



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Funded Projects: Sample Engagement Plans

October 31, 2013



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. To ensure privacy, the names of patient and stakeholder partners have been removed. However, we are committed to celebrating the great work of PCORI patient and stakeholder partners and look forward to publicly featuring that work in other ways.

These engagement plans are provided solely as examples for educational purposes, 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
October 31, 2013

Engagement Plan A: *Advance Planning for Home Services for Seniors*

OVERVIEW

The overwhelming strength of this grant proposal is the patient and stakeholder engagement. We have compiled a team of stakeholders, patients, and researchers who are motivated and determined to improve the decision-making and care of seniors in their own homes.

Stakeholders and patients have been involved from the conceptualization.

When the Funding announcement was released, the question below was posed:

- *An 84-year-old woman with several chronic diseases is having increasing difficulties managing at home alone, but does not want to leave her home or neighborhood for a nursing home. What are the benefits and drawbacks of different programs or services that might help her stay at home and remain independent safely?*

Dr. Lindquist, the PI, was extremely interested as this is a common issue that arises among the seniors she sees in her geriatrics clinics.

She contacted Ms. M., a senior citizen patient who receives care at an area hospital and clinics. Ms. M. is also a retired social worker and strong advocate for seniors in the community. Recently, she had been instrumental in forming a grassroots organization where seniors help other seniors in the community to enable them to remain in their own homes. Ms. M. has had prior experience working on research and policy-level projects and was enthusiastic about answering the above proposed PCORI question. Ms. M. recommended meeting with someone from an affiliated community group.

The PI met with a delegation of seniors from another retirement community, which included board members and Ms. C. Ms. C., herself a senior citizen and patient, is president of another grassroots senior-lead community group of North Chicago Seniors. The goal of Ms. C.'s community group is to help fellow community-dwelling seniors remain in their communities. The idea of a planning tool to help seniors understand and access home services came about. Ms. C. and Ms. M. went to the boards of directors for their community group, who enthusiastically supported this research.

A question remained: If seniors identify their needs through this tool, who would have the expertise to connect people to home services not offered through the senior communities involved in the project?

Ms. McM. is a social worker, geriatric care manager, and owner of a home care agency. Ms. McM. has worked with Dr. Lindquist on prior health and policy projects and had worked to

create and pass legislation in the state to regulate home care agencies. Ms. McM was ecstatic about the project and felt it was a “game changer” to plan for events instead of reacting to health crises.

Dr. Lindquist was also contacted by Ms. F., a home care nurse and a leader of an area agency on aging in a rural Indiana. She had read Dr. Lindquist’s publications and was interested in collaborating on research among her rural lower SES seniors. After phone call communications, Ms. F. and Dr. Lindquist realized common interests in helping seniors remain home and home services that Ms. F.’s agency also provided. Ms. F. was excited about the PCORI question and the early plans to form a planning tool that would educate seniors and assist them in making informed choices about home care. She brought the grant prospects to her group and they fully embraced participating.

Stakeholders and patients have been involved in writing of this grant proposal.

Each of the stakeholders above has written a part of the research plan. In particular, Ms. C. was the first to offer to write and was a highly motivated senior. She has promoted others in her senior community through the community newsletter the work on the grant proposal. She has asked to have a larger role and has technologically-savvy members interested in working with the web development of the APHS tool. Ms. F. has sent material on potential focus groups, possible ways of designing the content of the tool, and she has been useful in thinking about possible patient-centered outcomes. Numerous phone calls and emails have connected this panel of stakeholders and patients into producing a thoroughly discussed grant proposal. Dr. Lindquist then performed editorial work to make this grant proposal cohesive and provide guidance on the testing phases.

Stakeholders and patients plan to be involved during all 3 years of the study.

Each of the stakeholders and patients asked and expected to be involved during all three years of the study. The stakeholders and patients will be true members of the research team and meet monthly during the three years of the study. They will be instrumental in recruiting seniors and caregivers from their organizations for the focus groups, pilot studies, and randomized control trials. Our stakeholders and patients are taking this project very seriously. In the design of the APHS tool, the stakeholders and patients anticipate that they will give insight as seniors, caregivers, and resource providers. They are interested in building, refining, and testing the best APHS tool possible.

Stakeholders and patients will be compensated co-Investigators.

With their commitment and obvious dedication, the stakeholders are written into the grant as co-Investigators and will be compensated. They have written letters of support and submitted biosketches.

Stakeholders and patients will be active in the Dissemination of the APHS Tool or subsets.

Upon completion of the RCT, the stakeholders will meet to discuss the findings and further dissemination. It is highly anticipated that the APHS Tool will be successful in providing information to seniors that will enable them to make informed choices about home services and remaining in their own homes. If the RCT shows the APHS Tool is effective, we will disseminate the tool to seniors nationally through a national community network for seniors, which has given support to this proposal and has a history of dissemination of other projects nationally. The network connects senior communities throughout the country, and provides a network to share information and support seniors nationwide. We also plan to disseminate through national nursing associations of which Ms. McM. is a current board member. Further dissemination of study results would also occur through presentations at national meetings, publication of research findings in peer reviewed journals, and presentations at interested institutions both locally and nationally.

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If the APHS tool does not perform as expected in the RCT, the stakeholders and patients will convene to discuss what parts of the study proposal could be disseminated that they would consider helpful to seniors and their stakeholder groups. Examples are 1) specific subsections of the APHS Tool (e.g. validated risk assessments for hospitalizations or physical decline), 2) educational materials on how to design messages for seniors with low cognition or inadequate health literacy (e.g. cognitive load, shorter sentences), and 3) educational material on home services. The PI and Stakeholder representative forum will also discuss future plans – including what still needs to be done if anything to improve the tool.

