Building a Learning Health Care System

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Best Care at Lower Cost: The Path to Continuously Learning Health Care in America

Under the guidance of its membership, the Roundtable has developed and articulated a vision of this new system—a learning health care system that links personal and population data to researchers and practitioners, dramatically enhancing the knowledge base on effectiveness of interventions and providing real-time guidance for superior care in treating and preventing illness. A health care system that gains from continuous learning is a system that can provide Americans with superior care at lower cost.
PREFACE

Developing a continuously learning health care system is critical for the future of health care, as well as for the future physical and financial health of the nation.

There is no simple path forward; rather, actions need to be taken by every stakeholder if this vision is to become a reality.

Such concerted action will enable the nation’s health care system to evolve to one that continuously learns and improves, finally providing Americans with best care at lower cost.

Mark D. Smith, Chair

Committee on the Learning Health Care System in America
Exercise – Work in Pairs

1. Describe an important “learning” in your healthcare system that occurred in the past year. Something that has made a difference in your performance or the health of your patients.

2. What was the “method” that generated the knowledge in your learning? What was the catalyst that enabled your learning?

3. How strong is the “evidence” about what you learned? (1=very strong to 5=weak)
<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
<th>Other Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
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<tr>
<td>Testing</td>
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<tr>
<td>Evaluation</td>
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<tr>
<td>Time Series (SPC)</td>
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<tr>
<td>Mixed-Method</td>
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<td>Comparative Study</td>
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<td>Effectiveness Study</td>
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<tr>
<td>Other</td>
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</tbody>
</table>
Abstract Keywords: Approaches and Methods for Learning

Implementation
Innovation
Evaluation
Testing
Effectiveness Study
Analytic Study
Method development
Time-series
Statistical Process Control
Measurement Development
Comparative Study
Mixed-Method
Scale-up and Spread
Qualitative
Other

Topics for Abstracts
Presented at 2013 Scientific Symposium (this morning)
Components of a Learning Health Care System

1. Clarity of your HC system (purpose and structure)
2. System level measures (focus on prediction)
3. Explicit theory or rationale for system changes (prediction)
4. Appropriate segmentation of your patients
5. Sequential learning methods (for dynamic systems)
6. Multiple feedback loops and regularly scheduled learning events
7. Leadership to keep the organization focused on learning

Adapted from API, Tom Nolan, PhD
Translational Research


Where does Quality Improvement connect to a “learning system”?

Health Care Quality Improvement:

“A broad range of activities of varying degrees of complexity and methodological and statistical rigor through which health care providers develop, implement, and assess small-scale interventions and identify those that work well and implement them more broadly in order to improve clinical practice.”

* 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, Garrison, New York, October, 2004
Where does Quality Improvement connect to a “learning system”? 

Model for Improvement

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

Sequential Learning through PDSA Cycles

Hunches
Theories
Ideas

Very Small Scale Test

Follow-up Tests

Wide-Scale Tests of Change

Implementation of Change

Changes That Result in Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

Very Small Scale Test

Follow-up Tests

Wide-Scale Tests of Change

Implementation of Change

Changes That Result in Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?
Evaluating Quality of Evidence in Medicine

I. At least one systematic review of multiple well-designed Randomized Control Trials (RCT)

II. At least one properly designed RCT of appropriate size

III. Well-designed trials without randomization (single group, time series or matched case-control studies)

IV. Well-designed non-experimental, based on clinical evidence, descriptive studies or reports of expert committees

V. Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees

Randomized Clinical Trial ("Gold Standard")

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

*Clinical epidemiology*, Fletcher, Fletcher, Wagner

The randomized controlled trial: gold standard, or merely standard?  

The randomized controlled trial (RCT) is not a gold standard: it is a good experimental design in some circumstances, but that's all. Potential shortcomings in the design and implementation of RCTs are often mentioned in passing, yet most researchers consider that RCTs are always superior to all other types of evidence. This paper examines the limitations of RCTs and shows that some types of evidence commonly supposed to be inferior to all RCTs are actually superior to many.
Perspective: Enumerative and Analytic Studies

External Validity?

Environment in an Enumerative Study

Internal Validity

Sample

Selection

Measurement

Confounding

Chance

Conclusion

Clinical Epidemiology

Fletcher, Fletcher, Wagner

Prediction?

Environment in an Analytic Study (QI)

“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.”

A common view of evidence

Results from Quality Improvement Studies???

