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

Conflict of Interest Disclosure

Don Goldmann, MD

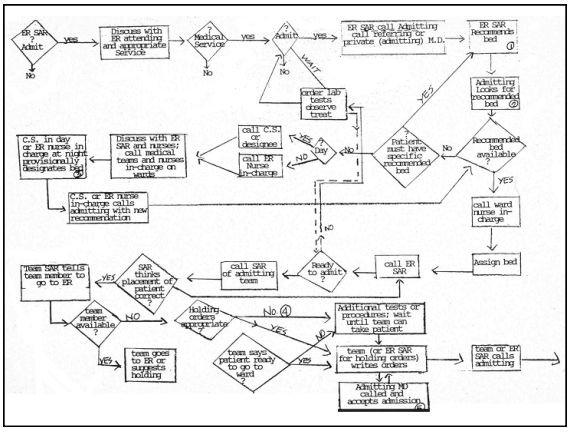
Has no real or apparent conflicts of interest to report.

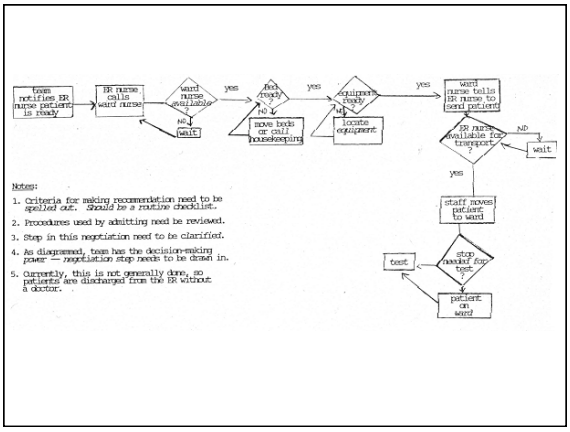
Roadmap

- 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

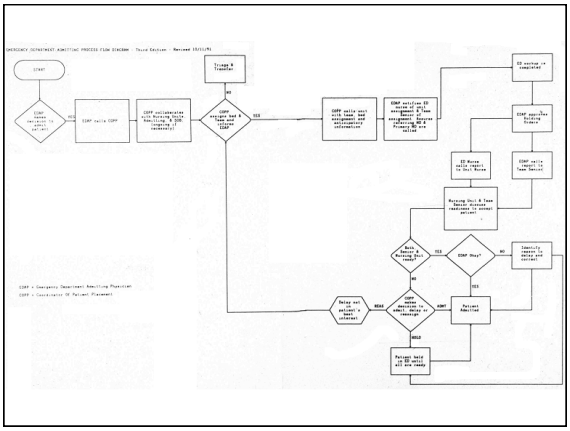
A Personal Journey

Improve Emergency Department Efficiency!





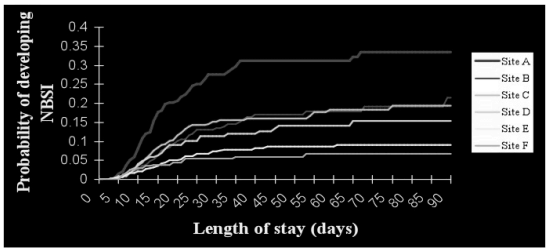
Hosted by Dr. Cyrus Engineer, John's Hopkins University
A Webber Training Teleclass
www.webbertraining.com



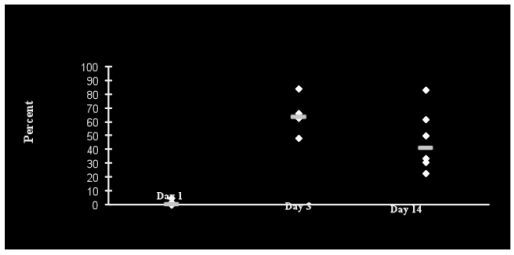
A Personal Journey

Epidemiology can take you only so far….