SUMMARY

I am confident that our team of investigators and stakeholders, who have been brought together through the PCORI grant announcement, will do amazing things for seniors, now and in the future. It has been in the production of this grant proposal that we have gotten to know each other and work closely with each other. We are looking forward to the possibility of working together more if this grant is funded as it will further solidify the budding relationships between our organizations. We have already begun to see how we can help each other advance our mutual goal to improve the home care of seniors. This group of stakeholders and investigators are true-believers and extremely dedicated to improving the care of seniors in their own homes. They are the strength of this grant proposal.

Engagement Plan B: *Creating a Clinic-Community Liaison Role in Primary Care: Engaging Patients and Community in Health Care Innovation*

This project engages patient partners and community stakeholders in several ways.

RESEARCH DESIGN

This project has engaged two patient partners as co-investigators. They were recruited through a member-governed organization's Governance Services Department. This organization encourages involvement by its patient members with a department that facilitates participation. The Director of Governance Services was briefed on an early iteration of our study concept and reviewed her files on patient members who had expressed an explicit interest in being more involved in improvement work at the organization. The research team reviewed the qualifications and backgrounds of the referred individuals, met them in person and asked two of them to join the research team. The individuals we have selected bring unique skills and experiences that have already greatly benefited our team and will keep doing so. One patient co-investigator is a community advocate who is expert in poverty and homelessness — running a nonprofit project that provides thousands of handmade hats and scarves to homeless individuals in the fall. She also is a part of and works closely with the local Islamic community. The other patient co-investigator has been a caregiver for seriously ill family members and has expertise in training and group facilitation. Both have particularly important insights into the connections between healthcare and community resources that are helping to shape our research. The patient co-investigators have contributed to developing this proposal. If it is funded, the patient co-investigators will attend all relevant team meetings. They will also help with decision making around key design issues and project activities such as designing materials and observing events and data analysis, as fits their expertise and availability. They will be compensated for their time with a monthly stipend that is within a range equivalent to the hourly pay of other key personnel.

INTERVENTION DESIGN AND IMPLEMENTATION

For designing and implementing the clinic-community liaison role, patient and community partners will be engaged through participation in the patient-centered design team and community advisory boards.

Community advisory panels (CAPs): The CAPs will help develop the clinic-community liaison role by providing a bridge between the Group Health clinics and the surrounding community. They will also provide guidance for data collection and analysis of the evaluation of the clinic-community liaison role. CAP members will be recruited through health and human services nonprofits and government agencies serving the communities that surround the three pilot

clinics. We will meet quarterly with the CABs during the project to review progress and elicit advice, including at least two in-person meetings per year. We may work with individual CAP members around design and planning issues that need more in-depth engagement and feedback. The CAP members will receive \$100 per year for participating in these quarterly meetings.

Patients taking part in the patient-centered design team: As described in the research plan, around 10 patient partners will be recruited to participate in designing the clinic-community liaison role. These patients will be recruited from patient populations at the three pilot clinics. We will be sure to design our recruitment methods to specifically target patients who provide important perspectives, such as patients who are ethnically diverse and have multiple chronic conditions or impaired access to healthcare because of age or disabilities. These patient partners will be critical to shaping the design and implementation of the clinic-community liaison intervention. The patient partners in the patient-centered design team will receive training about the member organization and care design processes, attend all care design and process improvement events, and participate in evaluation activities. They will be compensated \$1,500 for the first year and \$500 the second year for their participation (about \$20 per hour).

INTERVENTION EVALUATION

The evaluation data collection will also engage patient partners:

Patient Focus Groups: Around 36 patients at each of the three pilot clinics (total of 108 patients) will participate in nine focus groups exploring patient experiences with the new clinic-community liaison project and requesting their input on ways to improve the services provided. As the research team becomes familiar with the local communities surrounding the pilot clinics and decides on the specific subgroups that will be targeted for the focus groups, plans will be made to address potential barriers to participation, such as language differences, transportation, and trust issues. Patient partners will receive \$75 for their participation in the focus groups.

Patient Experience Survey: Patients will also be given a chance to participate in a patient survey. This survey will let them provide input on various patient-centered outcomes that we will monitor to evaluate the clinic-community liaison role. A total of 7,200 patients will have the opportunity to participate (3,600 at the pilot clinics and 3,600 at the control clinics). We will work closely with our survey department to address barriers to participation in the survey, such as low literacy and language barriers. Once data collection and analysis completed, we will share the findings with patients at the pilot clinics. To inform patients of our project findings, we will use in-person presentations (such as an evening open-house event) and/or specially designed written communications.

Engagement Plan C: *Long-Term Outcomes of Community Engagement to Address Depression Outcomes Disparities*

CLIENT PARTICIPANTS

The relevant patient or client populations for this proposal are clients in under-resourced communities of color, using Los Angeles as the example, who receive services from agencies supporting the “safety-net” or community members receiving public-sector services. The types of services agencies and therefore the types of clients for the study were determined in a stakeholder development process for the parent study, Community Partners in Care (CPIC) (Chung et al., 2010). Clients and community members and providers gave input into the types of locations relevant to supporting persons living with depression, and the list included primary care, mental health specialty, substance abuse locations as “traditional” services locations, and a range of social service agencies (family preservation, homeless-serving, prisoner-re-entry), and other “community trusted locations,” including faith-based agencies, senior centers, parks and recreation facilities, exercise clubs, and hair salons. To achieve a reasonable representative sample, county lists were combined with community leader nominations for a comprehensive list; and 50% of agencies and 85% of their eligible programs were recruited in two large areas serving a combined population of 2 million individuals. The clients who are participating in the study were systematically screened for depression when visiting these agencies and thus are broadly representative of the expanded “safety-net” viewed as relevant to supporting depression by clients and community stakeholders.

