Grand Rounds: Rethinking Clinical Research
PCORnet Building Trustworthiness in Research

September 16, 2016
Building Trustworthiness in PCORnet

Sharon Terry, co-PI, PCORnet Coordinating Center and Chair, PCORnet Engagement Committee
Building Trustworthiness in PCORnet

Hosted March 28-29 Building Trustworthiness in PCORnet meeting

We asked: how are we trustworthy and not trustworthy?

Meeting objectives were to:
- Describe the characteristics of trustworthy engagement
- Examine successes and failures in building trustworthiness in research initiatives
- Begin a robust dialogue around trustworthiness within PCORnet
- Create recommendations for the networks and stakeholders that comprise PCORnet

166 in person attendees and 357 webcast viewers

More than 40 speakers and moderators from within and outside of clinical research who fostered rich dialogue with meeting participants
Key Principles for Engagement and Building Trustworthiness

- Strive for **equity** among stakeholders
- Consider the **social determinants of health** (e.g. socioeconomic status, access to healthcare, literacy levels, culture, etc.)
- Consider the ways individuals **understand and experience** health and disease, accesses health services, and participate in research
- Be **patient/participant-driven**
- Create an environment that encourages **co-learning**

Result:
**More meaningful and impactful research** that matters to patients and clinicians and has the potential to accelerate the speed with which validated research findings move into clinical care.
Key Recommendations from Workshop

- Inculcate cultural humility
- Recognize and engage diversity
- Transparency – data, budget, privacy policy, projects
- Design governance built around citizens
- Train and support community researchers so that they can do PCOR
- Common collaborative environment with a wiki and sharing opportunities
  - Learn from best practices/lessons
- Support dissemination throughout research process
- Involve patients/participants more deeply in IRB’s
- Provide substantial $ in project budgets for engagement, dissemination
- Resources for clinicians to engage in research
What we have to LEARN
Building Trustworthiness
Working with Sexual and Gender Minorities

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9/16/2016
“They are only getting what they justly deserve.”

C. Everett Koop, describing the stance of Reagan’s advisers on AIDS
“At this point the patient became extremely emotional, accusing the psychologists of a complete lack of understanding of him as a person. He claimed that we … were more interested in our experimental results than in him.”

Thorpe, Schmidt, Castell (1963) describing a research subject’s response after 54 trials over 6 days of aversive conditioning pairing homoerotic images and electric shock.
Building Trustworthiness

A new role as researchers
- Participant inclusion in the processes of research development
- Participants as partners
- Respect and affirmation
Building Trustworthiness: Planning

Integrating sexual and gender minorities begins with planning

- First, plan to ask about sexual orientation and gender identity
Building Trustworthiness: Planning

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- Get guidance from sexual and gender minority stakeholders
Building Trustworthiness: Planning

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- Get guidance from sexual and gender minority stakeholders
- Respond to that feedback
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- Get guidance from sexual and gender minority stakeholders
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1. What sex were you assigned at birth, on your original birth certificate?
   Male
   Female

2. How do you describe yourself? (check one)
   Male
   Female
   Transgender
   Do not identify as female, male, or transgender
Building Trustworthiness: Planning

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- First, plan to **ask** about sexual orientation and gender identity
- Get guidance from sexual and gender minority stakeholders
- Respond to that feedback

1. What sex were you assigned at birth, on your original birth certificate?
   - Male
   - Female
2. How do you describe yourself? (check one)
   - Male
   - Female
   - Transgender
   - Do not identify as female, male, or transgender

   Do you consider yourself to be:
   - Heterosexual or straight;
   - Gay or lesbian; or
   - Bisexual?
Building Trustworthiness: Reporting

How we report our research is important
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- Sexual and gender minorities experience significant health disparities
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Building Trustworthiness: Reporting

How we report our research is important

- Sexual and gender minorities experience significant health disparities
- Understanding and *explaining* the sources of these disparities is important

Sexual and Gender Minorities  
Higher Rates of Suicide

[Image of the Pride Study logo]
Building Trustworthiness: Reporting

How we report our research is important

- Sexual and gender minorities experience significant health disparities

- Understanding and *explaining* the sources of these disparities is important

![Diagram showing the relationship between Sexual and Gender Minorities, Stigma & Discrimination, and Higher Rates of Suicide.]
Building Trustworthiness: Transparency

Be clear about your agenda and your team
Building Trustworthiness: Transparency

Be clear about your agenda and your team

- Have a link to your website which make your study goals clear
Building Trustworthiness: Transparency

Be clear about your agenda and your team

- Have a link to your website which make your study goals clear
- Include bios of your team, specific to this research study

Mitchell R. Lunn, MD
CO-DIRECTOR / The PRIDE Study
PRINCIPAL INVESTIGATOR / PRIDenet

Mitch is a long-standing advocate for sexual and gender minority (SGM) inclusion in research and higher education who lectures around the country on SGM medical education, SGM health, and SGM community engagement. He serves on the Advisory
Incorporate Feedback from Stakeholders at Every Step

- What is it like to participate in the research?
- How can the process of research be improved for the participant?
- Be prepared to adapt
Thank you!

