



Cystic Fibrosis Reproductive and Sexual Health Collaborative

Patient-Centered Outcomes Research 101

CFReSHC Eugene Washington Award Team



Cystic Fibrosis Reproductive and Sexual Health Collaborative

Patient-Centered Outcomes Research (PCOR) Training

1. Brief Introductions (5 min)
2. Warm up content (10 min)
3. What is PCOR? (20 min)
 - a. Small group activity x 2
4. PCOR builds on traditional research (10 min)
5. PCOR engagement principles (15 min)
 - a. Large group discussion (25 min)
6. Closing (15 min)

What we learned when we surveyed the community...



86%

of patients, caregivers, health care providers, researchers and research staff are interested in learning about PCOR

Top three training topics included how to...

Patient/Caregivers

- Openly communicate with researchers
- Build trust with researchers/providers
- Share expertise with researchers

Researchers/Healthcare providers

- Include outcomes that matter to patients/caregivers
- Partner with patients/caregivers
- Select relevant research topics

What we will cover today

By the end of this training, you will be able to:

1. Identify the benefits and value of patient engagement in research
2. Define the levels of patient engagement, from minimal to control
3. Describe and provide examples of the core principles of PCOR
4. Identify ways to turn PCOR work into academic productivity

True or False

Patient-centered outcomes research (PCOR) engages patients and researchers as equal partners.

True



False



What we mean by...

“EQUAL PARTNERS”

- Patients are partners not “subjects”
- Active and meaningful engagement
- Community, patient, and caregiver involvement already in existence or well thought out plan



“PATIENT-CENTEREDNESS”

- Research should reflect what is important to patients and caregivers

Why Engage?

- To influence research to be patient-centered, relevant, and useful
- To establish trust and a sense of legitimacy in research findings
- To encourage successful uptake and use of research results



Partnering in Research

Plan the Study

- Identify the research question
- Identify outcomes
- Craft study design
- Specify inclusion criteria
- Develop study materials

Developing Sexual and Reproductive Health Educational Resources for Young Women with Cystic Fibrosis: A Structured Approach to Stakeholder Engagement

Traci M. Kazmerski^{1,2} · Elizabeth Miller^{1,2} · Gregory S. Sawicki³ · Phaedra Thomas⁴ · Olga Prushinskaya³ · Eliza Nelson³ · Kelsey Hill³ · Anna Miller⁴ · S. Jean Emans⁴

Sought stakeholder input on the development of an educational resource for sexual and reproductive health care needs of adolescent and young adult women with CF

Stakeholders involved:

- Women with CF
- Parents of adolescents and young women with CF
- Adult and Pediatric CF providers
- Adolescent medicine providers
- Medical writers

Kazmerski et al. 2019 *The Patient*

Stakeholder input:

Content, language and design of educational resources

Impact:

- Dedicated online education guides of 11 different topics

Create sense of normalcy around SRH topics

- Online access
- Impact patient-provider communication

Partnering in Research

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Conduct the Study

- Assist with recruitment
- Collect and synthesize data
- Make decisions about study adjustments
- Revise informed consent materials

RESEARCH LETTER

Improving Surgical Research by Involving Stakeholders

Enrolling patients in prospective surgical trials is difficult, especially in the urgent and/or emergent care setting. However, there is growing support for including patients, caregivers, and other health care stakeholders in all phases of research to assist with identifying and incorporating outcomes important to the public, developing strategies to improve enrollment and retention rates, and accelerating the dissemination and implementation of results.¹⁻⁵ We report the effect of stakeholder involvement in an ongoing randomized clinical trial (RCT) (ClinicalTrials.gov, [NCT02110485](https://clinicaltrials.gov/ct2/show/study/NCT02110485)) of pediatric appendicitis.

Minneci PC, Nacion KM, Lodwick DL, Cooper JN, Deans KJ. Improving Surgical Research by Involving Stakeholders. JAMA Surgery. June 2016

STUDY DETAILS:

- Randomized controlled trial
- Investigated the effects of patient activation tool in uncomplicated pediatric appendicitis
- 20-member multidisciplinary stakeholder group was engaged in all phases of the study

