Enhancing Community Health Center PCORI Engagement (EnCoRE)

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EnCoRE Partners’ Geography
2014-2015
AIM

EnCoRE: Enhancing Community Health Center PCORI Engagement

AIM: To build health center capacity to engage in patient-centered outcomes research through an interactive 12-month long training curriculum, walking health centers through the steps and skills needed to develop a patient-centered research proposal.
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
During this live training, you may ask questions at any time in the Chat Window. This area is located in the lower left hand corner of your screen. These questions will be answered at the end of the presentation.
Audio Setup

Configure your PC for Audio

Configure Your PC
Click the Microphone/Gears icon or
Go to: Tools > Audio > Audio Setup Wizard

1. DEMO ROOM – Blackboard Collaborate
   File Edit View Tools Window Help
   AUDIO & VIDEO
   Talk Video

2. Tools Window Help
   Application Sharing Audio Chat
   Audio Setup Wizard... Microphone Settings... Speaker Settings...
   Adjust Microphone Level Up Ctrl+Shift+Up
   Adjust Microphone Level Down Ctrl+Shift+Down
   Adjust Speaker Level Up Ctrl+Up
   Adjust Speaker Level Down Ctrl+Down
   Use Telephone For Audio
This program has been reviewed and approved for up to 1.5 Prescribed CME credits by the American Academy of Family Physicians (AAFP).

Please complete the CE Evaluation launched at the end of the presentation and email eLearning@CDNetwork.org with a request for credits.
Presenters

Milton “Mickey” Eder, PhD
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Vicki M. Young, PhD
Chief Operating Officer
South Carolina Primary Health Care Association
Session 6: Study Design and Clinical Statistics
March 17, 2015

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Vicki M. Young, Chief Operating Officer
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Quality Improvement or Research?

Quality Improvement – a **systematic** pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product.

The Institute of Medicine

*Research* – a **systematic** investigation, including research development, testing and evaluation, designed **to develop or contribute to generalizable knowledge.** 45CFR46.102(d)
Validity: Are we asking the right question in the right way?

• **Internal validity** - the degree to which the program (intervention, treatment, independent variable) & not extraneous factors (confounding variables) cause the change that was measured.

• **External validity** - the extent to which the program (intervention, treatment, independent variable) can be expected to produce similar effects in other populations (generalizability)

• Validity -- the degree to which a research study measures what it intends to measure
Statistics and Study Design

The size of the sample that is needed to demonstrate an effect.

Sample drawn from a population should account for variation within the population and potential selection bias.

Do statistical tests allow us to confirm our hypothesis or reject the null hypothesis?
Power – probability of detecting when there is a difference.

<table>
<thead>
<tr>
<th>Power</th>
<th>Sample</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate</td>
<td>May not detect difference</td>
<td></td>
</tr>
<tr>
<td>Excessive</td>
<td>Will detect small differences</td>
<td></td>
</tr>
</tbody>
</table>

Minimum size of the sample needed to detect an effect of a projected size.
Clinical Significance

Real World application of knowledge – how large the differences in treatment effects are in clinical practice.
When is a treatment effect or the size of the change significant and to whom? Do the research results matter for the real world?

Effect size – measure of the magnitude of the change

Number Needed to Treat – another statistic to estimate how many patients need to be treated in a specific amount of time 1) to avoid a negative outcome (prevention), or 2) to effect a cure

Mental health – when a treatment alters the individuals relationship to dysfunctional and functional states.
Clinical Significance

The smallest clinically beneficial and harmful values of the effect. We can combine these values to suggest clinical significance.
Decision Analysis

Making decisions in clinical practice involves a careful analysis of harms and benefits associated with different treatment options. These decisions, often associated with high stakes and important long-term consequences, are frequently made in the face of competing priorities, limited resources and information and an incomplete clinical picture. Under such circumstances, a rigorous and objective analysis of outcomes and probabilities is essential to achieve the best possible decision given a specific clinical situation.

Screening and Diagnosis

- Why conduct screening and diagnostic tests?
- 5 Main Reasons for Diagnostic Tests are:
  - Establish a diagnosis in symptomatic patients.
  - Screen for disease in asymptomatic patients.
  - Provide prognostic information in patients with established disease.
  - Monitor therapy by either benefits or side effects.
  - A test may be performed to confirm that a person is free from a disease.
- Give an example of a test that falls under each of the areas
Sensitivity and Specificity

- **Sensitivity** is the proportion of patients *with* disease who test positive.
  \[ P(T^+ | D^+) = \frac{TP}{TP+FN} \]

- **Specificity** is the proportion of patients *without* disease who test negative.
  \[ P(T^- | D^-) = \frac{TN}{TN + FP} \]
# Sensitivity and Specificity

