Certificate Program in Practice-Based Research Methods

UTILIZING QUALITY IMPROVEMENT FOR PBRN RESEARCH

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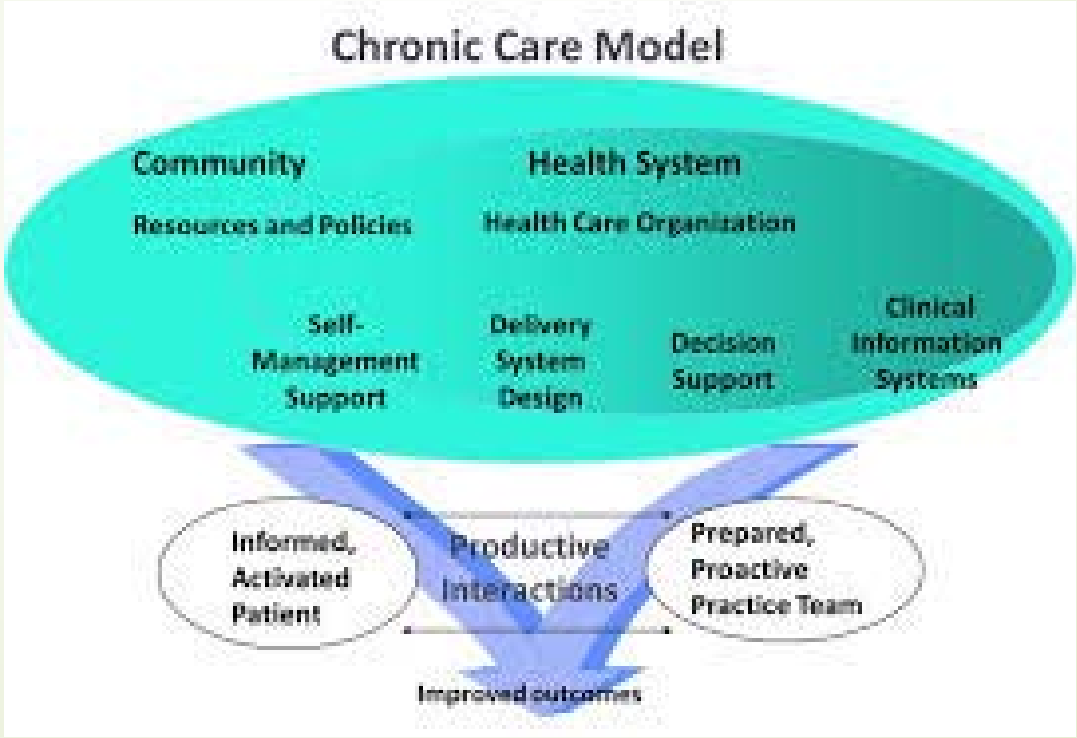
Utilizing QI for PBRN Research:

Chet Fox MD

Mary Dolansky RN, PhD

CONCEPTUAL MODEL
THE CHRONIC CARE MODEL



PRINCIPLES OF PRAGMATIC CLINICAL TRIALS IMPROVING CARE IN THE REAL WORLD

- CLINICALLY RELEVANT ALTERNATIVES
- DIVERSE STUDY POPULATION
- HETEROGENEOUS PRACTICE SETTINGS
- DATA COLLECTED ON A BROAD RANGE OF OUTCOMES

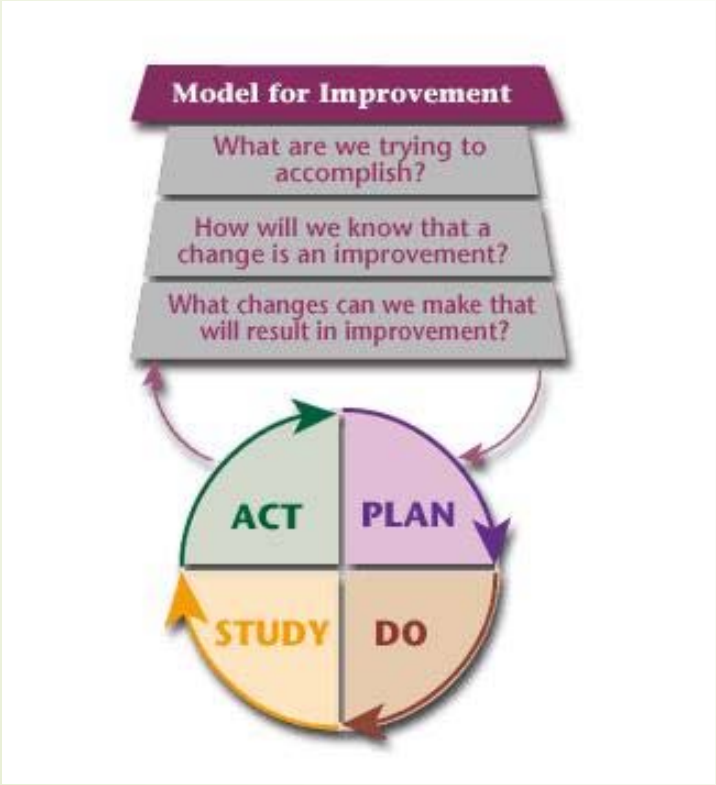
Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA.* Sep 24 2003;290(12):1624-1632.

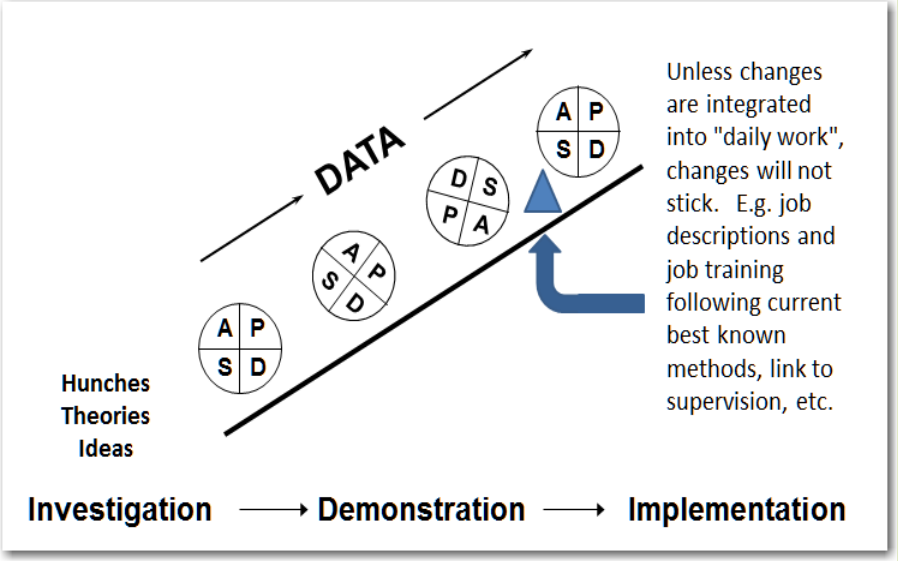
Why This Kind of Study Is needed?

- PEOPLE GET ONLY 50% OF EVIDENCE-BASED PREVENTIVE AND CHRONIC DISEASE CARE
- IT TAKES 7.9 HOURS/PATIENT/YEAR TO COMPLETE PREVENTIVE SCREENINGS
- IT TAKES 3.6 HOURS/DAY FOR STABLE PATIENTS AND 10.6 HOURS/DAY FOR COMPLEX PATIENTS TO DO CHRONIC DISEASE MANAGEMENT
- IT TAKES 17 YEARS FROM EVIDENCE IN THE LITERATURE TO BECOME ROUTINE CARE

- McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. *New England Journal of Medicine.* 2003;348(26):2635-2645.
- Yarnall KS, Pollak KI, Ostbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention? *Am J Public Health.* 2003;93(4):635-641.
- Ostbye T, Yarnall KS, Krause KM, et al. Is there time for management of patients with chronic diseases in primary care? *Annals of Family Medicine.* 2005;3(3):209-214.
- Balas EA, Boren SA. Managing clinical knowledge for health care improvement. *Yearbook of medical informatics.* 2000;2000:65-70.

PRINCIPLES OF QUALITY IMPROVEMENT
The Model for Improvement



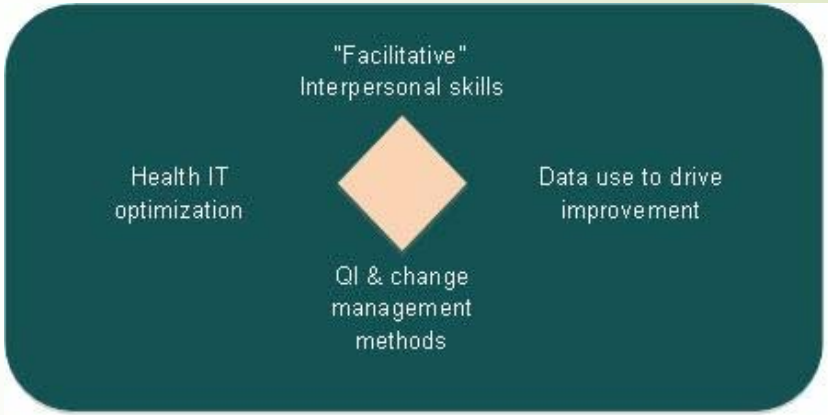


METHODS THAT WORK

- PRACTICE FACILITATION
- ACADEMIC DETAILING/ MENTORING
- AUDIT AND FEEDBACK
- COLLABORATIVE LEARNING

PRACTICE FACILIATION

- DEVELOPS LONG-TERM RELATIONSHIP WITH PRACTICE
- WORKS INTEGRALLY WITH PRACTICE TO SET UP EFFICIENT SYSTEMS FOR QI AND POPULATION MANAGEMENT
- WORKS WITH AND TRAINS STAFF IN EFFECTIVE TEAM MEETINGS
- HELPS SET UP EFFICIENT WORK FLOWS TO INTEGRATE INTO ROUTINE CARE
- HELPS PREPARE NECESSARY DATA AND REPORTS SO PEOPLE CAN KNOW HOW THEY ARE DOING
- CROSS POLLINATE IDEAS THAT WORK

