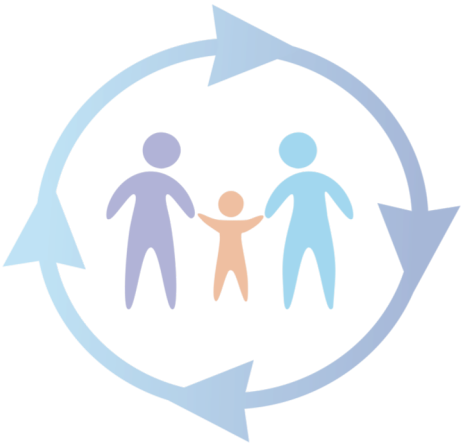
Connecting Improvement Science and Research

Peter Margolis, MD PhD

Learning Session 5
November 18, 2019



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Learning Objectives

1. Define the stages of development for studies of complex interventions
2. Observe the application of an improvement framework to design an improvement initiative
3. Discuss how the frameworks might apply to your own projects

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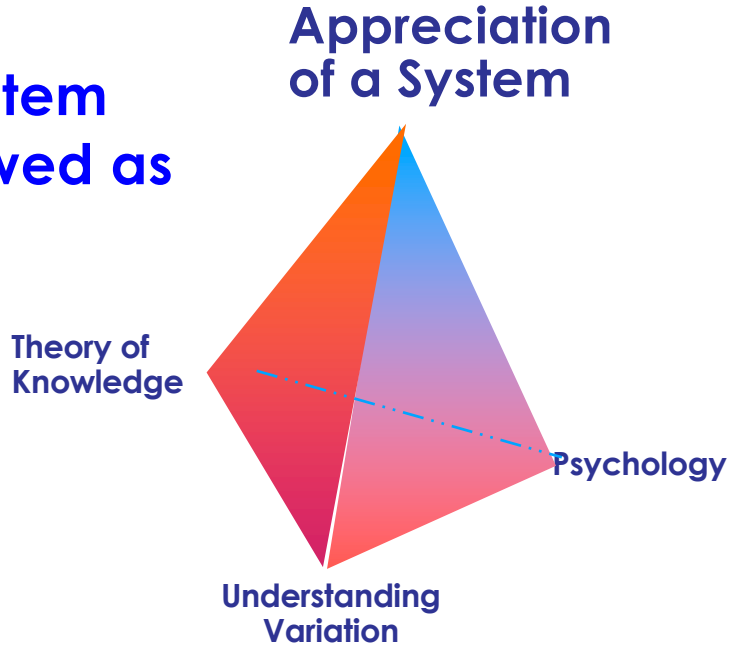
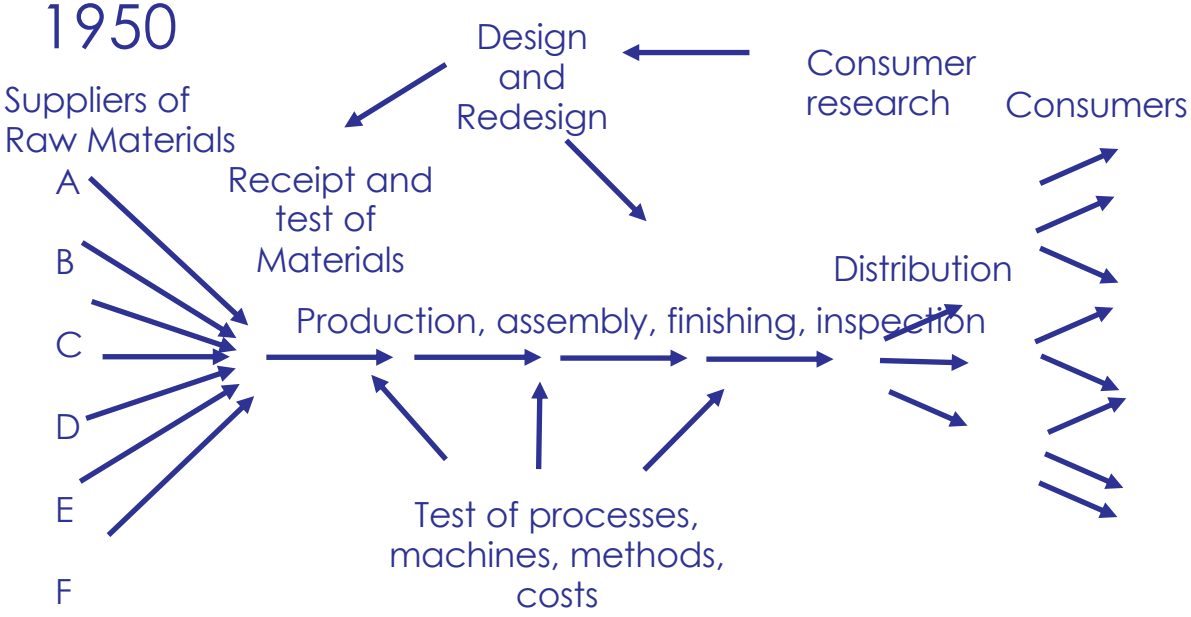
Science of Improvement: Appreciation of a System

The idea of viewing the organization as system derives from Dr. Deming's "Production Viewed as a System"



Deming's Production as a System, 1950



This flow diagram was the spark that turned Japan around in 1950 and onward. It displayed a system of production to top management and to engineers. (Deming, 1993)

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Definitions of a System

"A system is a network of interdependent components that work together to try to accomplish the aim of the system."

W. Edwards Deming, *The New Economics*

"A system is a whole which cannot be divided into independent parts." **Russell Ackoff, *Better Management for a Changing World***

"An interdependent group of items, people, or processes working together toward a common purpose."

Associates in Process Improvement, *Quality as a Business Strategy*, 1987

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Appreciation of a System – Key Ideas for Improvement

We can think of all work as a process.

A system is an interdependent group of items, people, and **processes** with a common aim.

If each part of a system, considered separately, is made to operate as efficiently as possible, then the system as a whole will not operate as effectively as possible.

People are a key part of systems in organizations – they want to do a good job and take pride in their work.

Every system is perfectly designed to achieve exactly the results it gets.

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Definition of Quality Improvement

Where does Quality Improvement connect to a "learning system"?

Systematic data-guided activities designed to bring about immediate positive changes in the delivery of health care in particular settings.

May involve:

1. Practical problem solving
2. Evidence-based management style
3. Application of theory-driven science to bring about system change

The Ethics of Improving Health Care Quality & Safety: A Hastings Center/AHRQ Project, Mary Ann Baily, PhD, Associate for Ethics & Health Policy, The Hastings Center, October, 2004

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Definition of Clinical Research

- Study of a drug, biologic, or device in human subjects
- Encompasses
  - translational research (study of laboratory findings in humans)
  - clinical trials of preventive and therapeutic strategies
  - epidemiology, behavioral research, and health services and outcomes research.
- Results in treatments (and drugs) that directly improve health care.

Harold Varmus, MD
www.najbr.org/public/research_definitions

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How are research and QI alike and different?

Reflect for a few minutes and then share

1. Purpose
2. Changeability of design or protocol
3. Role of context and confounders
4. Unit of analysis
5. Causal model (linear vs. system)
6. Integration into clinical process
7. Role of feasibility/implementation
8. Who benefits?
9. Analytic strategy
10. Funding source
11. Timeframe for reporting results

