Enhancing Community Health Center PCORI Engagement (EnCoRE)

Funded by:
This work was partially supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (NCHR 1000-30-10-10 EA-0001).

With support from:
N² PBRN – Building a Network of Safety Net PBRNs
funded by:
Grant # 1 P30 HS 021667

AHRQ
Enhancing Community Health Center PCORI Engagement (EnCoRE)

Session 1
Introduction to Patient Centered Outcomes Research (PCOR): Developing a Study and Study Questions

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EnCoRE Partners’ Geography
2014-2015
EnCoRE

Goal:
To adapt, enhance, and implement an existing year long training curriculum designed to educate and engage Health Center teams including patients, clinical and administrative staff in Patient Centered Outcomes Research (PCOR).

Objectives:
• Build infrastructure to strengthen the patient-centered comparative effectiveness research (CER) capacity of Health Centers as they develop or expand their own research infrastructure
• Develop, implement, and disseminate an innovative online training, which will be targeted to and accessible at no cost to all Health Centers and other primary care practices.
• Content will prepare Health Center patients, staff, and researchers in the conduct of community-led PCOR
Introductions

• Name
• Responsibilities
• Community Health Center Affiliation
• Prior Research Experience
• What are you hoping to learn from EnCoRE?
Session Goals

• What is the EnCoRE project?
• What are patient-centered outcomes?
• Why is patient-centered outcomes research important to Health Centers?
• How to ask a question and form a testable hypothesis
• Types of variables
• Introduction to clinical epidemiology and types of study designs
• Introduction to human subjects research
• Introduction to literature search/PubMed
Training Curriculum

• A year long structured program
  • Monthly training webcasts
  • Monthly “homework” assignments
  • Online clearinghouse of skill-building resources

• What will this series cover?
  • Basics of PCOR
  • Development of research questions
  • The structure of research design and protocols
  • Patient and community engagement
  • Human subjects protection
  • Data analysis and interpretation
  • Dissemination

Recommended Team Agenda:

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00-1:00 pm</td>
<td>Pre Lunch: Working team lunch meeting</td>
</tr>
<tr>
<td>1:00-2:00 pm</td>
<td>Webcast: Virtual Classroom</td>
</tr>
<tr>
<td>2:00-2:30 pm</td>
<td>Post Class Work: Team Meeting to Follow Up</td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Adjourn</td>
</tr>
</tbody>
</table>

Specific CHC responsibilities will include:
• Commit the time for a Team of 3-5 clinicians and staff members and patient representatives to participate in this project and participate in monthly webcasts and pre and post webcast related activities
• Identify one staff champion to lead this group of 3-5 clinicians and staff members
• Identify one or more patient representatives to participate
## Training Curriculum

| Session 1 – Introduction to PCOR - Developing a Study and Study Questions |
| Session 2 – Patient Engagement in Selecting and Designing Interventions for Testing and Outcomes for Assessment |
| Session 3 – Community Engagement for Selecting and Designing Interventions for Testing |
| Session 4 – Measurement, Defining Variables (dependent, independent, covariates) |
| Session 5 - Sample Size, Power Calculations, Sampling Methods, and Recruiting Plans |
| Session 6–Study Design & Clinical Statistics |
| Session 7- Biostatistics/Univariate Data Analysis |
| Session 8 – Bioinformatics |
| Session 9 - Research Ethics, IRB, FDA Regulations, and Good Clinical Practices (GCP) |
| Session 10 - Grant Writing, Fundraising, Project Planning, Identifying Study Partners, and Funders |
| Session 11 - Preparing Budgets, Work Plans, and Timelines |
| Session 12–Dissemination and Presentation |
Training Curriculum (Cont’d)

- The partners will develop the training course by building on existing CDN/N2-PBRN, NACHC, and CTSA training programs and PCORI training resources and adding any content gaps identified by partners or learners.
- The curriculum will incorporate previously developed and archived online training resources on research models and methodology using a “flipped classroom” learning model.
- All webinars developed during the project period will be posted on www.CDNetwork.org/ and www.CDNetwork.org for free global dissemination.
Goals for your Health Center

Short Term Goals:
- To gain meaningful understanding of PCOR engagement, knowledge, and methods
- To become “research engaged”
- To become PCOR “research-ready”
- To successfully submit PCOR funding applications to PCORI as well as NIH, AHRQ, and CDC
- To become partners, stakeholders, collaborators, and leaders in PCORI applications

Long Term Goals:
- To receive PCORI funding
- To publish PCOR results in peer-reviewed journals
- To aligning and integrating research and QI efforts
- To be prepared to incorporate results into practice with measurable impact on clinical, patient-centered and population health outcomes
- To increase the number of Health Center patients, clinicians, and staff participating as PCORI grant reviewers, and to improve the quality of those reviews over time
What is PCOR?
Why patient-centered outcomes?

