Quality Improvement Research vs. Implementation Science

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July 24, 2014
Quality Improvement Research Methods

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Confusing Terminology

- Implementation and Dissemination Science
- Improvement Science (Science of Improvement)
- Healthcare Delivery Science
- Systems Engineering
- Systems Strengthening

While there may well be meaningful distinctions among these approaches, fragmenting disciplines and confusing the field belie the essential commonalities of these approaches.
Key Attributes of Improvement Science
(Model for Improvement Methodology)

- Clear, measurable aim
- A measurement framework in support of reaching the aim
- Clear description of the ideas (content) and how these ideas are expected to impact results (the causal pathway from changes to desired outcomes, and their attributable effect)
  - Conceptual or logic model, or “driver diagram”
- Clear description of the implementation strategy (execution)
  - What will be done to ensure reliable adoption of the content
- Dedication to rapid testing (PDSA) - prediction and learning from tests
- Understanding/describing/visualizing systems (process map, value stream)
- Learning from variation and heterogeneity
  - Use of time-ordered data to detect special cause and improvement
  - Understanding why results differ by ward, organization, region
- Application of behavioral and social sciences
The Model for Improvement Simplified

Deming 1900-1993
System of Profound Knowledge

Appreciation of a System
Theory of Knowledge
Understanding Variation
Psychology

Langley et al 1997
The Model for Improvement

What are we trying to accomplish?
How will we know that a change is an improvement?
What change can we make that will result in improvement?

Model for Improvement

Act
Plan
Study
Do
Rigorous (Even Publishable) QI Is Possible Almost Anywhere

SQUIRE Guidelines

http://squire-statement.org/
Personal Experience
Effect of Standard Antibiotic Order Form on Duration of Prophylaxis

Before use of a standard antibiotic order form

After use of a standard antibiotic order form

Durbin et al. JAMA 1981;246:1796
Impact of Precautions Compliance on Risk of Respiratory Syncytial Virus Infection

Figure 1. Rise in Incidence Density of New Nosocomial RSV Infections with Increasing Levels of Exposure to Hospitalized Patients Shedding Virus, per 1000 Patient-Days.

If They Can Do It in Bogotá…

Reducing Post-Caesarian Infections
Cause and Effect Diagram

Perioperative antibiotic prophylaxis
- Utilization
  - Agent
  - Dose
  - Timing

Preparation of the skin before surgery
- Skin antisepsis
  - Antiseptic agent
  - Hair Removal
  - Application technique
  - Method
  - Timing

Surgical technique
- Technique
  - Training
  - Skill
  - Complications
  - Extraction of the placenta
  - Type of incision

Endometritis After Cesarean Section

Host & Antenatal Factors
- Preexisting host factors
  - Underlying diseases
  - Nutritional status

Prenatal care
- Bacterial vaginosis

Pregnancy-related conditions
- Chorioamnionitis
  - Clinical
  - Subclinical

Peripartum events
- Vaginal exams
  - Technique
  - Number

  - Labor
    - Presence
    - Duration

  - Rupture of membranes
    - Presence
    - Duration
Meta-Analysis the Effect of Antibiotic Prophylaxis on Infection Rates after Cesarean Section

# Priority Matrix

<table>
<thead>
<tr>
<th>Factor</th>
<th>Importance</th>
<th>Within the capacity of hospital personnel to improve</th>
<th>Timeframe for improvement</th>
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<tbody>
<tr>
<td>Antibiotic prophylaxis</td>
<td>4</td>
<td>4</td>
<td>short</td>
</tr>
<tr>
<td>Skin preparation</td>
<td>3</td>
<td>4</td>
<td>short</td>
</tr>
<tr>
<td>Surgical technique</td>
<td>4</td>
<td>4</td>
<td>medium</td>
</tr>
<tr>
<td>Antenatal factors</td>
<td>3</td>
<td>1</td>
<td>long</td>
</tr>
<tr>
<td>Peripartum events</td>
<td>4</td>
<td>2</td>
<td>medium</td>
</tr>
</tbody>
</table>
## Utilization and Timing of Antibiotic Prophylaxis for Cesarean Section

<table>
<thead>
<tr>
<th></th>
<th>% receiving prophylaxis</th>
<th>% receiving prophylaxis ≤1 hour after delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>70%</td>
<td>31%</td>
</tr>
<tr>
<td>Hospital B</td>
<td>32%</td>
<td>70%</td>
</tr>
</tbody>
</table>
Hospital A: Existing System

Plan to perform C/S

Prescribe prophylaxis?