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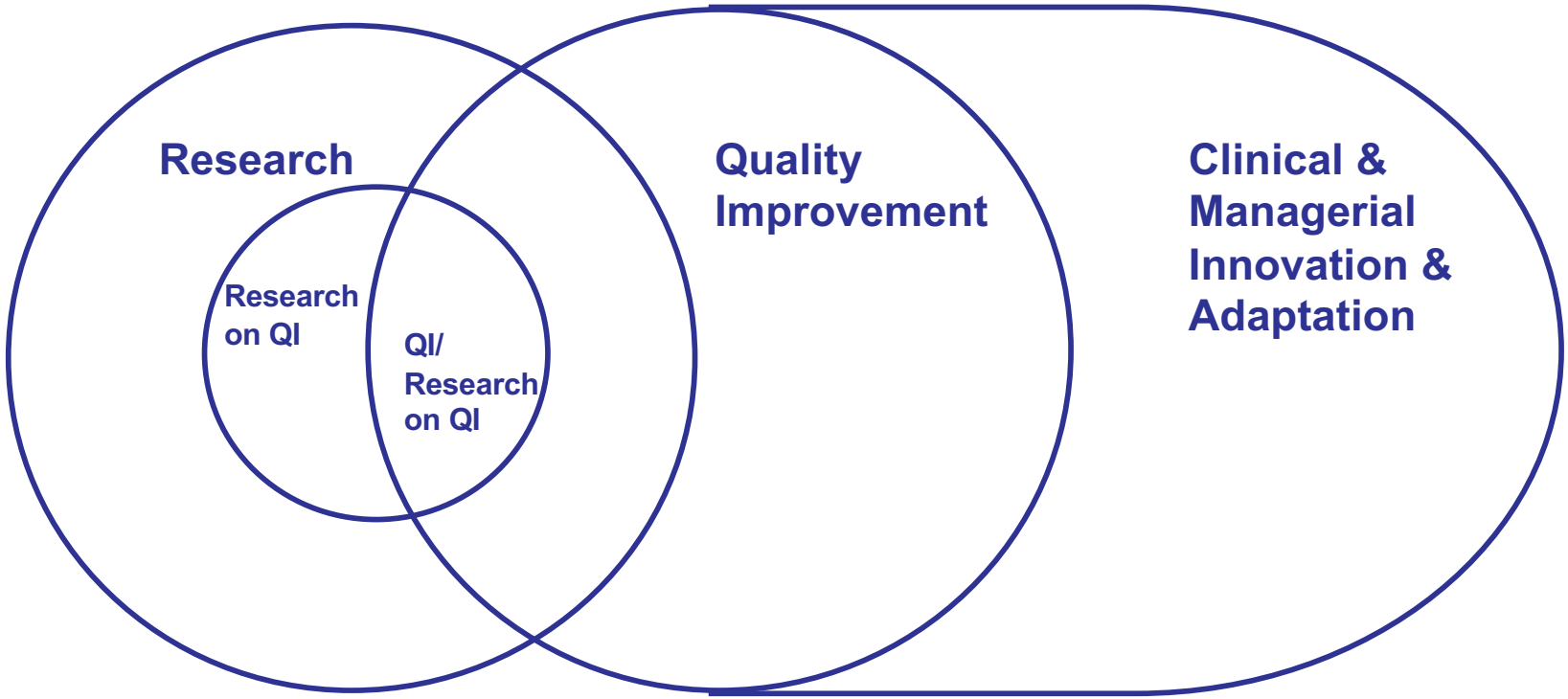
Overlap between Improvement and Research



Adapted from *The Ethics of Using QI Methods to Improve Health Care Quality and Safety. A Hastings Center Special Report.*

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A Definition of Quality Improvement Research

- The *design, development and evaluation* of complex *interventions* aimed at the re-design of health care system to produce improved outcomes

Margolis PA, Provost LP, Schoettker PJ, Britto MT. Pediatr Clin N Am 56 (2009) 831–841 doi:10.1016/j.pcl.2009.05.008

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- The challenge of QI—both intellectual and technical—was that **even if one knows <u>what</u> needs to happen** at the bedside, one does not know, at a system level, **<u>how</u>** to achieve that in a safe, efficient and sustainable way.

- And having **systems** as the unit of intervention, and perhaps analysis, poses immense challenges for both implementation and evaluation.

Steven Goodman
BMJ Qual Saf 2011;20:i97-i98

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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

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Characteristics of Health Care QI

- **Intervention** approach (changes to system)
  - Adapted and modified as study progresses
  - Multiple cycles for quick feedback and learning
  - Contextual factors (confounders) a major focus
- **Measurement** over time
  - Graphical analysis
- **Sustainability** a consideration from beginning
  - Building reliability a major early part of the effort
  - Involvement of local expertise
- **Multi-factor experiments**
  - Learn about complex systems with non-linear and dynamic cause and effect relationships

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Linking clinical epidemiology and quality improvement

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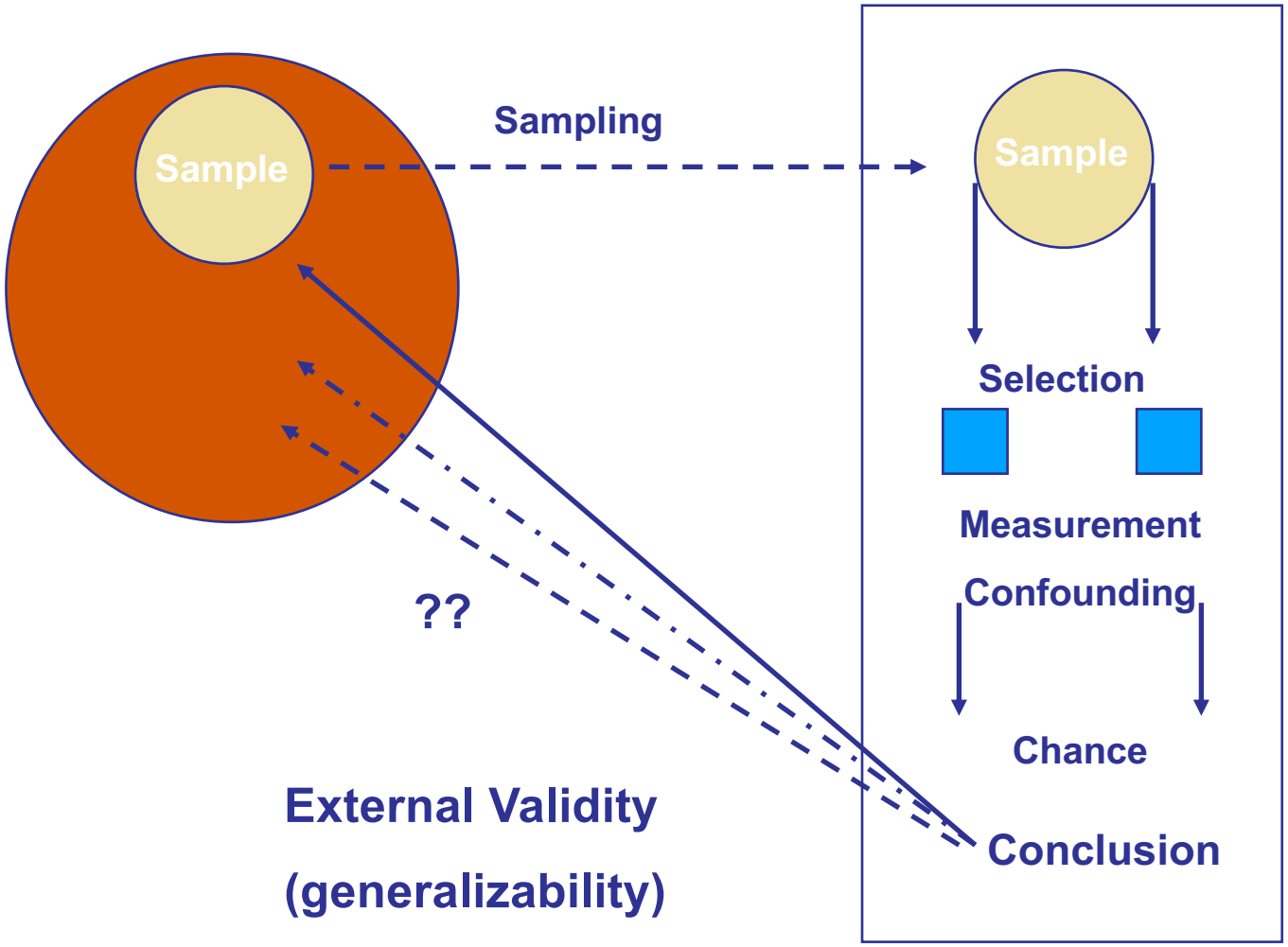
Internal Validity



Clinical epidemiology
Fletcher, Fletcher, Wagner

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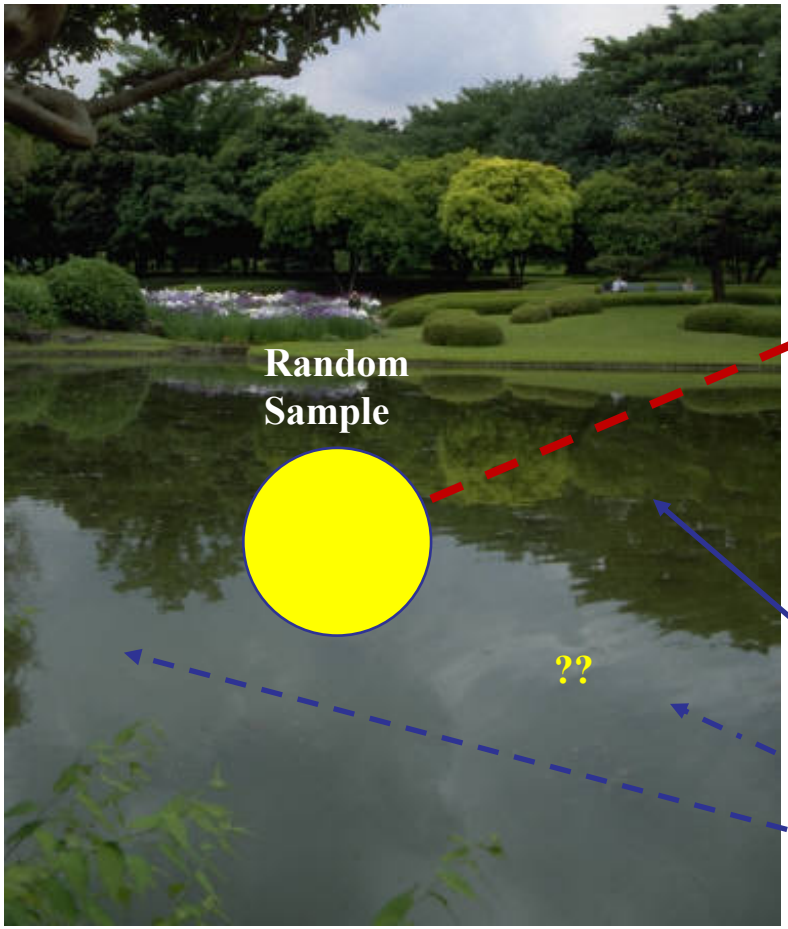
Environment for Observational Study



