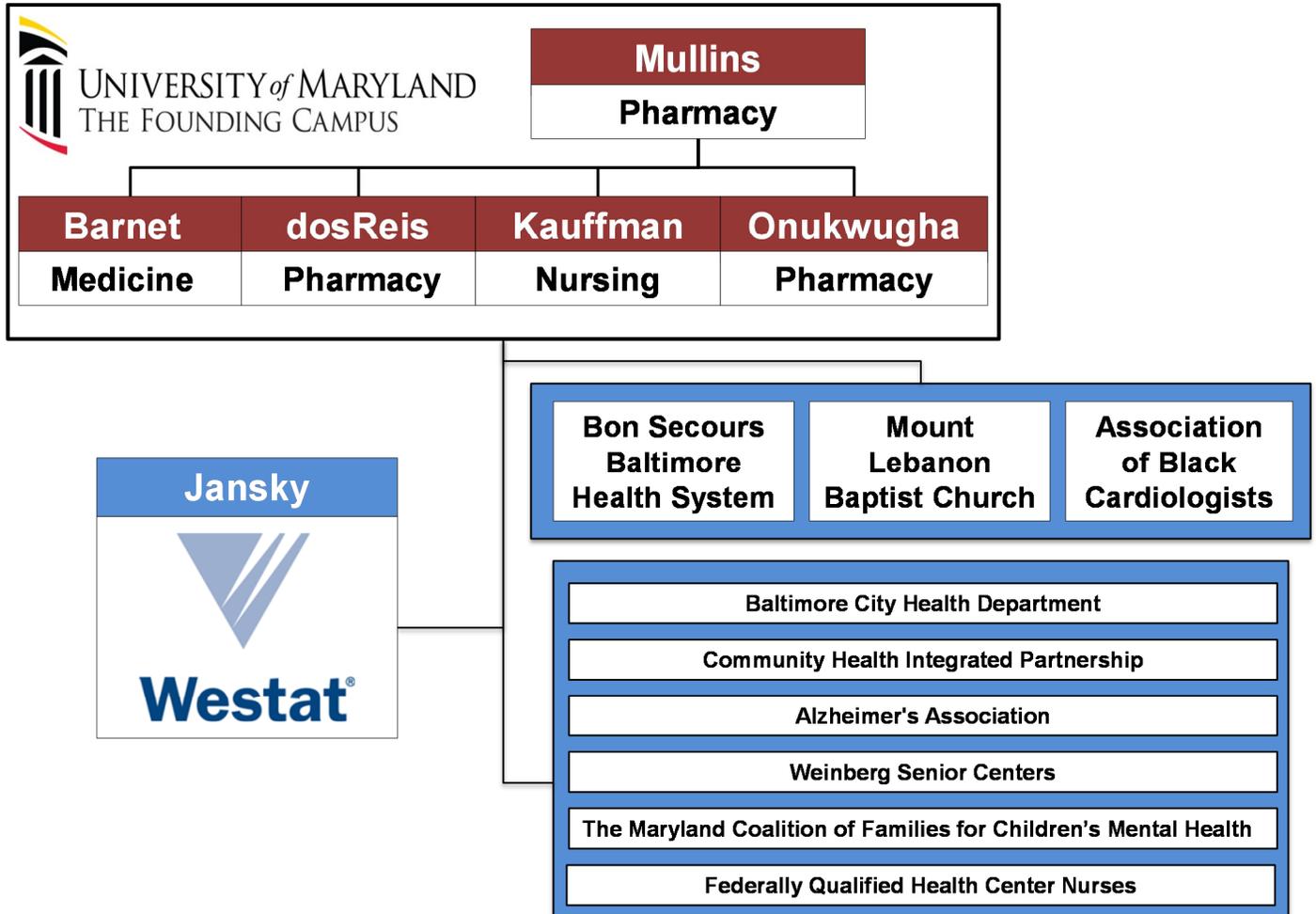


Integrating patients' voices in study design elements with a focus on hard-to-reach populations



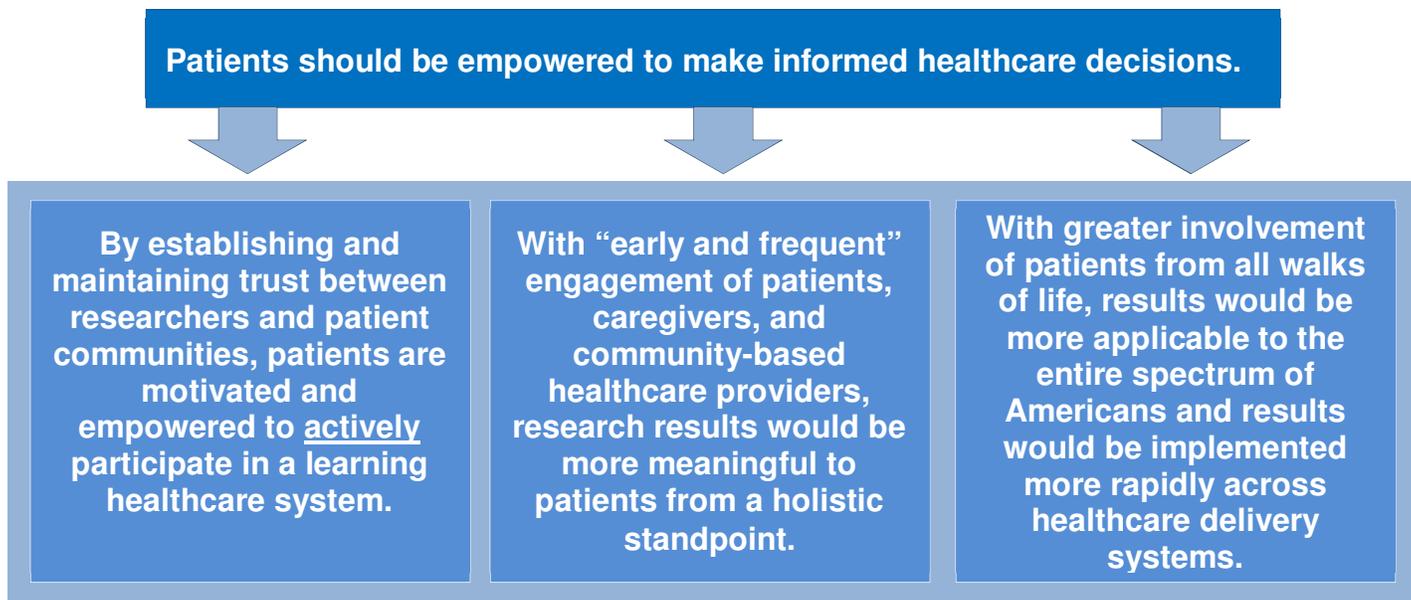
DISCLAIMER

All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. PCORI has not peer-reviewed or edited this content, which was developed through a contract to support the Methodology Committee's development of a report to outline existing methodologies for conducting patient-centered outcomes research, propose appropriate methodological standards, and identify important methodological gaps that need to be addressed. The report is being made available free of charge for the information of the scientific community and general public as part of PCORI's ongoing research programs. Questions or comments about this report may be sent to PCORI at info@pcori.org or by mail to 1828 L St., NW, Washington, DC 20036.

I. Lay Summary

Interviews to Identify Evidence for Eliciting Hard-to-Reach Patients' Perspectives in PCOR

Why was this study important?



Who are hard-to-reach patients?

Different people define “hard-to-reach” in different ways. For this study, people were considered hard to reach if they belonged to a group that does not typically participate in research due to cultural or socioeconomic barriers or physical or cognitive impairment.

What is PCOR?

Patient Centered Outcomes Research, also known as “PCOR”, involves patients and their care providers in designing research so that the research helps them make informed healthcare decisions. PCOR allows patients’ voices to be heard in assessing the value of healthcare options.

What was done?

The University of Maryland, Westat, and nine partnering organizations conducted 20 focus groups and one interview to hear from patients and their providers how best to engage hard-to-reach patients when conducting PCOR.



There were two parts to the research:

Part 1: Nine (9) advisors and community partners ensured that the questions asked in Part 2 were appropriately worded for patients.

Part 2: Twenty (20) focus groups and one interview were conducted with 160 individuals who gave advice on how to engage patients actively in research.

People were primarily recruited through University of Maryland clinics or one of the community partner organizations below:

Bon Secours Baltimore Health System
Association of Black Cardiologists
Mt. Lebanon Baptist Church
Community Health Integrated Partnership
Baltimore City Health Department
Weinberg Senior Centers
Alzheimer's Association
The Maryland Coalition of Families for Children's Mental Health
University of Maryland Federally Qualified Health Center Nurses

The 160 people who participated in Part 2 represented the following 10 groups:

- Low-income African American patients
- Low-income bilingual Spanish-English speaking patients
- Patients from an African American church
- Blind or visually impaired patients
- Deaf or hearing impaired patients
- Patients with mobility impairment
- Parents of children who have mental health conditions
- Caregivers of people with cognitive impairment
- Physicians who treat hard-to-reach patients
- Nurses who treat hard-to-reach patients

The focus group and interview discussions were based on the following questions, which were rephrased during Part 1 of the study:

Q1. What practical methods are effective in engaging patients and their surrogates in:
1) identifying and prioritizing research questions;
2) identifying outcomes that are meaningful to them
3) identifying comparators/interventions that are meaningful to them?

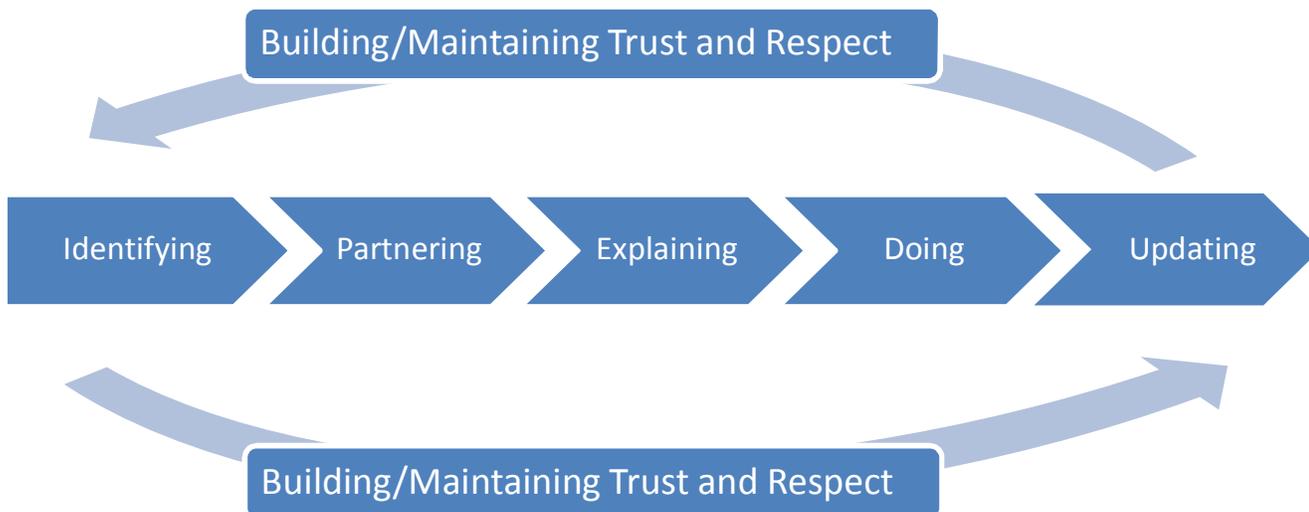
Q1i. What methods are effective in ensuring that the full spectrum of patients is represented, including hard to reach and under-represented patients?

Q2. What methods are effective in ensuring that informants understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision making?

Q3. What data are available that identify other factors and issues that are important to patients (or surrogates) that need to be considered?

What was found?

In order to make Patient Centered Outcomes Research (PCOR) more meaningful to patients and their caregivers, we recommend that all PCOR be conducted with a focus on building and maintaining trust, which is achieved via pre-engagement and then through a process involving continuous partnering with the community. The goal is to foster full and meaningful partnering between researchers and participants (i.e. patients and their communities and health care providers) in the research process.



How to Elicit Hard-to-Reach Patients' Perspectives and Partner with Patient Communities: 10 Solid Suggestions

- Use a period of "pre-engagement" when recruiting research participants and partners
- Involve the full spectrum of people that will be affected by the research, including hard-to-reach patients
- Provide a lay summary of study findings at an end-of-study celebration
- Build bridges for active patient engagement by creating and maintaining trust
- Realize that people may not be willing to openly disclose medical information
- Bring PCOR to communities where people live
- Keep people up-to-date on what is going on with the research
- Recognize that people make healthcare choices and participate in research based upon who they are as individual persons, not just as patients
- Provide education on exactly what is meant by the term "research"
- Make a sincere effort to "give back" to the community

II. Executive Summary

Researchers do not normally reach out to certain patient populations to engage them in the research process. Some reasons for this include investigator bias or the excess time and effort that it would require to engage them due, for example, to their geographic location or to their limited involvement with the health care system. Often the patients who are not engaged in research are those who are hard to reach and have greater health care needs because of receiving inconsistent or suboptimal health care. Such hard-to-reach patients include minorities, those who do not speak English well or at all, those with low socioeconomic status (SES) and those with physical (e.g. hearing, vision or mobility) or cognitive impairments. Eliciting the perspectives of all patients – not just those who are convenient to contact – on health-related questions is an area that the Patient Centered Outcomes Research Institute (PCORI) has identified as integral to patient centered outcomes research (PCOR) with the goal of improving the health of all citizens. Our research focused on the creation of methods for including patients in research design, implementation, and dissemination with a particular focus on hard-to-reach populations. These methods will help to ensure that future comparative effectiveness research (CER) is meaningful to patients.

Our contract focused on those patients who are least likely to be engaged in research, such as racial and ethnic minorities, patients with low SES, and patients with some type of impairment, including visual, hearing, mobility, or cognitive. We conducted focus groups and an interview with ten categories of patients identified as hard to reach: African Americans (predominantly of low SES), Bilingual Spanish-speaking patients (predominantly of low SES), hard to reach patients within faith-based organizations (principally African American), patients with mobility impairment, patients with vision impairment, patients with hearing impairment, physicians who treat hard to reach patients, nurses who treat hard to reach patients, parents of children who are hard to reach, and caregivers of patients with cognitive impairments.

This project had two phases of research:

Phase 1 drew upon the knowledge of key partners with experience in conducting PCOR in hard-to-reach patients and/or developing PCOR methodologies. The input from these partners informed the wording of the questions in the Phase 2 interview guide. During protocol development in Phase 1, the UMB and Westat research team and our partners identified broad content areas and potential themes of interest based on their research experience and the literature. This list served as a framework but did not preclude identification and exploration of other themes that emerged during data collection in Phase 2.

Phase 2 involved conducting FG/Is with hard-to-reach patients and their care providers, including clinicians (nurses and physicians), caregivers and parents. A minimum of one Interviewer/Moderator and one note-taker participated in each focus group/interview. During discussion, the interviewers/moderators engaged all participants in a manner that was inclusive and not judgmental to encourage expression of diverse viewpoints. From initial consent to conclusion, the focus groups lasted between 1 and 2 hours. Discussions were audio recorded (with consent of participants) and notes were collected in real time.

In Phase 2, a summary of each individual focus group/interview was produced, generally within 24-48 hours of the focus group/interview by the note taker and reviewed/edited by the individual who conducted the Interview. When other members of the team attended focus groups as observers, they also reviewed the summaries for accuracy and completeness. Synthesis across the individual summaries emerged from a series of three half-day meetings, along with individual work in between meeting by three of the faculty members (Drs. dosReis, Kauffman, and Onukwugha). This synthesis process involved extracting code from individual summaries, categorizing the codes according to themes and vetting both themes and verbiage for themes with other faculty members, including the Principal Investigator (Professor Mullins).

The University of Maryland, Baltimore (UMB) and Westat investigators and our community-based partners sought to further expand on the inherent diversity within each of the hard to reach categories by recruiting individuals with diversity in terms of age and gender. In addition, for the subpopulations that were not defined by race/ethnicity, we purposefully recruited racially diverse participants.

Our findings suggest that some key recommendations for encouraging meaningful participation of patients in PCOR include:

- Use a period of “pre-engagement” when recruiting research participants and partners
- Involve the full spectrum of people that will be affected by the research, including hard-to-reach patients
- Provide a lay summary of study findings at an end-of-study celebration
- Build bridges for active patient engagement by creating and maintaining trust
- Realize that people may not be willing to openly disclose medical information
- Bring PCOR to communities where people live
- Keep people up-to-date on what is going on with the research
- Recognize that people make healthcare choices and participate in research based upon who they are as individual persons, not just as patients
- Provide education on exactly what is meant by the term “research”
- Make a sincere effort to “give back” to the community

III. Significance, Scope and Aims

A. Importance of Eliciting Hard-to-Reach Patients' Perspectives

Researchers do not normally reach out to certain patient populations to engage them in the research process. Such hard-to-reach patients include minorities, those who do not speak English well, those with low socioeconomic status (SES) and those with physical (e.g. hearing, vision or mobility) or cognitive impairments. Some reasons include excess time and effort to engage them. Because these hard-to-reach-patients generally have greater health care needs than other patients, they need to be included if we want to achieve targets for healthier citizens. Our research centers on the creation of methods for including all patients – not just those who are easy to identify and engage - in research design and implementation. These methods will be central to PCORI's aim to ensure that future comparative effectiveness research (CER) is meaningful to patients.

B. Related Literature/Reports

The concept of patient and community involvement in research and clinical practice is not new. Patient-centered medicine was evaluated in JAMA in 1996¹. Community-based participatory research (CBPR) was being conducted in the early-1990s and was thoroughly reviewed in 1998.^{2,3,4} However, a 2006 Agency for Healthcare Research and Quality (AHRQ) assessment found that CBPR is not being utilized to its full potential.⁵ Additionally, uncertainty in clinical decision-making, health care, and health policy decision-making remains ubiquitous due to large gaps in high-quality patient-centered medical evidence.^{6,7} The goal of PCOR is to provide patients, their advocates and caregivers, health care professionals, policy makers, payers, government and other health agencies with evidence-based information to make informed health care decisions.^{8,9} Outcomes research studies historically were designed with relatively little input from patients. The Patient Protection and Affordable Care Act of 2010¹⁰ and PCORI symbolize a new era in which the most important stakeholder - the Patient - is accorded a key role in research.¹¹

C. Project Scope

Our contract focused on those patients who are least likely to be engaged in research, such as racial and ethnic minorities, patients who are of a low socio-economic status, and patients with an impairment, such as visual, hearing, mobility, or cognitive. The contract utilized the focus group methodology to elicit patient and provider perspectives on questions supplied by PCORI. The focus groups/interview (FG/Is) were conducted primarily in the greater Baltimore area with hard-to-reach patients and those who serve or care for them (family members, physicians and other health professionals). We planned to conduct two focus groups each from the following ten categories:

- African Americans, predominantly of low SES, from Bon Secours Baltimore Health System
- Bilingual Spanish-speaking patients, predominantly of low SES, from Bon Secours Baltimore Health System
- Hard-to-reach patients within faith-based organizations (principally African American)
- Limited mobility patients
- Patients with vision impairment
- Patients with hearing impairment
- Physicians who treat hard-to-reach patients
- Nurses who treat hard-to-reach patients
- Parents of children who are hard-to-reach patients
- Caregivers (e.g., adult children or spouses) of patients with cognitive impairments

D. Aims

The UMB and Westat research team and our community partners (See front page or **Appendix A** for a list of partners) collaborated to develop an interview guide, conduct FG/Is, and interpret and disseminate findings of FG/Is aimed at enhancing methods for engaging hard-to-reach patients in patient-centered outcomes research (PCOR).

The focus areas for the FG/Is were three questions from the PCORI Patient Centeredness Working Group's Request for Proposal – Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcomes Research (Interviews). These questions in their original form are:

Q1. What practical methods are effective in engaging patients and their surrogates in:

- 1) identifying and prioritizing research questions
- 2) identifying outcomes that are meaningful to them
- 3) identifying comparators/interventions that are meaningful to them?

Q1i. What methods are effective in ensuring that the full spectrum of patients is represented, including hard to reach and under-represented patients?

Q2. What methods are effective in ensuring that informants understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision making?

Q3. What data are available that identify other factors and issues that are important to patients (or surrogates) that need to be considered?

IV. Methods for Conducting Stakeholder Focus Groups

This project had two phases of research, as described in the Scope of Work (See **Appendix B.**) Each phase had its own IRB protocol (See **Appendix C** for IRB approval letters) and Focus Group guide. Phase 1 involved key stakeholders with experience in working with hard-to-reach patients and/or developing PCOR methodologies. Phase 2 involved focus groups and an interview with hard-to-reach patients and their care providers, including clinicians (nurses and physicians), caregivers and parents.

A. Study Processes and Procedures

A brief Interview Guide (See **Appendix D**) was developed for the “formative” Phase 1 focus group, which involved nine diverse stakeholders who participated on December 12, 2011. In support of our belief that the original PCORI questions were complex, we developed the Phase 1 guide to (1) ask key stakeholders' what are their definitions of PCOR and hard-to-reach, (2) to solicit their input on rephrasing the questions in terms that are meaningful to the target populations, and (3) to provide population-specific considerations. Our belief that the questions were dense was confirmed during Phase 1, and findings from this phase acted as the springboard for our data collection methodology and guide. The nine expert stakeholders assisted in rephrasing questions in a way that would be meaningful to hard-to-reach people, while maintaining the essence of the Patient Centeredness Working Group's original questions. In addition, their discussion points were summarized and presented back to the participants during the debriefing as a sort of member-checking exercise and further question refinement. The majority of these nine individuals continued to serve as advisors to provide feedback throughout the process and several of them helped with either identification of participants or communities for Phase 2 FG/Is. Based upon Phase 1, a separate Interview Guide was developed for Phase 2.

A1. Identification and Recruitment of Stakeholders

The vast majority of the nine individuals involved in the Phase 1 focus group represented a convenience sample of experts and community-based partners with whom the Principal Investigator had an existing relationship. The notable exception was the Assistant Commissioner of Health from the Baltimore City Health Department who was new to this group of experts. For Phase 2, we utilized five main avenues to recruit patients: Bon Secours Baltimore Health System, the practice-based research network to which Dr. Barnet belongs and other UMB clinics, the Association of Black Cardiologists, other Baltimore-based community or faith-based organizations (e.g., Mt Lebanon Baptist Church, the Alzheimer’s Association, and the Maryland Coalition of Families for Children’s Mental Health) as well as referrals from focus group participants and prior grant partners. Bon Secours Baltimore Health System assisted with patient recruitment related to racial/ethnic diversity and those with low socioeconomic status. Research Nurse Aurelia Laird, RN from Bon Secours Baltimore Health System, is bilingual (Spanish and English) and recruited African American groups, a limited mobility group, and all of the bilingual Spanish speaking patients.

Group	Recruitment Partner
African American	Bon Secours
Caregivers	Alzheimer's Association
Faith-Based	Mt. Lebanon Baptist Church
Physicians	Association of Black Cardiologists Community Health Integrated Partnership
Hearing Impaired	University of Maryland Weinberg Senior Living
Visually Impaired	University of Maryland
Nurses	University of Maryland Baltimore City Health Department
Parents	University of Maryland MD Coalition
Spanish Speaking	Bon Secours
Mobility Impaired	Bon Secours Weinberg Senior Living

A2. Process of Developing Focus Group/Interview Guide

A “real-time” synthesis of the statements from the nine key stakeholders who participated in the Phase 1 focus group occurred so that we could make sure that we captured the essence of their comments before they left the meeting. However, the development of the Phase 2 guide included more than the work conducted during that meeting. The confirmation with participants at the meeting was supplemented by an internal review and synthesis after the group concluded which led to the Phase 2 study design, role-playing exercise, and guide development (which also included input from Phase 1 participants).

The focus group lasted 2 hours. This allowed for 75 minutes for conducting the focus group and 45 minutes to obtain feedback on the phrasing of the questions and probes. The interview was conducted at the UMB campus. Phase 1 met three goals: (1) Interview a variety of stakeholders to identify relevant domains to be addressed in Phase 2 FG/Is; (2) Produce final questions and related materials for the Interview Guide for Phase 2 that reflect a modified framework; and (3) Obtain suggestions and referrals for stakeholders for Phase 2 FG/Is. At the conclusion of Phase 1, UMB and Westat collaborated to refine the Interview Guide that was used in Phase II.

Appendix E contains more information regarding the participants and findings of the Phase I focus group.

A3. Process of Conducting Focus Groups/Interviews

The first FG/I was held on the evening of January 24th, 2012 and the last was conducted on the afternoon of February 23rd, 2012. FG/Is were held between 10am and 8:30 pm and were coordinated with our partners to occur at times that were convenient for them. Locations for the FG/Is were dependent upon the group; the majority of FG/Is were held at the partnering organization or at the UMB facility where participants typically received care.

A minimum of one Interviewer/Moderator and one note-taker participated in each FG/I and individual in-depth interview. For the FG/Is with the caregivers, nurses, and physicians Dr. Karen Kauffman served as the primary interviewer. Dr. Susan dosReis conducted the focus groups with the parent groups, and Westat conducted the focus groups in the African American, faith-based, bilingual Spanish-speaking, and impairment populations. Prior to conducting a FG/I, all interviewer/moderators reviewed materials and made notes to ensure that the questions were framed appropriately for each stakeholder type.

Before starting the FG/I, written consent was obtained from all participants. We also collected demographic (gender and race/ethnicity) from each participant and provided each participant with a gift card as a means of thanking them for participating. During discussion, the interviewers/moderators engaged all participants in a manner that was inclusive and not judgmental so as to encourage expression of diverse viewpoints. From initial consent to conclusion, the focus groups lasted between 1 and 2 hours. Discussions were audio recorded (with consent of participants). Notes were collected in real time via laptop and through the use of flip chart pages. The notes taken via flip-chart assisted participants in building upon prior ideas and ensured that the note takers were accurately capturing the ideas being generated by participants. Using the notes and audio recording, the note-taker organized and cleaned the meeting notes, which were reviewed by the Interviewer/Moderator for clarity. The Interviewer/Moderator was also responsible for the addition of his/her reflections on the interview process including barriers and facilitators to data collection.

A4. Assuring Adequate Input

A major objective was to assure adequate input in terms of both diversity of participants and saturation of themes or suggestions for how best to enhance methods for engaging hard-to-reach patients in PCOR.

a) Diversity within and across focus groups

Diversity of patient and care providers was “hard wired” into the recruitment strategy based upon the ten categories of interviewees. However, both the UMB and Westat investigators and our community-based partners sought to further expand diversity within each category by recruiting individuals with diversity in terms of age and gender. In addition, for the subpopulations that were not defined by race/ethnicity (i.e. clinicians and other care providers and impairment communities) we purposefully recruited racially diverse participants.

b) Saturation

Theme identification from interviews began by reviewing the written notes from the FG/Is and categorizing the information. Following theme identification, the information was organized into a coding (logic) paradigm. Theme saturation was determined through an iterative process of simultaneous data collection and analysis. We purposefully looked for repetition and confirmation of themes and concepts that emerged from collected data.

V. Data Analysis and Synthesis

A. Phase I

A1. Real time synthesis

The Phase 1 focus group was strategically planned from 11:00 – 1:00 on December 12, 2011. In order to assure that we had captured the viewpoints of the stakeholders who participated in the Phase 1 focus group, Westat performed a “real time” synthesis in between sessions. Discussion points were summarized and presented back to the participants during the debriefing as a member-checking exercise to further question refinement. Given the condensed timeline for the project, this real time synthesis was necessary in order to obtain IRB approval for Phase 2 in a timely manner; however, as stated above, there was additional work following the Phase 1 focus group to develop the Phase 2 interview guide.

B. Phase II

B1. Summaries of Focus Groups/Interview

A summary of each individual FG/I was produced (See **Appendix E**), generally within 24-48 hours of the FG/I. The summary was produced by the note taker and reviewed/edited by the individual who conducted the Interview. When other members of the team attended focus groups as observers, they also reviewed the summaries for accuracy and completeness.

B2. Synthesis across Summaries

Synthesis across the individual summaries emerged from a series of three-half day meetings, along with individual work in between meetings by three of the faculty members (Drs. dosReis, Kauffman, and Onukwugha). This synthesis process involved extracting codes from individual summaries, categorizing the codes according to themes, and vetting themes and verbiage for themes with other faculty members, including the Principal Investigator (Professor Mullins). A summary of the synthesis can be found in **Appendix F**. The intent was to further stratify the findings by stakeholder type; unfortunately, there was so little time between the final focus group and the due date for the Final Report. A mapping of findings by stakeholder type will be included in a future manuscript.

VI. Results

Twenty focus groups and 1 interview were conducted. Detailed information concerning the location, date, and time of FG/Is can be found in the summaries in **Appendix E** and the calendar in **Appendix G**.

A. Study Participants

A1. Description of Participants

By design, almost all participants in both Phase 1 and Phase 2 were from the city of Baltimore. The advantage of this is that Baltimore has a disproportionate number of hard-to-reach individuals and the investigators had well-established relationships in several Baltimore communities, which facilitated rapid recruitment and increased the likelihood of honest responses from participants based upon an established environment of trust. The downside is the lack of generalizability beyond the hard-to-reach communities examined and the geographic area outside Baltimore. While speculative, we do believe that the results are likely to generalize to many urban environments across the US. Based upon a preliminary discussion with the Patient-Centeredness Working Group, we recruited 4 nurses who work in the rural, eastern shore of Maryland to obtain perspectives about non-urban-residing hard to reach patients.

A2. Gender and Race/Ethnicity Distributions of FG/I Participants

A table of race/ethnicity and gender distributions of participants for each of the ten categories of stakeholder is included below:

Phase I Focus Group	3			4			2			9
Phase II Focus Groups and Interview	AfAmF	HisF	NHWf	OthF	AfAmM	HisM	NHWm	OthM	Total	
African American	6				6				12	
Faith-Based	23								23	
Visually Impaired	1	1	2				3	1	8	
Hearing Impaired	1		9		1		4		15	
Mobility Impaired	9		7		1		2		19	
Bilingual (Spanish Speaking)		11			1	6			18	
Patient Total (Phase II)	40	12	18	0	9	6	9	1	95	
Caregivers	9				3				12	
Parents	15				2				17	
Nurses	4		14	1					19	
Physicians	8		1	1	5		1	1	17	
Grand Total (Phase II)	76	12	33	2	19	6	10	2	160	
F = Female M = Male AfAm = African American Hisp = Hispanic NHWh = non-Hispanic White Oth = Other										

VII. Process for Ensuring Credibility and Applicability of Findings

When working with diverse communities, it is possible that researchers could misinterpret statements that are made during focus groups. To address this potential problem, the results of the synthesis were vetted by various individuals from both Phase 1 expert stakeholders and leaders from the community-based partners.

A. Advisors from Community-Based Partners and Phase I

Four Phase 1 participants reviewed the findings and proposed standards with the Principal Investigator. In addition, the research nurse from Bon Secours attended approximately one-third of the weekly conference calls and discussed general findings with the Principal Investigator. The synthesis and proposed Standards also were reviewed by the Principal Investigator with the Research Chair for the Association of Black Cardiologists, Inc. (ABC) and the head of Health Ministries at Mt. Lebanon Baptist Church. The Chief Executive Officer of ABC also sent comments via email on the draft Standards and study findings.

B. Scientific Rigor

The scientific integrity of the qualitative analysis and related synthesis processes was overseen by Dr. Kauffman, who has conducted qualitative research for approximately two decades.

Dr. dosReis, who developed most of the themes from the coding also has significant experience with the process of qualitative synthesis and creating themes. In all cases, when a proposed theme emerged or a finding was suggested, investigators were careful to assure that there was an evidence base from the FG/Is to support the theme or finding. In cases where the evidence was mixed (e.g. some focus groups commented on a particular area while others did not), the phrasing attempted to reflect the diversity in viewpoints.

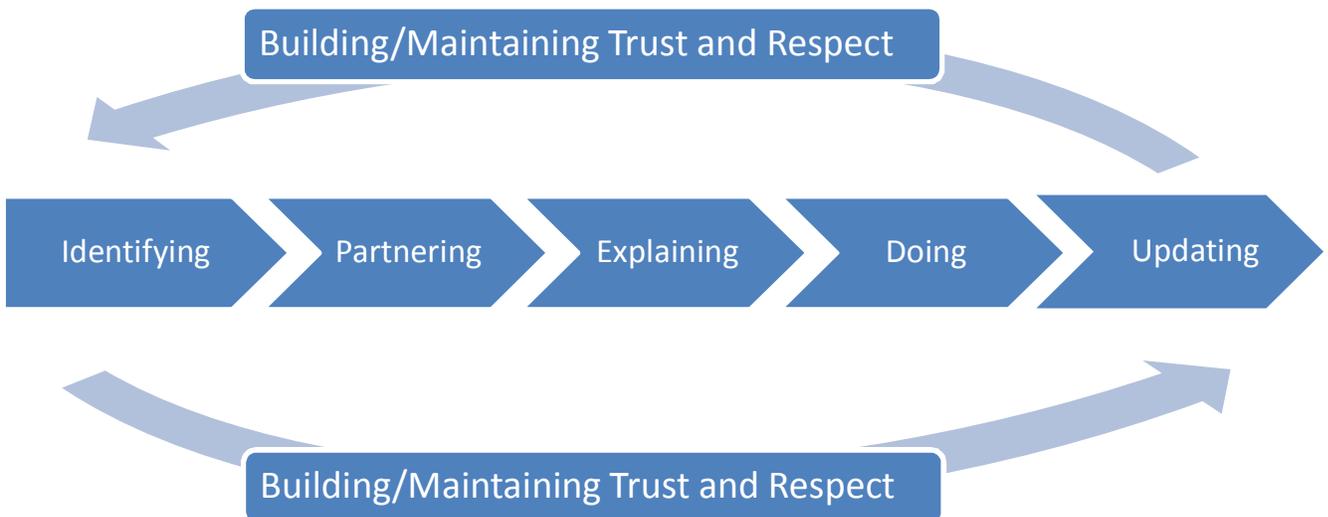
VIII. Findings

This section reports the findings of our focus groups and interviews for each of the three key questions addressing methods to engage hard-to-reach persons. We include salient sentiments that our focus group respondents expressed about the PCORI Methodology Committee's terminology. While some of these comments do not directly relate to the Committee's questions, they are relevant to PCORI's aims to be responsive to the values and interests of people engaging in research. This section ends with a list of key findings for PCORI to consider when identifying and defining best practices to create high-integrity, evidence based information to help people make informed decisions about their health care outcomes.

Undergirding the entire process of engagement from start to finish is building and maintaining trust, which is an iterative process involving pre-engaging, relating, communicating, and being there. Pre-engaging is the process of understanding both individual considerations (e.g. emotional and information needs) as well as the community and the environmental context in which people live. Researchers must be equipped to address these issues and have the resources to enable study participation and meet more pressing needs, such as providing transportation to navigate dangerous public spaces. This process assures cultural sensitivity and competence of the researchers that are essential for building trust. Relating is a process that has philosophical underpinnings: Researchers should not see themselves at a "higher" level than the study participants, but rather should be genuinely willing to partner with study participants, and understand the life ways and life needs of hard-to-reach study participants. It is often helpful to partner with members of the community to be successful in this process. Communicating is a process that takes several forms. Keeping questions

simple and simply asking questions without judgment are helpful in eliciting responses from study participants. Active listening, reading body language, and showing passion for the meaningfulness of the research topic are non-verbal ways to build trust. Being there is a process that is more about what happens in present tense; it also means the researcher needs to keep “coming back” and engaging with study participants as well as having consistency in who is present in “being there.” In other words, “don’t change people all the time.”

Trust is the backbone upon which the structure of all PCOR must be built. The overarching theme of all FG/Is was the need for trust to exist in order for hard-to-reach patients to be willing to participate in research. The word “trust” was one of the most commonly spoken terms by participants during FG/Is. When discussing trust, a variety of concepts were expressed that can be viewed along the research continuum, as portrayed below in the diagram that shows five components of partnering with hard-to-reach communities starting with identification of communities and individual patients; developing partnership based upon trust; explaining throughout the process about research in general, the relationship and expectations of all members of the partnership, and what patients will be asked to do if they participate in PCOR studies; respecting participants at all stages of recruitment and actually doing the research; and maintaining trust by giving back to the community and PCOR participants so that as future PCOR projects are conceived and implemented, the trust between researchers and participants facilitates expansion of the PCOR partnership.



A. Q1: Practical Methods for Engaging Hard –to-reach patients

- A. What practical methods are effective in engaging patients and their surrogates in 1) identifying and prioritizing research questions; 2) identifying outcomes that are meaningful to them; and 3) identifying comparators/interventions that are meaningful to them?
- i) What methods are effective in ensuring that the full spectrum of patients is represented, including hard-to-reach and under-represented patients?

This contract is focused on hard-to-reach persons thus items A.1., A.2, and A.3 were embedded within the sub-population of individuals specifically referenced in A.i; A.i was not considered to be an additional question for study participants. The topics under items A.1, A.2, and A.3 above were included as three distinct questions in the focus group interview guide. However, study participants had difficulty discerning nuances between A.1, A.2, A.3, and answered them similarly across all focus groups and interviews. It appears that while researchers view these as distinct methods, individuals whom we engaged in this research study did not see them as necessarily requiring different methods. Therefore, the study findings will address the broad concept of methods for engaging hard-to-reach patients. Further inquiry is necessary to ascertain practical methods for engaging persons to identify meaningful outcomes, and comparator/interventions.

Through the various FG/Is, we learned how the study participants think about and identify ‘hard-to-reach patients.’ Study participants **identified hard-to-reach patients** by impairments (i.e., cognitive, hearing, vision, mobility, and literacy), and illnesses (mental illness and drug addictions) and by age (children, men who are “macho” and feel “invincible”.) They identified people by where they live (nursing homes, assisted living, jails and prisons, transitional housing, and on the streets), by social indicators (uninsured, unemployed, low income, kids in gangs, undocumented immigrants, non-English speaking), and by what they do (selling drugs on the corner).

Practical methods for engaging hard-to-reach patients include partnering with people in formal and informal community leadership positions to provide entrée to meeting in places where hard-to-reach people commonly go and/or gather together. In addition to partnering with community leaders, using media will spread the word about opportunities where individuals can learn about and participate in research. While a list of categories of methods is available in the appendices, a summary of these methods follows.

Partnering with People: The range of people to partner with for PCOR reflects a wide gamut of individuals and organized groups. Individuals, such as the “mayor” of the block and “the man in the trench” live in the same community as hard-to-reach people and “look just like them.” Groups of people include health care professionals, employers, support group members, law enforcement and justice officers, and public service workers. Associations of people include communities and professions. Networks of people include social organizations such as sororities, fraternities, and federations such as the National Federation of the Blind. In rural settings, networks are most often comprised of families.

Meeting in Places: Places where hard-to-reach people go to and/or gather together ranges from public to private spaces. Public spaces that are open to everyone include street corners and local businesses such as laundromats, hair salons, banks, grocery stores. Community-specific spaces where services are provided for community members include centers for recreation, relocation, social services, and senior citizen activities. Semi-private places include emergency rooms and community clinics where hard-to-reach people who are underinsured or uninsured frequently seek

health care, and places of worship where people gather to share common ground and beliefs. Private spaces include housing such as long term care facilities, shelters, jails and prisons.

Using Media: Media, a means for mass communication and social marketing, have varying ranges of reach. Narrow reach media, reaching community-level groups, include such means as billboards on sides of buses and on hospital buildings, flyers in utility bills and other mailings, and local television and radio stations. Media reaching groups beyond the community include national television and radio, clips before movies. Media with the widest range include online bulletin boards, list serves, Facebook® and Twitter®.

B. Q2: Methods for Ensuring Informants Understanding

Methods to ensure that informants understand the pertinent clinical and research issues include understanding the literacy and comprehension of hard-to-reach patients and gathering information in ways that that are most appropriate for a specific community or individual. In addition, providing full disclosure about the research and modifying the consent process were important considerations underpinning an individual's understanding of the research. The spectrum of issues that were raised for each topic is described briefly here.

Literacy and Comprehension: The concerns about a study participant's ability to understand the research reflect the fundamentals of using plain language as opposed to "medical language" and asking participants to repeat things back in their own words and phrases, i.e., "teach back". It is also important to acknowledge the element of shame and that people may not be comfortable if their illiteracy were to be exposed. One must be careful that the individual is not covering up their illiteracy by simply agreeing with the process. The best way to overcome problems with literacy and comprehension is to be "straightforward" and "be specific and ask them if they understand." Individuals may need time to think about the study, talk with their significant others, and then come back with a decision. Another strategy is to offer a class or course for individuals to understand the research.

Gathering Information: The approaches utilized to gather information are important to consider since the patient's engagement is critical to gathering useful information. Terminology, phrasing of questions and the pace of the questioning provide opportunities to foster increased patient engagement. Using the appropriate terminology when gathering information is important because "research is an emotionally charged word." The ways in which questions are phrased is also critical. Asking open-ended questions creates opportunities to hear study participants' questions and concerns in their own words and avoids imposing the researchers' preconceived ideas about what is important to the study participants. Methods to address questions and concerns to assure understanding range from a slow and stepwise process over time to one in which "chunks" of information are provided in one setting. Partnering with community members such as community health volunteers assures cultural competence in responding to the questions and concerns and increases the likelihood that patients will understand the information that is being conveyed.

Disclosure: The process of providing full disclosure about the research is intended to avoid treating study participants as if they are "lab rats" and involves not only "what you say but who says it". This involves total honesty about the researcher's expectations of the study participants, clear explanation of risks and benefits of participation, and "what is in it for the researcher". It is as much about letting individuals know exactly what is involved as telling them why the investigator is doing the research. In telling people about the research, the depth of understanding involves not only "what you say but who says it."

Consent Process: Traditional IRB requirements for consent hinder more than they help individuals understand the research study. Often the consent forms use scientific jargon and fine print that people do not understand. The long consent forms “make patients nervous about what they are getting into” because the “risks are buried on page 8 of a 17 page consent form.” A way to address the long, cumbersome consent forms is to “culturally match the “consenter” to the person” or have individuals consent in “their own words.” During this process, it is important for the researcher to keep in mind that “people may just need what you are offering... they may not care about risks and benefits” and that full understanding may not be achieved.

C. Q3: Data Available to Identify Other Factors

Data that identify other factors and issues that are important to hard-to-reach people include particulars about their health and medical status, socioeconomic indicators, and difficult life situations. Each category is described further here.

Community Resources: A fundamental understanding of “how you define community” and the process of going “door-to-door” lead to successful ways to collect this information. The use of public transportation is a key source of community-based data that spans issues of safety and availability for hard to reach people. Other community resource indicators of include the availability of parks and recreation, community centers, supermarkets, corner stores, fast food places, and availability of fresh fruits and vegetables versus “junk food.”

Difficult Life Situations: Many people who are hard to reach have life experiences that place them at risk for judgment, stigmatization, and marginalization from their families, friends, and communities. Examples of data available to identify them include -police records, and frequent 911 calls to fire departments’ ambulance services. Crime rates identify communities at risk.

Health and Medical Records: The health of hard-to-reach people can be gleaned from records from medical offices, pharmacies, and community-based social services. Such places include I emergency rooms (ER) where people gain the only available access to care, schools where data on the use of t school lunches programs indicate the nutritional needs of a child as well as the family, since one can “follow a fat kid home and find a fat parent”, “well baby clinics” and the WIC program.

Medical Professionals and Health Facilities: Records of physicians, pharmacists, and “well baby” clinics are one place to gather community-based data. Non-medical, health-related places such as natural food stores and a GMC are yet another source of data on a community’s health priorities.

Socioeconomic Data: Traditional census-based data that include demographics and socioeconomic indicators are available to identify other factors important to people; however, study participants also reflected on the importance of knowing “where people are spending their money” or whether they need help to pay the bills. Information regarding financial assistance needs can be collected by searching utility company records for “turn off notices” and participation in energy assistance programs, and identifying persons receiving disability compensation.