The leadership of the study follows a Community-Partnered Participatory Research (CPPR) framework (Wells and Jones, 2009; Jones and Wells, 2007; Jones et al., 2010). This is a manualized variant of community-based participatory research, in which an effort is made in the initiative to identify and engage all relevant stakeholders for a given issue, including clients, family members, providers of different kinds, institutional leaders, and policymakers. A Council coordinates the study and facilitates broad input from stakeholders through larger community meetings and as needed advisory boards, which also interact. The Council supports working groups on particular issues to implement the work, and those working groups and the Council are led by community stakeholder and academic members, following principles of community engagement that emphasize respect, development of trust, equal authority, respect for differences, and focusing on community strengths and capacity building as well as improving equity, outcomes, and productivity through rigorous, partnered science. CPIC has been the signature project to both address a key, stigmatized mental health issue and to use this approach to implement a rigorous, randomized trial. As a result of following this approach, the engagement of stakeholders at all levels has been under the principles of community

engagement, development of trust, respect, and equity. The new study which builds on CPIC will similarly follow these principles to conduct a long-term client outcomes study and to conduct a qualitative evaluation of clients' outcome priorities and providers' capacities to address them. The Council and workgroups have included some client representation, although the Council largely consists of providers, administrators, unaffiliated community members, and consumer advocates. One reason that we have not had a more formal process of including depressed clients as leaders is that with 20 years of research experience with depression focused on underserved minority groups, we have learned that depressed clients often feel uncomfortable in a designated "depressed client" role given high social stigma concerning mental illness, where their disclosure could have implications for their work or social relationships. The exceptions are clients that have accepted an advocate role, and we have several examples of such clients in our Council. Instead, we include unaffiliated community members, clients who may or may not have a history of depression, and client advocates with a public story of a history of depression, or family members. We have also learned that because depression is so common, many participants, whether providers or "clients" have themselves had some history of depression which often comes out over time, sometimes in private conversations and occasional requests for referrals. Over time, we have tried different strategies to enable discussion of client priorities and one of the most successful has been using narratives or stories that have been de-identified, even accompanied by audio examples, to prompt researchers, staff, community members, providers, and clients to comment on outcome priorities based on these narratives. We have a large library of narratives from prior projects, but few actually explicitly discuss how clients make choices among different needs, route themselves to care to attend to their priorities, or negotiate their preferences with providers. The present study will help fill that gap, but will also provide narratives that together with our existing library can be used to stimulate workgroup discussions of client preferences and their fit with service program capacities.

We have also learned that even designated client advocates are more comfortable serving in a Council capacity if paired with another advocate or researcher, to provide support as needed. In this study, we will expand our Council with additional client representation. We will do so by inviting Council members to add a client representative that can be a formal advocate or board member, or a client not necessarily with a history of depression. We will also invite an equal number of unaffiliated community members so that clients do not have to be identified as such. The project data and narratives will provide rich information to stimulate discussions of client preferences without requiring clients to reveal their identity or talk about their own histories. We have also included research staff from academic and patient advocacy organizations with extensive experience facilitating client and community member participation for diverse populations, especially African Americans and Latinos. The second Aim of this project to

specifically elicit client priorities for outcomes, will also give a more formal representative voice of clients to the project. That part of the project specifically focuses on African Americans and Latino clients and stratifies clients based on some characteristics including for example history of homelessness and the services sector in which clients were initially identified as depressed. Thus, we will literally have the “voice” of clients from diverse ethnic groups and services sectors available to inform the project.

We also have the option of developing mechanisms to engage client representatives drawn from this diverse sample into dialogue with the Council or workgroups to discuss the progress of the study. This can be done by offering opportunities to participate in special telephone Council meetings to review key issues and questions that arise, as clients are being interviewed; or we can suggest that interested clients write us a letter with their views. This approach was used in the Partners in Care study, and about 50 letters were solicited with information on how they had interacted with their providers and coped with depression. However, the population for CPIC is a much more underserved population than that for Partners in Care, which focused largely on private, managed care programs and one public-sector site. We will explore the feasibility of special telephone conferences or webinars with the Council and initial client stakeholders for this project. We are piloting the strategy of asking Council members to invite a few clients to give input this fall as part of the main CPIC’s community feedback session to community stakeholders on the initial data from the project. At this conference, we will work with a small panel of client stakeholders to discuss their ideas about how to best engage stakeholders for the new study, facilitated by two experienced consumer advocates.

For the CPIC project, we already have excellent relationships through our Council with diverse agency leaders and providers, having fielded the study in 93 agencies, training nearly 500 providers and staff. We expect these good relationships to continue and given the positive 6-month outcome findings, the interest of agencies in the goals of CPIC seems to be increasing. We think this will set a very positive tone for their participation in this new long-term outcomes grant, in which we will be recruiting agency staff and providers into qualitative interviews, and hosting discussions with agency leaders and providers about the meaning of the data.

