You Got EBM in My QI! You Got QI in My EBM Process. Evaluating Two Great Processes That Integrate Together

Hans Kersten, E. Douglas Thompson, Erin Giudice, David Cooperberg, Jason Custer, Rani Gereige

PAS Annual Meeting

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Washington, DC

Drexel University College of Medicine

University of Maryland Hospital for Children

Miami Children's Hospital – We're here for the children

St. Christopher's Hospital for Children

You Got EBM in My QI Process! You Got QI in My EBM Process. Evaluating Two Great Processes That Integrate Together

DISCLOSURE STATEMENT:

Drs. Kersten, Thompson, Giudice, Custer and Gereige have *all* documented that we have nothing to disclose.

- David Cooperberg is co-recipient of Pfizer Medical Education grant #033690, "Designing and Evaluating a Quality Improvement Curriculum for Pediatric Residents"

Needs Assessment

- Who does EBM/QI/both?
- What are the barriers to implementing curricula and evaluating learners in EBM and QI?

Barriers to EBM and QI

EBM barriers	QI barriers

EBM steps

1. Ask
2. Acquire
3. Appraise
4. Apply
5. Analyze

Why include EBM curriculum in training programs?

1. To develop
   - Lifelong learning skills
   - Effective, efficient learners
2. To meet RRC for resident training and ACGME requirements for fellows in
   - Process of accessing, appraising and applying knowledge
   - Application of best medical evidence to the care of patients
   - Competence in EBM
3. To evaluate ACGME competencies
4. To report on the pediatric Milestones

Evidence-Based Medicine Milestones

- 1 of 21 Milestones to be reported to ACGME for every resident semi-annually, starting in 2013
- MK1: Locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems
  - Level 1: Explains basic principles of EBM, but relevance is limited by lack of clinical exposure
  - to
  - Level 5: Teaches critical appraisal of topics to others; easily formulates answerable clinical questions; efficiently searches the literature; a role model for practicing EBM

Evidence-Based Medicine and Curricula

- EBM Process coined
- ACGME mandate declared
- EBM curricula developed

Evidence-Based Medicine and Curricula

- Kersten 2005
  - 97% programs teach EBM
  - ~25% evaluate EBM
- Straus 2004
  - Commentary on teaching EBM to different learners
  - Develop “coordinated sharing” of tools
- Shaneyfelt 2006
  - Systematic review of EBM evaluation tools
  - Further develop EBP behaviors, skills

EBM Work Group

- EBM experts at 6 residency programs
  - Leaders in local institutions
    - EBM
    - Education
  - Multiple national presentations on teaching and evaluating
- Teaching venues at 6 institutions
- Spectrum of EBM projects

“EBM Working Group” at 2009 Annual PAS Meeting in Baltimore

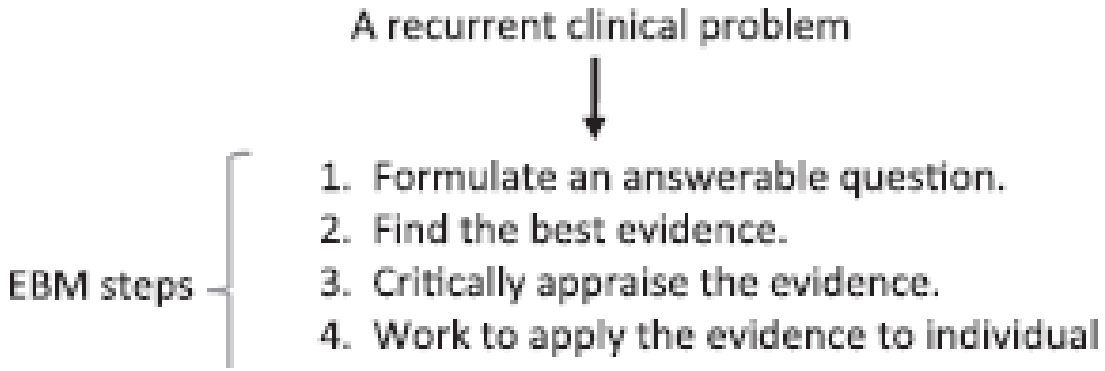
Case-Based EBM Module Development

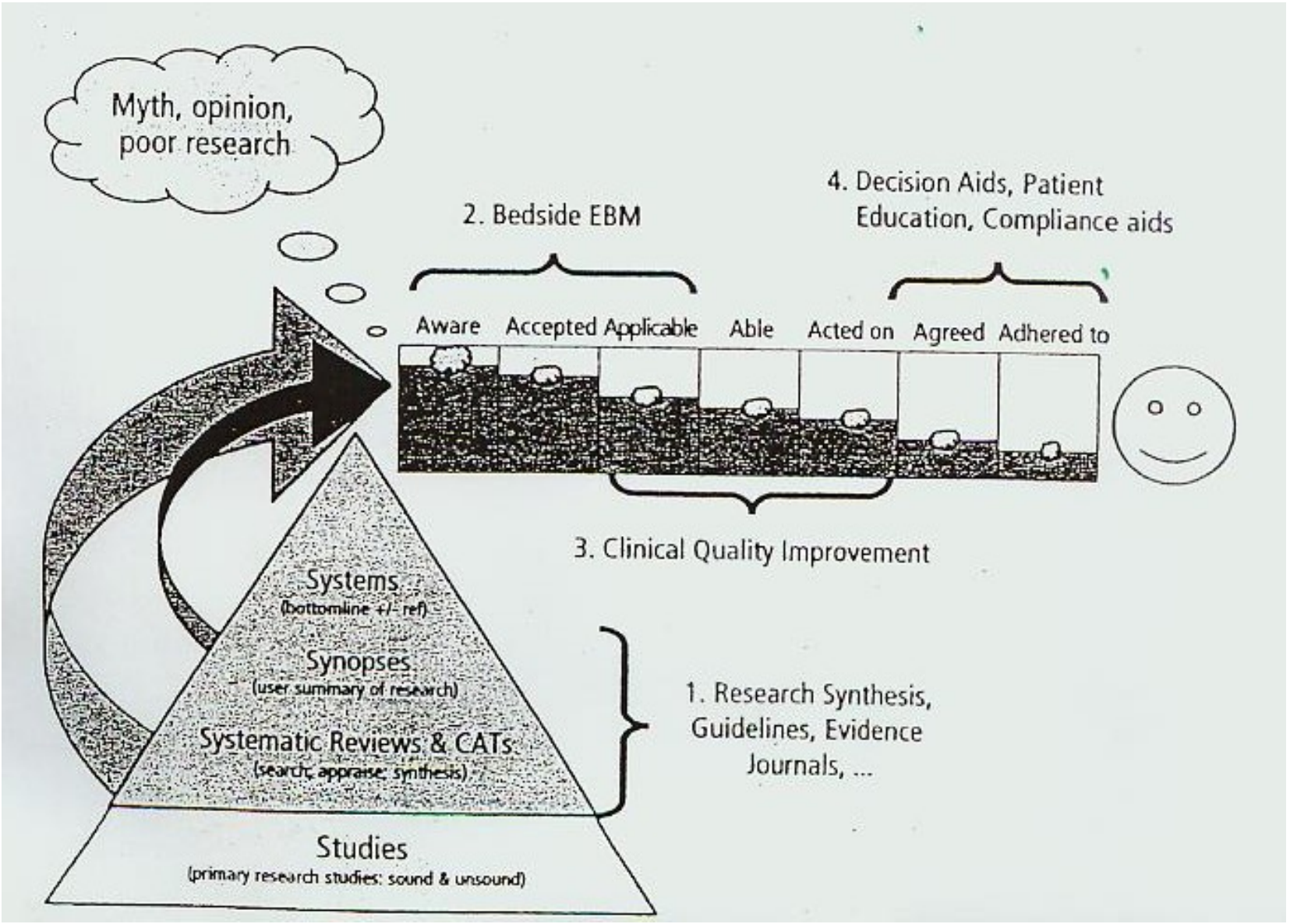
1. Developed EBM projects across multiple venues
2. Created a variety of EBM evaluation tools
3. Outlined EBM framework of skills
4. Linked EBM components to ACGME competencies
5. Compiled library of Case-Based EBM Modules

EBM and QI

EBM

- Do things right
- Synthesize and summarize flood of information
- Skeptical approach to innovation
- Good at getting evidence
- Difficult to take action or change practice


A recurrent clinical problem
EBM steps
1. Formulate an answerable question.
2. Find the best evidence.
3. Critically appraise the evidence.
4. Work to apply the evidence to individual


Myth, opinion, poor research
2. Bedside EBM
4. Decision Aids, Patient Education, Compliance aids
Aware
Accepted
Applicable
Able
Acted on
Agreed
Adhered to
3. Clinical Quality Improvement
Systems
(bottomline +/- ref)
Synopses
(user summary of research)
Systematic Reviews & CATs
(search, appraise, synthesis)
Studies
(primary research studies: sound & unsound)
1. Research Synthesis, Guidelines, Evidence Journals, ...

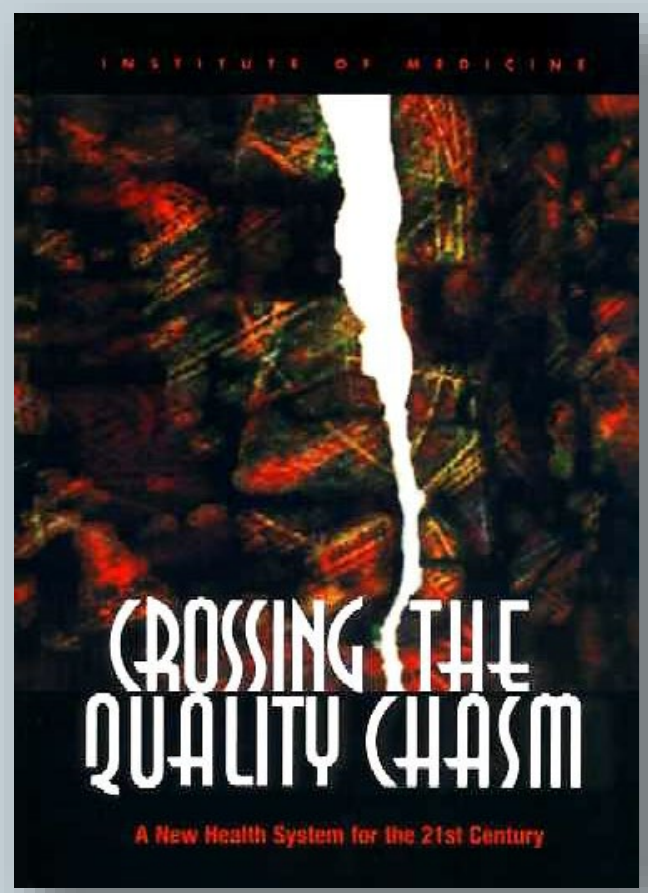
QI Process

Quality Improvement

- Developed to address recurrent problems within systems of care
- 1980s National Demonstration Project
- Institute for Healthcare Improvement