Social Networks and Social Media: Social contacts influence individuals in many aspects of their lives, including health care decisions. The range of locally based social influencers includes networks of support groups, friends, neighbors, and translators for those whom English is not their native language. Social media influences are wider reaching, such as radio and community newsletters. Social media is especially important for teenagers. A challenge with social influences

is the “negative imagery” these can have on individuals, thus understanding how this affects individuals is a potentially important source of data.

D. Importance of Terminology

Three salient points about terminology emerged from the focus groups that need to be considered as the PCORI Methodology Committee moves forward with the aim to engage hard-to-reach people in research that is meaningful to them: 1) “Patient-centeredness” was not reflected in the PCORI questions; 2) The phrasing of the PCORI questions was confusing; and 3) Don’t use “outcomes,” “interventions,” and “comparators.”

D1. Definition of Patient-Centeredness

A patient is more than the illness or condition being studied. For example, the diabetic woman who participates in a study on a new medical treatment for diabetes, who has a strong family history of diabetes with complications, and who has social determinants that affect her ability to effectively manage her diabetes, has issues to deal with other than following the intervention protocol. These issues should be factored into research design. Otherwise, nothing has changed and the medical model continues to dominate research.

D2. Confusing Phrasing of Questions

During the Phase 1 and Phase 2 FG/Is, it became clear that the verbiage of the questions in the original Request for Proposals was confusing, not only to hard-to-reach patients but also to researchers and other experts with experience conducting research. We attempted to rephrase questions to maximize the value of our qualitative research, but also suggest that future research is needed on how best to frame and phrase PCOR questions. Assuring that the phrasing of questions are comprehensible also will support future methods for engaging hard-to-reach people in identifying and prioritizing research questions; identify meaningful outcomes and comparators/interventions; and PCOR dissemination and implementation activities.

D3. Do not use “Outcome,” “Interventions,” or “Comparators”

These terms are research terms, and are rarely used by anyone outside the research enterprise, especially by people who are hard to reach and engage in research. They are neither “patient-centered” nor “person-centered” and using them contradicts the intentions of PCORI.

E. Key Findings

Additional key findings emerged from the focus group interviews that are critical to the success of PCORI's mission to identify and define best practices to create high-integrity, evidence based information that will help people make informed health care conditions. These findings are listed below in the words of the participants. When the meaning is evident, no further explanation will be provided for that particular finding.

1. "Do not put yourself (the researcher) higher than the participants".
2. "Give first; take later".
3. "Perceive study participants as the experts because they are teaching us".
4. Use "people" not "patient".
5. "Do not treat people like lab rats."
6. "Use high touch, not high tech."
7. "Do not impose views and judgments."
8. "People have to understand what is in it for the researcher".
9. "Acknowledge that study participants are giving more than the researchers are giving back."
10. "Some people you just have to leave alone".
11. "Certain health issues, they're stigmatized. You have to break down the barrier of stigma".

Beyond these key findings, there also are a series of "lessons learned," which are described in **Appendix H**.

IX. Deviations

There were several deviations from the scope of work, some of which were intentional to address issues that arose and some of which were unintentional and reflected the reality of the need for compromise when partnering with community-based organizations.

A. Non-physicians attending a physician focus group

The Association of Black Cardiologists recruited participants for their focus group using their membership list of individuals in the Baltimore area. Since non-physicians can belong to ABC, several non-physicians (e.g. two nurses and a social worker) participated in the ABC focus group that was held on February 1.

Mitigation plan for deviation: Individuals who participated in the ABC focus group identified their profession so we were able to separate out the physicians and non-physicians in the room. The interviewer (Dr. Kauffman) was aware of which participants were physicians and was able to address questions and analyze findings accordingly.

B. Merging of two focus groups of bilingual Spanish-English participants into one

While the individual responsible for recruiting understood that we wanted two separate groups, she determined that the best time for participants was during a 1 ½ hour block on a Saturday. The intent was to separate the participants into two focus groups; however, upon arrival to the community-based center where the focus groups were to occur, it became apparent that there was only one room and separating individuals into two groups in that one room was not feasible.

Mitigation plan for deviation: Instead of sending half of the participants home and risking alienation of focus group participants who had volunteered to give up part of their Saturday to participate, the lead interviewer made a real-time decision to proceed with a larger focus group. The information that emerged was informative, although there was relatively little new information that emerged from that focus group. This was principally because we had already conducted most of the other FG/Is and were nearing theme saturation, as described by the interviewer in her email after the focus group:

- *Most of the 18 participants offered comments during the discussion.*
- *I don't have the sense that splitting the participants into two separate groups would have encouraged additional comments. There was no one who was particularly dominating the conversation, and the conversation flowed smoothly. Everyone had an opportunity to comment.*
- *I believe we have reached saturation of the themes that have been expressed in the groups for both the African Americans and the Spanish-speaking bilingual groups (i.e., no new ideas were expressed in Saturday's group and almost all of the themes were identical to those expressed by the lower SES African American and faith-based groups).*

C. Low turn-out for visually impaired

The total number of participants (N=8) from among the visually impaired community was below the targeted sample size (N=12). This is the only one of the ten categories of stakeholders where we did not reach the target number.

Mitigation plan for deviation: While the number of participants was lower in the visually impaired focus groups, the participants were just as vocal as in other FG/Is and added new information that did not emerge from other FG/Is. Due to the constrained timeline, we decided not to conduct another focus group among visually impaired individuals and instead conducted a third focus group among hearing impaired individuals, where the investigative team felt we were more likely to obtain "new" information.

D. Oversampling of hearing impaired

The first two groups of hearing impaired patients were mainly individuals who had lost their hearing in their older age and the Principal Investigator and investigator team felt that these individuals are quite different from individuals who are born with impairment or lose their hearing at a younger age.

Mitigation plan for deviation: We conducted an additional focus group of individuals with cochlear implants recruited from the audiology clinic at UMB. While the number of participants was small (N=3), the individuals were diverse in terms of age, gender and race.

X. Recommendations in terms of Proposed Standards

A. Proposed Standards

Based upon conversations with PCORI staff, we decided to provide recommendations in the Standards Format that was sent to us by Anna Cottone. The next several pages reflect our current draft of those proposed Standards.

Standard #1: Pre-Engagement

Name of Standard	“Pre-engagement” of stakeholders as initial engagement step.
Description of standard	<p>“Pre-engagement” of stakeholders builds trust and motivates meaningful engagement. Prior to implementing a PCOR study, investigators should utilize a period of “pre-engagement” when recruiting research participants and partners. This allows time to assure that both partnering institutions and PCOR participants comprehend the study and have sufficient time to have their questions answered and concerns addressed. In addition, research participants often wish to discuss participation with family and friends; pre-engagement allows the potential PCOR participant to make an informed decision and feel comfortable participating so that those who choose to participate are better equipped and motivated to make meaningful contributions to PCOR. This “pre-engagement” may also apply to other phases of PCOR research involving patient engagement, such as partnering to identify and frame the research question or to disseminate findings.</p>
Current Practice and Examples	<p>There are examples of long-standing partnerships between researchers and communities including, but certainly not limited to, the Jackson Heart Study.</p> <p>Pre-engagement occurs informally when researchers return to populations where a relationship has been previously established and when recruiters keep patients informed of upcoming studies; however, most research does not work to establish a relationship with patients prior to beginning a new study. At the time of recruitment, patients often are asked to participate and consent on the same day; this does not allow sufficient time for them to decide whether they really are comfortable with participation.</p>
Published Guidance	<p>The concept and importance of community engagement is well supported but there is no previous guidance for conducting preliminary relationship building or pre-engagement.</p>

<p>Contribution to Patient Centeredness</p>	<p>The adoption of this standard would contribute to patient centeredness by building a foundation upon which meaningful PCOR could be performed. Patient recruitment currently represents only a small component of the overall research project and often begins with the research. Pre-engagement of patients well before research promotes an environment where a greater number of individuals will be more comfortable participating.</p> <p>In addition to this, the pre-engagement phase could also benefit the investigator in terms of also understanding the community's needs and what barriers/facilitators may impact the research study. For example, social norms may prohibit certain groups from discussing general health conditions, as described in the Respecting Patient Privacy standard. Barriers like this could be identified in the pre-engagement phase, and addressed early on or even before the research study begins through changes in the study design, which may have a positive impact on recruitment, retention, etc.</p>
<p>Contribution to Scientific Rigor</p>	<p>In 2004, an AHRQ report examined the state of the art of community-based participatory research (CBPR) and concluded that “Many CBPR studies had strong community-institution collaborations; relatively few combined this type of collaboration with solid research methods.”</p> <p>See: http://www.ahrq.gov/downloads/pub/evidence/pdf/cbpr/cbpr.pdf</p> <p>Pre-engagement might also help with retention, which would support scientific rigor.</p>
<p>Contribution to Transparency</p>	
<p>Empirical evidence and theoretical basis</p>	<p>While there is significant empirical evidence demonstrating the benefit to creating community buy-in with research projects, there are large evidence gaps concerning the value of relationship building <i>prior to</i> performing recruitment in a research study.</p>
<p>Degree of Implementation Issues</p>	<p>There are guidance documents for various elements of formative research (e.g., needs assessments, focus groups, key informant interviews) that currently exist, but no formal methodology for implementing a “pre-engagement” strategy for PCOR. The proposed standard is more feasible if future research funding were to be conditional on researchers addressing their approach for the implementation of the “pre-engagement” process and sponsors allowed appropriate budgeting for such activities.</p> <p>This standard is consistent with PCORI’s priorities of accelerating PCOR and methodological research and addressing disparities through promoting the inclusion of patient populations that require trust-building to ensure full engagement.</p>
<p>Other Considerations</p>	<p>Research is needed to identify and test the effect of performing relationship building activities prior to the recruitment phase and other phases of PCOR research where patient engagement occurs.</p>

Standard #2: Define Research

Name of Standard	Researchers must define “research” and its purpose for study participants and community-based study site personnel as part of engagement.
Description of standard	In order to effectively engage individuals, especially hard-to-reach patients, researchers need to provide education on exactly what is meant by the term “research.” In addition, there should be an explanation of the purpose of research in general and the specific PCOR project as well as what participation in the research project entails.
Current Practice and Examples	Researchers often assume that participants have a general conceptualization of research and immediately begin to talk about the specific project; the very word “research” carries very negative connotations in some communities.
Published Guidance	<p>IRBs require that the research project be explained to participants in language that participants can understand. Most guidance documents explain how to conduct research, but not how to explain research to patients.</p> <p>There are guidance documents for dissemination of research after it has been conducted: http://www.ahrq.gov/qual/advances/planningtool.htm http://aspe.hhs.gov/infoquality/guidelines/NIHinfo2.shtml</p> <p>There is less guidance on how to explain research to patients at the recruitment phase.</p>
Contribution to Patient Centeredness	The adoption of this standard would contribute to patient centeredness by helping to familiarize diverse patients, especially hard to reach participants, with what is meant by research.
Contribution to Scientific Rigor	PCOR results will be arguably more meaningful due to the inclusion of participants who fully grasp the purpose of the study.
Contribution to Transparency	Once the negative feelings and the confusion surrounding the term “research” are removed, individuals will feel more comfortable participating in research studies. This is consistent with the purpose of PCOR and will contribute to greater participation from traditionally under-represented groups whose misconceptions have kept them from associating the concept of “research” with a positive experience.
Empirical evidence and theoretical basis	The Tuskegee experiment is well known to influence (low) participation of African Americans in research because of lack of understanding and distrust of research.
Degree of Implementation Issues	<p>The concept of assuring that patients understand the risks and benefits of participation in research is universally accepted as an essential component of the ethical conduct of research. There is broad support for engaging hard-to-reach patients in the research process, many of whom have an inherent distrust of research.</p> <p>This standard is consistent with PCORI’s priority of communication and dissemination research.</p>

Other Considerations	Methodological research is needed to further identify the appropriate ways to accurately relate the concept of research to various hard to reach populations.
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Standard #3: Giving Back

Name of Standard	Engagement of participants in celebrating or disseminating information at key milestones of a research study.
Description of standard	<p>Participants want to be kept abreast of research progress and want a celebration or recognition at the conclusion of a study. Participants are aware of the fact that they “give more to the researcher than they get in return” and would like some feedback at various points throughout the research progress. In short, participants want the researcher to “give back” to the community in terms of feedback on the study.</p> <p>Providing a lay summary to participants is a minimum expectation. Researchers may also want to “give back” to the community in other ways, such as volunteering their time.</p> <p>Once research concludes, a plan for dissemination should be implemented to share the findings of the research study with participants and their community/organization in a timely manner in order to promote meaningful participation in future research studies. As a component of this dissemination, researchers need to be aware that research occurs in the community as well and that the setting of any follow-up should be appropriate for the patient group participating.</p>
Current Practice and Examples	<p>“Best practice” research groups do return to the communities and populations they studied to relay information on key findings in lay terminology; however, they are the exception rather than the rule. Many research teams neglect to take the time to “give back” or explain their results to their study participants.</p> <p>Some participants also want a celebration at the end of the study to recognize those who have contributed to science and the generation of new knowledge.</p> <p>Simple ways of providing feedback directly (e.g., via emails) or indirectly (e.g., via a study website where the public may view interim updates) include:</p> <ul style="list-style-type: none"> • Updates on percentage of patients enrolled at key milestones (e.g., 50% enrollment, enrollment completed) • Assistance with finding other research opportunities • Lay presentations at local community centers
Published Guidance	<p>Guidance for appropriately managing follow-up of patients for purposes of disseminating findings has not been established.</p> <p>The NIH does require a transition plan for patients following research studies funded by the NIH.</p>

<p>Contribution to Patient Centeredness</p>	<p>People do not view researchers as always having the patients' interests in mind and frequently want to know "what does the researcher get out of this?" Patients also would like to get something directly for participation.</p> <p>A major component of patient engagement is a commitment to giving something back. Adoption of this standard would ensure that PCOR remains centered on patients even after the completion of the research study, creating a lasting relationship that will encourage effective future participation. Current methods for dissemination are not patient centered and often do not express adequate appreciation of the research participants.</p>
<p>Contribution to Scientific Rigor</p>	
<p>Contribution to Transparency</p>	<p>"What ever happened with that study?" Research nurses often are asked that question by patients because patients were never told anything after they finished their participation. Changing this practice by consistently reporting results back to patients and communities would increase transparency of PCOR.</p>
<p>Empirical evidence and theoretical basis</p>	
<p>Degree of Implementation Issues</p>	<p>The standard represents an efficient means to promote the creation of meaningful relationships with research participants.</p> <p>This standard is consistent with PCORI's priorities of communication and dissemination of research and addressing disparities through its mechanism of creating relationships that will enable more effective engagement with subpopulations hesitant to trust researchers.</p>
<p>Other Considerations</p>	<p>One suggestion for a way to get people interested is to give out information or access to resources before researchers start asking patients and other stakeholders for participation, opinions, etc.</p>

Standard #4: Trust

Name of Standard	Establishing trust as a bridge for engagement that endures.
Description of standard	Establishing trust with PCOR partners and recruitment populations builds bridges for open and enduring engagement. Building and maintaining trust has emerged as a key factor in the decision process of hard-to-reach individuals considering participation in the research process and should be a major consideration when recruiting and interacting with study participants. Furthermore, there is a need for trust to develop between academic researchers and physician communities (e.g. primary care) from whom researchers expect to recruit patients.
Current Practice and Examples	Researchers currently rely on trust when seeking partners for recruitment but this trust can easily be lost if a participant or partner involved in recruitment activities feels misled about the nature of the research. Trust generally takes time to build and requires continued communications in between PCOR projects. If trust is established between (1) researchers and partners involved in recruitment as well as between (2) partners and patients, then research participants may be willing to volunteer to participate faster because of the existing relationships built on trust.
Published Guidance	“Borrowing” trust from key individuals invested in the community is often how recruitment is performed by researchers unfamiliar with the population they wish to study. This may work, but ideally the researchers themselves should be known to the community and should be actively engaged in the communities. Various articles (but few guidance documents) exist on the appropriate means for maintaining trust throughout and across PCOR projects. Good examples come from the CBPR literature.
Contribution to Patient Centeredness	This standard should be adopted as it promotes maintenance of genuine relationships that are essential to eliciting high quality PCOR.
Contribution to Scientific Rigor	Without trust, patient-reported outcomes may not be valid and reliable. This is true not only because PCOR participants will be more willing to truthfully respond to questions, but also because trust supports an opportunity for patients to ask questions so that they can meaningfully participate in research and respond to research questions.
Contribution to Transparency	Trust is paramount to transparency.
Empirical evidence and theoretical basis	

<p>Degree of Implementation Issues</p>	<p>Being honest with participants and demonstrating a commitment to a community is well supported as a means of successful engagement.</p> <p>Earning trust in certain communities can require a substantial contribution of time and resources.</p> <p>This standard is consistent with three of the priorities established by PCORI. It provides support for the creation of relationships to facilitate communication, promote the engagement of hard to reach patients, and increasing understanding of disparities that exist within a certain community.</p>
<p>Other Considerations</p>	<p>Many communities believe that trust must be earned. If results are not fed back to community physicians who help to identify patients for PCOR studies, they will be less motivated to participate in future PCOR.</p> <p>The development of a community advisory board to ensure that participants' concerns are heard through a party that is external and impartial to the research team is one element that could foster trust. This would help to ensure that participants are comfortable expressing their concerns.</p>

Standard #5: Respecting Patient Privacy

Name of Standard	Maintaining confidentiality in research to promote patient engagement
Description of standard	In designing a research study, investigators need to consider the possibility that individuals may not be willing to openly disclose medical information out of fear of being ostracized from their community. In addition, many cultures believe that personal information should be “kept in the family.”
Current Practice and Examples	Traditionally, researchers adequately protect medical information once it is collected. However, this precaution does not address some individuals’ reluctance to participate in a study because the mere act of participating in a study may reveal medical information they would prefer to keep to themselves.
Published Guidance	Guidance on the importance of tailoring messages to populations of interest does exist but is viewed as more critical after recruitment rather than during the recruitment process.
Contribution to Patient Centeredness	This standard plays a critical role in ensuring that all eligible patients are able to contribute to PCOR. Failing to consider that certain populations are not comfortable acknowledging they have a particular condition, much less talking about it in a group setting, will result in focusing on those outcomes that are meaningful only to individuals comfortable with sharing the nature of their condition. Moreover, some individuals do not feel comfortable even being asked general questions. For examples, certain minority groups such as African American and Hispanic men may not want to discuss their general health status with anyone lest it expose a “chink in their armor”.
Contribution to Scientific Rigor	
Contribution to Transparency	Developing methods for not only assuring patient confidentiality but also explaining to patients and research partners exactly how shared information will be kept confidential will assist with promoting transparency. Furthermore, there is a need to developed guidance for ways to broach the subject of health in a non-threatening manner (i.e., not just assuring confidentiality but also how best to ease into the subject in culturally sensitive ways).
Empirical evidence and theoretical basis	
Degree of Implementation Issues	<p>The standard of crafting a culturally-aware recruitment document is well supported.</p> <p>This standard is consistent with PCORI’s priority of accelerating PCOR and methodological research. In hard to reach populations, application of a successful means of communication can optimize patient engagement.</p>

Other Considerations	This standard should also address the concept of maintaining confidentiality in the context of research and clinical care. Researchers will typically promise that identified data will remain secure and won't be shared with anyone outside the research team. However, certain data that may be collected as part of research are and need to be shared with the participants' clinicians in order to provide high quality care. This distinction should be part of this standard and addressed in IRBs and study protocols. Better methods need to be developed to address sharing of data between PCOR researchers and clinicians.
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Standard #6: Person-Centeredness

Name of Standard	Person-Centeredness
Description of standard	People make health care choices and participate in research based upon who they are not only as patients, but as individual persons. Being viewed as a person, and not just a patient removes the stigma of having an illness or health conditions and addresses the multiple medical and non-medical conditions that influence informed decision making and participation in research.
Current Practice and Examples	<p>The term “patient” implies a health condition that requires management or a cure by a health care provider who may only know the person within the context of the medical model. It often implies a top-down relationship of a provider with the person who is expected to comply and adhere to a provider-prescribed treatment protocol. Using the term “patient” lessens the importance of understanding the social and physical environments of persons that strongly influence their decision making and participation in research, which contradicts the intent of PCOR.</p> <p>Researchers typically view study participants narrowly within the context of contributing data to complete their projects, thereby limiting full engagement with the patients. In practice, when patients feel listened to and respected, and are provided with “whole-person” care, particularly within the context of a sustained relationship, they are more likely to be satisfied, informed, and better able to make decisions about their own health and participation in research.</p>
Published Guidance	There is no published guidance on this standard.
Contribution to Patient-Centeredness	Viewing and treating the patient as a well-rounded, multidimensional person makes the patient feel more in charge of her/his own actions, and leads to mutual understanding and respect between the researcher(s) and the patient. , While using the term “patient” implies a focus on treatment and cure, researchers should mindfully broaden the conceptual field for other kinds of research, such as health promotion, health maintenance, disease prevention, and implementation science that focus on populations of persons, and not individuals as patients
Contribution to Scientific Rigor	Study participants who are viewed as persons by researchers will engage more fully and accurately in the research process when they feel more respected and less as “lab rats.” They will find value in their participation and encourage others to participate in research.
Contribution to Transparency	Person-centeredness will empower study participants to question processes to gain better understanding of the purpose, risks/benefits, interventions, and outcomes of the research.
Empirical evidence and theoretical basis	The evidence and theoretical basis in the literature for person-centeredness in research is in early development. As such, methodological research is needed to further identify the appropriate ways to accurately relate the concept of person-centeredness to various hard to reach populations and to determine the effects of this approach.

<p>Degree of Implementation Issues</p>	<p>Changing expectations in RFPs and proposals should not be difficult. Changing the mindset of researchers is a culture change that requires deliberate and persistent action by PCORI.</p> <p>This standard is consistent with PCORI's priority of accelerating PCOR and methodological research. It promotes engaging individuals by creating a more balanced relationship that promotes meaningful interaction between that person and researchers.</p>
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Standard #7: Community Engagement

Name of Standard	Diverse participation requires community engagement.
Description of standard	<p>Diversity and inclusion of hard to reach patients requires bringing PCOR to communities where people live.</p> <p>Optimal engagement can only occur when researchers consider that hard to reach people must be able to witness to and participate in the research process. The implication is that the phases of research occur in the physical spaces and communities inhabited by hard to reach people. The 'physical spaces' include community recreation centers, grocery stores, neighborhood blocks and do not necessarily include academic or corporate settings. The 'communities' include city neighborhoods and immigrant communities and do not necessarily include downtown (i.e. business) city blocks or suburban towns.</p>
Current Practice and Examples	Frequently, researchers require participants to come to them, which often results in including only the most motivated patients.
Published Guidance	Community-based participatory research offers excellent guidance for engaging diverse communities.
Contribution to Patient Centeredness	The essence of PCOR is to address the health concerns and answer the questions that patients have for "people like me," which requires greater inclusiveness and diversity.
Contribution to Scientific Rigor	Broader diversity increases generalizability and applicability of PCOR findings.
Contribution to Transparency	
Empirical evidence and theoretical basis	
Degree of Implementation Issues	<p>It's important to note that there likely will still be segments of every population that no matter how hard one tries to engage them, they will not participate. That being said, going to where the target populations frequent will encourage much more inclusiveness and diversity than traditional research studies have included.</p> <p>This standard is consistent with PCORI's priority of accelerating PCOR and methodological research.</p>
Other Considerations	

Standard #8: Full Spectrum Recruitment

Name of Standard	Full Spectrum Recruitment
Description of standard	Recruitment for PCOR studies should involve the full spectrum of individuals impacted by the medical condition or health-related question being examined, including hard to reach patients.
Current Practice and Examples	Government funding agencies typically require that sponsored research address priority populations, including hard to reach patients. However, recruitment of patients often remains limited to a catchment area that reflects a convenience sampling process that can leave out important subpopulations. Even among hard to reach populations, there are still individuals who are consistently easier to reach than others so diversity alone is insufficient evidence that “the full spectrum” of relevant patients is included in PCOR.
Published Guidance	<p>There are some slides, articles and general guidance on priority populations, which support the inclusion of more diverse patient populations. Examples include:</p> <p>http://www.ahrq.gov/about/annualconf11/chesley_perez_swenson/chesley.htm</p> <p>http://jama.ama-assn.org/content/305/4/404.full</p>
Contribution to Patient Centeredness	The concept that individuals with a given medical condition are heterogeneous is commonly accepted, yet heterogeneity within hard to reach patient groups is less understood. The adoption of this standard will ensure that the diverse spectrum of patients, not just those who represent the groups who are easily accessible to researchers, are engaged in PCOR.
Contribution to Scientific Rigor	Incorporating the views and opinions of a wider spectrum of individuals, rather than rely on the generalizability of findings from easily accessible patients will produce PCOR findings that are meaningful to a wider array of patients. This will enhance generalizability of PCOR.
Contribution to Transparency	
Empirical evidence and theoretical basis	
Degree of Implementation Issues	<p>The importance of engaging hard to reach individuals in the research process is widely supported.</p> <p>This standard is consistent with PCORI’s priority of accelerating PCOR and methodological research.</p>
Other Considerations	Additional time and resources may need to be committed in order to generate a relationship with individuals who have previously been left out of a research project. Appropriate funding for activities and processes that are required for broader patient engagement are necessary to fulfill this standard.

B. Implementation of Standards in Hard-to-reach populations

Many of the proposed standards are likely to apply to various patients and stakeholders, not just hard-to-reach patients and their care providers. However, since our focus was on the hard-to-reach populations described in this document, it will be important to vet our proposed Standards with others.

The implementation of all Standards in hard-to-reach communities likely will require special attention. We refer individuals to earlier sections of this report for guidance with a **strong recommendation that the issue of development and maintenance of trust with members of the hard-to-reach community is critical for rigor and feasibility of conducting PCOR in hard-to-reach populations.**

XI. Knowledge and Evidence Gaps

This study provides guidance for conducting PCOR in hard-to-reach patients. Future PCOR studies likely will produce more meaningful results if the proposed standards are applied. Nonetheless, there is a need for further methods development as well as health policy work in PCOR. Following are a few suggestions based upon the findings of the current project.

A. Future Needs for PCOR Methods Development

The following bulleted list includes areas where future PCOR methods development is warranted based upon our findings and experiences:

- Methods for “pre-engagement” of patients, partnering institutions and community sites
- Mapping of PCOR methods to phases of research, recognizing that the same methods for pre-engagement and recruitment likely differ from implementation of PCOR or translation/dissemination
- Methods for building and maintaining trust with PCOR participants and partnering organizations and communities, i.e. methods that describe “best practices” to pre-engage, relate, communicate, and be there for the participating individuals and communities
- Processes for providing feedback to PCOR participants in “real time” as a means for maintaining trust and goodwill without jeopardizing the scientific integrity of research
- Delineating which “best practice” methods used in community-initiated research (or community-based participatory research) can be applied directly to PCOR
- Methods for resource sharing and dissemination plans for PCOR-funded research
- Methods for understanding how parents and other surrogates respond, balancing between what is important to them versus what they believe would be important to their child or the actual patient
- Means for assuring that patients comprehend the specific PCOR project (e.g. to assure that they do not think that the PCOR study is an opportunity to receive care or obtain information about their conditions or treatments)

B. Future Needs for Health Policy and Research Needs

The following bulleted list includes areas where future developments are needed to address the important health policy and research needs, based upon our findings and experiences:

- Methods for identifying and setting priorities that address the needs of hard-to-reach patients so that minorities and those with rare disease are not “left out” of PCOR
- Research to identify diversity within (not just across) subpopulations with regard to PCOR needs
- Broadening the list of hard-to-reach patients to include other understudied populations
- A shift in the culture of research that will encourage and incentivize investigators to use PCOR methods in their studies, including financial and scientific recognition and support from academia, the government, and other policy makers

XII. Dissemination (Proposed)

The following bulleted list includes proposed dissemination strategies, conditional upon approval by PCORI:

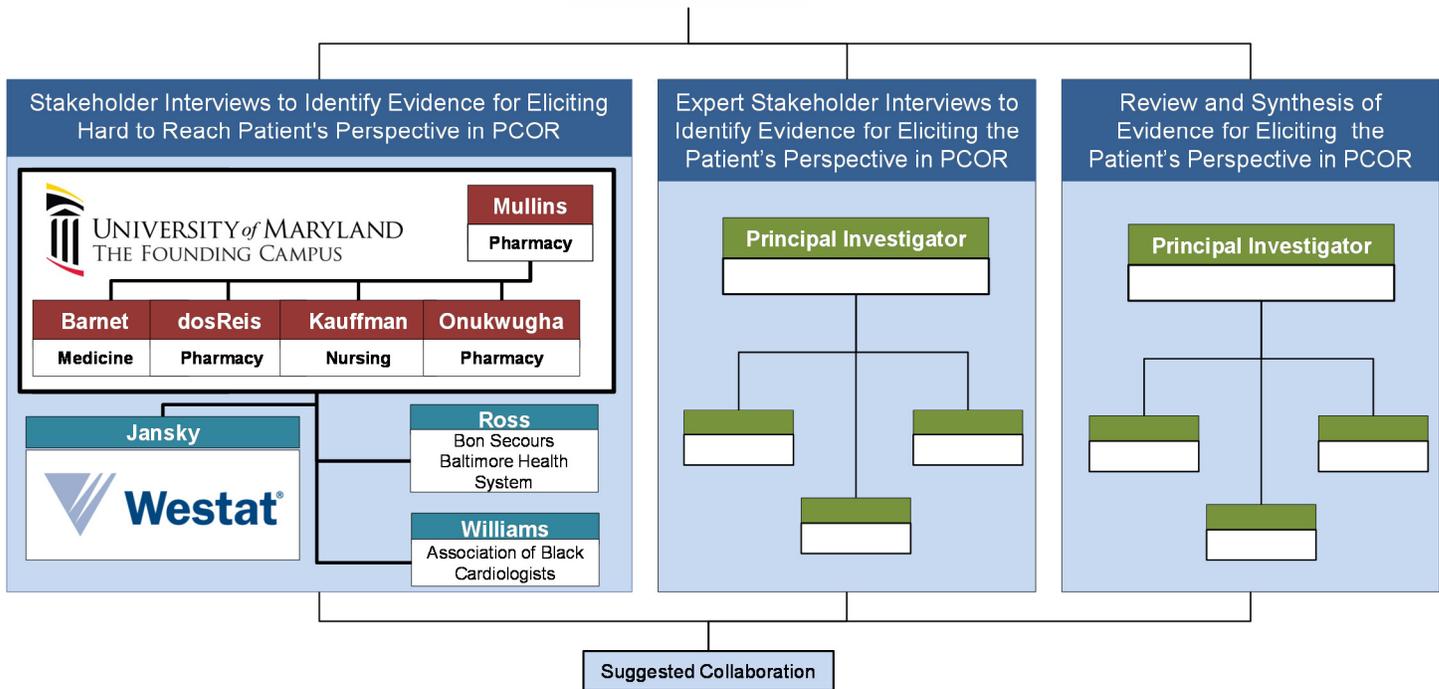
- Presentations of results to partnering organizations and study participants, including but not limited to:
 - Association of Black Cardiologists
 - Baltimore City Health Department
 - Bon Secours Baltimore Health System
 - Mt. Lebanon Baptist Church
 - UMB seminar series and grand rounds-type lectureships
- Presentations at national meetings such as
 - AcademyHealth
 - ISOQOL
 - ISPOR
- Publications of findings, possibly in conjunction with PCWG members and/or other PCORI awardees

XIII. Appendices

A. APPENDIX A: Partners

Alzheimer's Association
Association of Black Cardiologists
Bon Secours Baltimore Health System
Community Health Integrated Partnership
Maryland Coalition of Families
Taghi Modarressi Center for Infant Study, FITT Center, UMB Department of Psychiatry
Mt. Lebanon Baptist Church
Weinberg Senior Centers

B. APPENDIX B: Scope of Work



General Overview

University of Maryland and our partners will collaborate to develop an interview guide, conduct focus groups/interviews (FG/Is), interpret and disseminate findings of FG/Is aimed at enhancing methods for engaging hard to reach patients in patient-centered outcomes research (PCOR). Our partners include Westat, who will conduct FGI/s with patients and 2 community-based partners: Bon Secours Baltimore Health System and the Association of Black Cardiologists. The FG/Is will be conducted primarily in the greater Baltimore area with hard to reach patients and those who serve or care for them (family members, physicians and other health professionals). Our research will be coordinated with the PCORI Methods Committee and the recipients of the PCORI Eliciting Patients' Perspectives Interviews and Systematic Review grants.

In identifying hard-to-reach patients, we will pay particular attention to demographic characteristics (e.g., non-English language-speaking adults (Spanish and other languages based upon Baltimore demographics), patients with low income and/or other socioeconomic status, other characteristics that contribute to disparity, and impairment to mobility, sensory impairment (e.g., low vision, hearing), cognitive impairment. Our proposal is to conduct 2 focus groups with 6-8 individuals per focus group in each of the following categories:

- African Americans, predominantly of low SES, from Bon Secours Baltimore Health System
- Spanish-speaking patients, predominantly of low SES, from Bon Secours Baltimore Health System and other languages as feasible given the patients within Baltimore and language abilities of Moderators
- Hard to reach patients within faith-based organizations (principally African American)
- Limited mobility patients

- Patients with vision impairment
- Patients with hearing impairment
- Physicians who treat hard to reach patients
- Nurses who treat hard to reach patients
- Parents of children who are hard to reach patients
- Caregivers (e.g., adult children or spouses) of patients with cognitive impairments

If focus groups are not manageable due to schedules, we will conduct individual interviews to get the same number of stakeholders.

The FG/Is will focus on the following set of questions, which will be rephrased during Phase 1 of the study:

Q1. What practical methods are effective in engaging patients and their surrogates in:

- 1) identifying and prioritizing research questions
- 2) identifying outcomes that are meaningful to them
- 3) identifying comparators/interventions that are meaningful to them?

Q1i. What methods are effective in ensuring that the full spectrum of patients is represented, including hard to reach and under-represented patients?

Q2. What methods are effective in ensuring that informants understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision making?

Q3. What data are available that identify other factors and issues that are important to patients (or surrogates) that need to be considered?

Methods for Refining the Interview Guide and Conducting FG/Is.

While interview questions should be open-ended, there must be a structured approach to conducting interviews, which requires the development of an Interview Guide and related processes for conducting interviews. **We will conduct two phases of interviews following IRB approval.** Phase 1 will help to refine the phrasing of FG/I questions and probes. Phase 2 will utilize the refined set of questions.

Phase 1: Refining the Interview Guide, Questions, and Probes. In this “formative” phase, eight to ten diverse stakeholders, representing hard to reach patients and their caregivers, will be invited to participate in either a focus group or key informant interview with a subsequent debriefing to elicit their feedback on the scope and phrasing of questions. The 1 or 2 focus groups will last 2 hours and each interview will last 90 minutes. This will allow for 60 or 75 minutes for the focus group or key informant interview and an additional 30 or 45 minutes to obtain feedback on the phrasing of the questions and probes. Most will be conducted “on site” at the participating organizations or a local community-based center to maximize their full engagement in both the interview and debriefing; however if necessary, some will be conducted by phone. Phase 1 has three goals: (1) to interview a variety of stakeholders to identify relevant domains to be addressed in Phase 2 FG/Is; (2) to produce final questions and related materials for the Interview Guide for Phase 2 that reflect the modified Framework; and (3) to obtain suggestions and referrals for stakeholders for Phase 2 FG/Is. At the end of Phase 1, UMB and Westat will collaborate to refine the Interview Guide that will be used in Phase 2.

Phase 2: In-Depth Interviews. An Interviewer/Moderator for the FG/Is and a Note-taker will participate in each individual in-depth or key-informant interview as well as each FG/I. Westat will train staff by: (a) reviewing essential points for moderating (e.g., opening, probing techniques, handling difficult participants) and closing (summarizing the information for confirmation or clarification by the participants) the interview;

and (b) providing guidance for observation and recording of interviewees' body language and other relevant communication behaviors. Before starting the FG/I, oral consent (or written consent based upon the IRB's decision) will be obtained from all participants. UMB faculty members will attend a subset of patient FG/Is as observers and will take the lead in conducting FGI/s with the non-patient stakeholders (e.g., clinicians, family members who serve or care for hard to reach patients.)

Sample open-ended questions, reflecting how we propose to reword some of the questions are shown in **Table 1**, along with a partial list of probing questions. FG/Is will engage all participants in a manner that is inclusive and not judgmental so as to encourage expression of diverse viewpoints. The questions will be framed appropriately for each stakeholder type; as an example, we show distinct proposed phrasing for clinicians (e.g., physicians and nurses) and patients in **Table 1** to illustrate how we will rephrase across interviewees.

Table 1. Interview Questions Pertaining to Methods for Engaging Patients' Preferences

Question as stated in RFP: What practical methods are effective in engaging patients and their surrogates in identifying and prioritizing research questions? (Q1, Part 1.)	
Rephrasing for Clinician Caregivers	Rephrasing for Patients
<p>What method(s) for engaging patients (or surrogates) would provide objective processes for identifying PCOR questions?</p> <p><i>Probes:</i> What are the challenges/obstacles of involving patients in identifying research questions? How could these obstacles be overcome?</p>	<p>How can patients like you identify the most significant questions about your health care condition and treatment options?</p> <p><i>Probe:</i> What would make it easy or difficult for patients to identify significant questions about their health care condition and treatment options?</p>
Question as stated in RFP: What methods are effective in ensuring that informants understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision-making? (Q 2.)	
Rephrasing for Expert Stakeholders	Rephrasing for Patients
<p>Could you describe some of the key elements for determining whether patients fully understand the clinical and research implications?</p> <p><i>Probes:</i> How should clinical and research issues be framed so that patients have a good understanding of the risks and benefits? What would the informed consent process look like to ensure patients fully understand the pertinent issues?</p>	<p>How can we help patients understand the health benefits as well as the potential harms of alternative treatment strategies?</p> <p><i>Probe:</i> What would be a good way to describe to a patient how a research study can inform their decision about medical treatments?</p>

Conducting Interviews: Logistics. Melissa Ross, MA, will serve as project coordinator and support Professor Mullins in contacting individuals and organizations to facilitate setting up the interviews. Once a participant's interest is confirmed, Melissa will slot them into an appropriate FG/I. A calendar of availability will be maintained to coordinate dates/times. Each FG/I will be conducted by an Interviewer/Moderator and a Note-taker who will chronicle the content of the discussion. Discussions also will be audio recorded (with consent of participants) to supplement the comprehensive notes. Using the notes and audio recording, the Note-taker will organize and clean meeting notes, which will be reviewed by the Interviewer/Moderator. The Interviewer/Moderator will review for clarity and add his/her reflections on the interview process including barriers and facilitators to data collection.

For the proposed project, UMB investigators and Westat agree that:

- (1) There is value in using different approaches *across and within* different stakeholder types.
- (2) In some cases, it may be important for the Interviewer/Moderator to be physically in the same location as Stakeholders who are being interviewed; in other cases, this may be less critical. Part of this depends upon whether there is an established trust between those conducting the interviews and the interviewees.
- (3) Pragmatic considerations in light of the timeline and need for completion of the project within less than 4 months may limit the ability to schedule interviews with multiple stakeholders at the same location and time, *even when this would be ideal*.
- (4) We anticipate it will be easier to group Patients than Expert Stakeholders due to greater flexibility in patients' schedules and the fact that there is a larger patient pool from which to sample. Furthermore, recruitment of Patients will be greatly enhanced with the recruitment efforts by the Bon Secours Baltimore Health System and other physician and community-based partners.
- (5) We anticipate "group interviews" will be easier to facilitate when Stakeholders are affiliated with, or recruited by, the same institution (e.g., 6 interviewees from ABC or a church) than across institutions (e.g., we do not expect that hard to reach patients and physicians who care for them would be interviewed simultaneously).

Given these 5 considerations, we will proceed with FG/Is in a manner that attempts to utilize multiple methods for FG/Is, while balancing practical considerations due to time constraints.

Quality control and data management. Westat is a highly regarded research institution with a long track record in conducting field interviews and a firm commitment to data security. The Interviewers/Moderators and Note-takers will be assigned based on their expertise in conducting in-depth FG/Is. The Westat Task Manager (Liz Jansky) will receive an automated alert when interview notes have been posted by interviewers. Ms. Jansky will review summaries for comprehensiveness and quality and consult with the interviewer for clarification if needed. Ms. Jansky will meet weekly with project personnel.

Method used to systematically identify individuals with expertise in eliciting patients' perspectives within each Stakeholder Group to ensure a comprehensive sampling. We will utilize five main avenues to recruit patients:

- (1) Bon Secours Baltimore Health System
- (2) The practice-based research network to which Dr. Barnet belongs and other UMB clinics
- (3) Other Baltimore-based community or faith-based organizations (e.g., Mt Lebanon Baptist Church)
- (4) Referrals from Phase 1 interviewees and prior grant partners

Bon Secours Baltimore Health System will assist with Patient recruitment related to racial/ethnic diversity and those with low socioeconomic status. Samuel Ross, MD, who is the CEO, confirmed support from Bon Secours Baltimore Health System for the revised proposal via email with Professor Mullins. Research Nurse Aurelia Laird, RN from Bon Secours Baltimore Health System, is bilingual (Spanish and English) and has confirmed her willingness to assist with recruitment and conducting of interviews with Spanish speaking patients. Bon Secours Baltimore Health System served as the "minority serving health care system" partner on an NHLBI U-01 grant with UMB.

Physicians and other partners will assist with Patient recruitment related to impairment and patients who speak languages other than English or Spanish. As part of our outreach effort, we will recruit patients with impairment to mobility, senses (e.g., low vision, hearing), or cognition. This outreach will utilize UMB and Bon Secours Baltimore Health System clinics as well as snowball sampling, whereby patients may help to recruit other patients.

Methods used to determine that necessary number of interviews has been completed and that theme saturation has been reached within each Stakeholder Cluster (Hard to Reach Patients, Clinicians, and others who Care or Serve Hard to Reach Patients.) Standards in the field suggest that the number of completed interviews to reach saturation generally is about 30. It certainly will be feasible to conduct 30 patient interviews but we will not be able to interview 30 per patient subgroup type. We propose broad patient subgroups (e.g., low SES, those with a physical impairment) to be clustered for purposes of analysis so that saturation for the Patient Cluster can explore differences by type of hard to reach patient subgroup type. We are not restricting ourselves to a pre-specified target number of interviews but will target at least 100 individuals across the 3 Stakeholder Clusters (patients, clinicians, others). The final number of interviews will be based on whether we have achieved saturation within each of three main Stakeholder Clusters. We propose to convene focus groups with Patients from varied socioeconomic/ethnic groups (e.g., African-American, Hispanic) and disease states (e.g., cancer, cardiovascular, dementia, cognitive impairment). Based on an average size of eight participants per focus group and recognizing that some who agree may not make it to the focus group session, we anticipate recruiting approximately 150 Patients in order to have sufficient information to achieve theme saturation and our target of approximately 75 Patients. We expect to recruit a smaller numbers of clinicians and other stakeholders, such as 20-30 clinicians and 20-30 parents/caregivers.

Approach to Identifying Themes and Theme Saturation. During protocol development, the UMB research team, Westat, and our Partners will identify broad content areas and potential themes of interest based on their research experience and the literature. This list will be as expansive and inclusive as possible but is not intended to preclude identification and exploration of other themes that emerge during data collection. Theme identification from interviews will begin by reviewing the written notes from the FG/Is and categorizing the information. The next step will involve organizing the information into a coding (logic) paradigm. Theme saturation will be determined through an iterative process of simultaneous data collection and analysis. We will be looking for repetition and confirmation of themes and concepts that emerged from previously collected data.

