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

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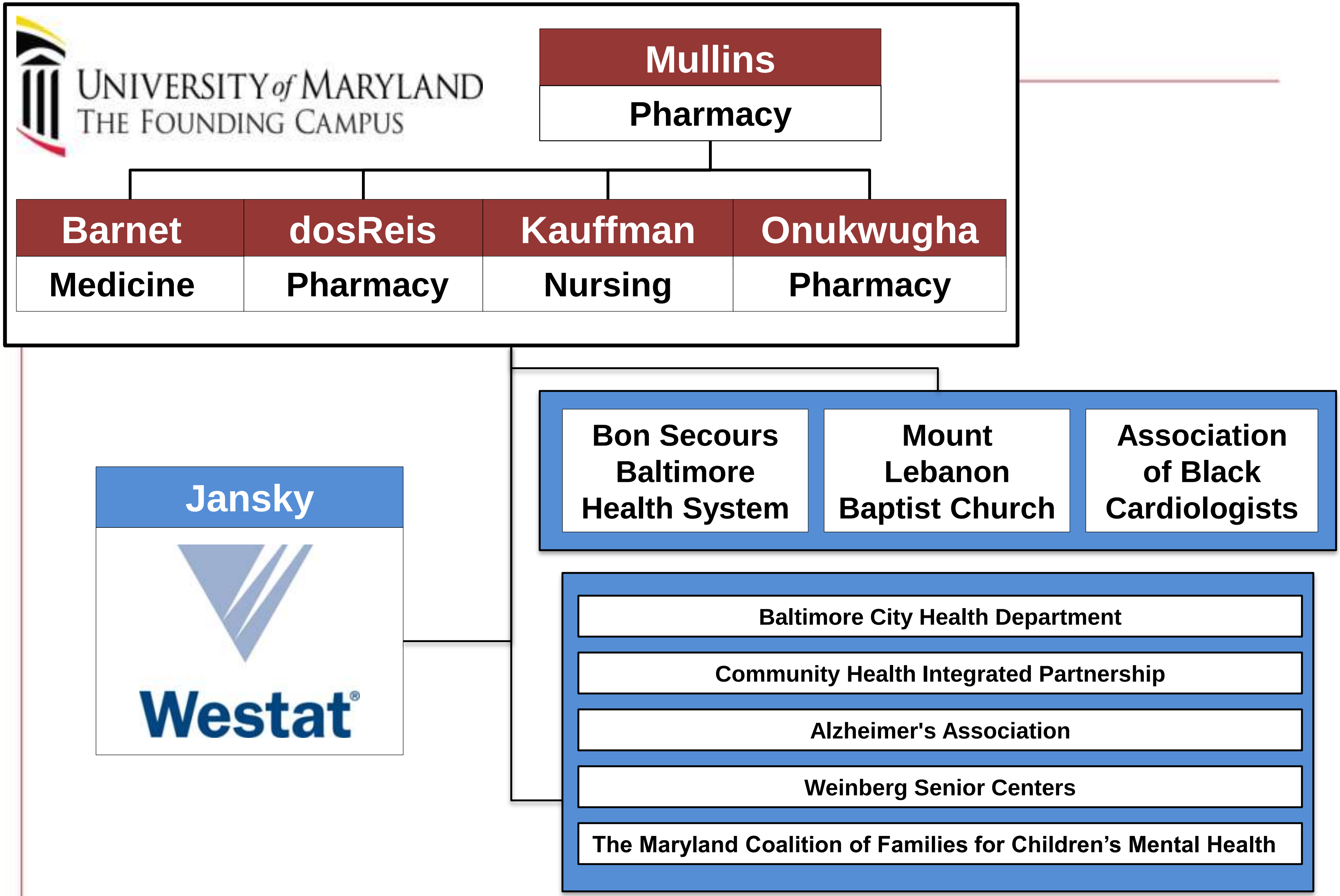

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Mount Lebanon Baptist Church

Association of Black Cardiologists

Baltimore City Health Department

Community Health Integrated Partnership

Alzheimer's Association

Weinberg Senior Centers

The Maryland Coalition of Families for Children’s Mental Health

Aims / Scope

- Focus on patients who are least likely to be engaged in research
- Conducted primarily in the greater Baltimore area with hard-to-reach patients and their care providers
- Focus groups were conducted with the following ten categories:

African Americans, predominantly of low SES

Bilingual Spanish-speaking patients, predominantly of low SES

Patients in faith-based organizations, predominantly 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 patients