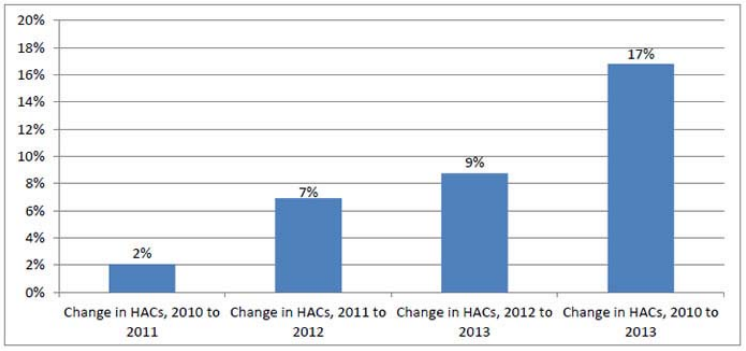


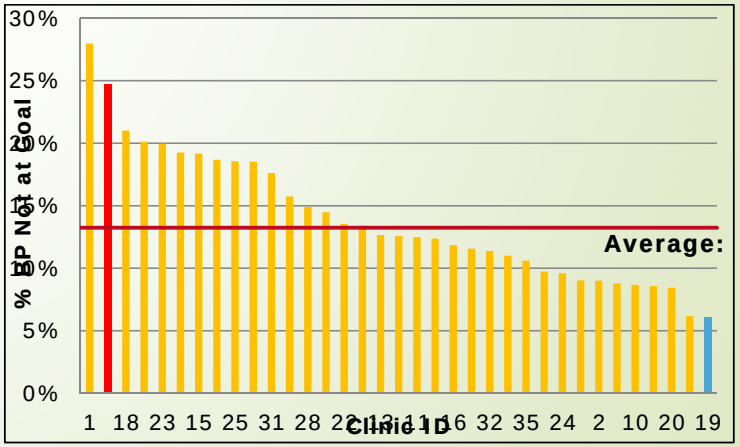
Academic Detailing/Mentoring

- Academic Detailing
  - Experienced MD Champions educate practice champions
- Academic mentoring
  - On-going relationship and support of practice champions
- Purpose: Clinician buy-in
  - To support efficiency instead of the dreaded “One More Thing”

Audit and Feedback

- Two Forms
  - Pre-post change over time
  - Benchmarking compared to other practice sites or clinicians





Collaborative Learning

- Video
- In-person
- Webinar
- Small group
- Large group
- Mixed; Practice managers, staff and clinicians
- Specialized: just staff; just clinicians etc

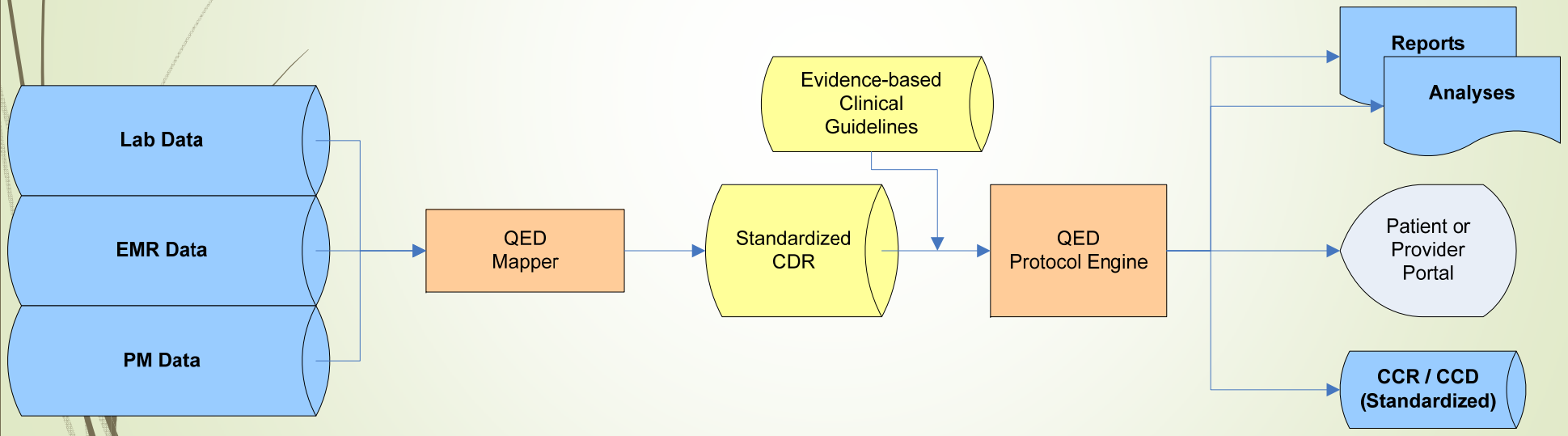
Key Elements of Success

- Goals:
  - Clear, easily measurable and feasible
  - Not too many
- Resources:
  - Time and personnel to do the project
- Data at the point of care and population reports
- Clinician Champions
- Site coordinator for local accountability
- Shared learning abilities

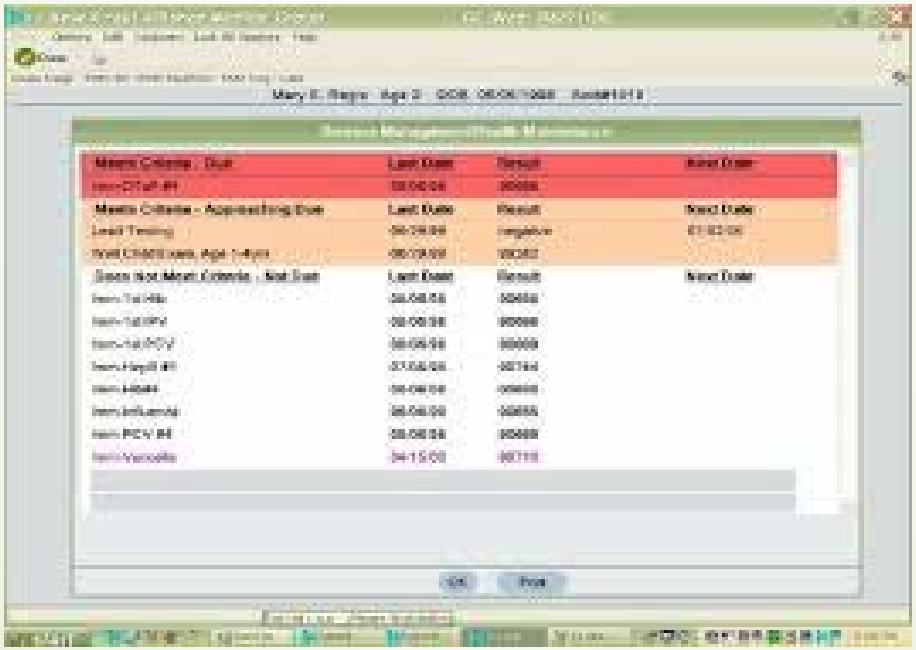
Develop the One page value proposition using the 5R approach PCORI grant as example

- Requirements
  - Practices must have ½ time behavioral health specialist who can see Medicare and fill out integration forms
  - $150,000 per practice site over 5 years
  - PCP, BH specialist, facilitator
- Resources
- Roles
- Responsibilities
  - Complete web based training and give all necessary research data
- Respect
  - This is attitudinal and underlies the project

Decision support plan



Point of Care Decision Support example

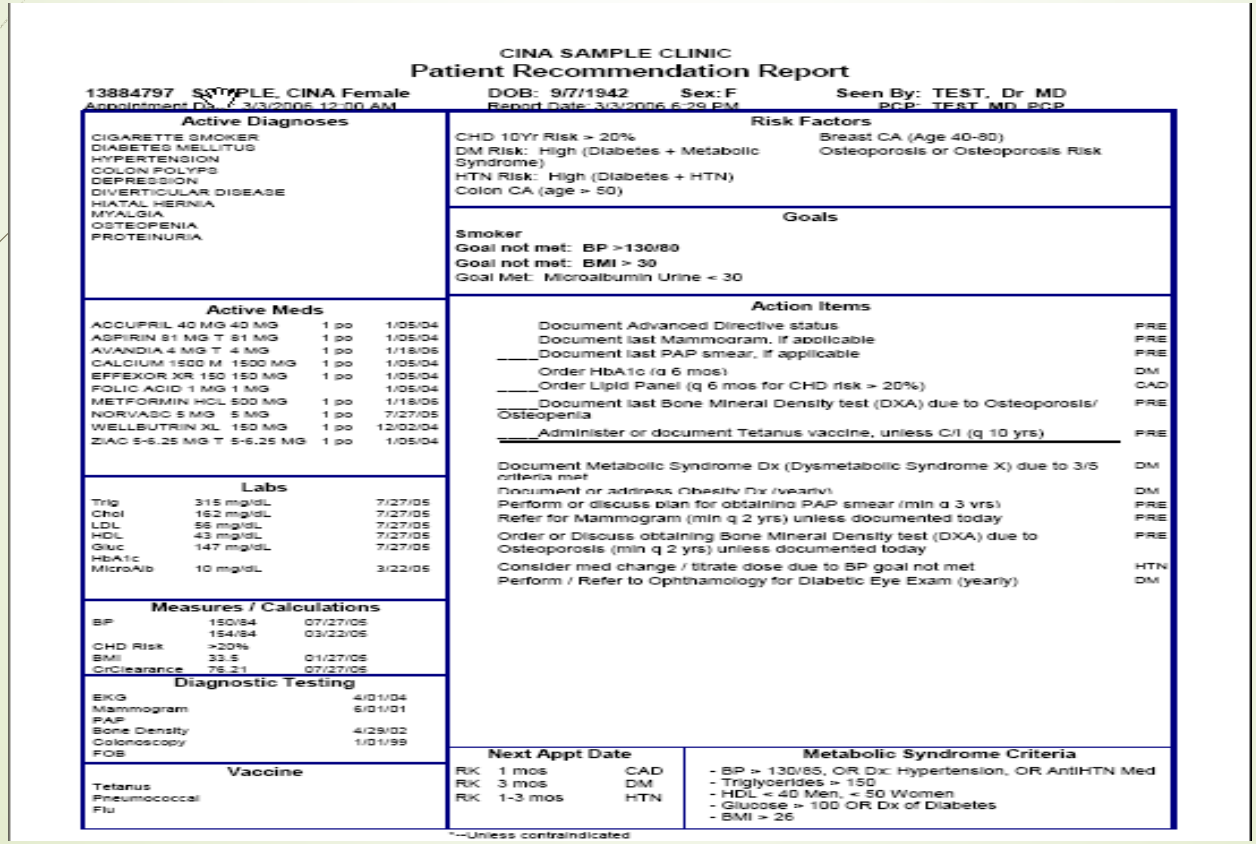


TRANSLATE CKD
Overview of a Pragmatic Clinical Trial

Comparative Effectiveness Trial

Computer Decision Support alone vs. Computer Decision Support + Virtual Facilitation