Description of approach for analyzing the data from the interviews in order to complete the components of final report as outlined. Westat will provide interviewer notes at the individual FG/I level and provide them to UMB investigators for qualitative analysis. Westat will also review the analysis results produced by UMB to assure that no methods or themes are lost in the process. We expect to analyze the first group of FG/Is so that the **first group of summaries are available in late December, 2011**. Analysis will identify themes that reflect methods for eliciting patients' perspectives for PCOR. The themes will be coded and categorized into concepts for ongoing comparing and contrasting until no new themes or concepts emerge. Dr. Kauffman will lead the research team in coordinating theme generation from FG/I summaries. All summaries will be analyzed by Dr. Kauffman with assistance from Drs. dosReis and Onukwugha so each summary will be analyzed independently by at least 2 of the 3 qualitative researchers. If inconsistencies are identified, team discussions will lead toward consensus of the thematic concepts that emerge from the data. The summaries will be analyzed by early February. The last step of the analysis will be to develop a narrative of the themes including verbatim phrases that best represent patients' perspectives. This process will maximize meaningful interpretation of the data, assure rapid analysis, and facilitate reaching consensus on findings.

Development of Draft and Revised Version of Report to Serve as Final Product. The outline of the "Components of the Report" will guide the format of our report, with a focus on the sub-headings that are most relevant to the revised proposal, which is narrower in scope. In addition we propose to add (1) a concise lay summary for the general public written at a 5th grade reading level and (2) an executive summary that would be written to inform policy makers and their staff. These two summaries will supplement the more in-depth information provided in the Final Report. We also plan to provide a Methods

section that discusses how we recruited Stakeholders for the interviews, how we performed interviews, and how we analyzed findings and categorized results by Stakeholder or Stakeholder Cluster.

Components of the Report Outline

- I. Summaries (Lay and Executive)
- II. Significance of Methods for Eliciting Hard to Reach Patients' Perspectives
 - a. Why is it important to elicit the patient perspective from hard to reach patients?
 - b. Review of prior reports and publications
- III. Methods for Conducting Stakeholder Interviews
 - a. Identification and recruitment of stakeholders
 - b. Process of developing approach and conducting interviews
 - c. Assuring adequate input (e.g., saturation)
- IV. Data Analysis and Synthesis
- V. Process for Ensuring the Credibility and Applicability of Findings
 - a. Advisors from Community-Based Partners
 - b. Scientific Rigor and Interpretability
- VI. Findings
 - a. Practical Methods for Engaging Hard to reach Patients
 - i. Practical Advice on How to Implement
 - ii. Issues of patients heterogeneity and adequate assurance of broad representation
 - iii. *Repeat for each component in "Components of the Report" Outlined in the RFP*
 - b. Effective methods for ensuring that informants understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision making
 - c. Data that identify other factors and issues that are important to hard to reach patients (or those who care for or serve them) that need to be considered
- VII. Recommendation and Best Practices
- VIII. Knowledge and Evidence Gaps
 - a. Where is there a need for future methods development and why hasn't that need been met?
 - b. Future health policy and research needs

Timeline including major milestones

We are fully aware of the need to complete this project within the agreed upon time frame and have produced the Gantt chart in **Figure 1** to provide objective milestones to assure completion of all task on time in order to produce the final report by March 1, 2012.

Figure 1. Tasks and Associated Deadlines to Assure Timely Completion of Project

		2011						2012											
		PROJECT WEEK	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
TASK	LEAD [‡]	NOV				DEC				JAN					FEB				APRIL 28 th
Project Kickoff	UMB																		
IRB Submission	UMB																		
Finalize Sampling/Recruitment Plan	UMB																		
Interview Guide Development	UMB/WEST																		
Stakeholder Recruitment	UMB																		
Phase 1: Refine Interview Guide	WEST																		
Phase 2: Stakeholder Interviews	WEST																		
Summarize Individual Interviews	WEST																		
Team Conference Calls	UMB																		
Methodology Committee Calls	UMB																		
Vetting By CBP*	UMB																		
Written Status Reports	UMB																		
Synthesis and Analysis of Findings	UMB																		
Best Practice Recommendations	UMB																		
Identify Key Knowledge Gaps	UMB																		
Final Report	UMB																		
Lay Report	UMB																		

[‡] Acronyms: UMB = University of Maryland, Baltimore; WEST = Westat
^{*}CBP – Community-Based Partners (Association of Black Cardiologists and Bon Secours Baltimore Health System)

Human Subjects, IRB and Recruitment of Women and Minority Participants. We wish to document that all members of the research team have taken Training in Human Subjects Protection and will follow all policies and protocols of both the University of Maryland and Westat IRBs (as well as any IRBs of participating institutions, if applicable). This includes but certainly is not limited to patient consent and voluntary participation. We will utilize Community-Based Partners and other Stakeholders to recruit participants and we will directly communicate with all potential and actual participants that their decision to participate or not will not impact their ability to receive health care at the University of Maryland or the affiliated institution that assist with recruitment. Modest incentives (e.g., \$25 gift cards) and drinks and snacks (soda, water, cookies and fruit) will be provided during the interviews, which we do not believe will provide undue incentives for participation. We anticipate an expedited review because of the subject matter of these interviews. We will purposefully recruit women and minorities for patient and Expert Stakeholder interviews.

C. APPENDIX C: IRB Approval Letters

C1. Phase I



University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: lrpo@som.umaryland.edu

APPROVAL OF RESEARCH NOTIFICATION

Date: December 8, 2011

To: Daniel Mullins
RE: HP-00051288
Type of Submission: Initial Review
Type of IRB Review: Expedited

**Approval for this project is valid from 12/7/2011 to
12/6/2012**

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced protocol entitled, "*Interviews to Identify Evidence for Eliciting Hard to Reach Patient's Perspective in PCOR*".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CFR 16.110 category(ies):

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

The IRB made the following determinations regarding this submission:

- Written informed consent is required. Only the valid IRB-approved informed consent form(s) in CICERO can be used.

Below is a list of the documents attached to your application that have been approved:

Eligibility Checklist for HP-00051288 v11-21-2011-1321894799451

Study Timeline

Moving comparative effectiveness research into practice Implementation science and the role of academic medicine.pdf

How the Recovery Act's Federal Coordinating Council paved the way for the Patient-Centered Outcomes Research Institute.pdf

Using science to improve the nation's health system NIH's commitment to comparative effectiveness research.pdf

Uncertainty in Assessing Value of Oncology Treatments.pdf

Generating Evidence for Comparative Effectiveness.20.pdf

The promise of comparative effectiveness research.pdf

List of Qs

Interview Script
List of Qs
Interview Script
Script for Recruitment
Contract with PCORI

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year**. The regulations make **no provision for any grace period extending the conduct of the research beyond 12/6/2012**. You will receive continuing review email reminder notices prior to this date; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond 12/6/2012. Investigators should submit continuing review reports in the electronic system at least **six weeks prior** to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.

C2. Phase II



University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@som.umaryland.edu

APPROVAL OF RESEARCH NOTIFICATION

Date: January 27, 2012

To: Daniel Mullins
RE: HM-HP-00051504-1
Protocol Version and ID #: N/A
Type of Submission: Modification
Type of IRB Review: Expedited
Modification request dated: 1/23/2012

Modification Approval Date: 1/25/2012
Approval for this project is valid until
1/9/2013

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced modification request for the protocol entitled, "*Phase II Interviews to Identify Evidence for Eliciting Hard to Reach Patient's Perspective in PCOR*".

The IRB approved this modification via expedited review pursuant to Federal regulations 45 CFR 46.110(b)(2)/21 CFR 56.110(b)(2).

The IRB made the following determinations regarding this submission:
- No specific determinations made.

Below is a list of the documents attached to your application that have been approved:

Eligibility Checklist for HP-00051504 v12-17-2011-1324179656870
Timeline (Updated 1.17.12)
How the Recovery Act's Federal Coordinating Council paved the way for the Patient-Centered Outcomes Research Institute.pdf
Using science to improve the nation's health system NIH's commitment to comparative effectiveness research.pdf
Uncertainty in Assessing Value of Oncology Treatments..pdf
Moving comparative effectiveness research into practice Implementation science and the role of academic medicine..pdf
Generating_Evidence_for_Comparative_Effectiveness.20.pdf
The promise of comparative effectiveness research.pdf
Focus Group / Interview Guide
Focus Group / Interview Guide
Script for Initial Interaction with Participants
Jennifer Huang- Human Subjects Protection training
Focus Group Interview Guide (Adjusted Questions Highlighted)
Liz Jansky Human Subjects Protection Training
Paula Lipman- Human Subjects Protection training

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.

D. APPENDIX D: Interview Guides

D1. Phase I

Focus Group Guide PCORI FGI – Phase I

Opening Statement 11:00 – 11:05

Thank you for agreeing to participate in this focus group. I'm Karen and I will be your facilitator for this discussion. This is Liz who will be your co-facilitator today. The main purpose of this discussion is to elicit feedback from you about how to best 'give hard-to-reach (HTR) patients a voice' in the healthcare research process. Specifically, we will ask you about general domains related to patient-centered outcomes research (PCOR), how to best phrase questions that will elicit outcomes that are meaningful to HTR patients, and best methods and considerations for engaging them in the research process.

By way of some background, the Patient Protection and Affordable Care Act of 2010 created an independent, non-profit research organization called the Patient-Centered Outcomes Research Institute (PCORI) to help people make informed health care decisions by producing and promoting research guided by patients, caregivers and the broader health care community. With your help in today's discussion, we will build reliable and understandable evidence available for use by patients and other health care decision makers.

In a focus group it is really important that you express yourself openly. There are no right or wrong answers. We want to know what you think. Although I am the facilitator, I would like the interaction to flow among you. If you would like to add to an idea, or if you have an idea that is different from someone else, feel free to jump in. You do not need to wait for me to call on you to talk, but of course only one person should speak at a time.

I would like to take a moment to confirm that your participation in this focus group is voluntary. We will audio-record this session in order to ensure accuracy in writing up our report. Your responses, however, will not be linked with your name and audio-recordings will be destroyed after analysis. Also, please be respectful and do not discuss what is said during the focus group with people outside the group. If you do not consent to be recorded, please let Liz know you would like to be excused.

Because we are recording the focus group, I'd like you to silence your cell phones and other electronic equipment. You might also notice that I may repeat or question some of the comments that you make throughout the discussion today. I will do this not only to ensure that we capture everything that's said in the group, but also to confirm that I understand the gist of what each of you says.

Are there any questions before we get started? Great, then let's begin.

I. INTRODUCTION & ICE-BREAKER 11:05 – 11:10

I'd like to start off by having each of you state your first name, describe your area of specialty and what capacity you interact with hard-to-reach patients.

II. GENERAL DOMAINS OF PATIENT-CENTERED HEALTH

11:10 – 11:20

1. As you know, we're here to discuss patient-centered health outcomes and the best methods of eliciting the perspectives of hard-to-reach patients. We'd like to begin the discussion today to get a general idea of this concept. When you hear the phrase, "patient-centered health outcomes," what comes to mind?

Probe (time permitting): What are the important domains that come to mind when you think of patient-centered health outcomes?

- survival/prognosis
- function
- treatment options and side effects
- quality of life

2. What comes to mind when you hear the phrase "hard-to-reach patients"?

Probe (time permitting): How do the domains you listed for health outcomes differ with regard to:

- African American patients?
- Patients of lower SES?
- Patients whose primary language is not English?
- Patients with limited mobility?
- Patients with vision or hearing impairment?
- Health providers who treat HTR patients?
- Caregivers of patients with cognitive impairments?

Thank you for your ideas about those concepts. So we're all on the same page for the remainder of the discussion, we will use PCORI's working definition of "patient centered outcomes research" as research that helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. We will also think of "hard to reach patients" as those who are non-English language speaking, patients with low income and/or other socioeconomic status, and patients with impairments to mobility, cognition, vision and hearing [*show slide*].

III. APPROPRIATE PHRASING OF PCOR QUESTIONS FOR HTR PATIENTS 11:20 – 11:50

As you know, a main goal of this discussion is to determine the most appropriate ways to phrase questions for HTR patient audiences. So what I will do is to show you questions as they have been worded by PCORI and then we'll talk about each one to come up with the most appropriate wording.

For each PCORI question, show the slide and ask the following:

- Q1. What practical methods are effective at engaging patients like you and your surrogates in identifying and prioritizing research questions?
- Q2. What practical methods are effective at engaging patients like you and your surrogates in identifying outcomes that are meaningful to you?
- Q3. What practical methods are effective at engaging patients like you and your surrogates in identifying comparators/interventions that are meaningful to you?
- Q4. What methods are effective in ensuring that the full spectrum of patients is presented, including hard to reach and under-represented patients?
- Q5. What methods are effective in ensuring that patients like you understand the pertinent clinical and research issues (e.g., framing risk-benefit tradeoffs) so that results can meaningfully inform decision making?
- Q6. What data are available that identify other factors and issues that are important to patients like you or your surrogates that need to be considered?

- 3. In your own words, what is the general concept this question is asking?
- 4. What is meant by [*specific phrase used in question*]?
- 5. Thinking about the HTR patients you interact with in general, how would you recommend rephrasing the question to best elicit information about [*general concept mentioned in #3 above*]?

IV. POPULATION-SPECIFIC CONSIDERATIONS 11:50 – 12:00

For the last part of this discussion, we'd like to learn from you any recommendations you have for approaching, engaging and collecting data from HTR patients, such as those you interact with. [*distribute handout of targeted populations*]

- 6. From your perspective, what hard-to-reach populations living in the Baltimore area are important to include in our study?

Probe:
 - racial/ethnic categories, cultural groups, religious groups, insurance status, diagnoses, health status, age, citizenship
- 7. For each of these HTR populations, what special considerations should we keep in mind to ensure we most effectively access, engage and elicit information from them?

Probe:
 - Are there physical parameters we should keep in mind?
 - Are there key community members/gatekeepers we should approach initially?
 - Are there data collection issues we should avoid or capitalize on?
 - Are there recruitment strategies/venues that work best to extend our reach?

8. We also understand that some of you expressed willingness to help us recruit patients. Please raise your hand if you would like to assist us in this capacity.

V. CLOSURE

Thinking back to our discussion, what else comes to mind that you think might be important?
Thank you for participating. You have all worked hard this past hour and we have learned a great deal from you. We appreciate your help with this important topic. We will now take a short break, and then we will move into our debriefing discussion.

D2. Phase II

Opening Statement

Thank you for agreeing to participate in this focus group. Today, we are going to be discussing how to involve people like [you/hard-to-reach patients (e.g. minority patients or patients with impairments) for whom you provide care/the person for whom you are a caregiver/your child] in studies that answer important questions about [your/their] health and health care. I'm [Liz/NAME] and I will be starting today's discussion with the hope that this will be a discussion among everyone at the table. This is [Jennifer/NAME] who will also ask questions, take notes to make sure that we remember what we learn from you, and keep a list of discussion topics in what we call a "parking lot." This will be used when there are important things we would like to discuss but which are not exactly related to the main purpose of the discussion. We'll save some time at the end of our talk today to circle back to the items in our parking lot.

We are delighted that you've agreed to join us in this very important discussion today. As {Aurelia, RECRUITER} may have explained to you, we are funded by the Patient-Centered Outcomes Research Institute (PCORI). PCORI's goal is to help people make better health care decisions by having a say in the research that affects their health.

PCORI's goal is different than most organizations that give money for research. PCORI wants [you/people] to have a say in what research studies should focus on so that future research can answer the questions that are most important to [you/them]. In most cases, researchers come into a community [like yours/like the ones where your patients live] to ask people to be a part of a research project without ever asking what is important to them. When the project is over, these researchers come up with results that are never reported back to [your/the] community, let alone, have a positive impact on its members. The fact that researchers have not built relationships with community members leads to distrust and makes it harder to answer the questions that would help people to make better decisions about their health and quality of life. PCORI would like to fix this problem by having people like [you/hard-to-reach patients for whom you provide care/the person for whom you are a caregiver/your child] work with the research team to put together studies where [you/they] can have a say about the types of questions asked and the outcomes that are studied. PCORI's goal is to create research projects that include people like you and me in the entire research process. So what I would like to do today is to invite you to role play with me as we walk through the research process together and I ask you questions about how we would conduct a study to help people maintain their health or become healthier.

➤ Before we continue on, I want to stop and see if you have any questions about what I've said so far. I would first like to go over a few "housekeeping" issues before we begin our discussion today. In a focus group it is really important that you express yourself openly. There are no right or wrong answers. We want to know what you think. I am here to guide you, and I would like all of you to discuss among yourselves. If you would like to add to an idea, or if you have an idea that is different from someone else, feel free to jump in. You do not need to wait for me to call on you to talk, but of course only one person should speak at a time.

I want to remind you that your decision to join this focus group is voluntary. That means that you do not need to answer any question that makes you uncomfortable and you may choose to leave at any point. We will record this session to make sure our notes are correct, but what you say will not be associated with your name in any report and the recordings will be destroyed after we've analyzed the discussions. Also, please do not discuss what is said during the focus group with people outside the group. If at any time you do not want your comment to be recorded, please let [Jennifer/NAME] know and we will turn off the recorders while you are speaking.

Because we are recording the focus group, I'd like you to silence your cell phones and other electronic equipment. You might also notice that I may repeat or question some of the comments that you make throughout the discussion today. I will do this not only to ensure that we capture everything that's said in the group, but also to confirm that I understand the gist of what each of you says.

➤ Are there any questions before we get started? [*Answer any questions that may arise*]. Great, then let's begin with introductions.

VI. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard-to-reach patients you serve.]

VII. SCENARIO

Now I would like to start our role-playing exercise where you imagine that you are a research [assistant /colleague] and will be helping me to decide how to do a [research project/study]. Imagine PCORI wants to help people in [your/the] community to get the best information they can that will help in making better decisions about their health. PCORI want us to describe how to include people just like [you/hard-to-reach patients for whom you provide care/the person for whom you are a caregiver/your child] in planning studies to come up with healthy solutions that will best fit the lifestyle of people who live in this community. So this means we'll have to think about what's most important to members of [your/the] community, what concerns they have, and what kind of outcomes we want to achieve.

To make this happen, we will have to go through several steps of the research process. First, we will need to figure out what we want to study. For the purposes of today's discussion, we have chosen to discuss the issue of [obesity, cognitive impairment] in your community just as an example that will help us best think about how we would go about addressing a widespread health issue. I would like to make very clear that we are not here to talk about how to solve the problem of [obesity, cognitive impairment] or any other health issue in particular, but instead, we will be talking about the process we would need to go through if we were to develop a research project together.

So after we decide what our main questions are to study, then we will have to pick different ways that we think might work together to improve health. We will also have to think about how we will invite people to participate in a project, making sure that every person has a chance to be involved. Next, we will need to make sure that we explain the project to people in such a way that they truly understand what is expected of them and what will or will not happen to them during the project. And finally, we have to think about all the ways we will get information to indicate whether or not we are achieving the outcomes we and they hope to achieve.

So that's the scene that I want you to keep in mind – that you are assisting me in designing a research project.

- Do you have any questions about the scenario before we begin our discussion? [*Answer any questions that may arise*]. Great, then let's begin the discussion.

VIII. FOCUS GROUP QUESTIONS

Okay, as I mentioned before, let's see how we can work together to create a project about [obesity, cognitive impairment]. [Obesity, Cognitive impairment] is a broad topic, so we first need to figure out what in particular that we want to study about [obesity, cognitive impairment]. For example, we can decide to look at [obesity, cognitive impairment] in children, or [obesity, cognitive impairment] in adults.

Usually, researchers from universities might come into [your /the] community and already have this project in their minds. But, they may not really understand [your /the] community, what people need and what people can offer. So, let's first make sure that we get the opinions of people in [your /the]community to see what issues are most important to them when it comes to [obesity, cognitive impairment].

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

Probes:

- Incentives
- Resources in the community - individuals (e.g., community organizer, minister)
- Resources in the community – places (e.g., church, community center)

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

If yes, probes:

- Who might these people be?
- Are there other ways that you can think of to make sure that we include their opinions in our project design?

Okay, now that we've figured out a way to reach everyone we can think of, we will need to decide what is the most important aspect of [obesity, cognitive impairment] that we need to focus on, what the goals of the project will be and what outcomes the study will address regarding [obesity, cognitive impairment].

2a. What are the best ways to get [you/hard-to-reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

Probes:

- Voting
- Spokespeople decide

2b. Are there any other ways to get people to talk about the goals of the project?

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard-to-reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

Probes:

- Show them a list of common concerns
- Showing them a picture with a caption

Now that we've decided upon our research questions, goals, and approaches to compare, we'll need to figure out where we will get our information to make sure the approaches are working.

3. Where would we go to find this information?

Probe:

- Which people would we talk to?
- What other types of information should we collect (e.g., family history, social support)?
- What in [your/the persons' who receive your care/hard-to-reach patients for whom you provide care/your child's] everyday life should be considered when we think about [obesity, cognitive impairment] (e.g., environment)?

So we're ready to recruit participants into our project. We'll want to make sure that everyone who is interested in participating in our project understands the benefits, risks, and even the possibility of nothing happening at all.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

Probe:

- How do we get people to trust who's conducting the project and to trust that the information they give will be kept private?

IX. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with *[refer to list]*. Thank you for participating. You have all worked hard today we have learned a great deal from you. We appreciate your help with this important topic. If anyone is interested in future research, please let us know, and if any additional thoughts come up that you would like to convey, please feel free to contact [Aurelia/RECRUITER]. Thank you very much for your time and input.

E. APPENDIX E: Individual Summaries

E1. Phase I

I. List of Participants

- Pediatrician, City health department, works with homeless, young children, substance abusers, “under accessers”
- Executive Secretary, Baptist church
- Health worker, working with patients of hypertension & diabetes, people having trouble accessing care, low income, county and inner-city
- Pharmacist, chronic medical diseases people having trouble accessing care, works with local health plans
- Fitness professional, activist, exercise and obesity clinic
- Pharmaceutical company employee with husband having cognitive impairment and dementia
- Executive Director, community health center providing holistic care
- Community health outreach worker/trainer, works in diabetes, hypertension, asthma, African Americans, males, helps with access issues
- Pharmacy quality alliance, mother has Type 2 diabetes and father has dementia

II. Demographics of Participants

- 4 Non-Hispanic White Females
- 3 African American Females
- 2 African American Males

III. General domains of patient-centered health

Defining patient centered health outcomes & related domains

- The patient is generating what’s meaningful to him/her; not overlaid from doctor, health insurance
- Patient is patient and not the illness. Not just treating diabetes but the woman with a family who has diabetes with social determinants that affect her condition. If it’s not patient-centered, it’s just the medical model.
- Often a lot of confusion if research is not presented correctly, so without buy-in, it’s wasted. People make statements to get funded and it sounds good, but they won’t collaborate with CBOs to make it happen. At least put the pieces in place to do the work.
- Mostly focusing on outcomes and looking at a result that includes so many other areas surrounding the patient. What kind of results are we getting that impact that individual and not the whole gamut of the project that you’re working on?
- Research is being done for the good of the patient, but patient may not understand that. Outcomes aren’t meaningful to patient. In concentrating on the outcomes the patient wants to achieve, as opposed to focusing on a number a patient may not feel.

- Short- and long-term outcomes. A lot of people focus on the “now.”

Defining hard-to-reach patients

- Persons are homeless, not on any registration (e.g., Medicare) for the system to be aware of them.
- Individuals who live in areas where there’s limited access to healthcare and social programs.
- One is physical perspective of not getting into care, but another one is systemic for people who are not accessing the care they need for whatever cultural, social, personal, etc reason (e.g., not getting a prescription filled).
- People can be engaged in the system but not engaged in their healthcare.
- Can be financial, geographic, awareness, but once in the system, they may not know what they can take advantage of and whether they follow the regimen or even understand what they’re asked to do – there are layers within hard-to-reach
- People only seen in the emergency room and no access to a primary care provider because of finances and/or trust. Some people have experienced times where they didn’t get what they were told or didn’t want to find out what they have because they wouldn’t know how to take care of it. People didn’t “have a right to go to the doctor.” People don’t know what to expect, don’t trust the doctor.

IV. Appropriate Phrasing of PCORI Questions for HTR Patients

General concepts to incorporate

- Use scenarios, visual formats, role play
- Guide discussions (e.g., with lists)
- Use incentives
- Capitalize on community forums
- Build trust, reach through organizations/people whom they trust. Remind them that their information will not be shared.
- Tailor to specific communities
- Simplify language
- Find out what matters to them
- Don’t always ask questions. Present videos and have them follow up with their feedback. Present a scenario or role play. Make it entertaining, positive and different from their daily lives.
- Emphasize what the benefit is for the participants
- Put the participant in the perspective that they are running things
- Let them understand that they are the researchers
- Ask: If you were the researcher, what would you ask to solve this question?
- Define illness first [or can state that there is a general broad topic area but need advice on identifying the research questions]
- State what solution they’re looking for. What kind of questions would you like to ask to get to this solution?
- Need to use a specific health issue. May need to educate patient on illnesses first, then ask what is meaningful to them. This will ground the conversation.

- Group patients with similar diseases together, ask their goals, give them prompts or guided effort with patients with similar health issues.
- Find out what inspired them to come to you. Clinical trials research can't be like what it used to be (i.e., regimented and structured).

Q1 Revised Questions:

- Can you help me, as a patient yourself, figure out how to get other patients to the table?
- How would I get you to come to a community meeting to talk about what's important? [or a specific condition, etc., diabetes]
- What's the best way for me to get your opinion?
- If I were going to decide how to spend money on a research project, what would be the best way to get your opinion of how to spend it?

Q2 Revised Questions:

- What is the first thing that you are concerned about this disease?
- What is the one thing that you fear most down the line?
- What is the one thing that you wish would go away? [will need to make it health specific]
- What is important to you [in terms of condition]?
- What outcome is important to you?
- What's the best way to reach you (i.e., before we have you there)?
- Have a list of example outcomes for diabetes, and ask them what is missing.

Q3 Revised Questions

- Tell me what you think might work?
- What have you heard about from friends, TV, etc. that you think might work?
- What has been working for you? If it stopped working, what happened?
- Are you willing to start something different? What would you do differently?
- What is the process to get to "what works?"

Q4 Revised Questions

None

Q5 Revised Questions

none

Q6 Revised Questions

- Include questions re: family history
- Include questions re: environment – important to know reality often contradicts what is taught in school (e.g., eating healthy when healthy food is not available).
- Include questions re: social support

- What do you think is important that you think should be considered?
- What is usually not considered that is important?
- What can I do to help you improve your health concern?

Debriefing Discussion

General Approaches and Practical Methods

How to gain trust?

- Gatekeepers
 - CHWs
 - work with FBOs, churches
 - speak the same language
 - Come from similar cultural groups, Indian groups, Hispanic groups, other cultural groups that people trust. May not be exact same culture, but a group that they trust
 - Need to go where they are, be accessible, need to be flexible, where they are located. Outreach workers do home visits, so we can do something like that. Where people are coming and gathering like the mall. Set up a kiosk at the mall. Just be where they are.
- Trust
 - Same ways to gain trust.
 - Be genuine, be consistent
 - Come by community to say hello, not just for work or research. Builds trust. Not because you need to get your blood or to do a study.
 - Takes time to build rapport. Can't be done overnight, have realistic expectations. Trust needs to be built by them. Don't force it. If you aren't genuine, they will let you know, they won't help you. From a person that is on the clinical side, but can understand the community, communicate, is a generous person. Research is good and bad, b/c don't always have leeway to build the trust.
- Health literacy expert
 - Participants were familiar with health literacy experts

Rephrasing questions

Rephrasing Q1

- First Part (from slides)
 - How to get them to the table?
 - How would I get you...
 - What's the best way...
- Possible rephrasing
 - Can you help me? We're trying to do research, can you come in and give us some advice?
 - We want to do research that it helpful to you?
 - "Want information, want data, want opinions, thoughts. We're trying to gather information."
- Is research an okay word?
 - Nope.
 - Lots of conspiracies with a lot of these communities. Even if they want to, they may have friends, families that aren't okay with research.
 - If you know population, people are getting educated about research projects. Some are astute now.

- Research is necessary, need to get benefits for them, and not just for researcher.
- If people ask if this is for research, you need to have a good answer. Example, “We’re trying to make research better.”
- Are there certain things that we can do/say to make people at ease and want to participate?
 - If personal info won’t be shared, need to reiterate that.
 - Reassure that their personal info won’t be shared.
 - Want to show examples of research that have good outcomes, already published, particularly if it’s specific to the condition/disease. So they can see that it is helpful. Need to disseminate. Find previous examples of how people disseminated studies, as a thank you; show them what are the good outcomes. Not the tradition of most hospitals.
 - Ask upfront before the research starts, and not after the fact. If you want true data, need to involve the community person. Often a researcher doesn’t really go out into the community to collect accurate data; provides fake data. Have a community person work side-by-side to help get true and relevant data (e.g., student who is nervous, uncomfortable in situation may forge data).
 - Cultural sensitivity.
 - Avoid falling into the trap of confirming what you think you know. Don’t just rely on certain venues (e.g., community center or church). Will also need to find those that are not connected to churches or community centers.

Rephrasing Q2

- 1st 2 bullets, “What is the first thing that you are concerned about this disease?” and “What is the one thing that you fear most down the line?,” are good to spark conversation. Good for engaging people.
- 3rd bullet, “What is the one thing that you wish would go away?,” not always helpful, too broad.
- Need more questions as further follow-up. Might vary by disease, individual. Think that it has to be disease specific gathering, or general health program at church?
- Talk more about a positive end. What is your goal? What is your benefit? Better than saying “something to go away.” Focus on desired outcomes.

Rephrasing Q3

- Concept of question seems to be, “do you understand what options are available to you?” Do they understand which choices they have? How to make the best choices themselves? What would they pick? Start off with something more direct
- Bullet #3, “What has been working for you? If it stopped working, what happened?,” add another part about what did you do to make it stop? Why did you stop it? They could have been the reason to make it start (e.g., access to meds, finances, becoming caregiver to someone else)
- Try to understand the value. People may not even know the first step, why they didn’t take the first step (e.g., meds).

Rephrasing Q4

- What does “full-spectrum” supposed to mean? Do you want everyone? Does it dilute findings if you include everyone? Struggling to understand what full-spectrum means. Not sure why we are asking patients this question. Is this a way to get others like you to become participants? Is this for stakeholders to answer? Or patients? A peer-to-peer question? Make sure that everyone is covered?

An age range, race, gender, ethnicity? It could be stakeholder or peer-to-peer (e.g., seniors). How to get your counterparts? Why aren't your peers here? Goes back to the first question, almost a tag on to the first question. Getting at how to reach these people?

- Possible rephrasing of questions:
 - Do you think that there is somebody that we are missing in this process?
 - Where do we find people like you that are missing the boat? [seemed like some people didn't like "missing the boat" phrase]
 - Is there a place in your community that we have not reached? Is there somewhere else that we need to go to? Let us know where they are, and we can reach them. E.g., where can we find other pregnant women in your community?

Rephrasing Q5

- Possible rephrasing:
 - What help do you need to better understand your disease so you can make a better decision about your condition? To reach your goals?
 - Give them some control. How can we better address your needs? Something missing? Let them take direction. [I think that this is something to keep in mind across all questions]
 - What do you think we should do? Show them the research methods, steps that we do so they can understand what is going on. Give them education, advice they need. How should you receive the information that came out of this? Patients get involved, do study, but what do they want to know after the study is over? Data? Bottom line? Dissemination? How it can help us get that playground down the street.
 - Like a consent form question. What we are doing will hopefully help you make a better decision.
 - Has to be something of a story before you begin this question. It's a complicated question. E.g. provide a scenario, about what the research is about, what will happen.
 - What is the best way for you to understand what the info is to help you make a better decision?
- [Daniel asks] how to bring people into studies?
 - Do it in layers.
 - After identify the pros and cons and ask them if they have apprehensions, do they need clarification? Makes people feel comfortable.
 - Decision making needs to be done upfront. Understand risks upfront.

Rephrasing Q6

- Provide examples like family history, although that is usually used.
- Environment isn't usually used, not traditionally asked.

Additional questions to add?

- Participants will think about it, will send emails later

E2. Phase II

Focus Group Category: Caregivers (Supplemental Interview)

Day/Time: Tuesday, February 14, 2012 4:00

Location: via telephone

Facilitator: Karen Kauffman

Co-Facilitator: Melissa Ross

Number of Participants: 1

1. How to engage caregivers to tell us what they need to know?

- Go to community meetings. Health fairs are also a good resource. When dealing with individuals with dementia or Alzheimer's, get primary care physicians to sit down and ask individuals within the community to express what is important to them.
- Community meetings.
- Billboards (especially outside of hospitals/healthcare facilities) – i.e. list resources, information, how to get in touch, what informational seminars they are having. Have sign up information on the billboard for the seminar you will host there. Contact the President of the hospital and get in touch with who is in charge with scheduling.
- Hair dressers, barber shops, the mall- set up a kiosk.

2. How do we find out what the community wants to be the result of the research?

- Do a follow-up on the individuals. Lead them in the right direction. That could be at a group meeting, but go individually and ask what they want to change regarding their healthcare.
- Hospital setting – ask patients and doctors what healthcare changes they want to see.
- Screening process – when people go in for free screenings, etc. ask them what healthcare changes.
- Again, go to barber shops, health fairs, etc. and ask.

3. What interventions would be meaningful?

- The physicians, not necessarily the primary care physician, have someone there to explain the topic, let them know what to expect.
- Be straight to the point

4. How do we reach those who are truly hard-to-reach? (caregivers who don't have access to PCP, nurses, hospitals, internet, etc. to ask what is important to them)

- Billboards, television – commercials, public announcements, advertisements in magazines.
- To reach those who do not have internet access, put a 1-800 number on the television advertisement
- The B Paper (the Baltimore Paper) – this is a free community paper, people pick them up all the time.
- Community newsletters
- Billboards again – do you have questions about ____? List email, phone (toll free), contact.
- Restaurant, church (church bulletins), grocery store, school, work, parks, amusement parks, downtown Baltimore Harbor, movies – put information in a movie clip before the movie starts.

5. What to keep in mind about participants of these studies?

- Keep in touch – either via telephone, email, face-to-face.
- Family history (important for researchers to know)
- What grocery stores are around you [ENVIRONMENT], what is in walking distance.

- Does the participant drive, can they get on the bus?
- Finance – can you afford what is required in the intervention?
- Are they willing to try to improve their health? Motivation?

PROBE: Why would someone want to participate, but not improve their health?

- Because some studies pay you.

6. How do we ensure that everyone understands the informed consent?

- This should be upfront and straightforward.
- Be specific and ask them if they understand.
- If they don't read, have someone talk to them one-on-one. Ask if they have any questions.

7. How should results and what difference the community's participation made be disseminated?

- Email address, send them a letter, send results through mail, telephone call, one-on-one information, Facebook, Twitter

PCORI Phase 2 Focus Group

Focus Group Category: Caregivers (Alzheimer's Association)

Day/Time: Wednesday February 1, 2012 11:30am

Location: Alzheimer's Association (Timonium, MD)

Facilitator: Karen Kauffman

Co-Facilitator: Melissa Ross

Number of Participants: 3

1. How do we reach caregivers to find out what is important to research?

- Community association (meets monthly and has newsletter) can be a vehicle to let people know what is coming. After introducing topic, use sequential meetings to include family, and provide something that will occupy/entertain children.
- Extend efforts by employers to have a forum to benefit the employee and employer as individuals are absent due to *caregiver* obligations.
- Community outreach through employers. Go into a community and have classes in work places, pass out literature to employers. Then use this to recruit/contact employees.
- [*Conversation goes off track* – individual recounting poor experience in the workforce as a result of his caregiver status]
- Physicians and medical staff should be educated concerning what is available and can use their relationship with patients to appropriately direct them to the correct resources:
 - *"It's not always about writing a script"*
 - Doctor's offices should be able to recruit researchers to individuals [caregivers] who are willing to talk to researchers.
- Reach caregivers through case managers/social workers. Have them ask permission to give the caregivers' information to researchers to contact them.
- Radio and TV advertisement that *"Hits them where they live . . . that grabs them"*, news broadcasts
- Must create a relationship where you are around a person and able to share with the person is going through a situation you can understand
 - (**Ex:** Neighbor was willing to take literature from participant but may have been reluctant to take it from a stranger)
- Contact support groups of the condition – sit in on these groups. Literature that comes from organizations but individuals must be proactive and sign up for this method. Comfortable setting.
- Corner stores, Payless, drug stores, (i.e. Rite-Aid and CVS), grocery markets, gyms, shopping malls – neighborhood stores, senior centers, adult rec centers – have literature available in these settings.
- Pharmacists, mailmen, fedex drivers, florists, [Mom would say] pastors, people who see people from the community on a regular basis.

- Have food to attract people to the table or kiosk, i.e. in a grocery store or mall.
- Individuals in rural setting may be harder to reach. In this instance, you must depend on family members of these individuals.
- Foreigners may also be harder to reach.
 - Language/culture specific centers. Immigrant specific grocery stores. Videos for those who cannot read.
- Screens in markets and gyms similar to what you see in the doctor's office – showing health information and contact information for research opportunities.
 - **Ex:** Broadcast general advertisement, similar to how some places play football games.

2. How would you identify the most meaningful and important treatment results? What is the end result?

- Ask people directly what challenges they are facing – see what common themes “bubble up”
 - Take common responses and go back to people and ask them to prioritize on a scale of 1-5.
 - Ask: *Which means the most to you? What is the most important?*
- Offer incentives for people to open up – take someone out to lunch – provide people with an opportunity for people to let their guard down, relax, and open up. *“If you come to my door and I don't know you, I'm going to slam the door in your face.”*
- It is annoying when surveys ask you the same question 5 different ways.
- Some valuable questions include:
 - *“Tell me what a typical day is like for you”*
 - *“Tell me what kind of help you would like to have if you could have any help in the world”*
 - *“What wears on you throughout the day?”*
- Look for things that keep coming up and then go back to the people and have them choose from the common answers and show them a list.
- *“What means the most to you?”*
- Involve caregivers in reviews of questions when you are making decisions about research.
- Incorporate caregivers into research groups.
- Have someone well versed in the topic being studied recommend what treatment results should be a priority.

3. How do you decide which intervention to implement?

- Ask directly, show a list and have patients vote (decide democratically).
 - Ask a physician/specialist to decide which intervention can address the most items from the priority list.
- Use a survey

4. Where would we go to see if our approaches are working? And what information should we have?

- Have a baseline and compare using checkpoints. Check in with participants via email and telephone and measure medical indicators.
- Researchers should check in with patients/caregivers in tangible ways (via visitation, phone calls, email, some meaningful way)
- If person in Adult Daycare, you could check with individuals at that location but if the individual is at home, contacts may be limited to the caregiver/family and health providers.
- Should include health and perspective of the caregiver – especially what were identified previously as challenges.
 - **Ex:** Prior research studies had a participant involved in research but she did not get a benefit from it. Additionally, researchers make suggestions but resources may not be available for participants to take action.

5. How do you determine that patients understand the risks/benefits to the intervention?

- Be honest and make sure expectations align to reality. This is critical.

- **Ex:** Participant involved in prior research and was not made aware of the duration of the study or that the study needed a blood sample/mouth swab. He was not made aware of the purpose behind these tests for the study.
- Explain the participant's role.
- Explain the WHY of what you are doing.
- **Give full information** – it's not fair to not fully disclose all the information you have available to participants.

Not necessarily trust.

6. How would you report findings back to the community?

- Community newsletters
- Send a letter stating the results that came from the particular project. The same organizations mentioned as places to make initial contact. *"Follow through"*
- This creates a process and will create trust by showing that research doesn't just go to a *"la la land"*. People will become educated and will move away from terms like "guinea pigs" and old fears.
- People like to see tangible results and what the researcher did with their information. Show them how their participation may help someone else, or how it will lead to things getting better. Educate.

7. What other groups should we be looking into?

- *Certified Nursing Assistants / GNAs / Medicine Aides and Technicians – "The backbone of nursing"*
- Police – could be a resource in their communities if they are properly trained
- Employers – who have a completely different perspective from patients

PCORI Phase 2 Focus Group

Focus Group Category: Caregivers (Alzheimer's Association)

Day/Time: February 9, 2012 11:30am

Location: Alzheimer's Association (Timonium, MD)

Facilitator: Dr. Karen Kauffman

Co-Facilitator: Melissa Ross

Number of Participants: 8

3. How do we reach caregivers to find out what is important to research?

- Incorporate awareness into clinician/staff training programs (esp. family physicians, nurses) so that clinician will be aware at the point of contact/start of need.
- At the college level – also promote awareness and partnerships.
- Reach out to administration/liasons in care facilities (including day facilities/assisted living)
- Partner with clergy/churches
- Contact senior citizen buildings
- Use websites to identify organizations of caregivers
- Engage those who are already leaders in their communities (via fraternities, sororities, churches, etc. and they will involve others).
- Train the people you send into the community. *"They are now your advocates. They are your warriors to have that flame and tell the communities about what they need to know about the research, what they need to know about the risks and benefit and to answer questions."*

4. How would you identify the most meaningful and important treatment results? What is the end result?

- Go directly to people – access through churches and schools
- TV advertisements, public service messages
- Keep questions simple when asking patients.

- Interact directly with people – “What do you know?”
- Use existing forms that individuals are already filling out (add a brief instrument)
- Create websites
- Create awareness through branding “paraphernalia”/promotional items with point of contact information
 - **Ex:** Participant asked about Alzheimer’s when seen wearing his shirt.
- It may take an entire support network and not just caregivers to identify – be sensitive to family dynamics. Include family members and friends in research.
- Make direct contact **Ex:** “Block walks”

5. How do you identify what interventions would be acceptable to them? How would we find out what interventions would be meaningful for them?

- Identify whether or not an intervention has been tested and what was found as a result of those tests. Be open about what the side effects may be.
- Unacceptable research would harm, scare, or have undesirable side effects
- Ask: “What would make you participate?” “Why have you not participated?”
- Categorize your approach – acknowledge facets to the individual (mind, body, spirit)
 - **Ex:** Approach spirituality in addition to medication – “What approach would you like?”

6. How do you determine that patients understand the risks/benefits to the intervention?

- “In the Black community there is a lot of fear about being lied to. The best method is to be honest and straightforward with people.”
- Don’t wait until problems/misunderstandings arise – check in regularly and get immediate feedback (Not through a questionnaire)
- Be **honest** about your goals and how you want to go about obtaining them.
- Clearly show the benefits and answer “What’s in it for me?” (besides money) from the perspective of the patient.
- Clearly state the “out clause” letting people know that they have no obligation.
- Do not treat people like lab rats.
- Incentives do not need to be monetary – a weekend in a day spa, a weekend away, or free medication would be acceptable, for instance.
- Address cultural differences – “culturally match” the consentor.
- “It’s not what you say but who says it” – Identify your group and an appropriate point of contact
- Consentor may need to be someone not in the “inner circle” of the research process – perhaps someone who is dealing with a relevant situation.
- Build on familiar faces/relationships/trust.
 - Have the community leaders you contacted go back and explain the risks/benefits to the community participants.
- Partner with the community members to train individuals as advocates.
- Do a brief one page survey to make sure they understand

7. What data are available to identify other factors and issues that are important to patients that need to be considered? What sources do you think patients use to learn more about health and healthcare?

- Demographic and income information
- Life experiences, health history, family health history
- Geography – specifically as it pertains to access to support groups (There tends to be a lack of resources outside of urban areas)
- What resources are available to the community? (transportation/safety)
- How do you define community?
- What is the strength of an individual’s spiritual background?

8. How do you disseminate the information once collected?

- Have true follow-up: don’t just give participants money without any information concerning your findings.
- Put the same effort into follow-up as you did in recruitment – use the same methods if possible.

- **Ex:** Reconvening this focus group.
- Give individuals a deadline for when the research will be completed and regular updates
- Use social media (for some groups) – create a twitter account or Facebook page for your study.
- Make your phone number available through caller ID (e.g. Have UNIVERSITYMARYLAND show up when we call) and leave messages people can follow up on if they choose to.

