Quality Improvement Science and Infection Prevention

Dr. Donald Goldmann, Harvard University

Sponsored by the WHO Patient Safety Challenge ... Clean Care is Safer Care

Quality Improvement Science and Infection Prevention

Don Goldmann, M.D.
Senior Vice President
Institute for Healthcare Improvement
Professor of Pediatrics
Harvard Medical School
Professor of Immunology and Infectious Disease and Epidemiology
Harvard School of Public Health

Hosted by
Dr. Cyrus Engineer
John’s Hopkins University

Sponsored by
WHO Patient Safety Challenge
Clean Care is Safer Care

February 1, 2011

Conflict of Interest Disclosure

Don Goldmann, MD
Has no real or apparent conflicts of interest to report.

Roadmap

• Personal journeys
  – Improvement and measurement lessons
• How IHI approaches improvement
  – Improvement theory and essentials
  – Will, ideas, execution
  – From R&D to spread and dissemination
• How much evidence is good enough?
• “Rigorous” examples from the front line
• Reliability and bundles
  – MRSA and other infection prevention bundles

A Personal Journey

Improve Emergency Department Efficiency!

Hosted by Dr. Cyrus Engineer, John’s Hopkins University
A Webber Training Teleclass
www.webbertraining.com
A Personal Journey

Epidemiology can take you only so far.

Cumulative Incidence of Bloodstream Infection: Cox model including only patient-related variables as covariates

Variation in parenteral nutrition utilization

Cox model including patient-and treatment-related variables as covariates

Overcoming Clinicians Distrust: Why Clinicians Are Skeptical About QI

- Many associate QI with old-style, punitive QA
- QI gurus overemphasize the industrial origins of QI and its “religious” aspects and promote specific tools to the exclusion of others (six sigma, lean, model for improvement)
- QI experts tend to focus on non-clinical processes and outcomes
- Teams trying to do QI “by the book” get bogged down in tedious process and settle for small incremental improvements

Hosted by Dr. Cyrus Engineer, John’s Hopkins University
A Webber Training Teleclass
www.webbertraining.com
Why Clinicians are Skeptical About QI

- QI leaders are not up front about the fiscal agenda
  - Increasing emphasis on value
- QI programs do not provide clinicians with the data they need to improve
- QI experts do not emphasize the academic potential of QI research

If they can do it in Bogotá…

Reducing Post-Caesarian Infections

Cause and Effect Diagram

Meta-Analysis the Effect of Antibiotic Prophylaxis on Infection Rates after Cesarean Section


Priority Matrix

Utilization and Timing of Antibiotic Prophylaxis for Cesarean Section

Hosted by Dr. Cyrus Engineer, John’s Hopkins University

A Webber Training Teleclass

www.webbertraining.com
Utilization and Timing of Perioperative Antibiotic Prophylaxis & Surgical Site Infections After Cesarean Section

Other Surgical Issues Addressed during the Project

- Excessive vaginal exams during labor
- Manual exploration of the uterus after delivery
- Shaving of the skin before surgery
- Infection-prone incision type
- Excessive repeat cesarean section

This may appear to be a sophisticated study, but...

- Amazing results can be achieved with real-time training and support – anywhere
- Time-ordered data is key
  - Time series analysis and multivariable techniques
  - Statistical process control
  - Simple run charts
- Practice with a personal improvement project
  - Getting the kids off to school on time
  - Getting to clinical rounds on time
  - Dinner with the family

Hosted by Dr. Cyrus Engineer, John’s Hopkins University
A Webber Training Teleclass
www.webbertraining.com
Quality Improvement Science and Infection Prevention
Dr. Donald Goldmann, Harvard University
Sponsored by the WHO Patient Safety Challenge ... Clean Care is Safer Care

Measurement Framework – A Key Requirement for QI
- Structure (facility design, improvement capacity, oversight committees)
- Process (key processes and practices tightly linked to the outcome of interest – adherence to CLABSI bundles)
- Outcome (CLABSI rates)

Aims should be:
- Strategic, important, “stretch”
- Actionable
- Measurable

Measures should be:
- Simple
- Digestible
- Graphic
- Possible to collect as part of routine work

