RESEARCH STRATEGY

A. Background

Methods for Engaging Patients and Stakeholders in Patient-Centered Research

While the PCORI Methodology Report emphasizes the importance of patient engagement in all phases of patient-centered research, it does not articulate how to accomplish that. The Agency for Healthcare Research and Quality (AHRQ) Report, "Engaging Stakeholders to Identify and Prioritize Future Research Needs" provides some guidance, but for the most part it focuses on project-specific rather than longitudinal engagement and engagement of patients and stakeholders by researchers rather than the converse, in other words a topic-focused, researcher-centric perspective (O'Haire et al., 2011).

We propose to study engagement methods from a patient/stakeholder perspective. PCORI research has typically focused on engagement between researchers interested in a particular disease or treatment and patients with the disease. Patient-centered research directed at improving primary health care has been slower to develop and largely missing amidst PCORI's funding portfolio. However, a variety of organizations with this mission are emerging. The time is right to make patients, patient advocates, researchers, and PCORI aware of them and to describe methods by which they can achieve sustained engagement with researchers. We plan to partner with four types of organizations, patient advisory boards (PABs), patient advocacy groups (PAGs), community coalitions (CCs), and primary care practice-based research networks (PBRNs). Collaboratively, we will describe the nature, purpose, and processes used by each type of organization, describe the methods they have used to engage patients, other stakeholders, and researchers, engage in collaborative learning and brainstorming to develop recommendations for improvements in these methods, and produce a synthesis of concepts and techniques that will direct further advancements in engagement and prioritization methods.

Prioritization of Research Topics

Whether at the practice or community level or at the level of funding agencies like PCORI, prioritization is a particularly critical process. The PCORI Methodology Report acknowledges the importance of prioritization but includes few specific recommendations. The AHRQ Report (O'Haire et al., 2011) lists a variety of strategies used by key informants (mostly researchers) including consensus development, voting, and Delphi techniques but without specifying the full range of factors that should be considered. PCORI review criteria include: 1) the number of people likely to be affected; 2) the potential impact on each affected individual; and 3) the likelihood that the research will have the desired impact. These are also components of strategic planning methods such as the Mobilizing for Action through Planning and Partnerships (MAPP) process used by community coalitions and of "value of information" (VOI) analysis. VOI also includes variables such as cost and impact time period in the calculation. However, VOI has, so far, not been widely adopted because of the technical difficulty involved in producing the required estimates (Myers et al., 2011). However, it is still possible that "conceptual VOI" (Fleurence & Meltzer, 2013; Meltzer, Hoomans, Chung, & Basu, 2011) could be helpful to PABs, PAGs, and CCs, PBRNs, researchers, and funders like PCORI. Efforts to simplify VOI calculations while preserving reliability and validity are ongoing (Wald, Leykum, Mattison, Vasilevskis, & Meltzer, 2014). It is likely that the groups with whom we have engaged can help us move these efforts forward.

We propose to describe the prioritization processes currently being used by PABs, PAGs, CCs, and PBRNs, and then, with their assistance, develop a methodology that helps them to be inclusive (i.e. take into account most of the relevant variables) and logically coherent (i.e. prioritization accurately reflects their values and situations). To do this we will provide descriptions of, and materials for, group discussion and individual or group activities that clarify, compare, judge, and measure the pertinent factors that contribute to overall prioritization recommendations. The results will be summarized for consideration by other similar groups and by PCORI.

B. Significance

Potential for the Study to Improve PCOR Methods

This study will address several gaps in PCOR methods for engagement and prioritization. We will focus on longitudinal engagement between existing community organizations and researchers rather than researcher-initiated, project-specific engagement approach, focused on specific diseases. These areas of emphasis are consistent with recommendations from published studies on research translation and knowledge transfer (Hanney, Gonzalez-Block, Buxton, & Kogan, 2003; Lerner & Simon, 1998; Ward, House, & Hamer, 2009; Yin & Moore, 1988). The results should be applicable to PABs, PAGs, CCs, PBRNs, academic researchers, PCORI, and other funders. In addition, they will enhance the ability of patient- and community-based organizations to inform a national research agenda for improving community health and primary health care. However, the results of this work should be broadly applicable to a variety of topics and settings.

Patient-Centeredness

The nature of this study is to improve engagement and prioritization methods so that research can more effectively incorporate the voices of patients and their caregivers. We believe that an important but underdeveloped channel for patient input is through existing patient- and community-based organizations. These organizations typically focus their efforts on issues of great importance to nearly all patients, issues such as access to high quality, patient-centered primary health care, and coordination between primary health care and community-based resources. However, they often function in isolation from one another and from the larger research and policy arena. Finding ways to connect them could give patients a greater voice within the community of researchers and the research foundering community.

The aims of this project are to better acquaint these organizations with researchers and researchers with the organizations, and to provide guidance to both regarding how to engage meaningfully and longitudinally. This should broaden opportunities for patient input and influence to patient-centered outcomes research beyond those of special interest groups.

It will also address prioritization, an area of tremendous importance for patients, the organizations, and PCORI. Simply asking patients for their input will do little to change the national research agenda unless decision-makers have valid and reliable methods for prioritizing questions and opportunities. Too often decisions about prioritization are made by those at the table, based upon their own opinions and interests or the availability of funding. A more logical approach such as conceptual VOI might create a more equal playing field, resulting in a more patient-centered agenda.

C. Study Design or Approach

Project Aims

With the help of six exemplary patient- and community stakeholder-groups, an experienced PAB that serves four safety net primary care practices in Buffalo, New York, a successful PAG serving the Latino population in Southern California, a community coalition in Stephens County, Oklahoma, and three mature practice-based research networks (PBRNs), the CRT (CRT) will describe the organizations, the successful methods and processes they have used to engage researchers, and the methods they have used for prioritization. We will then collaboratively, with the help of our two consultants, develop principles and techniques for strengthening engagement and prioritization methods. The Aims of the project are:

Aim #1: With input from exemplary PABs, PAGs, CCs, and PBRNs, and the results of a comprehensive horizon scan and key informant interviews, produce a Guide to the research community for the organizations and a Guide to the organizations for researchers including registries, purposes, processes, membership characteristics, and conferences.

Aim #2: Using several qualitative techniques, help participant organizations describe the effective methods they have used to engage with researchers, identify limitations and opportunities to enhance engagement in these settings, and speculate on ways to improve engagement methods. Summarize the results for each organization, for researchers, and for PCORI.

Aim #3: Help the same groups identify current prioritization methods, evaluate and discuss conceptual VOI as a way to improve those methods, and combine ideas and suggestions into a set of proposed principles and

techniques for improving prioritization methods. Summarize the results for each organization, for researchers, and for PCORI.

Overview of Study Design and Methods

This is a qualitative study. Its products will include a set of reports, peer-reviewed publications, and presentations intended to advance the engagement and prioritization methods used by organizations trying to improve patient-centered care and those recommended by PCORI. We will first synthesize information from a horizon scan and key informant interviews to develop Guides to the research community for patient- and community-based organizations and a guide to the organizations for researchers. We will then use appreciative inquiry and concept mapping to describe the current engagement and prioritization processes used by four types of health care improvement organizations. Finally, will introduce new ideas and use q-sorts, brainstorming, collaborative learning techniques, and iterative review and validation to propose enhancements to their current methods. A variety of reports will be produced for the different target audiences.

Context and Settings

Participant Organizations (General)

Patient Advisory Boards (PABs): The term "patient advisory boards," as used in this project, refers to groups of patients who form or are formed to advise a single primary care practice on problems with and opportunities for improvement of care processes. Members are typically volunteers who meet every one to three months. Community health centers are required to have community boards, which we would also consider to be PABs.

Patient Advocacy Groups (PAGs): PAGs are generally non-profit organizations that advocate on a local or national level, on behalf of underserved or otherwise vulnerable patients or patients with specific diseases, in an effort to improve the health care services available to them and/or to increase funding for research that would result in better care. Individual-level advocacy entails caregiving, navigation, and other activities to ensure that the needs of individual patients are met, while systems-level advocacy entails the development of policies to secure resources and improve systems of care for patients. For this study, we will be engaging a local, individual-level patient advocacy group.

Community Coalitions: Many communities throughout the country have community coalitions focused on improving the health of the entire community or underserved subgroups. Increasingly these efforts have been supported by the Centers for Disease Control and Prevention and state departments of health, and many coalitions are involved in the development of county health improvement plans (CHIPs), often using a process called Mobilizing for Action through Planning and Partnerships (MAPP). Members are generally volunteers who represent a wide variety of local public agencies and community-based organizations.

Practice-Based Research Networks: *According to* AHRQ, "PBRNs are groups of primary care clinicians and practices working together to answer community-based health care questions and translate research findings into practice. PBRNs engage clinicians in quality improvement activities and an evidence-based culture in primary care practice to improve the health of all Americans." More than 150 networks are currently registered with AHRQ through its PBRN Resource Center. PBRNs can be local, regional, or national in membership. They engage in a wide range of research and quality improvement initiatives. Most are affiliated with primary care departments in academic medical centers. Some, like OKPRN and LA NET, are non-profits but collaborate with academic researchers.

