, generate key findings about which integration models make the difference for which particular patients, and efficiently share that knowledge with the patients who need to make decisions about where to receive primary care.

Appendix 2. Patient Engagement Plan

Here we give our Patient Engagement Plan in additional detail. Our Engagement Plan is founded on the principle of *meaningful* participation. Patient and stakeholder partners are involved at every step of the research project—including analysis and dissemination—and the compensation for these partners is on par with that of the CORE research team.

Research Team Governance and Structure.

The research team has three arms:

***CORE Investigator Team*.** This team is made up of CORE and local medical university investigators, project management staff, analysts, and research assistants. They are responsible for administering the grant, for ensuring that all project deliverables are complete, and for conducting the data collection and leading the analysis.

Patient Advisory Panel. These 12 patients were invited to participate in CORE's Patient Advisory Panel in August 2013, when they held a meeting to discuss ways that health care reform could improve their experience of care. The findings at that meeting informed the selection of the research topic and question. The Patient Advisory Panel will be responsible for selecting the outcomes for measurement and setting the agenda for Learning Collaboratives.

Research Support Team. This team will consist of staff members from each of our partner clinics as well as staff from community-based organizations that partner closely with the clinic. They are responsible for refining the recruitment plan and for creating the dissemination plan.

Each of the three teams has a role in *creating* products for the project, in *reviewing* products, and in *signing off on* products. Many engagement plans offer opportunities for patients and other stakeholders to provide advice, guidance, input, or consultation—but do not offer them decision-making power. Our study is different: as you can see below, patients have the final say in the study question, the outcomes assessed, survey design, and in agenda-setting. Other stakeholders have the final say in recruitment and dissemination. The investigator team has the final say in data collection and analysis.

RESEARCH STAGE	ACCOUNTABLE	CONSULTED	GIVE FINAL APPROVAL
Topic Selection, Formulating Study Question	Investigator Team	Patient Advisory Panel	Patient Advisory Panel
Design of Recruitment and Consent Procedures	Investigator Team	Patient Advisory Panel	Research Support Team

RESEARCH STAGE	ACCOUNTABLE	CONSULTED	GIVE FINAL APPROVAL
Identifying Outcomes for Measurement	Patient Advisory Panel	Investigator Team Research Support Team	Patient Advisory Panel
Learning Collaborative Agenda Setting	Patient Advisory Panel	Research Support Team Investigator Team	Patient Advisory Panel
Data Collection	Investigator Team	Patient Advisory Panel Research Support Team	Investigator Team
Interpretation of Findings	Investigator Team	Patient Advisory Panel Research Support Team	Investigator Team
Dissemination Plan	Research Support Team	Investigator Team Patient Advisory Panel	Research Support Team
Final Dissemination	ALL PARTICIPATE IN DISSEMINATION		

Recruitment and Selection of Patients and Stakeholders

Patient Advisory Panel. The 12 members of the Patient Advisory Panel were recruited back in August of 2013. CORE recognized the need for a Patient Advisory Panel because our research consistently focused on low-income adults in the state, and our research team recognized that the experiences of the individuals that we study may be very different from our own. We are following a large panel of low-income adults in another study; we used that study database to randomly select 40 participants for recruitment. These individuals had explicitly indicated on prior surveys that they would be interested in participating in further research; they had also indicated that they had multiple chronic health conditions. Recruiters were given participants' names, contact information, DOB, race/ethnicity, and diagnoses; this information had been collected during previous surveys. Recruiters began calling using the random order generated during sampling, but as they went they tried to fill different categories. We wanted a Patient Advisory Panel that was made up of half men and half women. We wanted all age groups to be represented, and we wanted the panel to be ethnically diverse. We also wanted a range of health conditions to be represented, from chronic disease to mental disorders to substance abuse.

16 patients agreed to participate in the first Advisory Panel meeting; 12 of those showed up. We held separate meetings for men and women because past experience had shown that mixed-gender focus groups can have a censoring effect; we do plan to link these two halves in the Patient Advisory Panel in the future.

Why are the Patient Advisors names not included? Because our patient advisors are participants in other studies, and because we were not sure how we were going to use the information we gathered at the August 2013 Patient Advisory Panel, we recorded the sessions and asked participants to sign informed consents. During the consenting process, we informed them that their names would not be associated with any of the reports that came out of that panel session. In order to protect confidentiality, we are not sharing patient names. However, at the February 2013 Panel, we will seek permission to use patient names.