<table>
<thead>
<tr>
<th></th>
<th>Disease present</th>
<th>Disease absent</th>
<th>Total positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test positive</strong></td>
<td>TP</td>
<td>FP</td>
<td>Total positive</td>
</tr>
<tr>
<td><strong>Test negative</strong></td>
<td>FN</td>
<td>TN</td>
<td>Total negative</td>
</tr>
<tr>
<td><strong>Total with disease</strong></td>
<td>Total without disease</td>
<td>Grand total</td>
<td></td>
</tr>
</tbody>
</table>
## Sensitivity and Specificity

<table>
<thead>
<tr>
<th>Term</th>
<th>Calculation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>True positive (TP)</td>
<td>Counts in 2 X 2 table</td>
<td># Patients with the disease who have a positive test result</td>
</tr>
<tr>
<td>True negative (TN)</td>
<td>Counts in 2 X 2 table</td>
<td># Patients without the disease who have a negative test result</td>
</tr>
<tr>
<td>False positive (FP)</td>
<td>Counts in 2 X 2 table</td>
<td># Patients without the disease who have a positive test result</td>
</tr>
<tr>
<td>False negative (FN)</td>
<td>Counts in 2 X 2 table</td>
<td># Patients with the disease who have a negative test result</td>
</tr>
</tbody>
</table>

### Sensitivity

\[
\text{Sensitivity} = \text{True positive rate (TPR)} = \frac{\text{TP}}{\text{TP} + \text{FN}}
\]

- The probability that a patient with the disease will have a positive test result.

### Specificity

\[
\text{Specificity} = \text{True negative rate (TNR)} = \frac{\text{TN}}{\text{TN} + \text{FP}}
\]

- The probability that a patient without the disease will have a negative test result.

### False Negative Rate (FPR)

\[
1 - \text{Sensitivity} = \text{False-negative rate (FPR)} = \frac{\text{FN}}{\text{TP} + \text{FN}}
\]

- The probability that a patient with the disease will have a negative test result.
Sensitivity and Specificity

• Diagnostic tests trade sensitivity for specificity and vise-versa
  • Highly sensitive tests generally have larger number of false-positives and lower specificity
  • Tests with high specificity generally have larger number of false-negatives and lower sensitivity
• Highly sensitive test tend to be ideal for a screening examination
• Highly specific tests tend to be ideal confirmation
Predictive values incorporate both false-positive and false-negative results into disease probability.

Positive predictive value (PPV) is the probability of a patient actually having the disease if the test result is positive.

Negative predictive value (NPV) is the probability of the patient being free of the disease after a negative test result.

The predictive values are dependent on the prevalence of disease among the population of interest.

- Predictive value of a diagnostic test varies in different populations
- Without disease prevalence predictive values cannot be accurately estimated.
## Predictive Value

<table>
<thead>
<tr>
<th>Positive predictive value</th>
<th>Positive predictive value formula: ( \frac{TP}{TP + FP} )</th>
<th>The probability that a patient with a positive test result will have the disease.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative predictive value</td>
<td>Negative predictive value formula: ( \frac{TN}{TN + FN} )</td>
<td>The probability that a patient with a negative test result will not have the disease.</td>
</tr>
</tbody>
</table>
Receiver Operating Characteristic Curve (ROC)

• A plot of the true positive rate against the false positive rate for the different possible cut points of a diagnostic test.

• ROC curve demonstrates several things:
  • The tradeoff between sensitivity and specificity.
  • The closer the curve follows the left-hand border and then the top border of the ROC plot, the more accurate the test.
  • The closer the curve comes to the 45-degree diagonal of the ROC space, the less accurate the test.
  • The area under the curve is a measure of test accuracy.
Receiver Operating Characteristic Curve (ROC)
• Sources


Patient-Centered Outcomes Research

CONSENSUS DEFINITION as of February 15, 2012

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

• 1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
• 2. “What are my options and what are the benefits and harms of those options?”
• 3. “What can I do to improve the outcomes that are most important to me?”
• 4. “How can the health care system improve my chances of achieving the outcomes I prefer?”
1. PLANNING THE STUDY: Describe how patient and stakeholder partners will participate in study planning and design.