TRANSLATE CKD Study
Point of Care Decision Support



CINA SAMPLE CLINIC

Patient Recommendation Report

13884797 SAMPLE, CINA Female DOB: 9/7/1942 Sex: F Seen By: TEST, Dr MD

Appointment Dt: 3/3/2006 12:00 AM Report Date: 3/3/2006 6:29 PM PCP: TEST, MD, PCP

Active Diagnoses

CIGARETTE SMOKER
DIABETES MELLITUS
HYPERTENSION
COLON POLYPS
DEPRESSION
DIVERTICULAR DISEASE
HIATAL HERNIA
MYALGIA
OSTEOPENIA
PROTEINURIA

Active Meds

ACCUPRIL 40 MG	40 MG	1 po	1/05/04
ASPIRIN 81 MG T	81 MG	1 po	1/05/04
AVANDIA 4 MG T	4 MG	1 po	1/18/05
CALCIUM 1500 M	1500 MG	1 po	1/05/04
EFFEXOR XR 150	150 MG	1 po	1/05/04
FOLIC ACID 1 MG	1 MG		1/05/04
METFORMIN HCL	500 MG	1 po	1/18/05
NORVASC 5 MG	5 MG	1 po	7/27/05
WELLBUTRIN XL	150 MG	1 po	12/02/04
ZIAC 5-6.25 MG T	5-6.25 MG	1 po	1/05/04

Labs

Trig	315 mg/dL	7/27/05
Chol	152 mg/dL	7/27/05
LDL	56 mg/dL	7/27/05
HDL	43 mg/dL	7/27/05
Gluc	147 mg/dL	7/27/05
HbA1c		
MicroAlb	10 mg/dL	3/22/05

Measures / Calculations

BP	150/84	07/27/05
	154/84	03/22/05
CHD Risk	>20%	
BMI	33.5	01/27/05
CrClearance	78.21	07/27/05

Diagnostic Testing

EKG	4/01/04
Mammogram	5/01/01
PAP	
Bone Density	4/29/02
Colonoscopy	1/01/99
FOB	

Vaccine

Tetanus
Pneumococcal
Flu

Risk Factors

CHD 10Yr Risk > 20%
DM Risk: High (Diabetes + Metabolic Syndrome)
HTN Risk: High (Diabetes + HTN)
Colon CA (age > 50)
Breast CA (Age 40-80)
Osteoporosis or Osteoporosis Risk

Goals

Smoker
Goal not met: BP >130/80
Goal not met: BMI > 30
Goal Met: Microalbumin Urine < 30

Action Items

Document Advanced Directive status	PRE
Document last Mammogram, if applicable	PRE
____Document last PAP smear, if applicable	PRE
Order HbA1c (q 6 mos)	DM
____Order Lipid Panel (q 6 mos for CHD risk > 20%)	CAD
____Document last Bone Mineral Density test (DXA) due to Osteoporosis/ Osteopenia	PRE
____Administer or document Tetanus vaccine, unless C/I (q 10 yrs)	PRE
Document Metabolic Syndrome Dx (Dysmetabolic Syndrome X) due to 3/5 criteria met	DM
Document or address Obesity Dx (yearly)	DM
Perform or discuss plan for obtaining PAP smear (min q 3 yrs)	PRE
Refer for Mammogram (min q 2 yrs) unless documented today	PRE
Order or Discuss obtaining Bone Mineral Density test (DXA) due to Osteoporosis (min q 2 yrs) unless documented today	PRE
Consider med change / titrate dose due to BP goal not met	HTN
Perform / Refer to Ophthamology for Diabetic Eye Exam (yearly)	DM

Next Appt Date

RK	1 mos	CAD
RK	3 mos	DM
RK	1-3 mos	HTN

Metabolic Syndrome Criteria

- BP > 130/85, OR Dx: Hypertension, OR Anti\HTN Med
- Triglycerides > 150
- HDL < 40 Men, < 50 Women
- Glucose > 100 OR Dx of Diabetes
- BMI > 26

*--Unless contraindicated

Versus Facilitated Decision Support TRANSLATE

- **T**arget
- **R**eminder
- **A**dministrative Buy-In
- **N**etwork Information System
- **S**ite Coordinator
- **L**ocal Clinician Champion
- **A**udit and Feedback
- **T**eam Approach
- **E**ducation

Study Outcome Measures

Treatment Recommendation	Goal	Measurement
Control blood pressure	130	Means of last three systolic BP; will be based on last one or two if fewer than three available
Control HbA1C	<7.0	Last HbA1c;
Control LDL	<100	Mean of last two LDL; last LDL if only one is available
Use ACE/ARB		Documentation in EHR/pharmacy of prescription; yes/no for each time period
Refer to Nephrologist (GFR < 30)		Referral documented, if applicable
Eliminate smoking		Yes/no for each time period
Eliminate NSAID/Cox-2 use		Yes/no for each time period

Preliminary Results

- 35 Practices
- 10 States
- 21,105 patients
  - Data available for 3 years

- Pre- post in intervention practices improves:
  - Dx of CKD: 34%-44%
  - Use of ACE/ARB: 46%-51%
  - Referral to Nephrology for CKD stage 4: 29%-34%

Dissemination of Results

- 6 peer reviewed publications
- 20 national presentations
- TRANSLATE scoring framework used as a model of practice transformation for CMS 685 million dollar transforming clinical practice initiative

Qualitative Methods

- Surveys (conducted at baseline)
- Physician Interviews
- Analysis of all communications between facilitators and practice (emails, phone calls, meeting notes, etc.)
- TRANSLATE rubric scoring
- Site visits**

**Planned in original design, but not conducted

Baseline Physician Interview Themes

Major Theme	Sub-Themes/ Details
Limited awareness of evidence-based CKD guidelines	Inconsistent awareness of guidelines • Aware of diagnosis and recognition aspects only Inconsistent implementation • Using some but not all KDOQI guidelines • Adapts diabetes recommendations for screening • Varies by provider Not aware of guidelines
Inconsistency in CKD screening and diagnostic process	No set criteria • Not established or standardized • Gut feeling; #'s don't look good Broad spectrum of tests used to diagnose CKD Variety in which patients regularly screened for CKD
Use of health information management systems for other diseases to monitor care of CKD patients	Use of guidelines for diabetes and cardiovascular disease Use of CINA/EMR tools for other conditions • POC tools/registry • Guidelines installed in protocol engine • Flow sheets follow metrics established as national guidelines.
Difficulty explaining CKD to patients	Provider discomfort • Raises other issues- physician is not ready/or equipped to respond • Doesn't want to frighten the patient • Limited patient education materials • Physician knowledge of CKD limited Explaining the diagnosis • Impaired kidney function • Risk management • Part of the natural aging process Providing reassurance • Steps can be taken to prevent progression/dialysis • Manageable, if patient modifies risks and adheres to medical advice
Challenges caring for CKD and other chronic disease patients	Provider level • Competing demands; time, increased patient volume, complex patients • Need for provider education Patient level • Motivation/ engagement/compliance • Multi-morbidities • Social determinants of health issues Practice level • Competing demands • Insufficient support staff • Primary focus on other diseases • Lack of communication with specialists

Quality Improvement: Operations & Research

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Objective:

Differentiate between Quality Improvement and Improvement Science

What is Quality?
IOM's Six Aims for Improvement

Quality
IOM's Six Aims for Improvement

1. **Safe: Care in healthcare facilities should be as safe as at home**
   ***3rd leading cause of death**

2. **Effective: Care should be science based and evidence based**

3. **Efficient: Care and service should be cost effective**

IOM's Six Aims for Improvement (cont.)

4. **Timely: No waits or delays should occur in receiving care**

5. **Patient centered: System of care revolves around patient- appropriate**

6. **Equitable: Disparities in care should be eradicated- Geographic**

What is QI?

- The combined and unceasing efforts of everyone- health care professionals, patients and their families, researchers, payers, planners, educators– to make changes that will lead to better patient outcomes, better system performance and better professional development.
  - Batalden & Davidoff 2007

History

1. Origins in manufacturing 1980's
   - Deeming, Shewhart, Donabedian
2. 1993 HMO Group conference on Total Quality Management
3. Emphasis on links between improvement, change & learning
4. 1st projects: breast cancer & asthma

Mammography Quality Standard, 1992

Breast Cancer Surveillance Consortium

Luce, J., Bindman, A., Lee, P. (1994) . Brief history of quality improvement in the US.