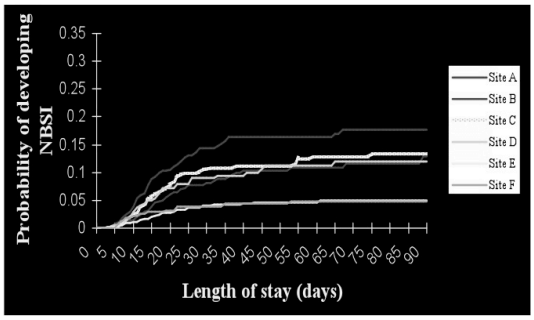
Cumulative Incidence of Bloodstream Infection: Cox model including only patient-related variables as covariates



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

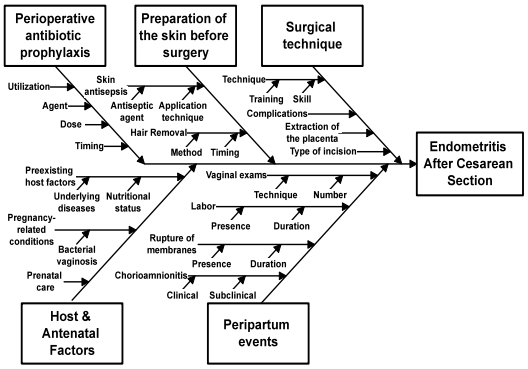
Why Clinicians are Skeptical About QI

- 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

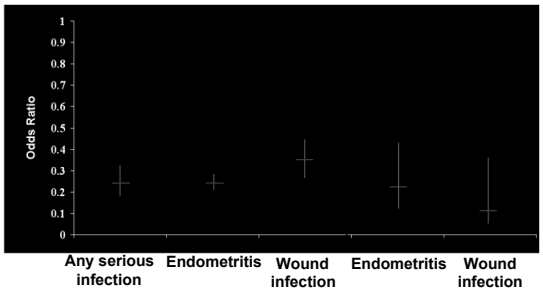
If they can do it in Bogotá…

Reducing Post-Caesarian Infections

Cause and Effect Diagram



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



Enkin M, et al. Prophylactic antibiotics in association with cesarean section. In: Chalmers, Enkin, Keirse eds. Effective care in pregnancy and childbirth.

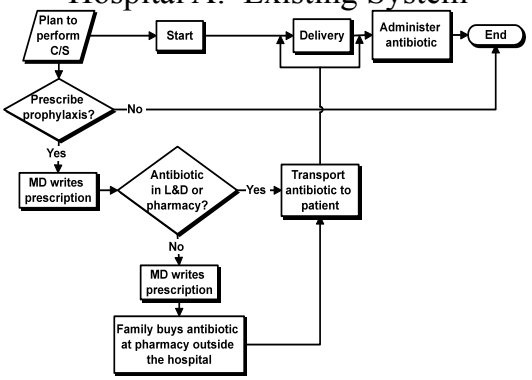
Priority Matrix

Factor	Importance	Within the capacity of hospital personnel to improve	Timeframe for improvement
Antibiotic prophylaxis	4	4	short
Skin preparation	3	4	short
Surgical technique	4	4	medium
Antenatal factors	3	1	long
Peripartum events	4	2	medium

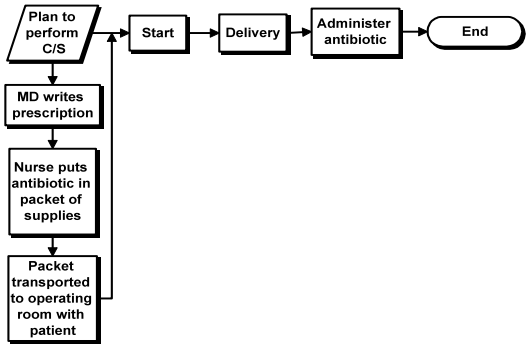
Utilization and Timing of Antibiotic Prophylaxis for Cesarean Section