Internal Validity

Sample

Selection

Measurement

Confounding

Chance

Conclusion

External Validity

(generalizability)

Clinical Epidemiology
Fletcher, Fletcher, Wagner

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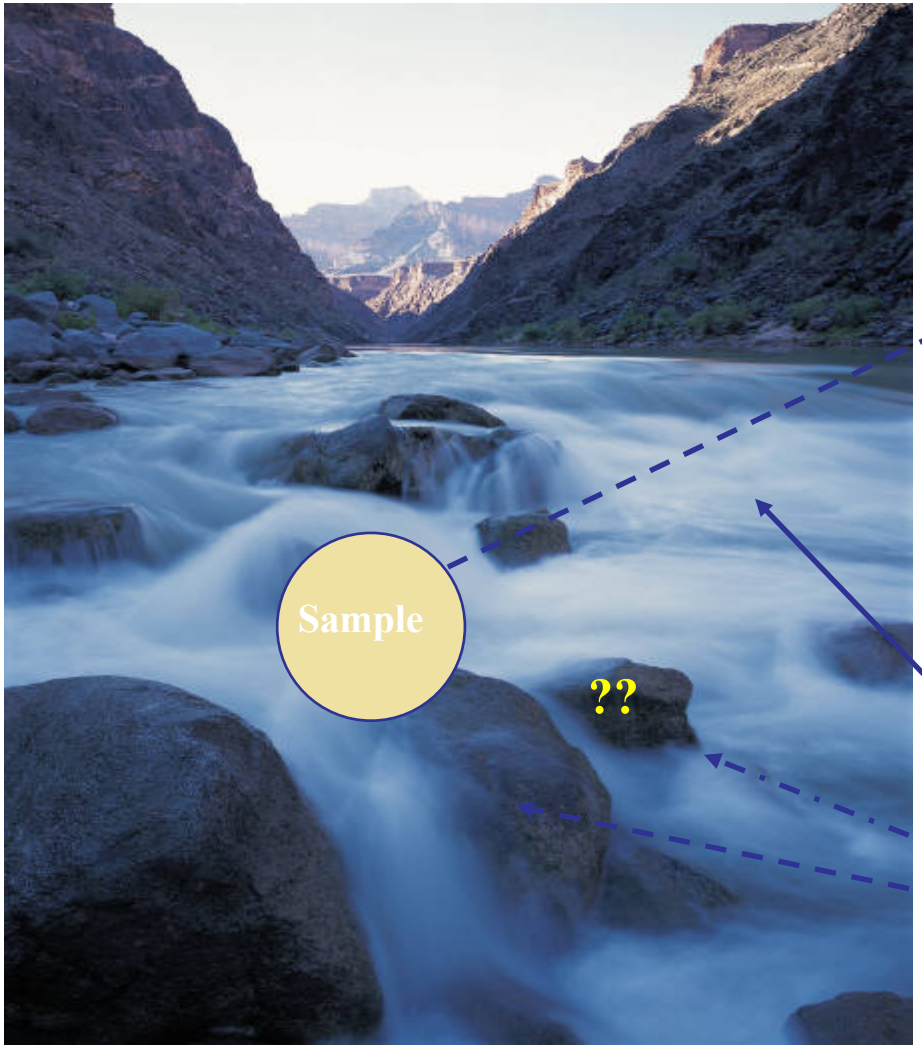
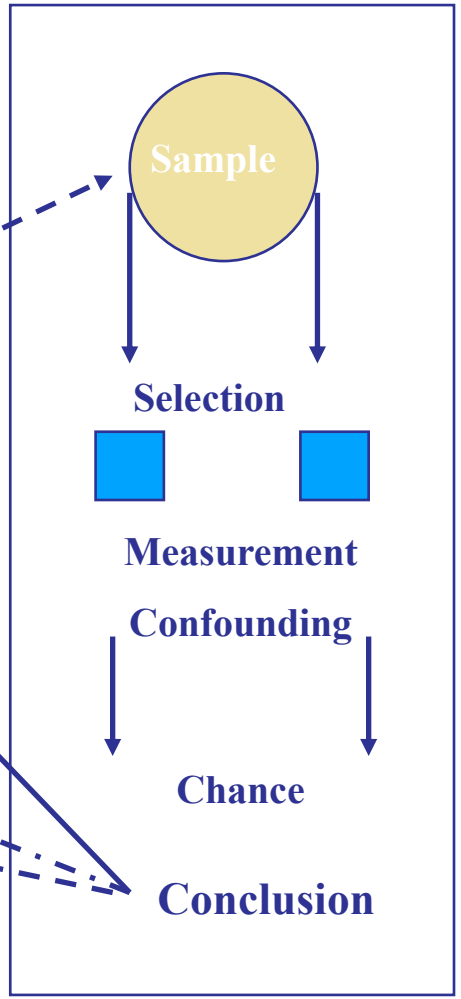
Environment for QI Studies





Clinical epidemiology

Fletcher, Fletcher, Wagner

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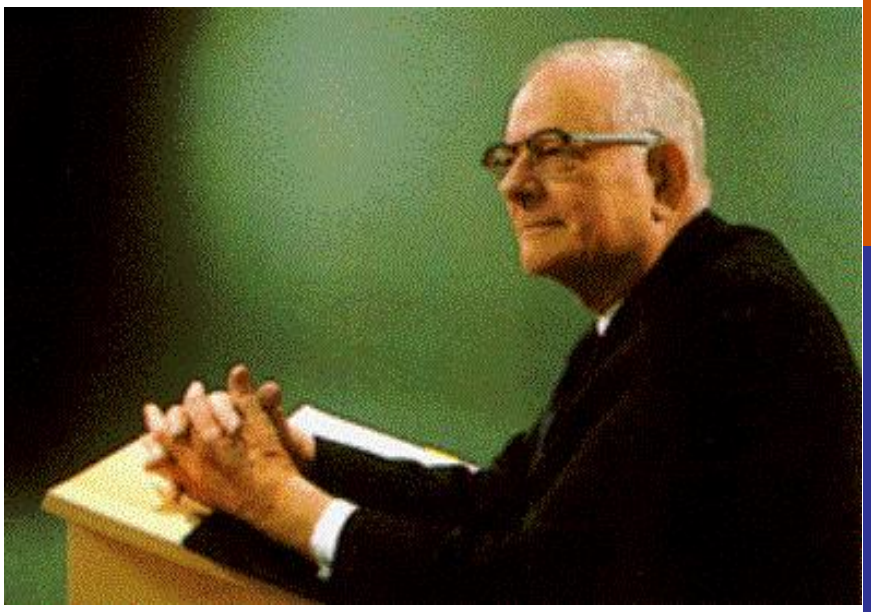
"Prediction is the problem"
– W. Edwards Deming



Gold Standard for Evidence in QI:

"Satisfactory prediction of the results of tests conducted over a wide range of conditions is the means to increase the degree of belief that the change will result in improvement."