PCORI Phase 2 Focus Group

Focus Group Category: Nurses (Baltimore City Health Department + PG County)

Day/Time: Monday February 6, 2012 6pm

Location: University of Maryland Baltimore School of Nursing

Facilitator: Karen Kauffman

Co-Facilitator: Melissa Ross

Number of Participants: 9

9. What are your practical recommendations for reaching hard to reach members of the community?

- Surveys
- Approaching individuals in an open and culturally sensitive way – respect their views and do not impose your views and judgment. Listen actively – listen to what they believe in and what they are looking for and be accepting.
- You have to have some type of relate-ability; look like them, come from where they're from, something.
- Have incentives.
- If you do not look like community members, go through someone who does. You will have better results.
- What researchers think is not important in this context. We should open up and share where we are coming from but then open the dialogue to hear what they have to say.
- They have to understand what is in it for the researcher, why the researcher is doing this.
- Integrate yourself into the existing community networks (Churches/neighborhood association) Coordinate your efforts with community leaders.
- People must know why you care especially when you do not come from the community. This is why talking about yourself is important.
- *“Perceive patients as the experts because they are teaching us”*
- Be sensitive of your demographic. **Ex:** You cannot go talk to people about asthma when they are about to be evicted. You must have resources available to meet more pressing needs.
- Be nonjudgmental and treat everyone the same.
- Be persistent. **Ex:** Participant making repeated offers of help to gang members who later accept
- Read body language.

How do you identify community leaders?

- Start with council representative
- Small businesses, like barber shops.
- Boys and Girls Club - Families will go there and support their children.
- Community clinics and activist groups.
- Talk to people selling drugs on the corner – see what it is they need. People neglect this aspect of our community despite the fact that they have unmet needs.

How do you get people to tell you what their real needs are if they are not forthcoming?

- Know what the community needs/is lacking before you get there.

- Build a relationship. Without a relationship, you cannot go into a community and expect to immediately get information.
- Develop trust by working with a liaison. But keep in mind they are using you for what you can provide and are not looking to bring you into the community.
- Keep coming back, build continuity.
- Show up in the community when you say you are going to. Do not cancel. Keep showing up.
- Have resources available.
- Make a commitment – not necessarily through health care. **Ex:** Participant coaches swim team.
- Follow through with what you say you are going to do.
- Use partnerships if you are an outsider.
- Volunteer work in addition to your professional work within the community you are utilizing is important.

10. What methods are effective in prioritizing questions?

- Ask community leaders who are able to speak on behalf of their community to identify the most pressing issue in their community. *“If you could give your families anything what would you do?”*
- Written list may not be a good way – verbal is better, especially in communities with low literacy. You could meet with community members and ask them to prioritize.
- **Ex:** Had flu shots to give away, contact at Salvation Army led participant to house for men with problems surrounding incarceration. Now has created a relationship. Do not place people in a situation where they are forced admit illiteracy or give information they are not comfortable giving.
- **Make a connection. Make people partners. Report back to the community.**
- Look at patients coming in and see what questions are being asked as they come in through the door.
- Continual feedback loop. You cannot go into the community one time. You must go back and make them feel that you are dedicated.

“Place problems in big bold letters on big sheets of paper and participants go around and stick numbered notes on what issues are the most important. Tally results up in the room as a group. This can also be done verbally.”

- People are sensitive to the fact that they do not read or write well, so be aware of literacy issues.
- Bring written documents down to a level that people can understand, or incorporate images.

11. How would we find out what comparators or interventions would be meaningful for patients?

- Intervention systems can vary depending upon the area of the city you are trying to reach.
- Consider spiritual aspects of interventions **Ex:** Demonic possession Thursdays
- Ask patient/surrogate directly. People all have different goals. **Ex:** Different goals for children with anxiety.
- Have individuals meet with their peers and researchers consistently to show you are concerned about them. Do not just ask the question, give cards, write articles, and do not come back!
- *“If you do not come back, I think you are going to miss the important stuff”*

12. What methods are effective at identifying hard to reach people?

- Track individuals through the emergency department who are not a participant in a medical home. Look at hospital and ER admissions.
- Attendance issues in school children.
- Churches
- Food banks, soup kitchens, homeless shelters. Programs designed to reach out to families in their homes.
- *“Driving around Martin Luther King. Looking under the bridge” (Homeless)*
- Parole officers (Only covers felonies / not misdemeanor offenders)
- Embassies
- Tracking students who are not taking advantage of free/reduced lunch.
- Students who are noncompliant with immunizations get kicked out after 20 days – access this list to access HTR.

13. How do you determine that patients understand the risks/benefits to the intervention?

- *“Phrase things in their own words”*
- Use the Teach-back method.
- Use your relationship to make sure that they connect with what you are saying – provide examples from their experience to give it relevance instead of quoting statistics. *“Personalize and individualize”*
- You must understand what their perceptions are. Their perception of risks and benefits may be quite different. **Ex:** Non-compliance in asthma because of fear of ‘steroids’
- Active listening (one on one) and having patients say it back to you in their own words to make sure they have heard both sides of the picture.
- *“Something like this cannot be done in a one shot deal”* – Give people time to think about it, talk to significant others, and then come back.
- The individual has to be completely comfortable discussing the information with you.
 - **Ex:** Residual mistrust from Tuskegee, Henrietta Lack, immigration
 - *“When we are talking about research, we are not really talking about helping people”*
- Participants need to understand if they will not receive a direct benefit.
- Let people know who will know that they participated. They may not participate if they feel you will *“roll them over to the man”*
- Go over risks/benefits one-on-one. Many may not feel comfortable asking questions in a group setting.
- People may be overly motivated by incentives and just keep saying *“Yes, yes, yes”* and give you skewed perspectives because they need what you are offering. They may not care about the risks/benefits.
- Must use appropriate language that they can understand. Health literacy.
- Confidentiality of consent form.
- Remember that “research” is an emotionally charged word.

How do you get people to understand that research can be meaningful to them?

- Start right at the very beginning being honest.
- Be willing/able to say “I (would) do this myself” **Ex:** participant having her children in the school where she practices.

14. What data are available to identify other factors and issues that are important to people that need to be considered?

- Must look at your age groups. **Ex:** Teens/tweens (Social media) – older people, target radio/TV – older still – community newsletters.
- Students signed up for free/reduced meals.
- Baltimore’s Neighborhood Indicators
 - *“Where are communities spending their money?”* Can show needs/desires, or lack thereof.
 - *(May not be valid in Baltimore City where decisions are made at a higher level*
 - *How communities are spending their money.*

15. What methods are best to disseminate information to people who participated in the research?

- *“You go back to the original group”*
- *“If they were worth your time because you needed them then you owe them the respect to go back and tell them what you found”*
- Don’t just publish your findings in a journal.
- Go back where you first met and *“complete the circle”*
- Give people an option of how they would like to receive the information. Some people may not want the information. People need to know upfront that this is an option but do not need to make an immediate decision.
- Have a party, a celebration.
- Send ambassadors to take the information and spread it around in their community.

- Involve the community – give individuals an investment in their research and allow them to decide how information is disseminated within their own community.
 - **Ex:** A documentary of the research allows people to share their part in the research and tell their story. May be especially important in individuals under 30.
- Media
- Intimacy and immediacy are important.

PCORI Phase 2 Focus Group

Focus Group Category: Nurses (FQHC and School)

Day/Time: Wednesday February 8, 2012 6pm

Location: University of Maryland Baltimore School of Nursing (+ Call in from Eastern Shore)

Facilitator: Dr. Karen Kauffman

Co-Facilitator: Melissa Ross

Number of Participants: 5 present, 5 from Eastern Shore

16. What are the practical methods that you think we could use to engage people in the community to identify questions about their healthcare that are important to them and that would be meaningful if we did research?

- Current instruments may be too long. May not be beneficial to ask to them open ended questions but showing them a video of things that are being done in other places to give them ideas of what is out there and then doing a video log interview would help get at what individuals find important.
- Possibly use audio tape if patient uncomfortable with video. **Ex:** Participant has experienced that patients are usually surprised when their input is sought.
- Open interviews
- Surveys
- At the time of discharge, following discharge instructions, nurses could take the opportunity to talk.
- Engage in common places people go: schools/afterschool programs, churches, Popeye's (fast food restaurants)
- Use community outreach workers.
- Be clear what the benefit is.
- Be aware of transportation barriers.

How would you find out what would be of interest to them?

- First show them what is going on in their community – GIS maps or something visual and epidemiological, but specific to their community.
- Utilize peer to peer educators/advocators, especially in culturally different communities.
- *"Research"* has negative connotation for some individuals.
- Use peers (i.e. teens addressing teens about drug abuse). Peer related is helpful.
 - Train someone that looks like the community members to go in and build a relationship, give them information about research. Go back, go to their church. It is important that community members recognize and trust this person.
- More likely to meet with success if information is coming from an individual who has the individuals trust. Trust can be built by staying active in the community and not leaving abruptly following the study. Part of the challenge, providers have a role in the community and will gain their credibility through their work. Researchers do not have this relationship but providers do not always do research. Persistence in the community will generate credibility for the entire team; *"You cannot just ride on your team member's credibility."* Especially in underserved areas, turnover makes patients reluctant to trust: *"Will you be here next year?"*
- Engage them in a location that is easily accessed by them and in their neighborhood.
 - **Ex:** One participant was involved in an intervention that taught members of a community about STDs in a Laundromat. The participants could continue to function (do laundry) and get stuff done while they participated.
- Talk with people one on one to get people engaged.
- It should be clear how patients will benefit. Have the researchers stay in the community following research (even after the researchers are no longer getting any benefit).

- Putting a (simple) questionnaire in an electric/utility bill, postage paid.
- If you are missing people, try going to grocery stores or pharmacies.
- Triangulate – you will miss people who have not accessed healthcare (1) providers (2) from people coming in (suggestion box – top three problems) (3) elderly populations

17. How do we determine what is most important to a given group of people?

- Take aggregate data to community to give them something visual to react to. Maybe information about the community they would not have seen in that perspective before (possibly Epidemiology data). Then ask the community members: *“Which of these things do you think is most important for you to address?”* There may be a huge problem in their community that they are not aware of because no one talks about it.
- Ask providers and the health department what they are dealing with, what they are seeing.
- *“Communities usually know what their own problems”* BUT individuals in the community have to have some consensus building where people can discuss priorities. It cannot simply be a vote, will require discussion at multiple venues.

18. How do we find out which outcomes people want?

- *“What is your perceived benefit from this research?”*
- *“How is research on [Condition] going to help you or your family live a healthier life?”*
- Drill down the answer to the person-level.
- Some people are in survival mode and not concerned with things that may not impact them.
- *“What would help you on a day to day basis?”*
- We need to explain to people why they see conflicting research results; explain measures of significance and levels of evidence.
- *“Where do you want to be five years from now?”* Their goals will define the nature of the intervention.
- *“What bothers/aggravates you the most?”* Determine the source of the aggravation and direct it into something researchable.
- How do you determine that patients understand the risks/benefits to the intervention?
- We need to have people determine what they want out of the future.
- Explain the probability in terms of that individual having a specific event/getting a specific condition.
- Tailor the study as much as possible to the individual, because everyone has different needs. Or you could group interventions by age group.
- *“Everyone knows things are possible but are not able to figure out the probability on their own”*
- *“What would living well with this disease look like to you?”*

19. What can we do to determine which interventions people would find the most meaningful if given the option?

- Ask individuals how they see themselves achieving the goals mentioned above.
- *“What specific tools would help you reach your outcome?”* (Medicine, BP cuff, stop eating Ramen)
- *“How do people in your community achieve better blood pressure?”*
- Do not bring in something that is culturally unacceptable/unrealistic
 - **Ex:** If they are eating on a \$3 per day budget, do not ask them to eat only fresh produce.
- Be aware of the community resources available.
- Design something that the community would have a buy-in with. Something that the community will be able to maintain or the researchers are willing to maintain after the intervention is over. You cannot withdraw a resource and expect the community to continue.
- What works best with interventions is making real personal connections with people. You can ask, they can describe what is wrong, and tell you their end goals but it is the continuous relationship that brings it all together. **Ex:** Participant works with teenagers who will tell her anything.
- Have a connection with people in the community. Work with groups to reach all demographics in a localized area.
- Can patients maintain their benefits following the intervention? (Sustainable) People will participate in research but then researchers take their information, all the incentives, and leave. After this, it becomes hard for people in the community to continue because the resources are not available in their community.

20. How do we know who the hard to reach people are and what methods should we use to find them?

- Go places where people are but where you do not usually try to engage them. (Laundromat example, grocery stores, schools, pta meetings, churches, elderly centers, walmart)
- People come from the city and ask questions, but never report back to the community. Research needs to be localized and have a reputation in the community. People need to know that the research is for them and for their community.
- Outreach to Department of Justice / Parole Officers
- Go out to the people. **Ex:** Mobile health center RVs
- Get to people's workplaces, migrant workers, those who cannot take off from work during the week.

How do you find out who they are in rural areas?

- School administrators, people who work with families.
- Senior centers, churches
- The police – who have unique access and awareness of where pockets of people are who are not getting access.
- Book clubs, card clubs.
- Programs the county health department provides for the underserved. **Ex:** Breast cancer/colon cancer screenings.

21. How would we know whether everyone who participates understands the risks and benefits of the projects?

(Informed consent)

- Make sure they have the competency to answer the questions (appropriate language).
- Have portions where they have to repeat back/answer specifically.
- Avoid long consent forms. Can make patients nervous about what they are getting into.
- Video vignettes, any strategy that does not rely upon people to read.
- Many individuals may not be comfortable if their illiteracy could potentially be exposed.
- Consent on day one, and then come back on day 7 for a “*verbal posttest*”
- Community advocates should be a part of the consent process as “*a check on the system*” because patients will be more likely to ask the outreach worker.
- Take short attention spans into account. “*How do you learn the best?*”
- Would it be possible for another study participant to walk new participants through the day-by-day process in terms that they might understand?
- Have a study participant mentor walk them through what the study entails.

22. What data are available to identify other factors and issues that are important to people that we need to consider?

- Look in newspapers for trends in a particular area/community.
- Find economic indicators (income levels) – where people are spending their money
- ER admissions, public health indicators, police records/crime rates, autopsy data (cause of death), BGE records (turnoff notices, energy assistance programs), calls to fire department
- Social information, i.e. education, income, transportation, occupations, unemployment rates.
- Public transportation availability
- Soil, water, air quality
- Disability compensation, food-stamps, child services, homeless shelters
- Census data
- Disability compensation records.
- Food stamp/school lunch program records.
- WIC
- Talk to area nurses – patients confide in nurses. Qualitative stories from patients that are routinely not captured. What patients choose to share about their problems: no money for prescription, must catch a given bus because it is the last one home.

23. What methods are best to disseminate the information to people who participated in the research?

- Written report – something participants can hold onto, share with others.
- Interactive community health fair that includes people that actually participated and some research team members that participants may have not met previously.

- Libraries
- Publish newsletter and mail to community members, place in grocery stores, convenience stores.
- Have a website, set up a system to send text messages to cell phones (especially for younger people)
- Facebook community page
- Close the loop by showing the community the findings and continuing research in that community. Keep the intervention alive if it worked.

PCORI Phase 2 Focus Group

Focus Group Category: Parents (Maryland Coalition of Families for Children’s Mental Health)

Day/Time: Wednesday January 25, 2012 12:00pm

Location: The North Charles Building (2701 N. Charles St)

Facilitator: Susan dosReis

Co-Facilitator: Melissa Ross

Number of Participants: 9

1. How would you reach out to individuals in the community?

- Newsletters, community paper
- Through schools, PTA, newsletters
- Support groups meetings, churches
- Transitional housing, clinics
- Word of mouth
- Sit and talk, explain to an individual what it is about. Learn through communication with each other.
- Health fairs
- Bulletins, MTA (On sides of busses)
- Soup kitchen / food pantries (Through volunteering – involvement in community)
- Food, making others feel welcome
- Do not be cold, standoffish, treat like a statistic – make direct contact like a person.
- You cannot accomplish this by simply putting out a notice.
- Facebook – more interactive than receiving a survey in the mail.
- Have “life”/health celebrations
- Important to involve children so they know how to utilize resources
- Courtesy calls – “Calling to see how you enjoy...” by an actual person
- Become a positive example in the community you are trying to gain access to
- *“There is nothing like an in-person contact to express yourself”* (Emphasis on eye contact)
- Become part of everyday life not just random encounters for research.
- Use visuals- pretty pictures on a survey.
- Learn to get outside of your comfort zone – this is where most researchers fail.
 - (Ex: Homeless individuals ***“untouchables”*** reached out to on a regular basis by participants church group and built relationships)
- Jails might be a good place to reach the untouchables
- *“Let them know that they gave you more than you gave them.”*

2. How do you get people to tell you what is important to them?

- Get to know them, have conversations. Find out what is wrong from the individuals perspective.
- With children: Include the child, do not just tell the child what to do.
- Make people feel welcome. Use music to relax people/get their attention.
- Share something about yourself – be able to relate.
- Make a connection
- Use a passionate person to engage people.

- Satisfying to listening to someone else that has gone through something similar – see the experience in question through the eyes of another individual.
- Let people know that they're giving more than researchers are giving to them.
- Sometimes you have to step out of your comfort zone (**Ex:** Participant taking a young girl wandering the streets into her own home)
- *"You're just as important as I am, your voice is just as important as mine"*

If you rip up a survey or won't talk on the phone, what do we do to learn about health care in your community?

- Health trailers, mobile health
- Use local health fairs
- Take advantage the vans handing out free phones throughout the city.
- Come to parking lot outreach ministries, have music playing, free health screenings, and free giveaways.
- Must place your personal judgments aside and make people feel comfortable, especially around homeless individuals.
- People are more willing to fill out surveys/participate if resources are made available to them. (Especially if the resource is something tangible)
- The homeless could be doing something other than speaking with you (seeking shelter, food, or money) – for incentive give them something they really need.

How do you make sure people know exactly what you are asking of them?

- Make sure the person doing the explaining is trained very well and be very well informed (Can't say *"I don't know"*)
- Put information in plain and simple language – break it down from the *"medical language"*
- Let the individual talk to you – be open in your relationship. Teach back method.
- Have someone as a spokesperson.
- *Use visuals/pictures to make people connect.* (**Ex:** Postcards and mailings on white paper with black letters get thrown away)

PCORI Phase 2 Focus Group

Focus Group Category: Parents (Young Children)

Day/Time: Thursday January 26, 2012 4:00pm

Location: Child & Adolescent Psychiatry (701 W. Pratt)

Facilitator: Dr. Susan dosReis

Co-Facilitator: Melissa Ross

Number of Participants: 8

1. Where do we go to find people to participate in our Study?

- Schools, libraries, recreation centers, churches/youth ministries and groups, transitional homes, streets, malls, health clinics.

Missing people in the community?

- Homeless shelters, transitional homes, out in the streets.
- Markets (Ex: Cross Street / Lexington)

2. Now that you're there – what is the best way to get them to participate?

- Have a booth to draw people in.
- Focus groups.
- Have something to draw them to you (Ex: food) and have understanding of "where they are"
- Build rapport and trust. Understand where they are coming from.
- Take steps to get to know someone and consider body language and feedback.
- *"Can reach anybody if you understand and really want to help them"*
- Audio and visual utilization in recruitment / music + colors.

- Have something in front of them (**Ex:** 15-20 minute empowerment class they can benefit from immediately or even at the back end. BP screening. Something quick and easy, a resource they can take advantage of.)

How to build these relationships?

- Get the person in charge of the school/recreation centers involved and utilize existing relationships.
- *“Be genuine.”*
- Networking
- There exists mistrust of researchers based upon poor experiences in prior research. Keep your word. If you say something is going to be done, do it. Trust is key.
- Stay open minded – do not put yourself “higher” than the participants.
- *“We’re here to help one another”*
- What can you tell me about the study? You’re asking me to be a part of it – what are the side effects, what benefit do you get from this?
- Researchers must provide more information – “Who better to tell me about research than someone who has already been a part of it?” Put information in writing.
 - (**Ex:** Personal experience with individuals who witnessed personality changes as a result of a trial.)
- Many participate in research to put food on the table, but they do not pay attention to the risks.
- Call and check on participants.
- Start early by including children in low-risk research (just-talking) to build trust and understanding.
- Listen to people – sometimes people are just looking for someone to talk to.
- “What are you selling?” (Research) – work to match individual problems/concerns with the appropriate research. Listen to people first to make sure it meets the participant’s needs.
- Meet basic needs first (housing/food) – especially for people in the street –*“When I come out of the research, I’m right back where I started. I’m doing this research for you, a couple of dollars and I’m back out on the street...”*
- Give first, take later.
- There are probably some we will never reach.
- Word-of-mouth.
- Be upfront about what the research will entail.

People we will never reach no matter what?

- People who feel they have been manipulated, tricked, or had their trust broken previously.
- Researchers must be careful not to neglect current relationships as it will have an impact on future research. Researchers may think you are not reaching them but just because it does not interest them does not mean they are not passing the information along to people they are networked with that may be able to utilize it.
 - (**Ex:** Read advertisements in news paper and never taken part because it’s just a “short little ad” and is not enough information. Word of mouth advertisement is superior)
 - (**Ex:** Good follow up/interaction by insurance company’s research division (Health Spending Card), designated support person for concerns. Gives a profile that you fill out.)

3. How do we ask questions that are important to people in the community?

- Do not ask the same questions over and over – *“Didn’t someone just ask me this?”*
- Can turn some people off – they realize you are just rephrasing/repeating yourself.
- Describe why questions are relevant so that people understand why they are being asked.
- Make questions relevant to the research at hand.
 - (**Ex:** Participant did not understand why when she went to ER with cut finger she was asked if she was pregnant.)
- Be persistent. Go into the neighborhood and show that you’re really concerned to build trust.
- Be aware of traditional values and generational values.

4. Are there any better ways for collecting information on what’s important?

- Utilizing social media – Facebook
- *“The natural way”* - Going door to door and having a conversation.
- Even just \$25 could motivate someone given the situation in their day to day life.
- Pull questions out based upon the conversation.

- There is importance to following up in a timely manner. Do not keep taking and taking and talking without giving back, especially if you are just calling randomly whenever the researcher needs information.

5. How do we make sure individuals know what research is about?

- Take the time to go over it with the person and read over the information.
- Make them feel comfortable.
- Be straightforward.
- Educational level may not mean as much as you think – do not assume because someone is educated that they will automatically understand. *“Some people do not understand what “interview” is outside of getting money for gas and electric bill.”*
- Be careful that they are not faking understanding and just agreeing, which happens.
 - Especially when incentives are involved. This may distract them from the risks.
- Let them know EXACTLY what is involved especially if they are taking trial medicine.
- If you don’t tell them all the facts, you run into issues .
- Honesty/trust play a role in participation – do not want participants to feel like they were tricked.
- Consistency in contact. Make sure that the same person that is doing the intake/interviews is around when the actual research starts.
- Don’t change people all the time – let people form a relationship with the researchers which will facilitates creating relationships with the network that the participant has.
- Avoid using “big words” and fine print. Break it down into their terms but be detailed.

PCORI Phase 2

Focus Group Category: Physician (Association of Black Cardiologists)

Day/Time: February 1, 2012 6:45pm

Location: Amiccis of Little Italy (Baltimore, MD)

Facilitator: Dr. Karen Kauffman

Co-Facilitator: Melissa Ross

Number of Participants: 10

24. What practical methods are effective in engaging patients in identifying and prioritizing research questions?

- Researchers should identify the needs of patients that would prevent/enable these individuals from participating in research (i.e. transportation). References were made to the importance of repeated contact with individuals to build a relationship. The importance of determining the demographics of the population of interest was brought up. Researchers should determine what the major concerns the community leaders and “man in the trench” (individuals out in the community) have. Another thread that was carried throughout several questions was the concept of *“Multicultural competence”*; just as patients respond to physicians who they can relate to they will be more likely to researchers who understand their needs/situation. This does not imply that the individuals have exactly the same background. Ex: In Ethnic communities, certain conditions are endemic – you should know what to expect going in. Depending upon the community, learn the family history. Give people the opportunity to think about it. Possibly give some suggestions based upon their family history/culture and they may pick up on one from a list and identify what would be the most important; it just may be something they had not previously thought of.
- Use a survey to find out the needs.
- Depending upon the individuals being researched, the level of comprehension must be consistent with their level of education (5th – 8th grade level). Explanation must be made less complex for the lay person. Keep things simple. Get directly to the point and you can avoid patients feeling intimidation, apprehension over comprehension, or fear of being exposed as not being educated enough. Do not want to burden patients with repeated/confusing questions.
- ABC did a video several years ago to educate patients about what research is and what it not. It played as a looped video, in the office where they had captive audience and helped to dispel myths to get a better “buy-in”.
- Use current medical problems as a foundation – *“The reason you were able to receive this treatment is because of previous people who participated in studies.”* Then discuss how there remain unanswered questions and how the

future generations, grandchildren could potentially benefit from participation. *Ex: Cancer treatment – “There is no treatment but you wish there was” – just as others in the future will wish for treatment.*

- When patients come in for a particular condition, screen them and find out what their interests are if a future study comes along so that you have a database/pool of willing participants ready.
- Another recurring theme is the establishment of trust. *“People do not accept knowledge if they do not trust you”.* Especially in African American groups, must bring up the distrust researchers have created in the past (Tuskegee) upfront and not skirt around the issue. Get a handle on this trust factor in the very beginning. Also important is who asks the question. If a physician asks, the patient may shut down. It may be more appropriate to have the nurse ask in the intake or through a PEER.
 - **Ex:** The CHAMP program trained community members to be health advocates. People will be more honest/open because the information is coming from someone at the same level and using the same language; someone separate from the system that they may associate with distrust.

25. How would you identify the most meaningful and important treatment results? What is the end result?

- Ask the patient, how do you think you would like to feel ten months from now? In doing this, how do you want to feel? What do you want out of this for you? Many people who enroll in studies 12-18 months. They all want to know what happens at the end of this process? What am I going to do at the end of this? Do not just cut them off.
- Think about benefits – “outcomes” may not mean anything to all participants.
- Must connect the outcome to something more tangible/beneficial.
- Ask – Do you understand what the goals of this study are? What do you think this study answers?
- Provide a list and ask them which are most important and which is the most important.

26. How do you determine that patients understand the risks/benefits to the intervention?

- Have someone repeat it back in their own words. *Ex: Investigator may have used terminology that indicated monetary payment but at the end of the study participants are surprised.*
- Follow up – start out with a series of things. Give information in small chunks – same as making a diagnosis – Do you have chest pain or trouble breathing? Then move to other diagnostic questions.
 - **Ex:** Part of the risk is cough nausea, vomiting. STOP. Then continue with a couple more.
- Avoid 17 pages of consent forms – what if the risks (ex: asthma attack) are buried on page 8? Break information down into a short form if possible. Ask open ended questions that include more than a yes/no. to open avenues into other discussion. Be straightforward when presenting the risks. *“Based on what I said, what is your understanding?”*
- Ask open ended questions about their understanding. They can fake yes/no questions.
- What is your interpretation of the benefits of this study? Do you see some way for this research to benefit you? If they say no – likely they will not be a participant long term.
- Let them know what it will do for them personally versus the population/research. Be honest. Do not let them benefit from something that they will not.
- Be extremely clear about money as an incentive and the exact amount that they will be receiving.
- Be upfront about whether there is or isn't an incentive. People may stick around when they otherwise wouldn't because they think they will get something at the end.
- Be honest about odds of receiving a placebo.

27. How do you identify what interventions would be acceptable to them? How would we find out what interventions would be meaningful for them?

- Allow patients to give feedback if they have had problems with something before (ex: people not comfortable having blood drawn) **Ask:** *“If you have been involved in research – what was good/bad about that particular project?”* If they answer no: *“Do you have a friend/family member what did they get out of it? Did they tell you anything positive or negative?”*
- Meaningful intervention would inform patients almost immediately about their own healthcare. All studies require screening process/physicals you may not know about and that could be a benefit since many individuals in the studies do not have primary care physicians and would have otherwise not been in the medical system.
 - **Ex:** Participant shared story about finding about diabetes through a weight loss study.

28. Who are hard-to-reach (underrepresented) patients and how would you reach them?

- Patients who live in rural and highly rural areas. Patients with no insurance who go to free clinics.
- Hispanic individuals. Especially if they are here illegally.
- Native Americans – contact their community leaders.
- Any group where trust is an issue – churches are a good place to start.
- Among non-church going people – may have to innovate and go to bars. Barbershops, social gathering places. Researchers need to identify where people are and learn how to get to those areas to get information to them.
- Mistake researchers make: Start to reach out prior to becoming culturally competent.
- All clinicians are not proponents of research. There needs to be a push to educate primary care providers about the benefits of research so they can educate their patients about the benefits of studies.
- Hard to reach can depend upon the study– **Ex:** may be harder to get younger people n hypertension but easy be the opposite in HIV.
- Homeless – researchers may need to walk the streets. Shelters open up at certain times and individuals will line up.

29. What data are available to identify other factors and issues that are important to patients that need to be considered? What sources do you think patients use to learn more about health and healthcare?

- Start out with the standard set of things; statistics. Then look at socioeconomic factors can give a large amount of information, demographics, transportation.
- There is a lot of negative imagery in the media that must be overcome when patients are being recruited into studies. Television lawyer advertisements are especially harmful and create a false perception about the lack of safety associated with treatments/pharmaceuticals.
- Bring in their families. Discuss what bad experiences they had and clarify whether their bad experience is a risk in the current research.

30. Additional Issues Raised

- Provide full disclosure when recruiting
- Physicians need to become more involved –the way physicians feel about research can be infectious
- Recruitment of minority participants needs to be high-touch (verbal) not high-tech (just handing someone a piece of paper)
- You have to have people on the research team that are involved in/related to the community in which the research is being done. Patients must feel that they can connect with the person that is making the first contact. On your research team, you must hire someone who represents the community you are recruiting from. The days are over where you have trust merely by your association with an institution/university.
- “People trust people who look like them”

PCORI Phase II

Focus Group Category: Physician (CHIP)
Day/Time: Tuesday January 24, 2012 6:00pm
Location: Glen Burnie, MD
Facilitator: Dr. Karen Kauffman
Co-Facilitator: Melissa Ross
Number of Participants: 7

31. How do you determine the most important questions your patients have about their healthcare conditions?

- Relate their life experience. Ask them what their expectations are and avoid preconceived notions.

- Be a good listener, try not to interrupt, allow them a chance to address the concerns that they have and then respond from there. Ask open-ended questions.
- Know community better, to illicit what interests its members.
- Oftentimes what is of interest to patients are not just health indicators, but also more practical factors (i.e. social factors)
- If you cannot be open-ended it would not be unreasonable to ask more closed ended questions.
- Must give some guidance to patients when asking what research they would be interested in.
- Make patients feel comfortable and that they are in a safe environment.

32. How would you identify the most meaningful and important outcomes?

- The term “*Outcomes*” is researcher jargon.
- Break the language down to a fourth grade level.
- You have to understand what they know about and what scares them about the disease.
 - **Ex:** In hypertension, some individuals more scared of just taking the medicine.
 - Translate these fears into “outcomes”
- What does research mean to you? For many African-Americans, the negative impact Tuskegee still looms over research.
- Surveys could be a good way to find out what patients are concerned about.
- You must be willing to accept that your patient’s outcome measure may not be what you expect or even meaningful to researchers.
 - **Ex:** “*I want to be able to wear my heels in church*” – you must be able to understand the patient and then translate these into health outcomes. This may be an area physicians get wrong a lot.
 - Find out what is meaningful to them and then extrapolate and relate it to a measurable outcome that you want to see happen for them.
 - Translate into something measurable.
- Do not assume that what is important on the population level is important on a personal level.
- Some clinical measures are not meaningful to patients.
- Get feedback from patients via questionnaires and patient satisfaction surveys. Learn what they want to know more about.

33. How do you determine what matters most to patients when they have to consider several options for a treatment or interventions?

- Have to put things in the context of patient’s lives. When you get patients talking, you have to give patients options and integrate options with patients’ lives. Has to be relevant to what happened yesterday in patients’ lives.
- Patients would like to have a better idea of what the long term/short term implications of compliance with their diabetes regimen.
- The intervention’s impact on function.
- The likelihood that the treatment will matter.
- Costs
- Long-term effects vs. short-term
- Ask open ended questions or give examples that will lead to open ended questions
- Repeat what you heard back to them and ask if you’ve missed anything.

34. Who are your hard to reach/underrepresented patients? Where are there? How do you find them?

- The elderly – you can find them through collaboration with colleagues in the area/community.
- Know the community. Know the resources in the community.
- Use collaboration to reach those who are most hard-to-reach.
- Churches know how to reach out but these people are engaged in their communities. (Not actually hard to reach)
- Local after school programs.
- Include patients from rural as well as urban areas. Include the outskirts of cities.
- Include “undocumented” individuals.
- Emergency rooms/Urgent care – This is the point of access for many underserved patients
- Homeless shelters/community centers

- “Hot spotter” program populations
- Truck stops, relocation centers, off highways, hole in the wall Hispanic restaurants.

35. What methods are effective in ensuring that patients understand the risks/benefits to the intervention?

- Have patients explain things back to you (Teach-Back method)
- Have a peer (someone “on their same level”) interpret for them.
- Have patients reword consent form, etc. in their own words.
- Provide people with the knowledge to where patients are able to form their own opinions.

36. Where do your patients go to learn more about their healthcare?

- The internet, their pharmacy/pharmacist.
- Grandmothers, mothers (Family traditions) – **Ex:** If you tell them something contrary to these beliefs, on the next visit you may have to explain to the relative passing the knowledge along as well.
- Neighbors, buddies/friends
- Relatives who work in healthcare, no matter how remotely (i.e. medical assistant).
- Ministers/Religion – you cannot ignore religion in decisions that a lot of people make.
- “Mom and Pop Natural Solution Stores” – GNC (Non-clinicians)
- The Dr. Oz television show.

Additional Discussion:

- “Give us choices in the methods and we can give our opinions on whether we’ve seen them work or not.”
- Ask patients how they came to their ultimate decision after the physician has explained their options and you may be able to get at what is important to them.
- Primary care physician can prevent patients from even taking the first steps in research. Integrate them into the research process as well.

PCORI Phase 2 Focus Group

Focus Group Category: Bilingual (Spanish and English Speaking)

Day/Time: 2/11/12; 12:30pm

Location: Jose Ruiz Community Center, Baltimore

Facilitator: Liz Jansky

Co-Facilitator: Jennifer Huang

Number of Participants: 18

Opening Statement

➤ **Before we continue on, I want to stop and see if you have any questions about what I’ve said so far.**

[None]

➤ **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let’s begin with introductions.**

[None]

X. INTRODUCTION

Let’s first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- I always want to learn about health
- Learn about health
- Want to know about health, for my children and myself
- For health of my brother

- Wanted to see what the survey was about. Curious about it.
- Want to see what the survey is about.
- I volunteer and work in the school setting. Interested in health
- Volunteer, interested in seeing what it's about.
- Just to listen
- Want to learn about my health

- Curious
- I teach Spanish, I'm interested in knowing more about health
- I'm interested in health for my baby
- Came here for information about health
- Just wanted to hear what the survey is about
- I'm supporting wife and family and what they are learning
- Volunteer here and want to know information
- I want to know more about my health

XI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[none]

XII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- Best way is to visit a store. Or health fairs.
L: *When you go to the stores, or health fairs, should we talk to people in person? Hand out flyers?*
- Both, could be a survey in person or phone. But best way is survey in person.

- Setting up a booth outside for a fair. Or, reaching out to the community, same concept. Set up a booth, reach out to the community, set it up, talk to them personally and explain clearly how they can improve their lives, their health.
L: *How would we engage the people at the booth? For example, if it's staying healthy day, have a booth that provide flyers, types of exercises, what fits best for them and what time they can exercise. And how to do it. What fits their schedule perhaps 10 minutes, could help improve them. Give them information. If you have a workshop that you will create in the future, demonstrate it. It could be in a different setting, but the booth could be an invitation to the workshop so they can see what exercises and demonstrate it so they can see what they can do at home at their own time.*
- Library. There are mom and child programs at the library.

- Engage with non-profits that are already doing this work and it relates to this.
L: *Non-profits that work with the particular population that we are talking about? Yes*
- Food stores.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

- Folks that have too much going on with their lives. Their schedule is too tight to check it out. We need to come to them, if they cannot make it to the workshops then find a way to see if the organization can support that and find them.

L: Would people be okay if we knock on the door? Probably not, but reach out in a public place, and then let them know if they cannot make it to the workshop, we can go to their home.

L: What about seniors? [no response]

L: Homeless? Depends on how you go about it. If you go to an outreach center that deals with these issues and have incentives, whether clothes or financial aid, they might be more likely more to listen to you.

L: Are there other types of incentives that might people interested in joining? Pharmacies.

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

- Focus on children; the small ones, most of them need more health.
- It seem that you have to pick your demographic first, and then see what is the most important issue for that demographic. Look at past research studies, there must be research out there.
- Do surveys. That will tell you a lot.

L: Hand out the surveys in hardcopy? Telephone? Can do it both ways. Can do it face to face too.

- Might be easier if there are incentives. What we mentioned earlier. Pharmacy, clothes. Or resources. I feel that you would hand those out anyway not matter what you do.

L: So we would always have that [resources] when we are reaching out the community? Yes

L: How would we decide which topic is most important?

- Depends on how much money you have.
- Look at local government it see what issues they can push. Might be other organizations or nonprofits that are pushing similar agendas. Maybe teaming up with CVS, Rite Aid, see what they have access to.
- Old people. They may have issues with insulin, blood sugar.
- Figure out what the majority needs. If a college student takes a survey, their needs aren't the same as a single parent. Find out what the majority of needs are and what is important.

2b. Are there any other ways to get people to talk about the goals of the project?

- I think first that you have to educate the parents. Most of the time the food is coming from home and they are using too much oil. Find out what food they are cooking. In the schools, approach the teachers, board or system to give more time for the kids to do exercise. Have to educate parents. They give food to the kids.

L: What happens if not everybody thinks the way that you do? Should we take a vote to see that we should educate the parents? The school system? Or do a survey? You could do a survey too.

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

- Integrate nutrition classes into the students' subject every day. Because they are ultimately making the decision about what they are going to eat. Put more focus on it.

3. Where would we go to find this information?

- If you want to know for sure what kind of project you are getting, you can do a follow-up process and reach back to those people that were in the program so you can monitor the process. Create a program where people can come back with and see their progress.

L: Do you mean talking to the children themselves or others involved in the program? Anyone that is involved, including children, teachers, parents. It's going to be a combination of all of us. Start with the parents educating them. That's going to be key. But when the kids go off the school, what is at the school. What are the teachers teaching them? So it's going to be a lot of people involved if you want to monitor the progress of the program.

- Find out what the local food options are. What the demographics are, where are the parents going to, what are the options for supermarkets? If that supermarket closed down where would parents go to? What do they buy at the supermarket? And restaurant options? I don't know how concretely you can get that information but that will get us to what is going on.
- Goes back to an example of what their day is like, what they eat, food intake. Someone will say, well, I get up at 7am. You can ask, what did you have for breakfast? Did you have a donut or fruit? Coffee, tea, milk. For lunch or dinner, how much time you had for sleeping? Exercising.

L: Like a diary? Pretty much

- Keep track of sales. If the sales for vegetables increase? In supermarkets, what kind of food do they sale there, what are the sales for produce, junk food.

L: So that's part of the environment idea, what they are consuming, what is out there? Yes.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

- You can go full circle to the first sheet [referring to the large sheet with responses], schools, fairs. Sounds like it's ongoing study. Going to those places, that we identified first, those non-profits, schools again. Engage and recruit from them directly.
- Best to get a group that is consistent. Places where you have participation. Versus a supermarket where people might just give you attention for that one day. And you might not see them again.
- They can fill out a survey, and information for a way to reach back to them for a workshop.

L: Would people feel comfortable with a survey? Not necessarily, but if you are genuine with information that you are going to provide, people will.

- Maybe consider someone bilingual, depending on demographics that the community caters to, so the person can fully understand what the goal is. And offering paperwork depending on demographics. Communicate verbally in their own language and have it written in their language so they can understand the goal.

L: Is it also helpful to have the same type of person? If I'm going to get young people involved, should I be a young person? Do I have to be the same culture of the person?

- Not necessarily, but it might help.
- It can be a positive experience with some people. Some people may feel that they can relate more. I'm taking a social work class now, my professor, she's Latina, she says that when she tells people that she's Latina, they might listen to her more. But my friend who is Caucasian, she has been through the [??]

school system and [can relate to others because of her experience – audio unclear]. So it depends on the person who you are working with and their expertise and experiences.

- I would say passion. I guess it depends on how motivated the person speaking to you is about it. And not necessarily ethnicity.

5. What are the best ways to disseminate the findings?

- Talk to the mayor. Present study, results. Hopefully they can also put some other initiatives in place that are like this study. And not just the same demographic, but other demographics. Have someone from the local media involved so they can report it out to the masses.

L: Radio, TV, billboards? All of the above. Especially newspapers, they if you are focused on one specific community, there are newspapers focused on specific communities.

- Having something concise, to the point. In colloquial language, this is the study, these are the results this is and what the change the results are going to bring. Because sometimes you can results, but aren't sure what it means. Need to have the next steps.

L: Would it be helpful to have someone in the community to write up this? Yes, and looking at the demographics, and see what is the most beneficial.

- Partner with colleges, do presentations in PowerPoint. I'm sure that professors that do research will give presentations for credit.

L: Are there other ideas to spread the good news to other levels, even in other countries? Going political in any way possible. Mayors, governors. Public speakers. They can say this happen in my town. It can happen in yours. Spreading the message in anyway possible.

L: Would it encourage other communities? If they did it in Baltimore, we can do it here? Yes. Exactly.

- Might also be beneficial to get other similar agencies working on other similar initiatives. Community might be inspired, but might be hard to get them into something. But if there is already an organization in that community and you say, this is what we did, this worked, and you consult with them, that might help.

XIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- Letting people know about different health related opportunities that are for them. I know that in Jersey, they have a dental school where they have a "give kids a smile day" and kids from disadvantaged communities get a dental checkup. Get them connected, they might not have time to look out for that [resources, opportunities]. Something that they can go to. Next month it could be doctors who are coming to local schools for free checkups.

L: Would we let them know about it in the ways that we talked about before, like flyers, word of mouth? Yes

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[none]

XIV. FACILITATOR/CO-FACILITATOR REFLECTIONS

Although more people participated in this focus group than anticipated, it was not difficult or unwieldy to manage. As we did not provide childcare services, several children were also in the room during the focus group, but were preoccupied and did not disturb the discussion. This group was unique from others as several participants were college students and a few appeared to have experience with working with non-profit agencies.

Several examples of engagement methods (e.g., surveys, flyers, health fairs) that were expressed in this group were very similar to what emerged from other groups (e.g., Lower SES AA and faith-based groups). There were, however, a few nuances that were particular to this cultural group. For example, participants expressed the need to ensure that project materials and resources are written or explained verbally in Spanish. When asked whether the person who is conducting the study needs to represent the demographics of the community, several participants stated that while it may help, other factors, such as speaking with enthusiasm and from personal experience is often more important than ethnicity. The ability to speak from personal experience in order to develop a personal bond and engage others into health-related projects was also expressed in other groups.

PCORI Phase 2 Focus Group

Focus Group Category: Faith-Based
Day/Time: January 26, 2012
Location: Mt. Lebanon Church, Baltimore
Facilitator: Liz Jansky
Co-Facilitator: Jennifer Huang
Number of Participants: 12

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? Great, then let's begin with introductions.**
[None]

XV. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today.