Background: QI in Healthcare

- Institute of Medicine Report 1999 To Err is Human
- IOM 2001 Report: 6 Aims
- Safe
- Effective
- Efficiency
- Timely
- Equitable
- Patient-centered



QI Curriculum: Importance and Relevance

- Medical Schools: "Undergraduate Medical Education for 21st Century" (HRSA)
- Residency: ACGME's Outcomes Project
- Post-residency board certification: ABP MOC requirements
- Pediatric Milestones: QI and Systems-based Practice

Maintenance of Certification				
6 Core Competencies	**Professional Standing**	**Lifelong Learning**	**Cognitive Expertise**	**Performance in Practice**
Patient Care	√	√		√
Medical Knowledge		√	√	
Practice-based Learning & Improvement		√		√
Interpersonal & Communication Skills	√			√
Professionalism	√			√
Systems-based Practice		√		√

QI Milestones

- PBL13: Systematically analyze practice using quality improvement methods, and implement changes with the goal of practice improvement
  - Level 1: Does not understand the principles of QI methodology
  - Level 5: Demonstrates continuous improvement activities and appropriately utilizes QI methodologies
- SBP2: Advocate for quality patient care and optimal patient care systems
  - Level 1: Attends to medical needs of individual patients (only)
  - Level 5: Identifies and acts to begin the process of improvement projects inside hospital and within community

Quality Improvement in Healthcare

- Systematic approach
  - Identify problems
  - Minimize variation in practice
  - Improve patient care
- Multidisciplinary
- Objective, data driven

➢Muething,S, Pediatric Hospital Medicine Conference, MN, July 2010

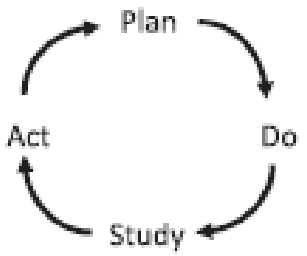
Components of QI in Healthcare

- **Intervention** approach (changes to system)
- **Measurement** over time
- **Sustainability** a consideration from beginning
- **Multi-factor experiments**

➢Provost, LP, Advanced Improvement Methods Course, Cincinnati Children's Hospital and Medical Center, 2011

QI process

1. What are we trying to accomplish? (Aim)
2. How will we know a change is an improvement? (Measure[s])
3. What changes can we make? (Change management)



EBM and QI

QI

- Do right things
- ‘knowing-doing’ gap
- Improves problems in processes
- Uses PDSA cycles to affect change
- QI connection to evidence has faded

EBM and QI

EBM	QI
• Do things right • Synthesize and summarize flood of information • Skeptical approach to innovation • Good at getting evidence • Difficult to take action or change practice	• Do right things • ‘knowing-doing’ gap • Improves problems in processes • Uses PDSA cycles to affect change • QI connection to evidence has faded

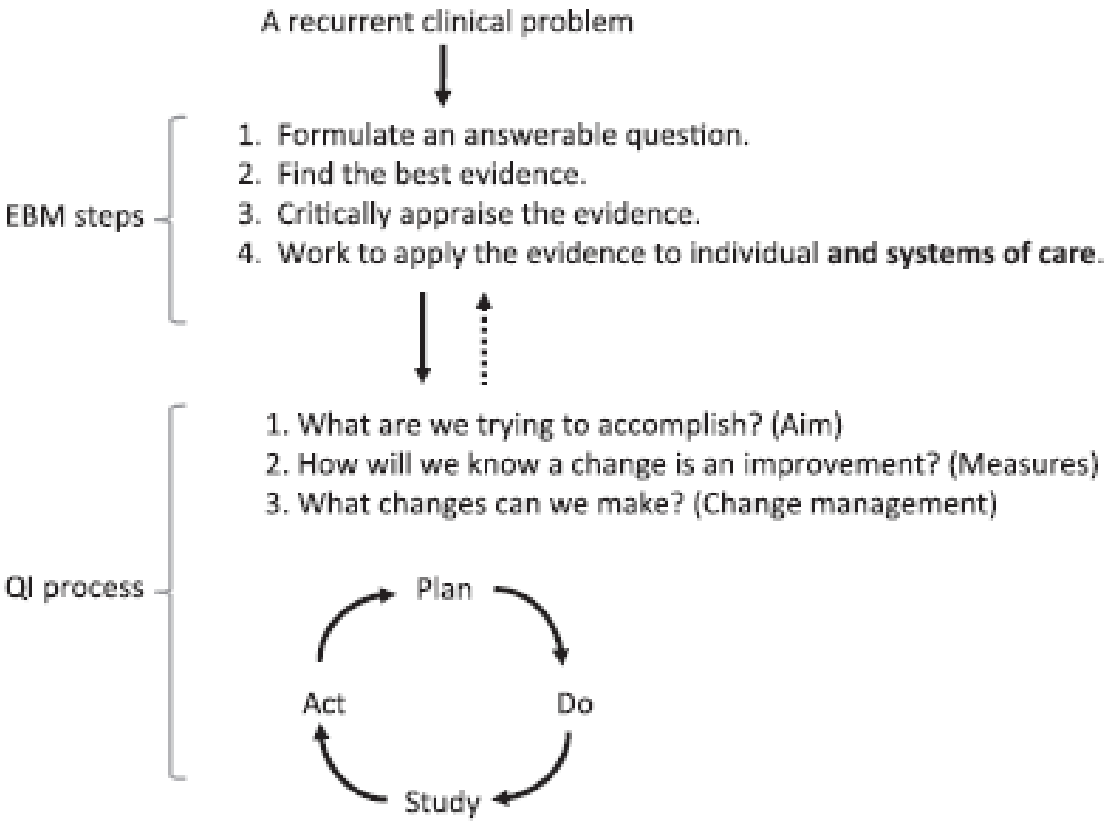
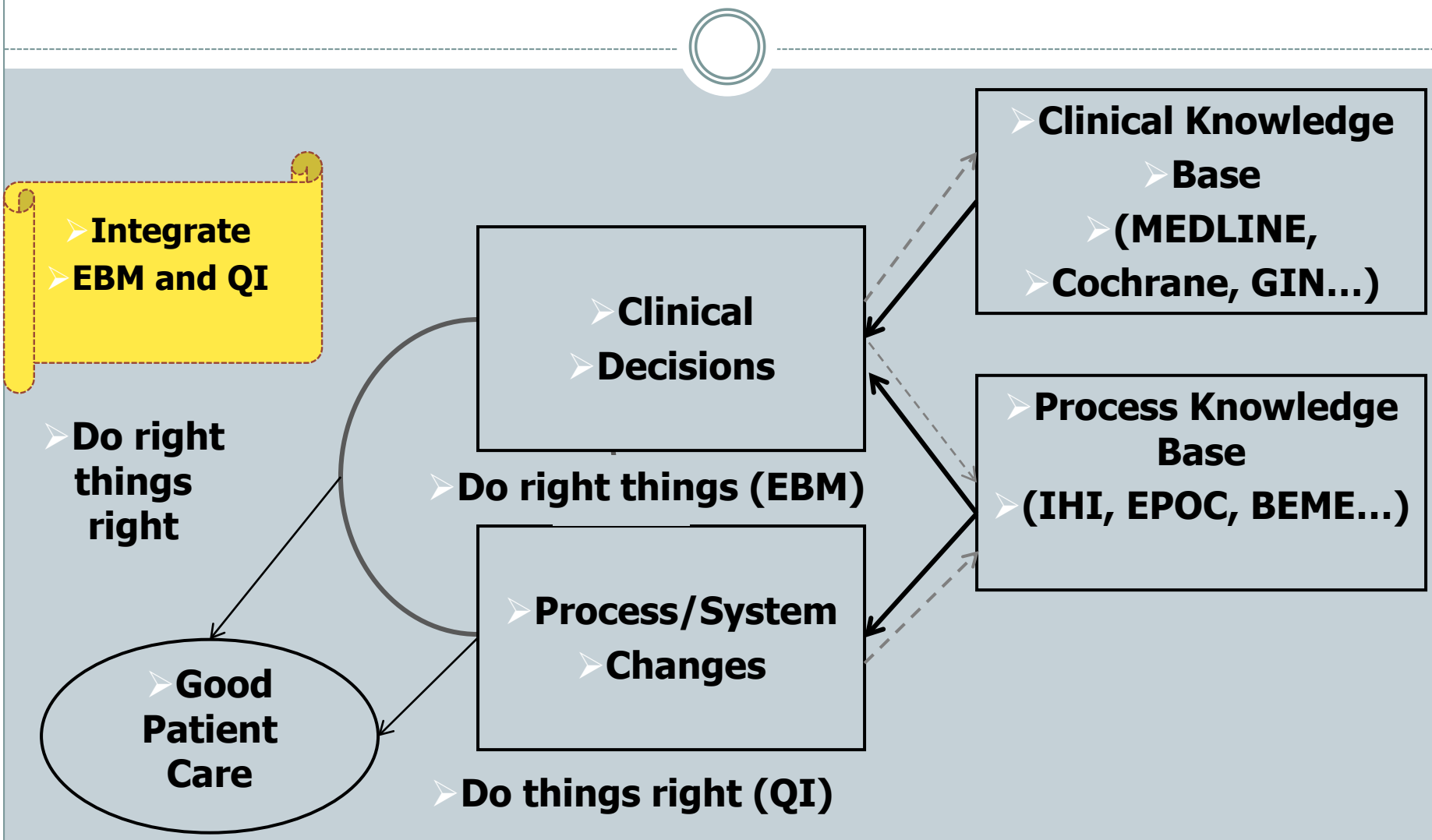


Figure 2 Proposed linkage between EBM and one model for QI.