Formal Evaluative Designs
RCT’s
“Rigorous”

Informal Narrative Study Stories and Anecdote
“Non-Rigorous”

Adapted from Donald M. Berwick, MD, MPP – *Eating Soup with a Fork*, IHI Forum, 2008
Another Possibility

“Rigorous” Learning

Fisher’s RCT’s

Linear Cause-and-Effect Relationships

Learning from Experience e.g. Halsted’s Conclusions

Poor Learning

Use RCT’s to study interventions to Healthcare Systems e.g. RCT’s to Study Rapid Response Teams

Complex Non-Linear Chaotic Systems

“Rigorous” Learning

Fisher’s RCT’s

Linear Cause-and-Effect Relationships

Learning from Experience e.g. Halsted’s Conclusions

Poor Learning

Use RCT’s to study interventions to Healthcare Systems e.g. RCT’s to Study Rapid Response Teams

Complex Non-Linear Chaotic Systems

Adapted from Donald M. Berwick, MD, MPP – *Eating Soup with a Fork*, IHI Forum, 2008
Another Possibility

“What Methods of Learning Go Here?”

- Linear Cause-and-Effect Relationships
- Poor Learning
- “Rigorous” Learning
- Complex Non-Linear Chaotic Systems
- Learning from Experience
- Fisher’s RCT’s
- RCTs to Study Health Care Systems

Adapted from Donald M. Berwick, MD, MPP – *Eating Soup with a Fork*, IHI Forum, 2008
Learning and Evidence

We need evidence... We can’t allow subjective hopes, wishes, and dreams to pretend to be truth when unforgiving nature is at work, or we will... do harm.

But the harm is equal if we treat a very complex world as if it were simple, if we treat each other as less than whole people and complex systems as simple and separate from us, and thereby reduce our capacity to learn, to converse, to explore, and to grow.”

Donald M. Berwick, MD, MPP – *Eating Soup with a Fork*
Even those who would like to see more RCTs conducted in QI (myself included) recognise the need for well-executed and well-reported improvement work using non-randomised designs. ..... 

.....Yet, RCTs still have an important role in the evaluation of complex interventions, especially when we want to advocate for their widespread implementation (eg, as with surgical checklists, medication reconciliation and rapid response teams, to name just a few examples). Without an RCT, we can have no idea what effects the intervention has in a range of institutions.
Box 1. Hierarchy of Study Designs for Intended Effects of Therapy
1. Randomised controlled trials
2. Prospective follow-up studies
3. Retrospective follow-up studies
4. Case-control studies
5. Anecdotal: case report and series

Box 2. Hierarchy of Study Designs for Discovery and Explanation
1. Anecdotal: case reports and series, findings in data, literature
2. Case-control studies
3. Retrospective follow-up studies
4. Prospective follow-up studies
5. Randomised controlled trials
The purpose of this article is to advocate for the use of quasi-experimental strategies to improve the scientific foundation of PDSA quality improvement in health care (p. 20)

*PDSA quality improvement is defined when data are collected to demonstrate that change by intervention resulted in improvement* (p. 21)
“For us, the experimental paradigm constitutes a heroic failure, promising so much and yet ending up in ironic anticlimax. The underlying logic...seems meticulous, clear-headed, and militarily precise, and yet findings seem to emerge in a typically non-cumulative, low-impact, prone-to-equivocation sort of way.” – Pawson & Tilley

Context + New Mechanism = Outcome

\[ C + M = O \]
Five Methods to Support a System of Learning for Health Care

1. **Recognition and investigation of special causes** using Shewhart charts.

2. **Study of informative cases.**

3. **Observational studies** of relationships between factors and responses.

4. **Natural experiments** (with factorial thinking).

5. **Planned Experiments** including the use of replication blocking, randomization, and experimental patterns.

Moen, Nolan, Provost
McGraw-Hill 2013, p. 346-347
Active and Passive Learning

Active

Category 1

Category 2

Effect

Passive

Category 3

Category 4

Causes

API - 2013
Method 1. Learning from Special Causes

Recognition and investigation of special causes using Shewhart charts.

What happened here?
Shewhart’s Theory of Variation (1931)

**Common Causes**—those causes inherent in the system over time, affect everyone working in the system, and affect all outcomes of the system

- Common cause of variation
- Chance cause
- **Stable process**
- Process in statistical control

**Special Causes**—those causes *not* part of the system all the time or do not affect everyone, but arise because of specific circumstances

- Special cause of variation
- Assignable cause
- **Unstable process**
- Process not in statistical control
The Shewhart chart is a statistical tool used to distinguish between variation in a measure due to common causes and variation due to special causes.