- Annesa.flentje@ucsf.edu
- http://www.pridestudy.org
• What is trustworthiness in a pediatric chronic illness community?
  • What role does it play in compassionate clinical care?
    • What role does it play in innovative research?
  • What do we lose without trustworthiness in this community?
What is trustworthiness in a pediatric chronic illness community?

“Patient engagement is not a factor, it is the product of compassionate medicine that places the child at the center of an evolving developmentally and culturally-sensitive conversation. Patient engagement is what happens when the system works, when providers shake off their metaphorical white coats and enter the clinical space as equals with caregivers and children.”
Sometimes, even if I stand in the middle of the room, no one acknowledges me.
What role does trustworthiness play in compassionate clinical care?

“As a patient with a chronic illness, I have become well-versed at shedding my humanity and emotions and leaving them outside the clinic room, like taking off my shoes when coming home. We are made to believe, through experience and myth, that doctors are only interested in data. I am so practiced in this belief – or perhaps in that fear – that I can recite my diagnostic and treatment history in full, like rattling off a monologue with the medicalized Latin words becoming normalized. Admittedly, I find tremendous comfort and status rooted in such words, they are my only signal to tell clinicians that I understand and that I am an “experienced patient.” I try to find innocuous ways of displaying my knowledge, like a show pony, as I ask, “Was there radiographic evidence of an obstruction?” or, “My stoma hurts when the peristalsis pulls at the healed stitches.”
Flat Jennie
@Flat_Jennie

Inspired by @LivingBeyondIBD, Flat Jennie is @ImproveCareNow's traveling friend who is dedicated to downright gutsy times raising awareness about IBD.

🔗 http://c3nproject.org/pac
🔗 improvecarenowblog.org
Joined March 2014

📸 142 Photos and videos
What role does trustworthiness play in innovative research?

“When we only include children as research participants and operate on a researcher’s agenda, we miss the textures and colors that shape the veracity of our findings. In other words, we continue to make children’s experiences academic and sanitize children into participants.”
Clinicians’ Perspectives on the Current Status of Preparation and Barriers for Pediatric Patients Undergoing Oculary Surgery

Jennie David, B.A., Michael Sad, Ph.D., Jennifer Murray, M.A., Drexel University

Background
In pediatric patients with progressive inflammatory bowel disease (IBD), undertaking oculary surgery is an important aspect of treatment. There is growing concern about whether comprehensive medical consultation and involvement in the decision-making process of the patient and family is done to ensure the best possible outcomes for the child. This study aimed to address clinicians’ perspectives on the current status of preparation and barriers for pediatric patients with IBD facing oculary surgery.

Methods
An electronic survey was circulated to a list of clinicians working in the field of pediatric IBD. The survey was designed to gather information on the current status of preparation for oculary surgery, barriers encountered during the process, and strategies being used to overcome these barriers. Participants were asked to rate their level of agreement with various statements about the preparation, consultation, and barriers they have encountered.

Results
The survey was completed by 70 clinicians. The majority agreed that comprehensive medical consultation and involvement in the decision-making process were important for ensuring the best possible outcomes for the child. However, barriers such as lack of clear guidelines, insufficient training, and limited access to specialized resources were identified. Strategies to address these barriers included advocating for more comprehensive consultation, providing ongoing training for clinicians, and increasing access to specialized resources.

Conclusion
This study highlights the need for further research and development of strategies to improve the preparation and reduce barriers for pediatric patients with IBD undergoing oculary surgery.
What do we lose without trustworthiness in this community?
“Now, instead of feeling embarrassment and discomfort at the idea of being associated with others with my illness, I feel a sense of honor and gratitude towards other patient advocates who have chosen to use their pill bottles as soap boxes in sharing stories to effect change.”
BUILDING TRUSTWORTHINESS IN PCORNET

NEELY WILLIAMS,
COMMUNITY-INVESTIGATOR MID-SOUTH CDRN,
STAKEHOLDER ADVISORY BOARD,
PCORNET ENGAGEMENT COMMITTEE MEMBER,
RECENT ACTIVITIES TOWARD BUILDING TRUST

• Developing Messaging that enhance trust across the projects
• Hearing the voice of stakeholders throughout the research process
• Intentionally engaging patients and other stakeholders in all phases of the research
FEEDBACK FROM COMMUNITY STAKEHOLDERS

• Being transparent
  • Sharing with patients/participants how the data will be used
  • How it will benefit the patients/community
  • Researchers “going out of their way” to engage patients
IN SUMMARY:

The MS-CDRN Stakeholders:

• Trust and Engagement requires transparency, and taking the time to talk to participants through the process, including discussing details about the data and how their data will be used.

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OTHER SUGGESTIONS

• Reporting results of research back to the patient partners/participants is necessary for building trust.

• Narrative data, Story telling is a primary way data is transmitted among many cultures.

• An important recent concept in building trust is the idea of Patient Reported Outcomes.

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