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The Keys to Evaluative Methods for Quality Improvement Interventions: Understanding and Analyzing Context

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Erin Holve, Ph.D., M.P.H., M.P.P.
- Senior Director of Research & Education, AcademyHealth
- Principal Investigator of the EDM Forum
- eGEMs Editor-in-Chief

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Today’s Moderator

→ Don Goldmann, M.D.
  – Chief Medical and Scientific Officer, Institute for Healthcare Improvement (IHI)
  – AcademyHealth Board of Directors
Learning Objectives

Two methodological frameworks for understanding and analyzing the role of context in QI interventions will be presented. At the conclusion of the session, participants will be able to:

→ Understand the importance of context in QI effectiveness
→ Understand and apply key frameworks for evaluating QI interventions
→ Understand how contextual variables can be studied across multiple settings
Today's Faculty

Gareth Parry, M.Sc., Ph.D.

Kathryn McDonald, M.M./M.B.A.
Evaluation of Improvement Initiatives

Gareth Parry, Senior Scientist, IHI
gparry@ihi.org

EDM Forum Webinar
July 1st 2014
Summary

1. Background
2. Why most improvement initiatives are found to “fail”
3. Program Theory
4. Improvement Phases and Degree of Belief
5. Recommendations
Background
Penicillin

The Nobel Prize for Medicine was awarded in 1945 to:

Sir Alexander Fleming

Ernst B. Chain

Sir Howard Florey
Penicillin

1928

- From a single petri dish he had discarded, Alexander Fleming identified a mold and named it *Penicillum.*

1930s

- Fleming tried with limited success to produce and test the effects of *Penicillin* as a surface antiseptic.

1939

- Ernst Chain took an interest in Fleming’s work and with Howard Florey identified the active ingredient and produced it in larger quantities.
- Tested it by injecting *Penicillin* into two infected mice – who recovered.
Penicillin

1940s

- With **Norman Heatley**, produced sufficient quantities to test penicillin in fifty mice.
- Tested it in three people who were dying from bacterial infections.
- Subsequent successful clinical trials led to funding to mass produce *Penicillin*.

1945

- Sir Alexander Fleming, Ernst Chain & Sir Howard Florey awarded Nobel Prize for Medicine
Penicillin

**Sir Henry Harris** said at the Florey Centenary lecture in 1998:

- "Without Fleming, no Chain; without Chain, no Florey; without Florey, no Heatley; without Heatley, no penicillin."

**Or:**

- Without Fleming, no **innovation**; without Chain and Florey, no **testing**, without Heatley, no **wide scale** use of penicillin
Why most improvement initiatives are found to “fail”
Conclusions: A multipayer medical home pilot, in which participating practices adopted new structural capabilities and received NCQA certification, was associated with limited improvements in quality and was not associated with reductions in utilization of hospital, emergency department, or ambulatory care services or total costs over 3 years. These findings suggest that medical home interventions may need further refinement.

Conclusions: Implementation of surgical safety checklists in Ontario, Canada, was not associated with a significant reductions in operative mortality or complications.
“The expected value of any net impact assessment of any social program is zero. This means that our best *a priori* estimate of a net impact assessment of a program is that it will have no effect.”

“… the data Ioannidis found were disturbing: of the thirty-four claims that had been subject to replication, forty-one per cent had either been directly contradicted or had their effect sizes significantly downgraded.”
Innovation: Small Number of Settings

Applied in a narrow range of contexts

Improvement in 100% of sites

- Effective
- Not Effective
Initial Testing: Small Number of Settings

- Applied in a wider range of contexts
- Improvement in 80% of sites
More Settings as Range of Contexts Begins to Expand

Applied in a wider range of contexts

Improvement in 70% of sites
Wide Range of Contexts

Applied in a wide range of contexts

Improvement in 50% of sites
Reduction in Effectiveness from Applying the Same Fixed-Protocol Program in Different Contexts
Reduction in Effectiveness from Applying the Same Fixed-Protocol Program in Different Contexts

Innovation sample

Evaluation sample

Immediate wide-scale implementation

% Effective

0% 50% 100%

Effective Not Effective
Effectiveness May Be Maintained If We Can Learn in What Contexts the Protocol Can Be Amended to Work

Learn which contexts it can be amended to work in as we move from Innovation to Prototype to Test and Spread

<table>
<thead>
<tr>
<th>Context</th>
<th>% Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>93%</td>
</tr>
</tbody>
</table>

Effective  Not Effective
Core Concepts & Detailed Tasks

Core Concepts

Use a reliable method to identify deteriorating patients in real time.

When a patient is deteriorating, provide the most appropriate assessment and care as soon as possible.