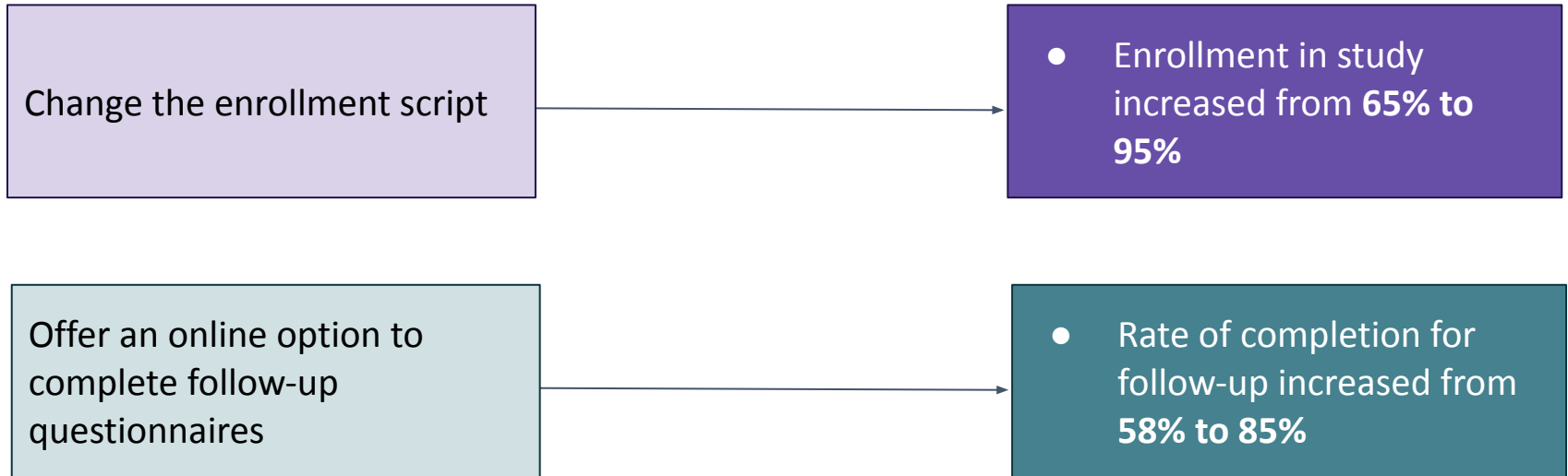
STAKEHOLDERS INVOLVED:

- Children ages 7-17 years and their families
- Community pediatricians
- Emergency medicine physician, surgeons and nurses
- Patient educators
- Payers

Minneci et al. 2016 JAMA

Stakeholder input:

Impact:



Partnering in Research


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Disseminate the Results

- Co-author and co-present in traditional formats
 - Develop non-traditional formats and methods
 - Begin planning for dissemination when planning the study
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What is PCOR?

Patient-Centered Outcomes Research: studies questions and outcomes that are meaningful and important to patients and caregivers.

Patient Engagement: meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders as equal members throughout the research process.

Comparative Effectiveness Research: The direct comparison of two or more existing healthcare interventions to determine which interventions work best for which patients and which interventions pose the greatest benefits and harms.

Small Group Activity - 5 minutes

Discussion Questions:

1. *Why are you interested in this training?*
2. *What do you hope to gain from this training?*