*Most common name is a control chart, more descriptive would be learning charts or system performance charts*

Provost & Murray, Jossey-Bass p. 113
Conclusion: This case study highlights the utility of statistical process control in the surveillance and investigation of CA-BSI.
LCBI’s: A Special Cause in August

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

- **Q3/04**: Revised Care Practices and CHG Scrub for Line Care
- **Q4/04**: CHG Scrub for CVC Insertions
- **Q4/04**: Maximal sterile barriers and CHG Interventional Radiology
- **Q2/05**: MaxPlus Cap in PICU B4 & A6
- **Q3/05**: MaxPlus Cap on A5N2
- **Q3/05**: MaxPlus Cap cancelled on A5N2
- **New CCHMC Collaborative Began, Q1/06**

CA-BSI NACHRI derived CVC bundle rolled out to hospital 3/15/07

**Desired Direction of Change**

- **Jan09**: Microclave Cap Use ICUs
- **Feb09**: Microclave Cap Use HemOnc/BMT
- **3/17/09**: Microclave Cap Use Housewide

Infections per 1000 Device Days

- **FY2005**: 2.9, 3.0, 2.7
- **FY2006**: 2.5, 2.4, 2.6
- **FY2007**: 1.9, 1.4, 1.6
- **FY2008**: 1.8, 2.1, 2.6
- **FY2009**: 1.5, 1.3, 0.8
- **FY2010**: 1.0, 0.9, 0.2

- **CVC-LCBIs**
- **Control Limits**
- **Goals [0.8 (Jul06-Jun07) / 1.0 (Jul07-Jun08)]**
- **Baselines**

Source: Infection Control Dept.

Updated Thru 31Aug09 by Art Wheeler, Legal/HPCE Depts.
Stratified by Common Cause and Special Cause Periods

This led to more discussions with two units
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
CCHMC Central Venous Catheter (CVC) Associated Laboratory Confirmed Bloodstream Infections (LCBIs)

Infections per 1000 Device Days

Q3/04 - Revised Care Practices and CHG Scrub for Line Care
Q4/04 - Maximal sterile barriers and CHG Interventional Radiology
Q2/05 - MaxPlus Cap in PICU B4 & A6
MaxPlus Cap on ASN2
Q3/05 - MaxPlus Cap cancelled on ASN2
MaxPlus Caps cancelled.
New CCHMC Collaborative Began, Q1/06

Jan09 - Microclave Cap Use ICUs
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3/17/09 - Microclave Cap Use Housewide
CA-BSI NACHRI derived CVC bundle rolled out to hospital 3/15/07

Spiros device evaluated 8/1/09-
33
API-2013

Chart Type: u-chart

Desired Direction of Change
Same Before (8hrs) and After (3 hrs) Data

Very different patterns on the six run charts – Unstable Systems
Considering both unstable-stable system issues and the probability of flawed thinking on the part of patients, should physicians believe they can use data to help patients choose between therapies that science says produce slightly different results?

**Most comparative effectiveness studies are conducted in unstable systems, where there are multiple sources of outcomes variation.** It is impossible to interpret the results of these studies appropriately without knowing the sources of those variations and their effects on outcomes.
Method 2. Study of informative cases.

Health is a very personal attribute, but the results of most research studies are reported “on average.”

A new treatment can be deemed superior to an existing one even though more than half of the people in the study receiving the treatment receive no benefit versus the existing treatment.

The “Number Needed to Treat” describes this; how many people need to be treated by the new method for one to benefit more than the comparison treatment.

Informative case studies are an important supplement to the evidence developed from RCTs. (Flyvbjerg, 2001.)

Gerring (2004) A “case study,” is best defined as an intensive study of a single unit with an aim to generalize across a larger set of units.
In this paper we examine:

(1) How organizations convert meager experience into interpretations of history by experiencing infrequent events richly;

(2) Processes for simulating hypothetical histories; and

(3) Some justifications for these two learning strategies and some of the problems involved.
Some Principles for the Case Study Method

1. Act with the individual, learn for the population
2. Every case is one of a kind
3. Build knowledge sequentially case by case revising theories and making them explicit
4. The “gold standard” of evidence is the ability to predict the outcomes of care over a variety of cases
Choosing Informative Cases

Extreme cases

Cases that provide large variation

Critical cases

Typical cases

Cases indicated by special causes
Insulin Pump since 2000 (Brings BG records to each visit)
a) 7/03 (12 y.o) Puberty and doing some self-care
   Mom takes over more care per provider suggestions.

b) 6/04 c/o frequent low blood glucose episodes.
c) 11/04 Changed from pump to injections by NY MD
d) 5/05 Back on pump. Pt does ALL self-care.
   Mom stopped coming into exam room due to frustration with HgbA1c
Case Study Approach to Learning

IHI, State Action on Avoidable Rehospitalizations Initiative (STAAR)

At beginning of the work STAAR asked all participants to conduct a “diagnostic case review” of five patients who were recently readmitted to the hospital.