- To find out more about the study
- To see if I can provide input
- Get more info about the study
- To learn what this study is about
- I would like more information about the program
- I received information to come, no idea what it's about, other than health issues. Interested in health issues.
- I was invited, like to see information about this
- Want to see what this is about
- Attended the initial meeting [Phase 1], thought that this would be interesting for others, wanted to help others. I coordinated the event, purposely for church members
- To learn more about the research study
- Anything that concerns health peaks my interest
- Wanted to find out information about what this is all about

XVI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? Great, then let's begin the discussion.**
[None]

XVII. FOCUS GROUP QUESTIONS

1. **How would we get your friends and family to talk about what's important about obesity?**

- I would say health and my family does have a concern for health. *L: So, going to people's family is one way? Approach people's families? Yes*
- Going to churches. Doesn't need to be a focus group, but it could be a survey, ask pastors to do a survey through church members. Talk to them, ask what they think leads to obesity.
- Senior centers. *L: Do we ask them one on one? Bring a flyer?* I would say that every Friday, they have a meeting, someone from an outside group comes in to discuss different topics with them.

- Schools. Recently on TV, saying that they are changing what they feed them. Pizza, French fries, school board, principals are talking about it. *L: Anyone else related to the school? Parent groups, PTAs, head start*

L: We're talking about obesity as a child issue. But if we are thinking about any disease, are talking about systems and social circles and local organizations?

- Could go to malls, place flyers in malls.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

- I was thinking about neighborhood centers that homeless people come into. If someone shared the information with them, that would be helpful. Whatever information they have to share, they come in, especially this time of year, they come in to get warm, get a sandwich. Perfect opportunity to get information to them.
- Senior living clusters are together. Not sure if there is a separate living senior center.
- Each senior living center has a building captain, a team that spearheads what is happening. *L: Approach that person as a gatekeeper of that building? Yes. They have a monthly meetings.*

L: What about those with mental or physical handicaps who are not connected to the mainstream?

- Adult daycare centers and medical adult day care centers look forward to opportunities for people to come in and do presentations, give info to their clients. You'd be surprised. They like to share, to be included.

L: If we canvass the local place where homeless people congregate, would that be effective? Or they would ignore us?

- Depends on your approaches. *L: What approaches are helpful? Bring sandwiches.*
- I'm thinking about food also. And that's one of the main reasons why they come in.

2a. What are the best ways to get people to identify the most common problems and decide which ones we should study?

- Have to be direct and just ask. *L: How would you ask if you were doing it with me? Try to get you to warm up to me. Just be honest and say, I'm with this group, we're doing a study about obesity. Do you mind if I ask you a few questions? Use a direct approach.*
- Are you asking about groups of people or individuals? *L: Either way. Whatever you think is best. I did participate in 2 such groups. I was called and asked to participate. When they explained to me that it was a health situation, they came to my house. L: Did you like them going to your house? I didn't say that I liked it, but it was okay. Once we began to talk, we warmed up to each other. L: Does it matter who's coming to your door? No, once I know that they are coming, I didn't have a problem with it.*
- I was thinking about people confined, not able to come out. Perhaps someone from the church can come to their homes or call them and let them know and give them the information.
- Lots of times you get surveys in the mail. Sometimes I send them back, sometimes they don't. So that could be another way.

L: What about email?

- [some nodded heads]
- No, don't send me any more emails.
- It's a younger generation.
- First, it will go in the junk box, because it's not from one of your contacts.
- If you had a family member, you can have a group meeting with your family to talk about it.
- I thought of a group that we meet with [retirement home]. We meet and I think that might be a way to reach people. [She then asks another participant who is also familiar with the home about this possibility]
- We have speakers come in [to the retirement home]. And a lot are trying to get information. You have a Pastor H., and we are there. And this [retirement home] is for former government employees, so you'll have a group. So there are groups all around the state.

L: Would it help to first hear information and then find out what people think? What kind of information would be helpful?

- I think that if you go to a group or find a group of people and talk about your experience you had with obesity, people would listen to you more about your experience instead of showing a movie. Say for instance, I am

obese and I talked to someone about it. And I told them about it, what happened and what I'm doing about it. That would get people to think about it.

- I think that a video would be helpful. Both personal testimony and video would be helpful. The individual viewing the video maybe able to identify with it. Same as the personal testimony.

L: Does the video need to have someone from the community? Or can it be "generic"?

- Generic is fine. It's more of about the subject as opposed to the person.
- You have a lot of sororities, fraternities, organizations that would benefit and be willing to give input. *L: Do they have regular meetings?* Yes, regular meetings.
- I was also thinking generic. You have people like Janet Jackson doing Nutrisystem and Jennifer Hudson doing Weight Watchers. But they can afford it. We don't need to see them. If I could, I would go on Nutrisystem, but what would my family eat?

L: What are the ways to decide/prioritize these problems? What are the ways to pick out the best concern to study?

- I hope that we wouldn't choose something so controversial that it would create a hassle. When you made a comment about taking McDonalds out of the neighborhood, you might have an issue from the babies wanting their French fries, to the late night snackers wanting their daily doubles. So pick something not controversial, so something that people would feel a desire to participate in. *L: So, feasibility. Like, is it even going to make sense.*
- I think it's who you gear your study towards. I'm the youngest person here in the group. This group has said, don't send me emails. But I think that for my generation, email is the best way to reach me. You have to think about the people, the audience.

2b. Are there any other ways to get people to talk about the goals of the project?

L: Are there any other from ways that you've already talked about before [referring to written responses for Q1]? Anything we wouldn't do?

[None.]

2c. We know that there are a lot of different things or approaches people do to become healthier. For our research project, we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, is there anything different that you would do from the list to get everyone's input just on which approaches we should study?

- A lot of the problem with obesity is from the preparation of food. So you can talk to parents, set up classes for them. Don't know how you would phrase that. But, could look at the preparation of food.

L: Okay, I want to stop. Now we're getting into the answers of how to solve the problem of obesity.

- Start with the school system. Educate them, how to do more healthy foods. A lot of things on TV about how to change menus, not eat processed foods. Prepare foods differently for children. Start at an early age.

L: So systems of preparing food.

- I have 2 great grandchildren that are overweight. We take them to the hospital for weight control. They have a program, but so far it hasn't worked. Their mother doesn't seem to be interested in doing what is given to her by the hospital.

L: Again, pulling it from the obesity issue, talking to the medical providers [is an approach]. And mom is the problem, so let's talk about that later in my next question.

- To partner with someone like MTA and do billboards on the bus. Can be pictures, one liners, something that triggers your mind to think to eat healthier. Picture of a banana split versus a yogurt.

L: So, building partnerships with organizations that are present in your community to do a little health marketing, showing pictures, messages [as an approach]

- Displays work really well. We had a benefit fair at my job yesterday. It was a simulation of a can of soda. If you drink a soda can one day/month, it had a picture of a 5 lb bag of sugar. When you look at what you are eating on a big picture, it will give you incentive to pull back a little bit more.

L: So visuals [as an approach]

- Yes

3. Where would we go to find this information?

L: One way to collect information is to weigh children. But in [participant's] case, the mother is the one that is preventing the children from losing weight. What other kinds of information should we look at?

- Cost
- Time
- Commitment
- Transportation

What kind of data will we pull together? Look at health statistics? Familial patterns?

- I think that there is a saying that if you follow a fat kid home, you find a fat parent. So I think that there is a familial connection.
- Talk to the parents about providing healthy foods, provide them information. *L: Pulling it away from the problem of obesity, am I hearing you say to talk directly to the people who will be involved in the study? Yes*
- Talk to the school system to get them to prepare healthier lunches. *L: Pull it away from obesity, talk to the systems that are involved in the health issue.*
- Look at control. Parental issue. Maybe no one is there to make sure that the kid is eating right, because the parents are working. *L: And looking beyond children, for adults, also social support, things like that? Yes*
- Consider demographics of the community. Is there a community center where the child can go after school? What resources does the center have? Are there video games, or things that the child can do to move around?
- How many stores does a child pass along the way to and from school? The corner store, CVS, fast food, McDonald's.
- When then children have lunch and someone is providing them something to eat they should have fruit around for the children. And look at the child's diet. *L: So we then have to look at the systems that are involved in the participants' lives.*

4. What is the best way for people to understand what our research project is about so that they can decide whether or not to participate?

- Word of mouth. *L: Whose mouth? Mine! I have a big mouth.*

L: Any particular leaders or anyone else in the community that would have clout?

- I think that it's good if the pastor could do the introductions, but better if you all sit down with small groups like this, talk about the research and what they're expected to do, and make sure that people have a full understanding of what they are asked to do and give yeah or nay.
- People affiliated with the church.
- If it's an outside organization, go to the leader. If a sorority, go to the one in charge.
- A family meeting. Explain to them in a roundtable discussion what's going on before they meet with the researchers.

L: Is there any particular way to gain trust?

- That's why it's a good idea to get the leader to introduce it and someone involved in the research to do the training. As much as you love the leader, they're too close to you. They may be too involved, so you need someone outside to give you the information.
- If you have someone already participated, that person can come in and speak to give you a boost.

XVIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

[None]

We have a few minutes left to go back to topics we put in the Parking Lot.

[None]

XIX. FACILITATOR/CO-FACILITATOR REFLECTIONS

This was a full group with a few of the participants more vocal than the rest. We went into the focus group concerned that using the example of obesity would detract the participants from the purpose of the discussion, to go through the research process, but we found that the example was useful and the participants had limited difficulty staying on track (aside from some tangents when thinking about the approaches). The facilitator edited the original focus group guide to indicate ways in which she phrased questions and inserted examples to ensure participant comprehension. Main themes we heard were for researchers to speak directly and openly with the community about the purpose of the study, why it is important that people get involved, and what can be expected from their involvement. They cited this focus group as an example of the correct way of going about engaging and collaborating with the community. They recommended having a respected member of the organization/community help the researcher gain entrée into the community, but once introductions were made, for the researcher to take over the process.

PCORI Phase 2 Focus Group

Focus Group Category: Faith-based

Day/Time: Saturday, February 4, 2012 at 10:00am

Location: Mt. Lebanon Baptist Church

Facilitator: Jennifer Huang

Co-Facilitator: Liz Jansky

Number of Participants: 11

Number of Observers: 1 (Gail Hunt from PCORI)

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[One person asked what PCORI stands for again.]
- **Are there any questions before we get started? [*Answer any questions that may arise*]. Great, then let's begin with introductions.**
 - No

XX. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- Invited by Ms. Mack
 - Mrs. Mack and Dr. Mullins asked them to pull people together. Thought it was a good idea for the church and the community.
 - invited by Ms. Mack
 - received letter from Daryelle and Ms. Mack
 - invited by Ms. Mack
- [Two more arrived after introductions]

XXI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [*Answer any questions that may arise*]. Great, then let's begin the discussion.**

[None]

XXII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- That's a hard question because they don't want to admit or they're in denial that they are obese or overweight, so to approach it...I don't know. That's a hard question. They're very sensitive about being obese.
- Through education first, because a lot of them don't understand the consequences of being obese, so it you explain to them the what is at the end of the road. But you have to explain to them what would happen.

J: What are some ways to spread this education? Are there some methods or venues to get people to open up or talk about it?

- What we try to do around here is an Awareness Sunday to have literature related to whatever topic. To educate them. To have resources to turn to, to have them to turn to. *J: Is this at a certain place?* It will depend on what the event is for. For example, in October we've done a cancer survivors group. We've had some speakers come in and do some presentations about cancer. Sometimes we'll make a note in a bulletin and tell them about additional resources around the church.
- In our home, we have an 8 y.o. and she's being looked at about maybe being a diabetic. Right now she's not, but she has to control the diet. I've changed my diet but my daughter's has gotten now so that she needs to change her diet. Because my daughter, she's a sweets person and a lot of salt, and now she's training her daughter to be a sweets person. And I always say Doritos and things are fine but in moderation. So we do sit down at family gatherings and I tell them that at these dinners that we need moderation. We do discuss it in our home.

J: So then family discussions and family meetings? Is that a useful method?

- Health fairs. We generally have a health fair in May to try to bring different vendors to address all health issues and then you offer incentives while they're there. Have free hot dogs and drinks and snacks and that gets them to stop and have a conversation.

J: Are there any other methods to get people to talk, either individually or get people together as a group?

- As a woman talking to one another in the neighborhood, we often talk about cooking so that's a way to talk about healthy cooking. Obesity is a very sensitive topic. And if you've lost weight, you can tell them what you've done, give them some recipes, so that's a way to spread information. *J: So women or people in neighborhoods coming together more informally?* Informally, as you talk to them, something always comes up about what you're cooking. And exercise as a part of that.
- To piggyback on what [participant] said, she was saying something about exercise. That's very good also to go to the different centers they have around and they have group exercise, swimming aerobics and then you get together as a group and talk about eating as a group. That's what I started doing. *J: So go to the place where the topic is happening? Yes. J: Are the meetings informal? Are the support groups? Yes.*
- With "Zumba Queen" down there [referring to another participant], we had a Zumba-thon which you can use that to address whatever topic of the day and then have somebody there, and during the breaks, to give information about different topics. *J: Does it matter who leads or puts these events on?* It depends on the topic, but between the Zumba Queen, our Aids Ministry chairperson and myself, we usually try to coordinate. We might put it together or independently.
- You have to be so careful because if you're the only one who's heavy in the family; as I grew up, I was not heavy but everyone else was thin, I was called fat. So I was always trying to do things to take weight off. So you have to be very careful even in your own home, and then they do drastic things and it's not good for their morale.

J: Suppose we weren't talking about obesity, but we were talking about something else like heart disease or getting flu shots. Are these methods something that could apply to other types of health issues, or are they specific to obesity?

- All methods work [group agreement]
- And family history. If you know that you have issues in your family, then it's easier to know what you need to stay away from. Often the parents don't tell the children what their grandparents had, and if families don't talk about it, then you find out by accident that this one had cancer, that one had cancer. It's like a hidden disease. So openness and discussion of family history is important.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

J: What other hard to reach groups can you think of to contact?

- I always think in terms of the homeless and the different community centers, and they always go into certain community centers and that's the perfect opportunity to bring them in or engage them. *J: What are some things to let them know and how to draw them in?* In some cases, a gentleman at these kinds of meetings said as he walked around his neighborhood, he would say to them, "We have these services. Why don't you come on down and see us?" So one-on-one inviting them. And he also made the comment that as these persons that are out there, they see you when you don't know that they're looking, so somehow you develop a trust with them so that if you invite them to something, they trust you enough to come.
- And when we do our HIV testing, we're actually in front of the church and will stop people as they walk by. So we can use that as a way of communicating what's going on and inviting them to participate.
- Good if we can start in the schools, particularly that middle school group, and educate them about diet and teaching them not to be obese. *J: Would it be educating students or teachers?* Both, and cafeteria workers. I think they're working on the cafeteria workers. And the parents. In middle school, that's usually when we see them start to really get heavy, eating a lot of junk food. And keep it out of the homes, if you can.

J: Are there other hard to reach people?

- People who don't have health insurance. The hospital doesn't want to see you if you don't have insurance. *J: Can we think of ways that we might be about to reach out to them or even find them?* Go where they go for their benefits.
- Free clinics or free testing.
- I don't think our doctors say enough about diet, our food and what we should be eating. They seem to be taking care of the health, but not telling us we're too heavy or giving us the right resources. They're not looking at it holistically.
- Yeah, and being proactive
- Low-income families would be a targeted group. *J: Is there a certain way to reach out to these families? Anything different?* I don't think anything different because it all has to do with giving them the information.
- But if you don't have the money and you go to these health centers, don't they have like a set-up for services?
- Yeah, fee for service
- A lot of times in those free clinics, it doesn't cover a lot of things. You might want to get a mammogram but since it's low income it might not cover it so you might not have the money to cover it, so you just don't go.
- Please include seniors in our study. They're another left-out group. They don't have family members and they don't have adequate transportation and when you do a service for them, they really appreciate that. And I have one person I'm talking with now and I take her to medical care and I just told her, "Why don't we look into a home visiting nurse, since it is winter time? You are heavy and don't like to walk that much. So why don't we talk to the doctor and get the nurse to come to your house?" She needs to get her BP checked every week [continued with more specifics about this particular woman.] So that is really a population to tap into.

J: What are some of the best ways to tap into that population?

- Home visits, telephone calls
- A dietician needs to go in there. *J: So if the dietician is already coming out, is that a way to get her engaged?* Sure, since [the senior woman] is really heavy.

J: Are there any community groups or centers that are targeted to senior citizen populations?

- Yes, we have quite a few but we have a lot of seniors who won't go so you have to go to them. *J: What are the reasons why? Is it transportation or another issue?* No, they just won't go. They say they don't like it. One person told me one time that it makes them feel really old. They don't want to be around all those old people. [laughter, general comments about how they are old]
- There are things out there that we don't really know about. My mom was sick and they sent out the home nurses to take care of her. And I didn't even know that they still have home doctors that will come take care of you, and they do the same thing that they do in the doctor's office, the blood work, xrays, everything. And now that this home physician comes in to see my mom, they do everything. And when I said something about it, no one knew that they had these doctors that come out. The nurse comes once a month. They do the flu shot, the xrays, everything they do at the doctors' office.
- Just to follow up, I was visiting someone on home hospice care, and her family was told she had x amount of months and now she was told she has x amount of time. And the doctors go out. My PCP goes out and visits seniors. People don't realize that doctors make house calls in the 21st century. So my role was to sit out and do what they do, but when her daughter called and said the doctor will come out, I was like, "Whoa, they come out?" But it's true. They do come out.
- Is that just for hospice or will they come out for someone who's elderly?

- For my PCP, if you can't get out, he will make time to get out to see the person. Nurses come out twice a week and the doctors come out.
 - I was under the impression that doctors come out except for hospice.
 - It's not just hospice care, it's other care [this discussion was moved to the parking lot.]
- 2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?**
- Surveys, and you can give them different options. Then, according to what the majority is addressing, then having a meeting to address it. *J: So with the survey, how would we administer it? Face-to-face? Email? Hardcopy in the mail?* Right, or it could be a hard copy that you give out at church.
 - And the same procedure in the community group meetings, because they address a lot of issues so that could be another venue that you could use.
- J: Are there leaders of the community group meetings? Certain positions or certain institutions?*
- This area, we have a community group that's the umbrella group for all of the neighborhoods and that's the best place to start because then you encompass all of the smaller neighborhoods.
- J: Could we email surveys?*
- I think in addition to, because there are many, many who don't have emails, and some who have it who don't like it, so I would say both ways would be best.
- J: Does the message need to come from a certain person in the community?*
- Speaking about community organizations, usually we had one in our neighborhood, so if we had any issues, we send it to the president and the president sends out an email or brings hardcopies to the meetings.
 - We have a parent representative group in our school and we address our problem like these in the group and have discussions. And also we have community dinners so we have parents come out once a month to discuss these issues. So like once a month. And they have been attended very well.
- 2b. Are there any other ways to get people to talk about the goals of the project?**
- Maybe a parent teacher, PTA meetings when you have a few parents. Not like it used to be.
- J: Is there anything not up here on these lists that you think of?*
- Daycare for the children.
- J: Is there anything on this list that would not be appropriate to get them to decide on the goals?*
[Participants shook their heads, no]
- Well I don't think there's anything on the list because each suggestion is a way to reach a specific group.
- J: As we go through this whole process of identifying the problem, identifying the goal, do you think it can be handled in one type of method to get people together or is it a separate method for each group?*
- It would be a combination of everything that you have there [on the list], because there's needs in the schools, teachers, parents, the doctors, schools.
 - That's a diverse group up there. That, right there, is our community. *J: So it's a matter of knowing who the members are, the different groups, knowing the environment?* Yes. *J: And outreaching to all these groups?* Yes
- 2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?**
- No other ways. I think we pretty much covered it.
- J: Is there any method that would not apply?*
- There again, same thing. We've given a lot of information to reach a lot of groups across the board.
- J: How would we pick one approach that will make everyone happy?*
- To choose, I think we would start with nutrition. Like [participant] said to changing the diet, everything else falls in place. So if we started there, and how to use it and then get the ball started. *J: So picking out the specific topic?* Yes.
 - What [participant] was saying about diet, but it has to go together with education.
 - And then again that's where the education comes in because reading labels is not something they like to do.

- I have two grandsons and they look like Laurel and Hardy. One's big and one's small. The older one is allergic to peanuts and shellfish, so knowing this, we have to be on the ball and read labels. Like when we go to restaurants, we have to be really careful. [This discussion was moved to the parking lot.]

J: Would we vote on a specific approach to make sure that we can prioritize these different approaches?

- Well that goes back to the survey. If we get people to go back to the survey and get people to do the topics from there.

J: Would we hold meetings to come to consensus in the community?

- We have had a town hall meeting for all the community to look at a certain issue. *J: Could this apply? Yes, we could try it.*

3. Where would we go to find this information?

- I think there are ways but I think people would be very reluctant for children to go through specifics and really be identified to go through.
- Or asking participants to do journals and that documents what they're going through.

J: Are there other people to talk to? Things in the environment?

- I was thinking about doctors or schools. Talking about playgrounds, I noticed that all of the playgrounds in the area are getting redone to come up to standards. We have about 6 in the area and they are all under renovations.
- And use clinics. Well baby clinics. They all have data.

J: Would we get information from families? Social support groups?

- It could be. Yeah families. Social support groups is good.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

- Flyers. *J: Are there certain places to distribute the flyers?* Have someone in your community and go house-to-house to pass them out.
- I was agreeing with [participant] with the house-to-house and then when you're in the malls, you can ask to post information, post in storefront windows, the MTA where groups of people are at. Community bulletin boards, you can post them there.
- Mailings, you can still do mass mailings even if says Occupant. *J: Do they need to come from a particular organization?* No, as long as you say occupant.
- Social network. Facebook or whatever they're doing.
- The church, because certain information that comes into the church, we post in our bulletin board and we just ask people to pick up the information.

J: Are there certain sources or person whom people trust?

- It matters. I think sometimes it does. If you look at people who came to the meeting. We trusted [the recruiter].

J: Are there other sources of trust? Or institutions or people that will make people participate?

- I think they respect the hospitals.
- University of Maryland.

XXIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- Do you have other groups you'll meet with after us?

J: There are 20 groups total and some hard to reach groups like hearing impaired, vision impaired. Some groups at Bon Secours. It should be comprehensive project that we're conducting. We're going to look for commonalities as well as unique differences just so we know the best way to get everyone's input.

- So in 2013, will we have an action plan?

Gail: In May we're coming out with the first round of grant applications, coming out with a request for proposals, and part of that is that typically organizations (university) will have partners in the community who will be part of the proposal and also part of doing the project and they have to demonstrate that they've included the community in the design, conduct of the research.

- So could we apply for a grant as a 501c3 we could apply? *Gail: Absolutely. I would suggest that you partner with a research organization, like University of Maryland and Johns Hopkins.*

Gail: after the research has been done, how do they think the findings should be disseminated to the community? Are there specific methods?

- I think the same way we reached them initially.
- Yes, like the way Dr. Mullins will come back out when we're finished.
- We can do it through the mail. Through email. When you have town hall meetings, you can update people with the results. *Gail: Would they be interested in these results? Yes*
- The community meetings

J: Would you prefer a certain format? Such as papers, presentations?

- All of them but make it simple so that people can understand it.
- I was in a study at Hopkins, and every time I participate, they send out information like [the consent form] in a newsletter in ways that I can understand and it's really very interesting. I've been participating for 9 years.
- I like presentations, colorful charts, pie charts, graphs, anything to look at.

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[Participants did not choose to revisit the topics in Parking Lot.]

XXIV. FACILITATOR/CO-FACILITATOR REFLECTIONS

Per Gail's addition, we should plan on adding a question to the guide about methods to disseminate study results. The use of the posted lists on the wall is a helpful way to orient the group to methods already discussed and to determine if there is anything missing and/or anything inappropriate for other data collection goals. A way to keep the participants from focusing too much on the disease-specific example is to NOT introduce the health example before the first question is asked, and only to offer it if the participants are having trouble understanding the nuances of the questions. Likewise, if the topic does begin to delve too specifically into the example disease, a helpful way to bring them back on topic is to suggest another disease, as Jennifer did during this group (e.g., "How about if we are talking about heart disease or encouraging flu shots?").

None of the findings from this group were significantly different from the first group at Mt. Lebanon, but the level of detail on certain topics was different and added more specificity to some topics (e.g., how to reach seniors).

Note that the recruiters, Daryelle Martin and Deloris Martin, were present in this group and had initially planned on being observers, but as the conversation ensued, they offered input as participants. Their participation has therefore been counted in the "participant" role. These two also acted as participants in the first Mt. Leb group.

PCORI Phase 2 Focus Group

Focus Group Category: Hearing Impaired

Day/Time: Thursday, February 23, 1 p.m.

Location: Audiology Department/U MARYLAND

Facilitator: Liz Jansky

Co-Facilitator: Paula Darby Lipman

Number of Participants: 3

Number of Observers: 1 (Danielle, Dr. Nguyen's student)

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**

[None]

- **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let's begin with introductions.**

[None]

XXV. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- Because Nicole asked me and I am grateful to everything she did.
- Nicole called and asked if I would do this.

- Same, Nicole called me. I helped with other things in the past so I am very anxious to help in any way to get medical information out so I am excited about this.

XXVI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[L describes scenario]

[None]

XXVII. FOCUS GROUP QUESTIONS

1. **How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?**

- Advertise put something in the local paper outlining what you want to do and asking for volunteers.

L – *Do they call us?*

- Can start with a call and bring them together to discuss whatever they think is helpful to them.
- Doctor's office, more information pamphlets that people can read. From our end it's visual not what we hear, if it caught my eye I'd be more likely to read it. I am on Facebook. The cochlear implant is amazing. My husband said maybe you should start a forum. What is important is where do we go most of the time?
- When you can't hear...we go to the library and read a lot.
- Or various events that happen, have so many activities that go on, like 3rd Tuesday business group; also non-profits. Friend went to Maryland school for the deaf; then to Strathmore [Hall in Rockville] to set up a table; there was something there that could help you. We have family and friends that go to Strathmore and they may see information that is helpful to us. Or a shopping mall may have a kiosk of information. I am here at the University of Maryland because my friend heard I lost my hearing and she told me to go here.
- I go to the gym; there are a lot of people there in the morning, those people are interested in taking care of themselves. That's a good place.
- Grocery store, gym, things people do on a daily basis. Some ways to go about it without [needing] a pot of money; internet, Facebook, forums.

L – *Where on internet get information...?*

- Site for people with hearing loss for people to share their experiences; called Cochlear America. They have groups that go all around, go to Disney.
- Is that local? Most not local....wouldn't it make a difference if we localize this, want to find someone close to associate with. I have friends who are audiologists and speech pathologists. Getting it out local that's what helps us.
- Spoken to people since had implant last May, people at gym know and they want to talk with me.
- Easiest way for me is the doctors refer me. I go to see what is new. If there is someone with a similar experience and they come to me and I can tell them. I went to University of Maryland NIH and lots of hospitals, people they referred me to for a better understanding. If you have a good relationship with your doctor, she can refer it to you. Once we know we will tell other people. If you put it in the newspaper you won't really want to do it because you don't really know about it. But you trust your doctor.
- People now more on internet, got to be something we can do. On Johns Hopkins site they are popping up information constantly. Would like to see that happen more. I can see things about my mom. While there you will connect with someone else.
- I am diabetic and get a weekly blog from Google that tells me all going on with diabetes. A lot of diabetics and I don't know how many people that are hard of hearing; will be more as time goes on. You might speak to someone like Google and ask if they'd have an internet site that people could access or where you send out information once a week once a month about cochlear implants, hearing impairment.
- If someone hard of hearing and also diabetic.....go back to internet again. But large percentage of deaf community on internet; it's going to be your #1 resource. I was sometimes shy to go to events because didn't think I'd understand everything.
- The site I mentioned does that. It sends information out in the summer that might be helpful such as tips on how to travel.

- Cochli-ear [implant manufacturer, sp?] that makes some of these also has a site, can tell about their experiences. I am sure there are many different sites.

L – I hear that you can read a pamphlet to participate in a research project, or website. Is it important that we give something out to the people we want to engage?

- Give something to us more tangible. Otherwise word of mouth for our friends. Don't necessarily trust ads.

L – Something tangible helps build trust?

- Yes.
- If you are marketing something, gotta give out information at a place that is as effective as possible. Not concerts or shows. I hear but don't catch shades and nuances of story. Gotta figure out where to go to get information distributed.
- On Facebook I put in a stupid question. I got yelled out by friend who has a nuclear spot [???]. And she is brought in to promote it and where you can go to get it. Was going to call her before I came here. It takes people like us to show the public we are capable. Not just a piece of paper, I am proof.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

L – Are there people we won't get through these methods?

- Yes, there are people who don't trust a lot of things. Will always be a big group opposed to it, will think the researchers are reaping the benefits and we get nothing back. A group that doesn't believe your research will help us.

L – That's the group we want to reach. Any ideas?

- We do our own research and communication, sometimes forget to go back to people you are dealing with. Typical in retail community, grab people and then you are done.

L – PCORI wants to take you and partner [with you] arm in arm through research process.

- Turn it around and help us understand the new stage. Don't know what to expect in 5 years, what will we need? We don't know. Process is unknown to us [referring to cochlear implant]. Not comfortable yet bringing in someone else. Hard to explain when people ask about it. Friend signs, I lip read. We have age generation to re: music. How to understand that and go to the next level.
- A lot of conditions have groups that meet. I was involved in diabetes, have groups at many hospitals, talk about what they do and tricks for blood sugar. Don't know if you have the critical mass of people with implants; don't know what percentage have implants. Might be .002%.
- Also insurance factor, one reason I wasn't going to bother. Have people hidden because of insurance and unknown, more out there than we really know, shut off by what we are afraid of.
- Being deaf is very peaceful [laughter]. People do okay because they have adjusted. They don't understand they'd have a more rewarding social life. Most restaurants I can't hear and have to ask wife later what they said. I am sure it is a pain to her. Because I don't catch everything.
- Reach out to audiologists in different schools. I was in public schools, only 3-4 of us there. Audiologists can reach out across the states to count who could use this attention. Kids learning sign language – give them a chance to make a choice. I went to Gallaudet because I didn't have a choice. Didn't do well because wore a hearing aid and didn't sign. We come from both ends and how can we reach out? Go to hearing aid centers to find people more profoundly deaf – can we bring them in? Establish relationships and we can go back to that. Not convenient to come here today but know that [my] doctor is a partner in this.

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

- In a lot of cases people don't really know what's important to them. I am exercising since retired and I recognize that if you don't you will hurt yourself in the long run. People go along doing the same things all the time. Don't take care of yourself. Keep doing it because it doesn't hurt at the time.

L – Educate them?

- Start educating kids in grade school about #1 how to eat.
- At our age start to panic, we all want good health. What is your family history, that opens up what becomes important to you. Know if you should be concerned.

L – How do we get everyone's opinion and pick what is important?

- They are all important can't pick. Have to help everyone understand. That's why you need individual focus group.
 - Pull everyone together and ask them their concerns. Do you know how to get there? Ask basic questions.
- L – Ask in a focus group, town hall, survey...?*
- Can guarantee that kids are gonna be eating junk food. Gotta start educating children when they are young.
 - But who takes care of the children? The parents.
- L – You are coming up with our strategy.....that comes later.*
- Sometimes see surveys with data; can you go to the schools and send survey to parents, ask can we help you further? Schools or churches, have a representative there handing out the survey say we are really interested. Take it back and see what comes up.
- L – First show data and what it says about the problem....?*
- Go to schools because they are responsible, what can we do to better health for family, come up with suggestion and put in "other" [on survey]. Know what people are talking about. Feel safer where we have a network of people we feel good about and trust.
 - They real way to identify problems is to educate people when they are young about stroke and seizure. 90% of schools don't teach health problems. What to do, how to identify. According to some people I had a seizure, people don't know why I lost hearing, became paralyzed, lost vision. Take notes to go to doctor to identify what's wrong and give your input.
 - University of Maryland is a strong focal point, maybe there is someone tangible to go back to. But who do we go to if we want to know more, have questions. Go into the community but my problem isn't his. But you opened something more I want to know who to go to. Put information on how to contact person on survey. That way not just a survey and now there's nothing more for me.
- L - Paper or internet?*
- Internet not good. Kids never do it [survey] without reward.
- L – What kind?*
- [example] If you tell 20 friends about the site gonna get some basic stuff like headphones. Why Facebook is there, where songs get big. If you post [survey] to 90 friends you get headphones.....something small so don't think a scam. Not money because then think it's a scam. Ask for basic personal information to get headphones, like address. To reward them. If you see a pop up that comes up saying you get a free iPod you don't believe it. You go there and they try to make you buy stuff.
- L – Let's say you were at Strathmore or fairgrounds and someone came up to you with a survey. Would that work?*
- No.
 - Has to be open ended questions and enough information for people to want to look. Need something exciting to attract us.
 - Probable hundreds of health fairs around the city where people are asking for representatives. I used to speak at senior groups on diabetes and even at schools. You can have a table at health fair with information and then they will fill out questions.
 - We should be at health fairs, or at University of Maryland. We should be there. Has to be tangible and a place we can identify.
 - If you have a couple speakers, senior groups always looking for speakers. Talk about hard of hearing. Don't know about cost or whether they are covered.
 - Use catch phrases "if you could hear better than you do today...." And you could find a way to get it done. Reality for us. Would make me stop. Do you know someone who could have a better life?
 - Lot of psychological problems [among hearing impaired]. People get paranoid.
 - Walls we come up against keep us away. Need someone that cares enough.
- L –If we are approaching a community of severely hearing impaired, should we get to know about them?*
- What are they interested in? Then introduce us to someone [like a spokesperson].
 - They see someone like [name of participant]. She is proof positive.
 - I explain this to people at gym. Go up to people with them [implants] and say more power to you!
 - Everyone has someone they know who can't hear too well.
 - Big fear wall in our world.

2b. Are there any other ways to get people to talk about the goals of the project?

L – Methods to find out the goals and approaches that we haven't already talked about?

- Health professionals could set up goals and that could give you a framework to get kids to stop eating as much or eating junk.

L – What if we came and said our community said reducing childhood obesity is our goal. Then you could help me with goals?

- Yes, to understand how our body reacts to fats and carbs. Should know basics to help themselves.
- Most people know what they have to do, like the 10 commandments, but that doesn't mean they will follow them.
- Get on news with special segments to reach out to the community. I have closed captions but so often local news focuses on stuff. Get a statement out there to community to help them understand other health issues. Get a spotlight and catch phrases and local doctors in community and website to check into. Has to come from a human being. I have been watching TV like Dr. Oz to understand health. Also like the Gazette – that's my local newspaper. Maybe will hear about a group session. I would reach for something like that.
- If talking about goals – it's to keep people as healthy as possible when they get older. So teach kids about basic nutrition. And how to keep a checkbook. Basic practical knowledge they can use forever.

L – That's a specific goal. But what is our method to decide the goal?

- Total health care, whether you are 58 or younger.

L – Have to pick a goal for our research study.

- I would say for us to take us to the next level. Should be about the hearing. Why I am here. [I would say] Hey this is awesome for me, want to tell you more about it.
- People still smoke, statistically can't count on living long if you are a heavy smoker.
- What can University of Maryland do to help me understand my health?

L - Not looking for a goal, but a method to decide. For example, you mentioned a survey at schools.

- But would I be more interested if I knew what Maryland offered.

L – Do education or provide more information?

- Yes, like a billboard to make me think about it. So many different departments at the University of Maryland, but tell me what is out there and I might come for more.

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard] to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

[asked with 2b above]

3. Where would we go to find this information?

L – Mentioned family history. That's a type of data we might look at to see if study is working. What other things to keep in mind to see if our study is effective?

- Feedback. Don't send people out, bring them back. A follow-up card, do you have any concerns. Need to hear back from them. Ask them if you saw people also interested? Word of mouth great way of doing it. We talk about it and get passed my hang up. Can you refer us to anyone else who might need our help? Keep me in the loop because I can help you.

L – Do I need to know anything else about you? Any other factors in your life that might be the reason why something isn't working.

- Jobs
- Hundreds of different issues. People run around doing things.
- Technology that's the reason why. He said obesity and health care. There is too much modern technology for everything. Kids don't go out to play, stay inside. That's nothing to do with health care. I eat junk food but I am in shape. I walk to the station, other kids get lazy. Don't have to work out every day to stay fit. Adjust your lifestyle.
- If University of Maryland had a 5K run with booths to promote good health, exercise. Get backup help with more information from people who are at an authoritative level. I am getting ready to do a 5K for a great cause.

L – So important to understand someone's social supports?

- Yes

- What if Maryland had a hotline where people could call about concerns, and you can direct them to someone in the hospital who can help them.

L – Access to resources?

- Yes. Different departments at Maryland. Awesome. Information on just about anything.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

- If you feel good with us. Have to have the relationship so you are comfortable with us. Know I have someone who will be brains and we are the experience. Make sure we have enough information to help you out.

L – Does it matter who invites you to participate?

- Yes. If it's a stranger or a regular person you won't be comfortable. If someone recruits and give you all the information, you will be more comfortable saying what you want to say because you trust the person.
- We all have a good relationship with Nicole, after you get implant she teaches you how to use it.
- Nicole has filled the emptiness from the doctor, doctor is more removed. They Nicole magic comes after that. Then happy people because you can hear again.

L – Would it work if people from the community were invited from flyers, email, mail?

- For some people but not majority, they won't be comfortable. We don't know them. A doctor or someone you trust. Have someone explain it to your parents and they tell you.
- To reach out have to have comfort zone.
- I chair health committee at our synagogue. I have tried to do programs with dynamite speakers on different subjects. We have advertised, called, flyers. It is really tough to get people to come to these things. Did one on diabetes, sure lots of people with it, and get 15 showing up. We did it 3 years in a row. Right that if people have good experience they will come again. Neighborhood thing called turkey trot now has many more people; collect money [story]. Hard to get people to come to meetings.

L – Important factor – word of mouth, people you trust...

- And time. If you set up a meeting today at 5 not everyone can come. Make it so we all can come or make it a day we are all free so the majority of people can come.
- Videoconferences also work. Can check in with you to develop strong basis to work with.
- Conference call on Skype and see people. That might work. If you have a group of speakers and go to fairs or senior meetings. Don't know how to get to the kids.
- Yeah, in the schools we have professional development day, instead of having people come have people talk about career and fun stuff and then people talk about serious stuff, and then fun again. Get bored if just about serious stuff. Will want to leave. Needs to be fun and interesting at same time.
- All come to a concert.

5. What are the best methods to disseminate the findings?

L – So if we have great results, how disseminate?

- Us, we had a good experience that is all you need. We know a lot of people and we tell them and the other people get interested and ask questions. Facebook is a good site.
- Brought all people in with implants last year. Get energy going, show they can hear the music. Make it exciting and get energy and then ask them to bring energy back to community. Networking with people and they gave us tons of ideas. Need a good networking of people. Bring us back and we will start and take a challenge to see if we can make it work. Come back with an idea that works. I feel great if I can help someone.
- Great, but probably we may be talking about other condition, heart, obesity. Sorta like good management, then you don't run into the problems. Hard to get people excited....oh I didn't have a heart attack.
- Why feedback is important.
- Can prove with large group of people what you have accomplished. From 1960 to 2000 what happened? Hard to really get people excited about that.
- Very individual thing.

L – Talk to them in person?

- Keep talking about it. Speak to groups.
- How about famous people that people identify with. We would listen to them more if they have overcome their weight.

L – Celebrity endorsements....

XXVIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- Would like to hear more.

L – Dr. Mullins wants to come back in the fall.

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[nothing]

XXIX. FACILITATOR/CO-FACILITATOR REFLECTIONS

This group was very informative. Although just three participants, they had a lot of helpful ideas. Almost all of the suggested methods are the same as other groups (eg, word of mouth, surveys, internet). Some deeper themes were also expressed as in other groups, including the following:

- Build a relationship with the people first; give the people something (information, access to resources) before you try to get them engaged.
- Have a hotline to give information and let people come to you.
- The field of health is too large to be able to ask people what's important, so it's best to come up with some suggestions to frame their thinking.
- Many people don't know what health problems they have so educating them beforehand is a good way to get them focused on what health problems are important to them.

PCORI Phase 2 Focus Group

Focus Group Category: Hearing Impaired

Day/Time: Friday, February 17, 2012 at 1pm

Location: Weinberg Senior Center

Facilitator: Liz Jansky

Co-Facilitator: Nicholas Buck/Paula Lipman

Number of Participants: 7

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let's begin with introductions.**
[None]

XXX. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- Thought you were going to check my hearing – that's what I came for. *L – We will discuss your participation in the research process. Are you okay with that? If not comfortable, feel free to go.*
- Because [name] convinced me to come; been wearing hearing aids for a long time; the hearing aids are very helpful.
- Because I do have hearing aids which are very helpful, without them I am totally deaf.
- Same focus; interested in hearing loss, hearing aids, technology. Thought coming down to a session that would focus on my area of interest but let's see where you are going here – how you guys want to handle your area of research.
- Sounded interesting.
- Can hear, but don't hear everything, miss out on a whole lot of things people are saying, have to ask people sitting beside me what did they say. No hearing aid. Have to ask people on telephone what did they say.
- Hear background noise even with hearing aid...

[Discussion of problems and costs associated with hearing aids; Lots of background conversation about availability of special phones, repeating what was said etc.]

L – We can use hearing aids as an example of an issue we might want to study.

XXXI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[None]

XXXII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- I have met several people here and they have severe hearing loss; they cannot engage in conversation. When we are at the table eating I have gently suggested they look into getting hearing aids because they withdraw from the conversation and they miss out on a lot. It's really sad. My children knew I needed them, it was the best thing I could have done for myself. *L – So you would encourage people without hearing aids to have assistive devices....so they could participate?* Yes, see their doctor and have a test done by the audiologist
- Many issues with hearing aids as a technology, quality, cost. If you look at the industry it is huge. If you are a potential user you have to decide how to get the [best] use. Very difficult because of different aspects and a tremendous amount of misstatements. Medicare is not in that business neither is the FDA, maybe they should be.
- [Rephrased the question] What should researchers do to engage people in research? If you come with a clinic, with an audiologist for example who can test people and show the technologies that exist. [Gave examples]. Can see how life could be better. *L – So are you suggesting we offer resources and then draw them together?* There's the hearing issue – when you ask people in a group, there will be hearing issues.

L – So one- on-one vs. focus group? [to group] Any other ideas?

- Friends and family. Sitting around with family I talk about things that interest me. Of what is going on in the world today. Casual, sometimes it's about problems that someone has or else. Whatever comes up.
- Exercise class, if I don't see her direct, I don't know how to follow....depends on how she is talking. *L – So one-on- one is best?* This is the first time I've been in a group... maybe it would be I don't know.
- Just read an article, only 14% of total population in U.S. who have hearing loss have hearing aids. Reasons are cost, insurance, not sure they really need it. *L - So this would be an important research study – how to get more people help....*
- Some people I can hear better than others...to be honest. I hear every word perfectly with some people. *L – Good example. Sometimes it's cost, other times it's about pitch. Two examples of research we could conduct....*
- Can be in environment of your apartment. Different piece of industry – volume improvement. In some places it helps. *L – Could do research on product, clinical....how decide which to do?*
- Look at grants, look at funding coming in the future. Hospital environments are moving in that direction. A lot of activity. If there is money there are ways to do [research]. Clear procedures.
- Sometimes people have wax in their ears. I work for the state and get one hearing aid for nothing.
- One of the big differences being here at the Village is the people...the memory problem, combined with hearing, combines it more difficult
- Yes, there's a lot of research on hearing and dementia...start losing ability. But you asked how to decide what piece of hearing to research first. Different wish lists, what are people most interested in. *L – And how do we do that...?* Go around the room and ask what is the biggest problem they have with their hearing. It would be interesting to see what it is.

L – Do we pick the top choice?

- No, because if you hear the kind of problems I have....the combination of the phone and hearing aid doesn't work well.
- That's because you don't have the right hearing aid....sent my hearing aid back to the factory...got one I can use for the phone.
- I have that with mine, but when the phone rings I am not going to go from "1" and then pick it and go to "3".

L – So it's not necessarily the one with the top number of concerns but the one that affects the quality of life most?