Yes → MD writes prescription

No → Antibiotic in L&D or pharmacy?

Yes → Transport antibiotic to patient

No → MD writes prescription

Family buys antibiotic at pharmacy outside the hospital

Start

Delivery

Administer antibiotic

End
Hospital A: Revised System

Plan to perform C/S

Start

Delivery

Administer antibiotic

End

MD writes prescription

Nurse puts antibiotic in packet of supplies

Packet transported to operating room with patient
Utilization and Timing of Perioperative Antibiotic Prophylaxis & Surgical Site Infections After Cesarean Section

Fancy statistical analysis is not necessary for most QI evaluation – as long as the data are analyzed in a time-ordered fashion.

Run charts or statistical process control charts will do.
Scottish Patient Safety Program (SPSP)
General Ward C. Diff Rate
January 2008 through August 2010

T1 Median = 1.2

T2 Median = 0.5 (58% Decrease)
Monitoring Patient Safety

- Voluntary event reporting
- Morbidity and mortality conferences/reports
- Chart auditing
  - IHI Global Trigger Tool
- Automated data mining
  - Patient Safety Indicators (AHRQ PSIs)
  - Automated trigger tools
- Random Safety Audit
Random Safety Audit

- Translated from industry (banking and random process audits via Paul Plesk)
- Real time by the front line
- Data and feedback virtually immediate
  - Reliability of key safety processes evident immediately
  - Motivating, enabling, reinforcing; builds self-efficacy and social norms (key elements of behavioral change theory)
- Combines audit and feedback with iterative PDSAs
  - Even better than “what can I try by next Tuesday”
Random Safety Audit

• Systematically monitors a subset of error-prone points in the system that have the potential to harm patients
• Items selected randomly to be addressed either on
  – On multi-disciplinary rounds (provider input required)
  – Any time during day (provider input not needed)
• Deck can be “packed”
• 20 items developed by expert consensus for testing in NICU (21st item added later)
• 4X6 “cards” include yes/no data form; trivia question on back
Staff Perceptions of the Random Safety Audit

- 84% of staff participated in rounds on which audit performed
- 100% agreed or strongly agreed that this improved quality and safety
- 95% agreed/strongly agreed that it increased knowledge of clinical guidelines and safety goals
- 9% agree with statement “asking a safety question of rounds took up too much time”
Interventional Study to Evaluate the Impact of Alcohol-Based Hand Gel on Hand Hygiene Compliance

- Phase I: Baseline period
- Phase II: Introduction of alcohol gel
- Phase III: Alcohol rub + QI
- Phase IV: Maintenance

Fig. 2. A, trends in compliance by study phase and type of intensive care unit. February through December. B, trends in compliance by month, February through December.
Effective QI?

- Satisfied with gel: 45%
- Gel helped with compliance: 42%
- Sticky, uncomfortable feeling: 53%
- Conveniently located: 57%
- Posters effective: 32%
- Knew there was opinion leader: 24%
- Received performance feedback: 68%
Try Something Yourself

- “I do not know who my doctor is”
- “I don’t see all of those errors you keep talking about”
- “You are always late for rounds”
IHI’s Roadmap for Moving from Innovation to Scale-up
IHI’s “Production” Model

AIM
Locate Will

Find, vet, and test Ideas

Demonstrate under varied conditions

Spread

RESULTS AT SCALE

Execution

Innovation, Prototyping

Pilot testing

Spread, Scale up
What’s Needed to Improve – Building, Implementing, and Spreading Evidence-Based Practice

• Three critical elements:
  – Will
  – Ideas (finding innovative concepts and building the evidence)
    – Where do the ideas come from?
    – How do we increase our degree of belief that the ideas are valid?
    – How do we implement and spread what works?
  – Execution (Implementation)
Degree of Belief in Change Ideas

- **High**: Innovation/Prototype Phase
  - (set design targets, develop Ideas and predictions, and draft an initial conceptual model and change package)
- **Moderate**: Pilot Phase
  - (test and revise/amend conceptual model and change package)
- **Low**: Adapt and Spread
  - (implement and disseminate a successful change package)
The Transition from Descriptive Theory to Normative Theory