	% receiving prophylaxis	% receiving prophylaxis ≤1 hour after delivery
Hospital A	70%	31%
Hospital B	32%	70%

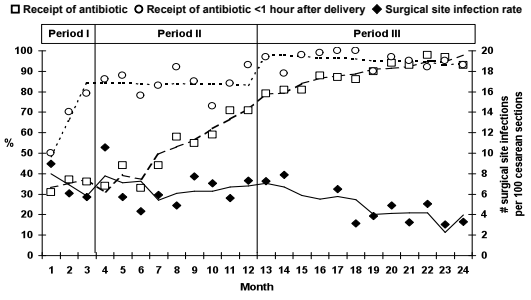
Hospital A: Existing System



Hospital A: Revised System



Utilization and Timing of Perioperative Antibiotic Prophylaxis & Surgical Site Infections After Cesarean Section



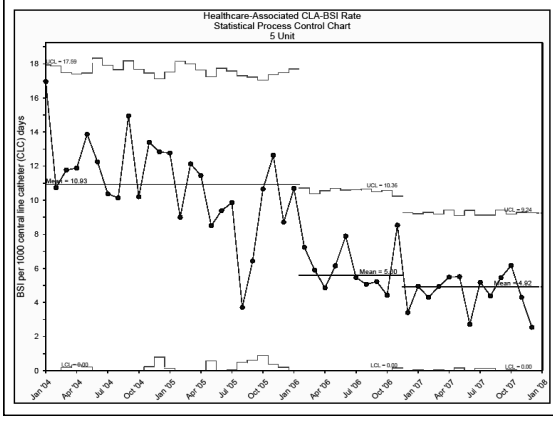
Weinberg M, et al. Arch Intern Med 2001

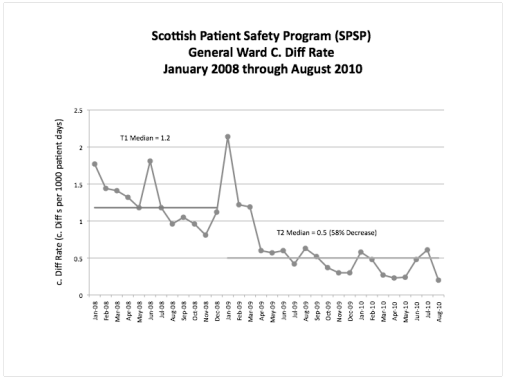
Other Surgical Issues Addressed during the Project

- 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





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

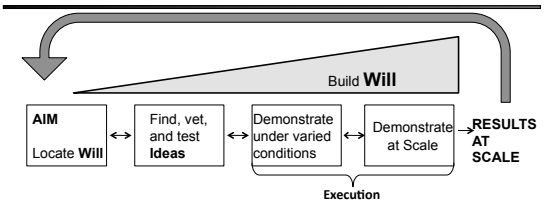
- Reduce Surgical Complications – Adopt "SCIP"
- Prevent Harm from High Alert Medications
- Prevent MRSA Infections
- Reduce Readmissions in patients with Congestive Heart Failure
- Prevent Pressure Ulcers
- Get Boards on Board