Participant Organizations (Specific)

Patient Voices Network (PVN): Established in 2010, the PVN is a unique organization made up of activated patients committed to building "a community of educated and involved patients working hand-in-hand with physicians in making decisions about their own healthcare." These patients and clinicians are a part of four urban safety net practices in Buffalo, NY. Three of these practices serve urban, mostly low-income African

American populations and the other serves mostly Latinos (28%) and refugees from 70 countries. The PVN developed as part of a National Institute of Minority Health and Health Disparities-funded project (R24MD004936) focused on improving cancer screening rates. Subsequently they have identified additional initiatives of importance to them. Often times their research questions are derived from their personal stories of challenges they face in managing their chronic disease and navigating the health care system. Recent projects have included development of a diabetes education curriculum for patients, and improvement of breast cancer awareness and screening initiatives. They are beginning a prostate cancer awareness project based on their priority to engage men in health care. They have also developed an appointment planning worksheet to improve the communication between patients and clinicians and assist in shared decision-making and goal setting. During the University of Buffalo's Family Medicine Residency Program orientation, patients from the PVN share their best and worst experiences with doctor-patient communication and model their communication preferences. The PVN intends to continue its efforts by recruiting new members and sites, developing new leadership opportunities and engaging in new projects. The diverse agenda of this endeavor highlights the type of "expert" patients that are required for work in primary care collaborations.

Upstate New York Practice-Based Research Network (UNYNet): UNYNet was established by the Department of Family Medicine at the State University of New York at Buffalo in 1998. It is a mature regional network with over 60 practices consisting of more than 200 clinicians serving a population of approximately 300,000 patients in eight counties in Western New York. Member practices are 32% rural, 35% urban, and 33% suburban. Their patients are 58% white, 38% non-white, and 4% Hispanic. UNYNet has completed over 30 projects and resulting in more than 60 peer reviewed publications. It has collaborated locally with a community collaborative and the Roswell Park national comprehensive cancer center. It is integral to Roswell Park's Center for Reduction of Cancer Disparities. It has also participated in several multi-network studies with regional networks. Funding has come from the NIH, the Office of the National Coordinator for Health Information Technology, AHRQ, the National Kidney Foundation, the Robert Wood Johnson Foundation, the New York State Health Foundation, the Susan G. Komen Foundation, and the New York State Department of Health.

Pathways to a Healthy Stephens County: In response to concerns about the health of Stephens County, the Stephens County Health Department and Duncan Regional Hospital partnered to lead an initiative focused on understanding and improving local health. Using the MAPP process developed by the National Association of City County Health Officials (NACCHO), the two organizations gained participation from local leaders, businesses, community organizations and residents. The resulting Stephens County Community Health Assessment provides a comprehensive look at current local health issues and lays the foundation for further development of the Community Health Improvement Plan (CHIP). Through the assessment process, the following four areas have been identified as priorities for health improvement initiatives: 1) healthy living; 2) mental health and substance abuse, safety/ injury prevention, and cancer. Community participation has been vital throughout the assessment process. By developing a shared vision and creating dialogue about health concerns, citizens and local partners gained a sense of responsibility for the future of Stephens County.

The Oklahoma Physicians Resource/Research Network (OKPRN): OKPRN is another mature regional primary care practice-based research network. Its 247 member clinicians, representing 139 practices, care for approximately 10% of the state's citizens. Founded in 1994 by Dr. Mold, it is now an independent 501(c)(3) non-profit organization, but most of the research is still directed by researchers at the University of Oklahoma Health Sciences Center (OUHSC). Half of the practices are rural. Member patient populations are 54% white, 33% non-white, and 13% Hispanic. Research conducted in the network has addressed common symptoms and health conditions (clinical research), administrative challenges encountered in primary care (process of care research), and ways to help primary care clinicians implement evidence-based practices. This work has attracted funding from more than 30 different sources and has resulted in more than 75 peer-reviewed publications. The network has established a highly valued listserv and website, an automated fax delivery system, tele-video connectivity, a group of practice facilitators/research assistants who work closely with

geographic clusters of practices over time, two network-wide meetings per year, and two newsletters per year. In addition, the network Director visits member practices frequently.

Latino Health Access (LHA): LHA is an award-winning, non-profit, 501c3 organization in Santa Ana, California created to assist with the multiple health needs of Latinos in Orange County and specifically the 92701 zip code. Sixty thousand people live in this area. The majority are immigrants from Latin America, and 95% are at poverty level or below. Founded by Dr. America Bracho in 1993, LHA's mission is to promote healthy living and disease prevention through empowering people to become owners of their own health. LHA programs rely on the Promotores model. Promotores de Salud are highly trained community health workers. They are recruited and hired from the communities where they live. LHA has been on the cutting edge of the Promotores movement for the past ten years and assists other groups across the nation develop Promotores' programs by offering a two-day, Basic Promotores Training. Nearly all of their programs have been in response to requests from community members.

Los Angeles Practice-Based Research Network (LA NET): LA NET is a non-profit, community-based PBRN focused on health disparities reduction. Established in 2002, it is governed by a Board made up of community physicians, nurses, and representatives from payer groups, local universities and concerned citizens. LA NET consists of 22 Community Health Centers and Federally Qualified Health Centers in L.A. County representing 116 unique practice sites, serving 500,000 patients, and providing more than 1,250,000 patient visits a year. Ninety percent of patients cared for at the practices are low-income; 80% of the patients are Latino, 10% are African American, 5% are Asian and Pacific Islanders, and 5% are other.

Core Research Team (CRT), National Advisory Council (NAC), and Other Participants

The CRT will consist of one representative from each of the participant groups plus four academic researchers (Tumiel-Berhalter, Mold, Norton, and Knox). The NAC will include all members of the Boards of Directors, Steering Committees, and Advisory Boards of the participant groups plus the four researchers and two consultants (Oakley and Hamm). All decisions about research methods and dissemination developed by the CRT will require final approval by the NAC. All members of the NAC will be invited to participate in the project as research participants. Other members of the participant groups may participate in the project if approved by their Board or Steering Committee.

Aim #1: With input from exemplary PABs, PAGs, CCs, and PBRNs, and the results of a comprehensive horizon scan and key informant interviews, produce a Guide to the research community for the organizations and a Guide to the organizations for researchers including registries, purposes, processes, membership characteristics, and conferences.

The CRT will develop a proposed set of characteristics by which to describe the types of patient- and community-based organizations involved in this study and academic researchers (e.g. what they tend to be called, where/how to locate them, why they exist, how they function, etc.). The CRT will also develop a plan for how to find information about these organizations and individuals. These categories and potential sources of information will be reviewed by the NAC, which will make additional suggestions.

Based upon this input, a horizon scan will be conducted in which information is sought from published literature, the internet, key informants, and other sources suggested by the groups (Amanatidou et al., 2012; Sutherland & Woodroof, 2009). A member of the CRT will prepare a summary of the information obtained, and the group representative to the CRT will present it to members of the organization for review and suggestions. Once all groups are satisfied with the descriptions, they will be put together into two Guides, one for use by the various organizations and one for researchers and PCORI. Drafts of the Guide will be reviewed by the NAC and the final versions will only be released upon their approval.

Production of the Guides will not only be helpful to the organizations and the research community, they will help the members of our CRT and NAC become closer and more effective in carrying out Aims 2 and 3.

Aim #2: Using several qualitative techniques, help participant organizations describe the effective methods they have used to engage with researchers, identify limitations and opportunities to enhance engagement in these settings, and speculate on ways to improve engagement methods. Summarize the results for each organization, for researchers, and for PCORI.

We will use appreciative inquiry (AI) and concept mapping approaches to systematically identify approaches used by our participant organizations to engage with researchers. Concept mapping is a process that helps individuals or groups to create a visual picture of concepts and processes currently in place. It results in a picture or map of what the group already knows about a particular topic and/or what they are currently doing. It therefore creates a starting place for further thinking, learning, and development. Dr. Oakley, a consultant to our research team, is skilled in this technique, which he will teach to the other members of the team, who will use it to address Aims 1 and 2. [The process involves brainstorming important topics, sorting topics according to theme, and ranking them in terms of importance or priority (Lanzing, 1997). Concept Systems Global Max software will be used to assist with analysis of the process (Concepts Systems, 2014). Using this software allows comparison of ranking between research and community members and between the four community groups participating. This helps to build consensus due to the visualization of shared priorities (Brennan, Brownson, Kelly, Ivey, & Leviton, 2012; Chiauzzi, Trudeau, Zacharoff, & Bond, 2011; Manafo, Petermann, Lobb, Keen, & Kerner, 2011).

After the CRT and NAC have agreed upon the specific approaches and logistics, members of each group will be invited to participate separately in their own settings. Participants will include group members of the NAC any other members of the organizations who wish to and are approved by their organization's governing body. We estimate that between 5 and 20 individuals will participate from each group and that the session will last approximately 4 hours. The sessions will be facilitated by the group's CRT representative, one other CRT member and Mr. Oakley. Participants will be asked to contribute written responses to a trigger question (e.g. "What is working in your current process of engaging researchers to build a research agenda around a community priority?") Each session will be audiotaped and transcribed. Narratives will be analyzed for content and theme and findings will be shared with participants.

A *Concept Map* will be generated based upon clustering input provided by initial forum participants. Bi-directional scaling and cluster analyses will suggest clustering for consideration by the group (each cluster a potential global objectives) as a potential element of engagement with researchers to design and implement a research project. Data rating analysis will be used to further suggest that generalized issues and activities surrounding specific clusters targeted as most important, or as possessing highest priority at that point in time. The Concept Map will also indicate the collective priority given to each cluster by the participant group and will also visually represent it the items found within each cluster bridge (tie together) as well. Thus the analysis will indicate if cluster may well represent a catch-all grouping compared to a grouping containing items of individual importance. The concept map will also visually suggest if the items within each of these clusters relate well to one another and if they are simply viewed by the group as actions/issues that can wait when compared to actions/ issues grouped elsewhere.