Carlile and Christensen, HBR 2002
Rigorous Learning in Complex Systems

- **Diverse designs** (quasi-experimental and adaptive trials)
- **Diverse learning and evaluation methods** (mixed methods)
- **Diverse analytic methods** (interrupted time series, SPC, multi-variable models)

Adapted from Berwick
Diverse Study/Evaluation Designs

- Examples include:
  - Cluster randomized trials and meta-analytic trials
  - Bayesian and Adaptive trials
  - Pragmatic trials
  - Action and community-based participatory research
  - Quasi-experimental designs (e.g., factorial, step wedge)
  - Context-sensitive mixed methods research/Realist Evaluation
  - Observational studies with attention to exposure and follow-up (including propensity scoring, instrumental variables)
    - “Big Data” Mining and advanced analytics
Developing and Describing your Theory and Implementation Approach
## Kirkpatrick Framework

<table>
<thead>
<tr>
<th></th>
<th>Experience</th>
<th>Learning</th>
<th>Process/Behavior</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What was the participants’ experience? Did the participants have an excellent experience working on the improvement project?</td>
<td>What did participants learn? Did they learn improvement methods and begin testing?</td>
<td>Did participants modify their behavior? Did they work differently and see change in their process measures?</td>
<td>Did the organization improve its performance (via outcome measures)?</td>
</tr>
</tbody>
</table>


Theory Building, Conceptual Models, Logic Models, and Driver Diagrams
Why Bother?

- Scientific quality improvement requires an explicit theory for achieving a specific goal
  - Theories should be accompanied by a clear statement of the predicted outcome and a measurement framework to guide testing of the theory
  - Interventions should be guided by the predicted causal pathway towards the desired outcome
  - PDSA cycles embody tests of a theory along the causal pathway from promising interventions to the desired outcome
Conceptual Models, Logic Models, and Driver Diagrams All:

- Clarify the theory and inform strategy for achieving outcomes
- Insure that everyone is on the same page
- Provide a framework for measurement
- Inform evaluation, whether internal or external
- Usually are required for competitive grants and contracts
- Allow other organizations or researchers to compare their project/study design to what others have used
Inputs
Resources invested and activities performed by each improvement agent/entity

Level 1 Participant Experience

Level 2 Learning

Level 3 Process/Behavior Changes

Level 4 Clinical, personal, organizational outcomes

Content Theory:
What changes will teams make that will result in improved outcomes?

Execution Theory:
What will the improvement initiative do that will lead teams to adopt the process changes?

Degree of Belief in Change Ideas

- **High**
  - Innovation/Prototype Phase
    - (set design targets, develop ideas and predictions, and draft an initial conceptual model and change package)

- **Moderate**
  - Pilot Phase
    - (test and revise/amend conceptual model and change package)

- **Low**
  - Adapt and Spread
    - (implement and disseminate a successful change package)
Conceptual Models

- Show dynamic interaction of multiple personal and environmental factors
- Generally take a broader theory-based view of a problem than logic models or driver diagrams
- Unlike logic models and driver diagrams, facilitate non-linear display of the interaction of factors that influence an outcome or behavior
- Most commonly used in sociology and behavioral science, but is a staple of health services research and can be adapted for any theory and outcome
Examples of Determinants for a Conceptual Model (Social Cognitive Theory)

- Environment
- Demographics
- Personal context (as perceived by the person)
- Expectations
- Values placed on outcome (expectancies)
- Self-control
- Observational Learning
- Reinforcements
- Self-efficacy
- Emotional coping/resilience
- Reciprocal determinism (dynamic interaction of person, behavior, and environment in which behavior is performed)

Bandura: Self-efficacy: Towards a unifying theory of behavioral change; Psychological Review, 1977; 84:191
Rich Pictures
Informed, Activated Patient

Prepared, Proactive Practice Team

Functional and Clinical Outcomes

*Some note that this is mainly a list of elements that does not show interactions
HIT/PHR – Oriented Planned Care Model

- Communication
- Optimized Care Plan
- Decision Support
- Health Promoting Actions

Improved Health Outcomes

Information Technology

Informed, activated patient

Prepared, proactive care team
Conceptual Model for Influenza Vaccination – Modified from Protection Motivation Theory

**THREAT APPRAISAL**

- **Perceived extrinsic rewards**
  - How would vaccination benefit others?

