BUILDING PRIMARY CARE RESEARCH INFRASTRUCTURE AT YOUR COMMUNITY HEALTH CENTER

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Editors
Shalini A. Tendulkar, ScD, ScM
LeRoi Hicks, MD, MPH
Karen Hacker, MD, MPH

Contributors

Harvard Catalyst Staff
• Karen Emmons, PhD
• Jonathan Finkelstein, MD, MPH
• Kerry Foley
• Evan Kutsko

Safety-net Infrastructure Initiative Staff
• Nazmim Bhuiya, MPH
• Jocelyn Chu, ScD, MPH
• Alice Knowles, MS
• Anne Shila Waritu, MPH
• Kelly Washburn, MPH
Toolkit Overview

• 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.
Contents

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 1
Quality Improvement & Research
Module 1 Learning Objectives

After completing this module, participants will be able to:

1. Describe why there is a need for primary care research.
2. Outline different paradigms of research
3. Discuss the value of engaging in research and/or quality improvement efforts from multiple perspectives
4. Describe the general steps required to initiate research.
The urgent need

• Access is uneven. “It was the best of health care, it was the worst of health care.”
• Outcomes are inadequate.
• Patients are not empowered.
• Costs are unsustainable.

Classic biomedical research paradigms applied to clinical care in community settings won’t get us where we need to go.
Building a learning health care system

• Vision of the IOM Roundtable on Value & Science-Driven Health Care
  – a learning healthcare system designed to generate and apply the best evidence for the collaborative health care choices of each patient and clinician; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care

Building a learning health care system

– Expanding the capacity to meet the acute, near-term need for evidence of comparative effectiveness to support medical care that is most effective and produces the greatest value

– Improving public understanding of the nature of evidence, the dynamic character of evidence development, and the importance of insisting on medical care that reflects the best evidence
The Triple Aim: Care, Health and Cost

• Describes the vision for reforming the American health care system through the pursuit of three aims:
  – Improving the experience of care
  – Improving the health the populations (e.g. geographic populations, employees, ethnic groups etc) and the distribution of health within a population
  – Reducing per capita costs of health care.

Why engage in research in health centers?

• To provide the best possible care to patients
• To facilitate recruitment and retention of primary care providers
• To make a health center more appealing to medical school/residency programs
• To bring in financial resources to the health center
• To facilitate more efficient use of resources
What methods, data sources, and research paradigms work best for primary care-based research???
It depends…

• …on the question
• …on the population and setting
• …on the available resources
• …on what you’d like to do
Unwinding the scientific method: creating new knowledge

• We come to understand things by observing the world in structured ways.
• We develop hypotheses, test them, and (if we’re not ideologically constrained) revise them.
• Sometimes, we intervene and then observe.
• We can be fooled by jumping to conclusions: chance, bias, and confounding.
Threats to what we think we “know”? 

- Bias
- Association
- Confounding
- Causation
- Generalizability

- Internal Validity
- External Validity
Paradigms: conflicting or complimentary?

- Translational
  - Including comparative effectiveness
- Health services research
- Quality improvement research
- Community-Based Participatory Research
The Translational Research Continuum

Basic Biomedical Discovery

What works under controlled conditions? (Up to phase III trials)

Clinical Efficacy

Clinical Practice

How can we change practice? (Dissemination and Implementation Research)

Community Practices

T1

“Bench”

T4

What is the effect on population health? (Outcomes research)

“Bedside”

T2

What works in real world settings? (e.g., Comparative Effectiveness Research)

T3

Community Practices
Comparative effectiveness: old wine?

- Patients to the research community: “What have you done for me lately”…
  - Focus on direct relevance to shared choices
  - Comparison to real alternatives
    - Changes in FDA authorization
  - Patient-centered outcomes
  - Use of both interventional (but more pragmatic) and observational designs
Health services research

- Study of systems for delivering care, including variation, access to care, quality of care.
- Study of strategies of care (quality) improvement, guideline implementation, and other health policy changes.
- Study of the health system as a whole, including health insurance, managed care, health care workforce.
- Study health at the level of the population.
Identifying the Research Interest

Dr. Hacker works in an urban pediatric setting. She is interested in learning about the factors associated with mental health symptom identification in her pediatric patients.