However, one challenge we face is the range of “providers” for this project, because of the breadth of agencies involved. The provider groups have different reference professional organizations, often do not meet with each other, and so forth. However, the CPIC Council, as well as intervention Councils for CEP, which offer an infrastructure moving forward for convening such diverse provider and agency stakeholder groups, has been an excellent forum for their interaction. We also have good relationships with family representatives. A major advocacy organization for African-American health issue is next door to a large mental health advocacy organization, which was an initial partner in developing CPIC, and an advisory board

member has been a former national President of this organization. A remaining group of stakeholders that will be critical to impact are policymakers. To field this project in Los Angeles, we met with relevant members of relevant city and county government and health offices. During the initial phase of the project, we offered an opportunity for community leaders in the project to discuss the project and issues related to health reform legislation with a representative of the Community Engagement Office of the White House. We also presented interim findings from the baseline phase of the study to the Dual Eligible office of CMS and met with members of the House of Representatives responsible for the areas of Los Angeles that are the focused communities for the study. We also engaged the project officers of our funding agencies as Council members, a strategy that was quite successful for involving a private foundation and a mental health policy institute. We hope to be able to regularly engage a PCORI project officer as a Council member if feasible and acceptable to PCORI. Over the next (and last) year of CPIC funding from our partnering mental health institute, we will be working as a Council to make presentations locally and nationally to policymakers about our initial findings, which could set the stage for further follow-up as findings emerge from the new long-term outcomes study. We think these may be of interest to policymakers in an era of healthcare reform and greater focus on how to manage under-resourced populations efficiently and with quality care. Thus, we acknowledge the importance of policymaker involvement, will include some policymakers in our qualitative interviews, and can build on our existing strategies to ensure engagement at this level in the new study.

SPECIAL AND VULNERABLE POPULATIONS, RECRUITMENT, RETENTION/PARTICIPATION

The client population for this new follow-up study for both Aims 1 and 2 is a highly vulnerable population. A majority are African American or Latino and over 60% have 3 or more chronic medical conditions plus mental health symptoms and/or diagnoses, and annual family income less than \$10,000; over half are uninsured; less than 30% has any active employment; and a high percentage have a history of homelessness. The agencies serving these clients are highly protective of them and trust in research and randomized trials are major issues. Fortunately, these issues were addressed in the main CPIC study through 2 full years of community engagement to enter into the trial and given this engagement and co-leadership, participation rates in the research has been high; 95% of clients approached agreed to be screened; 93% of those screened and who were depressed and eligible agreed to enroll; and then about 80% of those enrolled participated in at least one of the 3 follow-up baseline, 6-month or 12-month telephone surveys (1,019). Of these 1,019 depressed clients, 1,004 remained actively enrolled at 12-month follow-up; however, there is a significant sample for which continuing follow-up contact has been extremely difficult (perhaps 150 clients). Some of this is because of highly unstable financial situations, people losing cell phones, going in and out of jail and in and out of

homelessness. Yet we have been able to maintain a reasonable retention rate, through a combination of modest financial incentives, excellent relationships with agencies, and a perceived value of the study to clients. For example, to field the surveys, clinician investigators routinely followed-up for any who expressed suicidal ideation; among the 1,019 clients with any follow-up survey, we made over 300 suicide intervention telephone calls, with virtually universal expressions of gratitude and no known adverse outcomes. This intensive strategy, conducted in both intervention arms, was at the request of community agencies who were concerned that they did not have the resources or knowledge of clients' suicidal status to be able to respond. This strategy also brought a sense of good will of the project into the community, and what might have been an extremely difficult experience for the project became valued as a service to the community. Similarly, we have assisted clients in both intervention arms, through those calls, to understand what services they are eligible for, for example after California shifted to a "non-revocable" probation policy that left persons on probation, who formerly had been eligible for mental health services, without access to those services. Our community partners worked with us to identify resources for clients in high-need situations. As a result, we have been able to field an ethically responsible study inclusive of highly vulnerable clients that has generated good will in the community and has yielded acceptable participation and retention rates. We will follow the same procedures in the long-term follow-up study, where some clients will likely no longer be living in the Los Angeles area. We have some experience with identifying resources in other areas in this project from the completed 12-month follow-up surveys. We have also used these experiences in supporting vulnerable clients to inform the design of the new study, for example, through the focus on social determinants of mental health and competing needs that clients face in making decisions about obtaining services. We also have used community member, leader, and client input to modify the language of survey items to be more welcoming and acceptable to vulnerable clients. For example, the PHQ8 includes one item that refers to sadness or depression.

Community members suggested including a second version of the same item removing the word depression because they felt some community members in need would not use that word. We used both versions to permit comparing the usual and "new" version, and found that several dozen clients only entered into the study because of the community modified version, but clearly had high need. There is some risk that it may be difficult to as fully represent highly vulnerable groups such as those with homelessness, particularly in the qualitative studies. We are using a stratified random sample approach to help assure that there is over-representation in the qualitative sample of this vulnerable group, and the survey team has extensive experience tracking and outreaching to people with a history of homelessness. To help assure that the approach to clients is culturally acceptable and appropriate, lead community partners co-train the survey staff conducting the interviews. To assure that the survey staff are able to



handle the stress of interviewing depressed clients and can appropriately handle potential emergency situations such as suicidal thoughts, the clinician investigators also train the survey staff in lectures and role plays, while the community partners share coping strategies such as taking breaks and self-care activities. As a result, when answering survey questions about who supports them in the community for depression, clients will sometimes give the name of a survey staff member or one of the clinicians who made a suicidal intervention call. We will continue to follow these training procedures for the new study, both for the quantitative survey follow-up and the qualitative interviews.

Engagement Plan D: *Nueva Vida Intervention: Improving QOL in Latina Breast Cancer Survivors and Their Caregivers*

IDENTIFICATION OF KEY STAKEHOLDERS

Community-Based Organizations and Patient-Advocacy Groups

Nueva Vida, Inc. was founded in 1996 by a group of Latina breast cancer survivors and health care professionals in the Mid-Atlantic region. Led by executive director Larisa Caicedo (subcontract PI), Nueva Vida provides a broad continuum of culturally sensitive cancer support services for Latinas in the Washington, D.C., Baltimore, Md., and Richmond, Va., metropolitan areas. Nueva Vida developed the intervention to be tested in the proposed study and teamed with Dr. Graves to empirically evaluate their program. As the only independent survivor-driven cancer care organization for Latinas in the area, Nueva Vida serves over 4,000 individuals and their families, and reaches countless more as a resource to local and national healthcare partners seeking to improve care for Latinas. These services include patient navigation and assistance from diagnosis and treatment to recovery, survival and end-of-life care, community outreach and education, support groups for patients and their families, and collaboration with local and national cancer researchers.