Spatial Relationships Analysis: A review of spatial associations within the map (positioning and distances among clusters) may suggests interesting and perhaps noteworthy perceptions likely held by the group as a whole, such as clusters that link or associate with one another around central issues, even though they may be low priorities at present. These latter clusters may well serve as new bridges *or barriers* to buy-in once research takes shape. The analysis may also identify issues and/or actions involving a cluster that presently stand separate and distinct from the group's thinking in all other areas. Should such disassociation persist this type of cluster may become a hand-off issue.

Sub-Group Comparisons: A Participant Profile Table will provide sub-group breakout information along critical dimensions. Employing these dimensions as sort variables, either singularly or in combination, input offered by sub-groups of the whole will be separated out for comparison against other sub-groups and/or against the group as a whole. In an attempt to thoroughly assess the nature and degree of consensus among the highly diversified stakeholders participating in this project, multiple comparisons will be formulated and reviewed. The *Concept Systems* utility function known as Pattern Matching was employed for this purpose.

Once we have completed the concept mapping process, participants will be convened a second time to define a set of principles and design a process based on the results of the modified Q-sort aimed at helping community partners more effectively understand, communicate and engage with academic researchers around their research priorities. A Q-sort is a data collection procedure which can be used to elicit and evaluate an individual's, or group of individuals', viewpoints about a particular topic. Originally developed as part of the Q methodology, Q-sorts are used to access and evaluate individuals' latent thinking and decision-making process. There are four steps in conducting a Q-sort. First, a heterogeneous set of items related to the topic of study are identified and printed on individual cards. Next participants, individually or as a group, are asked to rank order the items according a specified set of conditions. Participants do this according to their own subjective likes, dislikes and decision-making processes. Finally, participants are asked to "think-out-loud" and provide a narrative for their ranking of each item. The purpose of the narratives is to elicit the decision-making processes and reasoning underlying participants' ordering of the stimulus cards. Data are then analyzed using both quantitative (correlation, factor analysis) and qualitative methods (content, theme, process). These discussions will be stimulated by the results of the concept maps and by input from the CRT based upon analysis of the transcribed audiotapes from all of the initial sessions.

We anticipate that the structure, format, and some of the content of the reports developed from this information will need to be different for the different audiences.(Frenk, 1992) Preparation will proceed as described in Aim 1 with iterative reviews by group members of materials produced by the CRT as described above. We project that at least three reports will be generated.

Aim #3: Help the same groups identify current prioritization methods, evaluate and discuss conceptual VOI as a way to improve those methods, and combine ideas and suggestions into a set of proposed principles and techniques for improving prioritization methods. Summarize the results for each organization, for researchers, and for PCORI.

Prioritization is important for all organizations with resource limitations. The prioritization processes used by patient stakeholder groups engaged with researchers have been studied by the AHRQ (O'Haire et al., 2011), and PCORI has reviewed that information and explored ways to support such groups in research topic prioritization (PCORI, 2013a, 2013b). Analogous prioritization procedures have been developed for other scientific fields (Sutherland & Woodroof, 2009).

Prioritization functions both as a political process and an exercise in rational decision-making. As a political process, it facilitates participation by representatives of the affected groups in the discussion and decision-making, and provides legitimacy for the agreed-upon priorities and the actions upon which they are based. As a methodology for rational decision-making, prioritization starts with the issues important to people and the ways that the available options address those issues, considers how many people are affected, estimates the likelihood of outcomes and the impact of the outcomes on patients, and estimates costs. Then it seeks to anticipate how an intervention or interventions would affect the uncertainties in any or all of those estimates, and how much it would cost to reduce that uncertainty if the intervention was selected.

Stakeholder participants in a prioritization process may be requested to make holistic judgments of entities (such as research topics), or to make decomposed judgments (such as of the quality of an outcome state that may follow from a treatment). Holistic judgments of research topics may be expressed using ratings, rankings, or voting (O'Haire et al., 2011). Decomposed judgments are guided by particular decision models. One form of these is a multi-attribute value model, used by PCORI in some 2012 and 2013 prioritization exercises (PCORI, 2013a, 2013b) in which participants made subjective judgments of how research topics fulfil different criteria (PCORI's 5 criteria: patient centeredness, burden of disease, and so on), and then the criterion judgments are combined into an overall score, weighting the criteria according to the participants' judgments of their relative importance. There are a variety of multi-attribute value models available (Dyer, 1990; Edwards, 1977; Edwards & Barron, 1994; Forman & Gass, 2001; Lancsar & Louviere, 2008; Saaty, 1990). While such a procedure encourages participants to consider the research topics from multiple perspectives, it does not embody the most realistic modeling of what happens in disease over time and of how treatments affect outcomes, and hence could be viewed more as a careful political prioritization process, than as a rational prioritization process.

Arguably the most comprehensive rational framework for guiding prioritization of research projects is Value of Information (VOI) analysis, which summarizes current knowledge relevant to the comparison of the effects of various treatments upon the outcomes important to patients, and estimates how research could affect this knowledge and possibly change the preferred treatment and the attendant benefits to patients. A VOI analysis provides a perspective on what the prioritization process should address: 1) what kinds of improved knowledge could be produced about the treatments or services being compared, 2) how much time and resources would be required to produce the improved knowledge, 3) what difference the improved knowledge could produce, in terms of physicians using it to make best choices for patients which would be different from the choices currently made; 4) how many patients would be affected, 5) how much each affected patient would be helped; 6) how likely it is that physicians would change their practice patterns based on the research, 7) how long it would take to disseminate the research results to them; and 8) how long the research results would be expected to be useful before being supplanted by subsequent developments.

Although the statistical methodology and decision analytical modeling techniques of VOI analysis (Basu & Meltzer, 2007; Fleurence & Meltzer, 2013; Meltzer, 2001) represent technological rationality, they are very difficult for non-analysts to understand, let alone to participate in. However, it has been proposed that a "Conceptual VOI" could serve as a structure for the stakeholder prioritization process (Meltzer et al., 2011; Wald et al., 2014). A Conceptual VOI could address the same questions that a statistical VOI addresses, structuring the relations among these concepts with their appropriate dependencies, yet using the participants' subjective judgments to produce the estimated parameters governing those dependencies. Insofar as patient representatives' understanding may be considered more relevant to some parts of the model (e.g., relative importance of different symptoms or disabilities to patients' current quality of life) than others (e.g., cost of treatment, expected reduction in uncertainty that a research program may produce), different parties may be assigned to estimate different parameters, or their estimates may be given different weights.

However, rational decision modeling approaches to research topic prioritization are more complicated and time-consuming than those that require holistic judgments, and they are harder for patients and non-statistician researchers to understand. Hence although they may produce better guidance in the sense of assigning higher priorities to those research topics that are more likely to improve the lives of many patients, they may be less successful as a political process for engaging patients and stakeholders in producing research topic priorities with acceptable legitimacy.

Our approach is not to impose one or another methodology upon the groups, but to observe their prioritization processes, to suggest incremental improvements to the process, and to offer assistance in implementing and evaluating those enhancements. Because of the many possible variants of prioritization, groups that engage in prioritizing their goals or projects often invent their processes as needed. The design of the process and the methods used might be coherent and the combination procedures accurately carried out, or they might be vulnerable to errors of various sorts. The process may be conducted in one stage or several. The participants might make judgments together by consensus, or make separate judgments or ratings and combine them with a procedure such as vote counting or averaging. The judgments might be holistic, about the possible courses of action (e.g., research topics), or they might be about components of the situation which would then be combined into an overall ordering using a general model.

Prioritization procedures developed ad hoc may have shortcomings. If the task is not clearly and uniformly understood by the participants in the process, there could be inconsistencies between what different individuals mean by their ratings. If the process does not recognize the relevance of all aspects of the situation, it will be incomplete although the participants may not realize this. The descriptions of competing options may have different amounts of detail or may include aspects that cannot be directly compared with one another. The process of combining different people's judgments may inadvertently introduce error. The process of integrating component judgments into overall assessments may not be carried out in a manner that preserves the meaning of the individual components. The process of interpreting the prioritization to end users can introduce errors, due to failures to explain the criteria that guided the prioritization, confusing the group itself or those with whom the group interacts. Finally, prioritization exercises suffer unavoidably from lack of feedback, in that when the group devotes effort to top priority projects, there will be information about the success of

those projects, but there will be no information about the success that would have happened if the same effort had been allocated to lower priority projects.

We will use concept mapping to help each of the participant groups characterize their current prioritization processes. Aside from a different trigger question(s) which will be determined by the CRT with NAC approval, the method will be identical to the one described above under Aim 2. This will be supplemented with the prioritization consultant's (Hamm) assessment of the process with respect to general principles of prioritization and the results of the analysis of content of the transcribed discussions of the initial sessions.

With guidance from Dr. Hamm, we will then introduce conceptual VOI as a way to generate discussion ways to improve each group's prioritization methods. Based on the group's and the consultant's assessments, candidate methods to improve the group's prioritization process will be identified and discussed with the group's liaison and then with the group. These suggestions will be tailored to the particular process the group uses and the types of entity that the group prioritizes.

If a group is willing to undertake a change in its prioritization process, the consultant will provide support to the group, training the group's prioritization process liaison person to provide an understanding of the reasons justifying the suggested improved methods, and the knowledge how to apply them, so that this person can guide the group in the application of the methods. The consultant will provide checks on the measurement and integration processes, if a process that requires them should be adopted.