- **Perceived intrinsic rewards**
  - How would vaccination benefit me?

**Vulnerability**
- What is the likelihood I would become ill from the flu?

**Response efficacy**
- How well does the influenza vaccine work?

**Response cost**
- What is the burden associated with influenza vaccination?

**Self-efficacy**
- Do I feel comfortable enough with the management of my disease that I can proceed with vaccination myself?

**COPING APPRAISAL**

- **Severity**
  - How serious is the flu?

**Environmental Factors**
- Residence (On campus vs. off)
- Access to vaccine
- Degree of medical engagement
- Level of parental involvement

**Personal Factors**
- Complexity of illness (duration, severity, medication requirement)
- Mental health status
- Age / Gender / Race
- SES

**Sources of Information**
- Experiential
- Peers
- Physician
- Media
- Family

**MOTIVATION FOR VACCINATION**

**RECEIPT OF VACCINE**

Courtesy Hayden Schwenk
Driver Diagrams

• Clear, intuitive, visual demonstration of the most highly leveraged interventions and factors that are believed to promote the desired outcome
  – It’s still a theory and predictive model
• Easy to “hang” measures on each key driver
• Promote specificity regarding the impact of specific changes on the key “drivers” and the causal pathway to the desired outcome
• May be useful to construct an “anti-driver” diagram or force field analysis to explicitly call out important barriers along the causal pathway
• Not ideal for showing complexity and interactions
• Ignore “less important” and unmeasured factors in determining the outcome
Aim: An improved system

- P. Driver
- S. Driver 1
- S. Driver 2
- S. Driver 3

Changes:
- Change 1
- Change 2
- Change 3
What Changes Should We Test?
Understanding the System for Weight Loss

**Outcome**

**Primary Drivers**
- Calories In

**Secondary Drivers**
- Limit daily intake
- Substitute low calorie foods
- Avoid alcohol
- Work out 5 days

**Process Changes**
- Track Calories
- Plan Meals
- Drink H2O Not Soda

**AIM: A New ME!**

```
System is perfectly designed to achieve the results it gets
-Donabedian
```
How Will We Know We Are Improving?
Understanding the System for Weight Loss with Measures

AIM: A New ME!

Primary Drivers

- Calories In
  - Daily calorie count

- Calories Out
  - Exercise calorie count

Secondary Drivers

- Limit daily intake
  - Avg cal/day

- Substitute low calorie foods
  - % of opportunities used

- Avoid alcohol
  - Avg drinks/week

- Work out 5 days
  - Days between workouts

- Plan Meals
  - Meals off-plan/week

- Drink H2O Not Soda
  - Sodas/week

Process Changes

- Track Calories
  - Running calorie total

- Etc...

Measures let us
- Monitor progress in improving the system
- Identify effective changes
AIM

Reduce death, disability, or other preventable harm among newborns and mothers across six-district service area

PRIMARY DRIVERS

Expand access to pre-natal care

Activate community members to promote health and connect peers with health services

Reliable delivery of pre-natal care bundle

SECONDARY DRIVERS

Increased use of tele-health services

Supportive community structures

Attractiveness of Health Services

Communication & transportation

Remove cost barriers

Spread information to communities

Identify and train community leaders

Open lines of communication

Community-based education

Adequate supply of necessary materials

Staff clinical knowledge and skills

Use of data for decision making
Always Understand and Plan for “Anti-Drivers”

Always Anticipate and Monitor Unintended Consequences
Logic Models

• Guide and focus project planning, resource allocation, tasks, and work over time

• Clear delineation of exactly what will determine a given outcome, including
  – Inputs and resources
  – Activities
  – Outputs
  – Outcomes (short, medium, long term)
  – Differentiate between “what was done” and results - Embody both execution theory and content theory

• Should enable evaluators to see exactly what was done, the intended “dose,” and the received “dose”

• Support testing and replication elsewhere
Other Important Elements of Logic Models

- Measurement framework
- Contextual and environmental factors
- Assumptions
- Timeframe
The Basic Logic Model: “If-Then”

Certain resources are needed to operate your program. If you have access to them, then you can use them to accomplish your planned activities. If you accomplish your planned activities, then you will deliver the intended amount of product/service to the intended audience. If you accomplish your planned activities to the extent you intended, then participants will see changes in knowledge and start testing. If participants start testing, then participants will change their behavior/processes. If participants change processes, then you will see changes in outcomes.

