Operationalizing Implementation Science in Research Projects

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Overview

• Selecting and using conceptual frameworks to drive projects & activities
• Study 1: Using PARIHS for a formative evaluation project
• Study 2: Using Proctor for a screening project
• Study 3: Using a combined Pronovost 4E and RE-AIM framework for a community health work project
Selecting and Using Conceptual Frameworks
What is a Conceptual Framework?

• An analytical tool that identifies a “set of variables and relationships that should be examined in order to explain the phenomena” (Kitson et al, 2008)
• Used to make conceptual distinctions & organize ideas
• Can usually be shown pictorially or in a diagram
Why Use Frameworks?

• Provide a **systematic** method for operationalizing, navigating & evaluating the complexities of implementation
  – Offer overall roadmap and directions
  – Help identify study design & how to best answer questions
  – Generalize knowledge about how to implement & sustain interventions across studies, settings & contexts
  – Identify what is needed to replicate successful implementation & ensure sustainability
Selecting Frameworks

• No single framework works for all studies - there are better fitting frameworks depending on the problem & question you want to address

• Implementation frameworks are not individual behavior change models – they focus on some level of provider or system & focus on acceptability, adoption, uptake & sustainability
Selecting Frameworks

• Core issues to consider:
  1. Goal and type of study
  2. Level of construct flexibility
  3. Amount of focus on dissemination vs. implementation activities
  4. Framework level – individual, organization, community, system, policy
  5. What are you going to do, implementation strategies
  6. How the framework can best guide your learning
Three Examples of Using Frameworks

1. Using PARiHS – Formative Assessment of Narcan Distribution in the Emergency Department
2. Using Proctor – The Hepatitis C Testing and Assessment Project (HepCAT)
3. Using the Pronovost 4E & RE-AIM Integrated Model (HIV CHW Project)
Study One:
Using the PARiHS (Promoting Action on Research Implementation in Health Services) Model for a Formative Assessment of Narcan Distribution in the Emergency Department
Study 1: Using PARiHS for Formative Assessment of Narcan Distribution

The Quality Gap and Evidence-Based Practice

– Narcan (naloxone) can reverse overdose
– Rescue kits available via Project ASSERT (ED “peer” program) 8am-11pm
– Only 8% of patients at risk getting kits

• Expanded initiative and policy to provide 24-hour coverage to ensure all at risk offered narcan. Three models:
  1) Project ASSERT
  2) outpatient pharmacy prescriptions
  3) inpatient pharmacy distribution
Framework: Promoting Action on Research Implementation in Health Services (PARiHS)

Facilitation: skills, style

Evidence: research, experience, data

Context: culture, leadership, resources

Implementation
Using the PARiHS Model

Mixed method formative evaluation to:

1. Examine early results of new policy (8 months)
2. Provide in-depth understanding of preliminary results
3. Identify barriers & facilitators to success
4. Identify improvement strategies if needed

Methods:

1. EMR review
2. Focus groups & KI interviews linked to PARIHS constructs
Early Results

- Still low numbers, extremely low uptake of non-Project ASSERT component
Results Linked to PARiHS Model

Facilitation:
-style included episodic & didactic training, no creation of partnerships in development or training

Evidence:
-belief in effectiveness, little clinical experience, patients not receptive

Context:
-leadership support, multiple resources, lack of consensus regarding ED PH role
Study Two:
Using the Proctor Model to Examine the Effectiveness and Implementation of the for a Formative Assessment of the Hepatitis C Testing and Assessment Project (HepCAT)
Study 2: The Hepatitis C Testing and Assessment Project (HepCAT)

• What is the best strategy to improve HCV screening & testing within primary care in settings with a large proportion of high-risk patients?
  ➢ Routine birth cohort testing
  ➢ Enhanced risk screening with targeted testing for all others

• 3 large CHCs in South Bronx, New York
Framework: Proctor Conceptual Model of Implementation Research
Using the Proctor Model - 1

• Evidence-Based Practice:
  – Getting people at risk for HCV tested; no evidence for routine testing for all (as with HIV)

• Implementation Strategies - multiple levels:
  1. Organizational (leadership engagement)
  2. Group/learning (training & ongoing support methods)
  3. Individual provider (primary level of intervention)