Potential Activities Include:

- Identifying the topic and developing the research question to be studied
- Creating the intervention
- Identifying the comparators
- Defining the characteristics of study participants

Real-World Examples:

- Epilepsy study: The patients and parents of patients with epilepsy pose the question: Which anti-epileptic drugs best preserve sufficient cognition to go to work or school and to function normally,
Pipeline to Proposal

Tier 1
• $15,000
• 9 months
• Build relationship, develop infrastructure, communicate

Tier 2
• $25,000
• 12 months
• Mature partnerships, define research questions and priorities

Tier 3
• $50,000
• 12 months
• Develop PCORI proposal

Conducting the Study!
Disseminating Study Results
Principles of Community Engagement

As we continue to try to improve our nation’s health, we must work together and keep in mind the community contexts that shape our health and well-being.  Regina M. Benjamin, M.D. M.B.A. Surgeon General

Figure 1.1. Community Engagement Continuum
PCORI’s Engagement Rubric:

1) Planning the Study
2) Conducting the Study
3) Disseminating the Study Results
4) PCOR Engagement Principles
   • Reciprocal relationships
   • Co-learning
   • Partnership
   • Trust, Transparency, Honesty
Developing a Research Project

How does partnership development fit into the research study development process?

Community engagement, partnership, and the research team: how do we put the pieces together?
Decision Points in Developing a Research Project

• Identify a Problem and Develop a Hypothesis
  • Study design, Literature Review

• Population of interest – Sampling strategy
  • Intervention, control, comparison groups

• Variables to be measured
  • nominal, ordinal, interval, ratio

• Analysis - what happened?

• Dissemination – reporting to others
## Types of Measures or Variables

<table>
<thead>
<tr>
<th>Data Types</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal (Categories)</td>
<td>Gender, Eye color</td>
</tr>
<tr>
<td>Ordinal (Order)</td>
<td>Size – small, medium, large</td>
</tr>
<tr>
<td>Interval (Scale)</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>Ratio (scale includes a zero)</td>
<td>A1c</td>
</tr>
<tr>
<td></td>
<td>Pain Scale</td>
</tr>
<tr>
<td></td>
<td>HIV Viral Load</td>
</tr>
<tr>
<td></td>
<td>Income</td>
</tr>
</tbody>
</table>
Displaying Data

• Numerical data can be placed into the text

• Can be presented in tables

• Can be displayed as a graph or chart (text needn’t repeat the data but can explain the relevance of the data for the topic)

Consider the amount of data and the complexity of the data
<table>
<thead>
<tr>
<th>State</th>
<th>Number of Grantees</th>
<th>Number of Delivery Sites</th>
<th>Total Patients</th>
<th>Total FTEs</th>
<th>Total Encounters</th>
<th>Percent Uninsured</th>
<th>Percent Medicaid</th>
<th>Percent Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>14</td>
<td>131</td>
<td>330,401</td>
<td>1,459.9</td>
<td>1,002,538</td>
<td>48%</td>
<td>28%</td>
<td>11%</td>
</tr>
<tr>
<td>Alaska</td>
<td>25</td>
<td>168</td>
<td>100,595</td>
<td>1,423.7</td>
<td>467,092</td>
<td>37%</td>
<td>26%</td>
<td>9%</td>
</tr>
<tr>
<td>Arizona</td>
<td>17</td>
<td>137</td>
<td>438,260</td>
<td>3,480.9</td>
<td>1,635,078</td>
<td>26%</td>
<td>41%</td>
<td>10%</td>
</tr>
<tr>
<td>Arkansas</td>
<td>12</td>
<td>99</td>
<td>163,797</td>
<td>1,179.2</td>
<td>563,715</td>
<td>40%</td>
<td>27%</td>
<td>13%</td>
</tr>
<tr>
<td>California</td>
<td>129</td>
<td>1,247</td>
<td>3,412,961</td>
<td>26,194.9</td>
<td>14,767,846</td>
<td>39%</td>
<td>46%</td>
<td>6%</td>
</tr>
<tr>
<td>Colorado</td>
<td>18</td>
<td>190</td>
<td>498,828</td>
<td>3,960.9</td>
<td>1,996,735</td>
<td>37%</td>
<td>42%</td>
<td>8%</td>
</tr>
<tr>
<td>Connecticut</td>
<td>13</td>
<td>199</td>
<td>327,165</td>
<td>2,668.7</td>
<td>1,600,236</td>
<td>22%</td>
<td>60%</td>
<td>7%</td>
</tr>
<tr>
<td>Delaware</td>
<td>3</td>
<td>13</td>
<td>40,274</td>
<td>323.3</td>
<td>144,910</td>
<td>37%</td>
<td>39%</td>
<td>6%</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>5</td>
<td>44</td>
<td>150,671</td>
<td>1,493.9</td>
<td>752,476</td>
<td>18%</td>
<td>57%</td>
<td>5%</td>
</tr>
<tr>
<td>Florida</td>
<td>48</td>
<td>429</td>
<td>1,128,651</td>
<td>7,305.4</td>
<td>4,291,035</td>
<td>44%</td>
<td>40%</td>
<td>7%</td>
</tr>
<tr>
<td>Georgia</td>
<td>29</td>
<td>179</td>
<td>338,996</td>
<td>1,865.6</td>
<td>1,068,633</td>
<td>51%</td>
<td>26%</td>
<td>10%</td>
</tr>
<tr>
<td>Hawaii</td>
<td>14</td>
<td>75</td>
<td>146,484</td>
<td>1,634.3</td>
<td>675,409</td>
<td>19%</td>
<td>53%</td>
<td>8%</td>
</tr>
</tbody>
</table>
Figure 1.9
Health Centers Are More Likely to Treat Patients with Chronic Illnesses Compared to Other Primary Care Physicians