It is anticipated that a toolbox of aids for the group prioritization processes will be developed that will include principles, techniques, exercises, tools, and computer (Excel) decision aids, which will be 1) coherent with respect to the concepts of VOI or of multi-attribute value assessment, 2) flexible and expandable, so they can be applied to what each group is interested in pursuing, 3) include materials, methodology and tools for making each of the concepts accessible, understandable, and usable for non-researchers and non-decision-analysts, and 4) have several ways to provide the methods to groups. Additionally reported will be a collection of acceptable methods for engaging groups with the prioritization ideas, letting them control the pace, the size of the amount they learn, whether they all learn it at once or they have a representative.

We again anticipate that the reports developed from this information will need to be different for the different audiences (Frenk, 1992). Preparation of these summaries will again proceed as described in Aim 1 with iterative reviews by group members of materials produced by the CRT as described above.

D. Project Milestones and Timeline

Iterative Development/Analysis Process

The following sequence of steps will be repeated in each of the participant organizations for each Aim, with the exception that Step 6 only applies to Aim 1, and Steps 7 - 17 only apply to Aims 2 and 3:

1) The CRT will meet by phone or videoconference to review the Aim and discuss proposed methods. Plans and assignments will be made for developing further specifications of methods based upon core team input.
2) The CRT will meet again by phone or videoconference to review the refined methods. Plans will be made for vetting the methods in each of the groups making up the NAC.
3) The group representative on the CRT with support from a methodological expert will present the proposed methods to the group and get their feedback and suggestions.
4) The CRT will meet to review feedback from the groups and determine what changes to make in the specific methods. The previously assigned subgroup will be tasked with making those changes.
5) The final methods will be sent to members of the CRT and then to the NAC to obtain final input/approval.
6) A member of the CRT will prepare a summary of the information obtained, and the group representative to the CRT will present it to members of the organization for review and suggestions.
7) The group's CRT representative, another CRT member, and the methodological expert will meet in person with the group and employ the agreed upon methods to obtain qualitative data. These sessions will be audiotaped and transcribed.
8) The concept analyses will be completed and sent to the CRT for review.
9) Copies of the transcribed tapes will be provided to all members of the core team for review and coding.

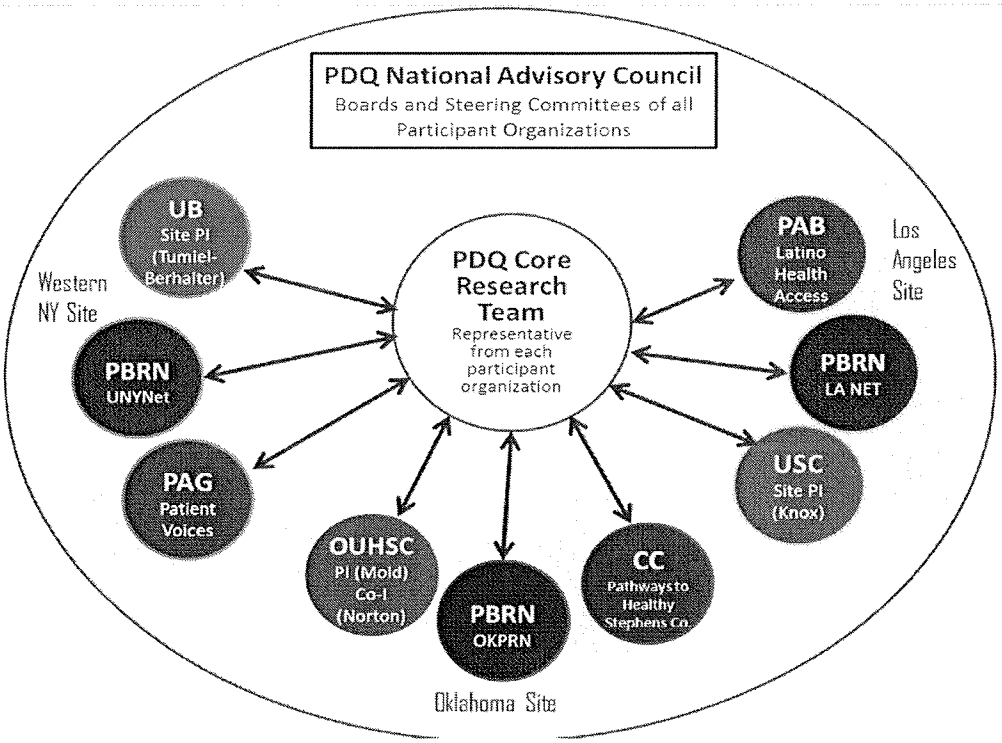
10) The CRT will meet by phone to review the results of the concept mapping, reach consensus on the transcription themes, and develop specific methods for the second set of group discussions. Plans and assignments will be made for developing further specifications of methods based upon core team input.
11) The CRT will meet again by phone or videoconference to review the refined methods. Plans will be made for vetting the methods in each of the groups making up the NAC.
12) The representative from the group on the CRT with support from a methodological content expert will present the proposed methods to the group and get their feedback and suggestions.
13) The CRT will meet to review feedback from the groups and determine what changes to make in the specific methods. The previously assigned subgroup will be tasked with making those changes.
14) The final methods will be sent to members of the CRT and then to the larger research team by the group representatives to obtain final approval or additional suggestions.
15) The group's CRT representative, another member of the CRT, and the methodological expert will meet in person with the group and employ the agreed upon methods to obtain qualitative data. These sessions will be audiotaped and transcribed.
16) The concept analyses will be completed and sent to the CRT for review.
17) Copies of the transcribed tapes will be provided to all members of the core team for review and coding.
18) The CRT will then meet in person in Oklahoma City to review and attempt to reach consensus on themes, generate additional questions, and propose a format and sections for the specified reports.
19) The proposed themes and report format and sections will be sent to the NAC by the group representatives to obtain final approval or additional suggestions.
20) The CRT will meet by phone or videoconferencing to review suggestions and make writing assignments.
21) Assigned authors will produce draft reports, which will be distributed initially to the CRT and then to the NAC by the group representatives to obtain final approval or additional suggestions.
22) Final revisions of the reports will be made by the assigned authors and submitted to members of the NAC and to PCORI.

	2015				2016				2017			
Activity	Jan-Mar	Apr-June	July-Sept	Oct-Dec	Jan-Mar	Apr-June	July-Sept	Oct-Dec	Jan-Mar	Apr-June	July-Sept	Oct-Dec
Contractual Agreements	X											
IRB Approvals	X											
Scheduling	X											
Equipment/ Software Purchases	X											
Aim #1												
Step 1		X										
Step 2		X										
Step 3		X										
Step 4		X										
Step 5		X										
Step 6			X									
Step 20			X									
Step 21			X									
Step 22			X									
Aim #2												
Step 1				X								
Step 2				X								
Step 3				X								

Step 4				X								
Step 5				X								
Step 7					X							
Step 8					X							
Step 9					X							
Step 10					X							
Step 11					X							
Step 12					X							
Step 13					X							
Step 14					X							
Step 15						X						
Step 16						X						
Step 17						X						
Step 18						X						
Step 19						X						
Step 20						X						
Step 21							X					
Step 22							X					
Aim #3												
Step 1								X				
Step 2								X				
Step 3								X				
Step 4								X				
Step 5								X				
Step 7									X			
Step 8									X			
Step 9									X			
Step 10									X			
Step 11									X			
Step 12									X			
Step 13									X			
Step 14									X			
Step 15										X		
Step 16										X		
Step 17										X		
Step 18										X		
Step 19										X		
Step 20										X		
Step 21											X	
Step 22											X	
Manuscript Prep												X
Final Reports/Wrap-Up												X

E. Research Team and Environment

(See also under Section C, Context and Settings)



Oklahoma

James Mold, MD, MPH, PI on this project, is a George Lynn Cross Research Professor and Research Division Director in the DFPM and the Co-Director of the Community Engagement Key Component Activity for the Oklahoma Clinical and Translational Science Institute. He is regarded as a national expert in the fields of primary care practice-based research and implementation research. He founded OKPRN in 1994 and serves on its BOD. He now directs the development of the Oklahoma Primary Healthcare Extension System, which is built upon community coalitions.

Barbara Norton, DrPH, the Project Manager for this project, is an Assistant Professor of Research, presently working to develop a community-based program of cancer control research within the state's new academic cancer center while also serving an active research team member in Family Medicine for projects requiring patient or community engagement expertise.

Haylee Root, BA is a member of the Board of Directors of Pathways to a Healthy Stephens County. She is Director of Community and Public Relations for Duncan Regional Hospital. Her responsibilities include working with physicians and other health care partners and handling public relations for the facility and its patients.

Margaret Enright, MPH, CDE, CPHQ works as a quality improvement coordinator for the Oklahoma Foundation for Medical Quality and is a member of the BOD of OKPRN. She is a certified diabetes educator.

Robert Hamm, PhD is a Professor in the OU-DFPM and an expert in judgment and decision-making. He will serve as a consultant on this project, assisting the participant groups to assess and improve their prioritization processes..