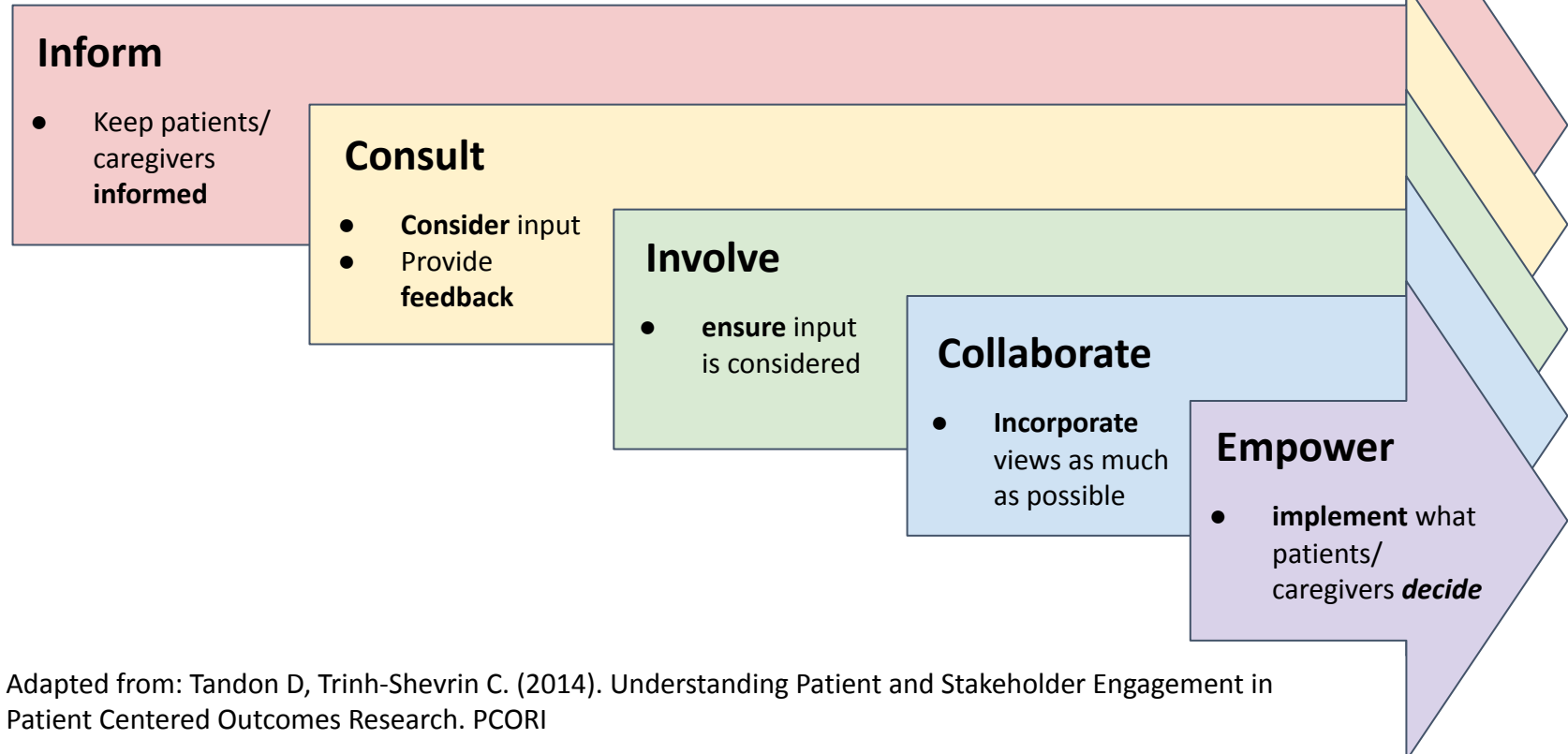
THINK

PAIR

SHARE

Spectrum of Patient/Stakeholder Engagement

Researchers:



Adapted from: Tandon D, Trinh-Shevrin C. (2014). Understanding Patient and Stakeholder Engagement in Patient Centered Outcomes Research. PCORI

Small Group Activity - 8 minutes

Discussion Questions:

1. *What is your experience with each level of engagement?*
2. *How are roles distributed differently at each of these levels? (e.g., patient/caregivers, researchers, healthcare providers)*