IHI Staff

IHI Blueprint: IOM’s Six Aims
- Safe – no needless deaths
- Effective – no needless pain or suffering
  – Services based on scientific knowledge to all who could benefit but not to those not likely to benefit
- Patient-Centered – no helplessness
- Timely – no unwanted waiting
  – No potentially harmful delays
- Efficient – no waste
  – No waste of equipment, supplies, ideas, energy
- Equitable – for all
  – Regardless of gender, ethnicity, geography, socioeconomic status
100,000 Lives Campaign “Planks”

- Rapid response teams
- Evidence-based care for acute myocardial infarction
- Prevention of adverse drug events (medication reconciliation)
- Prevention of central line infections (Central Line Bundle)
- Prevention of surgical site infections (correct perioperative antibiotics at the proper time and other elements of the Surgical Infection Bundle)
- Prevention of ventilator-associated pneumonia (Ventilator Bundle)

5 Million Lives Campaign Planks

- Reduce Surgical Complications – Adopt “SCIP”
- Prevent Harm from High Alert Medications
- Prevent MRSA Infections
- Reduce Readmissions in patients with Congestive Heart Failure
- Prevent Pressure Ulcers
- Get Boards on Board

What’s Needed to Improve

- Will
- Ideas
- Execution

- Where do the ideas come from?
- How do we increase our degree of belief that the ideas are valid?
- How do we spread what works?

IHI’s “Production” Model

AIM
Locate Will
Find, vet, and test ideas
Demonstrate under varied conditions
Demonstrate at scale
Build Will
Execution
RESULTS AT SCALE

Assessing Will (to Make Major Changes)

- What are we trying to accomplish?
- What investments are we willing to make?
- What activities should we de-emphasize?
- What conflicts are we willing to resolve?
- What risks are we willing to take?
- How much disruption in the organization are we willing to support to make the transition to a better performing system?

Four Steps on the Pathway from Innovation to Demonstration to Spread of Ideas

- R&D
- Prototyping
- Pilot Testing
- Spread and Dissemination

Hosted by Dr. Cyrus Engineer, John’s Hopkins University
A Webber Training Teleclass
www.webbertraining.com
Quality Improvement Science and Infection Prevention
Dr. Donald Goldmann, Harvard University
Sponsored by the WHO Patient Safety Challenge ... Clean Care is Safer Care

Four Steps – R&D
• R&D in 90 days
  − Scan the environment constantly for innovative ideas in healthcare and beyond
  − Prioritize topics and align with strategic aims and customer needs (Executive Team and R&D Team)
  − Develop
    • Conceptual/theoretical model for achieving a concrete goal
    • Logic model and key “drivers”
    • Corresponding hypotheses to be tested
    • Package of promising change concepts
  − Develop a “technical brief” and “technical specifications” for further work
  − Make “go” or “no go” decision regarding further development
  − Develop a learning and testing/prototyping plan

The Future of R&D?
• Distributed learning and innovation
  − P&G model (Tide To Go)
    • Metric: % of new products “not invented here”
  − Wiki, blogs, other social networking tools...
  − Some of the best innovations come from regions with constrained resources

Four Steps: Prototype Testing
• Prototype Testing
  − Specify aggressive goals and high-level measures ("raise-the-bar targets")
  − Intensively evaluate the validity and feasibility of the conceptual model, drivers, change package, and targets
    • Determine if even 1 or 2 highly committed organizations can achieve the targets
    • Determine whether to proceed with pilot testing, abandon the idea, or revisit R&D

Four Steps: Pilot Testing; Spread and Dissemination
• Pilot Testing
  − Expand testing to increase degree of belief that the changes will result in improvement under a broader range of organizations and conditions
    • Collaboratives, increasingly virtual
  • Spread and Dissemination
    − Scale up regionally and nationally
      • 100,000 and 5 Million Lives Campaigns
      • Durable network of “nodes” and “mentor hospitals”
      • Trust and verify – spread without adoption does not count

Framework for Execution

Models, Drivers and Associated Change Packages Must be Tested and Refined in the Real World
The essence of quality and systems improvement

Hosted by Dr. Cyrus Engineer, John’s Hopkins University
A Webber Training Teleclass
www.webbertraining.com
Quality Improvement Science and Infection Prevention  
Dr. Donald Goldmann, Harvard University 
Sponsored by the WHO Patient Safety Challenge ... Clean Care is Safer Care

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?

Act
Plan
Study
Do

How much evidence do we need before spreading a change strategy?

How much confidence do we need in the change concept?

