Case studies & How to Review

Outline for the evening:

• Case study #1 (CLASBI in Michigan – NEJM*)
• Short break?
• How to Review QI (JAMA paper*)
• Exercise (Spain Sepsis article*)
• Short break?
• Case study #2 (MICU Rehab – Arch PM&R*)

* In reading packet

Case Study –MHA Keystone Project

Reducing CRBSI in the ICU

Dale Needham, MD, PhD
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Pulmonary & Critical Care, and Physical Medicine & Rehabilitation
Johns Hopkins University
Medical Director, Critical Care Physical Medicine & Rehabilitation Program
Email: dale.needham@jhmi.edu and Twitter: @DrDaleNeedham
www.hopkinsmedicine.org/oacis
Catheter-Related Blood Stream Infection

Estimated CRBSI Cost in US: $2.3 Billion
Wenzel & Edmond, NEJM 2006; Pronovost et al NEJM 2006
Hopkins ICU as a Learning Lab

- Consistent with academic mission
- Develop interventions and evaluation
- Pilot test
- Package for broad use

Can One Institution Get to Zero?

Michigan Project Organization

- Keystone Center-MHA coordinated project
- Senior leader (VP) support at each hospital
- Centralized education & support from JHU
- MD & RN leader in each ICU
  - Bi-weekly conf call & bi-annual meetings with JHU
  - serve as trainers for their ICU
  - local engagement & project execution
- Partner with infection control staff to get data
- **No research funding to support ICU data collection**
  
  Funding for QI is 1% of funding for basic science & clinical research
Interventions in the Project

~3 mo. implementation period for each:
#1 CUSP: safety education & learning from defects
#2 Daily Goals Sheet: MD-RN communication in ICU

And then in any order:
• CRBSI Intervention
• VAP Intervention

For 18 mo. study period from 3/04 – 9/05, ICUs:
• rejected randomization; wanted control over timing
  – Conceded in order to achieve maximum participation in MI
• Joined project & started intervention at different times
• 46% started immediately & did not collect baseline data

Conducting a large scale, unfunded pragmatic study is like herding cats.

Key starting point

Model for Knowledge Translation

1. Summarize the evidence
   • Identify interventions associated with improved outcomes
   • Select interventions with the largest benefit and lowest barriers to use
   • Create interventions to behaviors

2. Identify local barriers to implementation:
   understand the process and context of work
   • Observe staff performing the interventions.
   • “Walk the process” to identify delays in each step of intervention implementation.
   • Encourage stakeholders to share concerns and identify potential gaps 
     or barriers associated with intervention implementation.

3. Measure performance
   • Select measures (process and/or outcome)
   • Develop and pilot new measures
   • Maintain baseline performance

4. Ensure all patients receive the interventions
   • Implement the “Four Es” targeting key stakeholders 
     • Establish goals for performance measures and minimum targets
   • Engage
   • Evaluate
   • Educate
   • Execute
   • Design an intervention “toolbox” targeted to barriers, employing 
     • Standardization, independent checks and reminders, and 
     • Learning team communications

JH QSRG TRIP Model: Stage 1

1. Summarize the evidence
- Identify interventions associated with improved outcomes
- Select interventions with the largest benefit and lowest barriers to use
- Convert interventions to behaviors

5 Key “Best Practices”

CDC Level 1A Recommendations
(strongly recommended & supported by well-designed studies)

- Wash Hands Prior to Procedure
- Use Maximal Barrier Precautions
- Clean Skin with Chlorhexidine
- Avoid Femoral Lines
- Remove Unnecessary Lines

No $ technology; no added staff; all behaviors

MMWR. 2002;51:No. RR-10, 1-36
JH QSRG TRIP Model: Stage 2

2. Identify local barriers to implementation: understand the process and context of work
   - Observe staff performing the interventions
   - “Walk the process” to identify defects in each step of intervention implementation
   - Enlist all stakeholders to share concerns and identify potential gains/losses associated with intervention implementation

This was done at local level

JH QSRG TRIP Model: Stage 3

3. Measure performance
   - Select measures (process and/or outcome)
   - Develop and pilot test measures
   - Measure baseline performance