Multiple other patient advocacy and support organizations as well as individual patients and caregivers are also partners in this project and in the development of the proposal. The research team includes four sub-contract PIs who are patient advocates, affiliated with breast cancer advocacy organizations.

DESCRIPTION OF ENGAGEMENT FREQUENCY AND TYPE

The idea for the proposed project originated with Nueva Vida thus stakeholders have been engaged from study conception. Below we highlight study milestones and prior or planned engagement of key stakeholders.

Study Conception – Nueva Vida, Inc., approached Dr. Kristi Graves with the idea of a study to formally evaluate their patient-caregiver intervention to look at the impact on QOL and communication outcomes.

Study Proposal Planning – During the course of study planning, 4 community-based organizations that are subcontracts for the proposed work have been involved. Dr. Graves and a research staff member from Nueva Vida spoke with each of the organizations at length. These discussions led to revisions of the choice of comparator (usual care vs. an active control), eligibility criteria (all women with breast cancer would be eligible vs. only women who had completed active treatment), and background of the interventionists (can be trained survivors, trained mental health professionals, or trained health educators). Our team also sought and

received input from a breast cancer patient advocacy committee and expanded study outcomes and Advisory Board membership to additional physicians based on their feedback.

Study Implementation – At the beginning of the study, we will convene a day-long Team Meeting with all research personnel, subcontract PIs and project directors from community-based organizations, Consultants, and our 5-member Advisory Board. The purpose of this team meeting will be to review -- and as needed, revise -- the proposed study design, outcomes, recruitment strategies, intervention topics, interventionist training, and assessment schedule.

Interventionist training – Once the proposed interventionist training is finalized following the study implementation team meeting described above, we will hold training in New York City for site interventionists. We chose New York since two of our partnering organizations are located there. We will encourage attendance of all site PIs and study interventionists to promote intervention fidelity. Training will be led by Nueva Vida staff, Drs. Graves, and consultants. We will invite one of our consultants, a clinician with expertise in providing support to caregivers, to attend the interventionist training. Key personnel will also travel to CA to train personnel who will be assisting the interventionists at one of our sites.

Team Teleconferences – We will engage in monthly (or twice monthly, if needed) telephone conference calls with team members from each site. These phone calls will allow for discussion of study implementation, Institutional Review Board protocols, recruitment, participant tracking, intervention delivery, and outcomes assessment. Dr. Graves and the study project director will be responsible for eliciting topics and agenda items prior to each call from the entire team. Consultants will be asked to join the calls when specific topics related to their expertise will be discussed. If any problems or issues arise, any team member can bring up the topic on the teleconference, or these issues can be brought to the attention of Dr. Graves or any of the site PIs at any time during the course of the study.

Annual Team Meetings – We will invite all members of the study team, Consultants, and the Advisory Board to attend a team meeting once per year. The purpose of these meetings will be to report on study progress to date, identify any difficulties with implementation of the intervention or outcome assessment, and discuss strategies for communicating study results to the wider community and interested stakeholder groups. One of our Advisory Board members (a cancer survivor and patient advocate), is the organizer of a biennial national Latino cancer survivor summit. This important meeting brings together lead researchers, service providers, community organizations, policy makers, clinicians, promoters, patients, and advocates to discuss current topics related to Latinos and cancer. In 2014, the topic will be *Latinos and Cancer After Health Care Reform* and will showcase best practices for improving health among Latinos. We will use the summit as a key strategy for disseminating information about the

intervention to a national audience. The summit has drawn over 750 attendees since 2008. Team members from a Latina cancer advocacy group and the other community-based organizations will take the lead on our conference submission and presentation.

Final Team Meeting – Approximately 4 months before the end of the study timeline, we will have a final team meeting with members of the study team, Consultants and the Advisory Board. At the final team meeting, we will focus the discussion on overall study results and on additional strategies to disseminate study results to appropriate scientific, community and stakeholder groups. Likewise, we will discuss ways to inform other community-based organizations that provide services to Latinos. Importantly, our team includes individuals with training in journalism and connections to large national organizations. As noted by the CEO of one of our partnering patient advocacy organizations in her letter of support, her organization will disseminate results to other advocacy organizations and explore ways to integrate the program into current practice. As an affiliate of a major support network, she also will guide our team on avenues of outreach to the 50 local support affiliates and 100 satellite locations.

BARRIERS ASSESSMENT

Facilitators to dissemination, implementation of results and incorporation into practice include:

- Delivery of the intervention in community settings and by organizations trusted by Latina survivors and their caregivers;
- Delivery of the intervention in Spanish and by bicultural interventionists;
- Engagement of key leaders, breast cancer survivors, caregivers and clinicians from community agencies and various stakeholder groups from study inception;
- Access to national conferences, lay publications, scientific publications, social media outlets relevant to Latinos and access to the support community relevant to people facing cancer;
- Relationships with stakeholders involved with numerous other community agencies and/or decision-makers relevant to Latino health and the health of other underserved minorities.

Barriers to dissemination, implementation of results and incorporation into practice include:

Lack of resources for incorporation into practice. The intervention itself can be delivered relatively inexpensively once the facilitators are trained. Our use of interventionists with different backgrounds (mental health professionals, survivor peers, navigators) is representative of the types of staff likely to implement the program at other organizations. We will use team expertise (e.g., experience with the train-the-trainer model for dissemination and implementation) and our collaborative network to identify effective strategies to overcome barriers related to resources/interventionist training.



