Reliability, Care Bundles, and Behavior Change

Don Goldmann, M.D.
Senior Vice President
Institute for Healthcare Improvement
Professor of Pediatrics
Harvard Medical School
Methicillin (oxacillin)-resistant *Staphylococcus aureus* (MRSA) Among ICU Patients, 1995-2004

Source: National Nosocomial Infections Surveillance (NNIS) System
Methicillin-resistant *Staphylococcus aureus* in Europe, 1999–2002

![Graph showing MRSA proportion per hospital and mean MRSA proportion in country for various countries in Europe.](image-url)
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
What Can We Learn from the Experience of Other Countries?

• Dutch (Northern European) “search and destroy”
  – All patients with MRSA isolated in private rooms
  – Patients from foreign hospitals, suspected MRSA carriers screened (nose, throat, perineum, sputum, urine, wound); quarantined until –
  – If patient +, healthcare workers and roommates screened
  – Positive patients, healthcare workers decolonized with mupirocin and chlorhexidine (90% success, but 25-50% recolonized 3-6 months)
    • New agents being developed
  – 1 patient or healthcare worker colonized with same strain as index patient, ward closed, + healthcare workers sent home, patients isolated/cohorted
  – Advance warning if colonized patient transferred to another hospital

• How applicable is this approach once MRSA is highly endemic?
“Search and Destroy”
Society of Healthcare Epidemiology of America Guideline

• Screening on admission for “high risk” patients (principally nose)
  – Real-time PCR tests quite promising
• Weekly screening for “high risk” patients (specific wards, long-term antibiotics, long stay, underlying diseases)
• Facility-wide screening if “high” rates of MRSA
• Isolate/cohort colonized patients (contact +/- masks)
  – But be careful – these patients tend to be colonized with other resistant organisms!
• “Consider” eradication of colonization, but not if endemic
• Flag colonized patients
• Antibiotic stewardship
Key Strategies

• Improve reliability of basic procedures
  – “Defect rates” of 60-80% are not tolerable
    • Screening cultures
    • Isolation Procedures
    • Hand hygiene
Clean hospitals are important but not sufficient!

Lack of isolation beds or space for cohorting is no excuse!
Tip

- A large portion of the CDC and NHS goals to reduce MRSA bloodstream infections by 50% can be achieved by reducing central venous catheter infections
  - VAP reduction would be a plus
- But this will never be achieved given current defect rates in CVC and ventilator care
Reliability Science

• Health care is riddled with defects
  – 40% compliance with hand hygiene!!??
  – What happens at Intel…..

• 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: Treatment of Pneumonia in Medicare Patients

• **COMPONENT:** 63.1% receive first dose of antibiotics within four hours of hospital arrival
• **COMPONENT:** 67.9% receive an antibiotic choice consistent with current guidelines
• **COMPONENT:** 81% have blood cultures collected before treatment
• **COMPOSITE:** 26% get all three of these
Reliability is failure free operation over time from the viewpoint of the patient
Defects in outpatient CHF care

Defects in hospital care

Acute CHF

Admission through discharge

Defects in outpatient care

Defect free care overtime from the patient’s viewpoint
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
10⁻¹ Performance
Intent, Vigilance and Hard Work

• Exhortation to work harder
• Awareness, education and training
• Audit and feedback of compliance data
• Common equipment, standard order sheets, multiple choice protocols, and written policies/procedures
• Personal check lists
10⁻² Performance Emphasis on Systems

- Design sophisticated failure prevention, identification, and mitigation systems
  - Decision aids and reminders built into the system
  - Desired action the default (based on evidence)
  - Redundant processes
  - Taking advantage of habits and patterns
  - Standardization of process based on clear specification and articulation
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 bundles, but performance drops dramatically with “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 bundle)
“Defect rates” of 60-80% are not tolerable
Raising the Bar

• Will, ideas, and execution
  – Establish the will to go beyond “we are doing OK” performance
  – Set aims that raise the bar, reaching beyond what has been achieved in health care thus far
  – Measure performance at this higher level
  – Develop and test changes that can bring an organization to a new level of performance
  – Learn from the changes and spread the benefits to the entire organization
Applying Reliability Science, Hazard Analysis, Evidence, and Quality Improvement to Dramatically Reducing Central Venous Catheter Infections
Guidelines v. Bundles

• 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
Hazard Analysis and Critical Control Point (HACCP)  
*aka* Failure Mode and Effects Analysis

- Originally a system that for identifying and monitoring specific foodborne hazards that can adversely affect 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
Hazard Analysis Process

For each step in the flow diagram, ask a series of questions appropriate to that step, such as:

- Are practice parameters clear?
- Are necessary supplies readily available?
- Is the system (both facility and equipment) designed so that correct actions are feasible?
- Are personnel adequately trained?
- Are personnel verified as competent in the procedure?
- Do personnel have the time to perform the task correctly?
- Can correct performance of the task be verified?
Then….