Rigorous Learning in Complex Systems

Diverse Study Designs

• Examples include:
  – Cluster randomized trials and meta-analytic trials
  – Bayesian and Adaptive trials
  – Pragmatic trials
  – Action and community-based participatory research
  – Quasi-experimental designs (e.g., factorial, time series designs)
  – Context-sensitive mixed methods research
  – Observational studies with attention to exposure and follow-up (including propensity scoring, instrumental variables)
  • Data Mining

Examples from the Front Line

Effect of Standard Antibiotic Order Form on Duration of Prophylaxis

Hosted by Dr. Cyrus Engineer, John's Hopkins University
A Webber Training Teleclass
www.webbertraining.com
**Quality Improvement Science and Infection Prevention**  
**Dr. Donald Goldmann, Harvard University**  
*Sponsored by the WHO Patient Safety Challenge ... Clean Care is Safer Care*

---

**Interventional Study to Evaluate the Impact of an Alcohol-based Hand Gel on Hand Hygiene Compliance**

- Phase I: Baseline period
- Phase II: Introduction of alcohol gel
- Phase III: Alcohol rub + QI
- Phase IV: Maintenance


---

**Effective QI?**

- Satisfied with gel 45%
- Gel helped with compliance 42%
- Sticky, uncomfortable feeling 53%
- Conveniently located 57%
- Posters effective 32%
- Knew there was opinion leader 24%
- Received performance feedback 68%

---

**Reliability and Bundles**

**Prevent MRSA Infection**

---

Hosted by Dr. Cyrus Engineer, John’s Hopkins University  
A Webber Training Teleclass  
[www.webbertraining.com](http://www.webbertraining.com)
MRSA in Europe

<table>
<thead>
<tr>
<th>Country</th>
<th>MRSA proportion</th>
<th>MRSA proportion per hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>0.8%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Germany</td>
<td>0.6%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Italy</td>
<td>0.5%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Spain</td>
<td>0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>UK</td>
<td>0.3%</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

Is this remarkable variation due to:
- Transmissibility and virulence of distinct genotypes?
- Size, design, or type of hospital?
- Case mix?
- Practice variation?
  - Compliance with known, measurable evidence based practices?
  - Less tangible features, such as culture and organization of an intensive care unit?
  - Are nosocomial infections an “expected” consequences of caring for very sick, complex patients, or intolerable, potentially preventable adverse events
  - Vermont Oxford NICQ visits to “best of breed” NICUs

A Modest Proposal…

- Improve reliability of basic infection control procedures
  - Hand hygiene
  - Isolation procedures
  - Screening tests

Reliability Science

- Health care is riddled with defects
  - 40-50% compliance with hand hygiene?!?
  - What happens at Intel…
  - What happens in Bowling Green…
- From the patient’s point of view, it’s “all or nothing”
- Reliability science offers robust approaches to reducing defects and harm in health care

Component vs. Composite Adherence

Contact Precautions

- **COMPONENT**: 80% hand hygiene, gloves on entering room
- **COMPONENT**: 78% gowns on entering room
- **COMPONENT**: 65% hand hygiene after removing gloves
- **COMPOSITE**: 50% get all three

Reliability is failure-free operation over time from the viewpoint of the patient

Hosted by Dr. Cyrus Engineer, John's Hopkins University
A Webber Training Teleclass
www.webbertraining.com
Defects in outpatient HF care  
Defects in inpatient HF care  
Decompensated HF  
Admission through discharge  
Defects in outpatient care and readmission  

Levels of Reliability
- Chaotic process: Failure in greater than 20% of opportunities
- $10^{-1}$: 80 or 90 percent success: 1 or 2 failures out of 10 opportunities (no consistent articulated process)
- $10^{-2}$: 5 failures or fewer out of 100 opportunities (process is articulated by front line)
- $10^{-3}$: 5 failures or fewer out of 1000 opportunities
- $10^{-4}$: 5 failures or fewer out of 10,000 opportunities

Blood banking and anesthesiology alone achieve the higher levels of reliability in medicine.

Reliability in Healthcare
- Remember, it’s “all or nothing” – not compliance with each individual component of “best practice”
- Most institutions do fairly well with individual components of evidence-based practice, but performance drops dramatically when the standard is “all or nothing”
- We are trying to decrease the “defect rate” and to achieve a reliability of performance to the $10^{-2}$ level (at least 95% compliance with the entire package of evidence-based practice)

Guidelines v. Bundles (Intervention Packages)
- Guidelines tend to be long, all-inclusive, and confusing
  - Many potential interventions are supported by some evidence
- Guidelines are difficult to translate into action and often are ignored by clinicians
- What if just a few key, actionable interventions, supported by strong evidence, were culled from the guidelines?