The purpose of the review was to understand the patient’s journey through the care system and identify gaps in quality from the patient’s perspective.

These reviews proved valuable not only in helping teams target the systemic problems in care coordination, but also in motivating professional interest in the use of quality improvement techniques to address them.
Case Studies and Context

Darryl is eight years old and has moderate but persistent asthma. He lives with his mother, three siblings (who also have asthma), and his maternal grandparents in an apartment in the Cottage Hill neighborhood. His mother works and cannot bring Darryl for his doctor’s appointments. He stays with his father on weekends. His father does not believe that Darryl has asthma. The boy has been admitted to the hospital multiple times since he was two months old, including one admission to the hospital’s intensive care unit. He has recently been discharged from the hospital because of another severe episode of asthma-related symptoms.

How could we re-design our health care system to take good care of Darryl?

## 5X Scale-up For Care of Childhood Asthma

<table>
<thead>
<tr>
<th>Number of Children Affected</th>
<th>System issues to overcome or questions to answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Can we make connections between the hospital and the pediatricians?</td>
</tr>
<tr>
<td>25</td>
<td>Can services outside of the hospital be coordinated?</td>
</tr>
<tr>
<td>125</td>
<td>Can all team members have access to the same information?</td>
</tr>
<tr>
<td>625</td>
<td>How should the optimized system be financed?</td>
</tr>
<tr>
<td>3125</td>
<td>Should we expand to overall child health rather than just one disease?</td>
</tr>
<tr>
<td>15,625</td>
<td>Can we reach our goal and sustain the performance?</td>
</tr>
</tbody>
</table>
Method 3: *Observational Studies*

One of the most famous series of observational studies were those that discovered the link between smoking and cancer.

The term epidemiology is now widely applied to cover the description and causation of not only epidemic disease, but of disease in general, and even many non-disease health-related conditions, such as high blood pressure and obesity.
Observational Studies (Vandenbrouke’s “2 views”)

One view is that of medical researchers who rejoice in discoveries and explanations of causes of disease. Discoveries happen when things are suddenly seen in another light: the odd course of a disease in a patient, the strange results of a lab experiment, a peculiar subgroup in the analysis of data, or some juxtaposition of papers in the literature. Researchers get enthusiastic about an idea, and try to find data—preferably existing data—to see whether there is “something in it”.

Observational Research, Randomised Trials, and Two Views of Medical Science
Jan P. Vandenbroucke, PLoS Medicine, March 2008 | Volume 5 | Issue 3
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.
A method to support learning from observations: Rational Subgrouping with Shewhart Charts

• The concept of *subgrouping* is one of the most important components in using the Shewhart chart method.

• Shewhart’s concept is to organize (classify, stratify, group, etc.) data from the process in a way that ensures the greatest similarity among the data in each subgroup and the greatest difference among the data in different subgroups.

• The aim of rational subgrouping is to include only common causes of variation within a subgroup with all special causes of variation occurring between subgroups.

• The most common method to obtain rational subgroups is to hold time “constant” within a subgroup e.g time series run charts and Shewhart charts.

*Health Care Data Guide*
p. 128-129
A method to support learning from observations: Rational Subgrouping with Shewhart Charts

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The aim of rational subgrouping is to include only common causes of variation within a subgroup with all special causes of variation occurring between subgroups.

The most common method to obtain rational subgroups is to hold time “constant” within a subgroup *e.g time series run charts and Shewhart charts.*
Shewhart U Chart for ADE’s at Aggregate Level

Same Data:

Shewhart U Chart for ADE’s subgrouped by hospital and quarter
Subgrouping on Adverse Drug Event (ADE) Rate (U chart)

Shewhart Chart with Aggregate Data

Systemwide Aggregate ADE Rate

Rational Subgroup by Medication

ADE Rate Subgrouped by Medication

Mean = 14.99

HC Data Guide p. 130
Understanding Variation in Vitamin A Supplementation Among NICUs

AUTHORS: Heather C. Kaplan, MD, MSCE, a,b,c Meredith E. Tabangin, MPH, d Diana McClendon, MPH, MSW, b Jareen Meinzen-Derr, PhD, e Peter A. Margolis, MD, PhD, b,c and Edward F. Donovan, MD b,e

PEDIATRICS Volume 126, Number 2, August 2010

Small Multiple Run Charts
Method 4: Natural Experiments

Natural experiments are observational studies which can be undertaken to assess the outcomes and impacts of policy interventions or other changes to a system.