Caregivers of hard-to-reach patients

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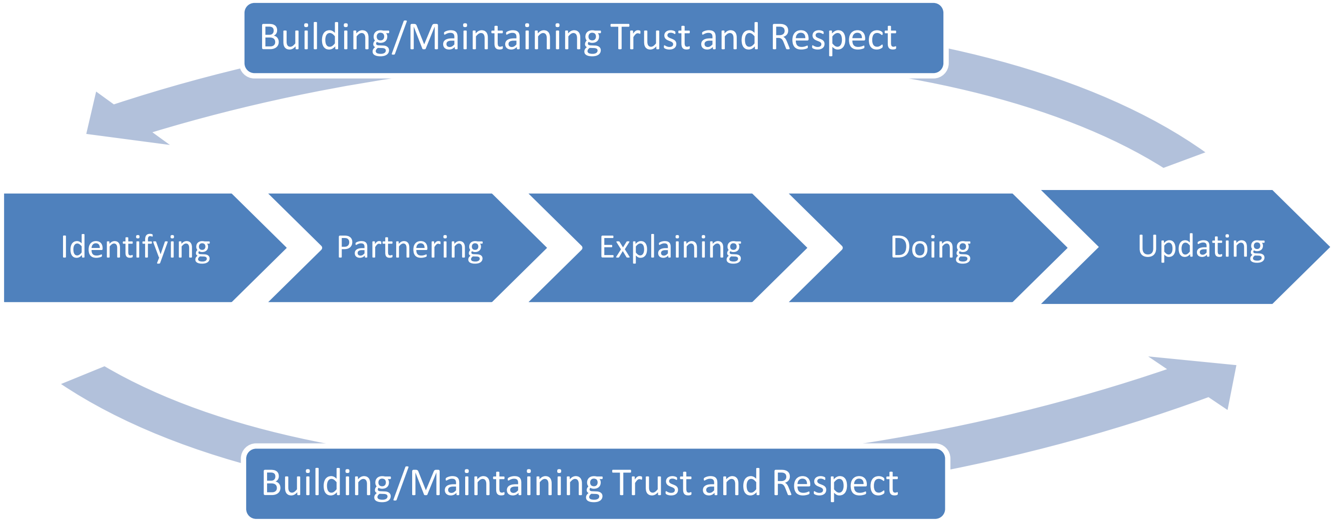
Study Participants

	AfAmF	HispF	NHWhF	OthF	AfAmM	HispM	NHWhM	OthM	Total
Affrican 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	**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	**76**	**12**	**33**	**2**	**19**	**6**	**10**	**2**	**160**

AfAm = African American; F = Female; Hisp = Hispanic;
M = Male; NHWh = non-Hispanic White; Oth = Other

Results – Key Findings



Building/Maintaining Trust and Respect

Identifying
Partnering
Explaining
Doing
Updating

Building/Maintaining Trust and Respect

Results – Key Findings

Q1: Practical Methods for Engaging Hard-to-Reach Patients

Study participants identified **hard-to-reach patients** by impairments, illnesses, by age, by where they live, by social indicators, and by what they do

Practical methods for engaging hard-to-reach patients include:

- Partnering with people
- Meeting in places
- Using media

Results – Key Findings

Q1: Practical Methods for Engaging hard-to-reach Patients

Partnering with People

Runs the gamut of individuals to organized groups:

- **Individuals** ("the mayor of the block")
- **Groups** (Health care professionals, employers)
- **Associations** (Communities and professions)
- **Networks** (Social organizations and federations)

Results – Key Findings

Q1: Practical Methods for Engaging hard-to-reach Patients

Meeting in Places

Ranges from public to private spaces:

- **Public spaces** (street corners and local businesses)
- **Community-specific** (centers for recreation and social services
- **Semi-private** (community clinics and places of worship)
- **Private** (housing and shelters)

Results – Key Findings

Q1: Practical Methods for Engaging hard-to-reach Patients

Using Media

Media have varying ranges of geographic reach:

- **Narrow reach media:** billboards on sides of buses, flyers in billing statements and other mailings, and local television and radio stations
- **Broad-reach media:** national television and radio, clips before movies
- Media with the widest range include online bulletin boards, list serves, Facebook and Twitter

Results – Key Findings

Q1: Practical Methods for Engaging hard-to-reach Patients

Components of Building and maintaining trust

- **Pre-engaging:** Understand the community
- **Relating:** Be genuinely willing to partner
- **Communicating:** Keep questions simple; Avoid making judgments
- **Being there:** Keep "coming back" and interacting with participants

Results – Key Findings

Q2: Methods for Ensuring Informants' Understanding

Methods to ensure that informants understand the pertinent clinical and research issues include:

- <u>Understanding the literacy and comprehension</u>
- <u>Gathering Information</u>
- <u>Disclosure</u>
- <u>Consent process</u>

Results – Key Findings

Q2: Methods for Ensuring Informants’ Understanding

Literacy and Comprehension

- Using plain language vs. “medical language”
- Teach Back method
- Individuals may need to make a decision

Gathering Information

- Use the appropriate terminology - “Research is an emotionally charged word”
- Ask open-ended questions to open up opportunities for discussion
- Methods range from providing information in “chunks” to taking “baby steps”
- Partner with community members who can train advocates

Results – Key Findings

Q2: Methods for Ensuring Informants' Understanding

Disclosure

- Let individuals know exactly what is involved
- Tell individuals why the investigator is doing the research
- Not only "what you say but who says it"