What are the gaps?

She examines the literature and looks for gaps in the current knowledge base on pediatric primary care mental health screening. Based on the gaps and her interest she develops a research question.
What is the specific research question?

What factors are associated with positive Pediatric Symptom Checklist (PSC) scores in children and what is the contribution of parental/personal concern about emotional and behavioral problems on mental health problem identification?
In order to answer this question, Dr. Hacker obtains electronic medical record data, including information on patient demographics and mental health screening from 1668 patients who received care in her setting.

Dr. Hacker seeks approval for her study from the Institutional Review Board.
After analyzing the data Dr. Hacker identifies several characteristics that are associated with a child having a mental health concern when screened during their primary care visits.

These factors include:

- having a parent who has expressed concern about their child’s mental health
- having public insurance
- living in an area with median household incomes of less than $50,000.

![Table 1: Characteristics of PSC-Screened Patients (n = 1668)](image)
Quality improvement: is it research? It depends.

<table>
<thead>
<tr>
<th></th>
<th>Quality Improvement</th>
<th>Classical Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Goal</td>
<td>Local improvement in process or outcome</td>
<td>Generalizable knowledge</td>
</tr>
<tr>
<td>Context</td>
<td>Embraces context</td>
<td>Attempts to eliminate effect of context</td>
</tr>
<tr>
<td>Cycle time</td>
<td>Rapid tests of change</td>
<td>Longer data collection, definitive results</td>
</tr>
<tr>
<td>Data analysis</td>
<td>More visual, level of certainty implicit</td>
<td>Statistical, explicit</td>
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</tbody>
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Quality improvement example

Model for Improvement

- Observe the world in structured ways.
- Develop hypotheses, test them, and revise them.
- Sometimes, we intervene and then observe.
- We can be fooled by jumping to conclusions: chance, bias, and confounding.

Examples of QI Resources from the Cambridge Health Alliance

- Balanced Score Card
- Senior Leadership Report
- Patient Experience of Care
- Risk Management

*Please see Appendix A for a sample QI report.*
Plan-Do-Study-Act (PDSA) Example

Dr. Smith is interested in improving diabetes medication compliance in her recently diagnosed clinic patients with diabetes. She decides to implement a patient education program to improve compliance rates.
Plan-Do-Study-Act: PLAN

• In order to plan this, Dr. Smith thinks about and articulates:
  – What her objective is and what she is planning to do
  – What she hopes to achieve with this strategy
  – Thinks about the “Who”, “What”, “When”, “Where” and “How” she is going to go about implementing and testing her idea
Plan-Do-Study-Act: DO

• Now that the planning is complete, Dr. Smith *implements* her plan and *observes* what happens over 30 days.

• Her observations include:
  – Patient reactions to the program
  – Provider reactions to the education program
  – Challenges in implementing education groups
Plan-Do-Study-Act: STUDY

- Next, Dr. Smith:
  - Reviews her observations and data
  - Synthesizes what she has learned
  - Draws conclusions about whether the educational program worked, what were contributors of success and what limited success.
Plan-Do-Study-Act: STUDY

• Dr. Smith
  – Develops a revised program based on what she learned.
  – Modifies what didn’t work
  – Implements a new program within 2 weeks of terminating the last one.