- Primary performance measure: CRBSI rate
- CDC already defined how to measure CRBSI (numerator) and Catheter Line days (denominator) to get CRBSI rate
  - most hospitals have trained HEIC staff to measure
JH QSRG TRIP Model: Stage 4

4. Ensure all patients receive the interventions
   - Implement the “Four Es” targeting key stakeholders from front line staff to executives
   - **Engage**: Explain why the interventions are important
   - **Evaluate**: Regularly assess for performance measures and unintended consequences
   - **Educate**: Share the evidence supporting the interventions
   - **Execute**: Design an intervention “toolkit” targeted to barriers, employing standardization, independent checks and reminders, and learning from mistakes

Strategies for Implementing Best Practices

- **Engage**: stories, baseline data, calc. harm avoided at *their* ICU
- **Educate**: Summaries of evidence supporting best practice
  - Behaviors – what we should DO
- **Execute**: next pages
  - Convenience
  - Reminders
  - Enforce
- **Evaluate**: Feedback – monthly site-specific data via run charts
## Strategies for Implementation

- **Convenience**: line cart with all necessary supplies
- **Reminders**: checklist for insertion (next page) and daily goals sheet for removal

### Room: AM Shift

<table>
<thead>
<tr>
<th>Date:</th>
<th>Nurse initials:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator Weaning</td>
<td></td>
</tr>
<tr>
<td>- Wont to Ps</td>
<td></td>
</tr>
<tr>
<td>- Exclude if SBT tolerated</td>
<td></td>
</tr>
<tr>
<td>Sedation/Pain Mgt</td>
<td></td>
</tr>
<tr>
<td>- Keep sedation level @ ______</td>
<td></td>
</tr>
<tr>
<td>- Change level to</td>
<td></td>
</tr>
<tr>
<td>Glycemic control</td>
<td></td>
</tr>
<tr>
<td>- Adjust insulin regimen</td>
<td></td>
</tr>
<tr>
<td>- Nissle: Low Dose ⊗ Medium Dose ⊗ High Dose</td>
<td></td>
</tr>
<tr>
<td>- Infusion</td>
<td></td>
</tr>
<tr>
<td>- NPH</td>
<td></td>
</tr>
<tr>
<td>GI / Nutrition</td>
<td></td>
</tr>
<tr>
<td>- Advance Tube Feeds to _____ cc/hr</td>
<td></td>
</tr>
<tr>
<td>- NPO for _____ (check insulin use)</td>
<td></td>
</tr>
<tr>
<td>- SLP consult today ⊗ PESS consult</td>
<td></td>
</tr>
<tr>
<td>I.D.</td>
<td></td>
</tr>
<tr>
<td>- Line placement today? ⊗ Yes ⊗ No</td>
<td></td>
</tr>
</tbody>
</table>

### Checklist

- **Before the procedure, did the operator:**
  - Obtain informed consent
  - Obtain supervision if needed (see roles above)
  - Perform a time-out briefing
  - Confirm hand washing/sanitizing immediately prior

- **Operator(s):** cap, mask, sterile gown/gloves, eye protection

<table>
<thead>
<tr>
<th>Critical Steps</th>
<th>Yes</th>
<th>Yes with reminder</th>
<th>Procedure Deviation: Complete PSN report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile gown/gloves, eye protection</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Sterile cap, mask, sterile gown/gloves, eye protection of all staff</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Proper gloves</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Sterile gown, gown, and/or mask</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Protective eyewear</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Operating equipment</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Procedure deviation: Complete PSN report</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
</tbody>
</table>
Strategies for Implementation

• Convenience: line cart with all necessary supplies

• Reminders: checklist for insertion; daily goals for removal

• Enforce: empower nurses to stop takeoff; letter to CEO re: stocking chlorhexidine within 6 weeks, 19% -> 67% of hospitals had chlorhexidine for central line insertion in ICU

Results - Participants

• 67 hospitals with 103 ICUs
  – 1625 ICU beds: 85% of ICU beds in MI
  – Non-participating hospitals were generally very small with limited ICU services
  – ~50% of hospitals were non-teaching
  – All types of ICUs: med, surg, CV, neuro, peds

• ~2,000 ICU-months, >375,000 catheter-days
Results – CRBSI Rates

Median (mean) overall CRBSI rates:

• Baseline: 2.7 (7.7) per 1000 catheter-days
• 0-3 mo.: 0* (2.3)  
  …sustained at median of 0* to end of study…
• 16-18 mo. 0* (1.4)

* p<0.002 for comparison with baseline

Similar for teaching v. non-teaching & small v. non-small (>200 bed)

Results – % Reduction in CRBSI

Using multi-level Poisson regression, reduction in CRBSI rates from baseline:

• 0-3 mo.: 38%* reduction
  …steadily increasing reduction in CRBSI rate until study end …
• 16-18 mo. 66%* reduction

* p<0.001 for comparison with baseline

Hospital teaching status & bed size:

• not independently associated with CRBSI rate
• did not have an important effect on the effectiveness of the intervention
For those who like *all* the numbers…

<table>
<thead>
<tr>
<th>Time period</th>
<th>(No. ICU)</th>
<th>Median rate (IQR)</th>
<th>Incidence rate ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>(55)</td>
<td>2.7 (0.6 – 4.8)</td>
<td>Reference</td>
</tr>
<tr>
<td>Peri-intervention</td>
<td>(96)</td>
<td>1.6 (0 – 4.4)</td>
<td>0.76 (0.57 -1.01)</td>
</tr>
<tr>
<td>0-3 months</td>
<td>(96)</td>
<td>0 (0 – 3.0)</td>
<td>0.62 (0.47 – 0.81)</td>
</tr>
<tr>
<td>4-6 months</td>
<td>(96)</td>
<td>0 (0 – 2.7)</td>
<td>0.56 (0.38 – 0.84)</td>
</tr>
<tr>
<td>7-9 months</td>
<td>(96)</td>
<td>0 (0 – 2.1)</td>
<td>0.47 (0.34 – 0.65)</td>
</tr>
<tr>
<td>10-12 months</td>
<td>(95)</td>
<td>0 (0 – 1.9)</td>
<td>0.42 (0.28 – 0.63)</td>
</tr>
<tr>
<td>13-15 months</td>
<td>(85)</td>
<td>0 (0 – 1.6)</td>
<td>0.37 (0.20 – 0.68)</td>
</tr>
<tr>
<td>16-18 months</td>
<td>(70)</td>
<td>0 (0 – 2.4)</td>
<td>0.34 (0.23 – 0.50)</td>
</tr>
</tbody>
</table>

Sensitivity analysis of only ICUs with continuous data from baseline onward:
IRR 0-3 mo. 0.62 (0.46 – 0.85) to 16-18 mo. 0.15 (0.07 – 0.32)

Potential Impact

Before project, 695 CRBSI at participants

Intervention: 38-66% reduction over 18 mo.

Cost: $12,000 - $54,000 per CRBSI

Benefit: 122 lives saved; $10 million/year
(assume 50% decr in BSI; 35% attributable mortality & $30k/CRBSI)

O’Grady MMWR 2002;51(RR-10):1-29
Warren Crit Care Med 2006;34:2084-9
Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study

<table>
<thead>
<tr>
<th>Study period</th>
<th>No of ICUs</th>
<th>Median (IQR) No of infections</th>
<th>Infection rate</th>
<th>Incidence rate ratio* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-21 months</td>
<td>89</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
<td>0.74 (0.63 to 0.88)</td>
</tr>
<tr>
<td>22-24 months</td>
<td>89</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
<td>0.67 (0.55 to 0.81)</td>
</tr>
<tr>
<td>25-27 months</td>
<td>88</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
<td>0.66 (0.54 to 0.81)</td>
</tr>
<tr>
<td>28-30 months</td>
<td>90</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
<td>0.66 (0.54 to 0.81)</td>
</tr>
<tr>
<td>31-33 months</td>
<td>88</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
<td>0.66 (0.54 to 0.81)</td>
</tr>
<tr>
<td>34-36 months</td>
<td>85</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
<td>0.66 (0.54 to 0.81)</td>
</tr>
</tbody>
</table>

IQR=intertuquartile range.