Detailed Tasks and Local Adaptations

- MEWS >=5
- MEWS >=4
  - 2 Nurses 1 Physician
  - 1 Nurse 1 Physician
  - 1 Physician

Theory

Action
Improvement Phases and Degree of Belief
Degree of Belief in Change Ideas

High

Moderate

Low

Innovation
To generate or discover a new model of care with evidence of improvement in a small number of settings.

Testing
Test whether a model works or can be amended to work in specific contexts.

Scale up and Spread
Implementation of models shown to apply in a broad range of contexts.
Degree of belief

Evidence
Degree of belief

Evidence

Act

Nick Black. Cochrane Lecture 2001
Program Theory
1) Generating the pressure (will) for ICUs to take part
2) A networked community
3) Re-framing BSIs as a social problem
4) Approaches that shaped a culture of commitment
5) Use of data as a disciplinary force
6) Hard edges
A Framework for Evaluation

The Kirkpatrick Evaluation of Learning Framework has four levels:

1. **What was the participants’ experience?**
   - Eg. Did the participants have an excellent *experience* working on the improvement project?

2. **What did the participants learn?**
   - Eg, Did they learn improvement methods and begin *testing*?

3. **Did they modify their behavior?**
   - Eg. Did they work differently and see change in their *process measures*?

4. **Did the organization improve their performance?**
   - Eg. Did they improve their *outcomes*?
**Content Theory:**
What changes will teams make that will result in improvement?
Explains how we predict that the change concepts and improvement drivers applied in the project will lead to improved outcomes.

**Execution Theory:**
What will the improvement initiative do that will lead teams to adopt the process changes?
Explains what improvement leaders or agents will do that will lead front-line teams to adopt the changes described in the content theory.

*Parry et al. Recommendations for Evaluation of Health Care Improvement Initiatives 2013 Acad Peds*
An Approach to Evaluation:

- Focus on **Learning** what it takes to bring about improvement.
- Improvement requires **social change**.
- **Concepts** rather than fixed protocols are a good starting point to test and learn whether improvement interventions can be amended to a specific setting.
- Provide a prediction, or **degree of belief** a model will achieve a particular impact in a specific setting.
- Align the **measurement** system to the **program theory**.
- **Rapid-cycle evaluation** approaches that will enable amendment to local settings.
Six Tips – Health Foundation

1. Planning for evaluation adds most value when included at the start of the program, preferably in the intervention or service development phase.

2. A collaborative approach to agreeing a clear theory of change is helpful. It can ensure that all stakeholders have the same understanding about what change is being made and how it will work.

3. It’s important to differentiate between what you are aiming to achieve within a specific timeframe and your longer term ambition.

4. Align evaluation design to program design, review the evaluation model regularly, be flexible and plan for change.

5. Understand the detail of the intervention, where in the system it is working and, last but by no means least, how the intervention interacts with its context.

6. Co-creating evaluations with those being evaluated can help to surface the tensions that can exist between local evaluation priorities and program priorities.

Louise Thomas: Evaluating local models of care: 6 tips from Health Foundation evaluations. 19 June 2014
http://t.co/YIOzKPo2Wl
### Improvement aim:

- **Innovation**
  - To generate or discover a new model of care with evidence of improvement in a small number of settings.

- **Testing**
  - To engage organizations and enable them to test whether a model works or can be amended to work in their context.

- **Spread**
  - To engage organizations to adopt models associated with a high degree of belief in their applicability and impact in a broad range of contexts.

### Evaluation aim:

<table>
<thead>
<tr>
<th>Content</th>
<th>Impact</th>
<th>Degree of belief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stuff</td>
<td>Generation</td>
<td>Model will apply in similar contexts.</td>
</tr>
<tr>
<td></td>
<td>Amendment</td>
<td>Model can be amended to work in specific contexts.</td>
</tr>
<tr>
<td></td>
<td>Estimate</td>
<td>Verify</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Execution</th>
<th>Impact</th>
<th>Degree of belief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development and Amendment</td>
<td>Amendment</td>
<td>The execution approach will lead to testing of the content theory.</td>
</tr>
<tr>
<td>Estimate</td>
<td>Estimate</td>
<td>The execution approach will lead to implementation of the content theory</td>
</tr>
</tbody>
</table>