Execution Theory

<table>
<thead>
<tr>
<th>Resource/Inputs</th>
<th>Activities</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
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</tbody>
</table>

Medium-term Outcomes

<table>
<thead>
<tr>
<th>Short-term Outcomes</th>
<th>Medium-term Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Long-term Outcomes

| 6                   |                  |

Content Theory
<table>
<thead>
<tr>
<th>Inputs</th>
<th>Activities</th>
<th>Outputs</th>
<th>Short term outcomes</th>
<th>Medium term outcomes</th>
<th>Long term outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are you doing?</td>
<td>e.g., training in QI, monthly data analysis calls</td>
<td>What are the reach and products of the activities?</td>
<td>What changes in learning do you expect to come from your activities and outputs?</td>
<td>What changes in processes do you expect as a result of your short-term outcomes?</td>
<td>What changes in organizational and patient outcomes do you expect ultimately?</td>
</tr>
<tr>
<td>e.g., staff, funding, space, external partners, materials, tools</td>
<td>e.g., 3 QI teams trained in improvement methods</td>
<td>e.g., teams complete PDSA cycles</td>
<td>e.g., teams complete PDSA cycles</td>
<td>e.g., blood protocol implemented with 80% reliability</td>
<td>e.g., 20% decrease in under-5 mortality</td>
</tr>
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</table>

**Assumptions**
What are you assuming about the ability to deliver the program in the above planned way?
- e.g., leadership is on board and the will is strong, surgeons will make the time to attend trainings and lead their QI team

**External factors**
What factors outside of the project may be a barrier or facilitator to reaching your desired outcomes?
- e.g., new incoming government that prioritizes x, high staff turnover in health centers

**Project Title**
(Month Year – Month Year)

**Primary Goal**

**Context**
3yr Federal grant funded project designed in two waves to work with all hospitals in 10 states that do hip/knee replacement to reduce hip and knee SSIs

The project is designed to use IHI’s strong relationships w/existing nodes and hospitals and nodes’ strong relationships w/hospitals to move work forward

**Inputs**
- $500,000 funding
- Project & communication management team: PC, PM, communications, director, field manager, clinical director
- Content experts: Surgical, infection control, nursing, and improvement faculty from IHI
- Network of state nodes, hospitals & national partners
- Experience of sites that have done this before
- Communication & technology infrastructure
- Learning from campaign tools
- Evidence that is ready for spread

**Activities**
- **Recruitment**
  - recruit nodes, hospitals, national partners
  - build/strengthen state-level relationships
  - states assigned to cohort 1 or cohort 2
- **Ongoing Development & Refinement of Content Materials**
  - understand and summarize evidence of interventions
  - gather existing materials from early adopters
  - continuous development & refinement of materials to guide the work
- **Support Implementation**
  - Build infrastructure where nodes & hospitals can share learning and adapt implementation to their setting: in-person, phone, and web-based support
  - Revise activities and approach based on learning from cohort 1

**Outputs**
- Nodes in 10 states recruited & assigned to cohorts; hospitals recruited for participation; relationship & support letters from national partners
- **Tools and communication structure for nodes and hospitals that support implementation**
  - IHI in-person visits
  - How-to guide
  - improvement tools
  - patient/family 1-pager
  - measurement tools
  - node meetings at 2011 and 2012 forum
  - monthly node calls
  - webinar call series
  - state-specific calls
  - electronic communications (website, listserv, email)

**Short Term**
- **IHI: Establish & Support Rapid Spread Network**
- **Node**
  - Recruit hospitals
  - Strengthen/ develop relationships with & among hospitals
  - Increased capacity to coach hospitals
  - Create links to related initiatives
- **Hospital**
  - Aims set; teams formed
  - Access and use tools
  - Increased knowledge of importance of bundle
  - Leadership buy-in
  - Increased surgeon, admin staff, lab, & patient buy-in
  - Implement and test new processes & tools
  - Learn from other hospitals
  - Provide feedback