The Improvement Guide, 2nd Edition, 2009

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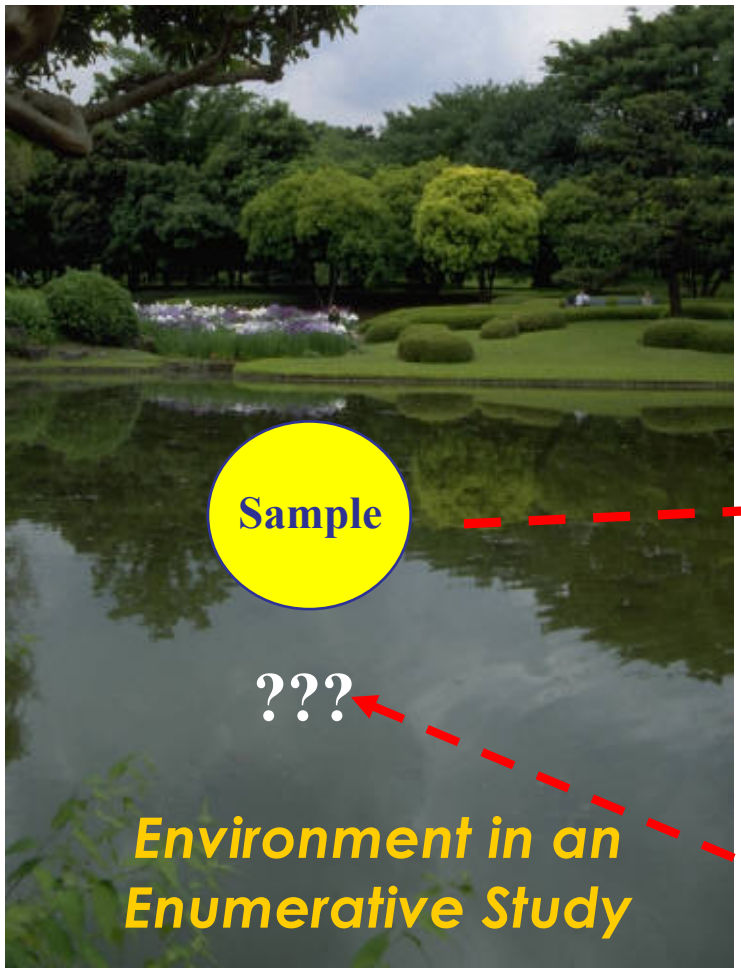
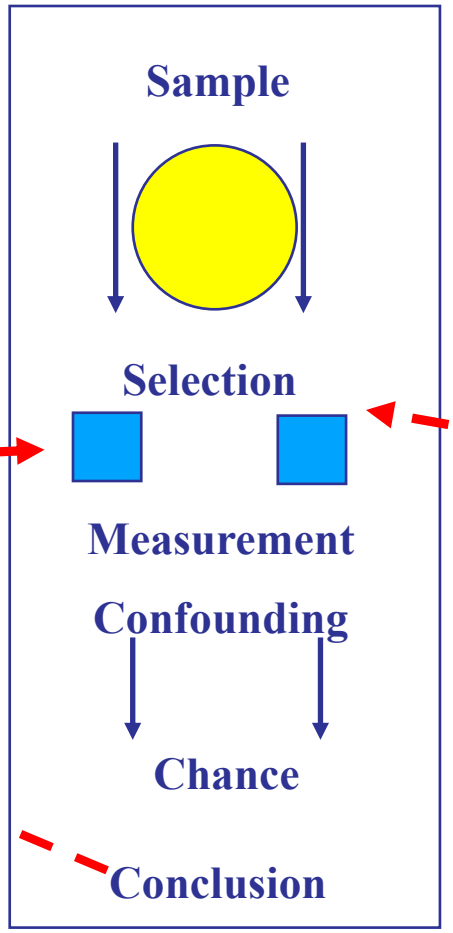
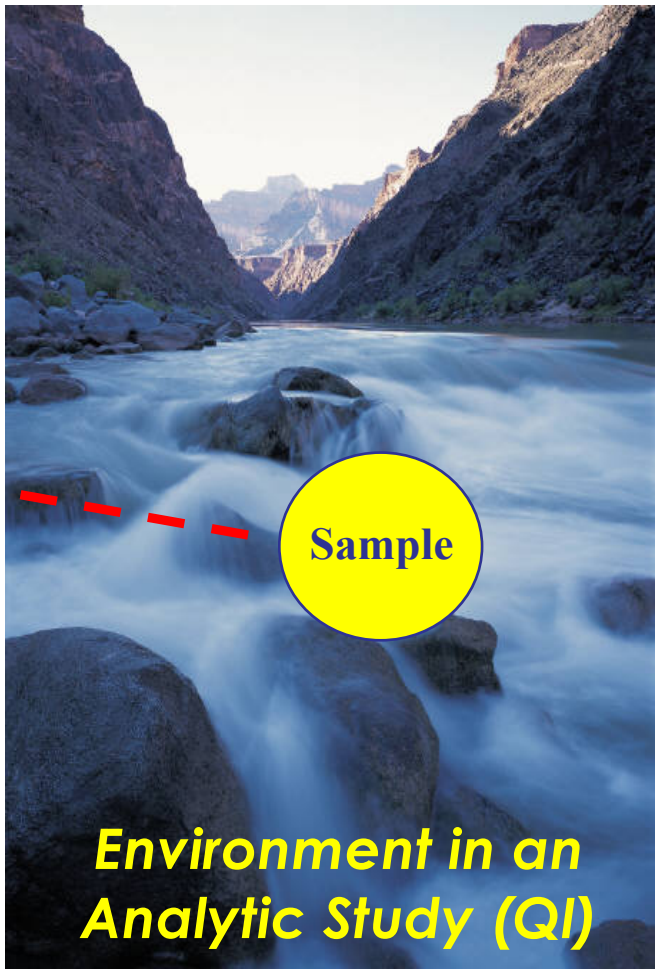
Perspective: Enumerative and Analytic Studies



Internal Validity





External Validity?

Clinical Epidemiology

Fletcher, Fletcher, Wagner

Prediction?

"Analytical studies: a framework for quality improvement design and analysis", L. Provost, *The British Medical Journal Quality and Safety 2011,* 20 (Supplement 1):i92-i96.

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Statistics vs. Experimental Design

"Statistical theory is used to describe the precision of estimates and the validity of hypotheses for the population studied.

Statistical methods provide no support for extrapolation of the results outside the population that was studied.

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):i92ei96. doi:10.1136

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Methods to Support a System of Learning

1. ***Recognition and investigation of special causes*** *using Shewhart charts.*
2. ***Study of informative cases.***
3. ***Observational studies*** *(learning from variation in current practice*
4. ***Natural experiments*** *(with factorial thinking).*
5. ***Planned Experiments*** *including both research projects using RCT's and the use of replication blocking, randomization, and experimental patterns in improvement projects .*

Moen, Nolan, Provost
McGraw-Hill 2013, p. 346-347

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Learning from Special Causes

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

An unexpected increase in catheter-associated bloodstream infections at a children's hospital following introduction of the Spiros closed male connector

Derek S. Wheeler MD [a,b,*], MaryJo Giaccone RN, MSN [c], Nancy Hutchinson RN, MSN, CIC [c], Mary Haygood RN [c], Kathy Demmel RN, MSN [c], Maria T. Britto MD [a,d], Peter A. Margolis MD [a,d], Lloyd P. Provost MS [e]

[a] James M. Anderson Center for Health Systems Excellence, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
[b] Division of Critical Care Medicine, Cincinnati Children's Hospital Medical Center, Department of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
[c] Department of Patient Services, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
[d] Division of Health Policy and Clinical Effectiveness, Cincinnati Children's Hospital Medical Center, Department of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
[e] Associates in Process Improvement, Austin, TX

Conclusion: *This case study highlights the utility of statistical process control in the surveillance and investigation of CA-BSI.*

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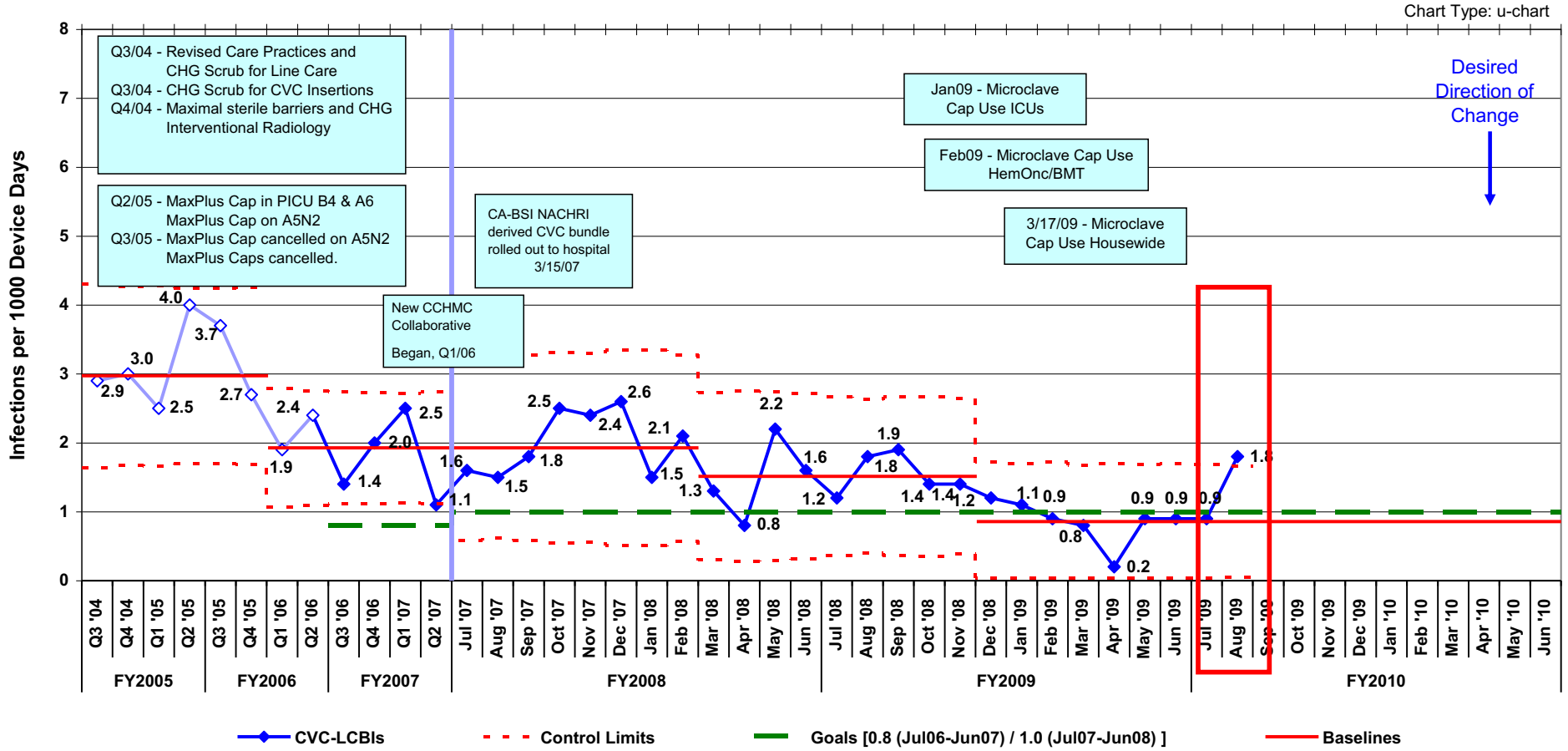
LCBI's: A Special Cause in August