- Different for everybody. What bothers me is that I can't go to the movies...
- Make a good survey of what is out. 7 – 8 major manufacturers...hundreds of smaller ones. New scheme, different concept. Don't follow the herd, be separate and different.

- I have a question – what is the goal of the research? *L – That is good question. Next on our list.*
- 1a. **Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?**
- [Didn't ask]
- 2a. **What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?**
- [This was covered in #1 above]
- 2b. **Are there any other ways to get people to talk about the goals of the project?**
- L: ...Then we have to decide our goal. Do you have ideas? Don't care what the goal is, but rather how we are going to pick it.*
- That is too technical for me, out of my league. [*L – but you are my research partner!....*]. I'd like to hear that movie, and what everyone is saying in a crowd like this. To pull people in they were having ice cream, but when she [speaker] gets talking, I have no idea what she is saying....don't know reason. We have 8, 6 people here, everyone has different problem.
 - Some people I can understand without my hearing aid....
- L: How do we figure out what is most important to research?*
- A vote, like a jury.
 - [side conversations about problems with hearing aids, hearing impairments, etc.]
- L – Let's change the topic away from hearing, to heart disease....? Does that help?*
- Are we gonna vote on that? I am for heart disease [laughter]
 - But I am interested in hearing who is the manufacturer of their hearing aids. Can we go around the table and have everyone say who their manufacturer is? *L: let's move that to the parking lot and return to it at the end of the discussion.*
- 2c. **We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?**
- L – Now have to figure out what it is we are going to compare. Think about heart disease (exercise, salt, health care) – different things we can do to see if we make a change....better cardiovascular health....*
- Talking about outcomes now... *L: Yes....so how pick the intervention we will do with our group?*
 - Matter of each personality, someone may have problems going to the gym.
- L - So feasibility...[recruiter asked question....]. If we decided we wanted to make a better hearing aid product...how figure out which we will try. Maybe different choices, how pick?*
- Back to heart disease? Stay with that?
 - Procedures...huge amount of knowledge in certain research centers that are available. In beginning get picture of what is the current outcome statistics, what are the preventive measures, are they adequate. Need more wellness awareness. Current thinking in heart disease. *L – So look at research and data....?*
 - Confused now. Talking about hearing or heart disease?? *L: Doesn't matter...discussion is about research. Switched to focus on research rather than problems with our hearing aids.*
 - Classical example of what has happened in medicine. They can see things with better instruments, better screening, analysis. A lot of research going on in new aspects of how you deal with a particular problem. Need tools and resources to do it [research]. Have to have some kind of expertise, now find a way to apply it to a particular set of problems. Simple guidelines on how to proceed. *L – But what if the guidelines are not feasible? Then drop out of it, don't do it in that direction.*
- L – Go back to hearing.... If hearing aid too expensive....are there ways to pick the right thing to study?*
- Go to an audiologist; get hearing test, one that is certified. Focus on what kind of hearing aid best meets your needs....I got the top of the line [more on hearing aid]. *L – So talk to your doctor, that is one way....*
 - I had the same thing....had to make an adjustment....
- [side conversations and background noise, people arriving]
- All gets down to the product, what is the best that will involve efficiency or cost. Problems of people here, could come up with 20 or 30 problems. Can't ever resolve all of those. Another example is birth control and how that affected people....it's basically the product and the costs....

3. Where would we go to find this information?

[Didn't ask]

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

L – So we are ready to start [our study]. Want to invite everyone who is interested. How do we invite them so they understand what we are going to do?

- Provide them with food, money. Depends how long and where you have to go. Do you have to travel? *L – Will payment help them trust us? Think so. My audiologist has her title, you know. Sometimes I wonder if they are selling you the better product because they make more money...*
- Another problem – the quality of the audiologist. Need people to service that product.... Include audiologist in the research
- Device requires a technician, engineer, so need that tuning, continuous tuning through life of the product. How bring product to market. May be experimental, may involve basics, try to get there to be successful. So much research is thrown out because it is not successful... *L – That's why we are having the focus group today, so that PCORI funds research that is meaningful and helpful. Steve Jobs very successful.... [moved to parking lot]*

4. What is the best way to disseminate the findings from the research?

- Newspaper
- TV, radio, newspaper, magazines
- Internet
- I listen to my audiologist

L – Are there other people you trust, other than audiologists?

- Other clinicians, they should be aware of hearing loss. Stress to patient to do something about it to improve quality of life. People withdraw from the conversation....most older people are afraid of that. That would be a way of encouraging them to explore what is available.
- I woke up one morning and was totally deaf.....husband called doctor...[long story]
- Straightforward and standard approaches to make research move. Want a backing, sponsoring, agreement ...issues to resolve before you can move ahead. Procedures are well defined in engineering, science, medicine. Team up with another organization to do what is recognized before you move ahead. Have to finish it and bring it out. Millions of examples on how to succeed in bringing a product to market. Need luck to be in your favor.

XXXIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

[None]

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

- [Discussion around table of manufacturers of hearing aids]

XXXIV. FACILITATOR/CO-FACILITATOR REFLECTIONS

This was an extremely challenging group to facilitate. A few of the respondents had trouble following the conversation (due to hearing impairments as well as cognitive difficulties, according to the recruiter). Moreover, almost all of them were under the impression they were coming to this discussion to either have a clinical evaluation by an audiologist or to discuss hearing aid products and other assistive technology. It was difficult to keep them focused on the topic of participation in research, and there were several interruptions during the discussion by people from outside the group. One participant approached me after the group ended to say that it would have been better for us to conduct our discussions one-on-one due to their difficulties with hearing. The recruiter also sat in on much of the group to help repeat or clarify my questions, and she remarked when the group ended how apparent their cognitive abilities have declined recently. She linked this decline to their hearing loss, citing the research about isolation and lack of mental stimulation/social connections.

I also had side conversations with a few of the participants before the recorders were turned on when they said that because they expected to receive clinical or product-related information, it would be helpful to offer information or other resources up front to encourage engagement from the targeted audience.

PCORI Phase 2 Focus Group

Focus Group Category: Hearing Impaired
Day/Time: Friday, February 17, 2012 at 1:00pm
Location: Weinberg Village
Facilitator: Jennifer Huang
Co-Facilitator: Joe Vandigo
Number of Participants: 5

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started?** Question asked about the risks. [Facilitator reviewed the section on risks on the informed consent form.]
- **[Answer any questions that may arise]. Great, then let's begin with introductions.**
[None]

XXXV. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- I currently using a hearing aid, I'm on my 5th pair. They invented me a hearing aid for my type of hearing loss. I lost my hearing when I was 5.
- I'm here because I don't hear very well in my right ear. As [participant] said, she had 5 pairs of hearing aids, and I don't know how much has been effective, because 99% of people said that their hearing aids are not effective.
- I brought along my hearing aid. I don't necessarily need to wear them all the time. If I wore them to the navy band, I would have to take them out because my ears would be exploding because of the noise. [Discussion of how hearing aids are larger and has hidden them by her hair. Pleased with her hearing aid company. Cost of hearing aids that make it unaffordable for everyone]
- My hearing problem started as a problem of medical mistakes [goes into her medical situation and car accident that led to further hearing loss.] I tried some hearing aids a while ago, but I lose things very easily. And these things are very little. I just found that the batteries are very tiny and I was concerned all the time about losing them. [more discussion about cosmetic qualities of hearing aids, audiology testing]
- [Provided details about hearing loss as a child due to medical reasons and a reaction to antibiotics. Wears a hearing aid on her left side.]

[Facilitator explained that she does not have experience with hearing aids and is not a clinician. She explained that the purpose of the focus group is to not discuss issues with hearing aids in particular. The focus group participants were disappointed about this and clearly wanted to discuss these issues and how to improve hearing aids. Some participants also brought various hearing aids as examples to the group. The confusion seemed to stem from the recruiter, who told participants that this was a "hearing impairment" focus group.]

XXXVI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[none]

XXXVII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- You've made the subject so broad, because if you live in these five buildings you may find 30 different health conditions. Have speakers that come in to speak to us, have food, and hand out pamphlets to provide information. I find that living here, when you do a group – a lot of people do not perceive that you care about them and then they leave and you never see them again. In Building 1, when they first opened, they had almost 100% participation. Now, people have reached an age that they don't want to participate, they aren't interested in talking to other people, they're not interested in leaving their apartment. We have struggles to get them to come out for shows, etc. They refuse to leave their apartment. In Building 5, you are new, and are more willing to come out. *Other participant disagrees:* I don't think so, you'd get 50% participation.
- Struggles at this age to even get people to come out for social functions - you have people that

J: Is it an access issue? Or the topic is not interesting? No – just not interested.

J: Or the topic is not interesting?

- I think in Building 5, we have too much going on.
- We have to make a decision on what you want to do especially in this community [goes into the various activities and schedules that are available] we are in the same groups, but our interests are varies. They didn't say before you come here, what are you interested in? Building 5 is new, we've been open 8 months. We're starting our own association, our own control. Each building has their own associations.
- I don't like to talk about health issues. And I also don't like other people talking about health issues. Because you end up having a contest with others, end up seeing who is better, or who is worse. So I rarely talk about my health issues.

J: So, would it be difficult to do for a researcher to do a focus group here? Well, this type of thing would be okay, but it's a different thing than making it personal. *J: So, a one-on-one discussion could lead into that competition?* Yes. I go to something like this [referring to focus group] and I don't mind, because I go to the processional and we talk about anything we want to.

J: When people come in to give presentations, do they discuss health topics? I live in Building 4, the programming is very varied. So you will get people speaking about health issues, you'll get a chef to talk about cooking. It feels good, there is plenty to do. But when you get older, you have health problems and you can't always get there because of how you feel and it's not because of lack of interest. You have to take that into consideration. When people move into a new building, it's fresh and new and they feel good about it. I know lately, I've missed a lot of things that I'd like to go to because of how I feel.

J: Is there a way to go to people rather than having people come to a group?

- You have language issues. There are a lot of Russian people and not all are bilingual. You can have a measure of communication.
- They have so many different activities, I can do my rehab here. [goes into detail about spinal injury and she is receiving her rehab at this facility, very convenient, access to programs, entertainment on-site in walking distance].
- Have access to all the buildings through a tunnel.
- We have movie nights, bingo, [details about the building structure, getting lost in the buildings]
- So to get back to your health issue about how to get people out of their apartment, we've all tried too. And we're the same age.

J: In terms of people coming in and giving presentations, is there a certain type of person from a certain institute that would draw more people to attend? Well, you put the hearing aid down, and got us interested in coming here and we all have hearing issues. But you kind of threw us off guard here because we're talking about more general health issues. We were here about hearing issues. You could clearly specify what you are looking. But you'll never get more than 50%.

J: Would it be feasible for a research team to knock on people's doors to talk about health issues?

- No, in Building 1, we put together a list of names and birthdates. And we still don't get participation.
 - If you put down a particular issue, like heart, cancer, then I think that you will get people interested. *J: So it would be better to start off talking about a specific health issue versus a general health discussion?* Yes, I think that it would have to be specific.
 - And if you make it more in the evening for dinner and suggest that they bring your family, then they can come too. And you can get the families in. We can do it if it's something right after dinner like 5:30.

J: If a son or daughter came with you to a group discussion, would that draw people out of their apartments?

- No.
- They have their own lives
- My sons come with me on Wednesday and they are with me for about 1 1/2 hours. I don't want to give that up. I want them to tell me what they've been doing during the week.
- Sundays are very busy, and families are either taking them out or bringing them back. And I'm on the first floor, so I see all of this starting with church.
- And this place provides you with shuttles, so it's wonderful. You hop out the door and get on a shuttle and go.

J: Are churches and synagogues a place where people can talk about health issues?

- I don't think so. I do not know that health issues would take off in a place where someone is going for religious services. You'd have to do a lot of advance PR to float that idea to make people comfortable with that idea. If you are in a congregation you might know someone personally or by sight, you don't want to talk about health issues. It's okay with those that you don't know, then it's fine. But when you know people, friends, neighbors, co-religionists, I wouldn't want to discuss anything of that situation.
- And doctors have pushed down our throats about the HIPAA act to not discuss anything. So for me, that backfired on them.
- I think that if they brought someone here and put it on the schedule and people knew that person was coming, they would come. If the name of the medical person, date and time was on the flyer, I think that you could get a nice amount of people. If people had a problem in that specific area.

J: So you will still need to make it about a specific health issue?

- I think that you could do ear, nose and throat. Or, someone can come in a talk about general surgery. If someone is scheduled for surgery, they can talk about different types of anesthesia for senior patients. You have to be more specific to the senior age group if you want to draw people. So that would bring people to the table. Or hear about it.
- You had a group here that came and they came because they thought the idea was about hearing impairment.
- But I think that if you had a program that said, general, general health, I think that you'd have people come.
- I think that if you had an audiologist do this group, you would have been swamped.
- Yes, I want an objective opinion on hearing aids.
- Because everyone is older, everyone has some type of a health concern. If you had some information to give us, I think that you'd have people come.

[More interruption from people walking through the room, suggestions to have the focus group in a classroom next time for privacy]

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

[none]

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

- Can you combine health topics, such as heart, diet, diabetes?
- We had a program here about that.
- If you get groups that could agree they are diabetic and groups that have heart problems, don't know if or do know it – have same health goals. [conversation about the poor quality of food at the center in terms of taste and nutrition]

J: Could we look at health problems, like diet, that affects many types of health issues? We could do that. And we could do a study on ears, hearing first. But after that, it would be nice to do more studies. Like diabetes. I think that is the biggest health issue that we have. We can't control language. At least you aren't drawing blood or specimens, so at least you won't scare people. Pick something and stick with it and make it special instead of general. Then find another area and make it special and eventually you will benefit everyone. (Ex: teaching the computer, learned a little bit)

J: Could we get people to vote to help us prioritize health issues? That might work. If you have a little bit of knowledge it is not dangerous, it's a good thing to learn.

J: Does that mean that we should first talk to everyone and educate everyone to not be scared to talk about these health issues?

- There will always be an audience. Everybody has something. You are bound to connect to maybe 25%. Are you talking about a program from the University of Maryland Medical Center or general? I was going to say that whoever is presenting it will also attract people. Maybe University of Maryland will attract more people than an individual. Because people know the University of Maryland and know that it's responsible and know that there is a hospital. I think that more people will feel comfortable to come to something like that.
- And you could have a group of them [people from the university].

J: And if they have a flyer, should it have University of Maryland on it?

- I would definitely put your branding on it. We do get lots of flyers.
- We get them in mailbox, under doors.

J: Does the message have to come from a trustworthy source to get people to come?

- Yes, that's my opinion.
- You could have a panel of some sort that will meet in Building 5, our biggest auditorium.
- A panel of people with University of Maryland behind it. I would certainly make an effort to come and I think that others would too.
- You could have a panel and give people a certain amount of time to speak. And then you could do a survey that was responding to certain health conditions and that would narrow the field.

2b. Are there any other ways to get people to talk about the goals of the project?

[Skipped due to time]

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

- You'd have to get a general opinion. But talking about obesity, you need to have a dietician and look at food being served as an observer without the facility knowing. And where it's coming from, how long it's been sitting

out. How it's been prepared. See how many helpings of food are left (goes into conversation about quality of food).

J: And how would we narrow down these approaches to decide which one we will implement?

- You can invite people from different caterers and they submit their food and then you can go to the next one. And then compare them. [Discussion of kosher caterer for this facility]
- I'm surprised that not more people are here because you offered food. And we don't get stuff. We get fresh food; well, it's not fresh it's canned.
- [discussion of exercise classes at facility] See how these classes are conducted. Have someone come in and see what they are trying to do.
- And I still like [participant's] idea for the panel. I think that the panel would be a big hit.

J: Would we have one panel to discuss [identifying, engagement methods, health issue, goals, approaches]? Or have several panels to discuss each stage of the research process? I think that you would need to spread it out. 1-2 professionals. Another month, another panel of other professionals. And another month, other professionals. You will see a path forming of how many people are responding to these things. And you can narrow it down.

[Interruption, participant had to leave early, people walking through room]

3. Where would we go to find this information?

[Facilitator provided an example for a project on childhood obesity]

- Have many grandparents here who take care of their grandchildren and the grandparents would be more interested. Utilize the English language of the children (For the Russian population).

J: So getting other family members involved? Yes.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

[skipped due to time]

5. Best ways to disseminate results back to the community?

- Our caterer needs to be Kosher. I don't know about the contract situation. [discussion about the caterer and quality of food]
- You might want to get involved with [oversight committee] that oversees the facility. [Facility manager] is employed by the realty company. She might be able to help you.
- [Other general discussion about how a program that is conducted at the center may not be generalizable as it will respond to center specific issues, regulations, needs, etc.]

XXXVIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

[Discussion of retirement, government rules and regulations for disability]

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[None]

XXXIX. FACILITATOR/CO-FACILITATOR REFLECTIONS

The group was well attended, although 2 people had to leave early due to scheduling conflicts. This group was held in an open eating area of a cafeteria rather than an enclosed room. Unfortunately, several people passed through the area to get to other rooms and buildings, which caused distractions throughout the group. Another hearing impaired focus group was conducted simultaneously in a larger conference room.

From the start of the discussion, it was clear that participants believed this was a group to discuss issues specifically related to hearing impairment and hearing aids. Apparently, the focus group coordinator explained that this was a “hearing impairment” group, which misled the participants and they expressed their disappointment. Several participants brought their hearing aids and materials and were ready to discuss their experiences with the aids. As this focus group was recruited from a senior center, the majority of comments were very specific to the facility. Engagement methods, solutions, and research topics were all very centered around the facility’s system and processes. When I attempted to select an example of a research topic that was removed from the facility so that they could think on a broader level, the participants preferred to talk about topics that were relevant to them and again reflected on the facility. Several of the themes that participants discussed are also related to general senior and aging issues, but not necessarily hearing-impairment.

Participants in this group preferred to begin the research study with a particular health topic and in general did not recommend starting with a broad health discussion. Several participants in this group also brought up issues of health and stigma, which was also discussed in other focus groups (e.g., lower SES AA). The difficulty to discuss health issues outside of the family, or even with friends and acquaintances is another barrier that must be acknowledged before engaging people in health projects.

PCORI Phase 2 Focus Group

Focus Group Category: Lower SES AA

Day/Time: 2/7/12, 10 am

Location: Bon Secours

Facilitator: Liz Jansky

Co-Facilitator: Jennifer Huang

Number of Participants: 6

Opening Statement

➤ **Before we continue on, I want to stop and see if you have any questions about what I’ve said so far.**

[none]

➤ **Are there any questions before we get started? [*Answer any questions that may arise*]. Great, then let’s begin with introductions.**

[none]

XL. INTRODUCTION

Let’s first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- I live in the neighborhood and senior citizens here need to know what the hospital offers. I’m on the CAB board for Total HealthCare, on the Consumer Advisory Board. My goal is to address the senior citizens. My goal is to get information and pass it to senior citizens in the neighborhood. They also have HIV and stuff like that. What this hospital has for these people. I’m an advocate of the HIV patients. Trying to get information for people like medical and housing. I’m also a patient. My primary care provider is here. The doctor that will do surgery on my knees is here. Also going to follow in the same footsteps as my father, who got Total healthcare started, he was on the board of Bon Secours. So why not follow him?
- I live in the neighborhood. I just signed up.
- I’m from the neighborhood. Came here to see what’s happening. All this is new to me.
- Good to find out information. Some might not pertain to you, but something might apply. I’ve been coming here to this hospital for 40 years, been living around here since a tiny child. So if there is anything new and maybe can help someone else, or myself, though this situation, then knowledge is the key.

- I don't really know what is going on; just want to know what the focus is about.
- I'm a cancer patient. My doctor is here. I have nothing but positive things to say about Bon Secours because they have really helped me. I've come a long way and am still going. I don't really understand what this is about, so that's why I come to find out something. Something that might pertain to my health or someone else's health.

XLI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[none]

XLII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- What they were doing in the neighborhood is to have health fairs. A day in the neighborhood where people can come out and get info. A lot of patients in the hospital live in the area. Could put out a mailing out in the neighborhood if you have their name and address, could do a major mail out for a health fair. The senior building, my parents live there, and a lot of information for the seniors, because 90% of the seniors come here. I live in the neighborhood, I live across the street. People in my neighborhood, elderly or not, they come here just like I do. So that could be a way to get awareness that information is available.
- I think it could be good to get a newsletter with updates. For instance, the avenues that scientists are taking with diseases. A lot of people are not able to get out. And they still need this information. Bu if it's sent to them through a newsletter, they can read it or someone can read it to them. *L: A newsletter in the mail? Yes.* But the ones that are able to come to the meetings it's fine. But I'm talking about people that cannot get out. They don't have people to even bring them out.
- Also, on the heels of what she's saying. Some people can't read, and some people are disabled and can't get out. Bon Secours has a TV commercial. Maybe the commercial can be extended to let people know in the neighborhood that there's information for senior citizens, and a contact number to get more info. If they can't read, the they can't get the info. But if they can hear it, they could participate more. TV ads, and not just flyers. If you can't read, then you can't get the info. Having a little community area here in the hospital where they can come to get the info to them. And word of mouth.
- Just get the knowledge out to do different things. Ads on TV.
- Between Bon Secours, you have 2 major churches. 100% of the people going to these churches, they have lived in this area at one point or still live in this area. Can get the church to pass out info after services, let them know that information is available.

L: Are there other organizations in the neighborhood?

- Yes, Bon Secours and Franklin Square, is where we have meetings for the community. They both meet together.
- Senior centers.
- I'm a member of ?? association. We have a meeting. *L: Is this a neighborhood association? Yes, they have meetings.*

- Why not partner with Total HealthCare? They have an OBGYN clinic, a family center. They have one on X street, and one on X street, and X street and on X avenue and X street. And that's broadening the spectrum for Bon Secours. So if we partner with them, let them know what Bon Secours is doing. And they have people in the same area too.
- Reaching the people that can't get out, you have senior buildings in this area, X streets, another option could be to go to those senior buildings. A lot of them have community rooms. So that could be an avenue too as well.
- And Bon Secours has transportation vehicles, mini buses. And MTA has transit buses, they can contact them, make sure they can get to their appointments. Total HealthCare has the same system to help patients get out and get to them. Between those 2 hospitals, they should be able to get to senior centers, to get people to the doctor, to meetings to find out what remedies they have for people.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

- The younger generation. Their attention span is not as developed as older generations. They would be the only ones that would be hard to reach. Anywhere from teen to 25. Their interest is not up there with health. They think that they are okay. they don't know that when you get older, things change.

L: What are some ways to get them involved?

- For teens, young adults, free food.

L: Where should we offer the free food?

- Block parties
- Fairs
- Jones Tavern. Every Tuesday they have a soup kitchen. And central Baptist church, they have a food give out on Saturday. So info can be placed there. St. James on X and X street. They have a soup kitchen on Thursday afternoon. Information can be handed out there. A number of small churches. *Another participant asks: How are you going to get the youth to these churches?* I'm saying that they are used to going to these churches and eat with their parents. Some of that information can still get out to these people. And they could give the info to them you, and it's called a peer group conversation.
- I've been in my home for 50 plus years. I'm found out that people have more of a tendency to listen to more of what you say. Word of mouth, you can really a lot of messages to people. I tell you, and you think about it, and then you tell him. Advertising is good; I don't have a problem with that. But, word of mouth.

L: Does it matter whose mouth? Can I come in?

- One of us, we would know what it's about, and we could pass it along to them. And if they are interested to follow-up on that, you can present it to them. And then let them make that choice.
- Teens, they get the info, they can pass it to school. I have grandsons, although they are mischievous, I hear them talk about certain things. They talk about smoking marijuana. Where do they get that from? Sometimes there is a great deal of youth that have HIV. And they need to get information for that. And where do they get that? Word of mouth.

L: So they are finding out about it from their friends? Yes

- My church has a program for unwed mothers, drug abuse, marriage counseling, they are doing the whole thing. I'm finding that a lot of other churches are doing that now. That's a good way to start. If you can get the youth into the church, get them interested, you've got something going. Believe me.

L: *Can you tell me about the block party?*

- Down on X street they close down the block. They have pass out the pamphlets, have hot dogs, toys to pass out to the kids. They have music, food.
- 2 churches across the street they block off the street every year, have a health fair, food, information. Cotton candy for the kids. Freebies at the tables.
- They have grants that they give to reputable associations to have these parties. So you don't have to pay for it out of your pocket with a lot of money. They put the toys, raffles, games.

L: *Does the city gives out these grants?*

- Yes
- And you usually don't have a problem getting here.
- Raffle games, to get people interested in going there.
- Like a carnival, cotton candy, hot dogs, free sodas. Police there to handle the traffic. They have games where you can win prizes and food setups.
- Then you have the other areas where you get the ladies what you're talking about. If you want to get your point across, this is why we're here, we're not just here to eat.
- In this community, the way to get people there is the promise of food. If you don't have free food, people won't come.
- For anything free, people will come.
- This summer there were people there with info about different things. Not sure if it pertains to Bon Secours. What people really need to know, they need to know the resources that are out here. There's a lot going on that people don't know about. I don't claim to know a lot, but I'm learning. It's for people that don't have the funds for their medical supplies. You've got to know where to go.
- They're not just the city that has areas of funding for that too. But, the federal government has subsidies that will come in the community and give out grants to people to help. Ron [Ryan] White is one thing, a foundation. Bon Secours had it at one time, but they discontinued it. It's very important to give to the community. It helps to pay for certain medication. Helps them with the cancer, HIV, even cirrhosis. It's a broad spectrum that these grants have not through the city, but the fed government. And they need to get this info about this too.

2a. **What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?**

- A lot of people think that seniors can get help. It's not true. it's for all people in need. This is the message that we have to get out. If you're in need, where can I get help? Not just because I'm a senior citizen or in a wheelchair or whatever. It's for all people.
- Not just for the seniors. For unwed mothers, Teenagers have the same problems. They don't have elaborate jobs, so they shy away from medication systems because of the stigma of, well you're on welfare. There are other avenues to get them medical assistance and help. It's not just for seniors, for anyone sick and in need. And they need to find out where these companies are and stuff like that. They have private sectors that give out grants. The private sectors that work on medical research give out grants to the community and teens and young adults. So, need to be able to know where to get this information. So they can get the help they need to get.

L: *Who will we know what are the needs? How will we find out the needs and pick out a good one?*

- Take a poll, tally up which has the most need. It changes for each age group. The needs change. It changes for people with health issues, with economy issues. It's 2 different types of need. Economic need and medical need. So that's one way of doing it.

L: If we take a poll, do we have a clipboard and we ask them when they come to our table?

- Have a designated table for information. Take a poll of what services you are in need of. Go by an age group, the boundary group, you living in this area, what's the need for this area? And then you can have men and women. What are the needs of men and women? Or do it by your area, neighborhood. What is the need of this age group in your area?
- With the churches, I think that's a good start. Let them know that these services are available to them. And then they can make a choice of what they need.
- Questionnaires at the churches too.
- We have a community association in this area. And we have meetings 1-2 times a month at the school and we talk about different things in the community like helping people with their mortgages and things like that. So it can be done. But, it's just got to get out there to the people.

L: Would we talk about it in general and ask for suggestions? Or do we write down the suggestions? We write some things on the board, and we discuss it. We get in groups and we discuss what's going on, how to make it better?

- At the fair, we get a booth down there, and can get the questionnaires out there. We can give them out to schools. Parents bring their small children to the schools, they can put the questionnaires there, flyers in the school system. Put out flyers in the stores. And for the questionnaires, put them there, so they can pick them up and fill them up while they shop. Have someone pick them. And you can understand what people's needs are.
- I think that because this hospital is the main source of this neighborhood, as people come in for different services, you can have an interest poll, what are the main services that you come to this hospital for? This hospital has a lot. They have a women's fair across the street where you can get all kinds of different services. So another way to just talk to the people coming in and out of the hospital. People picking up prescriptions, seeing a specialist, doctors.

L: Would it help to have someone present the info? Or leave a pile of paper?

- Have someone present it. If you have flyers, maybe people will walk past it. If you have someone presenting it, an actual live person, people will be more susceptible to stop and listen. So I think that it will be better to have a live person there. 90% of people will just walk pass it. especially the young adults. People will stop and talk to you, more then they will pick up paper.
- There's a lot of programs here mainly for females. For males, there needs to be an organization for males. We feel that we are invincible. Very few men, until they get an older age, they don't get checkups. Need to figure out how to get more men involved in their health. For most Blacks, that's how we were brought up. We're invincible, they don't get these things. Now, it took me a while for my first colonoscopy. Although I found out I was healthy, it still took a lot of time. The way that I was brought up, men need to be taken up on their health. We need to figure out how to get men to get in the hospital into these programs. Let the males know that it's good to be macho, but need to check up on their health too. I try to stay up on my health now.

L: This is making me think that there may be things that people aren't aware of. On our questionnaire, do we give them choices?

- Yes, you have to. Let them know that these things will be in the strictest confidence. We were also brought up at home that what goes on in the house, stays in the house. We don't want to bring it up outside. And that's a façade for all people. Our mothers, we have a cure-all that we were brought up on. And there are some meds are helpful, some are hurtful. Need to get yourself checked, tested. For your manhood, helps you live longer.

Prostate cancer is on the rise for me. And if you wait too long, and it's irreversible, then you're done. Men need to be able to get approached, to let them know that it's okay to go to the doctor. And it doesn't hurt. Especially for blacks.

L: So that could be a sample study that we come up with. How can we change that mindset?

- I think that whatever topic is chosen, it's going to have to be different focus groups. There's going to be a male/female differential. Things are different for males than females. Also need to be age groups. Different age groups needs or different services that need to be presented. So whatever service is provided is going to have to be broken down into groups. Male and female, 35-45 and 20-25 group. Different views for different age groups. At 25, I didn't need the services now that I have to get at 45. For any topic, cancer, aids, total health will need to be broken down into focus groups.
- And take the fear out of people. I'm just going to use cancer. At one time in my life, I would have told you no. I don't think that I'm going to have cancer. When I learned I had it, I learned to deal with it. This is what we need to let people know. It's okay to be checked. This is the only body we have. And take your children as well.
- We need to come up with a survey that comes down on the stigmatization of certain illnesses. Certain health issues, they're stigmatized. And once you break down the barrier of stigmatization, you'll see a relaxation, more people coming in to get checked. You have to break down the stigmatization barrier.

L: Should we try to break that down to get them involved in the study? Or do we break it down when we start the study?

- It starts at the survey. The survey can't really stigmatize a person. Our society has put a statement on certain illnesses. A lot of people don't have the information because they don't look for it because it's been stigmatized. There's stuff the CDC has put on the computer, but a lot of people are computer illiterate. That needs to be brought out. A lot of people don't have a computer either. If you don't have a computer, they can't get that info. Needs to be brought out verbally. Commercials.

L: So on the survey, should we put out some information about illness to reduce stigma? And then ask questions?

Exactly. Right. like what you said, their names won't be used and stuff like that, they won't be identified. If they get checked for certain things, give them an id number so it's personalized. If they want to do the treatment, they do the survey contact them, and they can come in if they so desire. But first, we need to break down the barrier of if there is something wrong with me, what will people say about me? You'll be surprised how many people don't get help because they don't want to be identified. We need to learn how to break down the barrier and get to them. And it's not just the seniors, but younger people too.

L: Does it matter who is going out that information? It could be a senior, a youth, as long as the stigma is eliminated.

L: So if we are trying to engage the youth, will it be better for someone to give out the info to be a youth?

- Yes, I think so. In a peer group. A peer is going to listen to a peer more so than an adult. That's like an adult trying to teach a younger child about marijuana. And the mother is smoking a cigarette. And the child is saying why are you smoking? But if you have a peer, they will listen more to a peer. Same things as alcoholism. Starts with the older gen, but stops with the younger gen. Same thing with the elderly. And elderly person talks to another elderly person and stuff like that. If a survey is given like that, it can break down barriers and stigmatization.
- For 15-25 year olds, there's stigmatism on mental health. So those with mental health issues in that age group might bond better with those of their age group. Just like an elderly person that might have deformities, they will most likely bond with someone their own age.

L: And who has the same problem that they do?

- Yes, whatever the issues, it's best to go into the issue with separate age groups. Like the 20 year old will relate better to a 20 year old than a 60 year old.

2b. Are there any other ways to get people to talk about the goals of the project?

- What I'm suggesting for our CAB for Total HealthCare is to give a class for different age groups, give them the knowledge for what needs to be done. How to approach people of their age group. Give them the information to carry it back to these people. Where they can get their health from? But in order to do that, that person themselves needs to be filled with the knowledge first to give to the community. So if a person says, you need to get this done. Well, how do you know that I need to get this done? The reason why I know whether it works or not is because I've done this. Human experience is the key to everything. If you give a class, teach them with knowledge and information with knowledge of how to approach these people, they can get it out easier. And people will be more cohesive to get into program to seek their health. But if you send them out there and they're saying, I'm doing this because I get 50 cents for every survey, a lot of people aren't going to do that. I'm done this because I've gone through this and want to give back to the community. I think that's basically why everyone is here. They've gained something from the community and want to give back to them. They want to have the knowledge to take it back to the community. And say, this is what's being done. This, this, and this. Well, how do you know? Well, I've been through it. I've had firsthand knowledge.

L: In the example, when you said that prostate cancer is on the rise. Is that the type of knowledge that you want to give to people? That this is a problem in our community?

- Like I said, about my colonoscopy, I avoided it for the longest. I just had it done a couple of months ago. Before I said, no. But in order for me to tell someone to get it checked, and say that it's not as bad as it sounds, I had to go through it myself. If someone says, how do you know? I can say, I had one done. It's not as scary as it sounds. It's better for your health. I can say, not only am I a candidate, I'm also the president.

L: Are you going to have a goal in my mind and say, my goal is for all men to have colonoscopies? Or are you going to say, what do you want the goals to be?

- It's important to have your health. It's not only important to you, it's important to me too. you've got to become a buddy with them. I want to see you do well. Well, if they ask you how do you know it don't hurt? Well, I've been through it. I'm in the process now, I'm on the CAB of Total Healthcare, and my goal is to let people know how to get the proper medication from, transportation. A lot of people have minute phones. If you call certain places, they keep you on the line forever and you get the wrong person. I'm in the process of eliminating that. With flyers, contact information directly to that person, if they aren't there, then leave a number and they will call you back. A lot of people are scared to call because it takes up all their time.

L: Is there anything you wouldn't do that is on this list?

- Wouldn't go out there to without knowing what I'm talking about.
- Wouldn't narrow it down to just one study. I can understand starting out with one. There's so many issues that face so many different people. I think that the best thing to do is to make a topic available for everyone. So, to narrow it down to just one research study, it will be redundant. So maybe it's the same issue for a cancer patient, but the same format as a diabetic patient. So the same format for teens both female and male, for safe sex. The research will have to be for more than just 1 group, because you don't get so many aspects on that one issue.
- That's why I said that we need to have an educated persons to give out the survey. Not just about one thing, but the broad spectrum. If you narrow it down to one thing, people might say how do you know about such and such a thing?

L: Educated about the topic?

- Yes
- Because you went through the prostate cancer, then it's best to pick someone who went through the process. She went through cancer, so maybe she can talk about how she's gone through it as a woman with cancer versus a man with cancer. So I have a spinal problem where my spine breaks. My knowledge would be someone with spinal injuries. If that person went through it, they can talk a lot about it. It should be a person who went through that.

- I do it at my church, my pastor asked me after I went through recovery. We talked about it and I'm seeing a more positive attitude with some of them after I have talked to them. The reason why she chose me is because I was so positive. Not a lot of people can go through this. I feel like I have really come to people to give them some comfort. I had people come and tell me what an inspiration I've been to them to help them through the process. I would give out my info to my church and community center. And clinics, or whatever, a group of people, that's how you get it out to them..
- No one can tell you better than someone who has been through it.
- That's what I've been saying, but we still need to be brushed up about our avenues, where to get help, resources. It's not just the cancers, prostate. If you are just armed with one thing, you aren't limited and the survey will be limited. If you are taught where this info is from and bring some knowledge, then you'll have a better chance. I get it because I've had the same done to me. I've learned that it won't hurt to check up on it.

L: Are there different methods to try to improve people's health? To get people better?

- Knowledge is half the battle. If you have the knowledge, it makes it easier for you to go through it. When my spine broke the first time, I had to basically go through my own experience. It's hard to go through something when you don't have any knowledge about what you are doing. It's easier if you have someone to say, hey, I've been through that too. I had to change my lifestyle, I had to be extra careful because I break easily. I think that having the knowledge of whatever situation, AIDS, a disease, or an affliction, having knowledge form a person who went through it, it's priceless.

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study? [no additional information]

3. Where would we go to find this information?

- Prevention, offering them information about how to take them before it gets to the point.

[L: Clarified question, aim to collect data to see if they aren't getting help, why?]

- The survey. You've asked them, have you had this done, are you a recipient of this treatment? Has anyone in your family had this illness? Most blacks have hypertension, diabetes. A lot of them don't know they have these things, are kept in-house.

L: Would we go somewhere to get his info?

- People have symptoms they are not aware of. People bring up their symptoms, clamminess, sweat, like with hypertension headaches, eyes get blurry. If they don't understand what they have, they think that they haven't eaten all day, they just have a headache. They call diabetes the silent killer. People walk around with diabetes and not know that they have it. I was watching the guy Browns who played with the Ravens, who died of diabetes and didn't know he had it. You don't have to be obese and aware of it, but you have to get checked and screened, and then you can become aware and prevent those things. Understand what prevention is to combat this. A survey, screening, survey to the screening is important. If you don't know about something or have the knowledge about something, it doesn't make any sense. With the survey, have you had these feelings, known anyone to have these feelings. Certain things are hereditary, someone in the family has had a heart attack, brain tumors, strokes, aneurisms. There are tell-tale signs of these certain illness.

L: Would we go to the doctor? Yes. A lot of people don't survive off of aneurism because they don't know they have t. if they knew the tell-tale signs, maybe they'll go and get themselves checked.

L: Would we go to the families?

- Yes [nodding heads]
- I have cholesterol, hypertension, although it's down. At one time, I thought I was invincible. Now I know I'm not. I had 2 vertebrae crushing on my spinal nerve. I had to get those checked. [goes into family history, importance of getting symptoms checked]
- If you don't know the symptoms, you don't know what to look for in order to diagnose what is going on. He says that blood pressure runs in family. If people don't know the symptoms, what to look for, they might now know. So get physical checkups, or acknowledge that they have headaches. A lot of people don't know what to look for because they don't know what to expect.
- The main thing is that we need to get out to people to go to the doctor, get a physical. There's a saying that your genes from your parents, grandparents, great grandparents, it can come from that. My brother, I'm 2 years older from him. He has bladder cancer also. A different type, but it's in the bladder. We both have it. My mother had 3 types of cancer. [conversation continued about family history]

L: So, family history is a source of information?

- Yes you've got to get screened for it. If you go to a good doctor, he or she will ask if there's this, that or the other.
- Back in the day, we had family doctors. Today, we don't have that. My youngest sister, she's deceased now. She died of an aneurism. I go to her doctor, my sister had lupus, my brother passed [continued discussion of family history]. So I had a lot triggered in my mind to get it checked out. So I get on my baby brother. So that's why when you see him, you see me. I'm his yang, he's my yang.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

- Literature
- A study, class or course for people to learn how to give out the survey for these illnesses.

L: Does this mean to get people in the community to learn how to administer a survey? Yes. [several people respond yes]

5. After our study is over, we will want to send the findings from our research back out to people so they can use the results, including members of the community, doctors, and nurses, hospital administrators, and heads of organizations. What are the best ways to disseminate the findings from our study out to these types of people?

- That's where the survey comes in from. A percentage of the survey, what people feel is important to them, the things that they need screened, their concerns. The survey is the main function for that. You count and find out what people need.

L: So, we go back out to do the survey? Go back over the survey and see what is mainly important to those people. When they come in to the screening for those illnesses, that will tell you what avenue most people are concerned about. But the survey is the first step because that tells you what they are concerned about.

- Because what he said that people don't know the symptoms of what they have, I think that putting literature out there that these are the symptoms for high blood pressure, diabetes, congenital heart failures. Just having some information out there and make this available. Make it available so a person can get a one-up, to see what diabetics go through. Some issues with heart failures, blood disorders, make the information about the symptoms available so people know that's what I need more information about.

- And they need to know where they can go and get this info free. Let people know that not everything has to have a dollar behind it. There are other avenues to get the info. And we know that because of the economy, people put their health on the back burner because they need to pay their rent. They need to get the resources.
- And that's where the survey comes from. And the survey can have more info on it, where they can get more info without disclosing, confidentiality.

XLIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- I want to continue to do what I can to help. [several people expressed this sentiment]

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

XLIV. FACILITATOR/CO-FACILITATOR REFLECTIONS

Participants in this group appear to be very closely connected to the hospital and surrounding neighborhood, stating that they have lived in the Bon Secours neighborhood for decades. Additionally, several participants in this group presented engagement and research ideas that were specific to the neighborhood that surrounds Bon Secours, including local health fairs, Bon Secours activities, and other existing events in the area. It was apparent that several members are informed of their community's health needs, data collection methods, and are already active in sharing health information. Several spoke from personal experience and participated in the focus group to "give back" to Bon Secours and the community.

Interestingly, youth and young adults were discussed as "hard to reach" populations, which were not discussed in previous groups. Additionally, various forms of stigma was discussed, including bringing shame to the family, gender roles for men, negative stereotypes for those receiving aid, and stigma specific to certain conditions. Engagement methods will need to address these constructs of stigma, in order to allow people to openly participate in the research process. Although participants also spoke of health fairs and other broad-based activities to distribute information to the community, it may require targeted methods to first address issues related to stigma. For example, participants spoke of peer to peer discussions and personal testimonies as ways to break down barriers related to stigma and to begin the engagement process.

PCORI Phase 2 Focus Group

Focus Group Category: Lower SES African Americans

Day/Time: Tuesday, February 7, 2012 at 1:00pm

Location: Bon Secours Baltimore Health System

Facilitator: Jennifer Huang

Co-Facilitator: Liz Jansky

Number of Participants: 6 (4 women, 2 men)

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let's begin with introductions.**
[None]

XLV. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- Has diabetes, wants more information about the lance pen

- Just came to participate in the group and to help out
- Came to be involved and learn along the way
- Came to give opinions to maybe help someone else, because we're here on earth to help one another.
- I came because it's helpful and everyone needs to learn from everyone else.
- About a year and a half ago, found out she's a diabetic and she needs to know what things a diabetic can eat, can't eat and so far she's not on insulin right now. Just taking the diabetic pills.
[One participant asked a question about being a partial diabetic. She wasn't sure about being borderline. She drinks a lot of water and thinks that that keeps your sugar down. Gave out suggestions about the more water she drinks, the more sugar goes out of the body. Her blood sugar stays down low. She just turned 60 and her eyes are changing. She's worn glasses since she was 4. etc . Dr. Mullins stopped the conversation to redirect the participant to understand that we are here to learn about how to do research that will answer the questions that we have. Jennifer moved it to the parking lot.]

XLVI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**
[None]

XLVII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- When you come to the groups, get literature and let your family read it or friends. *J: What kind of groups? Really, a group like this and really any kind of group that keeps people interested. J: Are there examples of groups in your community that people go to? Groups as far as different illnesses, high blood pressure, groups that are homeless.*
- Not only that, but alcoholism and drug addiction.
- A lot of the groups that people listen to, that the group's not for them but whatever I learn, I feel that you can learn for someone else.
- Support groups to address alcoholism and drug addiction. *J: So to go to these groups about whatever they are? Yes.*
- Some people, this group here, you're offering not money, but some of them do offer money. Some people just come for the gift card and not for the information that they really need. Sometimes people, like men for instance, they may shy away from issues like this because they're macho and this isn't going to help me, but in the long run, you really do need to sit down and listen. So as a whole, the whole family can sit down and know what's going on so that, as a whole, they might understand it better if it's the whole family going on. You're trying to get everyone to talk and just listen. I find that in my later years now, I'm more open about my health and like they said, the day that it [this focus group invitation] was presented to me, they called my phone, and I'm like I'm not doing anything, but I want to learn more about those issues, or problems that people have. The more information the more it will help you be more interesting. "I know I got this. If I go to this I will learn more." Some doctors don't give you enough information, but if you learn more then you can tell your doctor what you learned and it might make him more interested and he might try to go to something like this meeting.

