

Successes and Challenges Developing and Implementing Bundles in Infection Prevention
Dr. Don Goldmann, Harvard Medical School
Sponsored by WHO Patient Safety Challenge – Clean Care is Safer Care

Successes and Challenges in Developing and Implementing Bundles in Infection Prevention

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 No conflicts to declare

Hosted by Dr. Benedetta Allegranzi WHO Technical Lead Clean Care is Safer Care	Sponsored by WHO Patient Safety Challenge Clean Care is Safer Care
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What's Wrong with Clinical Practice Guidelines?

- Long, tedious
- Not much guidance regarding:
 - Relative importance and impact of each element
 - What to do about important recommendations for which the evidence is weak
 - Lack of relationship to a "learning healthcare system"
 - Sequencing
 - Implementation
 - Measurement
- Not written with decision support at the point of care in mind
 - A story – Where in the world is that IDSA CPG?

What's in a Clinical Pathway?

- Specification of a relatively homogeneous population
- Clear boundaries in time (start/stop) and place
- Evidence review
 - Method to reach consensus (e.g., expert meeting, Delphi)
 - Which evidence is solid, which is not (evidence grading)

What's in a Pathway?

- Process flow diagram, preferably leading to clear, measurable outcomes
- Measurement framework for key processes and outcomes
- Who does what, when, and where
 - Enriched by "how" and linked to "why"

Analogous Approaches

- Reliability
 - Bundles
 - Checklists
- FMEA and HACCP
- Lean Consumption

Reliability Science

- Health care is riddled with defects
 - 40-50% compliance with hand hygiene!??
 - What happens at Intel
 - Time for accountability?
- 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

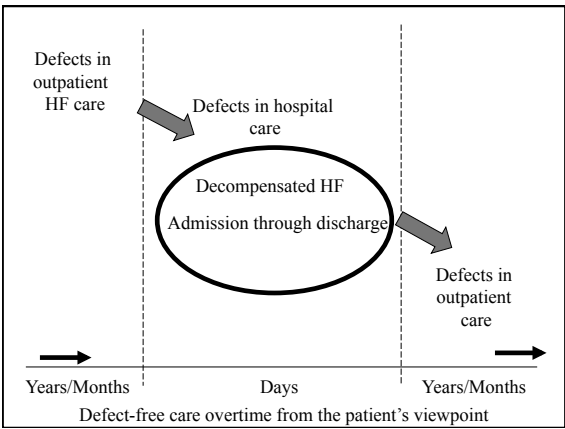
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**Component vs. Composite Adherence
Contact Precautions**

- **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: 90 percent success: 1 failure out of 10 opportunities (no consistent articulated process)
- 10⁻²: 1 failure or fewer out of 100 opportunities (process is articulated by front line)
- 10⁻³: 1 failure or fewer out of 1000 opportunities
- 10⁻⁴: 1 failure or fewer out of 10,000 opportunities

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

Reliability in Health Care

- 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 95-99% compliance with the entire package of evidence-based practice)

Bundles (Intervention Packages)

- What if just a few key, actionable interventions, supported by strong evidence, were culled from the guidelines and incorporated into care pathways at key action moments?

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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 (well, maybe....)
- 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
- In general, elements should occur at a specific point in time

Central Venous Catheter Bundle

- Insertion bundle (amenable to checklist, which also captures performance data and reinforces social norms)
 - Hand hygiene before inserting a catheter or manipulating the system and catheter site
 - Maximal barrier precautions for line insertion
 - Antiseptic prep used for catheter insertion as per hospital protocol
 - 2% chlorhexidine supported by evidence
 - Site selection
- Maintenance bundle (note that elements are spread out over time, complicating observation and checklist/documentation)
 - Alcohol or chlorhexidine hub prep, other measures
 - Timely removal

Antibiotic Stewardship

- A real challenge for bundles because interventions occur over time
 - Choice
 - Adjustment and de-escalation
 - IV/oral switch
 - Termination
- ? Better to think about a care pathway with standardized order-sets (checklists of a sort) and real-time visible reminders and decision support

Regardless....