• Outcomes – primary focus implementation & service
  1. Acceptability – agreeable, attitudes (qualitative)
  2. Adoption – willingness to implement (qualitative)
  3. Appropriateness – perceptions of fit (qualitative)
  4. Feasibility – can it be done (qualitative)
Using the Proctor Model - 2

- Outcomes – primary focus implementation & se
  - Fidelity – did they do it (screener & EMR testing data)
  - Penetration – % eligible that got it (EMR testing data, screeners done)
  - Sustainability – does the intervention stick (EMR testing data post-intervention)
  - Efficiency – did the right people get screened/tested (EMR testing data & risk data, screener risk & testing data)
  - Patient-centeredness – patient responses (qualitative)
  - Timeliness – getting people to care – (EMR referrals & linkage)
  - Equity – care does not vary by personal characteristics – (EMR demographics linked to screener EMR testing data)
  - Symptomatology - % tested who tested positive
# HepCAT Project Timeline

<table>
<thead>
<tr>
<th>Phase</th>
<th>Months</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Assessment</td>
<td>1-8</td>
<td>Stakeholder engagement (kick-off meeting, site visits); qualitative research activities; chart reviews; EMR data</td>
</tr>
<tr>
<td>Develop Materials &amp; Training</td>
<td>9-12</td>
<td>Develop risk screener; site visits; intensive training</td>
</tr>
<tr>
<td>Enhanced Risk Screener</td>
<td>13-18</td>
<td>Implement screener; targeted testing; ongoing support &amp; reminders; clinic “champions” and “boosters”; screener data; EMR data</td>
</tr>
<tr>
<td>Birth Cohort</td>
<td>19-23</td>
<td>Age based testing with reminder stickers; EMR data</td>
</tr>
<tr>
<td>Wrap-up</td>
<td>23-24</td>
<td>Post-intervention qualitative interviews, complete data analyses</td>
</tr>
</tbody>
</table>
Implementation Strategies

• Provider & staff training
• Champions
• Stakeholder engagement activities – feedback incorporated into structure (who should screen)
• Resources (staff from study at all sites, study staff put labels on to make intervention easy to do)
• Swag & props (pins, pedometers, laminated cards)
• Boosters & regular meetings
Enhanced Risk Screener Phase

Hepatitis C Screening

<table>
<thead>
<tr>
<th>History/Risk Factors</th>
<th>Yes</th>
<th>No</th>
<th>DK</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVER homeless</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVER incarcerated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVER snorted ANY drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVER injected ANY drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥20 lifetime sexual partners</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver disease (told by MD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Hemodialysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organ transplant pre-1992</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfusion pre-1992</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal Hepatitis C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labs: Elevated LFT (ALT: F ≥ 20, M ≥ 31)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Country of birth: if US specify PR _____________
Other reason for HCV test (specify) ____________

<table>
<thead>
<tr>
<th>Plan</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recent HCV Test?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV test ordered? (N/A = HCV+)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Birth Cohort Sticker

Hepatitis C Assessment & Testing Project (HepCAT)

CDC data show that people born from 1945-1964 (currently ages 45-64) are more likely to have hepatitis C than those in other age groups.

At CHCC, FHC, & CFCC, hepatitis C infection is 4 times greater in this age group.

• Is your patient currently aged 45-64?  □ Yes  □ No

  *If yes, a hepatitis C test is strongly recommended.*

• Did you order a hepatitis C test for this patient today?  □ Yes  □ No
Screening & Testing over Time

![Graph showing fraction screened and fraction tested over study weeks.](graph.png)
## Incremental Value of Screening Items