Research Support Team. The research support team will be comprised of 12-20 professional staff who work at or with our partner clinics. The team will be made up of administrators, clinicians, nurses, and support staff such as outreach workers and case managers. Research Support Team staff will be nominated by the executives at the partner clinics. Many of these clinics are waiting until the award is granted to nominate staff for the Research Support Team; however, we do have four stakeholders eager to participate:

- The Executive Director of a behavioral healthcare center
- The Director of Quality for a medical center
- The Chief Operations Officer, for a community health center
- A Clinical Psychologist

MEETINGS. The three teams will convene as a single group three times: once at project kickoff, and twice at Learning Collaboratives—intensive half-day sessions designed to advance co-learning. Otherwise, they will engage in separate meetings designed to enhance communication among peers. While we would like our patient partners to participate at all study meetings, previous research suggests that many patients do not feel equal partners when they are outnumbered by industry professionals, and may censor themselves. For that reason, we give them facilitated opportunities to work with other study staff, we invite them to ALL project meetings, and we give them structured opportunities to meet amongst themselves.

The Investigator Team will meet every other week and more often as needed. Meetings will be held at CORE and will usually last one hour. Minutes will be kept and shared with the other study teams.

The Patient Advisory Panel will meet quarterly at CORE. Meetings will be facilitated by the CORE Learning Systems Manager, who has extensive experience in facilitation, intercultural communication, group dynamics, experiential education, and adult learning theory. Minutes will be shared with other teams.

The Research Support Team will meet quarterly at CORE. Meetings will be facilitated by the Learning Systems Manager. Minutes will be kept and shared with other study teams.

TRAINING. At the project kickoff meeting, the Learning Systems Manager will review the steps involved in the research study, the expectations for participation on the research team, the methods of compensation, and the responsibilities of each of the research team arms. She will then facilitate a discussion regarding training needs and opportunities. Each of the study's research teams may have training needs or requests, and we want to be sure that patients and other stakeholders have adequate training to ensure that they can participate fully in the project. The Learning Systems Manager will develop a training curriculum in response to this first meeting.

PATIENTS AND STAKEHOLDERS ARE INVOLVED AT EVERY STEP OF THE RESEARCH PROJECT.

The following table specifies how patients and stakeholders are involved at every stage.

STAGE	PATIENTS	PROFESSIONAL STAKEHOLDERS
Topic Selection, Selection of Research Question	The topic emerged from patients. We asked them to tell us what matters when it comes to health care systems.	We refined our research question in partnership with executive-level leaders at safety-net clinics.
Study Design	Draft design will be presented at the study kickoff meeting. Patients will have the opportunity to give feedback and reshape the study design	Stakeholders will develop the recruitment protocol, since their patients make up the study population.
Outcomes Selection	Patients will identify and prioritize the outcomes to be measured in the study.	Stakeholders will review the outcomes selected by the patients and will brainstorm potential indicators to measure those outcomes.
Survey Design	The investigator team will present patients with a draft survey. The patients have final say in survey design.	Stakeholders will suggest indicators for the survey. They will also be able to provide input and feedback on the draft.
Qualitative Interview Design	Patients will be presented with the drafts of the first baseline survey, and will brainstorm and prioritize questions for the qualitative interview	Stakeholders will be presented with the drafts of the first baseline survey, and will brainstorm and prioritize questions for the qualitative interview
Agenda Setting	Patients set the agenda for the Learning Collaborative	Stakeholders can review the agenda and suggest additions or revisions
Qualitative Analysis	Patients will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.	Stakeholders will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.

STAGE	PATIENTS	PROFESSIONAL STAKEHOLDERS
Dissemination	Patients will lead dissemination at the Oregon CCO Learning Collaborative and the Community Advisory Councils. They will collaborate in writing and designing presentations.	Stakeholders will lead dissemination at the Oregon Legislature and at professional conferences. They will also collaborate in writing and designing presentations.

COMPENSATION. Members of the Patient Advisory Panel and the Research Support Team will be compensated equally. They will receive annual honorariums of $500, and they will also receive stipends of up to $500 annually to cover indirect costs, such as transportation and childcare.