What is QI

- Systematic - data guided activity
- Dynamic intervention
- Designed to bring immediate improvement to a local context

The Model for Improvement

- Identifying an area for improvement
- Proposing specific changes
- Testing the changes
- Evaluating the success of the changes
- Multiple pilot studies

Other models:
Six Sigma
Lean
Juran

Nolan and Nolan, 2000

QI Dimensions

- Philosophy- Culture- Learning Organization
- Practical problem solving (tool)- An evidenced –based management style (local level)
- An application of a theory-driven science of system change (science- Implementation science)

Lynn, J, et al. (2007). The Ethics of Using Quality Improvement Methods In Health Care. Annals of Internal Medicine, 146, 666-673.

QI Dimensions

- Philosophy- Culture- Learning Organization
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Lynn, J, et al. (2007). The Ethics of Using Quality Improvement Methods In Health Care. Annals of Internal Medicine, 146, 666-673.

QI Philosophy

- Personal level
- Organizational level
  - Culture
- Learning Organization

QI Dimensions

- Philosophy- Culture- Learning Organization
- Practical problem solving (tool)- An evidenced –based management style (local level)
- An application of a theory-driven science of system change (science)

Lynn, J, et al. (2007). The Ethics of Using Quality Improvement Methods In Health Care. Annals of Internal Medicine, 146, 666-673.

QI: Theory of Profound Knowledge

1) Knowledge of a system

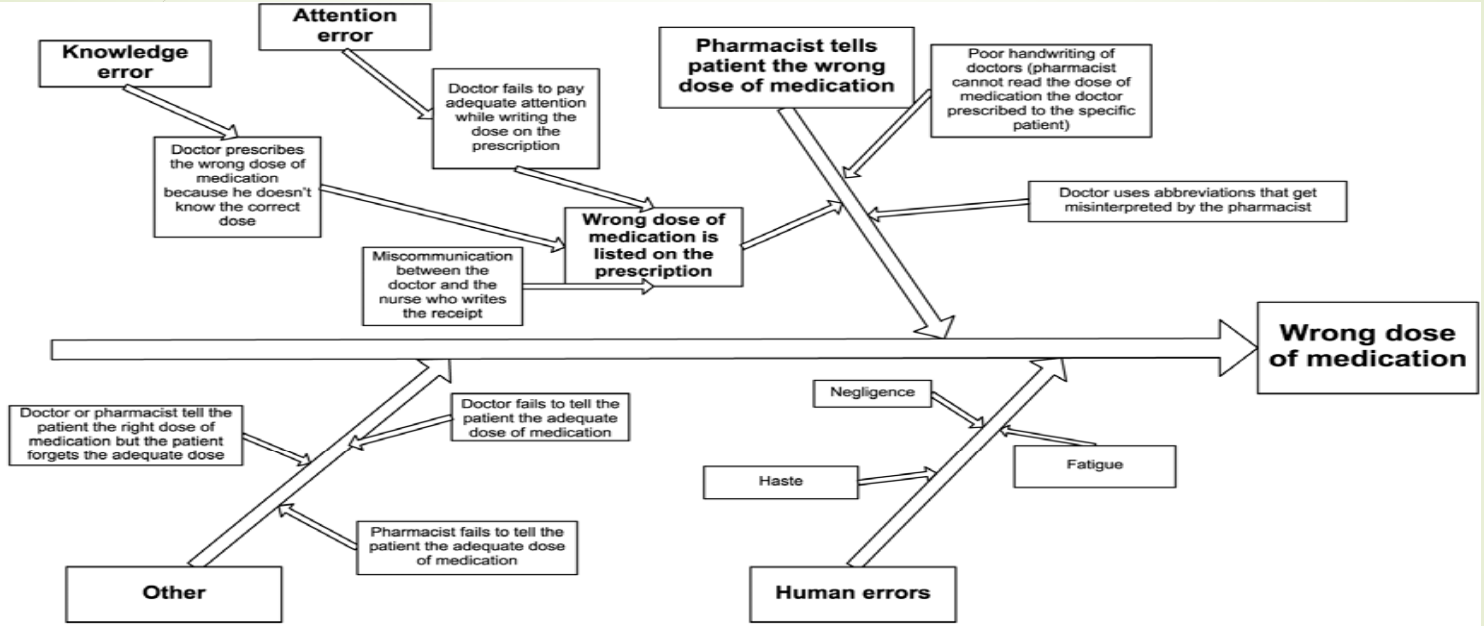
2) Knowledge of variation

3) Knowledge of psychology
Change management

4) Theory of knowledge ---PDSA

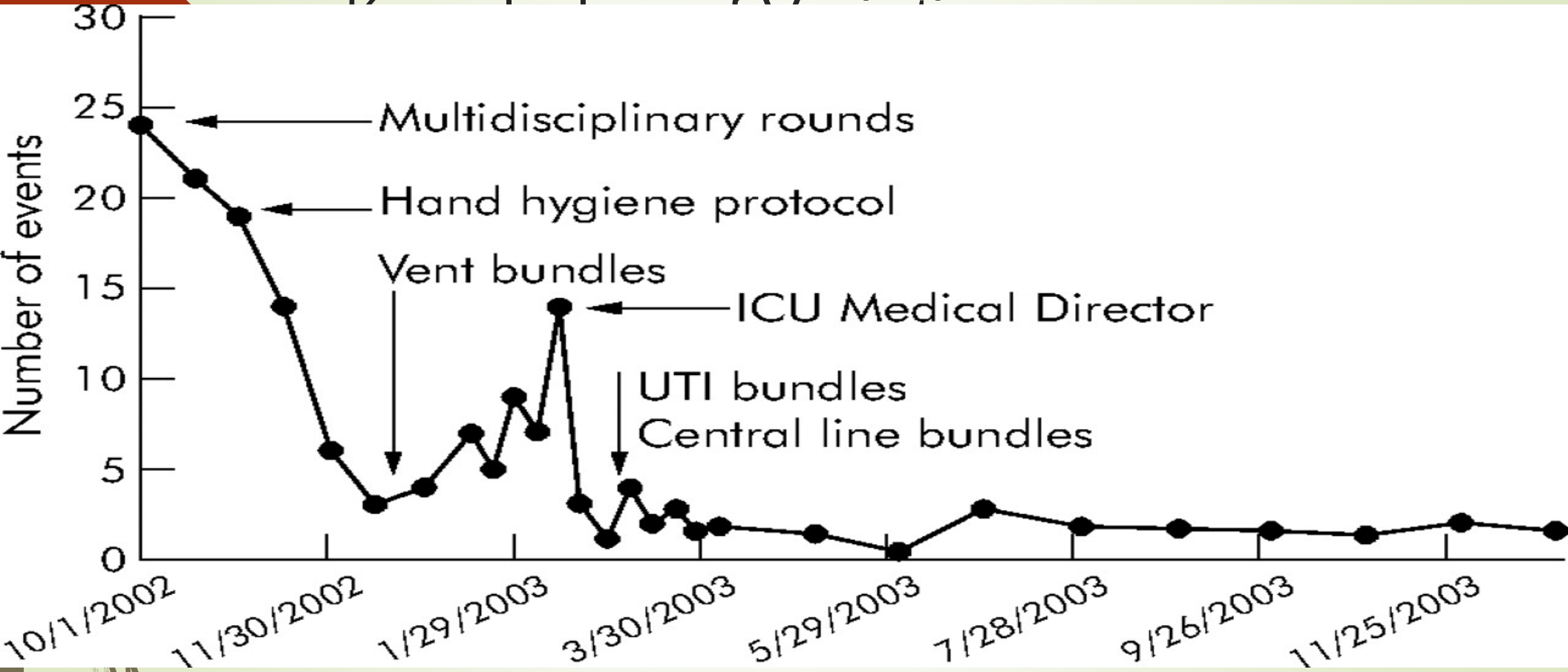
Batalden & Stoltz, 1993 & Batalden & Davidoff, 2003