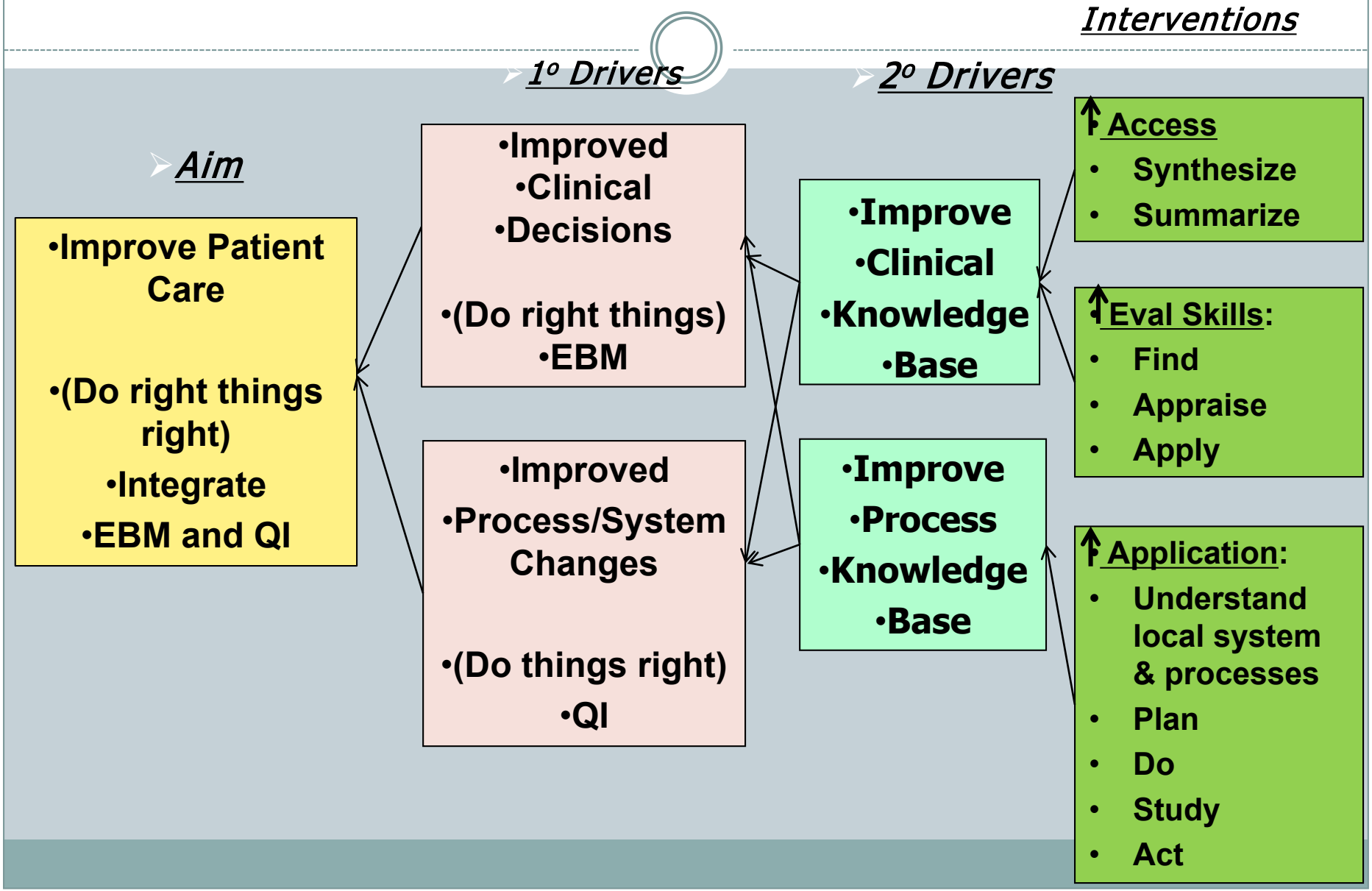
BMJ Qual Saf 2011;**20**(Suppl 1):i13–i17. doi:10.1136/bmjqs.2010.046524

Relationship between QI and EBM



Glasziou, P, Ogrinc, G, Goodman, S, Can evidence-based medicine and clinical quality improvement learn from each other? *BMJ Qual Saf* 2011;20(Suppl 1):13-i17

Key Driver Diagram



Curricular Goals

EBM Curriculum	QI Curriculum
1. Ask/answer important clinical questions (PICO) 2. Improve learners' ability to critically appraise medical literature (CAT)	1. Learn QI tools & methods ○ The Improvement Model ○ Plan-Do-Study-Act (PDSA) 2. Design/implement a QI project
Use published literature to improve individual practice habits to improve patient care	**Use ongoing measurement of local processes to design interventions to improve systems of care**

Distinct Goals

EBM

QI

EBM and QI together

- Establish clear connection between EBM and QI
- EBM recognize it is not sufficient to appraise, but must ask ‘what is the next action’?
- QI must check validity, applicability and value to proposed change
- Integrated EBM/QI should be taught, integrated and modeled in clinical training

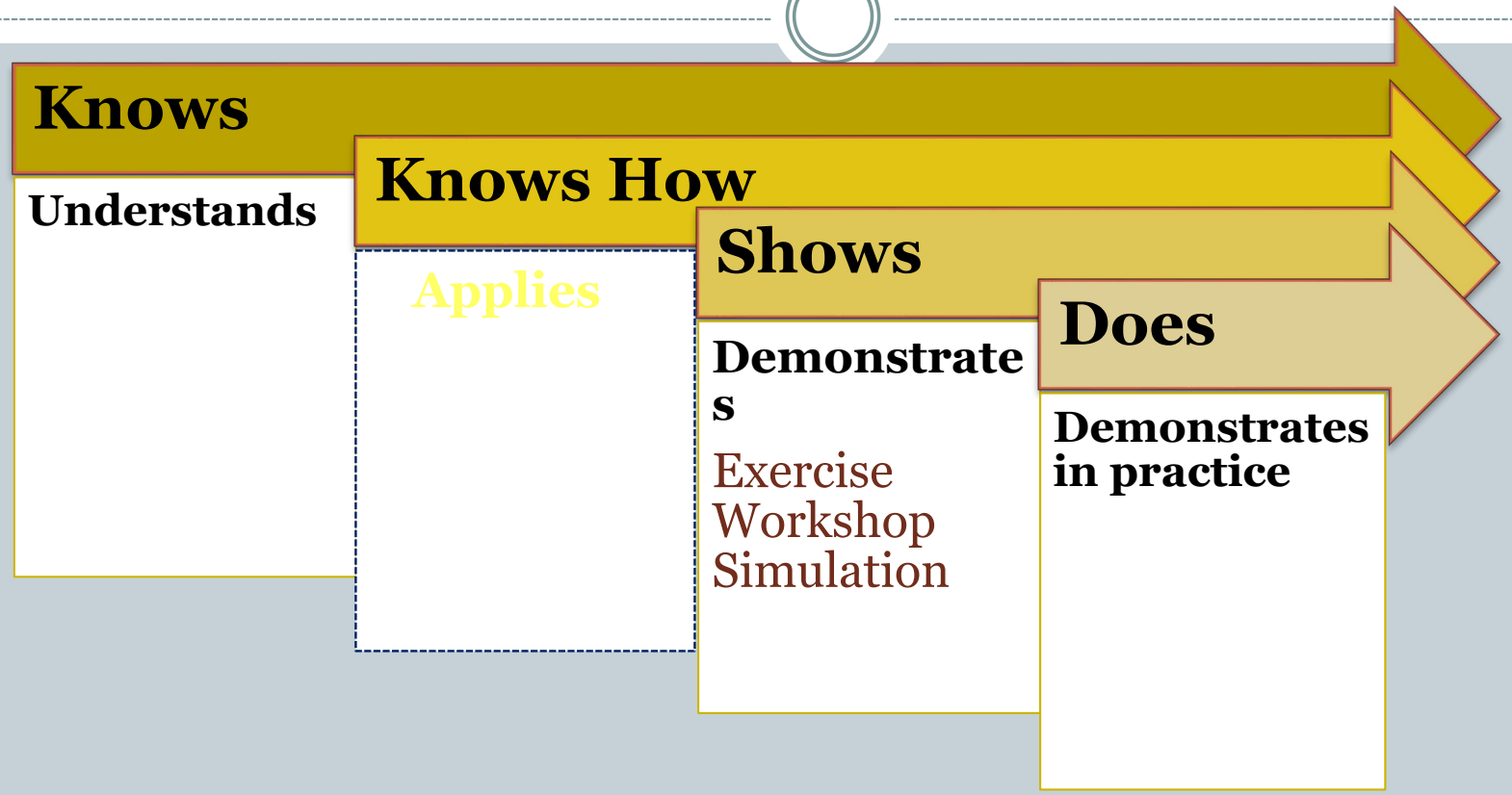
What would be the integrated goal?

- Improve Systems of Care by Creating and Implementing Evidence-based Clinical Practice Guidelines

Ways to Improve EBM and QI in Residency Programs

1. Bedside PICO question: Head CT (completed last year)
   a. EBM CAT
   b. QIKAT
2. Systems question: "That's the 3rd time in the past 12 months where HIV diagnosis was delayed…"
   a. EBM
   b. Design QI Project (QIPAT-7)
3. EBM Article on probiotics: "That's neat. We should implement that "
   a. EBM CAT
   b. QIKAT
4. QI Article on systems improvement: (systems-changing evidence) Before we implement, let's critique—is what they accomplished generalizable and applicable in our local context (QI Journal Club article)
   a. Apply SQUIRE Guideline to evaluate applicability to local context

Where Are Your trainees now?



Knowledge | Attitudes | Skills

Methods to assess milestones

Level 1	No reflection No understanding of systems
Level 2	MERIT
Level 3	QIKAT QI project team member
Level 4	QIPAT-7 (Assess PDSA skills, pediatric QIKAT II…)
Level 5	Integration of PDSA into daily practice Local, regional, national dissemination

Ways to Improve EBM and QI in Residency Programs

1. Bedside PICO question: Head CT (completed last year)
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Case-Based EBM Module Development

Module Components

1. Module overview
2. EBM Activities
   a. Description
   b. Completed EBM Project
   c. Completed EBM Project Evaluations
3. Blank EBM Evaluation Tools

Case-Based EBM Module

1. EBM Project assigned
2. Learner prepares assignment
3. Learner/attending review assignment
4. Learner presents project
5. Learner given feedback

EBM Evaluation tools

1. EBM Skills Assessment Tool (SAT)
2. EBM Presentation Assessment Tool (PAT)
3. EBM Critically Appraised Topic Tool (CAT)
4. EBM Teaching Assessment Tool (TAT)
5. Combined EBM-QI Assessment Tools

www.telegraph.co.uk

1. Evidence-Based Medicine Skills Assessment Tool (SAT)
   - This tool focuses on framing a PICO question and finding the evidence with BASIC critical appraisal
   - Applicable for: Novice-advanced beginner levels

2. Evidence-Based Medicine Presentation Evaluation Tool (PAT)
   This tool focuses more on presenting the EBM findings in a didactic or PowerPoint format
   Applicable for: Competent-Proficient levels

3. Evidence-Based Medicine Critically Appraised Topic Tool (CAT)
   This tool focuses more on summarizing the EBM findings and applying them to clinical settings
   Applicable for: Competent-Proficient levels

4. Evidence-Based Medicine Teaching Assessment Tool (TAT)
   This tool focuses more on teaching the EBM principles and giving feedback to learners
   Applicable for: Proficient-Expert levels

5. Combined EBM-QI Assessment Tool (EQAT)
   This tool focuses more on teaching the EBM and QI principles and giving feedback to learners
   Applicable for: Novice – Expert levels