**Medium Term**
In participating hospitals, >90% adoption of:
- Preoperative bathing or showering with chlorhexidine
- Preoperative a) nasal screening for Staphylococcus aureus carriage followed by b) decolonization of S. aureus carriers
- Preoperative skin preparation w/a long-acting antiseptic agent in combination w/alcohol

**Long Term**
Reduce surgical site infections in hip & knee patients in 10 U.S. states

**Assumptions**
SSI reduction is a priority; IHI & nodes are a trusted source of content; to achieve goal must effectively recruit and then engage to support flexible implementation; developing an infrastructure for teams to learn from each other will support successful implementation

**External factors**
- Other SSI focused projects e.g. Partnership for Patients detracted attention and also prioritized reduction of SSIs
- Shifting payment mechanisms for reimbursement for SSIs
**Develop Tools**
- How-to Guide
- Business Case
- Measurement Info
- Improvement Tools
- Patient/Family Materials
- Surgeon/MD Materials

**Disseminate and Coach**
- Monthly node calls
- Webinar Call Series
- Site-visits, town hall meetings, presentations
- Electronic Communications (website, list-serve, etc.)

**Actors**
- IHI
- State Nodes
- Hospitals

**Outputs**

**Nodes**
- Create linkages to related state-wide initiative and priorities
- Recruit hospitals
- Develop/strengthen relationships with and among hospitals
- Develop capacity to coach hospitals
- Track hospital progress
- Link hospitals to IHI resources
- Provide feedback to IHI

**Hospitals**
- Set aims
- Form teams
- Increase knowledge of the importance of specific practices
- Increase buy-in among leadership
- Increase buy-in among surgeons
- Develop capacity to implement and test new processes and tools
- Use tools to better inform patients of their role

**Outcomes**
- Up-take of three SSI prevention processes

**End Goals**
- Reduction of SSI’s
Patient Experience Collaborative Logic Model

**Inputs**

- **Partner:**
  - Funding
  - Contract with IHI
  - Project Steering Committee
  - Commitment and active involvement by hospital level leadership
  - Hospitals’ QI
  - Expertise
  - Support for proper team selection
  - Connect to Leadership Academy

- **Improvement org:**
  - Hospital Capacity Assessment
  - Patient Experience Drivers and Key Actions
  - Content from prior collaboratives
  - Team structure and processes
  - Core team and faculty expertise
  - Listserv
  - Evaluation support

**Activities**

- Engage each hospital’s leadership in developing project charter: aims, connections to extant key projects/strategies, cycle for review of progress, senior sponsor.
- Establish network of QI support across hospitals (Extranet, common rules for run chart displays)
- Develop Content DD, change package, measures developed, used and reviewed
- Promote listserv dialog
- Team coaching individual coaching as needed
- Carry out Learning sessions
- Carry out regular monthly Action Period calls
- Teams maintain PDSA logs and PPT storyboards
- Steering Committee reinforces system commitment (periodic public report to network?)
- Monthly reporting & feedback cycle
- Establish, maintain Extranet site for data sharing

**Short-Term Outcomes**

- Teams have will and resources
- Faculty and teams customize learning
- Teams are actively and transparently engaged in their plan
- Teams are contributing to an active learning community
- Project infrastructure supports teams

**Collaborative Outcomes**

- **Kirkpatrick Level 2:** By March 2013, 80% of teams testing changes
- **Kirkpatrick Level 3:** By 31 Dec 2013, 80% of teams reach (1) Nurse and Physician communication process reliability goals; (2) Leadership engagement performance demonstrated
- **Kirkpatrick Level 4:** By April 2014, 80% of teams demonstrate improvement in HCAHPS Nursing, Physician Communications and Responsiveness

**Impact**

- Improved HCAHPS scores (relative to secular trends)
- Integration of improved patient experience into standard practice
Peter H. Rossi: The “Iron Law” of Evaluation

“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.”

“It also means that the average of net impact assessments of a large set of social programs will crawl asymptotically toward zero.”

“In 2001, Michael Jennions, a biologist at the Australian National University, set out to analyze ‘temporal trends’ across a wide range of subjects … He looked at hundreds of papers … and discovered a consistent decline effect over time, as many of the theories seemed to fade into irrelevance.”