J: How about people calling you directly? Would that work okay?

- Yes, I think it would work because sometimes you know you have important stuff and you might write it down and you might not look at it again, and they'll call the night before and they'll remind you and give you the time of your appointment, so it's good to call and remind people sometimes.
- I'm just throwing this out there. I was born in 52, and back then, we had food and it was live, like the chickens. The food was better then back in the 50s and 60s but this food now is like processed food. Feeding our children processed food is not really good for our health. My mom used to tell us that if you eat the greens, that's good for you health with the vitamins with it. [told story about taking the juice out of the greens and "tearing it up" in the bathroom] but it's good that she did tell us about the juice, and the vitamins making the little bodies strong. [Jennifer tried to move the discussion to the parking lot] People need to go back to basics on the food and tell other people about the fruit rather than the candy.

J: Speaking of food, are there types of incentives that would be useful that other people would like to receive to come to events?

- But that's the point I was trying to make, with the gift card if you're doing a study and you're offering a certain amount of money if you finish the study. What if you're not offering anything in the study, well, this might make me come. They're coming for what they can get out of it. "Oh, yeah, I'm gonna come for the gift card. I ain't gotta participate." But, sitting there, you might learn something that you need to know that you didn't know. So it might catch something that you didn't know.

J: Are there buildings or organizations to go to?

- Yes, when you give out flyers and to state that it will help for you to participate as far as your grandparents and your parents and maybe you can participate as far as that. *J: Where would you put those flyers?* In the downtown area, Lexington Mall, where the fast food restaurants are at.
- Put it in areas where people be at all the time, like a lot of people catch the bus, markets, clinics, where people would go all the time.

J: What about people in the community? Are there certain people who may have more say than others?

- Yes, there are some senior citizen buildings that people have gatherings there, everyone coming to find out what's going on in the community. And a lot of churches.
- Go to school systems and educate the teachers and the principals, and especially the people in the cafeteria because they're giving the food to our children.
- She's right about it. Just like in my block, I live in Bolton Hill. There's always people who stick flyers in your door and let you know about committee meetings and so on. *J: Do the flyers have to come from certain places? Like does it say it has to be hosted by an organization so that you really trust where you would go?* Yes, like CVS or Rite Aids or Giants. A lot of supermarkets. Can give them out there as people are coming in or going out.
- The way things are going now it's kind of hard to believe what you see. Even though it might be something good for you, you're still like, "Should I or shouldn't I?" I think it's up to the individual, like you have to take a chance and it's up to the individual. Like, if you want to get up and leave then you can, and if it's not really pertaining to what you thought it was, then it's your right to leave. So some people have good intentions but they shy off to the right. So it's kind of hard, you have to use your own incentive – do I want to or do I not? It's good that we put on these papers [consent form] so we can sit and read but it's up to you to believe whether it's going to work or not.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

- With homeless, you have to go to them to give that out. Some will or some won't. You have to go to them. As far as participating, giving out gift cards. Because like I say, you have to give out gift cards. Like to the homeless. *J: So going to the areas where they hang out?* Yes, exactly. I believe they will come. *J: Is there a particular person or type of person that would be best to do this type of work?*
- Yes, someone to go to homeless shelters. A lot of homeless go to the shelters to lay down. So if you take the materials to the people, it will give them time to look at it.
- Someone who will be participating to go to the homeless out on the street to ask them. Someone who is not afraid to go to speak to them directly.
- But there's a lot of them that won't go to the shelters. They're on the streets. So you have to go to them. But I know my uncle is a reverend and he goes to different centers and they come to his church.
- Also you can go to the soup kitchens and the Franciscan Center, Our Daily Bread.
- I have a question for you. When you're asking for people who will be good for giving out the literature. So in my community, is it someone who looks up to you? Someone that will actually listen to you? "Well, if he's in it, then I want to go." Cuz the little area where I hang out, they call me the mayor. I'll keep it real. I used to be a druggie, and my giving back to that little block is like trying to help anybody. I don't care what color you are, where you're from. I would say a whole lot of people would take the time out if I presented it to them. You know, "They're having this fair today. Why don't you come on down? And they're not even offering anything. I went down. I'll go with you if you go. Why don't you bring a couple of friends with you?" They could pull them in. I know it's something good. [a couple of people nodding heads in agreement]
- What he was saying is honestly true, and I where I live at, I'm the same way. You know, "There's a certain thing going on tomorrow night." *J: So is it difficult to find out who [the key person is on that block]?* No, it's not because we're well known in the neighborhood. It's real good if you can talk to people and they'd be like, "Well yeah, she went last week and she learned a lot and let's go with her."

- A lot of people from the daycare, the homes, and they go to the daycares and maybe they'd bring the family with them so they can learn what's going on with the health.

J: Aside from homeless and senior citizens, are there other groups that are hard to reach?

- Some young ones. Some are and some not. A lot of them have sick elderly and young people that have been shot up and still on all types of pills and stuff like that. *J: What's the best way to reach these people?* With the flyers, that makes a difference. And when [participant] was talking about the gift cards, that'll bring them in and then once they come once, they'll keep coming back.

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

- Just take a look at all of them [health-related issues].
- I think if you focus on the foods, it'll cut down on the diseases, diabetes. So if you focus on the food. People are going to eat what they want to eat anyway. If you think about it, God puts all the food down here for us to eat and man makes the candy [Another participant asked to move this to the parking lot].
- I think, it's so many health issues so I think as the presenter, you will have to pick out exactly the main issues that you really want to present to the public and make a choice, because you can't...in some way you're going to have to cover all of it. Like, to start out like diabetes, this, this this and maybe the next one, we'll cover the rest. *J: But how would we make that list?* Like, with diabetes, it's a whole lotta things I don't know about diabetes so if we pick that, then we get as much information as we can, and then if you see like the main part of the group is like shying to one particular disease, then you know with this group here, they're trying to learn about the diabetes, so I know what I need to focus on. And then maybe the next group might be with another disease, but eventually you're going to have to cover the whole entire circle. I would say it would be up to you all with what we're going to start. *J: So like researchers coming in and looking at the data to make a suggestion like diabetes?* Right, so maybe if you go door to door to get an idea about the type of illness that they're mainly dealing with. So if I know it's diabetes, then I know that can be the start and that'll be to get me in the door. So you do the same thing, maybe do a survey in another two-block radius and eventually you'll do it all.
- With the young kids [that's a challenge] with a million diseases and they need to learn about different types of pills that they're taking and what they're about and they need to focus on that and that will bring it in the two-block radius maybe that'll help and go to different schools [agreement from another participant]. High schools and elementary schools. *J: Going to schools and doing surveys with the kids?* Yes. *J: Is this a health condition that helps younger people?* Yes. *J: So does it depend on age groups?*
- Yes, because for one thing, with the younger generation today, that's a challenge because you're going to have some that's going to be totally interested because they want to know and then you're going to have others who are coming for the gift cards and who aren't going to care about what you're talking about. "I ain't trying to hear that." But the same one that went out that door, will be the one later in life who will be wishing that they had that sit-down since they have the disease and they won't know nothing about it.
- They think they know more than what you know.
- The way to get the kids is to put it on the laptops.
- What she's saying is valid, but with those laptops, they're not coming for the information, but they're coming for the laptops and go out the door. If you just put it on laptop, it's not enough.
- It really depends on the kid.

J: How about text messaging? Or more technology?

- Yeah, but it still comes back that it's only going to affect the ones that really want to know. You can tattoo it on their head, but they ain't going to pay it any mind. And I'm not going to alienate them. It's the same with some adults. They're not coming for what they can learn but what you can offer. You got a hell of a job on your hands. *J: So is there any way to reach them?* I feel like this: you can talk all you want to, but if it's not interesting to them or if they don't have the focus on what we're talking about now. You can come in and say, "We were here on the 7th. Can anyone say what we were talking about?" Sometimes it's hard to reach people. If you don't want to be reached, you're not going to be reached. "You know, I was here last week, they were talking to about interesting stuff and I'm going to stay focused so I can pass it on to the next person." So it really depends on the person. And then a lot of times, you might talk about something, and you might say to yourself, "Damn, these people aren't even paying me no mind." But then next week, they'll come to you and say, "Yeah, I did get something out of it."

- And then you can have some people who are very interested in what you have to say. You have three different types of people. People who are here for what you have to give, people who sit just to sit and the people who are very interested.

J: So the focus today is to get to those people who really are hard to reach and how to still get them involved. So if we can think of creative ways to somehow get them involved and not just those who are already connected.

2b. Are there any other ways to get people to talk about the goals of the project?

- A lot of times what a lot of people were taught that what goes on in the house stays in the house, but I understand that too but if something is going on in your home as far as a sickness and no one knows why they were sick and how they got sick, maybe if you tell somebody, then maybe somebody can help and talk to him or her and going to the doctor. Like myself, I'm a hard person to try to get to go to the doctor. It took me 10 years before I went in to go get the knee surgery. Sometimes it gets so bad where you don't have a choice. It's a whole lot of stuff that is kept in the family that no one knows but whoever lives in that house. *J: Is there a way to use that, to use the family as a way to help people become educated about the health topic or get more involved in a research project?* I think there is a way, but honestly, it's up to the person. You can say, "Yeah, I went through this and I did this and I did this," but it's up to them whether they want to listen to you, but it's still them. If they don't want to go, all you can do is "Hey, I told them I was in their predicament." If they have that stuck attitude. And then if something happens to them, nobody knows. And then the family will start talking and everybody will wonder why they didn't get help for it. It's like that secret.

J: If obesity is our topic, and our goal is to come up with more playgrounds, are there ways to get people to come to an agreement about what that goal might be?

- I think we covered it.

J: Is there anything that you think may not work?

- I think they all would work. Maybe a few might work more than others, but once you find out which one really works, then you need to focus on it. This is what's really getting people to come in. *J: So it's kind of like checking in to make sure this method is working?* Yes.

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

[Jennifer gave an example of childhood obesity and the intervention of getting more playgrounds in the community.]

- More recreations need to be open. That brings the community together too. [redirected from obesity]
- Say if you have something like today's focus group, maybe sometimes radio stations or TVs. Put it on the radio. Like they're having today at Total Healthcare about coming in to get tested, gift cards. Sometimes you know people don't have the money to put stuff on TV and have that advertised on the radio.
- Youngsters go to the malls.
- Put it everywhere. If you make a flyer, put it everywhere where you think people hang out.

3. Where would we go to find this information?

[Didn't have time to ask]

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

[Didn't have time to ask]

5. What are the best ways to disseminate the findings?

- You know those balloons that go across the sky? Put the words on the balloons, especially in the evening when it's nice outside, people will go outside and look up. Or put it in the balloon up in the sky and throw the papers out.
- Get on the phone and call people that you deal with.

- Make signs and put it up on the side of the bus.
- J: It sounds like a meeting of somewhere to go?*
- Sure, and then they can find out for themselves.
 - If they hear it word of mouth, sometimes they won't go, but if they see that sign, then they can come there themselves.
 - And for [the gatekeepers of the neighborhoods], go into their community and make sure they get it out.
 - I think the flyers is the best thing
 - I think the busses is the best thing because they go all over Baltimore City because you can get people to come in quicker to find out what's going on and then they can take it back to the community. Some of the people will participate in what the people have to say.
 - They will participate if you give them the flyers.
 - Would the meeting be held? Like I said, the senior citizen buildings because a lot of them go there to find out what's going on in the community; And there are a lot of schools in the senior buildings. And a lot of schools.
- J: So a lot of the same places as identifying people? Right.*

XLVIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- It's interesting.
- I enjoyed it.
- I will come back
- I will help you all if you need my help.
- If you need help to bring the people in, I will do that.

Daniel: Many of these who come here may not benefit directly, but how do we capitalize on the fact that you come so you can help other people? How do we take folks that have health conditions and need answers to their questions but aren't the ones who come to volunteer to share?

- Word of mouth.
- One thing to me is a lot of people who have health issues, they're scared to open up. They know that have health issues and they know that they need to come out and get information. "You're sick and I know you need to read this literature. You may not think it will help you." It's going to take somebody strong to do that. So like in my little community, you know, like, [participant] we need you to take these flyers and pass them out. The only thing I ask is that you take it and then throw it in the trash. And the way Ms. Laird did on the day of her appointment, there was a devil here that didn't want me to have that information that she wanted to give to me. I apologize but the lady there didn't want me to have that information. We'll call him on the phone and we'll call him. So it just shows you a perfect example.
- Mine was word of mouth. The lady in the office was telling her about it.
- In my group, they had groups like this down in Lexington Market and a lot of people came in to see what was going on with the seminar. And it turns out it was pretty good so that worked.

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

XLIX. FACILITATOR/CO-FACILITATOR REFLECTIONS

This group seemed to reflect the lower SES African American demographic we were aiming for. A couple of participants had a hard time grasping the concept of discussing ways to engage and gather input from the community, and kept taking the conversation off track on topics related to their personal health experiences/beliefs. Jennifer redirected the group well, and similar themes were expressed during this group as were during the first lower SES African American group, including: the family not discussing current or historical health issues; men being too "macho" to discuss health; the importance of approaching or partnering with neighborhood "gatekeepers" as a way to promote interest in the study or health topic; and the use of incentives or resources as a way to engage a person. A new theme that kept resurfacing today was the idea that someone will only become engaged if he or she is personally interested and that no matter how hard you try to engage/what method you use, it depends on the individual. This issue seemed especially problematic when trying to engage young people.

PCORI Phase 2 Focus Group

Focus Group Category: Mobility Impaired

Day/Time: Friday, February 10, 2012 at 11:00am

Location: BSBHS

Facilitator: Jennifer Huang

Co-Facilitator: Liz Jansky

Number of Participants: 8 (1 male, 7 females)

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? [*Answer any questions that may arise*]. Great, then let's begin with introductions.**

[None]

L. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- Here to see what she can do or what she can help with
- Just here to find out what he can do
- Find out what her input can do to help and take whatever she can get out of it to help herself
- Here because she has high blood pressure, is anemic and then has arthritis...has a little bit of everything. Wants to see what she can learn.
- Here with her mother and see what she can learn
- Here to learn more about a certain type of health and see what she can learn. She can be an encouragement to her friends and family
- Here to help something and someone can help her.
- Here to help anyone she can help. She's a walker. Walks every day and will do anything in her God given strength to help others

LI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [*Answer any questions that may arise*]. Great, then let's begin the discussion.**

[None]

LII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- I can say my son helps me a lot. You know your children love you and are very concerned so he was telling me what he can do to help me, like vitamins and exercise. So every Tuesday, we have an aerobics class. So that's getting people together to get to know one another, talk to each other, not to be ashamed by one another. We come together to help one another

J: So I heard two ideas: one, getting family together and then secondly is to go with people who are already meeting together.

- I would tell people, look, I'm a diabetic because you never know when it might attack you. If your sugars too low, you're going to pass out. If your sugar's too low, you're going to pass out. So I just tell people, "Look, if I start looking a certain way, just dial 911" and I tell them what kind of medicine I'm on. Cuz otherwise, they'll look at you like you're high or drunk and they won't even help you. They'll step over you. So if you tell people what you want to help with.

- I'm a diabetic myself, and a lot of times when I talk to people, they always suggest to wear an emergency alert bracelet so they know who you should call.

J: So kind of like educating people around you?

- Let your family know the history so they can be tested early and they'll be tested early. So getting different generations involved and letting them know about the history.
- My mother died from a diabetic coma so when I go to the clinic, I tell them I want to be tested. The doctor don't know unless you tell them. They can't read their minds. So far, the doctor says I'm not a diabetic. Health is the most important thing, especially as we get up in age, so I always talk to my children. My oldest daughter died of breast cancer. She had it for a long time and didn't say anything. She was afraid she was going to have to go to the hospital. And I'm her mother, and I didn't know about it. Health is important. It's so good to talk to the children and explain what's going on with you. I'll sit down and explain things to them.
- I teach all my grandchildren how to give my diabetes shots, how much I'm supposed to get and which one I get. My little 6 y.o. granddaughter knows more about my medicine than anyone else in the house. She's on the phone with 911 when everyone else is trying to figure out what to do. I have muscle spasms myself and you can't move. They usually come in the middle of the night, and if I holler, the little one is always the first one to get there. She comes straight to my bag, get my medicine and my water, and doesn't hesitate.

J: What about outside the family? Are there other groups that can be helpful to reach people?

- A lot of times, people just don't like to talk about it [nodding in agreement] but not me. When I go to the hospital, I tell people that I want to know what's going on.

J: Are there any safe spaces where people can talk to people openly? There's a lot of stigma, but is there any kind of support group or safe spaces to meet with others to talk?

- Well, what I do in my building where my kids say, "MA!" but I can't help it. We watch out for one another. Be concerned for one another. Talk about love, but love is action. Just don't say I love you and then when you need, where are you? Like the lady in my building, I'm very concerned about her. Too much weight, but I come out and tell her because I have to. I tell her like a daughter and a friend. I say you need to stop eating this, drinking this, and you need to check to see if you're a diabetic.

J: What about places like churches?

- Yeah, I was going to say churches because one of my church members is the person who gives out information about health. One Sunday she gave out information about drinking water. One time she was saying that your legs need water. That's her job to give out health information to the church members.
- A lot of people don't drink water, and they trying to get stuff to disguise the water. You've got to drink that water, because your kidneys, your back and everything needs it. [continued with a story about her experience with drinking water and her pain going away]

J: So that's another example of word of mouth or an informal way of spreading information.

- Cranberry juice is also good. I have a daughter who I tell that you need to check water and check your urine. If it don't look good, there's something wrong. That's why a lot of people are on dialysis.
- I got my granddaughter drinking water. [more enthusiasm for water drinking all around]

J: How about community leaders that people can trust?

- Not really, because a lot of times, people don't want to talk about it. The first thing is that people don't want them to get in their business. What I do is first let them talk and see where it's going, and then ease it in onto the conversation. But when I need help, I don't have pride – "HELP!"

J: A traditional way is to have a survey. Would that work?

- [all say yes] We really need that. *J: It's not too personal?* A lot of people have that pride but that pride will kill them.
- My manager does everything that she can do to help, take the pressure and all that. But they don't come down.
- What I do, I go online a lot of times and find some information, and then take it to work or give it to my sister and brother.

J: What about senior centers?

- A lot of times, the elder people in my building get on busses that take them out. Or they get together to play cards and other things to keep themselves active.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

- Some people you just have to leave alone. Get up in age, they don't want to be bothered. And then you can't push yourself on them or you've got a problem. When I'm talking to a person, I look at their expression, their eyes, they don't want to be bothered so I just leave them alone and wait until the next time because I'm not going to give up.
- Or find out when in certain areas when their community meeting is, because I just moved into the area and the guy gave out a flyer. It's at the church and then we can get the information at that meeting.
- My older sister has clinical hour NA meetings. They go in there and talk about everything from the beginning to the end. You don't have to be ashamed about anything. And then they've got people to help you with everything – a ride, food, anything.

J: Are the homeless difficult to reach?

- No, because I used to work at DHS and they have programs to give them food, medicine [a nighttime program, shelter, where they have to leave in the morning]. I just got laid off, and my benefits stopped. So mainly it's hard for people who are unemployed to get their medical services.

J: How do we reach the unemployed?

- Set up meetings like this because when you try to talk to people about what you want to say. And then you can't talk to anyone in the office anymore because then you just have to call on the phone, so if you have a meeting you can get everybody together to find out how to continue with my health.

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

- You got a lot of them, especially disease going around. I really believe, like Bon Secours has a lot of programs to help people. They've got the program but they've got to want to get better. People have got too much pride.

J: So let's pretend its Bon Secours working on the health problem. What advice would you give to help them pick a health problem to address?

- Can't you go online to see what's the highest disease? And then picking the top one.
- Yeah, especially the one that's most important and then go down the line.
- I know you can't go to the doctors' office because that's PrivacyAct.
- And you know mostly the homeless people are very intelligent people. And then you've got older people who taught school all their life or did another job all their life and then they retire and there's nothing left to do. So now you're starting to wilt away. And then because they don't have or can't get out, they lose theirselves in their mind and they give up. A whole lot of them are sick and need some help, and they're not going to ask for help so somebody needs to help them.

2b. Are there any other ways to get people to talk about the goals of the project?

[Jennifer gives an example of heart disease as the topic of the study.]

- Well, for one thing, once you find out you have heart disease and the doctor tells you what to do, it's up to that person now. Because they got it and they want to go about it, they have to go about the rules.
- If they want to get well, especially someone addicted to smoking cigarettes [discussion of addiction to smoking]. Sometimes even God can't help you if you don't want help. [More stories of family death from lung cancer and a magazine article scaring her into stopping smoking]
- I asked some questions myself. How bad do you want it? What do you want? You just can't use excuses. [More about how to intervene with an addict].

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

- A lot of times, the doctors will give the people a prescription. *J: Okay, so we can go through the doctors?* Yeah, but it's still up to the individual. If you really want to be delivered, you have to go for it.
- God had to step in. If you try to leave him out, it's not going to work. You need somebody who's been through it to be able to reach out. *J: So does that mean that someone on our research project needs to have gone through the health issue we're studying?* Yeah, because you have to know something to talk about. *J: For every type of issues?* Every kind.

- If you're deep into it, you've got to know what you're talking about.

J: So would you trust it more?

- If you knew it's coming from someone who's tested and tried it, then you know they know what they're talking about.

3. Where would we go to find this information?

- The person that has went through it and knows what they're suffering from can be much greater help. [story about a woman in her building who wants to stop smoking]

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

[See #5 for issues of trust]

5. Best ways to disseminate results back to the community?

- The newsletter of the month or something to go in the neighborhood to give information.
- Then you can also call them and check on them.

J: How about in general?

- Word of mouth
- Put up flyers and pass them around.

J: How about at meetings or giving presentations?

- Yeah, that would work. If they come. *J: Where would the meetings be?* At the school.
- Gotta educate the kids too. Everyone's got someone in their family who's sick and needs something going on. Everybody's got a drug addict, diabetes.

J: Who would give out the flyer or make the presentation? Would it be a community member? Someone from the university?

- Somebody they know and trust.
- Like this, I heard about it because Mrs. Laird called and got me interested.
- I had met the lady from downtown. She was giving out pamphlets and stuff for people coming into the supermarket.

J: Would it have to come from someone from a certain position or institution?

- Not really, because if they're curious they're going to come. Like today, we're here. I can pass it on to where I live at.

LIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- I think it's good because you're reaching out.
- You've got your hand out so it's there for someone to grab hold.
- We learned from each other.

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[none]

LIV. FACILITATOR/CO-FACILITATOR REFLECTIONS

As this was the mobility impairment group, many of the participants used canes; yet difficulties with their physical movement were almost never discussed. When talking about their "community," most referred to their neighborhoods or residential buildings, and many of the themes expressed were similar to those of the lower SES African American groups. This is not surprising since these participants are also patients of Bon Secours and presumably fit the demographics of the lower SES African Americans. This was a challenging group to keep focused, because there were 2 or 3 participants who monopolized the conversation with personal stories about diabetes, drinking water, and smoking cessation. Despite this, themes that emerged and that were common to other groups include the idea that people from their community do not discuss health and the importance of talking to one's family about health history; the concept of personal readiness to attend or listen to a discussion about willingness; and the effectiveness of peer-to-peer communication or word of mouth, especially coming from someone who has experienced the disease/situation being discussed. Religion also came up quite a bit today with regard to a person's individual willingness to accept and provide information about health.

PCORI Phase 2 Focus Group

Focus Group Category: Mobility Impaired

Day/Time: Friday, February 17, 2012 at 2:30pm

Location: Weinberg Senior Center

Facilitator: Liz Jansky

Co-Facilitator: Nicholas Buck/Paula Lipman

Number of Participants: 11

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let's begin with introductions.**
[None]

LV. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- I have MS.
- Because I wanted to know what the study was about. I have impaired walking and wanted to know how I could be helped.
- Curious.
- Been on walker for 2 years, lose my balance, don't know what caused it. Maybe I can learn something or tell people what I know about it.
- Because my wife decided for me [laughter].
- Use a scooter and been using it for about 20 years. Curious.
- I have impaired walking.
- I have various problems such as arthritis, knee replacement, a variety of things. Taking a medication for cancer and it affects your bones.
- Have a walker about 2-3 years. Thought I could hear something and wanted to come and see....
- I have had my MS since 1980 and am walking now. Taking a new med called [name] and it has helped me walk quite a bit.
- Spinal problems [hard to hear, other conversations going on]

LVI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**
[None]

LVII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- In this community a lot of people have problems, talk about them, may get an idea from somebody else or they get an idea from you.
- Thinking about nutrition, a lot of people still don't eat correctly, or see information on TV about what causes cancer... L – Next we will talk about what it is we are going to study...
- Surveys
- Word of mouth, maybe I will give names [of surveyors] to others

- Magazines, gather information from all over US; they recommend self-help groups. I visited practically every MS group in the state. They need a lot of things, such as handicapped parking. Allowed one space for 25 people. Not enough spaces. *[Recruiter to participant] – Let's not get into that topic here. We can talk about it later.*
 - Have hotlines or support groups that you could call, instead of them calling you.
- L – Are there some people you would trust more than others?*
- Think some people are looking for a donation, have to limit that. Need to know it is a reputable company and all they want is a survey. Not a sales call.
 - My phone announces the number... if 800# ...don't answer.
 - Doctor's offices or hospitals, surveys are advertised with phone number.
 - Wish there was a way to get in touch with people working at mobility [??] to suggest how they can make our life easier. *L – So that's an example of a research topic we might come up with.*
 - Not everyone has a computer, a lot of people find out things on the computer.
 - Personal contact would be good but we are cautious today about giving information over the phone. If they identify themselves it's okay. *L – So helps if you have contact with U MD first, then you are comfortable giving info over phone..? As long as I can identify it's a legitimate organization, can give me information about what I can do about my particular circumstance.*
 - Have a hotline to call if I am having trouble, like AARP you can call anytime. Want to call them instead of them calling me. People get turned off with that. *L – So would you be okay if U MD partnered with AARP and gave you the info, and then they followed up and asked you some questions? Yes*
 - Good idea
- 1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?**
- L – Who wouldn't we reach with those methods? Would we reach everyone?*
- No
 - They don't get to the bottom [of the problem], tell you to learn to live with it. Good to talk to someone with the same problem. *L – So tap in through support groups? Doctor? Sure.*
 - When I got my power wheelchair....gave out their cards. Advertised for them because pleased with service.
 - Your doctor doesn't have that much time to give you tips. Felt like I was a complainer but he said no it was the medicines causing the problems.....
- L – Getting off topic here. I hear that there are key people that are spokesmen for the people you care for. Are there people in the community that you would look to for guidance?*
- [Recruiter] is very good, a good listener and comes up with good idea. I have learned how to get the resources that I need and whenever I am asked I pass that information on. A lot of people don't know to ask. Communication skills. I know where the department of disability is, Congress. But the things they focus on now are not important to us seniors. *L – That is why PCORI is changing system when it comes to research. Related to the Health Care Reform Act. Do research that is meaningful.*
 - Have a social service person in our building. She takes care of everything. Also [Social Coordinator] in Building One.
 - Senior centers, a lot of people go to them and trust them. Jewish Family Services. Trust.
 - Spent 3 weeks at Hopkins, slept ate there for chronic pain. They would have nutrition, physical therapy. Met once a week after we left to talk over what is going on. Kept in touch. Very helpful.
- L – So these are some people we haven't been able to reach. Are there others that you can think of that would be hard to engage?*
- People with dementia.
 - People with depression, it's almost like they don't want to be reached but they do.
 - Have to find words to encourage them. People with hearing impairments are just not listening. They are not tuned in just hearing white noise.
 - Some people are very private and they don't want to talk about things. I am one of those people. I would not go to [name] and say I am having this problem. Would prefer to go to my doctor. Have explicit faith in my doctors. All given to me by my daughter and sons. Feel nobody can give me the help that I want. I would definitely go to my family and also my doctors. This is just me.
 - Never gonna get 100% of people. If you can reach 60% can't really do anything about the other 40%. Just wasting your time, especially for people with dementia.

- Depression is a big part, but everyone is different. Hard to get everyone together. They don't have the same problem but might look like they do.

L – Is it important for me to learn a little bit about the people I want to engage before I start engaging them?

- Good idea
- You could contact them once a week, once a month. They will give you ideas. *L - Build a relationship?*
Yeah.
- Don't think it is important, just assume they will want to listen to you.
- That comes from the privacy...
- Since I have been here I have developed friendships. Some things I will talk about [with my friends]. Don't want to burden my children.
- People don't really want advice, they just want to talk.
- There is a problem with talking to strangers. Don't want to hear any complaints. Other half can't understand what your problem is.
- You can do all these things...[they ask] what do you need a wheelchair for? I do walk when I can. People don't understand the issues involved with mobility.
- Try to keep a positive attitude. Man with one leg, but he has his mind. As you get older you have to give up a lot of things. Car, mobility, friends. [explained she is the one who gives the center's social coordinator all of her information that's disseminated to the residents]

L – If you are my research partner, you will connect with people I am trying to reach?

- Definitely.
- If you let a person know that what you are doing is alright, sometimes it makes them feel better.
- If you decide you are going to be handicapped you gotta "pick up your big girl pants and move on." Would like to have a physician I could talk to specifically about mobility problems.
- I feel that whenever I meet anyone in the hall, I say "I am fine" because nobody really wants to know how you really feel.
- How do you cope with your personal problem. Everyone is different, some people are too sick, some gave up already. Some people just living day to day, a lot of apathy. Have to keep busy and learn how to cope.

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

L – Maybe we are not able to access them. But when we get together who we can, how do we decide what to study? What research topic is most important, most meaningful, to our community?

- Give them a way to give feedback, like a hotline. Where you can talk to someone, don't need to know their name.
- If he has a problem, could he contact your company and give them an idea, a tip?
- When someone gets your call, you could put out a small newsletter with what they are calling about and the answer to the question. They will see it applies to me. *L – First we need to collect the information before we can share it...*
- More research needs to be done on holistic and alternative medicine. There are a lot of natural ways that could help people. *L – So the focus could be nutrition, holistic medicine. Any other ways to gather people's opinions?*
- Another topic is the environment. The new car smell is toxic... *L – So how do we pick the best one [topic]?*
- Get your hands on a medical person who can answer your question.

[Recruiter] – We are trying to find out if there are many topics, how do we decide which to do the research on?

- Thought that is what they are doing right now...
- [sidebar conversations]
- People have given their opinions, everyone has different problems. Hard to pick one thing.
- We want to improve ourselves.
- There is no answer to that.

L – Let's talk more about the methods.

- Have to know where the government is willing to give money. Go where they will give money.
- Try petitioning.

L – How about surveys, voting, looking at data....?

- Yes, data would work. Making the data available to the public.

2b. Are there any other ways to get people to talk about the goals of the project?

L – Okay, let's say we have our topic. Have to figure out our outcomes. Maybe it's coping, maybe something else.

- Hopkins confiscated all of my medicines. Spend a fortune but does no good. Side effects.

L – Maybe goal is about medicines. So how are we going to pick?

- Coping – want to know how to handle a particular problem.

L – Suppose you all want different things. How pick the focus?

- Let the doctor get on television, or whoever knows the subject, talk about what is wrong with you. Bring that one subject out. People will say I have the same thing. Have a lot of hypochondriacs.
- Each person's situation dictates their needs.
- Have them write down what they need. *L – So get the majority in surveys then? Yeah*
- Gonna go where it is costing the taxpayer the most money to solve. What problem costs the most is the one that will get researched.

[Several personal stories – moved to the parking lot]

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

[didn't ask]

3. Where would we go to find this information?

[Didn't ask]

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

L – So now we have the questions we are going to ask. How introduce the study and invite participants?

- The different people in charge make a point to let us know. Never get 100% because some people don't participate in anything.
- People who work here....

L – So partner with people like that?

- I would ask my friends are you going to that roundtable discussion? You will have a group.
- See in this building, the once a month roundtable discussions with the residents.
- We have service coordinators, a lot of support staff, most have relationships with our residents. They trust us. *L – So have a meeting with [service coordinator] to tell her about our study? [lots of agreement]*
- Don't want the same people all the time. Let people ask questions of her. People coming together to tell us how they solved the problem, or doctor done something that helped them.
- How many people would come if you had a \$25 draw?
- [Agreement that incentives like food help, but not all the time...]

5. What is the best way to disseminate the study findings?

- Meetings
- Beacon [newspaper] is very informative [general chatter]
- Centralize their interest.
- Flyers, we are inundated with flyers. We have a monthly calendar of activities. This [focus group] was on the desk in the lobby.
- Word of mouth would also work. We would come and tell others about it to get bigger crowd.

LVIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

L – Any other topics you'd like to discuss?

- How chose right walker?
- Depression

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

LIX. FACILITATOR/CO-FACILITATOR REFLECTIONS

This was a full group, and many of the participants thought they were going to receive information about mobility impairment and assistive devices. Despite this belief, the respondents seemed to understand the purpose of the discussion and stayed on topic. As with some of the Bon Secours group, a few participants from this group mentioned that there will be people who just don't want to be reached or can't be reached. They encouraged us to either forget them and be happy with the people we do reach, or partner with people who are able to access these despondent individuals or explore therapeutic methods that will bring them to a state where they are ready/willing for engagement. This group also offered a common theme from previous groups – that we should provide the target audience with information or other resources prior to asking for their participation or opinions to questions.

PCORI Phase 2 Focus Group

Focus Group Category: Visual impairment

Day/Time: February 9, 2012

Location: University of Maryland Department of Family and Community Medicine

Facilitator: Liz Jansky

Co-Facilitator: Paula Darby Lipman

Number of Participants: 3

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let's begin with introductions.**
[None]

LX. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- At request of my physician and because I enjoy being of use in research
- Here because my husband asked me to come and it's good to get our perspective
- My doctor asked me to, think it is good to give a good...[trailed off, uncomfortable].

LXI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[None]

LXII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- The community we represent is as approachable as anyone else. It's how you ask them so you can access them. And of course when you ponder vision impairment there are different degrees and people communicate in different ways. There are some standard methods like email, some want access to surveys in braille or large print or alternative media. The basic answer is approach [us] like everyone else. Access them most effectively.

L – So depends on their level of impairment...?

- Level of impairment, training, experience.

L – Training?

- Educational or other experiences, [whether they have] access to assistive technology. Disproportionate number [of vision impaired] are underemployed and lack access to training so the methods will depend on their life experience. Avoid painting with a broad brush; look for what individuals ask you for. It's complicated; need a plethora of options to access people as much as possible.
 - Already covered [by other participant] in terms of logistics and approach.
- 1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?**

L – Do you think there are people in your community that we reach in an array of ways, but still resistant to participating?

- Let them know you are willing to listen to them and take their recommendations into account. It is helpful, especially if you ask them in advance. Ask what they need to participate fully in the research - transportation, materials or whatever they might need to part in the project.
- It is not my experience that people in our community are any more resistant than anyone else and may be a bit more amenable because society has taught us through assistive technology to come forward. [Gain] credibility by collaborating with entities that work with the visually impaired - rehab services (e.g., DOORS), consumer organizations, special educators (youth), the library for visually impaired and physically handicapped. To lend credibility to what you are saying.

• Especially if there is food [laughter].

L – You mentioned transportation, and braille and other assistive technologies to help bring them to the table?

• They know they can participate fully in the project. Know that you will acquire the items we need to help us.

L – That is part of our entrée when we approach community, to know challenges...?

• Different needs

• Enhance the entrée; know you are sensitive and thoughtful.

L – Would these methods reach all parts of community? Unemployed...?

• Go to rehab agencies, library for the blind – great resource of unemployed. [Unemployed] have discretionary time, senior centers; all give you access to some of the community. We are no more hidden than other distinct and disenfranchised community.

L – Does it help to have someone like you [participant] to be the bridge?

• Don't have to have me but it doesn't hurt. I have responded to study invitations that did not have a liaison from the community. It comes down to how open minded the person is to represent the whole spectrum.

- 2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?**

L – How can we decide what our research questions should be? Our topic may be health, but is there anything in particular we want to study...?

- The blind might be interested in how to access information about health, nutrition label type things, what food is healthy, especially for those without access to the internet.
- And issues of privacy that you might encounter in things like HIPAA legislation. Friends come to me as an attorney. [Sidebar] When I say blind I mean the entire spectrum of visually impaired... there is some discussion of what language to use but shouldn't worry about it too much in my opinion. There's a lot of angst in the community about HIPAA and the lack of education that general health care professionals have about vision loss. Misunderstanding, transcends the health care community, [many] think blind have other intellectual disabilities. People then don't deal effectively with HIPAA and privacy issues; they are not sure that they can sign the form appropriately. This could be managed with a little common sense.

L – [used participant's discussion of nutrition among the blind as an example we could focus on for our research]. Then what is the suggestion about how to find out what people want to know? Give them examples and have them choose?

- Sure, nothing inherent in blindness that would restrict methods. We have as broad an interest as anyone, may be more vision related, but could be "my blind grandmother has cancer." Don't prescribe narrowly but may veer toward ideas re: vision. Like you would with anyone else - give list, do surveys...
- Ask what top 3 things are most important to you as relates to health, and then have sense which issues are most important in this community.

- Get content suggestions but going to physicians with blind patients. One common denominator may be things that cause blindness like diabetes, obesity...[these conditions] show up disproportionately in the community. Nothing distinctive re: methods for securing topics.

2b. Are there any other ways to get people to talk about the goals of the project?

L – [Summarized options mentioned]. Any other ways to solicit opinions about our research questions?

- Organizations and newsletters, may have addressed this already.
- Put survey in targeted publications to reach community...[gave examples of publications]. Also the library might have a newsletter and could say they are soliciting information about a research study. Ask doctors to solicit their patient's on what they would like to discuss.
- *L to different participant – “your doctor approached you?”* Right. Agree with ideas just said...library, blind industries and services and DOORS...

L – Is there a problem re: access for people not getting out of their homes, and if they don't have internet, how to get their input?

- [People] are often sent to homes for older/blind (federal program); there are other home visiting programs but the older/blind is principle one. The truly housebound without travel skills really rely on their families. If you say globally to the world do you have someone [who is inaccessible] in effort to catch people who fall through the cracks. “Are there people you know in your family or otherwise that might not have access to this information?”
- Baltimore Sun. Blind person in their family sequestered in a dark room...
- I can walk down the street and people say...“I have a grandmother who is blind” or “I have a blind person at work... do you know her?” [laughter]

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

L - How pick which approach?

- How do *researchers* pick which one? Encouraging if you want community buy in – use to get their perceptions about what is important. Do it same way you solicit input if you want buy-in; otherwise researchers decide how they usually do.
- Depends if we wanted to compare to previous research, or is current research going to have a different outcome...
- Don't know...

L – PCORI does truly want community buy-in -- whatever research project we come up with.

- In blind community, then reach out to consumer organizations (e.g., Institute on blindness, Mississippi State has institute on blindness and research). Either grassroots or institutes doing blindness related research to get ideas of what would truly be valuable instead of marginal obscure stuff, instead of how we can deal with 75 % rate of unemployment.
- Has no meaning to us at all, one bizarre statement after another. Ask what is most meaningful to you then maybe you can add things up and then find the most common result.

3. Where would we go to find this information?

L – How decide collectively what goals we are trying to achieve?

- Are you trying to enhance quality of life, or trying to engage restoration of sight to mitigate blindness? When I am invited to do research I look to see whether I sense if there is a philosophical underpinning – I don't have trouble with research to minimize blindness but don't want to participate if it condemns blindness as inherently bad because they think blindness can't be coped with or managed. Not comfortable about that approach.

L – Is this true if you are my research colleague or a [study] participant?

- Both

L – Then, will we be making some decisions before we approach the rest of the community?

- Yes, we should think about what are the philosophical underpinnings, if what we are trying to achieve reflects what we think about blindness.
- Would say that there are people who might want to focus more on research to correct vision but as far as me as a research associate I agree with [other participant] – people are comfortable with their blindness....

L – I recognize there is another perspective; but are you saying you as a researcher would want to be comfortable with the goal?

[Note: 1 of the participants leaves]

L – How decide what approach to use?

- ...I am a little confused...

L – [Described some interventions re: obesity – playgrounds...] How do we gather input to decide which approach to use? Particularly from blind community?

- Mechanisms we have talked about, and then talking to people in blind community, professional community, rehab and social work communities so they are aware. Solicit their involvement through mechanisms we discussed.
- If you are asking through their doctors and asking them to participate, they are closely related...

L – You mean the doctor is a proxy?

- No, not representing the blind person, but providing different ideas on how to approach....work with....
- Using the medical professional to enhance the credibility of the work....is that what you mean [to other participant]?
- Yes [reply]

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

L – Where are we going to get our data from? What are the places (beside from the participants) to get data to see if approach is working?

- Go to the 3-4 institutes I listed, a variety of academic institutions. Get numbers of blind people, vision loss, number who read braille and any number of things depending on what you are studying. American Foundation for Blind in New York City, American printing house for the blind in Kentucky has data on kids K – 12. Go to AER for data about rehab and education; go to BANA – braille authority of North America.
- Different organizations focus on different aspects. Educators for mobility, how to get around; know specific aspects about people's life.
- Can get data on RP, macular degeneration

L – This sounds like national level data; what about improving local context, our neighborhood?

- Most could give geographic specific data. Locally best bet [to get data] if they can transcend confidentiality. The library for the blind, and the local state vocational rehab (for people who are old or seeking employment), or local school data.
- American Foundation for the Blind
- Can use census data, the national compendium on disability statistics, or internet.

L – To paint the whole picture...

- Yes

L – Let's pretend we want to study HIPAA; how describe study so they know our data are confidential?

- Provide the information in broadest number of formats available - electronic, large print, braille, recorded audio, or offering someone to read it to you. As long as they can access what's there they will be fine and appreciate that they can do it as independently as possible in format they are familiar with.
- Provide [information] ahead of time. All the information you need even before you come.

L – Should we have provided the consent document before you arrived today?

- In an ideal world sure. I am not worried it's that big of a deal; but if it was a drug study might want to know all the information. Read consent word for word if you have the time. If skimmed I assume you are not telling me what is negative. But ultimately there is nothing that any single blind person will tell you that will apply to everyone. Makes it both hard and easy – you can't create a general protocol - but easy because just need to ask them what you [they] like.
- May have to deal with blindness but could deal with other limitations such as mobility; ask what they need in advance.

L – Let's say now the study is done and we want to make sure everyone learns about findings. How do we disseminate messages to people in the community?

- No other new method....but haven't mentioned listservs that organizations have, magazines, newsletters, websites. Just the target audience is different not the mechanism.
- Same answers apply just different organization you go to. Maybe to the doctor's listserv.

LXIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- I am impressed that PCORI wants to solicit feedback from such a diverse community. Important, needed, good to know that it is recognized.
- Challenges are not inherent in being blind but in access to the training they receive. The answer is probably you can do it just haven't been taught how or have low expectations for yourself.

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[None]

LXIV. FACILITATOR/CO-FACILITATOR REFLECTIONS

The 3 participants required some assistance signing the consent form. One informed us that he just needed to have the pen placed at the location for his signature and some idea of the size of the space to sign. Part way through the focus group (Question 2a) the participant who was most involved in the discussion began using the "blind" rather than visually-impaired to describe this community. The participant who left before the discussion ended needed to leave because of transportation.

PCORI Phase 2 Focus Group

Focus Group Category: Vision Impaired

Day/Time: February 13, 2012 at 5:30pm

Location: University of Maryland Family Clinic

Facilitator: Jennifer Huang

Co-Facilitator: Liz Jansky

Number of Participants: 5 (2 female, 3 male)

Number of Observers: 2 (Beth Barnet, Steve Berberick)

Opening Statement

- **Before we continue on, I want to stop and see if you have any questions about what I've said so far.**
[None]
- **Are there any questions before we get started? [Answer any questions that may arise]. Great, then let's begin with introductions.**

[None]

LXV. INTRODUCTION

Let's first go around the room and have each of you state your first name and tell us why you decided to come today [or for nurses/physicians what type of hard to reach patients you serve.]