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



Institute for Healthcare Improvement

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

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

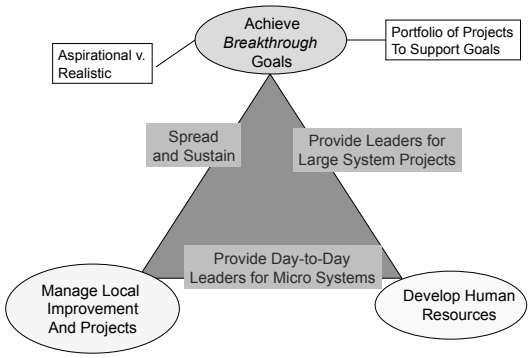
Four Steps: Prototype Testing

- 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

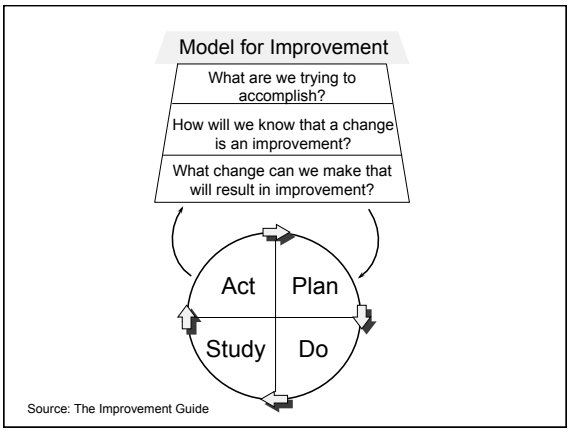
- Pilot Testing
  - Expand testing to increase degree of belief that the changes will result in improvement under a broader range of organizations and conditions
    - Collaboratives, increasingly virtual
- Spread and Dissemination
  - Scale up regionally and nationally
    - 100,000 and 5 Million Lives 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

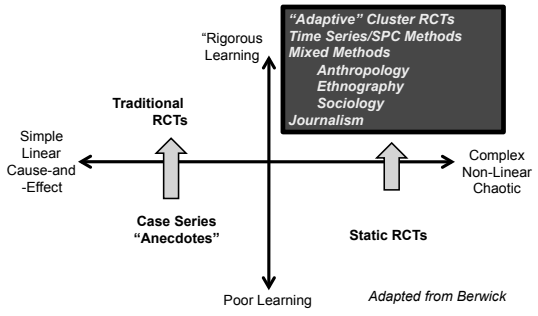
The essence of quality and systems improvement



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

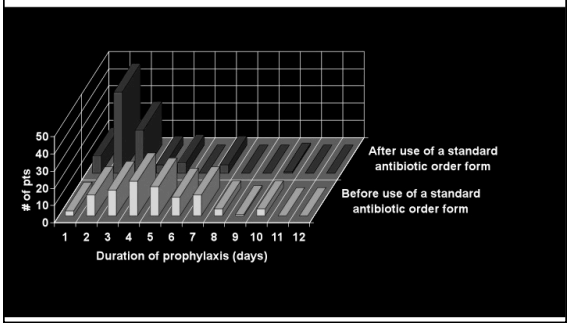


Diverse Study Designs

- 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



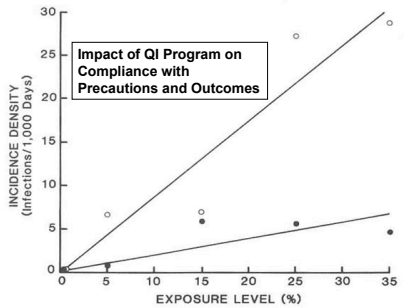


Figure 1. Rise in Incidence Density of New Nosocomial RSV Infections with Increasing Levels of Exposure to Hospitalized Patients Shedding Virus, per 1000 Patient-Days.

Leclair , et al., N Engl J Med 1987; 317:329-334 (ICP)

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

Harbarth S, et al.; Pediatr Infect Dis J 2002;21:489-495

Fig. 2

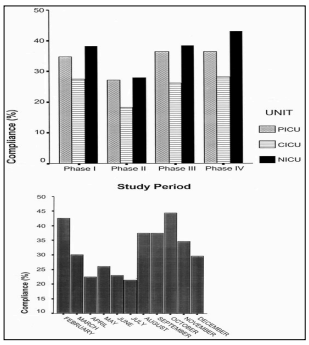


Fig. 2 . A, trends in compliance by study phase and type of intensive care unit. February through December. B, trends in compliance by month, February through December

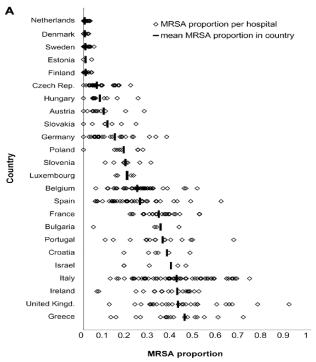
Effective QI?