New York

Laurene Tumiel-Berhalter, PhD is an Associate Professor in the Department of Family Medicine with a secondary appointment in the Department of Epidemiology and Environmental Health in the School of Public

Health and Health Professions. She serves as the Director of Community Translational Research in Family Medicine and serves and the Director of Community Engaged Research in the Buffalo Clinical and Translational Research Center. Her research is embedded in the UNYNET and Patient Voices Network.
Pamela Harold is founding member of the Patient Voices Network. She serves as a co-PI on grants funded by NIMHD and the WNY Affiliate of Susan G. Komen. She was one of the first Patient Ambassadors and works closely with 2 practices to implement diabetes and mammography screening projects.
Ranjit Singh, MD, MBA, the Vice Chair of Research in Family Medicine, is a family physician researcher who is expert in practice based research. He serves on the UNYNET Steering committee and has a particular interest in research to increase patient safety.
Ken Oakley Is the Chief Executive Office of the Lake Plains, Community Care Network and the NYS Rural Area Health Education Center. He has over 20 years of experience facilitating concept mapping, particularly with community coalitions with diverse stakeholders.

California
Lyndee Knox, PhD is the Chief Executive Officer of LA NET. Prior to her current position she was a faculty member in the Department of Family Medicine at the University of Southern California. She has expertise in both qualitative and quantitative research methods with a focus on health disparities.
Gloria Giraldo, DrPH is the Programs Director for Latino Health Access in Santa Ana, California and, in that role, is responsible for program planning, implementation, and results-based management to ensure sustainability. She is responsible for training community health workers across 5 states.
Vanessa Nguyen, MPH is Assistant Director of LA NET, serving as Project Coordinator on a number of network initiatives. Prior to that, she was a practice facilitator, working within safety net practices to help them to improve their quality of care.

All members of the CRT have worked with at least one other member of the team outside of their group, and several of us have collaborated with more than one other participant group. For example, Dr. Tumiel-Berhalter works closely with the PVN and with all three PBRNs. Ms. Harold is a member of the PVN and works closely with researchers at SUNY Buffalo. Dr. Knox works closely with LHA and with all three PBRNs. Dr. Mold works closely with the Pathways to a Healthy Stephens County and with all three PBRNs.

All members of the CRT have unique and complementary skills and experience as shown in the table.

	CBPR	Qualitative Methods	Dissemination	PABs	PAGs	CCs	PBRNs
Oklahoma							
Mold	X	Horizon scans, Qualitative analysis	X			X	X
Norton	X	Qualitative analysis				X	
Hamm		VOI					
Root		MAPP	X			X	
Enright		MAPP		X			X
New York							
Tumiel-Berhalter	X			X			
Oakley		Concept mapping				X	
Harold				X			
Singh							X
California							
Knox	X	Q-Sort, Qualitative analysis	X	X	X		X
Giraldo			X		X		
Nguyen					X		X

F. Engagement Plan

Patient and Stakeholder Engagement

The conceptual basis for the project is that, for existing patient- and community-based organizations, engagement with the research community is what is needed to impact patient-centered outcomes research, and that for engagement to be meaningful it should be sustained. This patient/stakeholder-centric perspective is contrasted with engagement of patients by researchers in order to obtain input on research methods for specific disease- or treatment-focused projects.

Our CRT will include representatives of the governing boards or steering committees of the PVN, UNYNet, Pathways to a Healthy Stephens County, OKPRN, LHA, and LA NET, in addition to four academic researchers from the OUHSC, SUNY-Buffalo, and LA NET. The Advisory Council will include the full boards and steering committees of the participant organizations, the academic researchers and the two consultants. All groups have agreed to participate in this project (see letters of support). These groups were selected due to existing relationships with academic researchers with varying degrees of research-centric and patient-centered approaches to developing research questions and implementing corresponding projects. The three PBRN's have experience working together through CoCoNet2, which is a network of seven practice-based research networks. This is the first time the PBRN's and community-based groups have come together with their research partners to evaluate their approaches to collaboration. Funding for this project will be shared equitably across all participating individuals and organizations. All participants are respected as experts. Power differentials among participants will be acknowledged and sensitively addressed.

The CRT and NAC will review and approve protocols, data collection methods, findings, analyses, and reports prior to their implementation or completion. The CRT will periodically assess the participation experience of members of the larger team and attend to their concerns. Participants will be appropriately acknowledged as contributors, collaborators, authors, and/or coauthors when appropriate. The CRT representatives will be responsible for bidirectional communications between the CRT and their organizations' governance boards.

By its nature, participatory design and processes work to ensure that the ideas, preferences, and concerns of patients and other stakeholders are incorporated and that the end products meet their needs (Israel, 2005). But for us, this is simply a starting point. Engagement is integral to this study because it is itself a study of engaged organizations and the processes they employ.

Researchers are engaged with individuals of various races, ethnicities, geographies (urban, suburban, and rural dwellers in several parts of the country (inner city Buffalo, NY; suburban Los Angeles County, CA; and rural Stephens County, OK) giving the project the opportunity to build capacity in medically-underserved communities and among people with multiple coexisting conditions. Both men and women will be represented in each of these groups. The PAB, PAG, and CC all have significant experience in the areas of investigation. The researchers and consultant add specific expertise in research methods (qualitative research methods, community-based participatory research, practice-based research, concept mapping, and judgment and decision-making.

We will reach the hard-to-reach by engaging community groups whose very purpose is to reach out to these populations. They have achieved the critical work in building trust and respect and have laid the essential pre-engagement groundwork. Patients will be well-represented by members of the Patient Voices Network, patient advocates by members of the Latino Health Alliance, community stakeholders by members of the Pathways to a Healthy Stephens County, and primary care clinicians by members of the PBRNs. This type of partnership between patients, key stakeholder groups, and the research team will be based on mutual respect, partnership, trust, transparency, and honesty, building upon the foundation of mutuality and respect that has characterized the prior community-research partnerships in each of these patient-engaged groups.

For example, the Patient Voices Network has worked with the University at Buffalo for 4 years. The relationship started as a research-centric collaboration and has evolved to a patient-centered research agenda. The research team serves as a technical advisor to the PVN. The PVN have created a role of Patient

Ambassadors who reach out to other patients and members of the community. The roles of the Patient Ambassadors vary but include: scheduling patients for diabetes classes; scheduling patients for on-site mammography; hosting the on-site mammography days by registering patients; escorting them onto the mobile mammography unit; and providing health education. They also interview patients as part of research projects and co-facilitate focus groups. These patients are CITI trained.

Each learning cluster of patients and advocates, clinicians, and researchers will provide evidence about what works in the context of their unique setting, populations, community norms, practice culture and history, and available resources. Patients will be given feedback about their questions/concerns throughout the process and allowed the opportunity to provide feedback on the progress/transformation of their initial question into the researchable questions. There will be plenty of opportunity for co-learning and the entire process is designed to be transparent to all parties.

The population of interest is identified by existing relationships with primary care PABs, PAGs, and CCs. They are generating the questions/concerns that will be the basis for formulating the researchable questions, and they are therefore engaged from the beginning of the study and will receive periodic updates regarding the progress of the project. Representatives of each group will be members of the CRT and will participate in strategic project planning and decision-making. Each representative will provide leadership for its group and will be responsible for bidirectional communication between their group and the CRT. The board/steering committee members of each group will participate as members of the National Advisory Council by providing advice on reach design, data collection, interpretation of findings and report generation. They will also serve as research participants by participating in key informant interviews and other qualitative techniques employed in this project. Shared leadership on the CRT is essential to ensure co-learning. We need to understand the barriers faced by community partners in reaching out to academic researchers.

The governing boards/steering committees of each participating group will play a pivotal role in the dissemination of research findings. We know that a single report will not meet the needs of all of our audiences. It is critical that we have versions that address the nuances of each group. Our community partners will not only play a role in the preparation of these reports but also in dissemination strategies to get the word out to larger groups and encourage more community groups to engage researchers. Members of the CRT will be reimbursed according to the needs of the community. For example, in some communities a stipend might be preferred, whereas in underserved communities, members might prefer gift cards that do not interfere with the receipt of benefits. Regardless of type of compensation, members of the CRT, governing boards, and other community participants will be compensated for their efforts on the project.

Meetings will be held in community settings convenient for community partners at times convenient for the community members, which may include evenings and weekends. The CRT will be conscientious of variation in health/research literacy and will refrain from using technical jargon. Dr. Mold, as facilitator, will make sure that everyone's voice is heard and that ground rules, founded on mutual respect, are followed. He will pay special attention to potential for intimidation and power dynamics that are certain to arise.

There may be predisposing factors for patients and other community stakeholders to participate in such projects, making them atypical of the greater patient population in terms of demographic, social and health status characteristics, in addition to beliefs and attitudes. There may also be enabling characteristics that make participation in the project feasible such as personal, family and community resources. A member of the Buffalo team, who is familiar with the project but not intimately involved, will conduct periodic interviews with CRT members to assess their satisfaction with the process. This information will be used to inform the process and interaction.

Our goal is to create a dynamic collaboration that builds on the strengths of community members and researchers. We will develop methods that will build capacity in the community and facilitate open communication between partners to conduct patient-centered outcomes research.