They are possible where there are different approaches or practices between regions, organizations, or providers, or other social units.

These situations can be exploited by researchers to help answer a research question, rather than one which researchers have designed or influenced themselves.

Observational studies + factorial thinking
Recognizing a Natural Experiment
Kim Smith (NHS Borders, Scotland)

3 CRA Questions are the factors

Natural experiment to validate the CRA and determine which of the screening questions are related to outcome

Outcomes: Lab Results on processed on same form

### MICROBIOLOGY LABORATORY
### MRSA SCREENING REQUEST FORM

<table>
<thead>
<tr>
<th>CRA Questions</th>
<th>Response</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the patient any previous history of MRSA colonization or MRSA infection at anytime in the past?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is the patient currently resident in a care home or institutional setting, or transferred from another hospital?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Does the patient have a wound/ulcer or invasive device which was present before admission to this hospital?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

Take nasal swab and perineal swab from patient and send swabs for screening for MRSA. If wound, ulcer or invasive device present, take appropriate swabs and send along with this form to Microbiology laboratory. (Blue Microbiology request form NOT required)

### Patient Management

<table>
<thead>
<tr>
<th>Patient isolated in single room</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient cohorted with other high risk patients</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Patient cohorted, not dedicated nursing staff</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Patient managed in open ward</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

### Laboratory Results

<table>
<thead>
<tr>
<th>MRSA isolated from</th>
<th>Nasal swab</th>
<th>Perineal swab</th>
<th>Wound/ulcer swab</th>
<th>Device swab</th>
</tr>
</thead>
<tbody>
<tr>
<td>sticker</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Approximately 7% of Patients screened had partly answered questions which were not included in the experiment.

Kim Smith (NHS Borders, Scotland)

<table>
<thead>
<tr>
<th>Nasal Swab Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ns</td>
</tr>
<tr>
<td>-----</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
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<td>5</td>
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<tr>
<td>6</td>
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<tr>
<td>7</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

Raw Data calculated into percentages
Nasal swab colonisation response plots identify a positive interaction between having a history of MRSA and having a wound.

Perineal swab colonisation response plots identify an interaction between having a history of MRSA and living in an Institutional setting.

Kim Smith (NHS Borders, Scotland)
Objective

The study goal was to evaluate interstage growth variation among sites participating in the National Pediatric Cardiology Quality Improvement Collaborative registry caring for infants with hypoplastic left heart syndrome and to identify nutritional practices common among sites achieving best growth outcomes. (Journal of Pediatrics, 2011)

<table>
<thead>
<tr>
<th>GI Medications</th>
<th>Home Surveillance Strategy</th>
<th>Oral Feeding Alone</th>
<th>Feeding via NG/NJ Tube</th>
<th>Gastrostomy Tube Feeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Saturations and/or daily weights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zantac</td>
<td>None</td>
<td>None</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Saturations and/or daily weights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zantac and Reglan</td>
<td>None</td>
<td>None</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Saturations and/or daily weights</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NPC-QIC Factorial Matrix C

Jeff Anderson, CCHMC
# NPC-QIC Factorial Matrix

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<th>Feeding via NG/NJ Tube</th>
<th>Gastrostomy Tube Feeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>Breast Milk</td>
<td>Formula</td>
<td>Breast Milk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80</td>
<td>9, 71, 129</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>Oxygen saturation</td>
<td>144, 144</td>
<td>128, 141, 146</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Saturations + daily weights</td>
<td>84, 103, 126</td>
<td>121, 127, 126</td>
<td>73, 117</td>
</tr>
<tr>
<td>Zantac</td>
<td>None</td>
<td>79</td>
<td>2, 108</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Oxygen saturation</td>
<td></td>
<td></td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>Saturations + daily weights</td>
<td></td>
<td></td>
<td>72</td>
</tr>
<tr>
<td>Zantac and Reglan or Reglan Male</td>
<td>None</td>
<td>13, 22, 86</td>
<td>139, 166, 167</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oxygen saturation</td>
<td></td>
<td></td>
<td>131, 137</td>
</tr>
<tr>
<td></td>
<td>Saturations + daily weights</td>
<td></td>
<td></td>
<td>12, 48</td>
</tr>
</tbody>
</table>
Analysis of Natural Experiment

Variation in Growth of Infants with a Single Ventricle
Jeffrey B. Anderson, MD, MPH1,2, et al.

for the National Pediatric Cardiology Quality Improvement Collaborative*
Method 5: Planned Experimentation

Using more complex study designs with PDSA test cycles (recommendation of Speroff and O’Connor (2004).