Difficulty involving caregivers. We will overcome this barrier by sharing successful caregiver engagement strategies such as asking survivors to first speak with caregivers and emphasizing the role of family. We may seek local funds to cover expenses related to the creation of print or web-based testimonials from patients and caregivers who have participated in the program.

Cultural barriers to participation in support groups or “therapy.” At Nueva Vida, these barriers were overcome by describing the program as *talleres* (workshops) and focusing on family involvement. Sharing testimonials of other Latina survivors and caregivers who have participated in print flyers may also work.

We will bring up all of these potential barriers and elicit other likely barriers to adoption into practice at our Annual Team Meetings to gather input across various perspectives and from all team members.

Engagement Plan E:

Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology

IDENTIFICATION OF KEY STAKEHOLDERS

This project will become an integral part of VTE Collaborative, a multidisciplinary team of a hematologist, a surgeon, several pharmacists, a nurse and a clinical informatician. We have received overwhelming support from the three leading patient organizations in the field of VTE prevention in the United States. These organizations have a wealth of patient, clinician, and policy making perspectives. The VTE Collaborative will be working in partnership with the three leading patient organizations in the field of VTE prevention. In addition, three patients who bring diverse perspective and experience with VTE have agreed to join our VTE Collaborative as co-investigators. One of the partners of the VTE Collaborative is a multi-disciplinary organization that focuses on thrombotic disease education, awareness, advocacy, research, prevention, and diagnosis (Letter of Support included). Their mission is to improve outcomes and quality of life of all patients by providing patients and healthcare providers with information to optimize venous thromboembolism (VTE) prevention. Another partner of the VTE Collaborative works to improve the quality of care by “providing both patients and healthcare providers with the most up-to-date information and expert insight on optimal use of antithrombotic therapy” (Letter of Support included). Their resources geared toward providing patient-centered care include an archive of numerous stories from patients who developed blood clots that could have been prevented with prophylaxis. Another member of the VTE Collaborative is a patient-led, voluntary health advocacy organization (Letter of Support included). In addition to a vast patient membership, this member has volunteers who include many of the top experts on blood clots and blood clotting disorders. They build programs that promote “public awareness, educate patients and healthcare professionals and promote supportive public and private sector policy.”

DESCRIPTION OF ENGAGEMENT FREQUENCY

We will engage patient stakeholders during the first six months of this proposal to refine the protocol, content, and methods for engaging hospitalized patients and clinicians. We will subsequently engage our patient stakeholders every 6 months after implementation to present results of the intervention and solicit feedback for improvement.

DESCRIPTION OF ENGAGEMENT TYPE

We have been in contact with the directors of the Collaborative member organizations in addition to our institution’s patient and family advisory council while writing the proposal for this intervention. Patient stakeholders will be nominated from each national organization to represent a variety of patient perspectives during the first six months of this proposal. We plan

to use the Delphi method to identify, prioritize, build consensus, and refine topics of greatest importance to patients for communication with their nurses, methods for communicating those topics, and items to empower patients to take an active role in administration of their prophylaxis.

Patient stakeholders will be sent via email the detailed research plan, the proposed printed patient educational materials, patient checklist, and an outline of clinician training materials. Stakeholders will be asked to critically evaluate the content and methods in this intervention and provide feedback for improvement. They will be asked to identify and prioritize patient-clinician communication needs. Feedback from all patient stakeholders will be compiled, addressed and incorporated into the final protocol and re-circulated to determine consensus.

BARRIERS ASSESSMENT

We are already aware that the problem of non-administration of VTE prophylaxis is not endemic to our hospital. There is patient safety and quality improvement interest for health care organizations to intervene to improve administration of prophylaxis for their patients that will drive implementation of this intervention far beyond this hospital.

A potential barrier to implementation is that patients may be unwilling to participate in the in-person intervention delivered by the health educator. Their preferences will be respected at all times. To implement the full intervention that we propose in other settings requires the existence of an electronic health record (EHR) system and the requisite technical support infrastructure capable of integrating CDS tools; however, implementation of EHR systems capable of CDS integration is a national priority.

Engagement Plan F: *Redesigning Ambulatory Care Delivery to Enhance Asthma Control in Children*

IDENTIFICATION OF KEY STAKEHOLDERS

We have engaged 10 parents early, from the planning phase to the design and validation of the paper-AT, and the design and pilot testing of the e-AT. Input from parents was received through 3 iterative focus groups (one for the paper-AT and 2 regarding the e-AT) and facilitated discussion to inform the development of this proposal including research objectives and outcome measures. Results from the 2 iterative e-AT focus groups have been accepted for publication addressing usability of self-management tools. In addition, we have identified other key stakeholders for whom the results of the research will be relevant. These stakeholders include representatives of the following groups: PCPs, insurance industry, an area pediatric clinical program, an area primary care clinical program director, and the state Asthma Program. We will solicit parent and stakeholder input throughout the proposed study to identify and include themes that are relevant to them.

For this proposal, we have recruited and worked with a parent representative, Ms. R. Ms. R.'s child is among children with asthma who have used the paper-AT, and she has been actively engaged in managing her child's asthma with the tool and in providing feedback to our research team. Upon funding of this proposal, we will recruit 5 additional parents to have a diverse group in terms of health literacy and self-management engagement. (Note: the 10 parents engaged initially helped us in designing and testing the e-AT and determining the research questions. For this proposal, we have involved one parent and are planning to recruit another set of 5 parents (for a total of 6 parents) as partners for this research project, which may include parents from the previous parent group) to have a diverse group in terms of socio-economic status (SES), health literacy and self-management engagement. In addition, we have recruited Dr. J, as the main PCP representative for this proposal. An additional PCP will be recruited at the start of the funding period.