LEARNING COLLABORATIVES. One of our explicit aims is to create a Learning Collaborative around integration—a network of patients and professionals who care about BHI. The Learning Collaborative will begin with the research team taking two separate half-day retreats to work together on this research study. The Learning Collaborative agenda will be set by patient advisors and facilitated by the Learning Systems Manager. It will include training, joint problem-solving, co-learning activities, and dissemination. After the project has concluded, we will share our findings with our extended community. Our Research Support Team has an extensive network of providers and health care leaders who are eager for results, but our patient advisors and our stakeholders at community-based organizations are equally eager to find out how they can use the information to advocate for better care.

Engagement Plan E: A Comparison of Treatment Methods for Patients Following Total Knee Replacement

KEY STAKEHOLDERS - This study involves several groups or stakeholders who are deeply engaged:

- **Patients:** Patients post TKR want evidence-based treatment options that may allow them to stay active, employed and independent. Patients have been involved from conceptualization to design of this study and will be closely engaged during the implementation and dissemination;
- **Providers:** The burden of uncertainty about the best treatments for patients post-TKR is felt at the level of the health care providers. This study involves several providers including physicians (orthopedic surgeons and physiatrist), physician assistant, physical therapists, and chiropractor who manage the care of older adults post-TKR;
- **Community Organizations:** The study is relevant to community organizations that serve as public advocates for older adults- - that offer group-based exercise programs to older adults. This also includes the the largest national nonprofit organization committed to improve function in arthritis;

- **Payers and Policy Makers:** Results of this study may prove pivotal in changing reimbursement for services after TKR. Third-party payers such as Medicare and private health insurance companies need evidence on the effectiveness of exercise at later stages post TKR as they bear the costs of escalating rates of TKR with suboptimal outcomes. Some health plans cover later stage rehab or group exercise while others do not;
- **Research Team:** The investigative team is deeply vested to provide the higher possible quality of evidence to guide the selection of exercise to improve function and physical activity of patients who undergo TKR.

Engagement Type and Frequency- We have assembled an Advisory Panel comprised of several stakeholders, each with different perspectives and areas of interest. Please see their letters of support that highlight their commitment. The membership of the Advisory Panel along with the dynamics for patient participation is in Table 3. We will meet semi- annually in person or via phone conference throughout the entire 3-year research timeframe. The PI has the infrastructure for hosting teleconferences with no expense to the callers. If needed, in addition to the meetings with all stakeholders, we will meet in smaller groups for more specific discussion of topics of interest. The PI has experience on conducting these meetings and will oversee the panel discussions, conducting them in a manner to allow all voices to be heard.

Table 3: Members of Stakeholder Advisory Panel (See Letters of Support)

Member	Type of Stakeholder	Title	Organization
	Three Patients	Research Participants	Community
	One Provider	Physician Assistant	a Bone and Joint Center
	One Provider	Physical Therapist	A Physical Therapy Practice
	Three Providers	Physicians- Orthopedic Surgeons*	a Bone and Joint Center an Orthopedic Surgery center
	One Provider	Physiatrist	a Rehab Medicine center
	Community organization rep	Executive Director	a Community Center
	Community organization rep	Asst. Executive Director	a community center
	Two Advocate organization reps	Chief Mission Officer Chair Board of Directors	a local chapter of a national advocacy organization
TBD	Payer	medical center representative	A medical center
Investigative Team	Clinical Researchers	PI, Co-Is and Research Coordinators	a university

Member	Type of Stakeholder	Title	Organization
* Several surgeon-members have agreed to participate in this advisory panel. This strategy will reduce burden and maximize the probability to have a realistic participation in this category of stakeholders.			

Members of the Advisory Panel have been and will continue to be engaged to provide input into the preparation, execution, and translation phases of the study as described below:

1) **PREPARATION PHASE:** Our research question and study design were heavily influenced by stakeholders' input.

Patients were involved through informal communication during research participation, structured interviews, and meetings to discuss study design. They have directly influenced the selection of comparators, outcomes, and study design as outlined in **Table 4.**

Table 4- Changes in Study Design Guided by Patients and Clinicians' Involvement

Prior to Input	After Input	Rational for Change
Two study arms: Outpatient Exercise vs. Usual Care	Three study arms: We included the Community- based Group Exercise	Patients and providers indicated that clinic-based physical therapy was expensive and that they experienced difficulty getting convenient appointments. They defended that community-based exercise benefit the patients and should be compared with outpatient exercise.
Patients in the Usual Care arm were not wait-listed for exercise	Patients in the Usual Care arm are wait-listed for exercise	Patients voiced that they would be less likely to participate in the trial if they would not receive some clear benefit from it. Being able to receive exercise upon completion of the 6-month control period was considered by the patients a good alternative to equalize the potential benefits from study participation.
Physical function was the main outcome of interest	Physical activity is included as a key outcome and will be measured at light and moderate intensities in free- living condition	Patients have invariably complained about the way that their knees impacted their daily routines. In addition, patients who participated in a prior study stated repeatedly that they believed that intense exercise at later stage post TKR helped them to be more active and that it is an important outcome of any successful treatment.
Few measures of physical performance	Several measures of physical performance, including the novel	Patients have expressed significant limitations in activities such as going up and down stairs, walking long distances, walking fast, balancing on one leg, and