- More than just bundles, checklists, and pathways are required to improve performance
- Culture, peer norms, teamwork, communication, clarity of purpose, leadership alignment and support, etc. are critical

Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program; Woods et al., Milbank Quarterly 2011; 89: 167-206

Failure Mode and Effects Analysis FMEA

- Examines design of systems in which faults or problems are anticipated and designs them out
- An engineering approach to error reduction

FMEA

- Risk Points:
 - Specific places in a process or system that are susceptible to error or system breakdown
- May result from:
 - Flaws in initial design of system
 - High degree of dependence on communication
 - Non-standard processes or systems
 - Failure or absence of backup or duplication

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Steps in FMEA

1. Set up a process flow diagram
2. Retrace flow diagram, assuming the worst to figure out what might go wrong
3. Determine what the effects of failure might be on the rest of the process

Steps in FMEA

4. Rank the estimated probability of occurrence:
1=remote, 5=possible, 10=almost certain.
5. Rank the estimated severity of the overall failure:
1=will not harm patients, 5=may harm patients, 10=will cause injury or death.
6. Rank the estimated likelihood error will be detected before accident takes place:
1=will always be detected, 5=might be detected, 10=detection impossible.
7. Calculate the "criticality index"
(mean of steps 4-6).

Steps in FMEA

8. Decide on interventions to lower the criticality index
9. Take action
10. Monitor error-prone points in system

Hazard Analysis and Critical Control Point (HACCP)

- A system that identifies and monitors specific foodborne hazards that can adversely effect the safety of a food product
- Pioneered by Pillsbury in cooperation with NASA, US Army, and US Air Force Space Laboratory
- In early 1960s, created food for astronauts that approached 100% assurance against contamination

Good Manufacturing Practice

- Developed by FDA to provide a roadmap for producing safe, pure, effective drugs
- Now mandated in blood banking
- Uses critical control point schema



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Lean Consumption

- Provides patients exactly what they want and need precisely when, where, and how they want it
 - We leave it to patients to figure out the system and have trained “navigators” to help them
 - The vast majority of time is wasted (without value to the patient)
 - “Mass customization”
 - Is there a patient on your clinical pathways team?
- Case study: hip replacement

Adapted from Womack and Jones, Harvard Business Review, March 2005

Problems and Paradoxes

- Do efforts to achieve reliable processes and care pathways stifle innovation?
- Do they nurture a learning health care system?
 - Learning from variation
 - Building evidence from n=1 trials
 - The power of registries – can pathways contribute richer clinical data?

An Effort to Learn from Clinical Pathways in “Real Time” at Boston Children’s Hospital - SCAMPs

SCAMPs

Standardized Clinical Assessment and Management Plans:

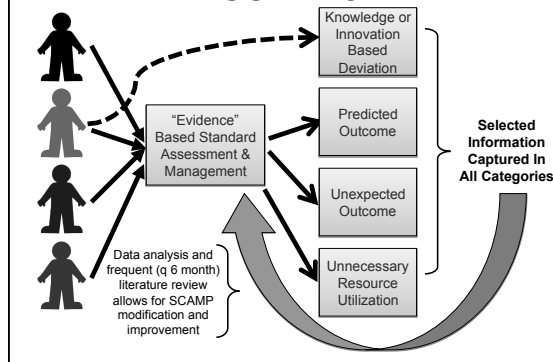
First Principles for SCAMPs:

1. There is no such thing as “best” practice... only sound practice that is constantly changing.
2. Very few decisions are informed by conclusive data... which are hard to acquire and often incorrect. Changes should be made on persuasive data.
3. Data collection should be targeted based on prior probabilities... but not so narrowly that important, unplanned consequences are missed.
4. Deviations are permitted... but the reasons must be recorded. These deviations will accelerate improvement.