<table>
<thead>
<tr>
<th>Factor</th>
<th># identified</th>
<th># tested positive</th>
<th>% of total positives</th>
<th>Cumulative %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever injected drugs</td>
<td>56</td>
<td>17</td>
<td>41.5%</td>
<td>41.5%</td>
</tr>
<tr>
<td>Ever snorted drugs</td>
<td>200</td>
<td>6</td>
<td>14.6%</td>
<td>56.1%</td>
</tr>
<tr>
<td>Elevated ALT (documented in EMR)</td>
<td>185</td>
<td>4</td>
<td>9.8%</td>
<td>65.9%</td>
</tr>
<tr>
<td>Transfusion before 1992</td>
<td>59</td>
<td>3</td>
<td>8.0%</td>
<td>73.1%</td>
</tr>
<tr>
<td>20+ lifetime sex partners</td>
<td>115</td>
<td>2</td>
<td>4.9%</td>
<td>78.0%</td>
</tr>
<tr>
<td>Maternal hepatitis C</td>
<td>10</td>
<td>1</td>
<td>2.4%</td>
<td>80.5%</td>
</tr>
<tr>
<td>Liver diseases (physician diagnosis)</td>
<td>23</td>
<td>1</td>
<td>2.4%</td>
<td>82.9%</td>
</tr>
<tr>
<td>Ever homeless</td>
<td>66</td>
<td>0</td>
<td>0.0%</td>
<td>82.9%</td>
</tr>
<tr>
<td>Ever incarcerated</td>
<td>67</td>
<td>0</td>
<td>0.0%</td>
<td>82.9%</td>
</tr>
<tr>
<td>Chronic hemodialysis</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td>82.9%</td>
</tr>
<tr>
<td>Transplant before 1992</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td>82.9%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34</strong></td>
<td></td>
<td><strong>82.9%</strong></td>
<td></td>
</tr>
</tbody>
</table>
Implementation Feedback

• Good reminder to focus on HCV
• Screener increased knowledge about patients
• Screener time-consuming
• General preference for screener
• Birth cohort phase difficult to buy into
• Remaining ambivalence
• Process too difficult and not realistic
Study Three: Using an Integrated Pronovost/RE-AIM for Project to Examine Using Community Health Workers to Improve Linkage and Retention in HIV Care
Study 3: Using CHWs for HIV Care

Project Goals:

1. Increase utilization of CHWs to improve access, retention & outcomes among PLWH
2. Strengthen HIV health care workforce & build capacity of RWHAP recipients to integrate CHWs into care team
3. Evaluate implementation & effectiveness of different CHW models
Project Structure & Activities

• 10 RWCA-funded sites across US to be funded to:
  – Implement program with limited funding & limited staffing
  – Receive training
  – Participate in evaluation

• 3 year project
  – 12 months: BU team planning: program, curriculum, training development, evaluation design
  – 18 months: program implementation & evaluation, ongoing training, collect & provide data
  – 6 months: complete evaluation

• Evaluation:
  – No additional funding for surveys or data provision
  – No funding for control/comparison sites
Evaluation

- Hybrid 3 implementation-effectiveness evaluation
  - Primary focus: Experience implementing the programs from multiple staff/organizational perspectives
    - Assessed via:
      - Client, CHW, and site experience with intervention
      - Integration of CHW program into setting
  - Secondary focus: does the intervention work?
    - Assessed via:
      - Changes in clinical markers, adherence, appointment attendance, changes in unmet needs
Pronovost 4 E Process Theory

1. Summarise the evidence
   - Identify interventions associated with improved outcomes
   - Select interventions with the largest benefit and lowest barriers to use
   - Convert interventions to behaviours

2. Identify local barriers to implementation
   - Observe staff performing the interventions
     - “Walk the process” to identify defects in each step of implementation
   - Enlist all stakeholders to share concerns and identify potential gains and losses associated with implementation

3. Measure performance
   - Select measures (process or outcome)
   - Develop and pilot test measures
   - Measure baseline performance

4. Ensure all patients receive the interventions
   - Implement the “four Es” targeting key stakeholders from front line staff to executives

   - **Engage**
     - Explain why the interventions are important
   - **Educate**
     - Share the evidence supporting the interventions
   - **Evaluate**
     - Regularly assess for performance measures and unintended consequences
   - **Execute**
     - Design an intervention “toolkit” targeted at barriers, standardisation, independent checks, reminders, and learning from mistakes

Overall concepts
- Envision the problem within the larger healthcare system
- Engage collaborative multidisciplinary teams centrally (stages 1-3) and locally (stage 4)
## RE-AIM Framework