Cincinnati Children's Hospital Medical Center

CCHMC Central Venous Catheter (CVC) Associated Laboratory Confirmed Bloodstream Infections (LCBIs)

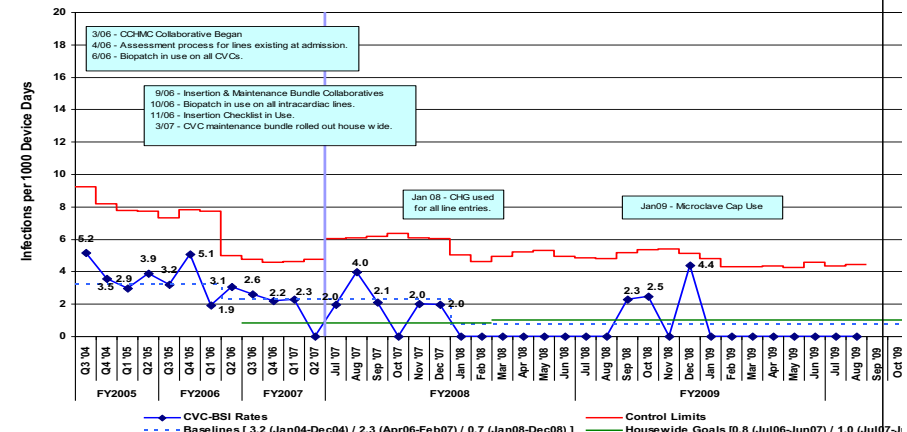


	Q3 '04	Q4 '04	Q1 '05	Q2 '05	Q3 '05	Q4 '05	Q1 '06	Q2 '06	Q3 '06	Q4 '06	Q1 '07	Q2 '07	Jul '07	Aug '07	Sep '07	Oct '07	Nov '07	Dec '07	Jan '08	Feb '08	Mar '08	Apr '08	May '08	Jun '08	Jul '08	Aug '08	Sep '08	Oct '08	Nov '08	Dec '08	Jan '09	Feb '09	Mar '09	Apr '09	May '09	Jun '09	Jul '09	Aug '09	Sep '09	Oct '09	Nov '09	Dec '09	Jan '10	Feb '10	Mar '10	Apr '10	May '10	Jun '10
Infections	24	26	21	36	34	24	18	24	15	21	27	12	6	6	7	9	9	9	5	8	5	3	8	6	5	8	8	6	6	5	5	4	4	1	4	4	4	9									
Device Days	8340	8741	8546	9034	9080	8890	9324	10054	10450	10667	11007	10491	3861	4094	3827	3625	3706	3434	3439	3790	3757	3651	3705	3840	4180	4484	4177	4159	4353	4306	4545	4326	4834	4476	4595	4483	4620	4874									

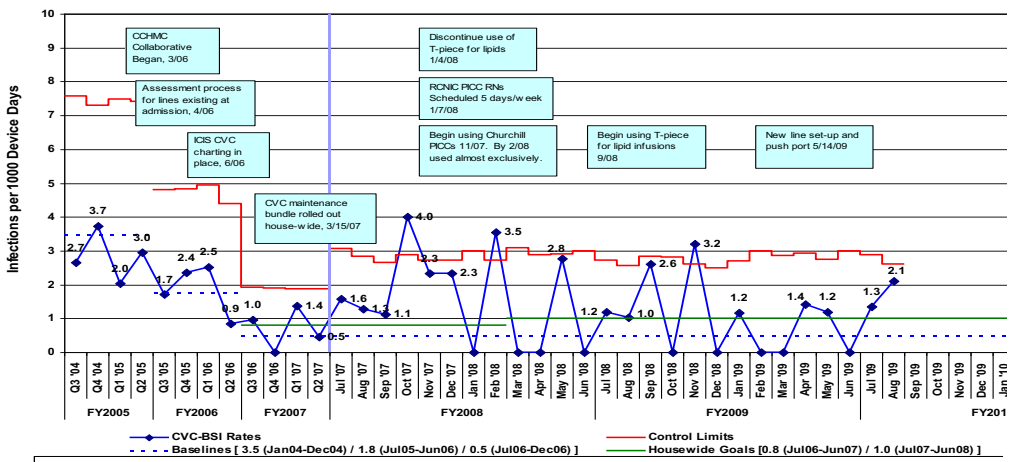
Updated Thru 31Aug09 by Art Wheeler, Legal/HPCE Depts.

Source: Infection Control Dept.

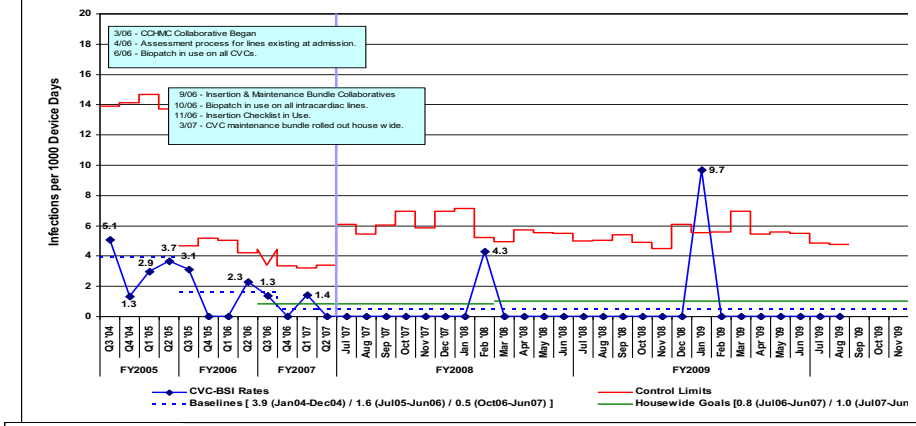
B5CC CENTRAL VENOUS CATHETER BLOODSTREAM INFECTIONS



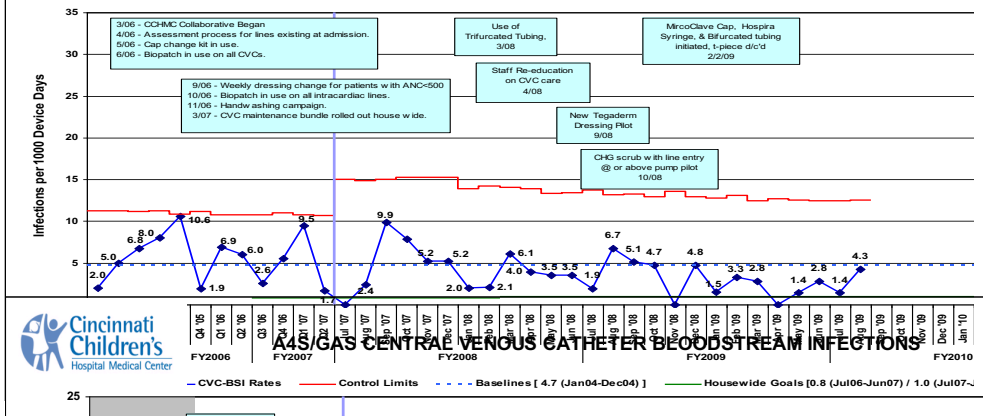
B4/RCNIC CENTRAL VENOUS CATHETER BLOODSTREAM INFECTIONS



