BUILDING PRIMARY CARE RESEARCH INFRASTRUCTURE AT YOUR COMMUNITY HEALTH CENTER

Harvard Catalyst
Community Health Innovation and Research Program
Grant # 1 UL1 RR025758-04

First Edition
This toolkit is designed to provide Community Health Centers with the elements needed to build a primary care research infrastructure.

The toolkit is organized in eight easily-navigated, interactive, stand-alone modules.
Module 1: Quality Improvement and Research
Module 2: Building Primary Care Research Infrastructure
Module 3: Data
Module 4: Study Design and Methods Overview
Module 5: Dissemination and Action
Module 6: Funding your Research
Module 7: Partnerships for Research
Module 8: Ethics and the Institutional Review Board
Module 4
Study Design & Methods Overview
Module 4 Learning Objectives

After completing this module, participants will be able to:

1. Discuss different study designs
2. Define key epidemiologic terms
3. Identify different methods used in epidemiologic research
4. Distinguish between qualitative and quantitative research
5. Learn about sampling strategies and understand why good sampling strategies are important
Climbing a ladder: Mounting Scientific Evidence

- Starts with observation, concludes with proof of causation
  - Case reports
  - Case series
  - Case control studies
  - Cohort studies
  - Non-randomized intervention trials
  - Randomized controlled trials
Three Key Epidemiologic Terms

• Exposure
  – Something an individual (or group/organization) is exposed to that is absent in another

• Outcome
  – Presence of a state or condition resulting from an exposure (or lack of exposure)

• Confounder
  – Characteristic that may be related both to exposure and outcome
Epidemiologic Triangle

Exposure → Outcome

Confounder
Explaining Epidemiologic Terms

• Exposure
  – Several Black male patients reside in a boarding home; many recently post-incarceration

• Outcome
  – Higher rate of chest X-rays with solitary pulmonary nodules for these patients

• Confounder
  – Higher rate of tuberculosis (TB) demonstrated among incarcerated populations
Why is one rung higher than another?

• By increasingly controlling for confounders
  – Case Observation: One resident with TB observed
  – Case Series: Ten residents with TB observed
  – Cohort Studies: Non-residents and residents both observed
Why is one rung higher than another?

- By increasingly controlling for confounders
  - **Clinical Trials**: Men placed outside boarding homes then observed
  - **Controlled Trials**: Observe men placed outside boarding homes, compared to men remaining in boarding homes
Commonly Used Methods

• Two types of cohort studies
  – Cross-Sectional
    • Qualitative interviews and focus groups
    • Quantitative surveys at one point in time
    • Physical exams or medical record review at one point in time
  – Longitudinal
    • Groups followed over time to look for differences
• Controlled and non-controlled clinical trials
# Qualitative vs. Quantitative Data

<table>
<thead>
<tr>
<th>Qualitative Data</th>
<th>Quantitative Data</th>
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<tbody>
<tr>
<td>Gain understanding</td>
<td>Prediction or Association</td>
</tr>
<tr>
<td>Textual data</td>
<td>Numerical data</td>
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<tr>
<td>Subjective</td>
<td>Objective</td>
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<tr>
<td>Methods</td>
<td>Methods</td>
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<tr>
<td>- Interviews</td>
<td>- Observation: case study, case series, cohort, case-control</td>
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<tr>
<td>- Focus groups</td>
<td>- Close-ended quantitative survey questions</td>
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<tr>
<td>- Observations</td>
<td>- Experimental: time series, cross-over, control group</td>
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<tr>
<td>- Open-ended survey questions</td>
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<tr>
<td>Analysis</td>
<td>Analysis</td>
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<tr>
<td>- Transcription (themes)</td>
<td>- Parametric</td>
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<tr>
<td></td>
<td>- Non-parametric</td>
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</table>
### Qualitative vs. Quantitative Data

<table>
<thead>
<tr>
<th>Qualitative Data</th>
<th>Quantitative Data</th>
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<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Strengths</strong></td>
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<tr>
<td>- Examine complex research questions</td>
<td>- Standard across many disciplines</td>
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<tr>
<td>- Deeper understanding of people’s experiences/behaviors</td>
<td>- Results can allow for generalization</td>
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<tr>
<td>- Exploratory (theory generating)</td>
<td>- Efficient way to test hypothesis</td>
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<tr>
<td><strong>Weaknesses</strong></td>
<td><strong>Weaknesses</strong></td>
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<tr>
<td>- Hard to generalize results</td>
<td>- Misses contextual details</td>
</tr>
<tr>
<td>- Time consuming/expense</td>
<td>- Not flexible (limited to outcomes outlined)</td>
</tr>
<tr>
<td>- Lower credibility in some settings</td>
<td>- Higher credibility in many disciplines</td>
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</tbody>
</table>

**MIXED METHODS APPROACHES ARE INCREASINGLY ENCOURAGED AND UTILIZED.**

http://obssr.od.nih.gov/scientific_areas/methodology/mixed_methods_research/index.aspx
Considerations When Selecting a Study Design

• What body of evidence (scientific theory and literature) exists on the research topic?
• Do you require numerical evidence?
• How much detail is needed?
• Is it feasible to collect the kind of data the study design requires?
• What is the size of your budget?
Selecting Participants

• Now that you’ve decided on a design, how do you select participants?
• Why not select the whole population?
Selecting Participants

- Surveying the entire population (e.g. Census) is costly, time intensive and often not feasible.
- Consider *sampling* participants instead.

