From PDSA Cycles to Implementation Studies:

Taking your QI to the next level using dissemination & implementation (D&I) science

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Disclosures

• Drs. McLeod and Tyler have no conflicts of interest related to this workshop content
Learning Objectives

• Describe the conceptual (and vocabulary) crosswalk between QI and D&I methods

• Understand when/why D&I methods could be applied to QI efforts

• Review literature that illustrates how D&I methods can enhance QI efforts and academic pursuits

Pre-Survey

• Have you participated in QI that utilizes the Model for Improvement?
• Have you submitted/presented/published a QI abstract or publication?
• Have you participated in a D&I research project or had D&I education?
• Have you submitted/presented/published a D&I abstract or publication?
The overlap

RE-AIM framework for D&I
- Reach (Who)
- Efficacy/Effectiveness (What)
- Adoption (Where)
- Implementation (How)
- Maintenance (When)

QI is the how on a local level

Definition of Improvement Science (QI)

- The science of improvement is an applied science that emphasizes innovation, rapid-cycle testing in the field, and spread in order to generate learning about what changes, in which contexts, produce improvements. It is characterized by the combination of expert subject knowledge with improvement methods and tools. It is multidisciplinary — drawing on clinical science, systems theory, psychology, statistics, and other fields.

Another Definition of QI

**Quality Improvement**
- Systematic and continuous actions that lead to measurable improvement in:
  - Health care services
  - Health status of patients

- As defined by The Institute of Medicine (IOM), and includes:
  - Six Domains of Health Care Quality: Safe, Efficient, Effective, Timely, Equitable and Patient Centered.

Methodologies and models in QI

![Diagram showing Methodologies and models in QI]
The Model for Improvement

1. Forming the team
2. Define the problem and the process
3. Setting aims
4. Establishing measures
5. Selecting changes
6. Testing changes
7. Implementing and spreading changes

An Aim Statement Should Answer Three Fundamental Questions

• What are we trying to accomplish? *Describe your overarching goal*
• How will we know that a change is an improvement? *Goals must be time specific and measurable*
• What changes can we make that will result in improvement? *Describe specific actions to be taken*
**SMART Aim**

- **Specific**: understandable, unambiguous
- **Measurable**: numeric goals
- **Attainable**: achievable, actionable
- **Relevant**: to stakeholders and organizations
- **Time bound**: within a specific timeframe

**SMART Aim**: Increase the percentage of responses on PRC question #22, related to ED visits, for “very good” and “excellent” from 69% to 78% by December, 2013.

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**Types of Measures**

- Outcome
- Process
- Balancing

*Multiple measures are almost always required to assure that the system as a whole is improved*
PDSA Cycle

- **P- (Plan)** a change or a test, aimed at improvement
- **D- (Do)** carry out the change or test (preferably small scale)
- **S- (Study)** the results. What was learned?
- **A- (Act)** adopt the change, abandon the change, run it through the cycle again.

The Model for Improvement
Why Test?

- Increase degree of belief
- Document expectations
- Build a common understanding
- Evaluate costs and side-effects
- Explore theories and predictions
- Test ideas under different conditions
- Learn and adapt

Small but steady

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?

Changes That Result in Improvement

DATA

- Implementation of Change
- Wide-Scale Tests of Change
- Follow-up Tests

Hunches
Theories
Ideas

Very Small Scale Test
• Multi-stakeholder team
• Literature review & process evaluation
• Identification of barriers through small tests
• Consensus-based protocol finalized
• Mandatory education for providers
A Pediatric Sedation Protocol for Mechanically Ventilated Patients Requires Sustenance Beyond Implementation*

Beryl F. Yaghmai, MD1; Jane L. Di Gennaro, MD, MS2; Gretchen A. Irby, PharmD2; Kristina H. Deeter, MD2; Jerry J. Zimmerman, MD, PhD2

Conclusions: Sedation quality improvement measures related to the use of opiate infusions, total days of sedation exposure, PICU length of stay, and mechanical ventilation days all deteriorated following initial successful implementation of a PICU sedation protocol. Implementation of a protocol alone may not lead to sustained quality improvement without routine monitoring and ongoing education to ensure effectiveness. (Pediatr Crit Care Med 2016; 17:721–726)
RIGOROUS IMPLEMENTATION STRATEGIES ARE KEY TO SUSTAINABLE IMPROVEMENT

The overlap
When to apply D&I Science to QI?

- Translation of research into practice
- Interventions for special populations (pathways/guidelines)
- Multi-center improvement collaboratives
- Desire to contribute generalizable knowledge (aka. Research publication)

Key D&I Vocabulary

- **Core elements** = essential ingredients
- **Fidelity** = adherence, dose, quality, participant responsiveness, and program differentiation
- **Adaptation** = PDSA within constraints of core elements
- **Consolidated Framework for Implementation Research (CFIR)** = intervention characteristics, inner setting, outer setting, individuals, process
- **Qualitative Research** = coding & analysis of interviews and observation data (NOT surveys)
- **Mixed Methods Research** = comparing qualitative & quantitative data (what do I learn when I interview the providers with the best versus worst adherence to our pathway?)
D&I Frameworks Commonly used in QI

- **RE-AIM**
  - Reach (Who)
  - Efficacy/Effectiveness (What)
  - Adoption (Where)
  - Implementation (How)
  - Maintenance (When)

  *Emphasis on outcomes design*

**Types of Outcomes**

*Should still think in context of outcomes, process, and balancing measures*
• Reach - % of departments receiving software, % of target population participating (penetration)
• Effectiveness - % of departments submitting data (trialability)
• Adoption - % of departments willing to fully implement (institutionalization)
• Implementation - % of departments implemented without support (compatibility)
• Maintenance - % programs still implemented and submitting after 1 year (confirmation)

D&I Frameworks Commonly used in QI
• Replicating Effective Programs (REP)

Emphasis on “Packaging” for generalizability
D&I Frameworks Commonly used in QI

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  – Pre-conditions
    • Need, local fit, can it be packaged?