Funds are requested to compensate 6 parents and 2 PCPs for their participation and effort (see Budget Justification for detail). The remaining stakeholders' time will be provided in-kind (see Letters of Support) as we already have an established collaboration from previous asthma projects. Representative of the Patient Population of Interests (Parents): Recruitment of parent partners will be from the existing cohort of parents of children enrolled in our paper-AT. To ensure well-balanced representation of parents in terms of characteristics that may affect participation in asthma self-management, we will divide parents into 2 categories, including frequent vs. infrequent users, based on objective measures of their participation in asthma self-management including frequency of use of the paper-AT. We will then randomly select in each group (block) 2 parents who are frequent users (Note: we already included one frequent user

parent in the conception of this proposal, Ms. R.) and 3 infrequent users, for a total of 6 parents. This balance will help us better assess facilitators and barriers of sustained parent participation in their child asthma self-management. Parents recruited will complete a survey to determine 1) the extent to which they are confident in self-management using the Patient Activation Measure Survey (PAM) and 2) asthma literacy using the STOFHLA.

Primary Care Provider (PCP) Representatives: We have recruited one PCP, Dr. J, to support our research team and provide insight regarding potential barriers to implementation of the e-AT at community clinics. Dr. J. has collaborated with our research team over the past 2 years in implementing ambulatory sensitive asthma quality measures across Intermountain facilities. He has also tested the e-AT at his clinic. Dr. J. will be assisted in his role by another PCP who will be recruited after the funding start date. Their time and efforts will be supported by the grant.

Furthermore, our project is supported by Dr. C., who is a PCP, and the director of a large primary care practice, and member of the Research Advisory Committee (see below). As a leader, Dr. C. will facilitate recruitment and secure participation of clinics in this project. Dr. C. has 27 years of experience as a PCP and has been the Clinical Programs Leader for a health system for 11 years where he oversees the implementation and coordination of system wide primary care provider initiatives. He has a strong relationship with PCPs in the state, including those contracted by his health system as well as independent PCPs outside his network. He has tested the e-AT and advocated its use by his clinics. Dr. C. has provided a letter confirming his support for this project. His time will be provided to this project as in-kind contribution.

Pediatric Clinical Program Director: Ms. C.R., APRN, MS will provide nursing and administrative leadership to facilitate implementation of the e-AT at community clinics. We have worked closely with Ms. C.R. to implement the asthma CPM and ambulatory sensitive asthma quality measures at Intermountain hospitals as well as during the development and testing of both the paper-AT and e-AT. Her time is provided by the Pediatric Clinical Program as an in-kind contribution to this project.

Clinical Nurse Specialist: Ms. K., RN, FNP has decades of experience as an asthma educator. She primarily works for Intermountain Healthcare. She assisted with implementation of the asthma CPM at PCMC and dissemination to other facilities. She has experience integrating new care processes into nursing and RT workflow. During the validation and pilot testing of the paper-AT and e-AT, Ms. K. acted as the main contact for parents in addressing their concerns during the project. Ms. K. worked closely with the research team through the conception and development of this research proposal. She participated in facilitated discussion with parents for both the paper-AT and e-AT and has established good relationship with parents currently using the tools. Her time will be supported by the grant.

Our plan to disseminate the e-AT to the community will utilize not only parents and stakeholders named above but also school nurses and insurance companies, who are other potential end users of the e-AT. To accomplish this, we have involved the State Department of Health Asthma Program and the state Medicaid office.

State Asthma Program: Ms. B., Health Program Specialist, is serving as a representative of the State Asthma Program, which is located at the State Department of Health. As schools are one of the venues that could be used to disseminate the e-AT in the community, we have involved the State Asthma Program. Schools are the optimal settings for implementing the e-AT as they already have the structure in place: school nurses, and an ability to reach large numbers of children. The e-AT will provide school nurses with more information to make informed decisions for students with asthma. The structured environment of schools permits the identification and education of a large proportion of the children in a community with persistent asthma. The mission of the State Asthma Program is to improve the lives of patients with asthma. We will use the existing infrastructure within the school system, which provides the potential for maintenance and broad dissemination of the e-AT, to implement the e-AT. A support letter from the program manager, supporting involvement of Ms. B., is attached.

Medicaid: Insurance companies are the potential beneficiaries of the e-AT application as use is associated with reduced ED and hospital admissions. The potential for cost-savings is attractive for insurance companies. The Assistant Director in the Division of Medicaid and Health Financing will provide insight on how the e-AT can be integrated with Medicaid incentive mechanisms, which will be crucial for broad dissemination of the e-AT. The State Medicaid program has provided a letter of support for the Assistant Director's participation. Her time will be provided as in-kind contributions to the project.

External Advisory Committee: We have selected an exceptional group of external advisors (See Letters of Support and Biosketches) who are highly experienced in quality improvement and/or asthma care. Our advisory committee brings outstanding expertise in health care as well as experience with innovative applications of high quality care delivery. The committee will include four physicians. As members of our current asthma project advisory committee, we have received input regarding the development and testing of the paper-AT and e-AT. The Advisory Committee will meet face-to-face with the project research team annually. We will review the progress of our work and plans for the upcoming year. We will seek the committee's input in various work phases via conference calls, e-mails and during the annual meetings. The Advisory Committee members will assist us in formative evaluation to determine ongoing project activity effectiveness and in summative project evaluation to determine our success in achieving the proposed specific aims by the end of the grant period.