Consent Process

- Traditional IRB requirements for consent hinders more than helps
- Consent forms use big words and fine print that people do not understand
- "Culturally match the consenter"
- Have individuals consent in "their own words"

Results – Key Findings

Q3: Data Available to Identify Other Factors

Data that identify other factors and issues that are important to patients include:

- Particulars about their health and medical status, socioeconomic indicators, and difficult life situations
- Medical professionals, health facilities, and community resources
- Social networks and social media

Results – Key Findings

Q3: Data Available to Identify Other Factors

Health and Medical Status

- The health of an individual can be gleaned from places of service and historical information

Socioeconomic Indicators

- Traditional factors such as socioeconomic statistics and demographic and income data were mentioned
- Participants also reflected on knowing “where people are spending their money”

Results – Key Findings

Q3: Data Available to Identify Other Factors

Difficult Life Situations

- Life experiences can shed light on what is important to hard to reach patients
- Police records and crime rates are one source of data

Medical Professionals and Health Facilities:

- Physicians, pharmacists, and "well baby" clinics are places to gather data
- Non-medical, health-related places such as natural food stores and a GNC

Results – Key Findings

Q3: Data Available to Identify Other Factors

Community Resources:

- Is safe public transit available? (Transportation)
- Availability of parks, a community center, supermarkets, corner stores

Social Networks and Social Media:

- Locally based social influences
- Wider reaching: radio and community newsletters
- Online social media is especially important for teenagers
- A challenge with social influences is the “negative imagery” these can have on individuals

Results - Standards

Pre-Engagement

Prior to implementing a PCOR study, investigators should utilize a period of "pre-engagement" when recruiting research participants and partners.

Allows time to:

- Assure comprehension
- Have questions answered and concerns addressed
- Discuss participation with family and friends

"Pre-engagement" may also apply to other phases of PCOR research

Results - Standards

Defining “Research”

In order to effectively engage hard-to-reach patients, researchers need to provide education on exactly what is meant by the term “research”.

- Do not assume participants have the same conceptualization of research as researchers
- The word “*research*” carries very negative connotations in some communities

Results - Standards

Giving Back

Participants want to be kept abreast of research progress and want a celebration or recognition at the conclusion of a study. Participants would like some feedback at various points throughout the research process; they want the researcher to “give back” to the community.

- Participants are aware of the fact that they “give more to the researcher than they get in return”
- A plan for dissemination should be implemented
- "Giving back" could also take additional forms that meet the needs of individuals or community members

Results - Standards

Trust

Establishing trust with PCOR partners and recruitment populations builds bridges for open and enduring engagement.

- Trust has emerged as a key factor in the decision process of hard-to-reach individuals considering participation in the research process
- There is a need for trust to develop between academic researchers and physician communities

Results - Standards

Respecting Patient Privacy

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.

- Many cultures believe that personal information should be “kept in the family”
- Traditionally, researchers adequately protect medical information once it is collected… BUT the mere act of participating in a study may reveal medical information they would prefer to keep to themselves

Results - Standards

Person-Centeredness

People make health care choices and participate in research based upon who they are as individual persons, not just as patients.

- “Patient” negates the social and physical environments of persons that strongly influences their decision making
- “Patient” implies a health condition; the health care provider only knows the person in context of the medical model

Results - Standards

Community Engagement

Diversity and inclusion of hard-to-reach patients requires bringing PCOR to communities where people live.

- Requiring participants to come to you will often result in including only the most motivated patients
- Community-based participatory research offers excellent guidance for engaging diverse communities

Results - Standards

Full Spectrum Recruitment

Recruitment for PCOR studies should involve the full spectrum of individuals affected by the medical condition or health-related question being examined, including hard-to-reach patients.

- Government funding agencies typically require that sponsored research address priority population
- Recruitment of patients often reflects a convenience sampling process
- Diversity alone is insufficient evidence that “the full spectrum” of relevant patients is included in PCOR

Results – Lessons Learned

1) Trust is the key overarching element for PCOR

2) Patient vs. person

3) Outcomes is an unfamiliar term

4) Research is an abstract concept for many hard-to-reach patients

5) Framing and phrasing of questions is critical for eliciting patients' views

6) Patients come into research with their own agendas

7) Community-based PCOR requires flexibility, compromise and time

8) PCOR investigators should give something back to the community

9) Hard-to-reach patients do not like being asked repeated questions

Evidence Gaps

Future Needs for PCOR Methods Development

- Methods for “pre-engagement” of patients, partnering institutions and community sites
- Mapping of PCOR methods to phases of research
- Methods for building and maintaining trust with PCOR participants and partnering organizations 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

Future Needs for Health Policy and Research (Cont.)

- 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
- 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 indentify diversity within (not just across) subpopulations with regard to PCOR needs
- Broadening the list of hard-to-reach patients to include other understudied populations