• 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

MRSA in Europe



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

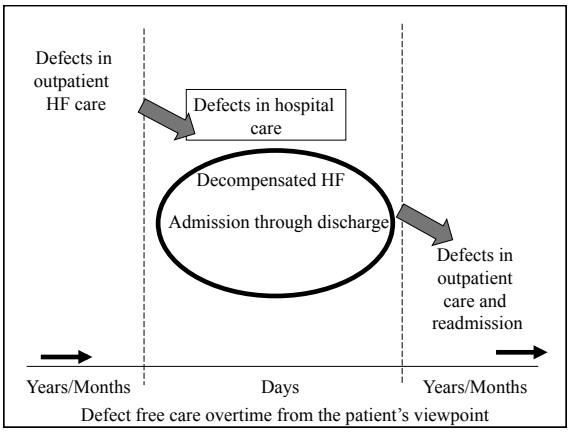
Reliability Science

- 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



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

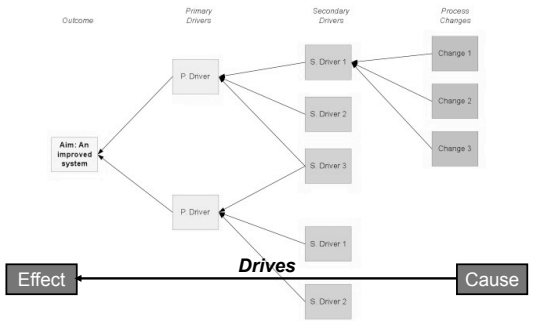
Quality Improvement Science and Infection Prevention
Dr. Donald Goldmann, Harvard University
Sponsored by the WHO Patient Safety Challenge … Clean Care is Safer Care

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

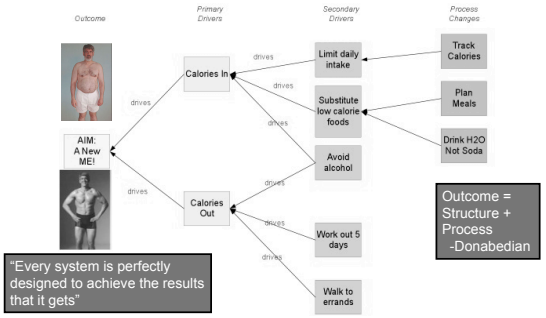
What Changes Can We Make?

Understanding the System



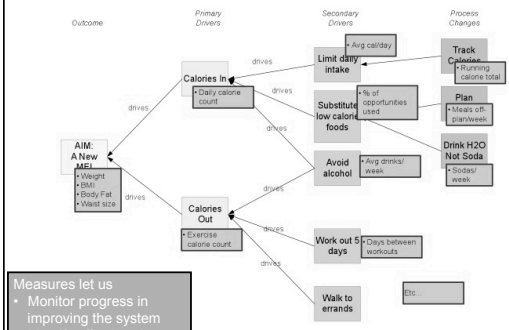
What Changes Can We Make?

Understanding the System for Weight Loss



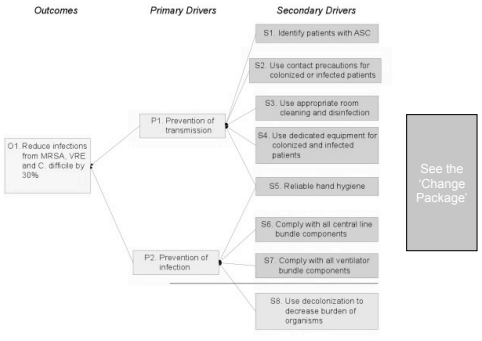
How Will We Know We Are Improving?