SCAMPs

- Practitioners agree to standardize practice for numerous clinical scenarios using carefully designed decision trees that reflect “sound” practice
- Selected data are collected about decisions and results based on pre-defined plausible outcomes, and are analyzed to improve practice
- Deviations from standard care permitted, but must be documented
- Standardized practices are designed and changed based on a combination of: 1) best clinical judgment, 2) prior empirical knowledge, and 3) empirical analysis of new data

SCAMPs



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SCAMPs Challenges

- Tons of work to create just one
- Only a tiny fraction of processes that need to be improved
- Analysis and amendment very time consuming
- Non-automated
- Ambiguities in evidence may not be resolved

More Care Pathway Challenges and Opportunities

- Even if all steps are solidly evidence-based and executed reliably, outcome may not move dramatically
 - Attributable effect usually lower than assumed
 - Reliability rarely is as high as needed to change outcomes
- Pathways started as nursing tools – they must be multi-disciplinary and inter-professional
 - But hard to get MDs, nurses, clinical pharmacists to communicate and round together

Challenges and Opportunities

- Clearly indicate to whom the pathway does and does not apply
 - Use cautiously in patients with co-morbidities and the frail elderly
- Incorporate checklists at critical points in the pathway
- Build in stop checkpoints (TGIDNTA)
- Use standardized order sets liberally to drive evidence-based prescribing and testing
 - Allow exceptions, but require documentation – a key aspect of a learning healthcare system

Challenges and Opportunities

- Allow clinicians to opt out of the pathway based on their experience and judgment
 - Require documentation of the reason for deviating from the pathway
 - Foundation for a learning healthcare system
 - Protection against litigation
- Draw on guidelines from professional societies, but respect need for local adaptation and complexity of implementation
- Be realistic about what it takes to maintain clinical pathways

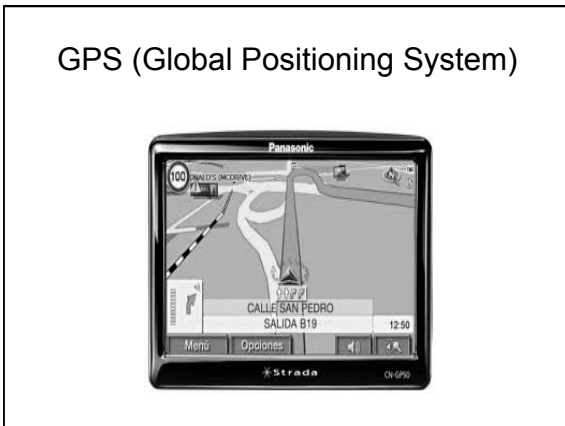
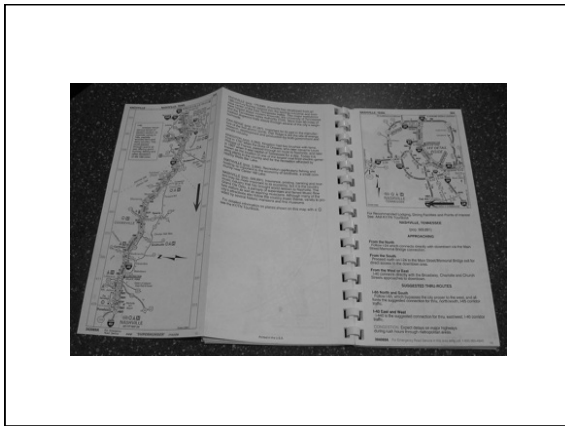
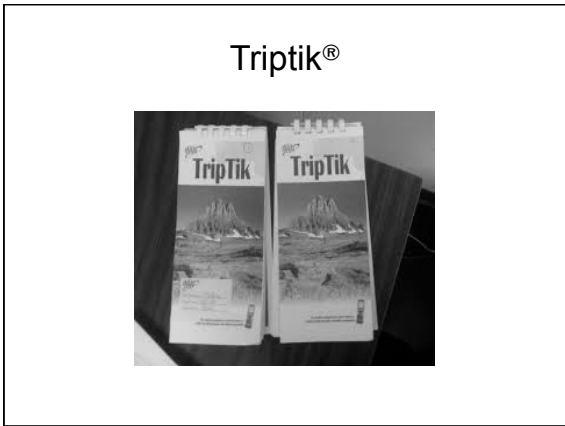
Challenges and Opportunities

- Embed quality metrics into clinical pathways so that data can be collected as part of routine work
 - Feedback data and make it visible
- Adopt and monitor “balancing measures”
 - The pneumonia treatment core metric