CAT module

HANS KERSTEN AND ERIN GIUDICE

Evidence-Based Medicine Critically Appraised Topic Presentation Evaluation Tool (EBM C-PET)

- Tool development:
  - Determined EBM skills to measure
  - EBM skill levels assigned (adapted Dreyfus' skill development: Novice to Expert)
  - Behavioral anchors developed for each level of skill
  - Videotaped EBM presentations
  - Assessed tool (validity, inter-rater reliability)

  - Funded by APPD Special Project grant to 3 residency program EBM experts

EBM skills measured with EBM C-PET

- Develop of PICO question
- Search to identify literature
- Critical appraisal
- Application to clinical scenario
- Creation of a CAT
- Place study in context
- Presentation organization
- Effectiveness of teaching tools
- Information synthesis
- Recognition of LOL
- EBM explanation
- Overall teaching
- Overall EBM skills

Levels of Learners	Novice	Advanced Beginner	Competent	Proficient	Expert
Places the current study in the context of other relevant research on the topic.	Does not place the current article into the larger context (i.e. no background information)	Makes reference to a few other sources of evidence on the topic *but does not* critically analyze their relationship to the current study	Makes reference to a few other sources of evidence on the topic *and begins* to analyze their relationship to other studies	Integrates information from the current study into the larger literature using critical analysis	Seamlessly integrates information from the current study into the larger literature using critical analysis *and* communicates how the article affects practice

EBM C-PET Tool performance

- Excellent internal consistency
  - Cronbach's alpha = 0.94 (across 3 raters for n= 27 presentations and CATs)
- Good inter-rater reliability
  - Intra-class correlation coefficient = 0.67 for all 14 items on the tool
- Content validity demonstrated using EBM literature review and expert consensus

- Results published in JGME 2013 (print June, on-line now)

EBMC-PETform.doc

Study Number _____

EBM CAT and Presentation Assessment *with* Level of Learners Anchors

Presentor: _____

Date: ____/____/_____

Evaluator: _____

Level of Learners	Novice	Advanced Beginner	Competent	Proficient	Expert	N/A	Question Evaluates*
1. Develop a well-built (PICO) question from a clinical scenario.	Question not in PICO format; took question from paper	Developed question from clinical scenario; *includes* appropriate Patient and Intervention	Developed a complete PICO question that has more broad/less specific measurable outcome (e.g. 'gets better')	Developed a clear PICO question that *includes* a specific measurable outcome	Developed a clear PICO question that *includes* a specific measurable outcome *and* is placed in context of what is already known.		Pres, CAT
2. Understand key search terms and use them to identify relevant literature.	Did not identify appropriate database for search (e.g. Google)	Used appropriate database, but did NOT use appropriate key words *and* limits in search; led to an unfocused search (1 of 3)	Used appropriate database, *and* used appropriate key words *or* appropriate limits (2 of 3)	Used appropriate database, key word *and* limits (if needed for search to yield <20 articles) to answer question (3 of 3)	Used best available database for search, appropriate key word *and* limits (if needed for search to yield <20 articles) to answer question (3 of 3+)		Pres
3. Critically appraise an article in the style outlined in EBM text.	Did not use correct critical appraisal process to evaluate the study/studies (e.g., therapy, diagnosis)	Used the correct critical appraisal process for the type of article (e.g., therapy, diagnosis)	Used the correct critical appraisal process for the type of article *and/or* described importance of findings *and/or* begins to show understanding of EBM concepts (e.g NNT, OR) (2 of 3)	Used the correct critical appraisal process for the type of article *and* described importance of findings *and* demonstrates understanding of EBM concepts (e.g. NNT, OR) (3 of 3)	Seamless understanding of the critical appraisal process *and* easily applies EBM concepts (e.g. NNT, ORs)		Pres, CAT
4. Apply critical appraisal to clinical scenario.	Did not mention relevance of the evidence to the clinical scenario	Mentioned the relevance of critical appraisal to clinical scenario	Adequately addressed the relevance of the evidence to the clinical scenario, *and* begins to analyze relationship	Addressed the relevance of the evidence to the clinical scenario, *and* more in-depth analysis of relationship to clinical scenario	Gave clinical background, explicitly related article to clinical scenario, *and* integrated the evidence into the clinical decision-making		Pres, CAT

Revised 01-04-10

Using EBM C-PET

- Watch videotaped EBM Journal Club presentation
- Review written EBM Critically Appraised Topic (CAT) for same case
- Complete EBM C-PET evaluation tool (start scoring while watching video)
- Discuss in small groups

ciTBI CAT presentation

QIKAT module

ERIN GIUDICE AND HANS KERSTEN

QIKAT

- QIKAT is a tool to evaluate learners' ability to apply QI knowledge to a scenario/clinical vignette

- Link EBM and QI for same case just reviewed (brain injuries after head trauma) using QIKAT Scenario #1

Pediatric QIKAT

Version #1 (2010-2011)

- Poor inter-rater reliability

Revised (Spring 2012)

- Face Validity
  - Cincinnati Children's AIM Course directors
- Internal Consistency
- Inter-rater Reliability
- External Validity

Pediatric QIKAT Validation

	St Christopher's Hospital for Children	Arkansas Children's	Colorado Children's
Pre- & Post Testing	Fall 2012 (10 pre/post pending) Planned pre- and post- ½ day session 2013	Nov 2012 (21 pre/post pending) Planned May 2013	10 PL-2s
Internal Consistency	PL-3s Spring 2013	Spring 2012 class (N=5)	4 attendings
Inter-rater reliability	pending	pending	pending

Scenario #1:

Resident A is concerned about the number of head CT scans that are done on pediatric patients in the Emergency Department. She, along with her inpatient team and radiologists, often question the indication during radiology rounds the next day. She reviews the literature and notes the following study: Kuppermann, N, et.al, Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. Encompassing 25 sites nationally, this Pediatric Emergency Care Research Network study enrolled over 25, 0000 patients between the age of 2 years and 18 years. The authors established a prediction rule for patients 2 years or older (with normal mental status, no loss of consciousness, no vomiting, non-severe injury mechanism, no signs of basilar skull fracture, and no severe headache) that had a negative predictive value of >99.9% (3798/3800).

Resident A is interested in implementing the evidence-based literature into practice by performing a quality improvement project in the Emergency Department. She needs your assistance as a quality improvement expert.

QIKAT Questions:

1. List 2 stakeholders who should be included early in the process

2. Create a global aim statement for this project

3. What might be her specific "SMART" aim statement?

4. What would be an example of a process measure?

5. What would be an example of an outcome measure?

6. What would be an example of a balancing measure?

7. List one initial intervention to test

QIKAT Exercise

- Pair up with person next to you and review Scenario #1 and answer the QIKAT questions together
  - Reference: Quality Improvement Definitions
- Review Scenario # 1: Answer 1 and Score this using Scoring Guide: Scenario #1

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HIV Systems Question

RANI GEREIGE AND E. DOUGLAS THOMPSON

MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports | September 22, 2006 / Vol. 55 / No. RR-14

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

QIPAT-7

QI Proposal Assessment Tool

- Definition of problem
- Identification of key stakeholders
- Evidence of Root Cause Analysis
- Choice of QI project
- Potential Interventions
- Proposed Intervention
- Implementation and Evaluation

Leenstra, JL, et.al, Validation of a method for assessing resident physicians' quality improvement proposal. *Journal Gen Int Med*. 2007;22(9):1330-34.

All bullets must be satisfied in each domain for a rating of 3 or higher

Definition of the problem
- Establishes problem magnitude/significance
- Identifies affected groups
- Clear statement of the problem

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Identification of key stakeholders
- Evidence of stakeholder consultation
- Description of impact of proposed intervention on stakeholders

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Evidence of root cause analysis
- Prioritizes causal factors
- Identified systems issues
- Utilizes at least one QI tool (eg, fishbone, systems walk, mind map)

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Choice of quality improvement project
- Likely to result in meaningful improvement to patient care (eg, clinical outcomes, safety, efficiency, or cost)
- Stimulates further inquiry

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Potential interventions
- Prioritization of multiple interventions
- Effort vs yield analysis

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Proposed intervention
- Directly addresses the problem
- Reasonable potential to change system for the better
- Impact on care captures ≥2 of the following (high yield/low effort, innovative, cost effective, sustainable)

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Implementation and evaluation of the intervention
- Clear plan and timeline for implementing the intervention
- Identifies measures of intervention success/effectiveness

Needs improvement	Meets expectations			Exceeds expectations
1	2	3	4	5
○	○	○	○	○

Comment

Summary comments

Figure 1. Quality Improvement Proposal Assessment Tool (QIPAT-7). The scale is anchored to the bulleted comments on the left. To achieve a score of 3 or higher, all bullets for each domain must be met. The box sizes for each point of the scale are simply determined by the heading labels; that is, smaller boxes do not indicate smaller intervals between scale steps.

QIPAT – Presentation

- Go to handouts

QIPAT – 7 Discussion

Ways to Improve EBM and QI in Residency Programs

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Systems Improvement and Situation Awareness

DAVID COOPERBERG AND E. DOUGLAS THOMPSON

Answer Key: Applying SQUIRE Guideline to Situation Awareness article for QI Journal Club:

SQUIRE Guideline purpose = how to report QI (modified from www. squire-statement.org/guidelines)

Not how to critique QI article

I. Definition of Terms related to this article
   a. **High Reliability Organizations**: (commercial aviation, nuclear power, wilderness firefighting) deal with constant/catastrophic risk yet maintain exemplary safety records (*see p 299 1st column)*
   b. **Situation Awareness**: 'knowing what is going on'; perception of elements (in environment within a given space/time), comprehension of their meaning, projection of their status in the near-future (*see p 299 1st column)*
   c. **UNSAFE transfers** (unrecognized situation awareness failures events: acute care floor to ICU transfer where patient received intubation, inotropes, or >/= 3 boluses in 1st hour after arrival or before transfer (*see p 299 2nd column*)
   d. **Serious Safety Events (SSE)**: deviation from generally accepted performance standards resulting in severe or permanent harm (*as defined in Muething 2012 article ref22*)

SSE Level of Harm
• Severe temporary harm: detectable harm, lasting for a limited time only, resulting in no permanent injury, yet causing great discomfort, injury, distress, and/or additional procedure, surgery, or resuscitation
• Moderate permanent harm: detectable harm, not expecting change in clinical status, and is greater than minimal harm but less than severe harm (eg, permanent, significant organ dysfunction [loss of neurologic function])
• Severe permanent harm: detectable harm, not expecting change in clinical status, and causing great discomfort, injury, and/or distress (eg, permanent loss of organ function [renal failure])
• Death: death attributed to deviation in care Framework developed by Healthcare Performance Improvement. (Muething article—ref 22)