Understanding the System for Weight Loss with Measures



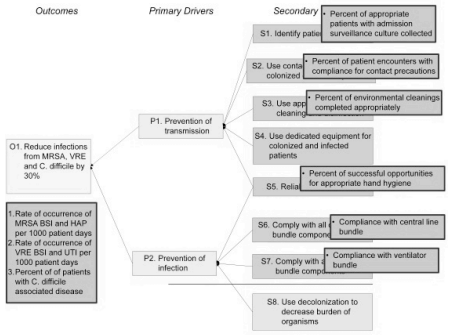
What Changes Can We Make?

Understanding the System for Reducing Hospital Acquired Infections



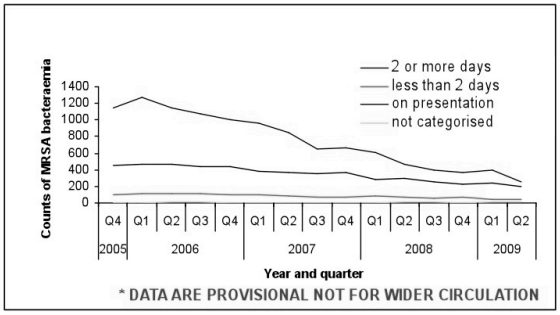
How Will We Know We Are Improving?

Understanding the System for Reducing Hospital Acquired Infections with Measures

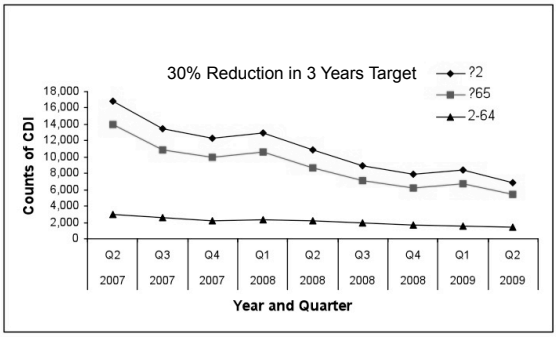


Hosted by Dr. Cyrus Engineer, John's Hopkins University
A Webber Training Teleclass
www.webbertraining.com

MRSA Bloodstream Infection



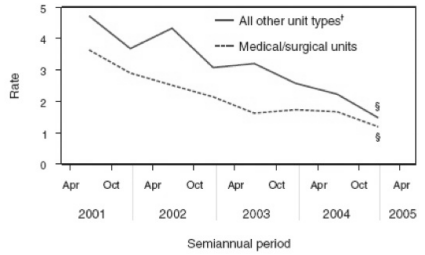
C. difficile



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)

Central line-associated bloodstream infection rate in 66 ICUs, Southwestern Pennsylvania, April 2001-March 2005



Pronovost et al.,N Engl J Med; 2006;355:2725
Decrease from 7.7 to 1.4 per 1000 catheter days in 103 ICUs

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)

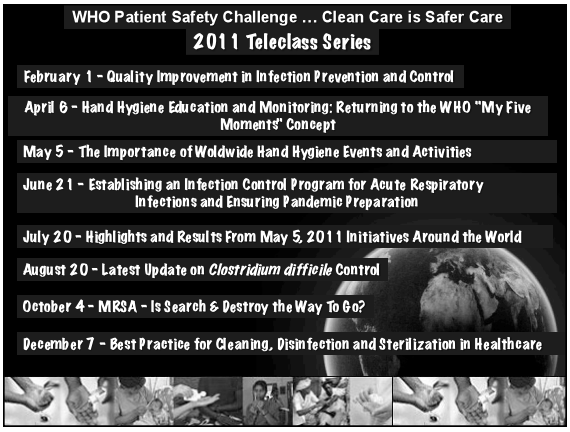
Note the paradoxes – what does this tell us about how bundles may work?

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*)

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

Action for sustained hand hygiene!

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