DISSEMINATION AND IMPLEMENTATION POTENTIAL

Our research team is committed to publicly sharing and disseminating knowledge and resources we produce from the study, consistent with PCORI's priority on rapid dissemination.
The DFPM at the OUHSC in collaboration with OKPRN has focused much of its research over the past 15 years on ways to disseminate and implement evidence-based practices in primary care. In-network dissemination and implementation methods have included an active listserv and website (www.okprn.org), a newsletter, performance assessments and feedback, elucidation and dissemination of best indigenous practices, academic detailing visits, practice facilitation, and local learning collaboratives. This work has contributed to recent efforts to develop a national primary care extension system. That system in Oklahoma involves county health improvement organizations linked to each other and to a wide variety of resources through a state hub, the Public Health Institute of Oklahoma. This system offers us the opportunity to transmit information to multiple stakeholder groups across the state efficiently and to follow-up with implementation support when needed. UNYNet (www.fammed.buffalo.edu/unynet) and LA NET (www.LA NETpbrn.net) use very similar dissemination and implementation methods. All three networks belong to a meta-network called the Coordinated Coalition of Networks (CoCoNet2), which also has a website (www.coconet2.org). UNYNET is also a member of DARTNET, another meta-network of PBRNs (www.dartnet.info). They also have a newly established list serve to disseminate findings and best practices to its members. Dissemination of PBRN research results beyond the networks has been accomplished through peer-reviewed publications, national presentations, national listservs, webinars which collectively reach thousands of professionals and community stakeholders.

LA NET has a long standing commitment to bridging the gap between research and community practice by making the best evidence accessible and useable to community advocates. Since 2002, LA NET has helped produce numerous toolkits and 'how to manuals' aimed at putting research in the hands of community members, including a guide to youth violence prevention based on best evidence funded by the CDC and Robert Wood Johnson Foundation and published by the American Medical Association, a toolkit for Level 1 trauma centers and youth service programs on violent reinjury prevention, and publication of an edited volume through Praeger Press International, Beyond Suppression, written by community members working to prevent violence in locations around the world who are seeking to inform and influence policymakers in their regions and beyond.

The Patient Voices Network has participated in local and national presentations to share their work with various communities, including other researchers, policy makers, funding agencies, etc. The participating PVN practices have bulletin boards dedicated to PVN where we communicate project information directly back to the patients. The PVN has a website (www.fammed.buffalo.edu/patientvoices) where projects are highlighted.

Our combined capacity for implementation and expertise in effective knowledge dissemination will allow us to develop a comprehensive and effective dissemination plan for this project focused on the three primary stakeholder groups: 1) members of organizations similar to our participant organization partners, 2) researchers and PBRNs, and 3) PCORI and other funders. Separate reports will be prepared for each audience and the venues and methods of dissemination will be tailored based upon recommendations from our CRT and NAC.

Dissemination Goals

We have identified several dissemination goals, and will work with our community partners to identify additional goals:

1) Communicate findings and tools to improve methods and standards used by PCORI and other funders when asking investigators to engage with patient and other stakeholders in comparative effectiveness and other health research;

2) Communicate findings and tools to increase the capacity of patient, advocate and community coalition (PABs, PAGs, and CCs) groups to serve as engaged research partners and investigators in their own right in patient-centered outcomes research, and
3) Communicate findings and tools to enhance the activities and capacity of PBRNs to serve as engaged research partners with patients and other stakeholders in conducting patient-centered outcomes research.

Dissemination Plan

A comprehensive dissemination plan including, but not necessarily limited to the following, will be developed by the CRT in consultation with the NAC. The audiences will include:

Patient Advocacy Groups:

- Presentations: CCPH annual meeting, CTSA community Engagement Annual meeting
- Publications: *Progress in Community Health Partnerships: Research, Education, and Action*
- Reports: Community Toolbox, the Community-Based Participatory Research listserv

Community Coalitions

- Presentations: Oklahoma Turning Point Annual Meeting; state public health association meetings
- Publications: *American Journal of Public Health*; Scientific and Public Summary Reports
- Reports: CDC - Healthy People Section, State Departments of Health - State Health Improvement Plans Sections, National Network of Public Health Institutes (NNPHI)

Patient Advisory Boards, Primary Care Researchers, Practice-Based Research Networks, and Clinicians

- Presentations/Webinars: National Association of Community Health Centers Annual Meeting and webinar; North American Primary Care Research Group (NAPCRG) Annual PBRN Meeting and Annual Meeting
- Publications: *Journal of the American Board of Family Medicine; Family Practice Management; American Journal of Quality Improvement*
- Reports: AHRQ PBRN listserv, national primary care professional associations, Patient-Centered Primary Care Collaborative

PCORI and Other Funders

- Publications: Scientific and Public Summary Reports; contributions to the PCORI Methodology Report

REPRODUCIBILITY AND TRANSPARENCY OF RESEARCH

We support PCORI's mandate to expedite the translation of research results into knowledge, products, and procedures to improve human health and its commitment to facilitate the evaluation of evidence-based claims. Since 1994, the Department of Family Medicine at the University of Oklahoma Health Sciences Center has served as a primary clinical resource and knowledge disseminator within Oklahoma and nationally. Through the OKPRN network of 150+ primary care providers and community stakeholders, we have made available numerous large de-identified data sets, analyses, practice guides, and community implementation toolkits related to quality improvement in primary care and have published over 80 articles relevant to community practice. Our demonstrated capacity for implementation and expertise in effective data sharing will help us in collaborating with other community stakeholders and will facilitate the reproduction of findings and use of the toolkits.

Our research partners, The SUNY-Buffalo Department of Family Medicine, working with UNYNet and PVNs, and LA NET and the LHA, have also built their reputations on the transparency of research findings and research translation in collaboration with local and national partners. Through these collaborations each has demonstrated a commitment to producing work that is effective in different communities and practices. Working through Patient Voices in Buffalo and LHA as well as other patient and community groups in Los Angeles, UNYNet and LA NET have a local presence in the community based on mutual trust, openness, and respect where research collaborations begin prior to the initiation of a project and are not complete until the findings are shared and next steps identified.

It is with this experience that UNYNet has come to lead the University at Buffalo's community-based research core within the Buffalo Clinical and Translational Research Center (www.buffaloctrc.org). LA NET specializes in training practice facilitators to assist safety net practices to implement best evidence in their settings. It provides assistance in guideline adoption, care team formation and staff training, workflow redesign, and IT optimization to support adoption and long-term maintenance of best practices in minority health care. In addition, LA NET partners with community organizations such as LHA to develop interventions informed by community experience and best research evidence.

Reproducibility of Important Findings

Because we have explicitly sought to engage a wide variety of stakeholders and participant groups in this methods study, we anticipate that select findings will be generalizable to a wide variety of settings, however there will be findings that are specific to the various regions and cultures. Therefore, we will account for the unique features of each of the participant organizations and sites, which may requires tailoring for particular populations.

An increasing number of primary care practices or practice groups establish patient advisory groups to engage their patients in shaping the care they receive. Since the early 2000's, PBRNs have played a pivotal role in bringing community health stakeholders (patients, practices and local health organizations) and academic institutions together in order to bridge historic gaps and amplify the potential of collaborative relationships by creating a learning health care system. Local and regional health improvement organizations are developing rapidly. For example, in Oklahoma, county coalitions called Turning Point Partnerships and certified County Health Improvement Organizations (building blocks of the new primary healthcare extension system), provide a more systematic mechanism for individual patient and community clinician voices to be heard at a higher, but still local, level where targeted solutions and innovations can be delivered in the most efficacious and actionable manner.

We will take steps to help further advance the reproducibility of findings by reaching out to and consult with similar organizations nationally in each domain of translation to determine the similarities and potential differences and how our method can be adapted and implemented in those environments. Recommendations pertaining to national variations of implementation will become part of our project reports and toolkits that we will design at the end of our project. We anticipate submitting a larger intervention proposal to build

methodological capacities of community-engaged research engines in other communities and within more sites within our existing infrastructure. After our initial work we will expand through COCONET, a collaborative of six practice-based research networks throughout the country, so we can further expand the effectiveness of these approaches in various communities.

Data Sharing Plan

We are committed to data access, production transparency, and analytic transparency as essential elements of the research process and we have reviewed the evolving standards for qualitative data researchers, adopted by other fields (Moravcsik, 2014). We commit, within nine months of completion of the study, to directly provide to PCORI all collected research data either in aggregated or de-identified format. In support of PCORI's data-sharing goal, we will also make our data as widely and as freely available as possible, while safeguarding the privacy of individual participants and protecting confidential and proprietary data.

We take seriously our responsibility to avoid the exposure of study participants and our community partners, to potential injury or ridicule. Since qualitative data lends itself to rich descriptions of people, places, and organizations, it can be challenging to adequately de-identify the data and still preserve data interpretability. As a result, where qualitative data cannot be de-identified without distorting its usability, we will provide aggregated data. Consistent with the study's governance approach, representatives of all community partners will determine the best approach to de-identification of the data.

In addition, we will provide a report that details our complete study procedures, including a full description of the study populations, participant organizations, and study communities; the sources of data and methods used for analyzing engagement and prioritization strategies and techniques; the analysis products including qualitative data matrices, and the qualitative data codebook used for analyses.

Budgetary Needs for Data Sharing Plan

While we expect that there may be additional expenses associated with the de-identification a large qualitative data set, we are currently unable to provide a cost estimate.

PROTECTION OF HUMAN SUBJECTS

This study will be conducted in a manner consistent with the "Common Rule" (Department of Health and Human Services (HHS), 2009), but as a community-engaged study, it also incorporates principles advanced by the community-engaged research field (CARE: Community Alliance for Research and Engagement, 2009; Ross, 2010; Ross et al., 2010).