Knowledge of a system



Source: Own Illustration

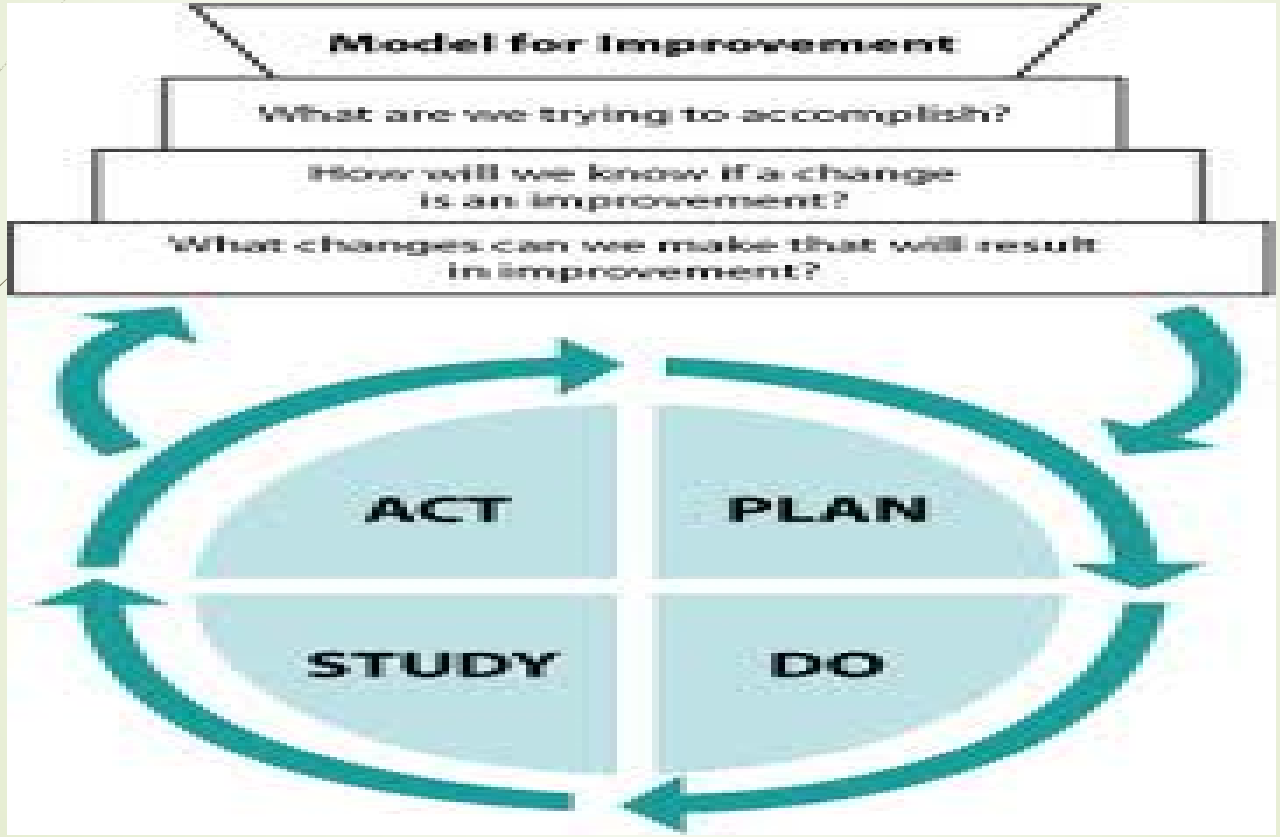
Knowledge of Variation



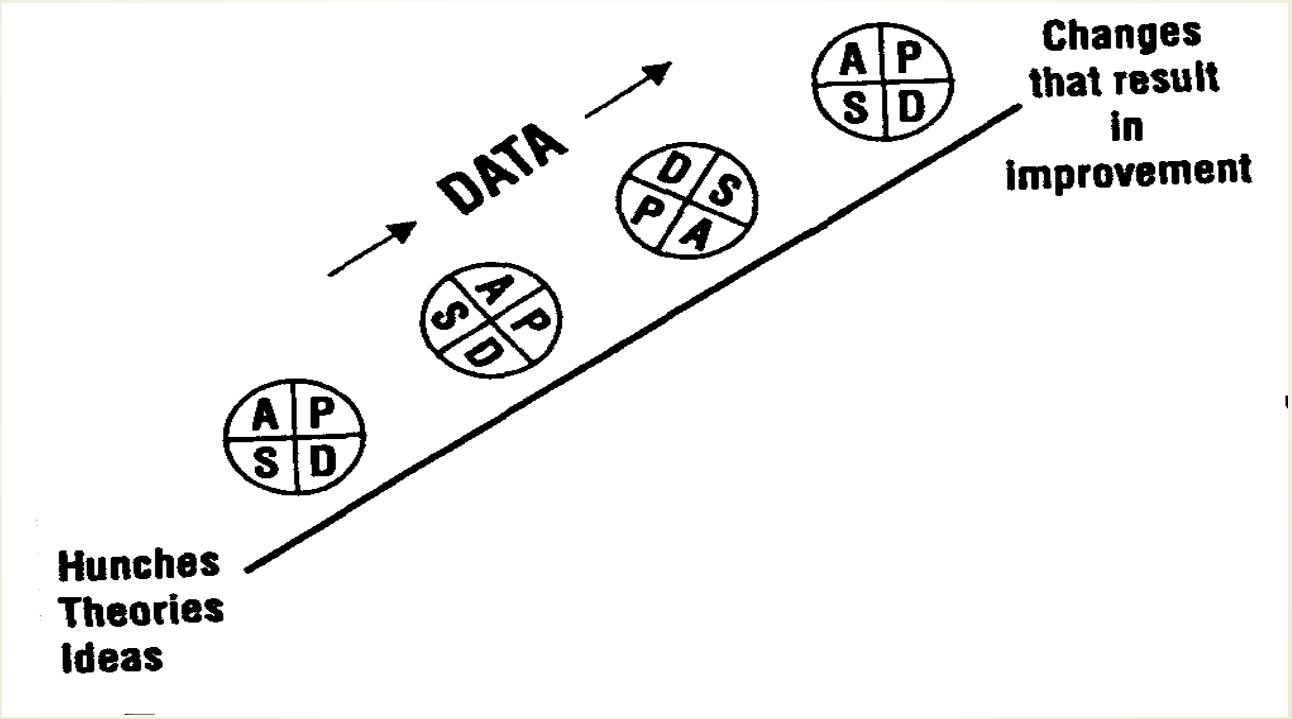
Psychology of Change
Change Innovation

- Education
- Reminder- Cue to action
- Champion model
- Audit and feedback
- Collaborative

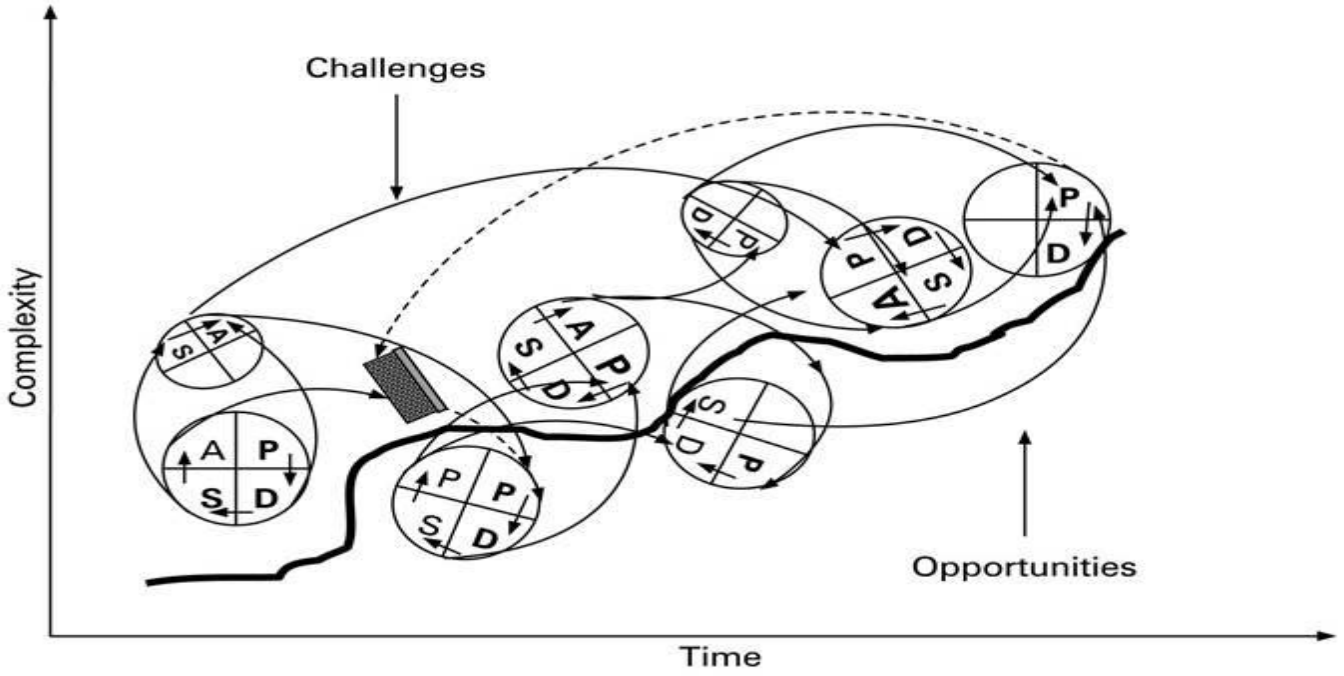
Theory of Knowledge



Using Sequential PDSA Cycles to Build Knowledge



Revised conceptual model of rapid cycle change.



P = Plan D = Do = Barrier —— = Direct flow of impact
S = Study A = Act ----- = Lingering background impact Arrowhead = Feedback or feedforward
Different sizes of letters and cycles and bold letters = denotes differences in importance/impact

Tomolo A M et al. Qual Saf Health Care 2009;18:217-224

Product: Story Board

Is Osteoporosis In Men Under screened?

Samta Jain MD, Bilori Bilori MD, Pete Spanos BA, Mary Dolansky RN PhD, Mamta Singh MD MS.

Introduction & Background

- Mortality rate in men in the year after a hip fracture is estimated up to 37.5% which is higher than women *(1)*.
- Osteoporosis leads to fracture in 1 out of 4 men above age 50.
- Fractures due to osteoporosis is more common than prostate cancer in men older than age 50 *(2)*.
- Bone mineral density screening in men≥ 70 years of age is recommended by the international society for clinical densitometry and earlier screening is required in the presence of fragility fracture or other known risk factors.
- The Endocrinology society recommends testing higher risk men (age ≥70 and men aged 50–69 with risk factors) with dual-energy x-ray absorptiometry *(3)*.
- For men≥65years with history of fracture and for men 80-85years of age without previous fracture, screening followed by bisphosphonate therapy may be cost-effective. It may be worthwhile including men ≥ 70 years as well *(4)*.

Aim

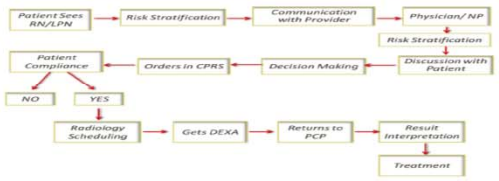
To increase the screening rate of osteoporosis in high risk males over age 50yrs in COE MD/NP resident clinic by 50% by the end of Aug 2013.

Methods

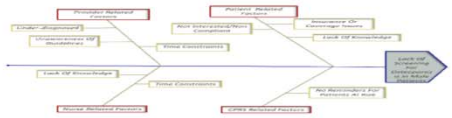
We extracted baseline data for patients enrolled with center of excellence MD and NP residents at Wade Park VA. 34 DEXA scans were done from year 2003 to 2012 for various indicators. Review of literature indicated that bone mineral density has been shown to decline consistently in high risk categories mentioned below.