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D&I Frameworks Commonly used in QI

• Replicating Effective Programs (REP)
  – Pre-conditions
    • Need, local fit, can it be packaged?
  – Pre-implementation
    • Convey core elements, training, logistics, facilitation

Emphasis on “Packaging” for generalizability
D&I Frameworks Commonly used in QI

• Replicating Effective Programs (REP)
  – Pre-conditions
    • Need, local fit, can it be packaged?
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    • Convey core elements, training, logistics, facilitation
  – Implementation
    • Ongoing support, retrain, evaluate, refine package

  *Emphasis on “Packaging” for generalizability*

D&I Frameworks Commonly used in QI

• Replicating Effective Programs (REP)
  – Pre-conditions
    • Need, local fit, can it be packaged?
  – Pre-implementation
    • Convey core elements, training, logistics (TIME), facilitation
  – Implementation
    • Ongoing support, retrain, evaluate, refine package
  – Maintenance and Evolution
    • Financially sustainable?, finalize package, facilitate adaptation

  *Emphasis on “Packaging” for generalizability*
Designing for Fidelity: from SMART aims to SMART design

- Simple – fewest core elements (think Einstein...)
- Maintainable – can efficiently achieve high fidelity
- Adaptable – flexible/trialability
- Reliable - consistent outcomes in different settings
- Transferrable – able to be institutionalized in various sociocultural & resource settings

Factors that Influence Fidelity

[Diagram showing various factors affecting fidelity, including implementer characteristics, intervention, organization/setting/community, population, and social, political, and environmental influences.]
D&I methods reporting: *Name the strategy and describe core elements*

- **Planning** – identifying barriers & facilitators, establishing leadership, building coalitions, buy-in, identify action targets
- **Educating** – developing materials, modes, target audiences, “campaigning”
- **Financing** – incentives, reallocation
- **Restructuring** – roles, clinical teams, records systems
- **Quality management** – new metrics, feedback, improvement teams
- **Policy changes** – credentialing, licensing standards

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D&I methods reporting: *Specify intervention*

- Actor
- Action
- Target
- Timing
- Dose
- Outcomes

Where to publish?

• BMJ – Quality & Safety
• Implementation Science
• Health Affairs
• Health Services Research
• Joint Commission Journal of Quality & Safety
• Journal for Healthcare Quality
• Pediatrics

Reviewer standards for QI vs. D&I manuscripts

Standards for Quality Improvement Reporting Excellence (SQUIRE)

• http://www.squire-statement.org/
• Common QI literature pitfalls:
  – Thorough description of previous studies (may be in adults!)
  – Rationale: describe QI frameworks (key drivers, process map), justify design and assumptions
  – Interventions: sufficient detail to reproduce it, who was involved (roles, skills, time committed)
  – Measures: ongoing assessment of contextual elements, balancing effects, measure validity
  – Interpretation/limitations: what about our context made it work? Detail local barriers/facilitators
  – Conclusions: Is it useful? Will it change practice? Is it sustainable? Next steps for study?
Reviewer standards for QI vs. D&I manuscripts

Standards for Reporting Implementation studies (STaRI)

• Split into Implementation Strategy and Healthcare Intervention

• Author common pitfalls:
  – Not stating it is an implementation study nor stating the strategy (see prior slide)
  – Rationale: why that strategy? Do we know the general effectiveness of the intervention?
  – Methods (description): Thorough description of pre-assessment adaptations, context, target populations, sub-population analyses
  – Methods (evaluation): process and economic evaluation as it pertains to current context, sample size (including allowing for subgroups), reasons for choice of analysis
  – Results: Fidelity and adaptations, results mapped to existing mechanism, resource use, harms
  – Discussion: needed policy changes, barriers to sustainability, next phase of research

One of the key challenges of using StaRI will be including the substantial descriptions of context, implementation strategy and intervention within the permitted word counts

http://www.bmj.com/content/bmj/suppl/2017/03/06/bmj.i6795.DC1/pinh034338.w2.pdf
Positioning of implementation studies and the focus of StaRI reporting standards*

Hilary Pinnock et al. BMJ 2017;356:bmj.i6795

*adapted from fig 12.1. in Brownson et al

Breakout sessions: *appraisal of the literature*

- #1 Clinical Pathway Effectiveness: Febrile Young Infant Clinical Pathway in a Pediatric Emergency Department.
- #2 Implementation and preliminary effectiveness of a real-time pain management smartphone app for adolescents with cancer: A multicenter pilot clinical study.
- #3 Evaluating Serial Strategies for Preventing Wrong-Patient Orders in the NICU.
- #4 The impact of transforming healthcare delivery on cystic fibrosis outcomes: a decade of quality improvement at Cincinnati Children's Hospital.
- #5 Improving transitions of care at hospital discharge--implications for pediatric hospitalists and primary care providers
Literature appraisal questions

- Strategies for identifying barriers and facilitators to fidelity (pre-condition/pre-implementation)?
- Implementation strategy used?
- Core elements defined?
- Adaptations described?
- Types of outcomes measured?

References

Model for Improvement:

- Back to the Basics: A Primer on Quality Improvement, 18th Annual National Forum, December 2006, Robert Lloyd PhD and Lindsay Martin MSPH'

References


References