What Is a Bundle?
- A grouping of best practices with respect to a disease process that individually improve care, but when applied together result in substantially greater improvement
- The science behind the bundle is so well established that it should be considered standard of care
- Bundle elements are dichotomous and compliance can be measured: yes/no answers
- Bundles eschew the piecemeal application of proven therapies in favor of an “all or none” approach

Five Key Interventions
- Compliance with Central Venous Catheter and Ventilator Bundles
- Hand hygiene
- Active surveillance cultures (ASCs)
- Decontamination of the environment and equipment
- Contact precautions for infected and colonized patients

Guidelines v. Bundles (Intervention Packages)
Prevent MRSA Infection and Colonization

- Colonized patients comprise the reservoir for transmission ("colonization pressure")
- High rates of MRSA colonization complicate empiric antibiotic therapy (e.g., vancomycin)
- Colonized patients have a high rate of MRSA infection
  - Nearly 1/3 develop infection, often after discharge
- Colonization is long-lasting, and patients can transmit MRSA to patients in other health care settings (e.g., nursing homes), as well as to family members

What Changes Can We Make?
Understanding the System

How Will We Know We Are Improving?
Understanding the System with Measures

What Changes Can We Make?
Understanding the System for Weight Loss

How Will We Know We Are Improving?
Understanding the System for Weight Loss with Measures

What Changes Can We Make?
Understanding the System for Reducing Hospital Acquired Infections

How Will We Know We Are Improving?
Understanding the System for Reducing Hospital Acquired Infections with Measures

Hosted by Dr. Cyrus Engineer, John's Hopkins University
A Webber Training Teleclass
www.webbertraining.com
Quality Improvement Science and Infection Prevention
Dr. Donald Goldmann, Harvard University
Sponsored by the WHO Patient Safety Challenge ... Clean Care is Safer Care

**Central Venous Catheter Bundle**
- Hand hygiene before inserting a catheter or manipulating the system and catheter site
- Maximal barrier precautions for line insertion
  - Hand hygiene
  - Non-sterile cap and mask
  - Sterile gown and gloves
  - Large sterile drape
- Antiseptic prep used for catheter insertion as per hospital protocol
  - 2% chlorhexidine supported by evidence
- Site selection
- Timely removal
- (alcohol hub prep, other measures)

**Reduce Ventilator-Associated Pneumonia**
- Elevation of the head of the bed to between 30 and 45 degrees
- Daily “Sedation Vacation” and daily assessment of readiness to extubate
- Peptic ulcer disease (PUD) prophylaxis
- Deep vein thrombosis (DVT) prophylaxis (unless contraindicated)
- (chlorhexidine mouth care)

Note the paradoxes – what does this tell us about how bundles may work?

**Reduce Surgical Site Infections**
- Appropriate use of antibiotics
  - New issues: MRSA screening, change in first line antibiotics?
- Appropriate hair removal
- Post operative glucose control (major cardiac surgery patients cared for in an ICU)*
  - Perioperative normothermia (colorectal surgery patients)*
- But no correlation with better outcomes in recent JAMA paper (JAMA. 2010; 303:2479-85)

**Hosted by Dr. Cyrus Engineer, John’s Hopkins University**
A Webber Training Teleclass
www.webbertraining.com
A Hand Hygiene “Bundle”

- Staff knowledge
- Staff competency
- Alcohol and gloves available at the point of care
  - Operational, full dispensers providing correct volume of rub
  - At least 2 sizes of gloves
- Correct performance of hand hygiene + gloves worn for standard precautions
  - Concurrent monitoring and feedback
  - Focus on leaving the bedside
  - Staff accountability

5 May, 2011

SAVE LIVES: Clean Your Hands: WHO’s Global Annual Campaign

Aiming for hand hygiene sustainability is the focus for SAVE LIVES: Clean Your Hands 5 May, 2011. Using the WHO Hand Hygiene Self Assessment Framework can help you …

- Plan your own activities
- Undertake self-assessments
- Construct ways to highlight and share the 5 May message

Act on the WHO SAVE LIVES: Clean Your Hands messages …

REGISTER TODAY.

www.who.int/gpsc/5may/en