II. What is the study hypothesis?
   a. ***A system of care that proactively identifies, mitigates, and escalates risk will improve situation awareness and decrease UNSAFE transfers and SSEs*** *(see p 299 2nd column)*

III. What is the SMART aim statement (specific, measurable, action-oriented, realistic, and timely)?
   a. ***Within single-site quaternary children's hospital, reduce the rate of UNSAFE transfers per 10,000 non-ICU patient Days by 50% within 20 months (start Nov 2009/ 'by June 30, 2011')*** *(see p 299 2nd column)*

Intro:

- **Why is this important**
  - Nature and severity of local problem *(see p 299 1st paragraph 1st column)*
    - *Rapid Response system have variation in effectiveness*
      - *Poor Situation Awareness*
        - *Monitoring*
        - *Identifying Risk*
- **Aim statement**

PEDIATRICS
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Improving Situation Awareness to Reduce Unrecognized Clinical Deterioration and Serious Safety Events

Patrick W. Brady, Stephen Muething, Uma Kotagal, Marshall Ashby, Regan Gallagher, Dawn Hall, Marty Goodfriend, Christine White, Tracey M. Bracke, Victoria DeCastro, Maria Geiser, Jodi Simon, Karen M. Tucker, Jason Olivea, Patrick H. Conway and Derek S. Wheeler

Pediatrics 2013;131;e298; originally published online December 10, 2012;
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QI Journal Club Questions

1. (Methods) Planning the Intervention: (*see p 299 3rd column 'Event Review'*)
   - **Who was the team involved?**
   - **What did they review to identify potential predictors of clinical deterioration?**
   - **What 5 risk factors did they find?**

Brady P, et al. Improving Situation Awareness to improve unrecognized clinical deterioration and serious safety events. Pediatrics 2012;131:e298

Rapid response teams (RRTs) are designed to identify and respond to events in the hours prearrest.[1–3] Although interventions and contexts have varied substantially, these teams have demonstrated decreased codes outside the ICU and hospital-wide mortality in several studies.[1–4,7,9,10,12,13] Variation in the effectiveness of RRTs may be due to insufficient processes around monitoring and risk identification.[1,4] Potentially preventable morbidity and mortality from unrecognized deterioration remain, often due to ineffective clinical monitoring that we believe represents poor situation awareness (SA).[14] SA (ie, "knowing what is going on") exists at 3 levels and is defined as "the perception of elements in the environment within a volume of time and space, the comprehension of their meaning, and the projection of their status in the near future."[15–17] We believe improved SA drives better recognition of early deterioration and is essential in efforts to reduce "failure to rescue" from codes outside of the ICU, an event associated with a 50% to 67% mortality.[18,19]

High-reliability organizations (HROs) (eg, commercial aviation, nuclear power, and wilderness firefighting) deal with constant and catastrophic risk yet maintain exemplary safety records.[20] Our institution began a journey to become an HRO with the Agency for Healthcare Research and Quality HRO Learning Network in September 2005.[21] Learnings from this network fueled improvement work and introduced the concept of SA. Our organization has targeted serious safety event (SSE) reduction as a strategic improvement goal since 2006. Our efforts to reduce SSEs, defined as severe harm or death after variation from expected practice, have resulted in significant and sustained reduction.[22] Before SA work, SSEs among inpatients had not decreased. Poor SA was a common etiology. To achieve our aim and facilitate rapid learning, our project team defined a precursor outcome measure that we believed would capture events that both represented SA failures and occurred more commonly than inpatient SSEs in our center.[23] We prospectively defined unrecognized situation awareness failures events (UNSAFE) as the transfer of patients from the acute care floor to the ICU where the patient received tracheal intubation, initiation of vasoactive medications for hemodynamic support, or ≥3 fluid boluses in the first 60 minutes of ICU care or before arrival in the ICU. We believed these events represented potentially delayed transfers that are precursors to codes outside the ICU or SSEs. With focused improvement work beginning in November 2009, we aimed to decrease UNSAFE transfers by 50% by June 30, 2011. We hypothesized that a system of care that proactively identified, mitigated, and escalated risk would improve SA and decrease UNSAFE transfers and SSEs.

METHODS

Setting

Cincinnati Children's Hospital Medical Center is a 523-bed academic, quaternary-care, free-standing children's hospital. Resident teaching teams care for the majority of hospitalized patients. Less commonly, direct hospitalist and nurse-practitioner models are used. Our RRT (called a medical response team [MRT]) has been in place since 2006 with defined activation criteria.[2] A modified version of the Monaghan pediatric early warning score (PEWS) was tested and spread across the hospital in 2007.[24]

Human Subjects Protection

Our study was reviewed by the institutional review board and deemed exempt systems improvement. Individual patient care was discussed among clinicians in the course of identification and mitigation of risk. Medical record review was performed by the lead investigator by using a secure password-protected internal database and our hospital's electronic health record (EHR).

Event Review

Two investigators (Dr Brady and Ms Goodfriend) reviewed 20 consecutive SSEs and 80 consecutive ICU transfers to identify potential predictors of deterioration. The presence of at least 1 of the following 5 risk factors was found in each case: (1) family concern about patient safety, (2) high-risk therapies including unfamiliar therapies on the unit (eg, insulin use outside of the diabetes unit), (3) elevated PEWS of ≥5, (4) watcher or a patient where a clinician had a "gut feeling" that the patient was at risk for deterioration or "close to the edge," and (5) communication concern that may impact patient safety.

Intervention

The SA intervention included the following: (1) a formalized process where bedside nurses proactively identified these 5 factors, (2) unit-based huddles where charge nurses and physicians discussed identified factors and developed mitigation plans, (3) initiation of 3-times daily inpatient huddle where individual patient risk was discussed and specific predictions made, (4) development of a continuous learning system to evaluate SA and UNSAFE transfers, and 1 year later (5) development of a "robust" and explicit plan for patients identified as having 1 of the risk factors. Figure 1 provides a model of communication and action pathway for identification of patient risk. Figure 2 is the key driver diagram that illustrated the study team's belief in hypothesized drivers needed to

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QI Journal Club Questions

2. (Methods) In planning the intervention the team used a Key Driver Diagram (*see p 300 Figure 2)*

- **Describe each of the following elements in the Key Driver Diagram**
  - **Aim**
  - **Drivers**

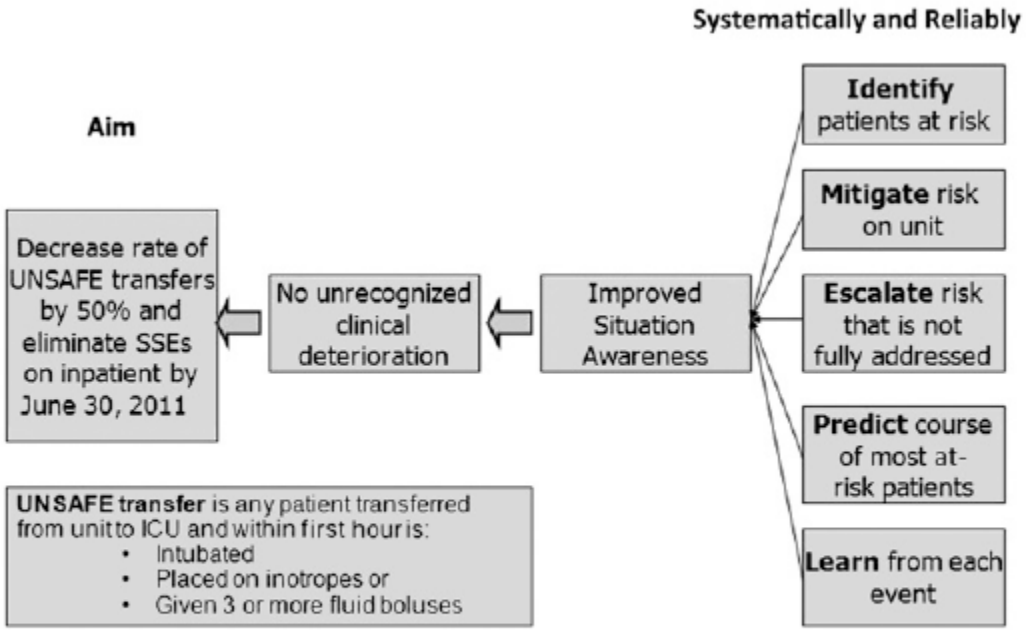

FIGURE 2

Key driver diagram illustrates the drivers (at right) that would lead to aim through improved situation awareness and no unrecognized clinical deterioration.

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QI Journal Club Questions

3. (Methods) Initial Intervention (*see p 300 Figure 1 and text 'Proactive Identification of Risk, Unit-based Huddles, and Three times daily inpatient huddles ' p 300)*

- **Describe the initial intervention**
- **List one QI principle the team applied prior to February 2010.** *(see p 301 Table 1)*