- Steroids use > 5mg > 3mths
- Hypogonadism (testosterone ≤ 2ng/ml)
- Systemic lupus/Inflammatory Bowel Disease/Rheumatoid arthritis and Sarcoidosis

Process Map

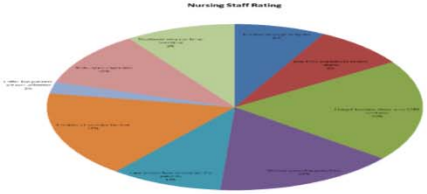


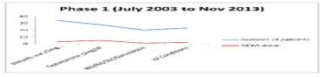
Determining Factors

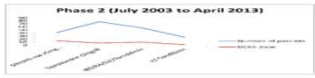


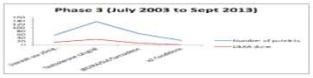
Results

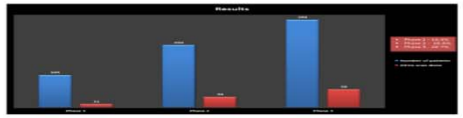
- Balancing measures for our project were identified mainly as increased work load on radiology department, scheduling issues, cost factor and patient anxiety.
- We decided to run a survey to create awareness of importance of screening among MD residents, NP residents and nursing staff.
- Our survey results are displayed below











Conclusions

- Osteoporosis in men is under screened as reflected through our baseline data.
- The barriers to screening in residents and nurses were identified mainly to be low on priority to discuss with patients, unclear guidelines, no electronic medical record system reminder and difficulty ordering the test.
- No clear screening guidelines exist but data supports that fractures lead to sizeable mortality and morbidity, increased number of hospitalization and thereby increasing healthcare costs. Our data suggests that significant knowledge gap has resulted in poor screening rates. We attempted to narrow this gap by creating awareness amongst residents and nurses.
- Our data revealed continuous improvement in screening rate of osteoporosis as outlined above in the graphical presentation.

Discussion

- Our data analysis suggests osteoporosis screening rates in men are low at our VA medical center. It would be interesting to determine the screening rates throughout National VA centers and further the whole of United states.
- We predict that the national screening rate for Osteoporosis in men is low and there is a significant room for improvement in this area.
- Readily available data through electronic medical record system and multidisciplinary team approach helped us continue the project.
- Limitations of the project includes that few high risk categories of men were included, only residents and nurses were involved for intervention and limited support staff available to impart education.
- We hope that we continue to educate medical professionals on a larger scale regularly thereby increasing the screening rates. This will need adequate support staff and dedicated time to continually improve awareness.

References:

1. Ebeling PR . Osteoporosis in men. *N Engl J Med 2008;358:1474-82*
2. http://www.nof.org/articles/236
3. Watts NB et al. Osteoporosis in men. *J Clin Endocrinol Metab, June 2012, 97(6):1802-1822*
4. Schousboe JT et al. *Cost-effectiveness of bone densitometry followed by treatment of osteoporosis in older men. JAMA.* ***2007 Aug 8;298(6):629-37***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Explanation and Elaboration (E&E) in PDF is available for downloading from Quality and Safety in Healthcare.
RECENT NEWS
SQUIRE at IHI National Forum 2013
15 NOV, 2013
The SQUIRE faculty will be teaching a learning lab at the IHI National Forum in Orlando, FL, on December 8, 2013. This session advances participants' writing skills with the goal of moving their healthcare improvement efforts to scholarly publication. Participants will bring their own improvement work—at any stage of development—for use in hands-on writing exercises. Faculty will employ a new draft version of the SQUIRE publication guidelines for reporting healthcare improvement to help participants prepare their work for
Get Involved
Have you implemented a quality improvement in healthcare that you'd like to write about? Have you already published an article? Do you know of a journal or organization that has adopted the SQUIRE guidelines?
Please contact us and let us know about it.
How to cite SQUIRE
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Japanese (PDF)
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SQUIRE Screencasts
Why and how SQUIRE was developed, and how it might help you

Published in final edited form as:
Acad Emerg Med. 2014 March ; 21(3): 274–282. doi:10.1111/acem.12337.

Reducing Blood Culture Contamination in Community Hospital Emergency Departments: Multicenter Evaluation of a Quality Improvement Intervention

Wesley H. Self, MD, MPH[a], **Joyce Mickanin, MSN, RN**[b], **Carlos G. Grijalva, MD, MPH**[c,d], **Freda H. Grant, BS, MT, ASCP**[e], **Michelle C. Henderson, MSN, RN**[f], **Glenda Corley, BS, MT, ASCP**[f], **D. Glen Blaschke II, MD**[g], **Candace D. McNaughton, MD, MPH**[a], **Tyler W. Barrett, MD, MSCI**[a], **Thomas R. Talbot, MD, MPH**[c,h], and **Barbara R. Paul, MD**[b]

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[b]Community Health Systems Professional Services Corporation, Franklin, Tennessee

[c]Department of Preventive Medicine, Vanderbilt University School of Medicine, Nashville,

QI Dimensions

- Philosophy- Culture- Learning Organization
- Practical problem solving (tool)- An evidenced –based management style (local level)
- An application of a theory-driven science of system change (science)

Lynn, J, et al. (2007). The Ethics of Using Quality Improvement Methods In Health Care. Annals of Internal Medicine, 146, 666-673.

2010
Improvement Science

A field of research focused on healthcare improvement. The primary goal of this scientific field is to determine which improvement strategies work as we strive to assure effective and safe patient care.