### Evaluation approaches:

<table>
<thead>
<tr>
<th>Type</th>
<th>Descriptive, observational, experimental</th>
<th>Adaptive comparative studies, randomized cluster and stepped-wedge designs.</th>
<th>Adaptive comparative studies, randomized cluster and stepped-wedge designs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative</td>
<td>Kirkpatrick Levels 3 and 4.</td>
<td>Kirkpatrick Levels 1 through 4. Longitudinal data analysis, eg. control chart and interrupted time series methods</td>
<td>Primarily Kirkpatrick Level 3, secondary Kirkpatrick Level 4 Longitudinal data analysis, eg control chart and interrupted time series methods, to provide an estimate of the improvement associated with an amended execution theory.</td>
</tr>
<tr>
<td>Qualitative</td>
<td>Clarify details of the model.</td>
<td>Identify how teams did or did not learn and apply their learning, in their local context. Recommendations for how to amended content and execution theories.</td>
<td>Identify how teams did or did not learn and apply their learning, in their local context. Recommendations for how to amended the execution theory and point to issues with the content theory.</td>
</tr>
</tbody>
</table>
In alignment with the PDSA methodology, the improvement field, must “Act” and consider how to apply the lessons learned in the future design of improvement initiatives.

Studying and improving our own approaches is a vital component of learning what it takes to bring about improvement,

**Findings:**
- Some improvement.
- Many lessons on what makes an effective collaborative.
Thank you!
References


THE CONTEXTUAL FACE OF QUALITY IMPROVEMENT

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http://healthpolicy.stanford.edu
Center for Health Policy & Center for Primary Care and Outcomes Research (CHP/PCOR)
Overview

- Motivation for considering context
- Key concepts
- Relevant frameworks and theories
- Applications to research and practice
Motivation

• Why do some improvement strategies succeed in some situations and not others?
• What are the indications for particular strategies to work?
• “Context” has potential to enable, thwart and/or interact with quality improvement interventions
• Goal: Anticipate transferability of an intervention package from one context to another
Pawson and Tilley’s realist CMO framework: develop plausible explanations for “how” interventions produce their results, AND under “what” conditions

Figure Source: Theory Driven Inquiry Website (Belgium) [http://www.itg.be/internet/ds/tde/tde.html](http://www.itg.be/internet/ds/tde/tde.html)
What is a Quality Improvement Intervention (QII)?

- **Quality improvement**: “formal approach to analysis of performance and systematic efforts to improve it” (RWJF)

- **Quality** per Institute of Medicine STEEEP
  - safety, timeliness, effectiveness, efficiency, equity, patient-centeredness

- **Intervention**: newly created attempt to improve performance...able to package and replicate
  - Often multi component designed to change behaviors and actions
  - Other names: strategies, initiatives, programs
What is Context?

• That which is not defined as mechanism or outcome of the intervention

• What contexts matter?
  • Those which might influence mechanisms and/or outcomes of the intervention

• Blurring issue and perspective
  • a visual may help…
Visualizing QII and Context

**ORIGINAL HOSPITAL**
- Performance feedback
- Nurse empowerment
- Checklist
- Dedicated cart
- Educational intervention
- Practice survey

**HOSPITAL A**
- Checklist
- Dedicated cart

**HOSPITAL B**
- Performance feedback
- Nurse empowerment
- Checklist
- Dedicated cart
- Educational intervention
- Practices survey
- Leadership Intervention
- Systems Intervention

**Context:**
1. Performance feedback system in place
2. Nurses already empowered
3. Physicians previously educated on insertion
4. Practice surveys ongoing
5. Enthusiastic leadership
6. Adequate resource commitment
7. Responsive system to identify equipment issues

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**Context:**
1. Adequate resource commitment

---

**Context:**
1. Enthusiastic leadership (implied)
2. Adequate resource commitment (implied)
3. Responsive system to identify equipment issues (described)
Audiences for Context Sensitive Perspective

- Delivery system practitioners
- Policy makers
- Researchers
  - Phases of QII development and testing

<table>
<thead>
<tr>
<th>Research Phase</th>
<th>Typical Approach/Goal</th>
<th>Context Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Evaluation/Proof of Concept for a QII</td>
<td>Develop logic model of mechanisms related to improving quality target</td>
<td>What are the enablers and barriers to potential interventions working in our context?</td>
</tr>
<tr>
<td></td>
<td>Use logic model: design, implement, and test intervention in one setting to evaluate effectiveness</td>
<td>What context factors should we describe, measure, and/or monitor?</td>
</tr>
<tr>
<td>Initial QII Evaluation</td>
<td>Test with more rigorous methods, expand to more than one setting to evaluate effectiveness and context sensitivity</td>
<td>What context factors should we measure consistently across sites?</td>
</tr>
<tr>
<td>Further QII Evaluation for Promising Interventions</td>
<td>Design scale-up plan; implement and monitor over time</td>
<td>Which context factors that influence effectiveness are fixed vs mutable?</td>
</tr>
<tr>
<td>Scale-up and Spread of Effective QII</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Theories and Frameworks

• Organizational theory
  • Macro and micro, in between, interactions

• Health care improvement frameworks
  • RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance
    • Glasgow RE et al. American J of Public Health 1999
  • CFIR: Consolidated Framework for Implementation Research
    • Damshroder LJ et al. Implementation Science, 2009
Applications – Conceptual Level

CFIR Constructs

**OUTER SETTING**
Patient Needs and Resources

The extent to which patient needs, barriers and facilitators known and prioritized
- Issues with ID band discomfort and resultant removal identified by baseline survey. One size/type of ID band not good for all children. In response, some hospitals worked with vendors to develop bands for vulnerable patients (skin integrity, difficulty keeping band in place in NICU patients).