As a community-engaged methodological investigation of patient engagement and prioritization, this study will involve patients, community stakeholders, and members of practice-based research networks in dual roles: 1) as research partners in a collaborative research endeavor where their input is integral to project development, implementation, analysis, and dissemination and 2) as research participants or "subjects" – the sources of the research data, insights, and generalizable findings to be obtained through observation, interactions with researchers, and participation in a prioritization exercise (intervention). The community partners will bring to the study, in both of these roles, their perspectives, values, knowledge, and experiences essential to answering the questions being posed. Moreover, it should be noted that the study will engage with community partners on two levels – 1) as individuals who are members and designated representatives of a participant organization and 2) as organized community entities, each having its own identity and integrity as well as a collective history, knowledge base, and set of values related to health care issues and research. Because we will engage with community partners as individuals and as collectivities, we are attentive to human subjects considerations on both levels.

Organizational Research Partners

Memorandum of Agreements (MOUs). MOUs will be prepared with leadership from each of the participant organizations (PAB, PAG, and CC) and PBRNs that are participating in this study. These MOUs will serve as an expression of respect and partnership, as well as a commitment by the OUHSC Department of Family Medicine to equitably distribute research resources. The MOUs will include the purpose of the research partnership, the role and responsibilities of each party in the research partnership and study development, potential risks and protections against those risks, the resources to be provided, and the expected individual and community benefits resulting from research processes and findings. The MOU process will be initiated between researchers and the participant groups as soon as notice of funding is received. The PI will develop a basic template to be reviewed and approved by each participant organization. Once approved, the template will be appropriately completed and sent to the lead representative of each organization. Each lead representative will take it to a meeting of their organization to be approved by a vote of its members. As requested, the site PI will be present to start the process of open communication and answer any questions.

Core Research Team (CRT)

Individual community partners, chosen by their participant organization, will function as members of the CRT, and they will meet the same standard of training in human subjects protections as do academic researchers (i.e., completion of the university-mandated CITI training course and additional requirements). A curriculum was developed by the Buffalo team to assist community-based members of the research team, particularly those with low-literacy levels with limited computer access to complete all training modules. This is didactic in nature but provides a forum for trainees to discuss the challenges and implications of human subjects' research. We will also provide assistance for community-based research team members who need assistance navigating the computer based system.

Research Participants

Others, who are members of the PAB, PAG, CC, and PBRNs will participate as research partners as a function of their membership in the participant organizations. While it would be difficult for all of these individuals to complete a comprehensive human subjects' protections course, all will participate in a training

session on Human Subjects Protections in Community-Engaged Research (Ross et al., 2010). All individuals will be required to provide informed consent in order to participate.

Informed Consent with Individuals. Consistent with HHS guidance, we will consider informed consent to be an ongoing process, beginning with our first contact with CRT members and first meetings with participant organizations. Consent documents will be prepared in the language in which the participants are conversant. At present, it is expected that English and Spanish will be the two required languages. The consent documents will be presented to community partner CRT members by the site PI in that location at the time of the first CRT meeting. Similarly, the consent form for members of the participant organizations will be presented at their initial meeting in which data is collected about research engagement practices. Consent forms will be designed for participants to participate in a series of focus groups related to the research topic, and these may include surveys throughout the process. This will ensure that community partners consent once for the entire process rather than having to consent each time they participate. Consistent with PCORI's goals related to reproducibility and transparency, the consent forms will include a request for long-term storage of, and access to, de-identified study data. All consent forms will be signed and collected at the time of first contact. If an individual prefers to have additional time to consider their participation in the study or declines consent, an "open door" invitation will be made should the individual choose to later participate. Great care will be taken to communicate that study participation and consent is completely voluntary and that individuals may withdraw from participation at any time. All consent forms will be maintained by the site PIs in a locked file in a secure location during the study period. Following completion of the study, all consent forms will be maintained by the PI for a period of three years following the close of the study.

Because the project will engage members of underserved communities, it is expected that some participants will have backgrounds characterized by limited educational achievement. As a result, all materials developed for participant groups will be reviewed by the CRT for readability appropriate to the average educational achievement of community members. English is the language of all participant group members in the New York and Oklahoma sites, but in the case of the Los Angeles site, Spanish is the preferred language of the majority of patient advocacy group members. As a result, there will not only be a Spanish version of the consent form offered, there will also be a knowledgeable translator present to assist the site PI. Even at other sites, when consent is requested, it will be co-presented by the site PI and the leader(s) of each community partner organization to enhance communication and better ensure that consent is given voluntarily.

In order to adequately interpret our findings, it is it essential that we be able to describe each of the community partner groups. As a result, we will collect certain socio-demographic information from participants for aggregated descriptive statistical purposes. No other personal health information will be collected. The participants will be provided with the contact information for the Principal Investigators, and the Community Partner Organizations, as well as the University IRB, for questions and concerns regarding their participation. Unique identifiers will be used to link the participants with process and descriptive data. All data will be kept separately from participant identifiable information. The codes that link participants with the data will be kept in a locked filing cabinet under the direct supervision of the University PI and will be accessible to the community partners if necessary.

Certain meetings and prioritization exercises will be digitally audio-recorded, transcribed, and analyzed for common themes. In the transcriptions, individuals will not be identified by name or description, and the recordings will be destroyed once they have been transcribed.

Most importantly, the CRT, with ongoing input from the groups they represent, will establish mechanisms for safe, open and free communication between researchers and community partners.

Protecting the Privacy of Subjects and Confidentiality of Data. The study will involve a variety of public/private participant organizations. Because interpretation of the findings requires knowledge of the settings and types of community partners involved, it is not possible to assure privacy of the names of these organizations or the settings in which they function in the reporting and dissemination of findings. Similarly, due to the focus group approach to data collection, it is impossible to maintain confidentiality among the members of each group. This will be made explicit in signing MOUs with participant organizations. However, we will not reveal the name of any individual participating in this study, and all data shared with PCORI will be de-

identified to protect the identities of individual participants. All documents with personal identifying information (i.e., consent forms, demographic data, focus group participation lists, etc.), will be secured in a password-protected file, separate from other data collected for the study, on secure file server at the University of Oklahoma, and security provisions comply with HIPAA security regulations. Normal security includes the use of encryption on all exchanges of data that include individually identifiable patient data, administered individual accounts with password authentication as a minimum, physical security for hardware and physical records, and HIPAA compliance training for all personnel with access to patient health data. While the study will not collect individually identifiable patient data, we will adhere to these standards as they could apply to data derived from the participant groups. Documents with personally identifiable information will be destroyed within three years of the end of the study. We will stress the importance of maintaining confidentiality within the group and respecting the comments made by each individual.

Potential Risks of Proposed Research to Participants. Risks to individual participants are minimal in this study, and although certain socio-demographic information will be collected, it will not be linked to any particular individual. Some demographic information will be used to pay or remunerate participants. Consent forms will include an explanation of the remuneration process and how personal information will be used in compliance with pertinent university regulations. The participants of this research project will be patient advisory board members, patient advocates, community health coalition members – all of whom also represent primary care patients, and members of practice-based research networks who represent primary care clinicians and other community stakeholders committed to primary health care improvement. Because participation in the study requires a voluntary commitment of time, it does pose a potential loss of productivity and income, but steps have been taken to compensate participants at a level commensurate with anticipated time commitments.

Potential Benefits of Proposed Research to the Participants and Others. As previously mentioned, the participants will receive an incentive for their participation in the process. Participants will have firsthand knowledge of the research process and have an influence on identifying research questions that matter. They will have the opportunity to take leadership roles in the process and build skills and expertise to engage in community-engaged, patient-centered research on local and regional levels. Participants will meet others across the country that have similar experiences to them and will have the opportunity to network with providers and researchers.

Potential Risks/Benefits of Proposed Research to Participant Organizations and their Communities. Moreover, the study has considered potential risks and benefits to participant groups and the communities they represent. The MOUs with each participant group will delineate potential risks and benefits to participant organizations, based on pre-implementation discussions between the PI and each organization's governing boards. Risks are minimal since the study's activities are consistent with, and will be incorporated into, the normal functions of each organization. Potential benefits include enhanced access to resources and increased organizational capacity to engage in health research on a local and regional, and to contribute to the national health research agenda.

Resource Sharing Plan. We are committed to equitable sharing of resources. The PBRNs are being compensated at a lower overall rate than the other participant groups since fewer members will likely be involved compared to the PABs, PAGs, and CCs. The meetings and discussions with participant groups will take approximately 12 hours per year (one 4 hour meeting each quarter). The CRT will spend approximately 2 hours per month in planning meetings, 4 hours per month of individual work (polling group members, coding transcripts, and reviewing reports), and an additional 2 days per year in annual meetings in Oklahoma City. Each group will be responsible for deciding how to distribute compensation between their designated representative and other members of the group and in which form (e.g. cash vs. gift cards). In all cases, in-person meetings will be scheduled at times and locations most convenient and comfortable to those participating.

Inclusion of women and minorities. No clinicians, staff members, or patients will be excluded from participation based on gender, age, ethnicity, or race. The project will benefit from the inclusion of women and minorities.

Inclusion of children. No children will be involved in the study. Only adult participants over age 21 years of age who are members of patient advisory boards, patient advocacy groups, community coalitions, and practice-based research network boards will be included in the study.