Patient-Centered Outcomes Research (See www.PCORT.org)

• “...considers patients’ needs and preferences and focuses on outcomes most important to them.”
• “...can help patients and other healthcare stakeholders, such as caregivers, clinicians, insurers, policymakers and others, make better-informed decisions about their health and healthcare options.”
• “...answers patient-centered questions, such as:”
  • “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”
  • “What are my options, and what are the potential benefits and harms of those options?”
  • “What can I do to improve the outcomes that are most important to me?”
  • “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”
What is PCOR?

Why are patient-centered outcomes important?

Patient Centered Outcomes Research (PCOR):

- “Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people”
- “Is inclusive of an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life”
- “Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination”
- “Investigates optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives”

See [www.PCORI.org](http://www.PCORI.org)
Types of PCOR

- Infrastructure
- Methodology Studies
- Observational Studies
- Individual Randomized Controlled Trials (RCTs)
- Cluster RCTs
- Pragmatic Clinical Trials (PCTs, Individual or Cluster)

For more information see www.PCORI.org
http://www.pcori.org/content/research-we-support
Randomized Clinical Trials (RCT)

- **Prospective**: treatment precedes outcome
- **Randomized**: treatment assignment at random
- **Controlled**: comparison group
  - Placebo
  - Standard treatment
  - Alternative treatments – head to head comparison (cf. Comparative Effectiveness Research)
- **Single Blind**: treatment group assignment is unknown to participant
- **Double Blind**: treatment group assignment is unknown to both investigator and participant
Why is community-based collaborative work important for PCOR?
In an average month:

- 1000 people
- 800 have symptoms
- 327 consider care
- 217 physician’s office (113 visit primary care)
- 65 CAM provider
- 21 hospital outpatient clinic
- 14 home health
- 13 emergency department
- 8 hospitalized
- <1 in an academic health center
Clinical Epidemiology

applies epidemiological principles and study designs in clinical settings using medically defined populations as opposed to population settings.

Closely related to:

• Comparative Effectiveness Research (CER)
• Patient-Centered Outcomes Research (PCOR)
## Types of Measures or Variables

<table>
<thead>
<tr>
<th>Types</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal</td>
<td>• Gender</td>
</tr>
<tr>
<td></td>
<td>• Eye color</td>
</tr>
<tr>
<td>Ordinal</td>
<td>• Size</td>
</tr>
<tr>
<td>Interval</td>
<td>• Blood Pressure</td>
</tr>
<tr>
<td></td>
<td>• A1c</td>
</tr>
<tr>
<td>Ratio</td>
<td>• HIV Viral Load</td>
</tr>
</tbody>
</table>
Recoding Measures

Example: Systolic Blood Pressure (mmHg)

<table>
<thead>
<tr>
<th>Interval</th>
<th>SBP</th>
<th>90-250 mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ordinal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hi BP</td>
<td>SBP</td>
<td>&gt;140</td>
</tr>
<tr>
<td>Borderline BP</td>
<td>SBP</td>
<td>120 -140</td>
</tr>
<tr>
<td>Nominal BP</td>
<td>SBP</td>
<td>≤ 120</td>
</tr>
<tr>
<td><strong>Nominal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hi BP</td>
<td>SBP</td>
<td>&gt;140</td>
</tr>
<tr>
<td>Type of Variable</td>
<td>Type of Analysis</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>Nominal</td>
<td>Frequencies $\chi^2$</td>
<td></td>
</tr>
<tr>
<td>Ordinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interval</td>
<td>Means</td>
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<tr>
<td></td>
<td>t-Tests</td>
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<tr>
<td></td>
<td>ANOVA</td>
<td></td>
</tr>
<tr>
<td>Ratio</td>
<td>Regression</td>
<td></td>
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</tbody>
</table>
Human Subjects Research

Governed by the Office of Human Research Protections (OHRP; www.hhs.gov)

The Belmont Report
www.hhs.gov/oip/humansubjects/guidance/belmont.html

Human Subjects Protection Certification
phrp.nihtraining.com/users/register.php

Collaborative Institutional Training Initiative (CITI)
https://www.citiprogram.org/
Self-Assessment

1) Does your Health Center have experience conducting any type of research?