- Develop preventive measures at each critical control point
- Determine critical limit for each control point and develop routine monitoring plan
- Use QI methods to design corrective action when critical limit has been exceeded
Hazard Analysis:
Critical Control Points in CVC Care

- CVC insertion with hand hygiene and maximal barrier precautions
- Skin prep with 2% chlorhexidine (or other agent)
- Care of administration system connections and ports
  - Sterile field
  - Hub prep
  - Injection port prep
- D/C of lipids and catheters as soon as possible
CVC Bundle Elements

• 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 but FDA warning for neonates
Quality Improvement for Catheter Insertion

- Train all who will insert catheters and check competency
- Put all needed supplies in a standard, readily available pack on a cart
- Use a checklist to insure all components are completed correctly
- Empower nurse to stop procedure if mistakes are made (“matron’s charter”)
- Feed back data (e.g., days between CVL-associated infections) in graphic format
CVC Infections are not a right of passage

Dramatic improvement is possible

Some ICUs have gone months without a CVC infection (or a ventilator-acquired pneumonia)
Central line-associated bloodstream infection rate in 66 ICUs, Southwestern Pennsylvania, April 2001-March 2005

Centers for Disease control and Prevention.
Critical Control Points in Hand Hygiene and Barrier Technique

• Precautions followed when patient on isolation?
• Hand hygiene prior to initial patient contact?
• Gloves donned as per “standard” precautions?
• Hand hygiene before inserting/manipulating invasive device (e.g., IV catheter connection)?
  – Hand hygiene performed when going from contaminated to clear body site?
• Hand hygiene after gloves removed?
• Hand hygiene when leaving bedside?
  – Including after touching potentially contaminated objects or surfaces?
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 non-latex gloves
- Correct performance of hand hygiene
- Gloves worn for standard precautions
The behavioral change literature suggests that multi-faceted approaches have the best chance of succeeding...
Behavior Change Strategies

- Leadership endorsement, empowerment, facilitation
- Focused education
- Training, practice observation, and competency certification
- Workplace reminders (posters, emails, patients)
- Opinion leaders and role models
  - Model desired behaviors; make hand hygiene a “social norm”
  - Academic detailing using customized tool kits
  - Social marketing
Behavior Change Strategies

• Incentives and rewards (reinforcement)
• Self-efficacy - provide support to help staff develop confidence to make changes and experience the feasibility of change
• Enabling measures (alcohol-based hand rubs as an adjunct to sink-based handwashing)
• Engineering measures (strategic placement of alcohol-based hand rubs)
• Monitoring (audit) and real-time feedback – random audit checklist
New Approaches to CVC Infection in Dialysis

- Antimicrobial lock
  - Vancomycin
  - Taurolidine
  - Minocycline/EDTA
  - Gentamicin/Citrate (or heparin)
  - Ethanol
- Coated/impregnated catheters
- Mupirocin, lysostaphin and other topicals
New Approaches to Prevention -- Vaccines/Immunoglobulins

MSCRAMM polyclonal, monoclonal antibodies (Inhibitex)
- microbial surface components recognizing adhesive matrix molecules

- Anti-lipoteichoic acid (LTA) (Biosynexis)
- Anti-poly-N-acetyl glucosamine, PIA
  - Adhesin, capsular polysaccharide
  - Common to S. aureus and S. epidermidis
- C5, C8 capsular polysaccharide vaccine (NABI)
  - Just failed and studies discontinued
CA-MRSA
Reemergence of an Old Menace?

• Genotypic similarity to phage type 80/81a
  – Pandemic in the 1950s
  – Severe nursery outbreaks
• Strains of 80/81a from the 1950s/60s and contemporary CA-MRSA generally have Panton-Valentine Leukocidin (PVL) + genes for 17 other toxins and 16 superantigens
• CA-MRSA is “fitter” than nosocomial MRSA
  – Replicates faster
  – Makes bacteriocins to inhibit other skin flora
CA-MRSA Community Outbreaks

• Various settings
  – Sports participants: Football, wrestlers, fencers, rugby players
  – Prisons
  – Men who have sex with men
  – Military recruits
  – Daycare centers

• >70% of children presenting with staph infections to emergency departments in some U.S. cities have CA-MRSA

• Nosocomial CA-MRSA outbreaks now occurring
Vancomycin-Resistant Enterococci (VRE)

- The promiscuous vanA gene
  - Transposons
  - The fertile soil of the GI tract
  - Has spread to MRSA
- Environmental survival
- Aminoglycoside and beta-lactam resistance compounds the problem…
- Multiple selective pressures
  - Vancomycin
  - Cephalosporins
  - Metronidazole
- Mathematical models suggest infection control is key
Mathematical Models of Transmission of Antibiotic Resistant Bacteria Tell a Clear Tale for MRSA and VRE

• Transmission is related to the rate of introduction of patients colonized with resistant strains
  – Screen for colonization
• Transmission is related to the number of clinician-patient encounters
  – Have adequate nurse:patient ratio
• Antibiotic control has little value if barrier technique and hand hygiene compliance is not very high
  – Improve compliance dramatically
Key Strategies

• Know the MRSA burden in each hospital (colonization, not just infection)
  – Knowledge is a pre-requisite for informed discussion
  – This requires screening cultures
  – The problem often is greater than it seems