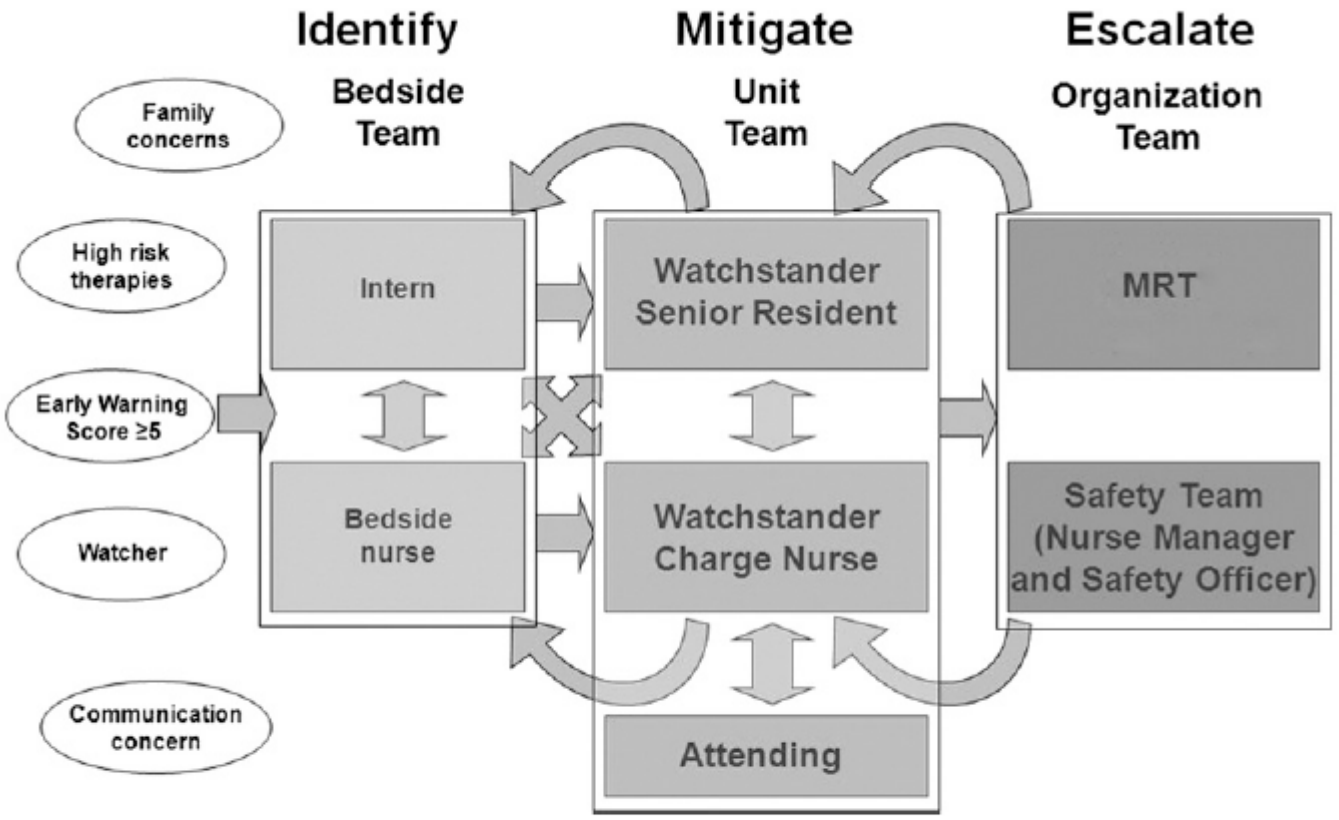

FIGURE 1
Identify, mitigate, and escalate model illustrates which risk factors were systematically identified and how standardized communication about risk occurred throughout the center.

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TABLE 1 Specific Interventions, Settings, and Timing for Each Intervention

Category of Intervention	Specific Interventions	Setting	Timing
Proactive identification of risk	Risk categories prototyped and tested on small scale	1 general pediatric unit	November 2009
	Algorithm developed and tested throughout unit	1 general pediatric unit	December 2009
	Algorithm tested and adapted on different patient populations	4 units including subspecialty and surgical care	January 2010
	Algorithm posted and spread throughout hospital	All acute care units	March 22, 2010
Unit-based huddles	Huddle tested on small on 1 unit	1 general pediatric unit	November 2009
	Adapted to include residents only when risk identified	1 general pediatric unit	December 2009
	Tested and adapted on 4 units	4 units including subspecialty and surgical care	January 2010
	Didactic and case-based education for charge nurses	Conference room	February and March 2010
	Spread throughout hospital	All acute care units	March 22, 2010
Three-times daily inpatient huddle	Safety officer attends and each charge nurse lists any patient risks that were not fully addressed with predicted discharges and admissions	4 test units at 8 AM	January 2010
	Safety officer and MPS round on each unit	4 test units at 4 PM	January 2010
	MPS rounds on each test unit	4 test units at 12 AM	January 2010
	3-time daily inpatient huddle extends to all units	All acute care units	March 22, 2010
	Explicit predictions for calls of medical response team made	All acute care units	April 2010
	Afternoon rounds moved to huddle in conference room with each charge nurse in attendance	All acute care units	October 2010
	Overnight rounds moved to huddle in conference room	All acute care units	January 2012
Continuous learning system	ACA form prototyped	4 units including subspecialty and surgical care	January 2010
	Weekly report with rates of risk identification and escalation and UNSAFE transfers along with patient-level story about situation awareness	All acute care units	March 2010
	Control plan developed for identifying and acting on special cause with process measures and UNSAFE transfers	Used on all acute care units as needed	July 2010
	Database that combined data from ACA forms and admit/transfer data from EHR developed and tested and went into production	Used by Manager, Patient Services to track patients on all acute care units	September 2010
Robust plan	Robust plan checklist generated and tested by 1 charge nurse	1 unit that specialized in transitional tracheostomy and ventilator care	March 2011
	Checklist adapted and tested with all nurses on unit	Same transitional care unit	April 2011
	Physician event note template created and tested in EHR	Same transitional care unit	June–July 2011
	Identified risk factors placed in EHR in format to be scanned by safety officer and other leaders	1 neurosciences unit	July–August 2011
	Checklist, template, and risk factors in EHR spread	All acute care units	September 2011

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QI Journal Club Questions

4. (Methods) Intervention *(see bottom of p 300 and text of 1st and 2nd column of p 301 'Continuous Learning System to Evaluate SA (situation awareness)'*

- **What did the team use to rapidly identify process and outcome failures?**
- **How often did they communicate process and outcome data at the unit-level (microsystem)?**
- **How did they communicate to staff?**

Continuous Learning System to Evaluate SA

The final component of our planned intervention was to develop a data system to rapidly identify process and outcome failures and direct this information to project leaders and leaders on individual units. To achieve this aim, (1) apparent cause analysis (ACA) forms were completed within 1 hour of each floor to ICU transfer to identify potential UNSAFE transfers and associated process failures, (2) a password-protected database was constructed to integrate information from these forms and the EHR, (3) process and outcome data were distributed each week to unit level clinical and medical directors with a story of patient-level SA, and (4) a control plan was designed with inpatient leaders to identify special cause on tracked process and outcome measures and target further interventions.

Robust Plan

One year after SA work began, the improvement team worked with 1 inpatient unit to develop and test a checklist tool to improve the mitigation/escalation process for patients with identified risk (Table 1). During multidisciplinary discussions, we proposed a "robust plan" bundle which included the following: (1) plan with proposed treatment change, (2) explicit communication with care team, (3) prediction of expected outcome, (4) outcome deadline, and (5) escalation plan (usually the MRT or discussion with SOD/MPS) if outcome was not achieved by a predefined deadline. This tool was tested, adapted, and spread throughout the remaining inpatient units (Fig 4). Subsequent testing integrated risk identification within the EHR and added focused discussion of a robust plan during safety rounds.

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QI Journal Club Questions

5. (Methods) Study of Intervention (*see p 302 'Study of the Intervention')*

- **What was the study design?**
- **What tool did the team use to measure the reliability that each shift identified risk?**

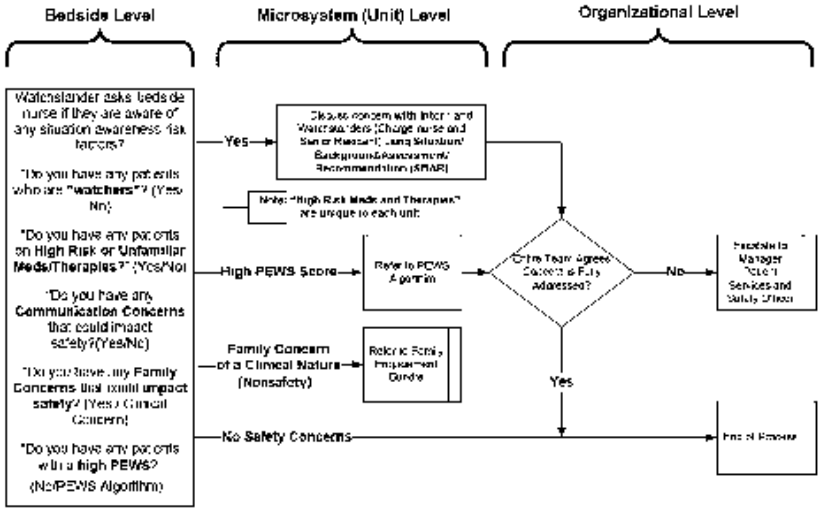

FIGURE 3
Situation awareness algorithm illustrates the tool used during education and early phases and the specific questions and communication pathways.

Study of the Intervention

In our observational time series study, data were collected on process measures of systematic identification, mitigation, and escalation of risk that we believed would improve SA and decrease UNSAFE transfers and SSEs. To evaluate the consistency of huddles and how well the identify, mitigate, and escalate intervention was implemented, data initially were collected from each unit on each nursing shift to measure the reliability that each shift identified all patients at risk and mitigated or escalated that risk. This was captured through a checklist-based form that followed the flow of algorithm of Fig 3 and was completed by each charge nurse. The tool was tested and evaluated with charge nurses from several units during early phases. Before spread throughout the hospital, 116 charge nurses received training on the process and tool through a 1.5-hour learning session. Validity of process data were evaluated through discussions during inpatient huddles by investigators, SOD, and MPS. UNSAFE transfers were identified from the ACA process and validated against review of the EHR for each ICU transfer. SSEs were captured through a safety reporting process as previously described.[22]

Analysis

Primary analysis of both process and outcome measures was performed by using statistical process control charts. For the primary outcome of UNSAFE transfers, results were tracked by using both a days-between-*t*-chart and rate chart. Established rules for identifying special cause were employed.[25–27]

RESULTS

After testing on 4 inpatient units from January 1, 2010, to March 21, 2010, the unit-level huddles and proactive inpatient huddles began on each of the 14 noncritical care inpatient units on March 22, 2010. The process measure evaluated the consistency of huddles and specifically how frequently patient risk was identified and mitigated or escalated each nursing shift on each unit. The number of units by week where ≥90% of weekly nursing shifts fully identified and mitigated or escalated patient risk were tracked on run charts and revealed both improved and sustained performance for 11 months of tracking (Fig 5). On each participating unit, 90% to 95% of identified risk was mitigated by the primary team with no escalation needed. Each inpatient huddle took less than 30 minutes. Although initially there was substantial variation in the number of patient risks that were escalated, a median of 2 risks for each huddle were escalated the first year. This increased over the study period with a median of 7.5 concerns escalated in May 2012.