2) Is your Health Center currently conducting PCOR?

3) Is your Health Center ready to conduct PCOR?

4) What would it take to get ready to conduct PCOR?

5) Why is participating in research important to my Health Center?
Exercise #2

Develop a patient-centered study question

What questions would your health center like answered?

Remember PCOR addresses…
“Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”

“What are my options, and what are the potential benefits and harms of those options?”

“What can I do to improve the outcomes that are most important to me?”

“How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

quoted from www.PCORI.org
Exercise #3

1) Who is your target patient or clinical population

2) Who are the most important patient and clinical subgroups?
Patient-centered CER of Home-based Interventions to Prevent CA-MRSA Infection Recurrence (CAMP-2)

Funding by:

Patient Centered Outcomes Research Institute (Grant # Pending)

The Rockefeller University Center for Clinical and Translational Science (CCTS) Pilot Grant and Administrative Supplement (NIH-NCATS Grant # 8-UL1-TR000043)

AHRQ Grant # P30 HS 021667
CAMP Qualitative Findings: Convergence of CER/PCOR Interests

- **Patients**: Responses from the RPPS patient focus group indicated that many patients participated in the CAMP study in order to contribute to knowledge about CA-MRSA transmission and recurrence. Outcomes that patients were most concerned about include: *recurrence*, pain and inability to work.

- **Clinicians**: “[It is assumed that] colonization is ongoing, because we’ve had patients return with recurrent infections. ...If you just use systemic antibiotics, the nasal colonization persists. Another question to consider is if the source is in the house. We can take all measures to decolonize the person but if the infection is still in the house (pet, towel, sheets, etc), then it’s a huge factor.” – Dr. Balachandra

- **Laboratory Investigators**: “Does the MRSA *recurrent* phenotype reflect a single or multiple genotypes?

- **Clinical Investigators**: 31% of MRSA+ wounds and 28% of MSSA+ wounds are *recurrent*
CAMP-2 Research Design

Usual Care (CDC Guidelines-Directed) (n=139)

- Incision & Drainage
- Oral Antibiotics

Usual Care (CDC) + Experimental Intervention (n=139)

- Home Assessment
- Patient Decolonization & Environmental Decontamination (after Huang, 2014)
Identify measures: patient-centered vs. clinical
Example for Skin and Soft Tissue Infections:

<table>
<thead>
<tr>
<th></th>
<th>Patient Centered</th>
<th>Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dependent Variable(s)</td>
<td>Abscess, furuncle, folliculitis, boil, carbuncle, cellulitis</td>
<td>MRSA+ vs. MSSA+ lab result</td>
</tr>
<tr>
<td></td>
<td>(dermatological symptoms)</td>
<td>(microbiology diagnosis)</td>
</tr>
<tr>
<td></td>
<td>Recurrence on self or family</td>
<td></td>
</tr>
<tr>
<td>Independent Variable(s)</td>
<td>Prevention self-efficacy</td>
<td>Environmental contamination</td>
</tr>
<tr>
<td>- Environmental Treatment</td>
<td>Decision-making autonomy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Home decontamination vs. usual care)</td>
<td></td>
</tr>
<tr>
<td>Independent Variable</td>
<td>Pain</td>
<td>Clinical response to treatment</td>
</tr>
<tr>
<td>- Clinical Treatment</td>
<td>Ability to work</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
<td></td>
</tr>
<tr>
<td>Covariates / Confounding Variable(s)</td>
<td>Illness burden, Medication adherence</td>
<td>Comorbidity, Antibiotic Treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- The use of asthma drugs in pregnancy
  - Type in search box asthma drugs pregnancy

- Use MeSH
  - with or w/o subheadings

- Combine using AND, OR

- Filters
  - limit to dates of publication, language, age, gender, etc.
Exercise #5

Engage other Health Center colleagues in Team formation

Lets make a list of other colleagues that might be interested in joining you and contact them this week...