- His wife read the notice about this and has always been interested in healthcare and thought they should do it because of her interest. He thinks it's good to do to get their voice out into this kind of research. *J: Where did the notice come from?* My wife told about it. I think it was an email on the listserv. It was a letter sent from the Baltimore Chapter of the National Federation of the Blind, sent by Dan Frye.
- Most of my career has been spent trying to convince companies and organizations to incorporate the needs of people with disabilities in their programs. So I felt that I had to come.
- Referred by their physician and her daughter's pediatrician. They do a lot of this stuff with this kind of advocacy stuff through their involvement with the National Federation for the Blind. When this came up, it was a up our alley. We had a lot of positive experiences with the UMD hospital, and we said, "hey, if there's anything we can do to help at educating the staff more," so when this came up, it was a great opportunity.
- One of the things with blind people is that people say, "Boy, do we have this great idea for blind people." But then when you hear the idea, you say, "Did you really talk to any blind people before you came up with this great idea?" because from a blind person's perspective, this great idea is really not that great. So the opportunity to meet with you and to give back is always important, because one of the things they strive for is to break down misconceptions about blindness and about what blind people can do or not do. We like to take advantage of opportunities to educate people.
- I come from Egypt and I had some personal experience with visual impairment, but the trouble was back home, they did not appreciate this problem and my voice was simply not heard. And when I came here, I was fascinated by the difference in terms of how people really care about people with impairment. I believe very important insights come from people hard to reach patients.

LXVI. SCENARIO

- **Do you have any questions about the scenario before we begin our discussion? [Answer any questions that may arise]. Great, then let's begin the discussion.**

[None]

LXVII. FOCUS GROUP QUESTIONS

1. How would we get [your friends and family/ people in the community] to talk about what's important about [obesity, cognitive impairment]?

- In our family, it's not a difficult subject. It's almost a constant subject. With the number of chronic diseases that we represent. It's not hard to start talking about health; it's kind of nice to stop talking about health [laughter]. I think in general in our family, we don't think of ourselves patients. We just think of ourselves as people who happen to have certain conditions. And in general I see a lot of, sort of a divide where people are referring to the average person as a patient, thinking of it from the clinical model. And I think that in itself is pretty alienating regardless of what the disability is.
- The whole time we've been here, you've been using the word community. And I presume by community, you mean people that are visually impaired and have blindness. Is it a correct assumption? *J: That's tricky. I think it's however you want to define it. I think some people would define it that way. Some people may define it as their neighborhood; some people if they are part of a support group online with people they never met*

who may live many states away could be part of their community. So it's always kind of a tricky term, so it's however you define it. We'd just like to hear your perspective about it.

- One of the ways we learned about this topic itself is from someone who posted it on a listserv, on email listserv. So online, for those who have the technology and those who have the ability to be online. So blind people in general do rely a lot on online interactions, but then you have a great group of blind people, and I'm talking about the blind community here, who don't have access to computers and don't have the technology and training, and that's a whole different population there which would be left out. But for me and my space, it really is via an online canvas -- a printed online bulletin board, something in a pamphlet, something printed in a magazine. Those items, they'll get to me. If it's accessible, that's the way the data gets to me.
- I think -- because I was defining community for this purpose as our blindness community -- I think in the community just like in the broader public, we always talk about how it's a cross-section of society, so you're going to have people who are cognizant of their physical health. And people on the opposite side of the spectrum just like you would in any other population, but I think within the blindness realm, there are some limitations where we don't know what things are out there, so if you're not someone who takes an active role in your health and trying to research things and asking questions and following up with your physician, you're not going to have as much access to things, like at the doctor's office, you're not going to be able to see the bulletin boards or things like that that help to educate yourself.
- I would say, in terms of the community too, that generally people don't like to think of themselves as a community because that seems to imply some sort of general mindset and cooperation, and there's so much diverse opinion and perspective. But also, in terms of visual impairment, more than half of the people with visual impairment are older, elderly people, in nursing homes, over 80, and I think it's harder to reach out to that community. It's a whole nother subset of community.

1a. Are there other people that still may be left out, such as those who are often the most hard to reach (e.g., the homeless, the elderly, people with mental or physical handicaps, people who don't go to see medical providers)?

J: So can we talk about the elderly and people who don't have access to computers? What are ways to reach out to them?

- There are a couple of different populations you've been talking about, and the main thing is feet-on-the-ground outreach. Like going to a senior citizens home and doing a seminar about health, healthcare, going to them and presenting to them. Another group is the young male demographic who, I can't tell you the last time I went to the PCP, because we don't go unless we're about to die or get run over by a car, so there's always going to be that group that's -- and for all the young males, that's just hard because we think we're invincible. No matter how much we see in health, I think the thing that actually has started to make me think more about healthcare and my own personal health is actually having a family. Despite hearing all this stuff before. You've got to take better care of your body; you've got to do these things. You ignore some of those things until there's a reason to. So for the senior citizens, it takes actually going out and finding them. And same could be said for the community of blind people. We're part of the National Federation for the Blind and we have chapter meetings every month, so finding the pockets and going to them is sometimes a way to make it work.

J: Is it difficult for a researcher to go into the meetings? Does there need to be a connection established?

- I think you can find chapter presidents online like on the NFB website. It's a simple matter of reaching out to the chapter president and saying, "hey, we have this." We're always looking for program ideas, either at the chapter meeting or they can put it out after chapter meeting, we have some researchers who are trying to do studies.
- The Baltimore chapter meeting has already done something like that, on diabetes. We had research participation for websites. There was one on a sleep test, so I think it is just getting connected with that as a resource that researchers can get involved in. I think a lot of the NFB affiliates would be interested.
- It's like a huge network, like the AARP of blindness so it's very powerful, in every state.
- There are other groups too -- American Foundation for the Blind, American Council for the Blind -- NFB is the largest one but there are other little sub-groups.
- The one other thing I would say too and something we used in college, on activities boards, is if you want a crowd, give them free food. Free food brings people. It's ridiculous!
- One way to conceptualize this whole process. I think researchers mostly think about how to reach out to visually impaired populations, but the other strategy is to attract them. These concepts are quite different

because in order to attract them is kind of a challenge. And example is like putting forward, understanding what are the demographics. Where are they? By, for example, blindness, visual impairment, [other stages of visual impairment], every kind of vision impairment, and seeing where are they. And once you know where they are – of course there's a portion part where we'll never know where they are -- but at least you can kind of get a sense when you find this sample can get you the next sample. It's kind of a networking opportunity.

- When people are blind, you have people who are well trained and who can get out and get around, which is a growing percentage of the population. But then you have a percentage, which I think is the majority, who can't get out and don't get around. And even if there was a notice to come for free food at this particular place at this time, you couldn't reach them. You wouldn't even know about them, perhaps. These are the people in the nursing homes, or those in those kind of shelters. So to get to those people, you really have to go to them and go to those places, like a senior center, where they have supports for them already and they don't have to worry about travel. I think that group might even have different perspectives on what's important to them healthwise than the population is mobile.
- Another way to reach people in the blindness community, although I guess it doesn't necessarily have to be in the blindness community, you partner with, get in touch with the vocational rehab agency in the state. They won't give you the contact information but they can pass along the information to their clients. So you can reach people with disabilities. For students, you may be able to contact the disabled student services office, and again they won't give you the contact information because they can't but they can pass along information to the people who receive services there.
- There is also different state libraries for the blind and the National Library of Congress has Braille books and recordings for the blind, and those are really good places for certain populations, like seniors, for example because maybe they're not identifying yet as being blind because they've been sighted their whole lives but now they're losing their vision but they're really adjusting to it yet or identifying as being blind, but they'll use those services because they're free to read newspapers. There are also like radio newline services. Or maybe those programs, because they're free and they'll benefit from them. And they can use them anonymously without having to identify as being blind.
- And the ALS program is for people who physically can't turn pages, so again, blindness is the main source but there other groups.
- In terms of getting the researchers to really understand populations whom they want to reach out to, I can't think of a better way for them to attend a conference, like a national or statewide conference, where there are people with disabilities and advocates working together. They really understand the community, not just from a textbook. But they sit around and figure out what the real problems are and the real concerns. That's where you're going to hear about them. That's where all the advocacy and discussion is happening to set policy.

J: So getting into the discussions and really listening to the voices? Right. Being there.

- That's one of the problems we have with the ophthalmology field, but other doctors like even pediatricians. Doctors are fixated on fixing things, and if you can't fix the problem, it's the worst case scenario. So doctors feel that they've failed because they can't fix if the person is blind. So by attending conferences, it would help us because if doctors knew the way to refer those patients to make contacts and to get people the things that will help them now. Like there's research going on and that's well and good, but that's not here today. And people need to live today and people need to know how to live their lives today. It's the other aspect of how do you help this patient live today. A lot of times we haven't gotten the medical field to make that connection that this doesn't have to be a failure because I haven't figured out how to solve this problem. That I can help this patient overcome this, and if someday the medical research catches up and there's a cure for blindness, that's good, but until that day comes, we have to people to know how to live today with it and not treat it like you're gloom and doom.
- When I'm hearing [participant] talk, it seems like being really patient centered, but some of the research that's going to go on and hopefully will go on won't just be about clinical interventions but it might be about educational rehabilitation that will totally change lives if people can understand the best practices, just not fixing the physically piece that's not working. *J: So it almost sounds like the needs are not aligned with the researcher, but if they actually listened to what this person's needs are, then they would see there's a huge disconnect.* [general agreement]
- During the course of discussion, two practical ideas came into my mind. I think if a researcher wants to look for a blind person, they should put themselves in his or her shoes. Let's say for example, I am visually impaired, but how will I know about this research opportunity or having my voice being heard. I think the first way, if I'm being contacted by a disability office in that institution (e.g., someone from a university setting who

probably knows about your presence), but the smarter idea is that someone probably knows someone who is not visually impaired, such as a spouse or living with a friend or family, and is probably a caregiver. Therefore, reaching out to this person can serve as a more efficient way to reach out that person, especially those who are not in the community and always indoors. *J: Is it hard to find those caregivers?* I don't think so, because caregivers are by definition, out and about everywhere in the community. They go home but it happens that the people they're living with are having these problems. For example, do you know someone having trouble seeing? If yes, pass this information to them and let them know there is this opportunity. Other than just going directly to that visually impaired individual because the challenge is how will he or she know?

- That might be an angle to get to the elderly population, because they have children who are looking out for them. I was thinking out in the community, cab drivers know who the blind people are, the banks, the grocery stores, they know who their blind customers are. They're amazingly connected.
- This is more of a different, long-term approach, but [participants] used to work for the National Federation of the Blind so we're always trying to do things to advocate for blindness in the public. But going in the healthcare arena, doing things like educating in the university field so that doctors who are coming up in optometry, nurses, so that when they come across – definitely across the board for all medical personnel but especially those because that's where the blind person is initially going to come through, they know how to deal with this person. So maybe educating those people about resources that are available and talking to them so that when they run across these patients, they know where to refer them to. This might not necessarily work for research now, but that would be a good long-term strategy

J: So do you think all this type of work that means really understanding these people's lives and these needs, do you think that this type of work needs to be done before they even try to go out and engage people in research projects?

- There are tons of research projects going on about blind people, but those are usually specific about that person. They're not usually being included in general research. Let's say there are studies going on about like arthritis. Somehow, everyone in that study is completely normal; it's not like they take a cross-section of the community. They're like hand-selected. That's why I really think it's critical to include more people with disabilities in that type of research. Because the rest of the different populations, we're pretty small in different groups and we become sort of an obscure, irrelevant sub-population of what the healthcare community even thinks about. It needs to be integrated to get the very best. For example, insulin pumps, those were developed, even though there's a huge incidence of blindness in diabetes, none of the research in developing the insulin pump and how it works, the consumer interface, was done to make sure it included the part of the population who's really going to need it. They have not been included in the research and the pilots.
- I think why it's important to do some of this background before you do, we were approached by someone who created a new kind of cane, and they thought it would be really great because it had these sensors and give you these kinds of cues, but it was designed by a sighted person who was thinking about worst-case scenario that had to do with blindness, like, "if I was like this, how would I function?" without actually knowing what it's like to function as a blind person, so when they brought it to our organization and had us test it out, it wasn't something that we even wanted to use. So maybe knowing a little something about the group that you're targeting beforehand would have helped out the research.
- Because of [participant's] point about especially not just blindness related studies but in general, because about, we have to consider making things accessible because a blind person may need this someday. Could a blind person use this? I will tell you that I probably would be more interested in general health studies than I would about [eye condition] because there's no cure for it. I don't care. If it's about anything else that I'm living with today with what I have and what I need. Sometime in the future, if there's this perfect cure for it that doesn't cause me pain for the next 20 years of my life, then that's fine. But I have to focus on the other things and being involved in my health care on things that maybe will affect me, whether I come down with diabetes and get equipment that I can't use. Or from the pharmacy side, how do I identify the prescription labels, how do I identify the medication with technology that's currently not there.

J: So that's a lot of good information, about what kind of background work needs to be done up front, and making sure that all types of research needs to include everyone.

- It's not only up front, but it's hard to find these patients. They're hard to reach. If you go for it one time before it starts, then you miss opportunity to engage them afterwards. One patient can give input in the middle, in the end. The timing would be very beneficial throughout the whole process. It's a loop.

2a. What are the best ways to get [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/parents] to identify the most common problems and decide which ones we should study?

- I think you basically give people a survey. Survey your potential group to see what their concerns are. Are you going to please everybody? No, probably not, but you're going to find out what the majority of your audience is concerned about. *J: Do we put it out the same way that we used to engage people?* Yes, I think we would. And it may be that the first time you go, you bring that with you and then you have a hook to follow up, like, "The last time we were here, we went over this survey" and then have a more targeted discussion about this issue. So maybe it's something you do that first go round. You find a way to provide a survey. If it's a blindness-related group, you may need to think of different ways to provide that survey. On the listserv, it can be emailed as an attachment and people can fill it out and maybe bring it with them. You may need people to come with you to be readers to help people do it at the event. If you can get it in braille, bring it with you to the event.
- If you're going to use technology based like an online survey, you're going to limit the population who can access it, but even for those who can get to it, you need to make sure that whatever's done online has to be done in an accessible way. It's very easy to create something online that's not accessible [general agreement]. And then you have transportation issues if you're trying to get everyone together to fill out a survey, you're going to miss a part of the population. So I always think the great equalizer is if you can get phone numbers. Everyone, unless they're blind and deaf, can talk on the phone. You don't have to worry about transportation issues, and so on and so forth.

J: If we do a phone survey, does the phone call need to come from a particular organization?

- The question about the phone call idea is that I don't know how easy it would be to get those numbers from any, I don't think a rehab center would ever be able to give out those numbers. So I think it would be a step to contact the agency and let them know, and they can make the contact and see if they would feel comfortable giving out their phone number. But if that steps cleared, then I think the phone is the great equalizer.
- Once someone volunteers to be part of the study, then the phone is a very good way to communicate.
- There's always that issue of the response rate in any survey. If you can get the mail and read it, probably you're going to throw it away. Having to participate in a phone survey, one day you're home, the next you're not and then the third time you don't want to do it. The whole survey is one way and is an important way, but we have to bear in mind the response rate issue. The other way is to go for the caregiver. This is key to ask whatever it is that you want to ask. Also there is this online forum where people will share their thoughts, and they express their view upfront. *J: Would it be to look at their responses online and look for themes or do some sort of survey through that online forum?* Well, you could do both, but I was thinking the first, like observing passively what they say. And the other thing is that when you're looking through the list of diseases, you're not going to please everyone. So generally it'll be related to disease prevalence. The more people have that disease X, the more people are going to talk about it. So prevalence studies can also serve, regardless of being blind or not, people will usually talk about the disease if they have it or if they know someone who has it.
- To figure out where to put the research effort and money, statistically you can get the most prevalent conditions but you could also be missing some really critical, lower incidence conditions that are totally disabling or really affecting people's lives debilitating that may be more obscure so it can't just be a popularity contest. In terms of caregivers, I just throw out the caution that caregivers may have different opinions than the people they're caring for, so try to get as close to the source as practical. You may use the caregiver to get access to the person, but I know that the parents of children who are blind have totally different opinions of what the problems are than what the kid thinks.
- And I know a lot of people who don't live with a caregiver.

J: What about seniors or children, does it make sense to look at the caregiver's perspective and then also try to get to the source and see if they match up, or is it still best to go to the source?

- I think it's best to go to the source. I guess the best way to say this is that we don't know what that person's going through. The only person who knows what that person wants is that person, and sometimes much the same way, my parents and I differ on how concerned I should be about my blindness in a great way and the same could be said for a senior who is losing their vision. Their child could overact when the parent is doing just fine, so I think it's always best to always go to the source.

2b. Are there any other ways to get people to talk about the goals of the project?

[not asked]

2c. We know that there are a lot of different things or approaches people do to become healthier. For our [study/research project], we will need to decide which of these approaches make sense for the community and that will achieve the goals we're hoping for from our project. To make this decision, what would [you/hard to reach patients for whom you provide care/the person for whom you are a caregiver/your child] do differently to get everyone's input on which approaches we should study?

[Are there other new methods?]

- I think it really depends on what you're looking at. For example, my mind started thinking about what are some target issues that are relevant to the blind populations that I could see, like childhood obesity with blind kids. I know that's a problem across the board, but particularly with blind kids because they don't get out and play enough because they don't have the mobility skills, they don't have the peer skills. They don't know how to overcome it, but they can learn. So in that situation there may be a higher rate or in the adult population, they may not have the travel skills so they order take-out all the time, so I think you have to look at what your issue is. *J: So like tailoring our approach to the needs of the different types of people?* Yes, because I would say in those situations, I would say that the intervention would be teaching the people about blindness skills – how to travel independently, how to advocate in a social setting -- but the researcher might have a totally different approach but that which is maybe not necessary. Like the playground is a great idea, but the blind child doesn't know how to get around the playground and won't use it.
- Not only that, but the researcher has to set the high expectation, but the people monitoring the child has to have high expectations. You can build the playground, but if the people who are around that blind child think that blind child is going to get up and do things by themselves, nothing's going to happen because the child still is not getting activity. [personal story of participant having to go to adaptive PE and playing a board game 3 days a week with someone with Downs Syndrome, despite being on the wrestling team] So it's high expectations and hold them to the same standards that you would hold any other group. The blind child needs to be held to the same standard of treatment and intervention that the sighted child is being held at; otherwise, the results aren't going to be the same.
- I think one concept about research seems very far away from the average person. And so much about your language about research, I think to reach more average person, I think you need to drop the word research. I think you should say "patient centered" or "person centered" or "consumer centered solutions." There really needs to be the bottom line solution.

3. Where would we go to find this information?

- This is kind of something we ran into a lot. We wanted to do research but there wasn't a lot out there for a baseline, because I don't think a lot of people do a lot of research where they actually consult blind people. So I don't know if there are a lot of ideas.
- Well, to come from the legislative point of view, you can try to mandate that as part of physical education at school. You people have to take some sort of BMI or get tested, that way the research would be there from year to year. But that doesn't tell you why I'm no less obese from year to year, but it would be a thing for that particular. And I guess test people's blood pressure. But if you're looking to get research and you're not going to be able to track that student from year to year, you can always try to get a mandate for physical education, and you tested kids for something and that way HHS can get that information.
- I think in terms of getting data points, if your average population you're having everyone fill out a form every 3 weeks, but a visually impaired person can't get that data back to you, then you have to figure out another way to make it accessible. Sometimes the technology to see improvement, like not having a scale to weigh yourself with voice output, is just not available. If it's just about gathering the data, I think it should follow the same pathways but making sure it's going in an accessible way.

4. What is the best way for people to understand what our [study/research project] is about so that they can decide whether or not to participate?

[Not asked]

5. Best ways to disseminate information?

- There's the Journal of Vision Impairment and Blindness and the Journal of Blindness Research. Those are two resources for others who are looking to do research. There are libraries that have newsletters or recordings that go out to their patrons. There are places that sell accessible products like for diabetes, so maybe putting some information in their literature.
- I think disseminating in a means that doesn't rely on vision, so like radio or TV. And don't put them in these small banners at the bottom of the TV screen. If someone says it loud, that's much more meaningful to this population. But to the general population, magazines and journals but not just in scientific journals, like Reader's Digest, talk shows.
- There's a new technology called Anything Newline for the blind. You call up this computer and it will read to you like 800 newspapers. It's all free. But they also have individual local channels, so they have channels for different regions, Maryland Information Channel. Or there's a national channel if it's really big.
- It's like over 200 newspapers, international newsletters, mainstream magazines, like Parenthood, Sport and Fitness magazines, that are more of your mainstream things that are good things to put your health topics
- I think going to the regular media is a good thing and is always wanting to report on good or bad. And to have the multimedia research. It may be the blind targeted community person who may not see it, but maybe the brother sees it.
- You can't underestimate the power of peer communication because there's such trust there.

LXVIII. CLOSURE

Those are all of the questions I have for you. Thinking back to our discussion, is there anything else that comes to mind that we didn't already talk about?

- A lot of issues about including people with disabilities into things has to be at the policy level, at the top level, because it will trickle down. You can't just have one little office over here in this one little corner that's supposed to make sure that the university's accessible or that the company is. It really has to be very top-down. It has to be checked or it won't happen. Accountability. And including researchers with disabilities in the research is very powerful, because one person properly placed can have a lot of impact.
- And the other thing I would say is that if you're doing the research on blindness, you're really got to get a cross section on older younger and realize going into it that the experiences of those blind people have been different as far as what type of training they've had.

We have a few minutes left to go back to topics we put in the Parking Lot. Let's start with [refer to list].

[nothing in parking lot]

LXIX. FACILITATOR/CO-FACILITATOR REFLECTIONS

These participants were seemingly highly educated and knowledgeable of research. As such, they quickly grasped the focus of the discussion and there were almost no irrelevant conversations. Some important themes that emerged are as follows:

- There was considerable discussion about the importance of understanding who the target audience is and what their needs and interests are as a step PRIOR to conducting methods of engagement and participation in the research process.
- Given the diversity among the vision impaired, it was difficult for the participants to think of the "blind community." As stated in the first vision impaired focus group, similarities among blind people are often categorized according to the level of training they have received (ie, how well they have learned to adapt to the sighted world).
- As with the African American groups, the idea that young men are not interested in health because of their belief of "invincibility" could be a barrier to engage them in research. It may take an influence such as having a family to generate their interest.
- Aside from the particulars relevant to this population and their needs, the general methods of engagement, collecting input and dissemination were similar to those given by the other groups.

F. APPENDIX F: Synthesis of Summaries of FGI/s from Appendix E

Methods to Engage Hard to Reach Patients	Caregivers	Parents	Vision Impaired	Mobility Impaired	Cognitive Impairment	Low SES AA	Bilingual	Faith Based	Physicians	Nurses	Hearing Impaired
PLACES TO GO											
Church											
Senior Citizen Centers											
Adult Day Care											
Nursing Homes											
Schools/after school programs											
Transitional housing											
Homeless shelters											
Jail/Department of Justice/Parole office											
State vocational rehab agencies											
State libraries											
Libraries for the blind											
Community/Recreation Centers											
Markets and Grocery Stores											
Corner stores											
CVS/RiteAid/Payless											
Hair salons/barber shops											
Doctor's offices											
Banks											
Emergency Rooms											
Soup kitchens/food pantries											
Relocation center											
Soup kitchens											
Fast food restaurants (Popeye's)											
Boys and girls club											
Immigrant-specific grocery stores											
Gyms											
Disabled student services offices											
Go where they go for their benefits											
Where you catch a bus											
Ethnic restaurants											
Truck stops											
Hospitals/healthcare facilities											
Inner Harbor											
Community bars											
Native American cultural centers											
Kiosk at mall											
Workplace											
Mobile clinics											
County health department											
Laundromat											
Salvation Army											
Community clinics											
Embassies											
SPECIAL EVENTS											
Health Fairs											
Booth outside a fair											
ORGANIZED GROUPS											
Sororities/Fraternities											
Community associations (neighborhood organizations/associations)											
National/local meetings of organizations (such as the national federation for the blind)											
Support group meetings											
Block walk to make direct contact											
Non-profits											
Community dinners											
In rural areas it is family networks above/beyond TV/radio because few community organizations											
Book clubs/card clubs											
Activist groups											

Methods to Engage Hard to Reach Patients

Give people the opportunity to think about it
 Good listener, try not to interrupt
 Talk to people one-on-one
 Get directly to the point
 Don't keep asking the same questions over and over
 Bring out verbally
 Have someone present it
 Simple networking (one sample recruiting another sample – i.e., snowball)
 Word of mouth

Being There

Persistence in the community
 Keep coming back
 Integrate yourself into the existing community networks
 Consistency in contact – don't change people all the time
 Reach out to the community/reach out in a public space

Pre-Engagement

Understand the environment and the context in which people live [Understand that a homeless people could be getting money or food, value their time-PYC 1/25/12]
 Have resources available to meet more pressing needs
 Be sensitive to your demographic
 Learn family history

Pearls

High touch not high tech
 Address stigma
 Give first take later
 Perceive patients as the experts because they are teaching us
 Do not impose views and judgment
 Build relationship
 Ask expectations and avoid preconceived notions
 Stay open-minded to not put yourself higher than the participants
 Be non-judgmental and treat everyone the same (pg. 2 BCHD and PG nurses February 6ht)
 People have to understand what is in it for the researcher
 Acknowledge that patients are giving more than the researchers are giving back

INCENTIVES

Providing Food
 Entertainment- music
 Balloons – words in the balloons
 Van's giving away free phones
 Provide transportation
 Attract versus reach out to people
 Raffle games
 Carnivals where you can win prizes
 Provide child care

INSTRUMENTATION

Questionnaires in a church
 Instruments are too long
 Take a poll
 Survey in person
 An educated person to give out the survey (someone who knows the topic)

OTHER 'UNCATEGORIZED' TOPICS

Takes too much time/minutes on the person's phone (Low SES 2/7/12)
 Know what to expect going in
 Make topic available to everyone
 GIS
 Use current medical problems as a foundation
 Dispell myths- Tuskegee



Methods to Engage Hard to Reach Patients

MEDIA/ADVERTISING

- Online bulletin boards
- Websites
- Radio/News/Media
- Public transportation (MTA buses)
- Newspaper/community paper
- Videos
- Put in an electric/utility bill postage paid
- Put information in a movie clip before the movie starts
- Community newsletters
- Facebook & Twitter/social media
- Visual pictures to get people to connect to something
- Flyers in a store
- Put on laptops for kids
- Ads in magazines
- Magazines
- Hotlines
- On the computer
- Pamphlets

INDIVIDUALS

- Cafeteria workers who work with children
- Door-to-door
- Cab drivers
- Off-highway
- Knowing the mayor
- Council representative
- Disability officers in universities
- Include more people with disabilities (pg. 6 Vision Impaired February 13th)
- Concerns of 'man in the trench'
- Caregivers
- Parole office
- Use ambassadors to take information and spread it around the community
- Spokesperson
- Friends
- Employers
- Case managers, social workers, doctors
- Pharmacists, mailman, fedex, florist, pastor
- Community outreach workers
- School based wellness/school nurses
- Social service coordinator
- Doctor
- Family

BUILDING TRUST

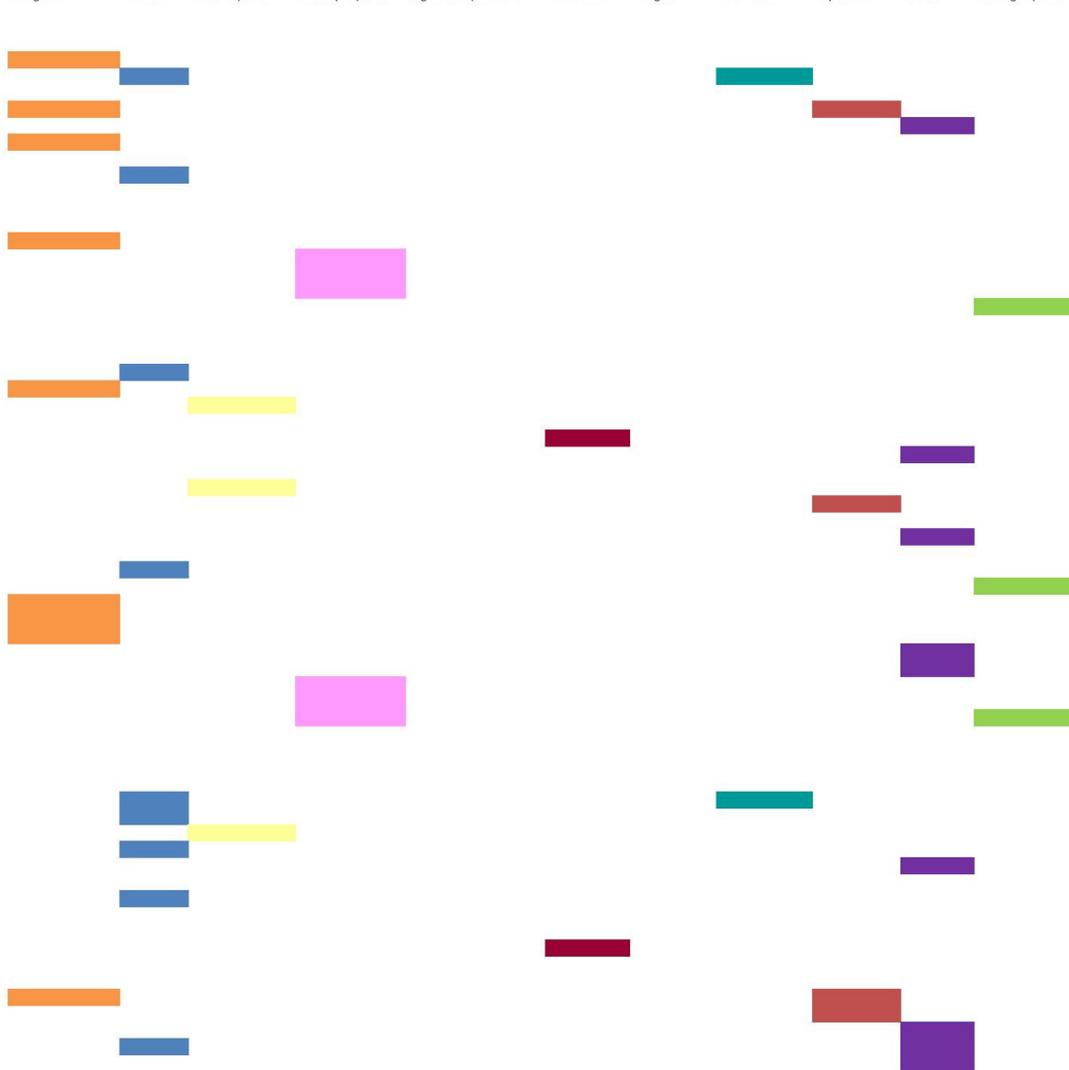
Relating

- Personal testimony
- Communicate with passion
- Philosophical underpinnings (pg. 5 visual impairment February 9th)
- Spirit with which you approach individuals
- Approach in an open and culturally sensitive way
- Have some type of reliability – look like them, come from where they're from
- Be genuine
- Understand that a homeless people could be getting money or food, value their time
- Demonstrate it
- Break down barriers

Communicating

- Simply ask
- Keep questions simple
- Talk to people selling drugs on the corner
- Read body language
- Active listening

Caregivers Parents Vision Impaired Mobility Impaired Cognitive Impairment Low SES AA Bilingual Faith Based Physicians Nurses Hearing Impaired



Methods to Engage Hard to Reach Patients

Uninsured
Partner with colleges
Be honest
WIC
Home visiting program
People must know why you care, especially when you're not from the community
Do what you say you are going to do
Do not place people in a situation where they are forced to admit illiteracy
"Be aware of what could be needed and have resources that they can be connected to"
"Keep in mind they are using you for what you can provide and are not looking to bring you into the community" p1
Share where we are coming from
Bring your family
Talk about a specific issue
Meeting one-on-one is better than in a group



Methods to ensure informants understand pertinent clinical and research issues

LITERACY AND COMPREHENSION

Individuals may not be comfortable if their illiteracy could be exposed
Have patients explain things back to you (i.e. Teach back); phrase things in their own words (Teach Back)
Have peers of the patients interpret for them
Use plain language; break it down from the medical language
Use visuals and pictures to make people connect
Have someone repeat back in their own words
Ask them their own interpretation of benefits
Be careful that they are not faking understanding and just agreeing
Do not assume because someone is educated that they will automatically understand
Give people time to think about it, talk to significant others, and get back to you
Repeat what risks and benefits; make sure they understand both sides
health literacy
be aware of dialect; can't necessarily just speak in language
if they can personally connect to what you are saying; relate risk factors to their experience
Perception of risk; they have to feel safe and they have to be able to address fear with facts
Educate them until they get to the point where they have an opinion
Be specific and ask them if they understand
Straightforward
Study, class or course for people to learn how to give out the survey
Communicate in native language- might need someone who is bilingual
Provide the information in different formats- electronic, large print, Braille, audio, someone reading it

2/8 RN;
1/24 MD; 2/6 RN; 1/24 MD; 1/25 PAR; 2/6 RN; 2/1 MD
1/24 MD; 1/24 MD;
1/25 PAR; 1/25 PAR
1/25 PAR;
2/1 MD; 2/6 RN;
2/1 MD;
2/1 MD;
1/26 PAR;
2/6 RN;
1/24 MD;
2/1 Alz;
2/14 Supl Interv;
2/7 AA_1;
2/11 Spanish
2/9 VisImp

2/7 AA-2
2/9 VisImp
2/10 MobImp
2/11 Spanish
2/12 VisImp
Didn't have time to ask
Not asked

CONSENT PROCESS

Avoid long consent forms; can make patients nervous about what they are getting into
Avoid 17 page consent form - what if risks are buried on page 8?
Avoid big words/ fine print
Provide out-clause so people know that they have no obligation
"Culturally match" the consentor to the people
Have patients consent in their own words
People may just need what you are offering and be very agreeable; they may not care about risks/benefits

2/8 RN;
2/1 MD;
1/26 PAR;
2/9 Alz; 2/1 Alz;
2/9 Alz;
2/6 RN;
2/6 RN;

INFORMATION GATHERING

Give information in chunks
Ask open-ended questions including more than a yes/no to open avenues for discussion
Be straightforward when presenting risks
Partner with community members to train individuals as advocates
"Personalize and individualize"
"research" is an emotionally charged word
Slow process; baby steps
Roundtable discussion
Give the information ahead of time

2/1 MD;
2/1 MD;
2/9 Alz;
2/9 Alz;
2/6 RN;
1/24 MD;
2/17 MobImp
2/9 VisImp

DISCLOSURE

Let them know exactly what is involved
Honesty
Be honest about who will know that the individuals participated; confirm you will not "roll them over to the man"
Check in regularly
Do not treat people like lab rats
Tell me why you are doing what you are doing

1/26 PAR;
1/26 PAR; 2/1 Alz;
2/6 RN;
2/9 Alz;
2/9 Alz;
1/25 PAR;

"it is not what you say but who says it"
"Somebody they know and trust"

2/9 Alz;
2/10 MobImp

UNCATEGORIZED

Literature
church, go to the pastor
sorority, go to the one in charge
family meeting

2/14 Supl Interv;
1/26 Faith;
1/26 Faith;
1/26 Faith;

Data that identify other factors and issue that are important to patient (or surrogates)

HEALTH AND MEDICAL

ER admission	2/8 RN;
autopsy data	2/8 RN;
health history	2/9 Alz
Follow a fat kid home and find a fat parent; familial connection	1/26 Faith;
School lunches	1/26 Faith;
Ask people coming to the hospital	2/7 AA_1
Family history	2/7 AA_1
Disease prevalence in the community	2/10 MobImp; 2/13 VisImp

SOCIOECONOMIC INDICATORS

BGE records (turn off notices, energy assistance program)	2/8 RN;
Demographic and income data	2/9 Alz
Find where people are spending their money using economic indicators	2/8 RN;
enrollment in free and reduced means (fudged many times) although we only get half of the qualifying people	2/6 RN;
stories from patients that are not routinely captured (eg. No money for prescription)	2/8 RN;
disability compensation	2/8 RN;
socioeconomic status statistics	2/1 MD;
Control, parental issue, no one is there because parents are working	1/26 Faith;
Where it is costing the taxpayer the most money to solve/what problem costs the most	2/17 MobImp
Find out where there is funding/grants	2/17 MobImp; 2/17 HearImpLiz

COMMUNITY RESOURCES

community resources (transportation /safety)	2/9 Alz
"how do you define community?"	2/9 Alz
transportation	2/1 MD;
Door-to-door	1/26 PAR; 2/7 AA_2
Baltimore's Neighborhood Indicators	2/6 RN;
Data on where communities spend their money	2/6 RN;
public transportation availability	2/8 RN;
community investment: who is building a park, who has public transportation, who shut down a community center ?	2/6 RN;
who is protesting cuts to close recreation centers?	2/6 RN;
demographics of the community, is there a community center? Are there video games or things they can do to move around?	1/26 Faith;
how many stores does child pass along the way from school? Corner store, CVS, fast food, McDonald's	1/26 Faith;
Schools	2/4 Faith; 2/7 AA_1; 2/7 AA_2
Supermarket sales; if the sales for vegetables increase? What kind of food do they sell there, produce? Junk food?	2/11 Spanish
What are the teachers teaching them?	2/11 Spanish
Restaurant options?	2/11 Spanish
Ask people at church	2/7 AA_1
Ask people at community association meetings	2/7 AA_1
Put a survey in a targeted publication to reach community	2/9 VisImp
Organizations and newsletters	2/9 VisImp
Reach out to consumer organizations, either grassroots or institutes	2/9 VisImp
"As the presenter you will have to pick out exactly the main issues that you really want to present to the public and make a choice"	2/7 AA_2
"Have a targeted discussion about the issue"	2/13 VisImp
"Try to get as close to the source as practical"	2/13 VisImp
"To reach the average person you need to drop the word 'research'"	2/13 VisImp
"Go around the room and ask"	2/17 HearImpJen
Vote	2/17 HearImpJen

G. APPENDIX G: Calendar of Focus Groups, Interviews, and Synthesis Meetings

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
Jan 23	Jan 24	Jan 25	Jan 26	Jan 27	Jan 28	Jan 29
	Physicians (CHIP)– 6PM*	MCF – 12 PM*	Mt. Lebanon-1:30PM^ Parents of Young Children-4:30PM*			
Jan 30	Jan 31	Feb 1	Feb 2	Feb 3	Feb 4	Feb 5
		Alzheimer’s Assn.– 11:30A* ABC – 6:45PM*			Mt. Lebanon- 10AM^	
Feb 6	Feb 7	Feb 8	Feb 9	Feb 10	Feb 11	Feb 12
BCHD Nurses – 6PM	AA (BSBHS)– 10AM^ AA (BSBHS) – 1PM^	FQHC Nurses – 6:00PM*	Alzheimer’s Assn.– 11:30A* Vision Impaired – 3PM^	Mobility Impaired (BSBHS)–11AM^	Spanish Speaking (BSBHS) – 12:30PM^	
Feb 13	Feb 14	Feb 15	Feb 16	Feb 17	Feb 18	Feb 19
Vision Impaired- 5:30PM^	Caregiver Interview 4PM*	Meeting of PIs to Synthesize Results		Hearing Impaired (2 groups)– 1PM* Mobility Impaired - 2:30PM*		
Feb 20	Feb 21	Feb 22	Feb 23	Feb 24	Feb 25	Feb 26
		Meeting of PIs to Synthesize Results	Hearing Impaired – 1PM^			

*UMB Focus Group

^ Westat Focus Group

H. APPENDIX H: Lessons Learned

H1. Trust is the key overarching element for PCOR

The existence of trust is key to motivating partners and communities to participate and to enrolling patients in PCOR. Building trust is not a step in the patient engagement process, but rather an overarching paradigm that needs to be ubiquitous throughout PCOR efforts. **See also Sections VIII A and 3 as well as Standard #4.**

H2. Patient v. Person

Individuals generally view themselves as individual persons not patients for a variety of reasons. In the context of their daily lives, most people do not think solely about a specific medical condition when making health-related choices. People do not like to be identified by their disease and want their care providers to address their broader concerns related to the quality of their life. **See also Section VIII D and Standard #6.**

H3. Outcomes in an unfamiliar term

Even when we used the phrase “health outcome,” we heard that the term “outcome” is not in the vocabulary of most hard-to-reach patients. In Phase 1, several stakeholders felt that we could ask questions such as: “What is important to you about your health? What worries you about your health?” or “What do you hope to achieve by taking this drug?” to get at the most important outcomes. **See also the Phase 1 Summary and Section VIII D.**

H4. Research is an abstract concept for many hard-to-reach patients

The term “research” is confusing to many individuals and has negative connotations for many hard-to-reach patients. In Phase 1, several stakeholders felt that the word “study” should be used in place of research. In Phase 2, we learned that there is a need to educate not only patients but also community-based partners and recruitment/study sites to assure that there is an understanding of (A) general principles of research and (B) the specific research project and protocol that is being conducted. It may be necessary within a PCOR study to first explain to certain hard-to-reach patients what the general purpose of research is before getting into the specifics of a particular PCOR project. **See also Section VIII B and Standard #2.**

H5. Framing and phrasing of questions is critical for eliciting patients’ views

It was a bit disheartening to learn the three of the four words in the PCOR acronym are confusing to patients. The prior paragraphs described concerns about the words patient, research, and outcomes. Beyond these three words, the framing of questions is also challenging if the intent is to elicit patients’ viewpoints regarding PCOR. It was very clear from both Phase 1 and Phase 2 qualitative assessments that careful attention needs to be paid to assuring that questions are comprehensible to patients. It is not sufficient to merely use language at the fifth grade level, but also necessary to make sure that the context of the words and the intent of the question is clear. **See also Section VIII D.**

H6. Patients come into research with their own agendas

Our project had a written research protocol in place regarding patient recruitment. Moreover, study investigators and partners explained the purpose of our research during recruitment and at the beginning of each focus group. Nonetheless, several individuals wanted to ask questions about their medical condition to either those conducting the interviews or other participants. Some patients wanted to discuss broader health or health policy concerns. In the context of our focus groups, we used “the parking lot” for these discussion items; however, when conducting PCOR, site investigators may need to address medical needs and questions posed by their research participants. **See also Section VIII B and Standard #1.**

H7. Community-based PCOR requires flexibility and compromise

We were extremely fortunate to have existing partnerships and relationships with organizations and individuals in the Baltimore community. Even with these established ties, there were instances in which our research protocol needed to be adapted to meet the abilities and desires of our partners. On the surface, need to be flexible and open to compromise seems relatively harmless and perhaps even desirable for establishing genuine partnership and trust; however, these positive aspects must be balanced with the implications for protocol violations and scientific integrity when conducting PCOR in the community. **See also Section IX B and Standard #4.**

H8. PCOR investigators should give something back to the community

PCOR investigators should be committed to answering patients' questions about their health. However, patients may have questions that are quite different than the focus of the PCOR research, as described two paragraphs above in this section. While it is infeasible to spend the time and money to address all questions that patients have, PCOR investigators should – at a minimum – be willing to present their findings in the communities where they conducted their research. **See also Section VIII A and Standard #3**

H9. Hard-to-reach patients do not like being asked repeated questions

Several times, we heard that many patients from the hard-to-reach communities are frustrated by being asked the same questions over and over. In fact, many are tired of being asked questions at all. It sets up a dynamic between researchers (or physicians) and hard-to-reach patients that has the opposite of the intended effect of engaging the patient. Alternatives to asking questions include role playing with patients and answering their questions rather than asking your questions. Addressing hard-to-reach patients' questions and concerns and providing food or other means of making the environment seem less formal before staring into research questions will likely facilitate more open and honest answers when PCOR questions are asked.

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