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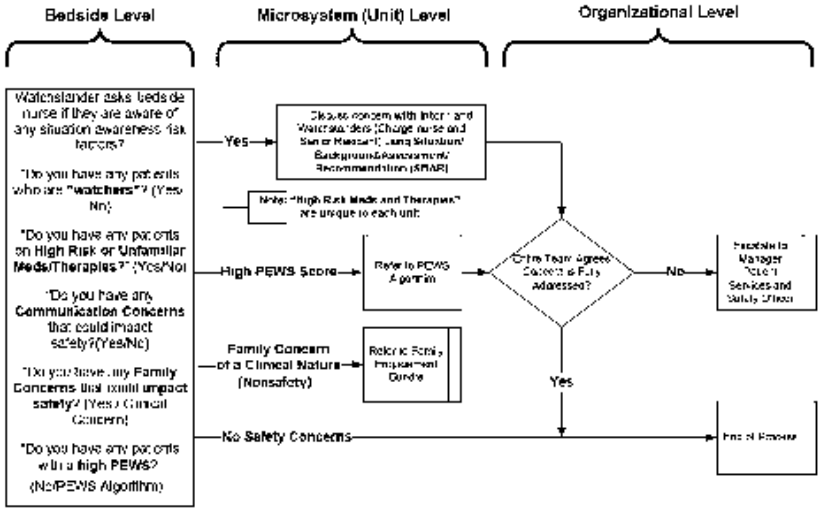
QI Journal Club Questions

6. (Methods) Analysis (p 302)
   - **What analytic methods were used?**

QI Journal Club Questions

7. (Results) *(See p 302 3rd column and p 304 Figure 5)*

- **Did the process measure (identify, mitigate or escalate patient risks) improve?**
- **Was the improvement sustained?**



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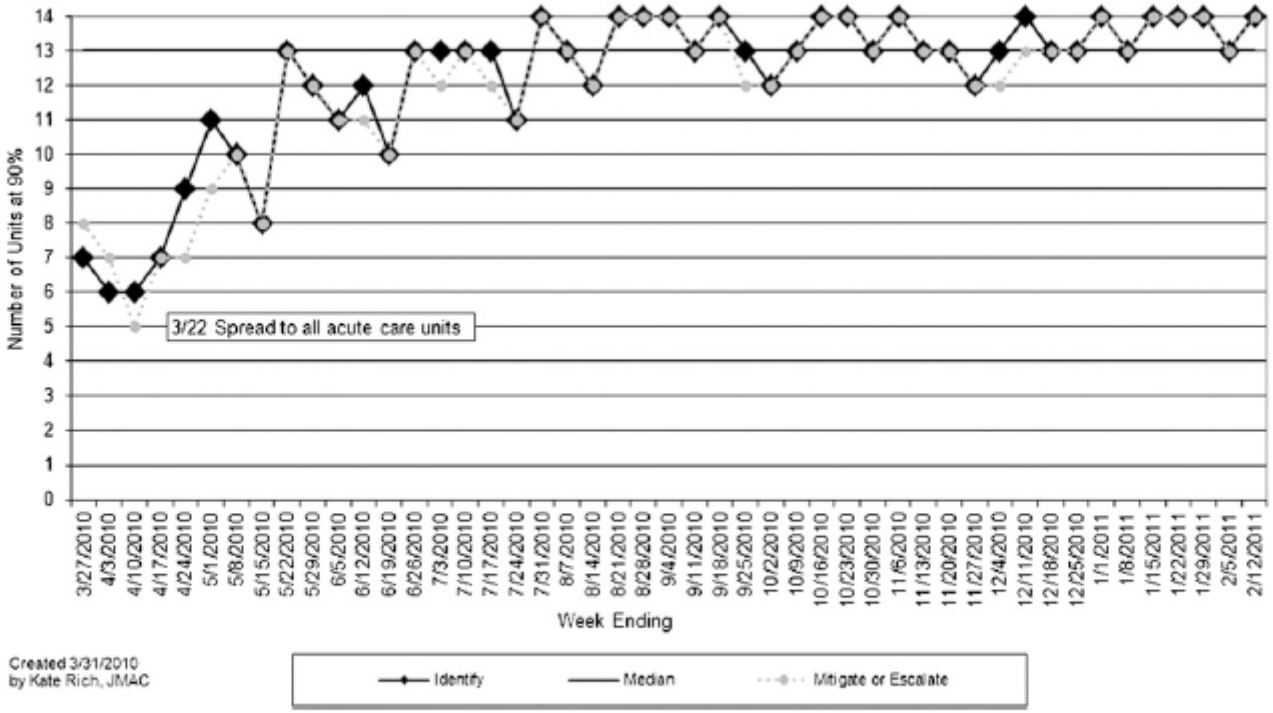

FIGURE 5

Process measure run chart illustrating the number of units by week where ≥90% of weekly nursing shifts fully identified patients at risk (solid line/diamond) and where ≥90% of weekly shifts fully mitigated or escalated that risk (dotted line/circle).

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QI Journal Club Questions

8. (Results) *(see p 303 and Figure 6)*
   - **How did the outcome measure (rate of UNSAFE transfers per 10,000 non-ICU patient days) demonstrate 'special cause' variation?**

The rate of UNSAFE transfers per 10 000 non-ICU inpatient days is displayed in Fig 6. An initial decrease in UNSAFE transfers occurred, though it did not meet rules for special cause and was not sustained. Analysis of UNSAFE transfers through an ongoing ACA process revealed that in the vast majority of UNSAFE transfers, patient risk had been identified but not fully mitigated on unit or escalated to the MRT or safety team. This led to focused improvement work on development of a robust plan as detailed above. After spread, the rate of UNSAFE transfers improved from a baseline of 4.4 to 2.4 transfers per 10 000 non-ICU inpatient days, meeting criteria for special cause variation with 8 points below the median line (Fig 6). Additionally, a significant change in the days-between inpatient SSEs from 100 days to >400 twice was observed in association with the intervention. Shortly before this work began, the number of MRT activations and PICU transfers per month increased significantly in association

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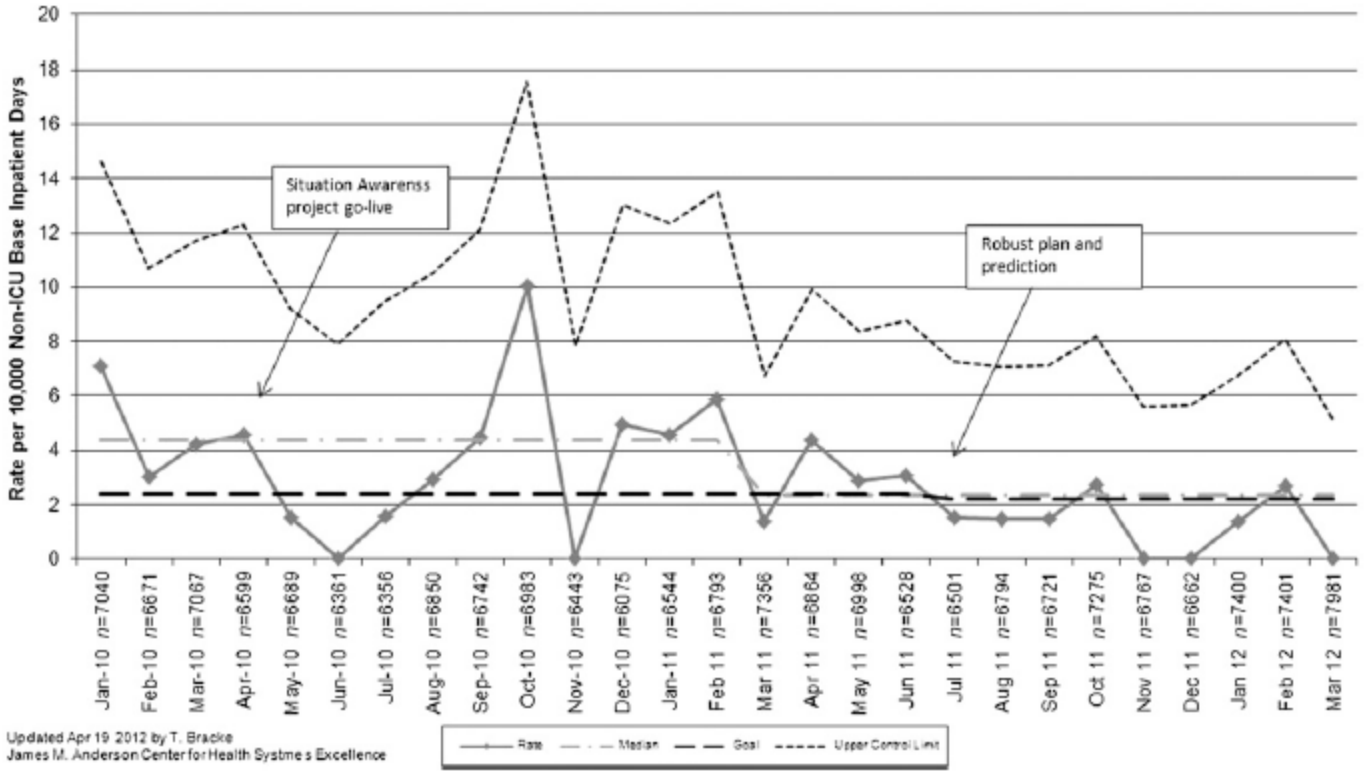

FIGURE 6

UNSAFE transfer rate chart. Rate of UNSAFE transfers per 10,000 non-ICU patient days at base location by month (n = non-ICU inpatient days by month).

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QI Journal Club Questions

9. (Discussion)
   - **What key change in care delivery contributed to success?** (*see p 306 column 1; also Figure 4 on p303)*
   - **What were some limitations including confounding, bias, or imprecision that might have affected accuracy (internal validity)?** *(see p 306 3rd column)*

measures in place that did not reveal a decrease in reliability of our intervention, we further studied where the process failures occurred regarding UNSAFE transfers. With this data, we learned that although 1 year into the intervention we had a system that identified risk, we did not systematically address this risk. We found that even on our most high risk patients, the language of plans included terms such as "continue to observe." Without explicit and time-bound plans, clinicians were observing patients until they received aggressive resuscitation that met criteria for UNSAFE transfer.

Our second stage of interventions testing a robust plan and prediction was designed by a multidisciplinary team of leaders and front-line physicians, nurses, and respiratory therapists. The improvement team believed that a shared mental model or team SA would not be achieved without explicit prediction and contingency planning. We believed that this was because level 3 SA (the projection of current event status in the near future) was still often not achieved. This may have been due to the limits of individual clinicians in making near-term projections (eg, this tachycardic patient will be in shock within 4 hours if we do not aggressively hydrate) but was believed to more commonly result from doctors, nurses, and other members of the care team not explicitly sharing their mental model. Our basic theory was borrowed from hypothesis testing in the scientific method and explicit predictions in plan-do-study-act cycles. The goal was to increase accountability and to make disconcerting data (eg, patient did not improve as predicted) clear to each member of the team. The spread of this intervention and its integration into proactive inpatient huddle was associated with a sustained decrease in UNSAFE transfers.

One strength of our work is that we created a system of care built on reliable processes, not individual clinicians. We were able to build these processes into the workflows of busy clinicians and provide via the inpatient huddle a valued activity for charge nurses as they gained insight and assistance with their sickest patients. Our sustained reduction in UNSAFE transfers over the last 12 months is further evidence of the success of building interventions into work flow. Importantly, this intervention did not add additional clinicians to our system of care but instead clarified roles and processes for charge nurses, MPS, residents, and attending physicians. The additional responsibilities of SODs are on the order of 1.5 hours per day. We believe our work builds upon previous interventions to address patient deterioration such as rapid response systems and PEWS. The proactive and standardized nature of our intervention offers an important answer to afferent limb failures of the MRTs.[14] Our intervention supplements the early warning score with other risk domains, most powerfully for us was that of the "watcher" or patient that a clinician has "a gut feeling is close to the edge." We believe this employs the tacit knowledge of experienced clinicians and hence likely will achieve greater sensitivity than any numerical scoring tool, especially since we combined this concept with objective data.[29,30] We also believe that assessment of risk as relayed by family and as emerges from communication problems has substantial face validity in identifying and predicting deterioration. Our final risk category was that of high risk therapy and borrowed from HRO thinking on the need for special oversight and procedures with new and unfamiliar therapies; for example, we believe the administration of insulin on short-stay surgery unit has a fundamentally different risk profile than doing so on diabetes unit. We therefore target these high risk therapies and address any knowledge gaps in close to real-time. Our intervention is perhaps most similar to that of the Rover team as described by Hueckel et al.[31] Although both are proactive in assessment of risk, meaningful differences include our intervention's staffing model and broader scanning for risk.