Ideally your team would consist of 4-6 individuals from each Health Center: 1-2 clinicians, 1-2 individuals involved in Health IT/EHR work, 1 health educator, and a patient representative.
<table>
<thead>
<tr>
<th>Role in Study</th>
<th>Role In CHC</th>
<th>Name</th>
<th>Credentials</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
</table>

Exercise #5
Homework

• Identify research interests
• Develop testable question
• Complete human subjects protection training (collect certificates)
• Begin literature search on PubMed.gov and compile relevant articles
• Engage team members (use template)

Due date October 4, 2014
Email to Project Coordinator:
rtayler@CDNetwork.org
Introduction to Collaborative Community-Based Research


Presenter:
Jonathan N. Tobin, PhD, FACE, FAHA
President/CEO, CDN, Co-Director for Community-Engaged Research
The Rockefeller University Center for Clinical and Translational Science (CCTS), Professor, Department of Epidemiology & Population Health, Albert Einstein College of Medicine of Yeshiva University
How to Sign Up for CDN ListServ

- Visit: [www.CDNetwork.org](http://www.CDNetwork.org)
- Click on “Join Our Mailing List”
- Fill in your information

OR

Send an email to eLearning@CDNetwork.org
How to Get a CE Certificate

• Fill out SurveyMonkey.org link that launches in the window
• Complete survey
• Send an email to eLearning@CDNetwork.org with your name, the title of the session, and the date you completed it
## Upcoming Sessions

<table>
<thead>
<tr>
<th>DATE</th>
<th>SESSION</th>
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<tbody>
<tr>
<td>10/21/14, 3:30 PM EDT</td>
<td>1. Introduction to PCOR</td>
</tr>
<tr>
<td>11/18/14, 2:00 PM EST</td>
<td>2. Patient Engagement</td>
</tr>
<tr>
<td>12/16/14, 3:30 PM EST</td>
<td>3. Community Engagement</td>
</tr>
<tr>
<td>1/20/15, 3:30 PM EST</td>
<td>4. Measurements and Descriptive Statistics</td>
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<tr>
<td>2/17/15, 3:30 PM EST</td>
<td>5. Sample Size and Sampling Methods</td>
</tr>
<tr>
<td>TBD</td>
<td>6. Study Design and Clinical Statistics</td>
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<tr>
<td>4/21/15, 2:00 PM EDT</td>
<td>7. Biostatistics and Univariate Data Analysis</td>
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<tr>
<td>5/19/15, 2:00 PM EDT</td>
<td>8. Bioinformatics</td>
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<td>6/16/15, 2:00 PM EDT</td>
<td>9. Research Ethics</td>
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<tr>
<td>7/21/15, 2:00 PM EDT</td>
<td>10. Grant Writing and Fundraising</td>
</tr>
<tr>
<td>8/18/15, 3:30 PM EDT</td>
<td>11. Preparing Budgets and Timelines</td>
</tr>
<tr>
<td>9/15/15, 2:00 PM EDT</td>
<td>12. Dissemination and Presentation</td>
</tr>
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Primary Text:
• SB Hulley, SR Cummings et al., *Designing Clinical Research: An Epidemiologic Approach* (NY: Lippincott Williams & Wilkins; 2nd Ed. 2001)

Additional/Supplemental Texts & Resources:
• RM Merrill *Introduction to Epidemiology* (Boston MA: Jones and Bartlett, 2010, 5th Ed)
• Univ of Pittsburgh - Epidemiology Super Course  [www.pitt.edu/~super1](http://www.pitt.edu/~super1)
• Univ of North Carolina – Epidemiology eText  [www.epidemiolog.net](http://www.epidemiolog.net)
• CDN Clinical Research Training Webcast Library  [www.CDNetwork.org](http://www.CDNetwork.org)
• Rockefeller University Center for Clinical and Translational Science Webcast Library  [www.CDNetwork.org/Rockefeller](http://www.CDNetwork.org/Rockefeller)
Additional Suggested Resources

Application Exercises & Web-based Resources

Key Concepts
- Use Epidemiologic Vocabulary & Concepts
  
  www.pitt.edu/~super1
  www.epidemiolog.net

NLM - PubMed
- Search, Retrieve, Review ≥ 1 study in your area using the current design
  
  www.ncbi.nlm.nih.gov/pubmed

CDC - NCHS
- Identify and explore ≥ 1 public data-set that measures your primary research interest
  
  www.cdc.gov/nchs/nhanes.htm
  www.cdc.gov/nchs/nhis.htm

Study Design
- Do try this at home (& at work!)
  FOLLOW YOUR OWN NATURAL HISTORY!
For additional information, please email:

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