Study more than one change at a time to learn about interactions.

Consider use of the use of replication, blocking, randomization, and various experimental patterns to increase the validity of the cycle.
Planned Experimentation

An experiment is a study designed to provide a basis for action. It is structured around changing one or more measures of components of a system to determine the affect that these components have on a process or outcome measure.

A Plan, Do, Study, Act Cycle (PDSA) test is a type of experiment.

The RCT is one of the simplest types of experiments with usually only one factor of interest and background variables held constant.

Planned experimentation (PE) is a collection of approaches and methods to help increase the rate of learning about improvements to systems, processes or products.
Sequential Learning through PDSA Cycles

Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

Use of Planned Experiment Methods

Hunches
Theories
Ideas

Very Small Scale Test

Follow-up Tests

Wide-Scale Tests of Change

Implementation of Change

Changes That Result in Improvement

APSD

APSD

APSD

APSD
The purpose of this article is to advocate for the use of **quasi-experimental strategies** to improve the scientific foundation of PDSA quality improvement in health care (p. 20)

**PDSA quality improvement is defined when data are collected to demonstrate that change by intervention resulted in improvement** (p. 21)
The rigor of a PDSA quality improvement study design is strengthened using replication schemes and research methodology to address extraneous factors that weaken validity of observational studies.

<table>
<thead>
<tr>
<th>Study design</th>
<th>Characteristic</th>
<th>Primary concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time-series (AB)</td>
<td>Continuous, longitudinal data</td>
<td>Historical control</td>
</tr>
<tr>
<td>Equivalent time-series (ABAB)</td>
<td>Replication</td>
<td>Carry over effects</td>
</tr>
<tr>
<td>Multiple baseline (AAAB, AABB, ABBB)</td>
<td>Lagging of interventions</td>
<td>Contamination</td>
</tr>
<tr>
<td>Factorial</td>
<td>Experimental design</td>
<td>Confounding</td>
</tr>
</tbody>
</table>
Fisher’s Tools for Experimentation

**Planned grouping** - managing background variables or confounders

**Randomization** - impact of nuisance variables

**Replication** - increase degree of belief

**Experimental pattern** - learn about each factor of interest

HC Research focuses on **Randomization** (e.g. the RCT gold standard)

QI focuses on **Replication** – build prediction over a wide-range of conditions.
Improving our ability to contact adolescent women with an STI: results of a planned experiment

17th International Scientific Symposium on Improving Quality and Value in Health Care
Orlando, FL
December 5, 2011

Jill S. Huppert, MD, MPH
Associate Professor, Division of Gynecology,
Cincinnati Children’s Hospital Medical Center
**Design Matrix: $2^2$ factorial**

<table>
<thead>
<tr>
<th>NP Cell Phone</th>
<th>Patient Card</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On</td>
<td>On / Active</td>
<td>On / Inactive</td>
<td></td>
</tr>
<tr>
<td>Off</td>
<td>Off / Active</td>
<td>Off / Inactive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inactive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Replication: entire experiment repeated after a 4 month break and change of EMR

Jill Huppert, CCHMC
% of women reached in 7 days - update

Last Date of Visit in Group

- % of Patients
- Mean
- Desired change
- Control Limits

New EMR

Jill Huppert, CCHMC
Lessons Learned

Challenging but feasible to run a planned experiment in the ED

Difficult to operationalize and implement some changes

- Worked to stabilize confidential # in EMR
  - Time constraints
  - Changing clinical environment
- Care outside of planned experiment

Smaller number of women with STIs during when the experiment was running?

Jill Huppert, CCHMC
“Orchestrated” Testing:
Coordinate PDSA testing in a collaborative or network to evaluate Ideas for improvement
## Why call this “Orchestrated Testing?”