<table>
<thead>
<tr>
<th>Condition</th>
<th>Health Centers</th>
<th>Private Physician Offices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>8%</td>
<td>11% **</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11% ***</td>
<td>15% ***</td>
</tr>
<tr>
<td>Asthma</td>
<td>8% **</td>
<td>8%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>28%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Note: Statistical significance measures compared to value for private physician offices; *** p < .01, ** p < .05, * p < .10

“Common chronic conditions” include visits where the primary diagnosis listed for the visit is an ICD-9-CM diagnosis code for hypertension, asthma, diabetes, heart disease, and selected psychotic conditions and other psychoses. Excludes visits classified as “pre/post surgical,” all visits to non-primary care physicians, and any visits where the patient did not see a physician.

Figure 9.1
Health Centers Are Not Present in at Least a Quarter of the Counties with Unfavorable Primary Care Needs

- Rural: 63%
- Primary Care Provider: 54%
- Preventable Hospitalizations: 53%
- Uninsured: 50%
- Mammography Screening: 47%
- ED Visits: 42%
- Health Status: 38%
- Diabetes Prevalence: 36%
- Not English Proficient: 36%
- Low-Income: 34%
- Low Birthweight: 33%
- HIV Prevalence: 25%

Note: Counties with Unfavorable Primary Care Needs were identified by being in the either bottom or top quintile depending on the primary needs indicator. Low-Income map presents census tracts, but analysis for this figure was conducted at the county-level. Source: NACHC, Health Wanted 2012. NACHC analysis of data obtained from University of Wisconsin Population Health Institute County Health Rankings 2011; U.S. Census Bureau; and HRSA.
Figure 1.5

Health Center Patient Mix Is Unique Among Ambulatory Care Providers

Notes: Other public includes non-Medicaid SCHIP and other state-funded insurance programs.
* Combined total of individual sources exceeds “All visits” because more than one may be reported per visit.
Figure 1.2
Health Center Patients are Predominately Low Income

- 72% are 100% FPL and below
- 14% are 101-150% FPL
- 7% are 151-200% FPL
- 7% are over 200% FPL

Source: Federally-funded health centers only. 2012 Uniform Data System, Bureau of Primary Health Care, HRSA, DHHS.
Note: Federal Poverty Level (FPL) for a family of three in 2012 was $18,500. (See [http://aspe.hhs.gov/poverty/12poverty.shtml](http://aspe.hhs.gov/poverty/12poverty.shtml]). Based on percent known. Percents may not total 100% due to rounding.
Figure 2.4
Health Center Patients by Insurance Status, 2002-2012
Figure 4.2
Health Centers Have Experienced Tremendous Growth in the Number of Patients and Visits for Medical, Dental, and Mental Health Care, 2000-2012

Histogram

Note: Mental health does not include substance abuse.
Source: 2001-2012 Uniform Data System, Bureau of Primary Health Care, HRSA, DHHS.
Life expectancy vs GDP/capita

2011 or nearest year

Source: OECD Health at a Glance 2013
Scatter Plot

Life Expectancy at Birth (yrs) vs. Health Care Spending ($US per capita)

- Countries represented: AU, JP, ES, NZ, FI, UK, SE, AT, CA, DK, LU, KR, PT, MX, PL, SK, CZ, HU

- Doctor visits per year:
  - >12
  - 8-12
  - 4-8
  - 0-4

- The scatter plot shows a correlation between life expectancy at birth and health care spending per capita.
Patterns: Correlations not Causality

Normal distribution

Right-skewed distribution

Bimodal (double-peaked) distribution

- Positive linear: $r = +0.82$
- Negative linear: $r = -0.70$
- Independent: $r = 0.00$
- Curvilinear: $r = 0.00$

http://2012books.lardbucket.org/books/beginning-psychology/s06-psychological-science.html
Discussion Questions

How have we talked about significance?

What is the relationship between data and evidence?

Do you think that PCOR is helping add a humanistic perspective to medicine?
Additional Questions?

And Discussion
Next Webinar

Biostatistics
Tuesday, April 21st
2:00 - 3:30 pm EST
Thank You!

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