“… 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 to Prototyping: Small Number of Settings

- Applied in a narrow range of contexts
- Improvement in 100% of sites

Graph showing % Effective:
- 100%
- 50%
- 0%

Legend:
- 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

<table>
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<th>Context</th>
<th>Time</th>
<th>% Effective</th>
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<tbody>
<tr>
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<td>100%</td>
</tr>
<tr>
<td></td>
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<td>80%</td>
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<td>60%</td>
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<tr>
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<td></td>
<td>50%</td>
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</table>

Effective | Not Effective
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

1. Immediate wide-scale implementation

- Innovation sample
- Evaluation sample

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<thead>
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<th>% Effective</th>
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<tr>
<td></td>
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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
Core Concepts & Detailed Tasks

RRT

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

Action

- 2 Nurses 1 Physician
- 1 Nurse 1 Physician
- 1 Physician

Theory
Core Concepts & Detailed Tasks

- Core Concept (Theory)
  - Describes the underlying principles that underpin a new model or intervention.

- Detailed Tasks (Action)
  - Describes the detailed actions and activities, associated with a core concept, that are applied at a local setting.
Suggestions

• Focus on learning what it takes to bring about improvement.
• Improvement requires social change (hence the key role of behavioral and social sciences)
• 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.
Ten Tips
Tip 1

- Select projects that really will make a difference to providers and patients
  - Focus on clinically relevant projects that substantially improve those processes of care that are tightly linked to the outcomes of interest to providers and patients
  - Think of a headline the CEO or CMO would want to feature on the organization’s website
Tip 2

• Set bold, clear, measureable aims and a specific timeline for achieving them
  – Think of fundamental advances that will measurably impact care and outcomes and engage clinical staff
Tip 3

- Assemble a multi-disciplinary team including providers, stakeholders, and methodologists, tailored to the specific aim of the project
  - Be agnostic with respect to disciplines and titles when assigning roles and rewards
  - If publication is anticipated, define roles and authorships very early on
    - Giving appropriate first authorships to non-MDs does not jeopardize publication in leading journals
Tip 4

• Be creative in recruiting experts
  – Behavioral scientists, sociologists, economists, epidemiologists, statisticians, qualitative researchers, and other experts often are looking for opportunities to partner with clinical researchers, especially if there is a prospect of co-authorship
Tip 5

- Adopt the most rigorous study design possible without disrupting routine work unduly
  - Incorporate data collection into usual activities of professional staff (eg: infection control, clinical pharmacists)
Tip 6

• Do everything possible not to sacrifice data quality and completeness
  – Develop simple data collection tools that also simplify and increase reliability of daily work
  – Checklists and standardized order sets are especially useful
Tip 7

- Take advantage of emerging certification requirements for clinical staff and make improvement academically viable
  - MOC requirements can be satisfied by improvement activities (eg: Vermont Oxford’s NICQ collaborative)
  - Morph “good citizen” work, such as CPG development and evaluation, into publications and other CV-worthy work products
Tip 8

• Do not assume that substantial external grant funding is required to perform credible quality improvement work
  – Leverage institutional resources
  – Encourage development of institutional small grant awards for quality improvement
  – Consider support from payers, industry, and professional societies
  – Look for “free” hands, such as graduate students
Tip 9

- Pay careful attention to the ethics of quality improvement work, but try to craft projects that are unlikely to require formal IRB approval
  - More later, but remember
    - Poorly designed projects are unlikely to yield useful knowledge and arguably are not ethical
    - Patients have a right to expect that unexpected consequences will be considered and monitored
Tip 10

• Anticipate publication
  – Apply the SQUIRE guidelines
  – Write a “dummy” abstract and construct “dummy” tables and figures
  – Be clear about authorships
  – Make the most of “negative” studies

Davidoff et al., Qual Saf Health Care 2008;17 (Suppl 1):13-19
Assessing Will (to Make Major Changes)

- What are we trying to accomplish?
- What investments are we willing to make?
- What activities should we de-emphasize?
- What conflicts are we willing to resolve?
- What risks are we willing to take?
- How much disruption in the organization are we willing to support to make the transition to a better performing system?
Framework for Execution

Achieve *Breakthrough* Goals

- Manage Local Improvement And Projects
- Develop Human Resources
- Aspirational v. Realistic

- Portfolio of Projects To Support Goals
- Spread and Sustain
  - Provide Leaders for Large System Projects
  - Provide Day-to-Day Leaders for Micro Systems