DESCRIPTION OF ENGAGEMENT FREQUENCY

All Stakeholders: We will use the timeline (see project timeline) as a management tool in monitoring and managing project progress. We will begin with a kick-off meeting (retreat) involving all stakeholders, which will take place during the first quarter of the funding period. The meeting will address the overall project and preparation plan for dissemination, as well as solicitation of stakeholders' input. We will continue with quarterly meetings with all stakeholders so that we can discuss progress and issues raised during the research. The stakeholders will be involved in all steps of the research project. In Year 3, the meeting will focus on preparing the materials for dissemination and identifying and addressing barriers to broad dissemination of the e-AT beyond participating clinics.

Parent Partners: We have engaged parents from conception of the paper-AT and e-AT to the testing and evaluation periods of these tools. We will continue engaging them throughout the study period including publication of results and broad dissemination of e-AT in the community.

Frequency of Stakeholders' Involvement:

1. Parents will be required to take online training regarding introduction to Clinical Research Methods and Human Subject Protection during the first month of the funding period.
2. Engagement of parents will include the following:
 - a. Kick-off meeting that will be held in the first month of the funding period
 - b. Quarterly meetings with all stakeholders
 - c. Additional monthly meetings in year 1 and 2, and quarterly meetings in year 3,
 - i. Discuss research progress and issues to resolve.
 - ii. Solicit their inputs and address them in the study.
 - iii. Discuss results and dissemination plan.
3. Deliverables will be assigned at each meeting, which may require interim discussions within groups outside the set monthly meeting times in order to complete assigned tasks before the next meeting.

DESCRIPTION OF ENGAGEMENT TYPES

All Stakeholders:

1. Stakeholders engagement will include quarterly meeting as described above.
2. In addition, we have included Dr. J., as the main representative of PCPs. An additional PCP will be recruited at the start of the funding period.
3. Engagement type will include facilitated discussion. Our project includes an experienced facilitator, who has previously helped facilitate discussions and focus groups with parents, patients and physicians. The facilitator will be assisted by someone who also has experience in facilitated discussion and other methods of parent engagement.

Parent Partners: Stakeholders engagement varies depending on research phase, including:

1. Early Conception of the Research Proposal:

- a. Prior engagement includes 3 iterative focus groups and facilitated discussion of parents and children (older than 12 years). The development of the e-AT application was guided by information generated from a focus group formed from a sample of children and their parents who used the paper-AT. Our research team developed a list of the e-AT application requirements including functionalities for children, parents and PCPs. This list was augmented and/or changed with additional software requirements suggested by patients and parents from the focus group.
- b. In 2 consecutive patient/parent e-AT focus groups and facilitated discussion several concerns were identified and changes were made to ensure acceptability of the application and relevance of the content. In addition, parents expressed interest in assessing the tool's effectiveness and in identifying and addressing barriers to sustained use of the e-AT.
- c. Ongoing feedback during the paper-AT evaluation included written comments from parents and/or patients via mail about the tool in the back of the form for us to consider (paper-AT) or during follow-up phone calls with our nurse specialist about the tool.

2. Preparation of This Study Proposal:

- a. For this proposal, we have recruited and are working with a parent representative, Ms. R. Her child is among those who have used the paper-AT and has been engaged in managing her child's asthma with the tool. We will recruit 5 additional parents upon funding so that we can have a well-balanced and diverse group of parents with different levels of health literacy and self-management engagement. Research questions and hypotheses, selection of outcomes measures and methods were informed from input received from parents during 3 iterative focus groups and facilitated discussions. The content of the proposal was also discussed with the parent representative and she provided input as to our future research objectives.

3. During Implementation Period (after funding approved), patient engagement will include:

- a. Facilitated discussion
- b. Iterative focus groups
- c. Input on design and planning
- d. Assist the research team in identifying current practices related to the use of the e-AT, identifying challenges, recommending solutions, and setting future priorities
- e. Advise the research team in effective methods of incorporating the e-AT in family daily life
- f. Network and share information between families and community resources. (Parent partners may make presentations and provide training as needed to families)
- g. Assist in the development and review of dissemination materials for families
- h. Represent concerns of parents of children with asthma
- i. Monthly conference calls (during the first 6 months) organized by the core research team to exchange information and progress
- j. Review site performance data monthly
- k. Monitor project goals and providing ongoing support of the research project

- l. Ongoing discussion regarding strategies for overcoming expected barriers in consultation with their faculty mentor
 - m. Review study progress, and assist in solving issues and challenges as they arise
 - n. Conduct peer-to-peer meetings with parents
4. Dissemination Period:
- a. Parents will be involved in manuscript review
 - b. Assist in crafting of the implementation manual (with participation of other key stakeholders).
 - c. Advocacy activities to facilitate broad dissemination of the e-AT

BARRIERS ASSESSMENT

Parents: Specific Aim 3 of this project focuses on identifying facilitators and barriers to sustained parent use of the e-AT in self-management. This information will result from interpretation of responses from the semi-structured surveys. This aim will provide an in-depth understanding of barriers to and facilitators of the e-AT application use as a self-management tool by parents. This information will be augmented with data generated during facilitated discussion. We will review these barriers and determine strategies to overcome them during dissemination. Results will be used to inform broad dissemination of the e-AT after addressing barriers of successful use.

Other Stakeholders: We will conduct several facilitated discussions with PCP representatives, the State Asthma Program representative, a health system Clinical Program representative, the insurance company representative (Medicaid) and a health system Primary Care Program representative. Facilitated discussion will be led by a skilled facilitator and assistant. Facilitated discussions will be conducted twice/year to identify barriers associated with implementation of the e-AT at the level of clinics, schools and insurance companies including possible incentive and solutions to address these barriers. We will use quality improvement standard methodology with use of flowcharts, a fishbone diagram and determination of leverage points. We will determine an effective intervention to facilitate broad implementation of the e-AT.