• Then she studies the new program over the next 30 days.
**Benefits of Engaging in Research/Quality Improvement**

**PATIENT**
- Improved patient care & outcomes
- Access to better & novel tests and treatments
- Informed evidence-based interventions and programs for patients & families

**PROVIDER**
- Improved care of my patients
- Enhanced clinical skills
- Leadership opportunities
- Engagement in critical thinking
- Meaningful research partnerships
Benefits of Engaging in Research/Quality Improvement

**ORGANIZATIONAL/INSTITUTIONAL**

- Improved practice, community, system-level outcomes
- Ability to address public health priorities
- Supportive environment to explore patient safety & quality improvement

**GLOBAL**

- Contribution to clinical knowledge evidence-base
- Facilitated application of research to clinic/community/population
Community-based participatory research (CBPR)

- **Equitable** partnership with the community in
  - Choosing research questions
  - Carrying out research
  - Utilizing complementary skills, assets, knowledge
- Often iterative
- Primary goal is often improved health for the engaged population
Identifying the research interest

A health coalition (HMI) in a city with a substantial Asian population is interested in conducting a needs assessment to understand the health needs of Chinese and Vietnamese adults in their community.

What is the specific research question?

HMI reaches out to key stakeholders in the community, including Dr. Tendulkar, an academic researcher from a local research and evaluation organization and determines the key health areas of interest to the group using their knowledge and qualitative (non numerical) data from community stakeholders.
Where to start?

• The group develops a survey instrument.
• The group discusses an effective and community acceptable strategy to access and recruit community survey participants.
• Dr. Tendulkar obtains approval from her CHC sponsored institutional review board mechanism.
Where to start?

Bilingual outreach workers (OWs) trained by Dr. Tendulkar in data collection techniques seek out participants in approved community locations frequented by the target population. Over 280 Vietnamese and Chinese participants complete the survey.
What did she find?

Dr. Tendulkar’s team analyzes the data and shares the findings with the core team. The team identifies several priority health areas of concern in the survey population including:

- Mental health symptoms
- Healthcare access concerns
- Chronic disease concerns
- High risk behaviors
Dissemination of study findings

In order to disseminate and further interpret the survey findings, the core team presents the findings to:

Providers

Community Members
Impact of research on community

• As a result of this research:
  – School administrators are working more closely with families on mental health.
  – There has been an increase in city-wide efforts to outreach to marginalized populations regarding health care and health insurance.
Steps in initiating research

• What’s the question?
• Who are the partners?
• What’s the design?
  – What will we know at the end
  – What won’t we know
  – Have we thought about chance, bias, and confounding
• Where are the resources?
• What could it lead to?
What’s the question?

- Questions of Interest to you
- Feasible
- Fundable
- Timely

- Impactful
  - Locally?
  - Beyond?
Who are the partners?

- Other clinicians (think across disciplines)
- Academic researchers
- Others with methods expertise
- Health care delivery system
- Insurers
- Public Health
- Community groups
What’s the design?

Classical research hierarchy:
  Case reports
  Case series
  Case control studies
  Cohort studies
  Non-randomized intervention trials
  Randomized controlled trials

Based only on internal validity!
Your best design?…

It depends!
Where are the resources (data and $)?

• Electronic medical records*
• Available claims data*
• Patient feedback (surveys, focus groups)*
• What will it all cost?
  – Investigator time
  – Research assistants (data collection)
  – Analysis
  – Participant costs (e.g. incentives, parking, childcare, transportation, refreshments etc.)
• Internal and external funding sources

*Messier than you think.
What could it lead to?

• Improved care!
• Another study…
  – Larger, more certain conclusions
  – More generalizable, more impact
  – External funding
• Different collaborations
• Career satisfaction, change in trajectories
Summary: it depends

• Your burning (or smoldering) questions
• The impact you’d like to have
• How you want to spend your most limited resource: time
• It will be a lot more rewarding if you have the:
  – Right question
  – Right design
  – Right partners
  – Right data
  – Right resources
Discussion Questions

• Consider your current clinical environment. What are some of the issues you would like to investigate?
  – Do you have access to data?
  – Will you have any partners to work with?
  – What would results be used for?
  – Will you need IRB approval?
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Karen Hacker, MD, MPH
Executive Director of Institute for Community Health
Director of Harvard Catalyst Safety-net Infrastructure Project, CHIRP
KHacker@challiance.org

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