Prior to Input	After Input	Rational for Change
	measure of patients' ability to seat and stand from the floor	standing up from a chair. We will assess the performance of the patients in all of these activities. In addition, they unanimously suggested that we test their ability to get up from the floor since they have substantial difficulty with it.
No measure of harm	Measures of harm including fall risk	Patients and providers were concerned about the risk of falling and possible harm of more intensive exercises.

Providers provided input during study development and helped to shape the usual medical care arm. They provided key input to the individualized outpatient rehabilitative exercise arm. All providers supported the need to test the effectiveness of exercise at later stages after TKR and the inclusion of a community-based exercise group.

The community groups provided input about the community-based group exercise that will take place at the community centers. They have been engaged with the development of the research design by allowing the PI to observe their group exercise classes for older adults, and to meet with the fitness instructors who teach these classes and older adult members of their organizations. The senior fitness instructors at these centers collaborated to develop pragmatic exercise protocols.

2) EXECUTION PHASE:

Patients will edit recruitment materials and do a trial-run of study procedures to ensure that the paperless system of data collection is age-appropriate and that the research personnel are well trained. They will also help to spread the word about our study through their social media contact lists. Patients will be instrumental in providing peer-information about the study for potential participants who would like to discuss study participation with someone who has been part of research studies. Patients will also form a team of Patient Partners who will interview subjects who have participated in the intervention arms of the study to collect information on their experiences and suggestions (for details see Introduction to Revised Application). The information collected during the interviews will be key to shaping the delivery of interventions to improve the care and outcomes of patients who undergo TKR. Along with other lay members of the Advisory Panel they will also give feedback on any potentially counterintuitive results.

Providers, along with patients, will be asked to provide input to maximize recruitment and retention, and will help to interpret research findings from the stakeholder category to which they belong. Three prominent orthopedic surgeons will be actively engaged with the direct referrals of patients who have had TKR.

The directors of the community centers, , will forward information about our study through their membership email lists, e-newsletters/print newsletters, bulletin boards, and allow us to place informational brochures in their facilities. They will also sponsor breakfast meetings where the PI will present information about the study. The community group representatives and payers will be asked to provide interpretation of the results from public health, community policy, and health plan perspectives.

3) TRANSLATION PHASE: We plan specific steps to aide in the dissemination of the research results.

Patients will be asked for their input on the development of lay summaries of the study results and will assist with the design and editing of informational booklets and pamphlets for patients who undergo TKR.

Providers will help to facilitate presentations to disseminate the research findings at national meetings and conferences with their respective professional associations.

The payers will assist with dissemination of the research results to their network providers and work with the PI to organize regional meetings where the findings can be presented to clinicians.

Community and advocate organizations will disseminate the research results through email newsletters to their members such as the community centers newsletter and a national patient advocacy organization's Magazine.

ASSESSING BARRIERS – The Advisory Panel will discuss the potential barriers to study execution/implementation and dissemination throughout the three year of the study. We will collectively develop a strategic dissemination and implementation plan that draws upon the strengths and resources of all our involved stakeholders. We recognize that the perspectives of the stakeholders are likely to differ widely, and at times will conflict. Conflicts generated during the Advisory Panel meetings will be ultimately resolved by the PI or a Co-Is outside of the Advisory Panel.

All stakeholders will be compensated for their collaboration (See Budget Justification). The investigative team- including consultants- will be compensated as study personnel. The directors of the community centers will receive substantial funding from this grant to cover the costs associated with engagement on the study. Patients and other stakeholders will be reimbursed to participate in all activities and meetings.