Targeted planned enrollment. Study participants will be drawn from the membership of the six participant organizations according to the following anticipation demographic distribution:

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	1				**1**
Asian	1	1			**2**
Native Hawaiian or Other Pacific Islander					**0**
Black or African American	20	3			**23**
White	20	16	13	5	**54**
More than One Race			4	2	**6**
Total	**42**	**20**	**17**	**7**	**86**

Governance and Conflict Resolution. Although the study does not warrant a Data and Safety Monitoring Committee, we with work with all members of the CRT to establish a governance process, including definition of principles, decision-making and monitoring roles, priorities, and shared accountability. We will facilitate opportunities for community partner members of the CRT to fully exercise their rights as research partners and to freely offer guidance or concerns, especially those that maximize benefits and minimize risks for community partners. Given the diversity of the CRT, we will place a high priority on effective project management, attentiveness to community partner interests, and awareness of each community's cultural values as strategies to minimize the risk of conflicts. A consensus decision-making model will be used, and if differences should arise, we will work toward constructive dialogue by identifying mutual goals attainable only through collaboration (Mitchell & Shortell, 2000).

In the event that concerns of a consented participant arise and cannot be resolved by the CRT, the individual may withdraw from study participation at any time without consequence. In the unexpected instance that significant concerns of a community partner arise and cannot be resolved at the CRT or investigator level, they will be referred to the University of Oklahoma Office of Research Administration. If still unresolved, the community partner will have the option of withdrawing from study participation according to the provisions of their signed MOU.

IRB Review

The application and study protocol will be reviewed by the following Institutional Review Boards prior to implementation:

- University of Oklahoma Health Sciences Center (OUHSC) Office of Human Research Participant Protection (HRPP)
- University of Buffalo (UB) Social and Behavioral Sciences Institutional Review Board (SBIRB)
- University of Southern California Office for the Protection of Research (OPRS)

Multi-Site Research

There will be one traditional subcontract with SUNY-Buffalo and service contracts with Pathways to a Healthy Stephens County, OKPRN, LA NET, and LHA. Each agreement specifies the roles and responsibilities of all parties.

Importance of the Knowledge to Be Gained

This study will increase the opportunity for community members, patients and providers to drive the patient-centered outcomes research agenda.

REFERENCES CITED

Amanatidou, E., Butter, M., Carabias, V., Konnola, T., Leis, M., Saritas, O., . . . van Rij, V. (2012). On concepts and methods in horizon scanning: Lessons from initiating policy dialogues on emerging issues. *Science and Public Policy, 39*(2), 208-221. doi: DOI 10.1093/scipol/scs017

Basu, A., & Meltzer, D. O. (2007). Value of information on preference heterogeneity and individualized care. *Med Decis Making, 27*(2), 112-127. doi: 10.1177/0272989X06297393

Brennan, L. K., Brownson, R. C., Kelly, C., Ivey, M. K., & Leviton, L. C. (2012). Concept mapping: priority community strategies to create changes to support active living. *Am J Prev Med, 43*(5 Suppl 4), S337-350. doi: 10.1016/j.amepre.2012.07.015

CARE: Community Alliance for Research and Engagement. (2009). Principles and Guidelines for Community-University Research Partnerships. Retrieved April 16, 2014, from http://www.yale.edu/hrpp/resources/docs/PrinciplesandGuidelinesforCommunityResearchPartnerships10-27-11

Chiauzzi, E., Trudeau, K. J., Zacharoff, K., & Bond, K. (2011). Identifying primary care skills and competencies in opioid risk management. *J Contin Educ Health Prof, 31*(4), 231-240. doi: 10.1002/chp.20135

Concepts Systems, Inc. (2014). The Concept System Software. Retrieved May 1, 2014, from http://www.conceptsystems.com/content/view/the-concept-system.html

Department of Health and Human Services (HHS). (2009). Protection of Human Subjects (45 CFR 46). Retrieved April 20, 2014, from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Dyer, J. S. (1990). Remarks on the Analytic Hierarchy Process. *Management Science, 36*(3), 249-258. doi: DOI 10.1287/mnsc.36.3.249

Edwards, W. (1977). How to use multiattribute utility measurement for social decisionmaking. *IEEE Transactions on Systems, Man, and Cybernetics, 7*(5), 326-340. doi: Doi 10.1109/Tsmc.1977.4309720

Edwards, W., & Barron, F. H. (1994). SMARTS and SMARTER - Improved simple methods for multiattribute utility measurement. *Organizational Behavior and Human Decision Processes, 60*(3), 306-325. doi: DOI 10.1006/obhd.1994.1087

Fleurence, R. L., & Meltzer, D. O. (2013). Toward a science of research prioritization? The use of value of information by multidisciplinary stakeholder groups. *Med Decis Making, 33*(4), 460-462. doi: 10.1177/0272989X13486979

Forman, E. H., & Gass, S. I. (2001). The Analytic Hierarchy Process - An exposition. *Operations Research, 49*(4), 469-486. doi: DOI 10.1287/opre.49.4.469.11231

Frenk, J. (1992). Balancing relevance and excellence: organizational responses to link research with decision-making. *Soc Sci Med, 35*(11), 1397-1404.

Hanney, S. R., Gonzalez-Block, M. A., Buxton, M. J., & Kogan, M. (2003). The utilisation of health research in policy-making: Concepts, examples and methods of assessment. *Health Res Policy Syst, 1*(1), 1-28.

Lancsar, E., & Louviere, J. (2008). Conducting discrete choice experiments to inform Healthcare decision-making. *Pharmacoeconomics, 26*(8), 661-677. doi: Doi 10.2165/00019053-200826080-00004

Lanzing, Jan. (1997). The Concept Mapping Homepage. Retrieved May 1, 2014, from http://users.edte.utwente.nl/lanzing/cm_home.htm

Lerner, R. M., & Simon, L. A. K. (Eds.). (1998). *University-Community Collaborations for the Twenty-First Century: Outreach Scholarship for Youth and Families*. New York, NY: Garland Publishing, Inc.

Manafo, E., Petermann, L., Lobb, R., Keen, D., & Kerner, J. (2011). Research, practice, and policy partnerships in pan-Canadian coalitions for cancer and chronic disease prevention. *J Public Health Manag Pract, 17*(6), E1-E11. doi: 10.1097/PHH.0b013e318215a4ae

Meltzer, D. O. (2001). Addressing uncertainty in medical cost-effectiveness analysis: Implications of expected utility maximization for methods to perform sensitivity analysis and the use of cost-effectiveness analysis to set priorities for medical research. *J Health Econ, 20*(1), 109-129.

Meltzer, D. O., Hoomans, T., Chung, J. W., & Basu, A. (2011). Minimal modeling approaches to value of information analysis for health research. *Med Decis Making, 31*(6), E1-E22. doi: 10.1177/0272989X11412975

Mitchell, S. M., & Shortell, S. M. (2000). The governance and management of effective community health partnerships: a typology for research, policy, and practice. *Milbank Q, 78*(2), 241-289, 151.

Mold, J. W., & Gregory, M. E. (2003). Best practices research. *Fam Med, 35*(2), 131-134.

Moravcsik, Andrew. (2014). Transparency: The Revolution in Qualitative Research. *PS: Political Science and Politics, 47*(1), 48-56.

Myers, E., Sanders, GD. , Ravi, D. , Matchar, D. , Havrilesky, L. , Samsa, G. , . . . Erinoff, EG. . (2011). Evaluating the Potential Use of Modeling and Value-of-Information Analysis for Future Research Prioritization Within the Evidence-based Practice Center Program. Rockville, MD: Agency for Healthcare Research and Quality.

O'Haire, C., McPheeters, M., Nakamoto, E. K., LaBrant, L., Most, C., Lee, K. V., . . . Guise, J. M. (2011). Methods for engaging stakeholders to identify and prioritize future research needs. Rockville, MD: Agency for Healthcare Research and Quality.

PCORI. (2013a). An Orientation to PCORI's Research Prioritization Process: PCORI.

PCORI. (2013b). Pilot Testing PCORI's Process for Prioritizing Research Topics: PCORI.

Ross, L. F. (2010). 360 Degrees of human subjects protections in community-engaged research. *Sci Transl Med, 2*(45), 45cm23. doi: 10.1126/scitranslmed.3001162

Ross, L. F., Loup, A., Nelson, R. M., Botkin, J. R., Kost, R., Smith, G. R., Jr., & Gehlert, S. (2010). Human subjects protections in community-engaged research: a research ethics framework. *J Empir Res Hum Res Ethics, 5*(1), 5-17. doi: 10.1525/jer.2010.5.1.5

Saaty, T. L. (1990). How to Make a Decision - the Analytic Hierarchy Process. *European Journal of Operational Research, 48*(1), 9-26. doi: Doi 10.1016/0377-2217(90)90057-I

Sutherland, W. J., & Woodroof, H. J. (2009). The need for environmental horizon scanning. *Trends in Ecology & Evolution, 24*(10), 523-527. doi: DOI 10.1016/j.tree.2009.04.008

The Center for Appreciative Inquiry. (2014). Retrieved May 1, 2014, from http://www.centerforappreciativeinquiry.net/

Wald, H. L., Leykum, L. K., Mattison, M. L., Vasilevskis, E. E., & Meltzer, D. O. (2014). Road Map to a Patient-Centered Research Agenda at the Intersection of Hospital Medicine and Geriatric Medicine. *J Gen Intern Med.* doi: 10.1007/s11606-014-2777-1

Ward, V., House, A., & Hamer, S. (2009). Developing a framework for transferring knowledge into action: a thematic analysis of the literature. *J Health Serv Res Policy, 14*(3), 156-164. doi: 10.1258/jhsrp.2009.008120

Yin, R. K., & Moore, G. B. (1988). Lessons on the utilization of research from nine case experiences in the natural hazards field. *Knowledge in Society, 1*(3), 25-44.