<table>
<thead>
<tr>
<th>Orchestra</th>
<th>Orchestrated Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sections: the wind section, brass section, string section and so forth.</td>
<td>Multiple test sites that are all different</td>
</tr>
<tr>
<td>Led by a conductor who sets and maintains the tempo (speed), dynamics, and interpretation, including articulating style.</td>
<td>QI “Conductor”</td>
</tr>
<tr>
<td>All sections cooperate to create symphony, that means sometimes I am resting and not playing</td>
<td>Each site has it’s own assigned test</td>
</tr>
<tr>
<td>All members of the orchestra agree to standardize and tune</td>
<td>All sites agree to the standard changes and the test plan</td>
</tr>
<tr>
<td>All orchestra rehearse and perform</td>
<td>Preparation, execution, and reporting by all sites</td>
</tr>
<tr>
<td>All sections contribute to the whole and there can be no performance if any section is missing.</td>
<td>All tests must be completed to have an experiment. Each site gets more out of the experiment than they put in.</td>
</tr>
</tbody>
</table>
Potential Benefits and Challenges of Orchestrated Testing

1. Increase power for learning (larger sample size) from multiple sites.
2. Design allows more than one change to be tested at once (including synergy/antagonism)
3. Potentially better design (standardization and replication) than current before & after testing each change independently
4. **Bottom line**: Learn more, with less resources, and faster than the current approach
5. Down side? More complex to set up and manage
## Proposed $2^{4-1}$ Factorial for Hospital Readmissions

<table>
<thead>
<tr>
<th>Current Follow-up Practices</th>
<th>Standard Teaching</th>
<th>Enhanced Teaching and Learning</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Handoff</td>
<td>Handoff</td>
</tr>
<tr>
<td>Current Handoffs</td>
<td>Enhanced Communication</td>
<td>Current Handoffs</td>
</tr>
<tr>
<td>Early Discharge Needs Assessment</td>
<td>Unit 3</td>
<td>Unit 8</td>
</tr>
<tr>
<td>Post-Hospital Follow-up</td>
<td>Current Assessment</td>
<td>Unit 1</td>
</tr>
<tr>
<td>Early Discharge Needs Assessment</td>
<td>Unit 5</td>
<td></td>
</tr>
</tbody>
</table>

Each test with a different hospital or floor, STAAR project, 2012
Children’s Hospitals NICUs Lower CLABSI Rates through Planned Experimentation

**Background**

- **SLUG Bugs**: Standardizing Line care Under Guideline recommendations
- The first CHNC/CHND CQI multisite collaborative project
- Designed to reduce central line associated blood stream infections (CLABSI) in children’s hospital neonatal intensive care units (NICUs)

**Project Description**

- Literature review, expert opinion and benchmarking survey identified potential best practices associated with CLABSI reduction
- Development of Clinical Practice Recommendations “CPR”
  - Support local center practices when limited evidence
- Orchestrated Testing with Factorial Design
  - Advantages:
    - Allows multiple changes to be tested at a time
    - Potentially better design than traditional “before & after” testing
  - Disadvantages:
    - More complex to design, implement, manage and evaluate

**Unique Project Characteristics**

- Orchestrated testing in planned experimentation allowed simultaneous, rapid testing of multiple factors and the interaction of these factors
- Central reporting of monthly process compliance data and outcomes
- Unique opportunity to understand the impact of process measure compliance
- The effect of four “CPR” factors were studied:
  - Monitoring of hub care compliance
  - Use of clean or sterile tubing change techniques
  - Monitoring unit policy on limitation of central venous catheter access
  - Assessment of need for central line
- Centers were allowed to choose the factors that fit within their practice culture
- The Institute of Healthcare Improvement (IHI) breakthrough series method provided the operational framework
- IHI extract provided a centralized repository for data capture
- 17 Children’s Hospital NICUs participated in the collaborative

**Smart Aim**

- Reduce CLABSI in NICU patients by 15% in 14 months

**Measures**

- **Outcomes Measure**: CLABSI rate for the collaborative
  - Smart aim for participating sites set by each hospital
- **Process Measures**:
  - Compliance with each of the four factors
  - Target compliance greater than 90%
  - Minimum expected compliance greater than 75%
- **Balancing Measures**:
  - Infants requiring placement of a new central line after removal

**Results**

- **CLABSI rate reduced by 23%**

- **Compliance**:
  - For centers with adequate reporting there was no association between compliance and CLABSI rates
  - 16/17 centers achieved an average of 73% compliance with required factors
  - 13/17 centers achieved greater than 90% compliance