Engagement Plan F: Improving Care Coordination for Children with Disabilities Through an Accountable Care Organization

G. Research Engagement Plan (Criterion 5)

The idea of the proposed study originated through the PI and Co-PI's current research project studying ACOs as they develop in the private sector. Through this study, it became readily apparent that a critical concern among ACO leaders was how to successfully include children with disabilities in their ACO populations, a position that policy makers in at least two of the four states included in the study were actively promoting. To understand this issue further, we engaged in multiple conversations with local patient advocacy groups, state Medicaid administrators, managed care representatives and researchers. A state-based patient advocacy organization was already involved in monitoring and communicating concerns about the state policy change to mandated managed care for ABD children on behalf of the ABD community to Medicaid. They were extremely excited by our proposal idea and expressed interest in being involved. Thus, we have included two representatives from the group as co-investigators on our research team to lead our Patient Advisory Panel. In addition to engaging patients through the Patient Advisory panel, our study will formally include over 2,800 direct patient voices through focus groups, interviews and surveys of patients and caregivers of disabled children and 20 stakeholder voices through our key informant interviews with ACO leaders and providers.

Engagement of Patients and Stakeholders in Our Research Activities

Patient and stakeholder engagement is central to this grant proposal. Below we highlight several examples of how patients have already contributed to the research proposal and how we anticipate patient engagement in this research going forward. Table 2 provides summary of these activities.

Development of the research question and study design: Our early meetings with patient advocacy representatives and stakeholders were critical in identifying the importance, relevance and feasibility of our research idea. Initially, we were interested in comparing experiences and outcomes of ABD children in the pediatric ACO (i.e., PFK) compared with the other 4 children's hospitals in the state that were not part of an ACO. However, stakeholders cautioned that identifying the pediatric "non-ACOs" would be challenging due to the rapidly evolving adult ACO market, which often included children, in the state. In contrast, an arrangement with the state and managed care plans in a predefined region of the state made patient attribution to the ACO clear. Stakeholders suggested a more informative comparative analysis would evaluate how ABD children were affected before and after the policy change, thus leading to the refinement of our research questions and our proposed quasi experimental study design.

Proposal Development: Patients and stakeholder input was substantial in our proposal development. In addition to shaping our research questions and study design, they have provided perspective on important methodological issues we should consider in our research. For example, they helped us determine the appropriate sampling dimensions for the focus groups to achieve variability in perspectives while allowing for focused discussion. They have also raised an important issue of stratifying the ABD population by risk and severity in our analysis, to recognize the heterogeneity in care coordination needs among ABD children. Thus, our interview guides include questions to help identify the severity of disability and we will include indicators to control for risk and severity in our quantitative analysis. The terminology we use to describe disabilities and the ABD population provides another example of how patient engagement informed proposal development. Our patient co-investigators have reviewed and modified the drafts of our recruitment and interview guides (Appendix C) to ensure the language we use is consistent with terms preferred in the patient community.

Study Implementation: After funding is approved, patient engagement will occur on several levels. We will formally assemble our patient advisory panel. They will assist the research team in helping us pilot test our patient/caregiver focus group and interview guides and advise us on important questions that we did not include and help us refine or eliminate existing questions. We will then engage approximately 110 patients and caregivers through10 focus groups and 30 in-depth individual interviews. We will also reach out to caregivers of the estimated 8,080 ABD children in our sample to complete a caregiver survey on care coordination, with a goal of 2,750 responses. The Patient Advisory Panel will help us assess our recruitment efforts, assist us in interpreting preliminary and final results after data collection, and monitor project goals.

	Patients			**Stakeholders**
	Patients	**Caregivers**	**Patient Advocates**	**ACO leaders, providers, care coordinators, policy makers, payors, researchers**
Study Conception & Research Design				✓
Proposal Development			✓	✓
Data Collection				
Development of Focus Group/Interview Guides*	✓	✓	✓	
Focus Groups /Interviews	✓	✓		✓
Caregiver Surveys		✓		
Data Analysis and Interpretation				
Focus Group/Interview Data*	✓	✓	✓	

Survey Results*	✓	✓	✓	
Claim/EMR Data Results*	✓	✓	✓	
Triangulation of Qualitative and Quantitative Analysis *	✓	✓	✓	
Dissemination of Results*	✓	✓	✓	✓

Dissemination: The Patient Advisory Panel will assist us in developing our final dissemination plan. The Patient Advisory Panel will be involved in reviewing our final reports and the case study white paper. They will be invited to review manuscripts for academic journals as well. We will present our study results at an annual state based advocacy group conference, with specific emphasis on the role of patient and stakeholder engagement in the research. If invited by patients and stakeholders, we would welcome opportunities to present our findings to patient advocacy organizations or local conferences.