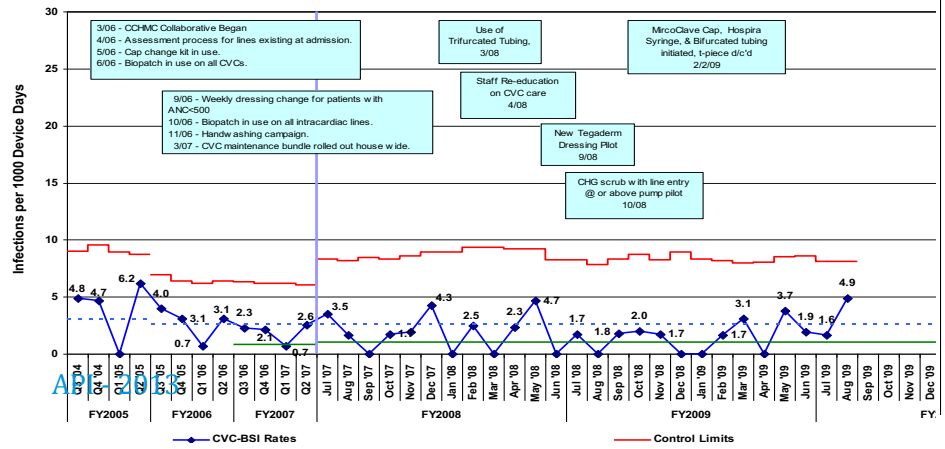
B6HI CENTRAL VENOUS CATHETER BLOODSTREAM INFECTIONS



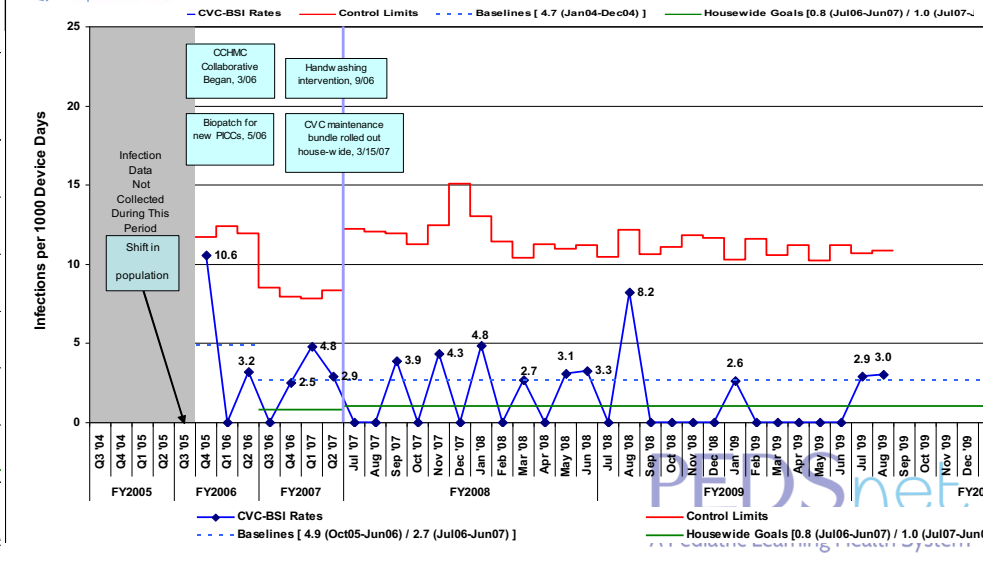
A5N CENTRAL VENOUS CATHETER BLOODSTREAM INFECTIONS



A5S CENTRAL VENOUS CATHETER BLOODSTREAM INFECTIONS



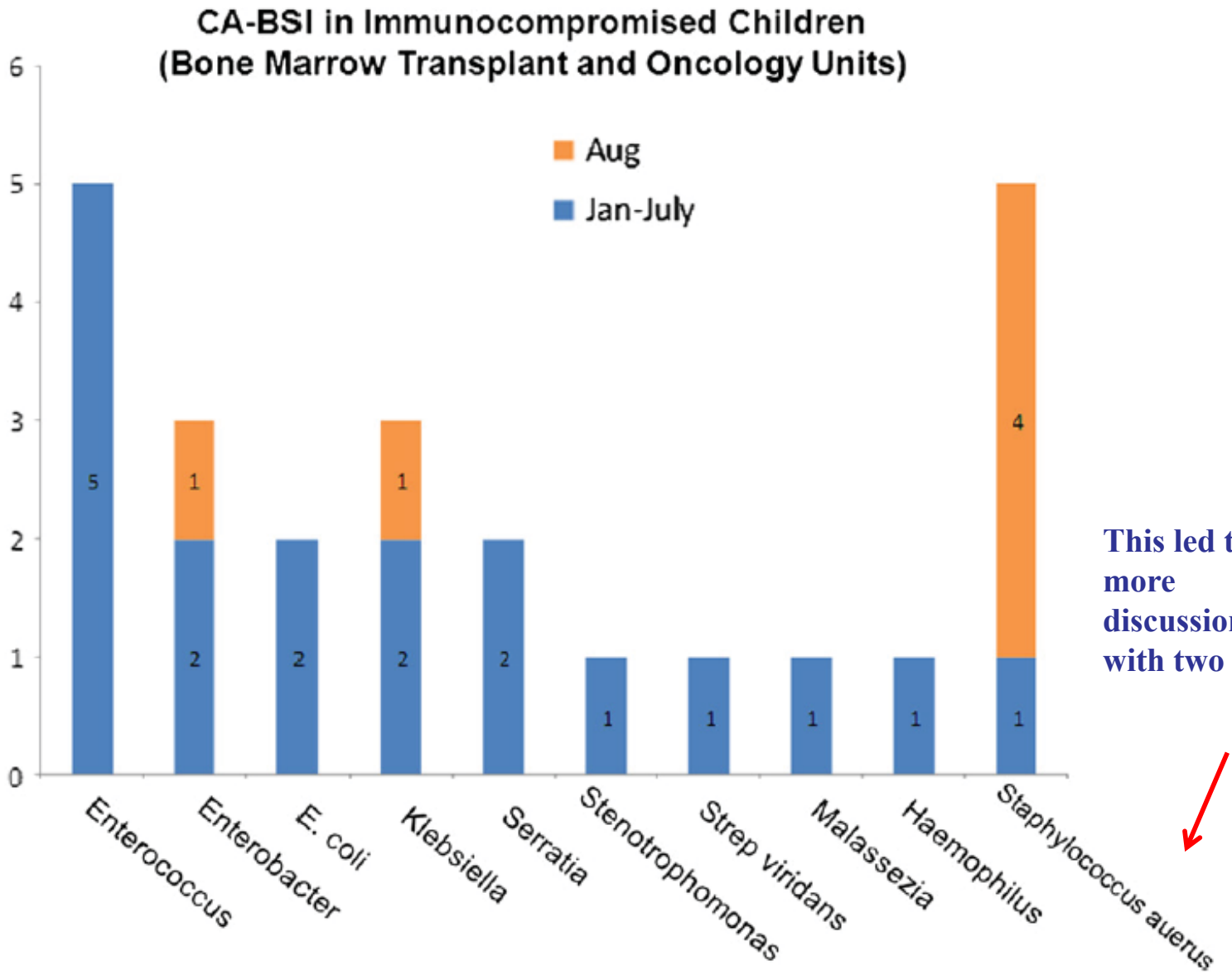
A4S/GAS CENTRAL VENOUS CATHETER BLOODSTREAM INFECTIONS



APIC 2013

Pareto Chart of Isolated Pathogen

Stratified by Common Cause and Special Cause Periods



This led to more discussions with two units

Eureka!

Pharmacy-initiated product testing trial

- initiated 8/1/2009
- discontinued 9/2/2009 due to "leaking"

We discovered that the Spiros Closed Male Connector had been introduced in these two units around the same time as the special cause signal