Because our goal was rapid improvement of a single site, we chose a time series design, which did not allow us to address secular trends or establish causality. We believe this design was appropriate for our innovative intervention that evolved and improved through iterative quality improvement methods. This design exposed the study to potential unmeasured confounding from safety work. We do not feel this was a particularly large risk because time series data reveal the rate of inpatient SSEs had not improved in previous years' safety work and because there were no other large interventions targeted at this population. Additionally, it is uncertain how our results would generalize to medical centers with different patient populations, staffing models, quality improvement capabilities, and safety cultures. A final limitation is that we did not have a measure of SA to reveal that this improved as an effect of our intervention. Available measures of SA involve simulated events and typically require "pausing" the event to perform assessment.[32] Clearly this was not possible or ethical in course of clinical care. A recent proposed measure of SA relied on accuracy of prediction that was fundamental to our work.[33] We did use SA for much of our conceptual model, but we cannot say definitely if improved SA was the mediator between the identify, mitigate, and escalate intervention and our decreased rate of UNSAFE transfers.

Our institution additionally has applied and tested models to improve SA and

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QI Journal Club Questions

10. (Discussion)

- **What factors may affect generalizability (external validity)?** *(see p 306 3rd column)*
- **Do you think this intervention could be applied your institution? If so, how?**

QI JC Discussion

Challenge

- Are you ready to have a QI journal club at your institution

Wrap-Up

INTEGRATING EBM AND QI

EBM

QI

Improved Patient Care

Integrating EBM and QI Questions

- What you doing presently?
- How can you envision doing it?
- How would you do it in your setting?

Deliver **Effective** Care

- When evidence exists, how can we ensure that care is evidence-based?
- Are we underutilizing effective methods?
- Are we utilizing ineffective methods?

- Solution
- Academic study → identify "best practice altering evidence"
- Develop and disseminate evidence-based clinical guidelines
- Use QI tools to measure adherence to key elements in guideline
- Link adherence to outcome

Next Steps: An Integrated Approach

- QI and EBM → an integral part of all clinical encounters
- Students/Clinical Teachers as co-learners
- Collaborate to optimize processes to benefit patients

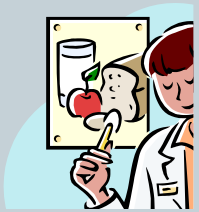
Cooke, M, et.al, Mainstreaming Quality and Safety: a Reformulation of Quality and Safety Education for Health Professions Students. *British Medical Journal of Quality and Safety*. 2011; 20 (Suppl 1): i79-i82

Parallels

- QI “Movement” can learn from the EBM “Movement”
- How to integrate into everyday care
  - Analogous to a specific PICO question
  - How did our ____ system perform for this patient?
  - How can we improve our system?

EBM/QI Collaboration

- EBM: Provides the What (the evidence)
- QI Methods: Provide the How (how to implement)
- Together we can improve patient outcomes



Design QI Project to Produce Generalizable Results

- How?
  - Test changes under multiple conditions
    - Pilot
    - Test (similar institutions/environments)
    - Spread (diverse institutions/environments)
  - Multi-site collaboration
  - Planning to disseminate findings?
  - Don't forget IRB approval/exemption
  - Use SQuIRE Guidelines as format to publish your QI results

Ogrinc, G, et.al, The SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines for quality improvement reporting: explanation and elaboration. *Quality and Safety in Health Care*. 2008;17(Suppl 1):i13-i32.

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- Fletcher, et.al, Clinical Epidemiology

Future Directions

- Take postcard
- Write 3 goals you want to accomplish in the next few months when you return to your institution
- Receive postcard in mail in 3 months

- NOT SURE WHERE WE PUT THIS

Objective Evaluation Tools

- **MERIT**
- **Pediatric QIKAT**
- **QIPAT-7**

MERIT

Mayo Evaluation of Reflection on Improvement Tool

Learner self-reflection tool

- Personal characteristics
- Systems issues
- Problem of merit

➢Wittich, CM, et.al, Validation of a method to measure resident doctors' reflection on quality improvement. *Med Ed* 2010. 44:248-55.

Example

- Resident A is concerned about the number of head CT scans that are done on pediatric patients in the ED.
- She asks a question
  - P: In children with minor head injury
  - I: Does obtaining a head CT
  - C: Compared to using clinical judgment alone
  - O: Predict clinically important traumatic brain injuries (ciTBI)

➢Objective 1: Translate clinical evidence into practice

Integrating EBM and QI

WE HAVE TO DECIDE IF ANY OF THESE SLIDES HAVE A ROLE:

IF NOT, THEY SERVE A FUNCTION FOR OUR WORKSHOP LEADERS TO GAIN QI PERSPECTIVVE

Challenge of Integrating EBM and QI

- Intellectual and Technical—even if one knows what needs to happen at the bedside, one does not know, at a system level, how to achieve that in a safe, efficient and sustainable way

- Using systems as the unit of intervention, and perhaps analysis, poses immense challenges for both implementation and evaluation

➢ Goodman, BMJ Qual Saf 2011;20:i97-i98

Central Principle to Randomized Control Trials

Subject experts must rely on their understanding of the mechanisms in place to extend results outside the population.

- Provost LP, BMJ Qual Saf 2011;20(Suppl 1):i92-i96

Standards of Evidence

Clinical Research (What)

"Of all research designs, the **randomized control trial** with adequate numbers of patients, blinding of therapists, patients and researchers, and carefully standardized methods of measurement and analysis is the best evidence for cause-effect relationships."*

Quality Improvement (How)

Satisfactory prediction of the results of tests conducted over a wide range of conditions.

Clinical epidemiology

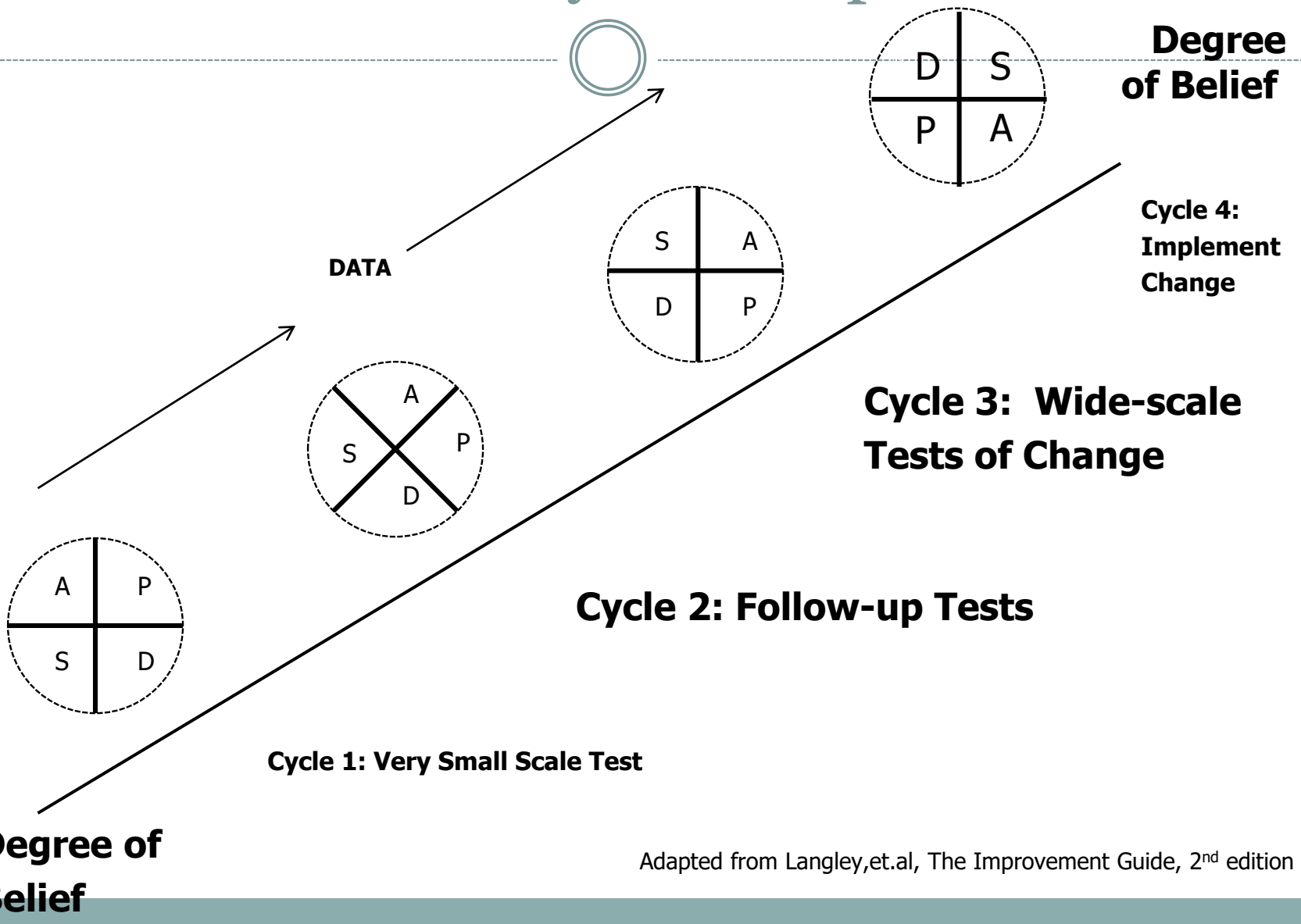
➢Fletcher, Fletcher, Wagner

QI (how) examines context

- Will today's observation be the same as tomorrow's? (chance)
- Will the change work under all conditions? (selection)
- Is the experiment robust enough
  - Other causes have been ruled out (confounding)

➢Provost, ,Advanced Improvement Methods course, 2011

PDSA Cycle Ramp



Adapted from Langley,et.al, The Improvement Guide, 2nd edition

Approaches to Designing QI Interventions

- Eliminate waste, errors and unwanted variation in a process or system
- Improve current process or system
- Develop a completely new process or system

Langley, G, et.al, The Improvement Guide 2nd edition, 2009