A Useful Analogy? – Getting from A to B with Stops along the Way

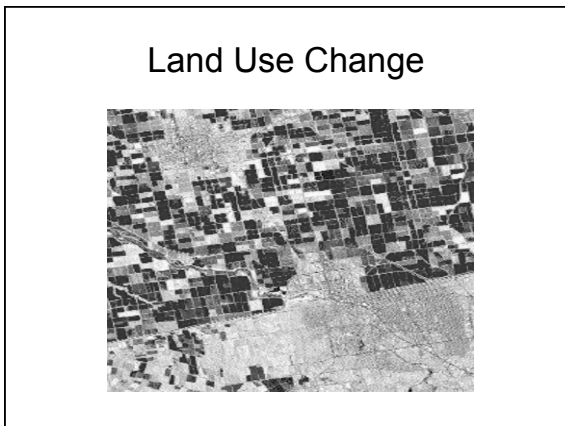
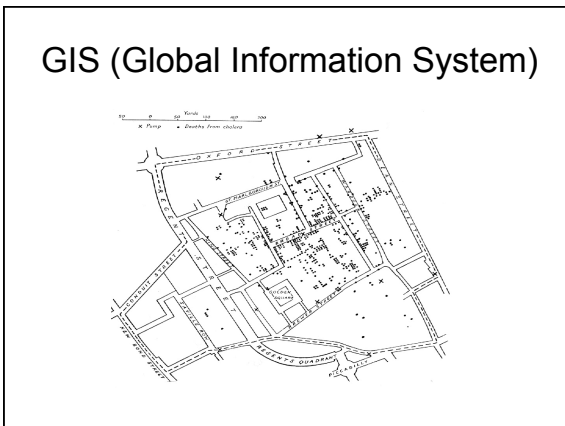
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Which is Better?
 What Would Make Both of Them Better?

- Real time “hot links” (Memphis-style barbecue)
- Real time feedback (potholes, accidents, traffic – some of this happens already)
- Learning from drivers who took another route



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Innovating at the Front Line

- Harvest intrinsic motivation
- Carve out and protect time
- Provide financial support
 - Most innovative industries spend >5% on innovation
- Provide support from a central R&D/innovation team
 - RAs
 - Qualitative and ethnographic methods
 - Behavioral science
 - Economics
 - Systems engineering

Innovating at the Front Line

- Tolerate risk
 - Fail frequently, quickly, and well
 - “Culture of safety”
 - Build trust
- Celebrate and reward success
- “Not invented here” mentality

Innovating at the Front Line

- Noticing, testing, adopting and rewarding disruptive innovation
- Promoting and celebrating positive deviance
- Respecting those quirky folks with strange ideas

Learning at the Front Line – The Power of Close Observation



Carolingian Church – Einshardsbasilika, 824-827



St. Georg Reichenau, 900

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Caen, Abbaye aux Dames, 1062-c.1115



Notre Dame, Paris, 1163-1345



Salisbury Cathedral, 1220-1258



Amiens, 1220-1288



Church of Santa Monica, Madrid



The Church of Brasilia

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St. Michael weighing souls - Autun



Angels lifting souls into heaven
Autun

Demons pushing souls into hell
Autun

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February 8 Behavioural Change in Infection Prevention and Control , Prof. Andreas Voss	Clean Care is Safer Care
March 7 Achievements in Improving Injection Safety Worldwide , Dr. Selma Khamassi	August 8 Processing Medical Devices in Settings with Limited Resources , Dr. Nizam Damani
April 17 Implementing Change: The Technical & Socio-Adaptive Aspects of Preventing Catheter-Associated Urinary Tract Infection , Prof. Sanjay Saint	September 5 Successes and Challenges in Developing and Implementing Bundles in Infection Prevention , Prof. Don Goldmann
May 7 Keeping the Hand Hygiene Agenda Alive: Acting on Data and the Influence of Global Surveys , Prof. Didier Pittet	October 2 The Role of Education in Low and Middle Income Countries , Prof. Shaheen Mehtar
June 6 Economic Impact of Healthcare-Associated Infections in Low and Middle Income Countries , Dr. A. Nevzat Yalcin	November 7 Measuring Impact: Key to Infection Control Scale-Up and Sustainability , Prof. Jacqui Reilly
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