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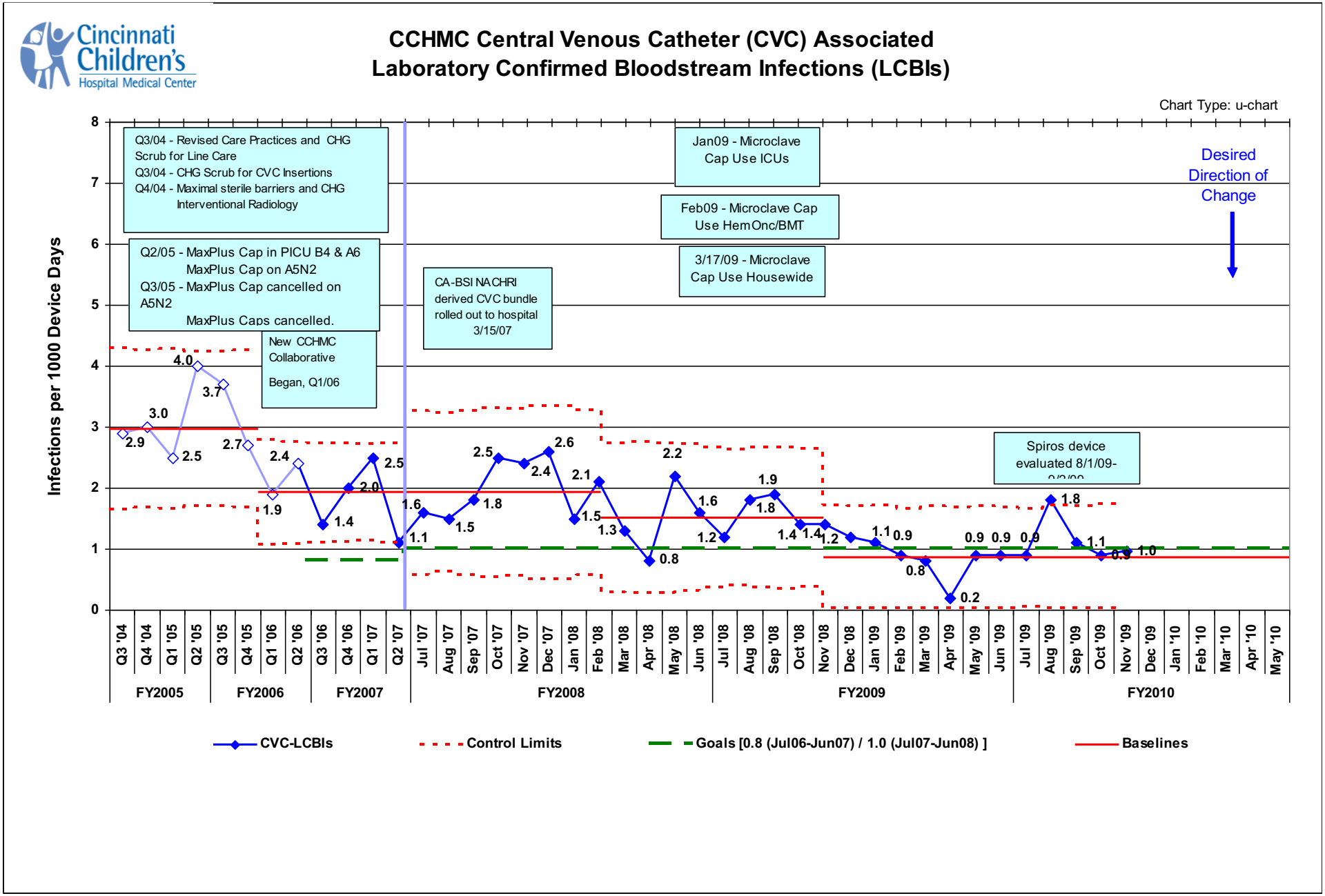
Cincinnati Children's Hospital Medical Center
CCHMC Central Venous Catheter (CVC) Associated Laboratory Confirmed Bloodstream Infections (LCBIs)
Chart Type: u-chart
Infections per 1000 Device Days
Q3/04 - Revised Care Practices and CHG Scrub for Line Care
Q3/04 - CHG Scrub for CVC Insertions
Q4/04 - Maximal sterile barriers and CHG Interventional Radiology
Q2/05 - MaxPlus Cap in PICU B4 & A6
MaxPlus Cap on A5N2
Q3/05 - MaxPlus Cap cancelled on A5N2
MaxPlus Caps cancelled.
New CCHMC Collaborative
Began, Q1/06
CA-BSI NACHRI derived CVC bundle rolled out to hospital 3/15/07
Jan09 - Microclave Cap Use ICUs
Feb09 - Microclave Cap Use HemOnc/BMT
3/17/09 - Microclave Cap Use Housewide
Desired Direction of Change
Spiros device evaluated 8/1/09-
FY2005
FY2006
FY2007
FY2008
FY2009
FY2010
CVC-LCBIs
Control Limits
Goals [0.8 (Jul06-Jun07) / 1.0 (Jul07-Jun08)]
Baselines

QI Studies Emphasize Graphical Analysis

- Systems change over time
- Graphical analysis reveals trajectory
- Makes it possible to predict future performance

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Sterman – Complex Systems

A **complex system** is any **system**

- featuring a large number of interacting components (agents, processes, etc.)
- whose aggregate activity is nonlinear (not derivable from the summations of the activity of individual component)
-
- and typically exhibits hierarchical self-organization under selective pressures.

1. Constantly changing.
2. Tightly coupled.
3. Governed by **feedback.**
4. Nonlinear.
5. History-dependent.
6. Self-organizing.
7. Adaptive and evolving.
8. Characterized by trade-offs.
9. **Time delays** in feedback channels
10. Counterintuitive.
11. Policy resistant.

Business Dynamics: Systems Thinking and Modeling for a Complex World, John D. Sterman, McGraw Hill, 2000

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Why are complex systems hard to improve?

Delayed response

Significant challenges for learning exist because the temporal spread between making a change and observing its effect is substantial or because the complexity of the system makes it difficult to predict all the consequences of a change.

Integration/Coordination/Synchronization

Systems that are to be improved reach across multiple organizational boundaries and the system's components are separated by time or space such that changes to the system are usually large in scope and often must be phased in.

Behavior change

The behavior of a large number of individuals working or living in different circumstances must be changed.

Disruption

A new technology, market forces, or other circumstances negate existing business models or other aspects of the status quo and require the design of a new system on a large scale with accompanying transition issues.

***The Improvement Guide, 2nd Edition*, Chapter 11: Improving Large or Complex Systems**

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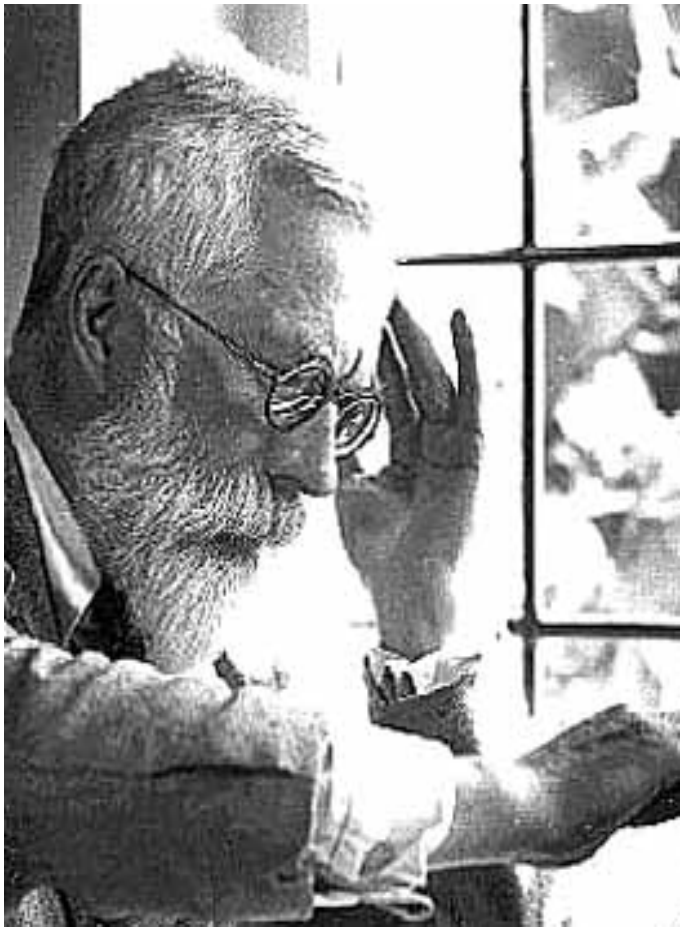
How to design the right study?



Sir Ronald A. Fisher 1890-1962

Principles

- Well defined objective
- Sequential experiments
- Partitioning variation
- Degree of belief
- Simplicity of execution