Select a *subset* of the population
Sampling is critical because it has implications for your ability to generalize (or extrapolate) your research findings back to the population at large!
Sampling

- **Probability sampling** is where every person (or unit) in the population has an equal (greater than zero) chance of being selected to participate in your study.
  - E.g. You are conducting a survey about smoking patterns in adults in Cambridge. You visit every household in Cambridge and randomly select one person in each household to respond to your survey. Person “represents” the population.

**Probability sampling strategies facilitate generalizability**
Probability Sampling Strategy

• Simple Random Sampling
  – Select every Nth person from a school

• Cluster Random Sampling
  – Divide population into clusters or groups (e.g. city into neighborhood blocks)
  – Select random sample of neighborhood blocks
  – Randomly select individuals from each selected neighborhood block
Sampling

• Non-Probability sampling is where some individuals (or units) in your population have no chance of being selected to participate in your study or where the probability of selection cannot be accurately determined.
  – E.g. You are conducting a survey about smoking patterns in adults in Cambridge. You visit every household in Cambridge and survey the adult who happens to answer the door.

  Non-probability sampling strategies can make generalizability challenging
Non-Probability Sampling Strategy

• **Convenience sampling**
  – Sample is drawn from a population that is readily accessible and convenient.
  – Findings from a study using convenience samples cannot be generalized (or extrapolated) back to the whole population.

• **Snowball sampling**
  – This method is effectively used when a desired sample characteristic is rare.
  – This strategy relies on referrals from an initial group of participants and relies on them to reach out to other participants.
Tips for Sampling

- Clearly define your target population.
- Clearly define your study eligibility or inclusion criteria.
- Discuss feasibility and acceptability of proposed sampling strategy and your capacity to implement this strategy.
Case Study
Developing a Research Study

1. Identify a problem, issue, concern important to the patient population and clinic
2. Review existing literature
3. Define the research question and hypothesis
4. Design a study based on literature review, theories and methods
5. Collect and analyze data
6. Implement interventions and practices based on findings

Case Study: Developing a Research Study

The next several slides will walk you through an example that will enhance your understanding of the process of developing a research study.

Dr. Pieter Cohen observed that Brazilian immigrant women were visiting ambulatory clinics and emergency rooms with a variety of symptoms. These visits revealed that the women were using compounded diet pills from Brazil at high rates.

Hmm...how many Brazilian immigrant women are taking these pills? Why?
What is the specific research question?

• Dr. Cohen’s encounter with these patients led him to ask several questions:
  – How often are these pills prescribed in Brazil?
  – What are in these pills?
  – What are the effects of taking these pills?
• He searched in the medical literature to learn more about compounded diet pills.

Let’s search on PubMed to see what the research literature says about imported compounded diet pills.
What is the specific research question?

- Dr. Cohen read that these pills are commonly prescribed in Brazil.
- He found that the prescription medications in the compounded diet pills can lead to serious harmful health consequences.
- He came across a study on the use of compounded diet pills, and the study showed that 86% experienced side effects, and a third of the diet pill users contacted their providers about side effects.
What is the specific research question?

• Dr. Cohen found no published studies on the use of these compounded diet pills by Brazilian women in the US or by women from other immigrant groups.
• He decided to study…

What is the prevalence, associated factors, and potential side effects of imported compounded diet pill use among female Brazilian immigrants living in the US?
Where to start?

- Review existing patient data to identify issues important to the patient population and/or select high priority issues for your organization
- Review existing literature to determine whether this issue has previously been investigated and in which population
- Identify the gaps in the literature
- Define the research question
- Explore the feasibility of the question
- Refine the research question
Where to start?

- Two month study period
- Female participants recruited from 1 Internal Medicine primary care clinic and 2 local Brazilian churches in an urban community of MA (convenience sample)
- Eligible women were born in Brazil and were between the ages 18-50 years old
- IRB approval obtained from Dr. Cohen’s organizational IRB
Where to start?

- Eligible women recruited, completed approved consent form and then completed a “Health Habits” survey
- Survey development was guided by interviews and focus group with patients, providers, interpreters, community members and organizer
- Survey elicited information on:
  - demographics, education, work, use of any type of medicine from Brazil, body weight perception, diet practices in the US, advice to lose weight and if relevant, diet pill usage
- All women received educational materials about compounded diet pills in Portuguese language following survey completion
Analyze Data

- SAS statistical analysis software version 9
- Calculated response rate
  - Requires knowing your “denominator”
- Calculated frequencies
  - data pill use, demographic variables, current weight satisfaction, ever tried to lose weight in the US, and told to lose weight by provider
- Used analytical tests to understand statistical differences in use of diet pills between diet pill users and non-users
- Used regression models to identify factors associated with pill use
Implement Results

• The study results led to the following recommendations when caring for Brazilian immigrants:
  – Provider screening for compounded diet pill use
  – Providers, nutritionists, and health counselors use of culturally appropriate counseling on safe dieting methods when advising patients to lose weight
Discussion Questions

• What are some factors to consider, unique to your setting (e.g. the composition of your patient population), when designing or implementing a research study in your organization?

• To what extent are providers at your organization engaged in research and/or quality improvement efforts?

• To what extent have providers at your organization received training in research and/or quality improvement methods?
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