<table>
<thead>
<tr>
<th>Re-AIM Concept</th>
<th>Key Questions for Concept</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH</td>
<td>Who is expected to benefit? What percent of those are actually exposed to intervention? Who are they (demographics)?</td>
</tr>
<tr>
<td>EFFECTIVENESS</td>
<td>What is the impact of the intervention on the proposed outcome (clinical markers, retention, adherence)?</td>
</tr>
<tr>
<td>ADOPTION</td>
<td>What settings applied the program? Who applied it?</td>
</tr>
<tr>
<td>IMPLEMENTATION</td>
<td>How was the program applied? How consistently was it applied in the way it was intended?</td>
</tr>
<tr>
<td>MAINTENANCE</td>
<td>Is the program maintained over time?</td>
</tr>
</tbody>
</table>
Integrated Implementation Model

1. Summarize the evidence
   Identify interventions associated with improved outcomes
   Select interventions with the largest benefit and lowest barriers to use
   Convert interventions to behaviors

2. Identify local barriers to implementation
   Observe staff performing the interventions
   “Walk the process” to identify defects in each step of implementation
   Enlist all stakeholders to share concerns & identify potential gains & losses associated with implementation

3. Measure performance
   Select measures (process or outcome)
   Develop and pilot test measures
   Measure baseline performance

4. Ensure all patients receive the interventions
   Process & Program Outcomes:
   - Reach
     (4Es: Engage & Educate)
     Number, percent of target audience & demographics
   - Effectiveness
     (4Es: Evaluate)
     Linkage intervention outcomes & impact on quality of life & VL
   - Maintenance
     (4Es: Evaluate)
     Program sustainability & patient effects
   - Implementation
     (4Es: Execute)
     Methods & delivery of linkage interventions
   - Adoption
     (4Es: Execute)
     Representativeness & number of settings & clinicians

Overall Concepts
Envision the problem within the larger healthcare system
Engage collaborative multidisciplinary teams centrally & locally
Why this Integrated Framework?

• Integrating a process implementation model & evaluative model will help us drive both intervention implementation & evaluation.

• Helps ensure model works for sites & increases their buy-in by maximizing our focus on how the implementation & evaluation should be planned, organized, and scheduled.

• Pronovost model well-suited for larger scale projects that include multiple sites with centralized support and TA. Cyclical nature of model allows for formative work & feedback to drive modifications & adaptations.

• Pronovost model does not provide clear evaluation methodology. RE-AIM provides ideas for quantitative outcome measurement.
Using the Integrated Framework

- Steps 1 - 3 of Pronovost model will be used to create a single CHW intervention to be evaluated in Step 4.
  - Step 1: summarize the evidence regarding effective CHW programs & transferability to HIV as appropriate
  - Step 2: identify local barriers to implementation
    - Needs assessment
    - Observation: “walk the process” & qualitative methods
  - Step 3: identification of performance measures, pilot
  - Step 4: integrate the 4Es into RE-AIM outcomes
    - Engage and Educate components integrated within the Reach dimension of RE-AIM
    - Evaluate component integrated within Effectiveness and Maintenance components
    - Execute component of integrated within Implementation and Adoption
<table>
<thead>
<tr>
<th>Dimension</th>
<th>Measure(s)</th>
<th>Data Source(s)</th>
</tr>
</thead>
</table>
| REACH             | % eligible who get CHW intervention  
                      Dose of intervention received  
                      Demographics                                    | Medical chart data  
                      Client survey                                      |
| EFFECTIVENESS     | Impact of the intervention on clinical markers, retention, adherence,  
                      unmet needs, stigma, self-efficacy,  
                      health literacy                                   | Medical chart data  
                      Client survey                                      |
| ADOPTION          | Frequency of adoption  
                      Where is program adopted                           | CHW encounter form  
                      Site visit tools                                    |
| IMPLEMENTATION    | Specific activities & dose  
                      Integration of CHWs into team  
                      Adaptions to protocol                              | CHW encounter form  
                      Fidelity monitoring tool  
                      CHW satisfaction survey  
                      Qualitative interview  
                      Site visit tools                                    |
| MAINTENANCE       | Consistency over time  
                      Budget impact                                     | CHW encounter form  
                      Cost analysis                                        |
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HRSA
AHRQ
Project Assert