Improvement Knowledge

Batalden & Stoltz, 1993 & Batalden & Davidoff, 2003

1) Knowledge of a system

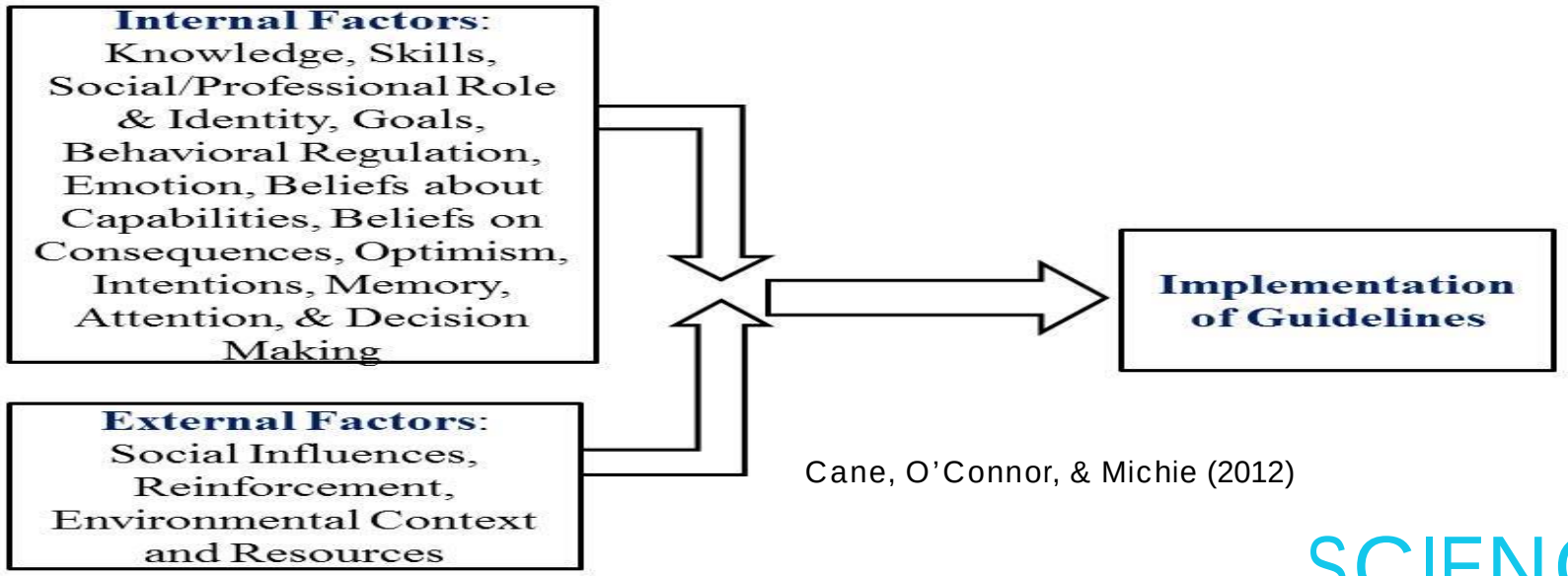
2) Knowledge of variation

3) Knowledge of psychology

Change management

4) Theory of knowledge PDSA

Knowledge of a System
Theoretical Domains Framework

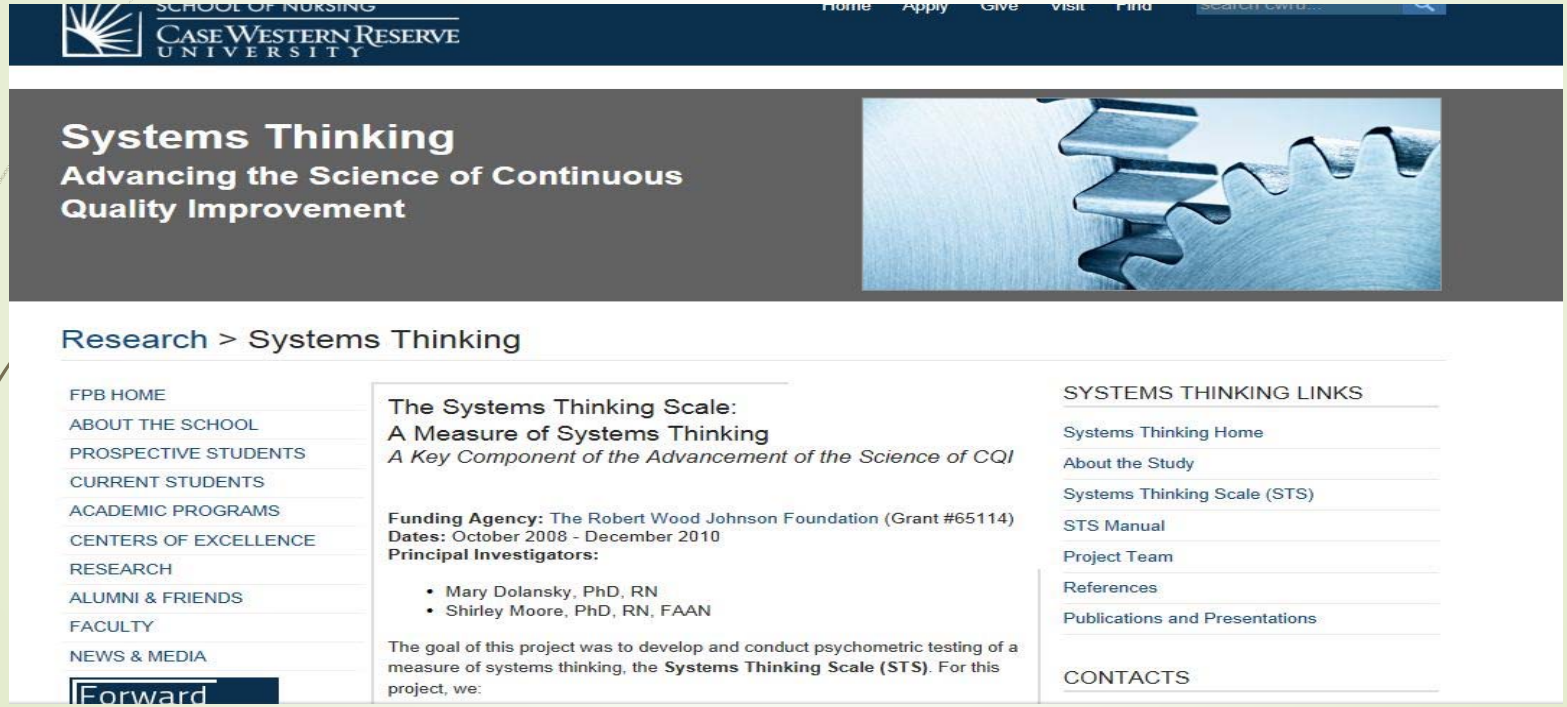


Cane, O'Connor, & Michie (2012)

SCIENCE

Systems Thinking Scale

http://fpb.case.edu/systemsthinking/index.shtm inking Scale



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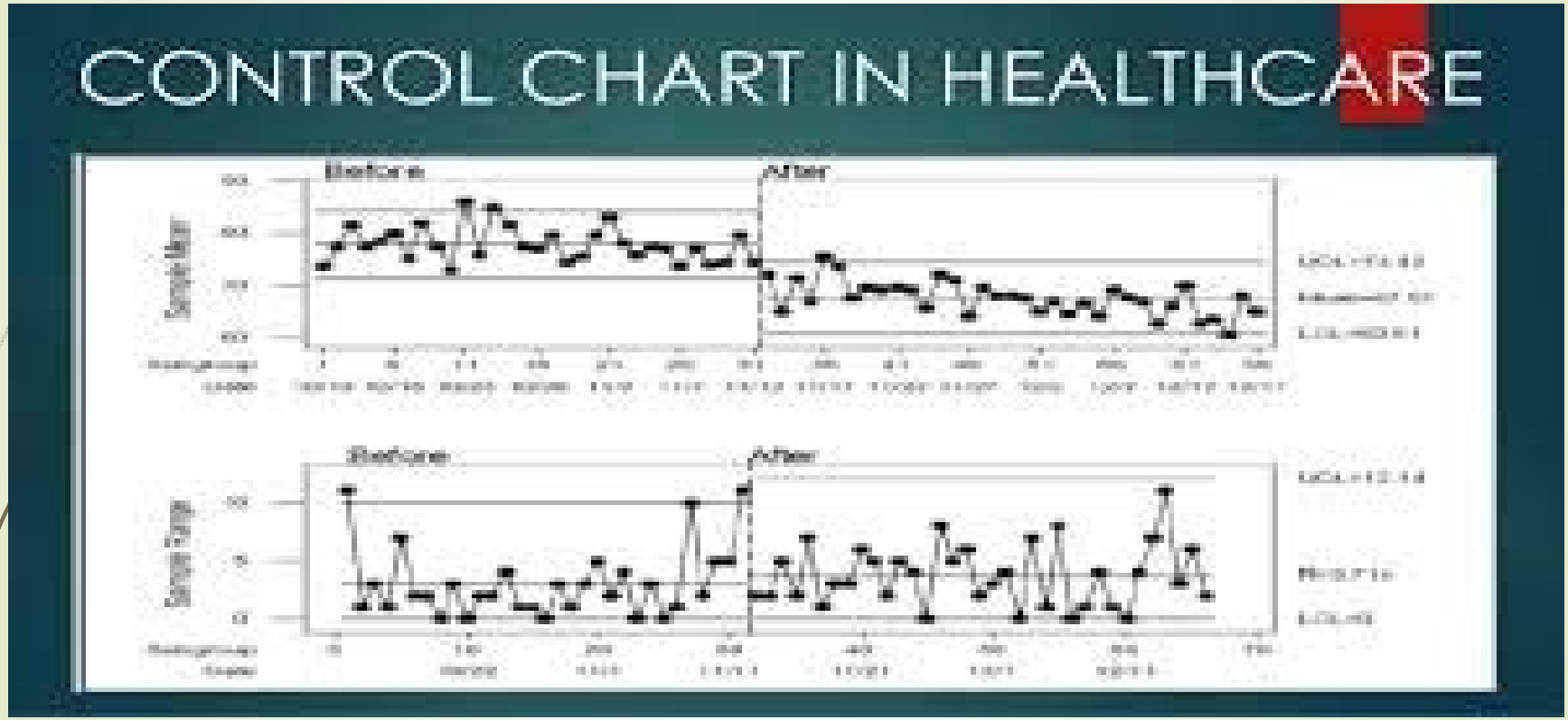
Knowledge of Variation



SCIENCE

Knowledge of Psychology/Change Management

Implementation Interventions

- Education
- Reminder- Cue to action
- Champion model
- Audit and feedback
- Collaborative

SCIENCE

Effectiveness of Knowledge of Psychology/Change management Interventions

(Bero et al., 1998, Grimshaw et al., 2001)

Little or no effect

- Educational materials
- Didactic educational meetings

Sometimes Effective

- Audit and feedback
- Local opinion leaders
- Local consensus processes
- Patient mediated interventions

Generally Effective

- Educational outreach visits
- Reminders
- Interactive educational meetings
- Multifaceted interventions including two or more of:
  - Audit and feedback
  - Reminders
  - Local consensus processes
  - Social marketing

Theory of Knowledge

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advancing methods, improving health

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Home » Research » Adaptive Interventions » Why Use a SMART Design to Build an Adaptive Intervention?

Why Use a SMART Design to Build an Adaptive Intervention?

Adaptive Interventions

Adaptive interventions have four critical components.

1. **Sequence of decisions regarding patient care** - Most interventions require decisions such as, "If the patient is unresponsive to the initial treatment, what treatment should we provide next?" or "Once the patient has stabilized, what treatment is needed to prevent relapse?"

2. **The set of treatment options at each decision point** - For example, if a patient is unresponsive to a drug, should the dosage be increased, should the drug be discontinued, or should counseling be increased? All of these are treatment options.

3. **Tailoring variables** - These are the factors used to trigger a change in the treatment. These can be things like early signs of nonresponse, manifestation of side effects, or environmental or social characteristics. The idea is to identify the variables that best indicate when the appropriate treatment has changed.

SCIENCE

Other Uses in Science

JAN
Informing Practice and Policy Worldwide through Research and Scholarship

PROTOCOL

Testing a post-discharge nurse-led transitional home visit in acute care pediatrics: the Hospital-To-Home Outcomes (H2O) study protocol

Heather L. Tubbs-Cooley, Rita H. Pickler, Jeffrey M. Simmons, Katherine A. Auger, Andrew F. Beck, Hadley S. Sauers-Ford, Heidi Sucharew, Lauren G. Solan, Christine M. White, Susan N. Sherman, Angela M. Statile & Samir S. Shah On behalf of the H2O Study Group*

Accepted for publication 6 November 2015

Correspondence to H.L. Tubbs-Cooley:
e-mail: heather.tubbs_cooley@cchmc.org

Trial registration: The Hospital to Home Outcomes Study is registered on

TUBBS-COOLEY H.L., PICKLER R.H., SIMMONS J.M., AUGER K.A, BECK A.F., SAUERS-FORD H.S., SUCHAREW H., SOLAN L.G., WHITE C.M., SHERMAN S.N., STATILE A.M. & SHAH S.S. (2016) Testing a post-discharge nurse-led transitional home visit in acute care pediatrics: the Hospital-To-Home Out-

Qualitative
QI
RCT


Time for Change

COMMENTARY

The Science of Improvement

Donald M. Berwick, MD, MPP, FRCP

In the early 1890s, Dr William Halsted developed radical mastectomy for breast cancer. Surgeons performed the Halsted procedure for more than 80 years even though there was little systematic evidence for its success. Then a new breed of scholars subjected the procedure to formal methods of evaluation unknown to Halsted.[1] The methods—randomized controlled trials (RCTs) principal among them—led to a surprise: radical mastectomy had no advantage over simpler forms of treatment.[2]

This is but 1 example of the hard-won victory of evidence over belief in medicine. The pioneers of the formal evaluation of medical practices raised questions that traditional practitioners did not welcome. But in time, formal evaluation prevailed.[3,4] The pioneers developed a hierarchy of evidentiary rigor relating the design of a study to the confidence that could be placed in the findings, from the lowly, nearly valueless anecdote to the royalty of evidence, the RCT.