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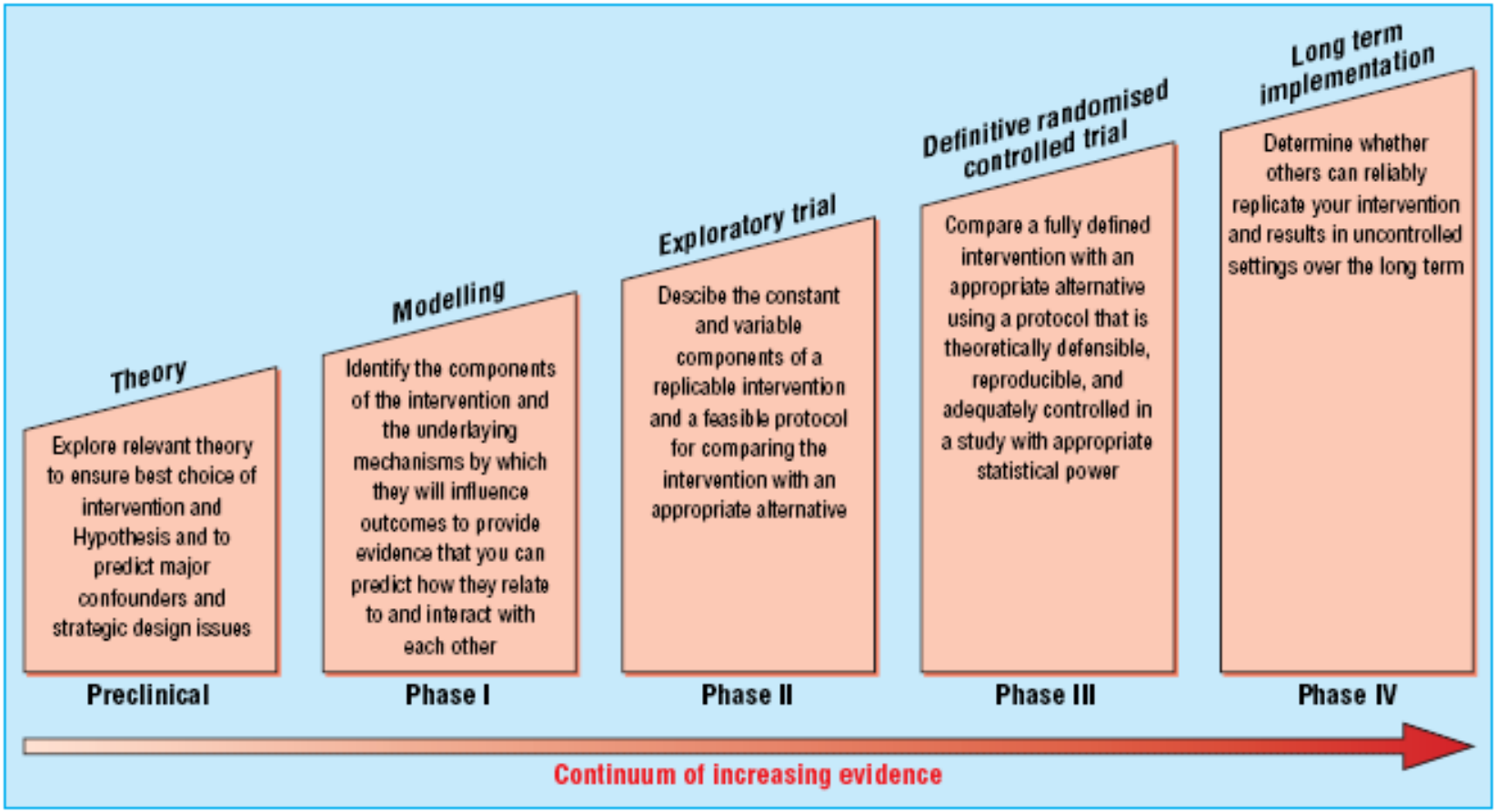

Fig 1 Sequential phases of developing randomised controlled trials of complex interventions

MRC Biostatistics Unit, Institute of Public Health, Cambridge CB2 2SR

David Spiegelhalter
senior scientist

Department of Public Mental Health, Imperial College of Science, Technology, and Medicine, St Mary's Campus, London W2 1PD

Peter Tyrer
professor of community psychiatry

Correspondence to:
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raymond.fitzpatrick@nuffield.ox.ac.uk

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Critiques of Campbell Model

- Based on phases used in evaluation of drugs
- Linearity implied by diagram
- Limited guidance on how to approach developmental and implementation studies
- Assumption that clinical trials provide template for evaluation
- Lack of guidance on how to tackle complex or non-health sector interventions
- Lack of attention to context

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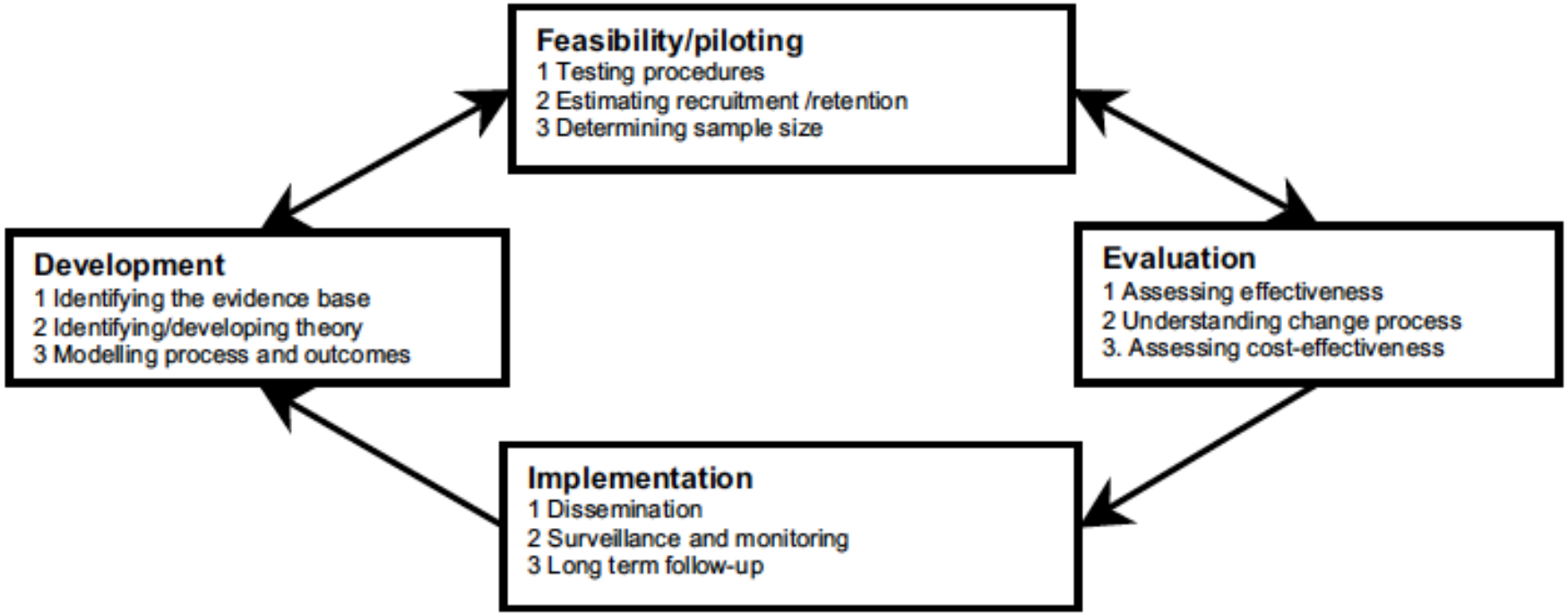
Revised Model

Figure 1 Key elements of the development and evaluation process



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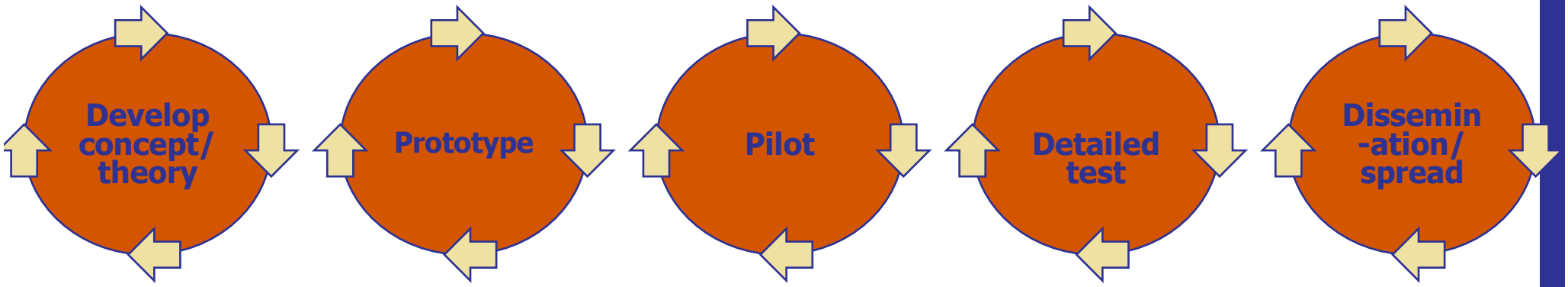
Trajectory of research



Framework for design and evaluation of complex interventions to improve health
Campbell M et al. BMJ 2000;321:694–6

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Bradford Hill's Attributes for Establishing Causation

1. *Strength of association*
2. *Consistency*
3. *Specificity*
4. *The relationship in time*
5. *The biological gradient or dose response curve*
6. *Biological plausibility*
7. *Coherence of the evidence*
8. *The experiment*
9. *Reasoning by analogy*

None of these attributes assures a cause and effect relationship by itself, but ***taken together or in subsets***, application of them can build degree of belief in the theory of cause and effect that is being claimed.

Why aren't more investigators doing this work?

- Unit of analysis is the clinical site
  - Need lots of sites
- Limited numbers of patient outcomes at any one site
- Reward system unfavorable
- Requires management across stages of research
  - Current academic research models often "ad hoc."
- Need for clinical "laboratories" where care can be re-designed
- Lack of clarity about research stages impedes publication

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Summary

- Data analysis and statistical testing do not address important sources of uncertainty
- Statistical process control methods well suited for complex systems and learning in real time
- Experimental design enables exploration of mechanisms
  - multifactor designs, contextual variables introduced through blocking and replication.
- Science of QI evolving rapidly with many methods issues
  - context, unit of analysis, ethics