**External Policy and Incentives**

External strategies to spread interventions
Improving patient ID first goal of the Joint Commission’s National Patient Safety Goals since 2003.

**INNER SETTING**
Structural Characteristics

Social architecture, age, maturity, and size of an organization
Freestanding children’s hospitals; children’s hospitals within academic medical centers; community hospitals. Data on size included.

**Readiness for Implementation**

Tangible indicators of organizational commitment to QII
- Leadership engagement noted on safety walk-rounds.
- For all the institutions, collaboration among nurses, physicians, and quality professionals ensured collaborative was a priority. Data sharing at all levels.

**INDIVIDUAL CHARACTERISTICS**
Knowledge and Beliefs About the Intervention

Individuals’ attitudes toward and familiarity with QII
Survey used to identify attitudes at outset (eg, belief that checking the band not needed because “I know my patient”).

Self-efficacy

Individual belief in their own capabilities to act
Engaging all levels strengthened desire to change and will to sustain gains made.
**Application: Prioritized Contexts**

RAND-led Patient Safety Practices Project (excerpt)

<table>
<thead>
<tr>
<th>Context Domain [CFIR Analog]</th>
<th>Factors</th>
<th>Importance to Specific QII? Example: Medication Reconciliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Structural Organizational Characteristics [Inner Setting: Structural Characteristics]</td>
<td>Size, Location, Financial status, Academic status, Organizational complexity</td>
<td>Y</td>
</tr>
<tr>
<td>2. External Factors [Outer Setting: Peer Pressure; External Policy and Incentives]</td>
<td>Regulatory requirement, Payments or penalties, Local sentinel event, Marketplace competition, Competing demands</td>
<td>N</td>
</tr>
<tr>
<td>4. Implementation and Management Tools [Inner Setting: Implementation Climate]</td>
<td>Staff education and training, Designated staff time to implement, Use of audit and feedback</td>
<td>Y</td>
</tr>
</tbody>
</table>

*Based on voting by Technical Expert Panel, Y=yes; N=no
Applications: Measurement

• For any given study
  • Based on logic model of context factors
  • Practical considerations

• For knowledge building across studies…harmonization desirable…starting points
  • Shekelle PG et al (RAND Patient Safety Study)
    • http://www.ahrq.gov/research/findings/final-reports/contextsensitive/context.pdf
  • Kaplan HC et al (Systematic Review of Context Influence)
    • Milbank Quarterly 2010
  • Need repository of context measures, analogous to AHRQ Atlases (e.g. Care Coordination Measures Atlas)
Applications: Reporting

• SQUIRE (Standards for Quality Improvement Reporting Excellence) has 6/19 items calling out context elements...

• Let’s reverse engineer a “context checklist”
  ✓ who (champions, supporters) and what (events, observations) triggered… changes, and why now (timing) [Item 5]
  ✓ how elements of (setting) identified/characterized [Item 8]
  ✓ planning… and implementing the intervention [Item 9]
  ✓ contribution of context factors to effectiveness [Item 11]
  ✓ strength of association between changes and context factors [Item 13]
  ✓ interpretation and inferences about settings where intervention more or less effective [Item 17]

SQUIRE web site: http://squire-statement.org/guidelines
From Considering Context to Caring About It, A Lot!

• Scratched the surface of a complex topic

• Progress requires
  • ongoing partnership in a learning health care system among practitioners, policy makers and researchers
  • through research phases from proof of concept (innovation) to testing to ‘scale up and spread’
  • and with frameworks that consider varying contextual levels at play from macro to micro

• Keep view of context simple enough, but not overly simplified
  • PICOTS → PLICOTS extending Evidence-based Practice Center approach to summarizing studies
    • PICOTS: population, intervention, comparator, outcomes, timing, setting
    • PLICOTS: adds “L” for logic model and “C” for context
Discussion & Questions

Château de Fontainebleau: 800 Year Context Project
Submitting Questions

To submit a question:

1. Click in the Q&A box on the left side of your screen
2. Type your question into the dialog box and click the Send button
Thank You

Please take a moment to fill out the brief evaluation which will appear in your browser.