Concurrently, a similar story of hard-won learning unfolded in the so-called quality movement. Scholars illuminated the scale and types of defects in the processes of care and the outcomes, including high rates of unscientific care,[5] inappropriate care,[6] geographic variations in practice,[7] latent disagreements among specialists,[8] and often-unrecognized medical injury to patients.[9] Like the pioneers of evidence-based medicine, students of medical quality were at first largely ignored, but no longer. In 1999 and 2001, the Institute of Medicine published 2 landmark reports on the evidence for quality failures[10,11] and called urgently for redesign of care systems to achieve improvements.

The story could end here happily with 2 great streams of strained, progress may be the victim. For example, the RCT is a powerful, perhaps unequaled, research design to explore the efficacy of conceptually neat components of clinical practice—tests, drugs, and procedures. For other crucially important learning purposes, however, it serves less well.

Recent controversies about the evaluation of rapid response teams provide a case in point. These controversies show the importance of adjusting research methods to fit research questions. Although only 10% to 15% of inpatients resuscitated outside intensive care units survive to hospital discharge, early warning signs are present in a large percentage of patients who ultimately experience cardiac arrest. Rapid response team systems bring expert clinicians to the bedsides of deteriorating patients before arrest occurs. In the mid 1990s, based largely on reports from Australian investigators, the Institute for Healthcare Improvement and others began introducing the concept to willing hospitals. Local experience strongly suggested that these systems often, although not always, were associated with improved outcomes, including reduced anxiety among nursing staff; increased interdisciplinary teamwork; decreased cardiac arrests outside of intensive care units; and, in some cases, declines in mortality.[12,13]

The evidence base took a turn in June 2005 with the publication of the Medical Early Response Intervention and Therapy (MERIT) Study,[14] a cluster randomized prospective trial that claimed to find no beneficial effect of these teams on several primary outcomes. Controversy has continued since then regarding the scientific evidence for rapid response systems.

In fact, the MERIT trial was not negative; it was inconclusive. The study team encountered an array of serious problems in execution, common in social science. For example,

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FEATURE ARTICLE

An Instrument to Differentiate between Clinical Research and Quality Improvement

BY GREG OGRINC, WILLIAM A. NELSON, SUSAN M. ADAMS, AND ANN E. O'HARA

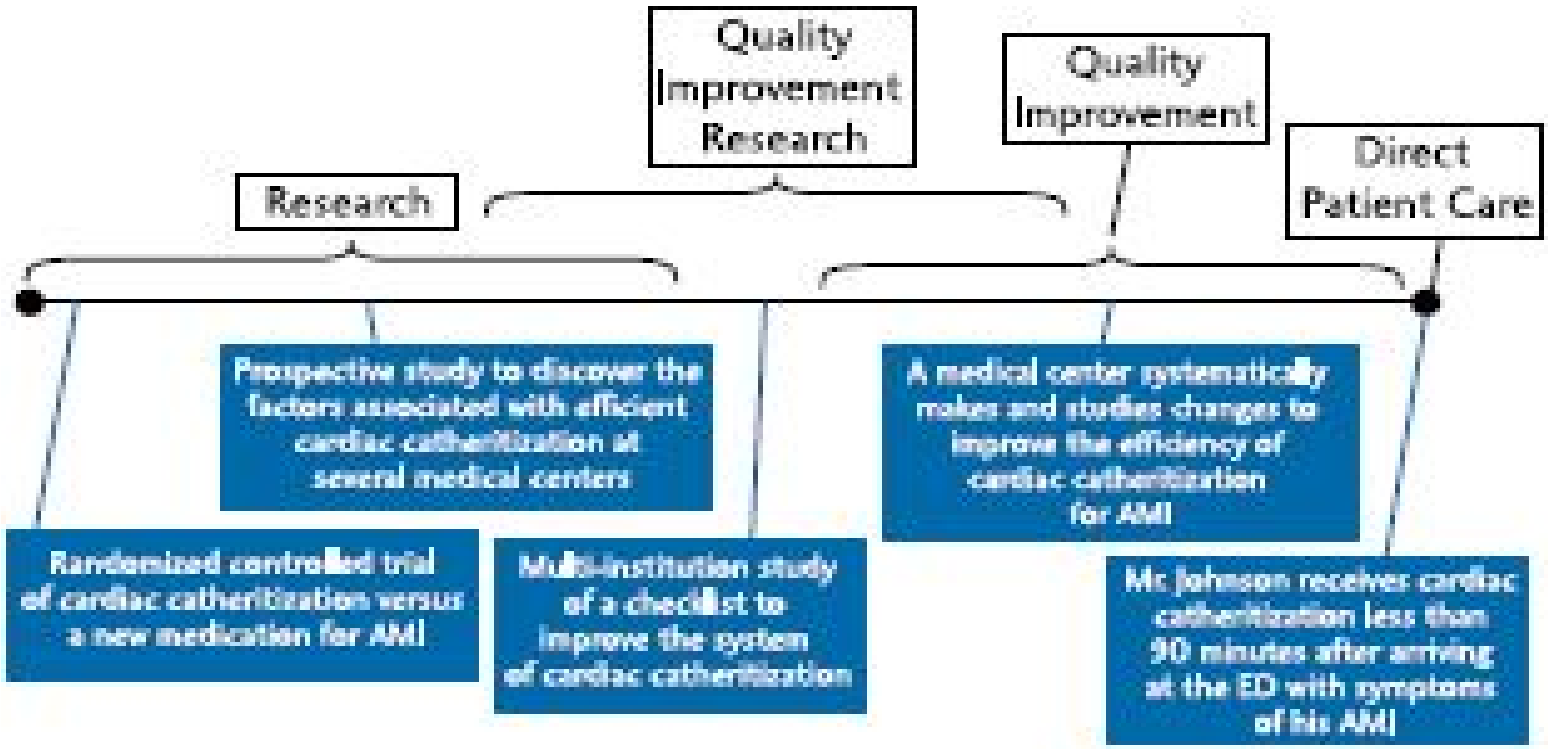
There is increasing recogni- opment, testing and evaluation,

FEATURE ARTICLE

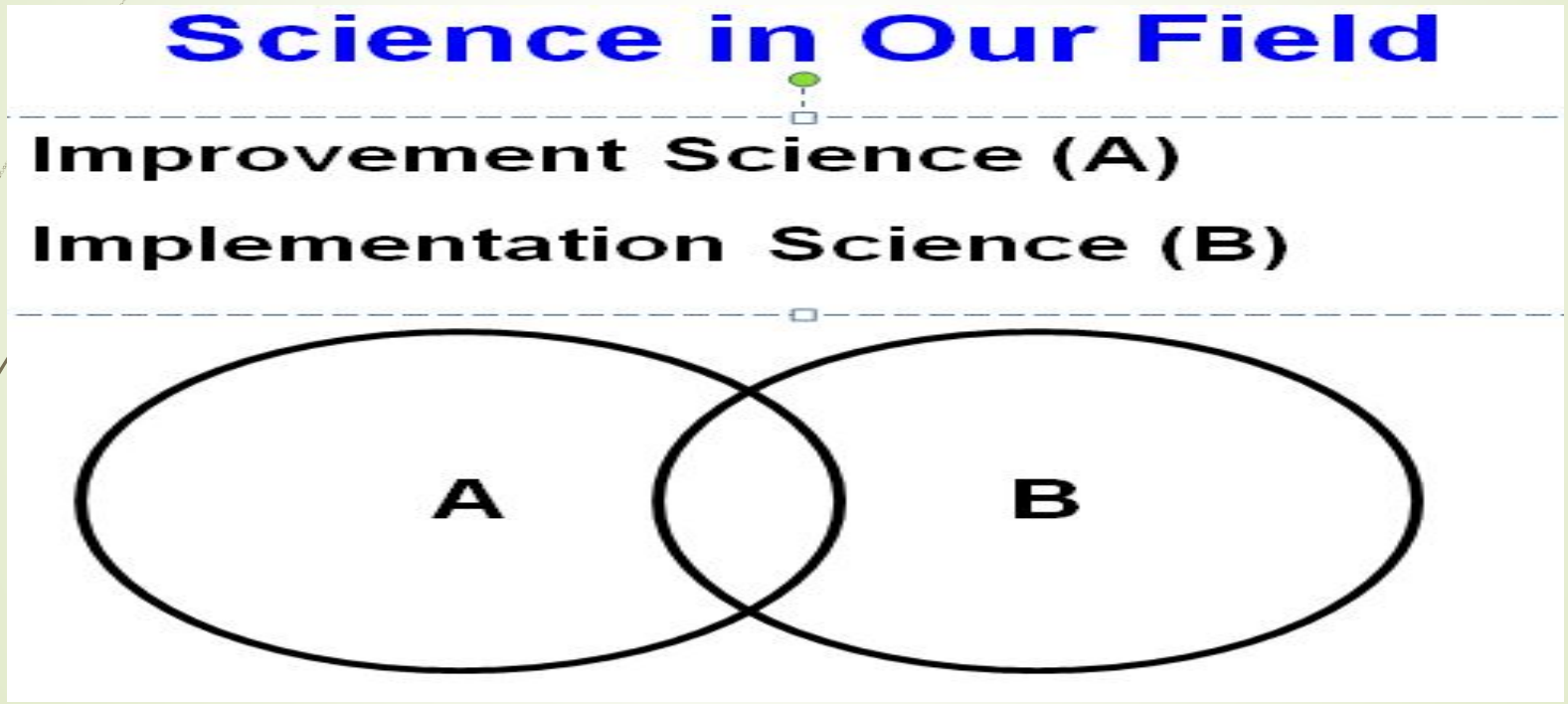
An Instrument to Differentiate between Clinical Research and Quality Improvement

Greg Ogrinc, William A. Nelson, Susan M. Adams, and Ann E. O'Hara 1

Figure 1.
Depiction of the continuum of clinical research, quality improvement, and patient care activities. Examples are provided relating to care, improvement, and research for acute myocardial infarction (AMI).



Topic for Discussion



organizations

IHI.org

organizations

Summary

- What is Quality
- What is QI
- Philosophy, Local application, Science

Questions

The End