THINK

PAIR

SHARE

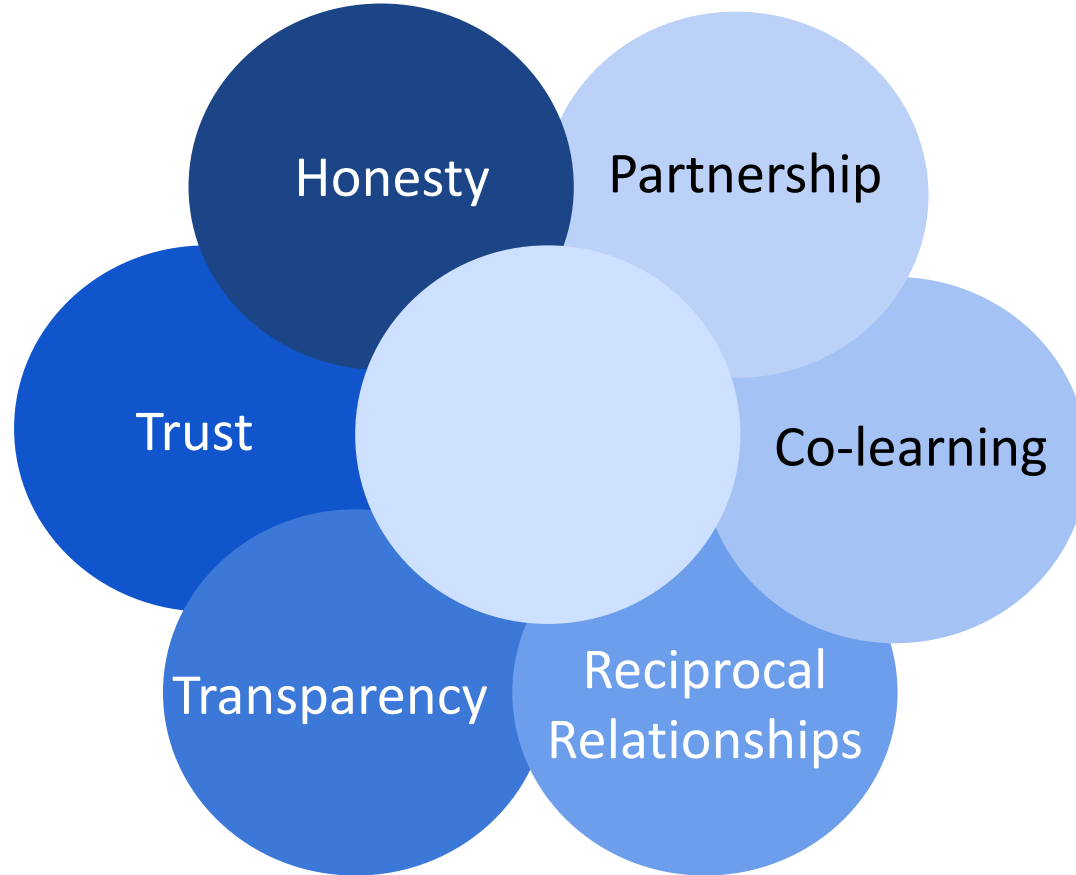
How PCOR Augments Traditional Research

	Traditional Research	Patient-Centered Outcomes Research
Research Objective	Based on epidemiologic data and funding priorities	Patient input in selecting relevant issues
Study Design	Based on scientific rigor and feasibility	Includes scientific rigor, but with patient partner input to ensure study design is culturally acceptable
Grant Writing	Conducted by PI and research team without any patient involvement	Researchers collaborate with Patient-Partners during the entire grant process (Question-->LOI-->Application-->Implementation-->Dissemination)
Recruitment & Retention	Based on scientific issues and methods regarding how to reach patients	Researchers collaborate with patient-partners on recruitment and retention strategies

How PCOR Augments Traditional Research

	Traditional Research	Patient-Centered Outcomes Research
Instrument Design	Instruments adopted/adapted from other studies. Tested and validated.	Instruments adopted from other studies and tested/adapted by researchers and patient-partners
Data collection	Conducted by researchers or individuals with no connection to the community	Patient-partners involved in some aspects of data collection
Analysis & Interpretation	Researchers own the data, conduct analysis and interpret findings	Researchers share results of analysis with patient-partners for comments and interpretation
Dissemination	Results published in peer-reviewed academic journals	Results disseminated in the community as well as peer-reviewed journals

PCOR Embodies Six Engagement Principles



Case study

- Please reflect on the following questions upon completion of the module:
- 1. For researchers/health care practitioners/policy-makers: What skills are most important to you when engaging patients in research?
- 2. For patients: What skills do you think are most important for you to become engaged in research?
- 3. All stakeholders: What skills do you think you still need to improve/develop? What assumptions do you hold about patient engagement in research?
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Potential PCOR Barriers



- Avoiding ***tokenism***
- Supporting patients as ***credible participants*** especially those from vulnerable or marginalized populations
- Understanding the role of patients/caregivers on the research team as ***equal partners***
- Identifying ***ethical issues*** in having patients/caregivers on the research team
- Equitably and sustainably ***compensating*** patient/caregiver partners

Large Group Discussion #1 (15 min)



How can we overcome some of these barriers?

Patients, Caregivers or other stakeholders

- What could be barriers to your participation in PCOR?
- Examples: time commitment for a 3-year project, travel, your health

Researchers, Healthcare providers, or policy-makers

- What could be the barriers to the different types/levels of engagement?
- Resources?
- Support?
- Expectations?

Large Group Discussion #2 (15 min)



What are some opportunities to engage in PCOR?

Patients, Caregivers or other stakeholders

- What are the opportunities you see for your participation in different types of engagement?

Researchers, Healthcare providers, or policy-makers

- What opportunities do you see for including patients at the different engagement levels for your research project?
- Clinical intervention?
- Policy initiative?

Resources

Patient-engagement planning tool:

<http://nlsupport.ca/getattachment/8dc1f539-d225-46fa-ba8d-2d06da934486/Patient-and-Public-Engagement-Planning-Template.pdf.aspx>

Helpful articles:

Shippee ND, Domecq Garces JP, Prutsky Lopez GJ, Wang Z, Elraiyah T, Nabhan M et al. 2015. [**Patient and service user engagement in research: a systematic review and synthesized framework.**](#) *Health Expectations*.18(5):1151-1166.

Staley K. 2015. [**'Is it worth doing?' Measuring the impact of patient and public involvement in research.**](#) *Research Involvement and Engagement*. 1:6.
<https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-015-0008-5>

Bombard Y, Baker GR, Orlando E et al. 2018. [**Engaging Patients to Improve Quality of Care: A Systematic Review.**](#) *Implementation Science*. 13: 98. <https://link.springer.com/article/10.1186/s13012-018-0784-z>

Questions?



Thank you for attending today's session!

- Erin will email the link to our post-training survey.
- Receive a \$15 Amazon gift card after you attend the session and complete the post-training session.

Please note: The University of Washington requires us to record full names, permanent addresses and social security numbers of all people who wish to receive gift cards. Your information will be stored in REDCap, a secure, HIPAA compliant database.