**Lessons Learned**

- Planned experimentation provided an opportunity to understand the impact of multiple CLABSI reduction practices studied simultaneously
- Factors studied should be clearly defined, measurable and clinically relevant
- A more rigorous monitoring of compliance is essential to understanding practice
- Orchestrated testing:
  - Allows each site to select processes that fit their culture
  - Benefits all participating sites from the knowledge gained through the collaborative process
  - Can be successfully utilized for NCU quality improvement collaborative, establishing best practices for improved outcomes
## 4-Factor Design Matrix for CLABSI Collaborative (2⁴⁻¹ Factorial Design)

<table>
<thead>
<tr>
<th>Test</th>
<th>Hub Care Compliance</th>
<th>Tubing Change</th>
<th>Limitations on CVC Access</th>
<th>Line Removal Assessment</th>
<th>Hospitals</th>
<th>Total Line Days</th>
<th>CLABSI Rate Study Period (Jan 12-Dec, 12)</th>
<th>Change in CLABSI Rate Study - Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Base line (Jun 11-Dec, 11)</td>
<td>Study (Jan, 12-Dec 12)</td>
</tr>
<tr>
<td>1</td>
<td>Not Monitoring</td>
<td>Clean technique</td>
<td>General CVC Access</td>
<td>No</td>
<td>TEAM B</td>
<td>5685</td>
<td>8570</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Monitoring</td>
<td>Sterile technique</td>
<td>General CVC Access</td>
<td>No</td>
<td>TEAM C</td>
<td>2216</td>
<td>4168</td>
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</tr>
<tr>
<td>3</td>
<td>Monitoring</td>
<td>Clean technique</td>
<td>Special situation CVC Access</td>
<td>No</td>
<td>TEAM D, E</td>
<td>9255</td>
<td>16751</td>
<td></td>
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<tr>
<td>4</td>
<td>Not Monitoring</td>
<td>Sterile technique</td>
<td>Special situation CVC Access</td>
<td>No</td>
<td>TEAM F</td>
<td>3609</td>
<td>5488</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Monitoring</td>
<td>Clean technique</td>
<td>General CVC Access</td>
<td>Yes</td>
<td>TEAM H, A, K</td>
<td>13571</td>
<td>24140</td>
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</tr>
<tr>
<td>6</td>
<td>Not Monitoring</td>
<td>Sterile technique</td>
<td>General CVC Access</td>
<td>Yes</td>
<td>TEAM I, J</td>
<td>6223</td>
<td>11517</td>
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</tr>
<tr>
<td>7</td>
<td>Not Monitoring</td>
<td>Clean technique</td>
<td>Special situation CVC Access</td>
<td>Yes</td>
<td>TEAM L, N</td>
<td>7225</td>
<td>14575</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Monitoring</td>
<td>Sterile technique</td>
<td>Special situation CVC Access</td>
<td>Yes</td>
<td>TEAM O, P, Q, R</td>
<td>18775</td>
<td>29621</td>
<td></td>
</tr>
</tbody>
</table>

**Total 16 NICU’s**

**66559 114830**

Results at 2014 PAS Conference
Lessons Learned

♦ Planned experimentation provided an opportunity to understand the impact of multiple CLABSI reduction practices studied simultaneously
♦ Factors studied should be clearly defined, measurable and clinically relevant
♦ A more rigorous monitoring of compliance is essential to understanding practice
♦ Orchestrated testing
  – Allows each site to select processes that fit their culture
  – Benefits all participating sites from the knowledge gained through the collaborative process
  – Can be successfully utilized for NICU quality improvement collaborative; establishing best practice for improved outcomes
Five Methods to Support a System of Learning for Health Care

1. Recognition and investigation of special causes using Shewhart charts.

2. Study of informative cases.

3. Observational studies of relationships between factors and responses.

4. Natural experiments (with factorial thinking).

5. Planned Experiments including the use of replication blocking, randomization, and experimental patterns.

Moen, Nolan, Provost
McGraw-Hill 2013, p. 346-347
"A Personalized Learning System is designed to make possible a more rigorous, collaborative, and individualized approach to care. Enable patients, families, clinicians, and researchers to work together to accelerate innovation, discovery, and the application of new knowledge.... “
This session will describe the importance of Shewhart charts, informative cases, observational studies, and natural and planned experiments in building a health care learning system.

A system for learning and improvement in health care should incorporate five components:

1. Recognition and investigation of special causes using Shewhart charts
2. Study of informative cases
3. Observational studies
4. Natural experiments
5. Planned experiments (including the use of blocking, replication, randomization, and experimental patterns)

Together these methods of learning provide evidence and insight into innovations and changes that improve patient and system outcomes.