Catheter related bloodstream infections rate over time after implementation.
Impact of a statewide intensive care unit quality improvement initiative on hospital mortality and length of stay: retrospective comparative analysis

Alison Lipitz-Snyderman, postdoctoral fellow; *Donald Steinwachs, professor;  †Dale M Needham, associate professor;  ‡Elizabeth Colantuoni, assistant scientist;  §Laura L. Monroe, professor;  ¶Pearl J. Shinovest, professor

**Design** Retrospective comparative study, using data from Medicare claims.

**Setting** Michigan and Midwest region, United States.

**Population** The study period (October 2001 to December 2006) spanned two years before the project was initiated to 22 months after its implementation. The study sample included hospital admissions for patients treated in 95 study hospitals in Michigan (238,937 total admissions) compared with 364 hospitals in the surrounding Midwest region (1,091,547 total admissions).

### Table 3: Adjusted odds ratios for mortality in Michigan hospitals and comparison hospitals

<table>
<thead>
<tr>
<th>Study period</th>
<th>Adjusted odds ratio* (95% CI)</th>
<th>Study group comparison group</th>
<th>P value†</th>
<th>Wald test‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-implementation</td>
<td>0.98 (0.94 to 1.01)</td>
<td>0.94 (0.95 to 0.98)</td>
<td>0.373</td>
<td>—</td>
</tr>
<tr>
<td>Project initiation</td>
<td>0.97 (0.92 to 1.01)</td>
<td>0.97 (0.94 to 0.99)</td>
<td>0.981</td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>0.90 (0.86 to 0.93)</td>
<td>0.91 (0.89 to 0.93)</td>
<td>0.513</td>
<td></td>
</tr>
<tr>
<td>Post-Implementation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-12 months</td>
<td>0.83 (0.79 to 0.87)</td>
<td>0.88 (0.85 to 0.90)</td>
<td>0.041</td>
<td></td>
</tr>
<tr>
<td>13-24 months</td>
<td>0.76 (0.72 to 0.81)</td>
<td>0.84 (0.81 to 0.86)</td>
<td>0.007</td>
<td></td>
</tr>
</tbody>
</table>

*Adjusted odds ratios compare odds of death for period of interest to each group’s baseline period and were calculated using logistic regression analysis. Analyses were adjusted for age, sex, race, primary diagnosis (using Healthcare Cost and Utilization Project clinical classification level 1 categories), Charlson-Deyo comorbidities, time of discharge, hospital bed size, hospital teaching and urban status, hospital ownership, with generalised estimating equations with robust variance estimation to adjust for clustering of patient admissions within hospitals.

†P values for test of equality of study and comparison group effects were obtained from interaction terms for group by implementation and two post-implementation periods.
Limitations

Not cluster randomized clinical trial
- Study design not accepted by ICUs
  - ICUs wanted control over timing of implementation
  - Used dif. study design to maximize participation

However, support for casual-effect:
- Temporal trends less likely to explain effect
  - staggered implementation over 1 year with 18 mo. f/u
  - no large decrease in CRBSI rate elsewhere in USA
- Improvements were sustained
  - Growing benefit with prolonged exposure to intervention

... subsequent support for cause-effect (2 papers)...

A multicenter, phased, cluster-randomized controlled trial to reduce central line-associated bloodstream infections in intensive care units*

Jill A. Marsteller, PhD, MPP; J. Bryan Sexton, PhD; Yea-Jen Hsu, PhD, MHA; Chunju Huo, PhD, MHS; Christine G. Holzmueller, BLA; Peter J. Pronovost, MD, PhD, FCCM; David A. Thompson, DNSc, MS, RN

Objectives: To determine the causal effects of an intervention proven effective in one past study in reducing central line-associated infection rate declined to 1.33 in the intervention group compared to 2.16 in the control group (adjusted incidence rate ratio 0.19; \( p = .003 \); 95% confidence interval 0.06–0.57).

Setting: Forty-five intensive care units from two hospitals in two Adventist healthcare systems.

Intervention: A multifaceted intervention involving evidence-based practices to prevent central line-associated bloodstream infections and the Comprehensive Unit-based Safety Program to improve safety, teamwork, and communication.

Measurements and Results: We measured central line-associated bloodstream infections per 1,000 central line days and reported quarterly rates. Baseline average central line-associated bloodstream infections per 1,000 central line days was 4.48 and 2.71, for the intervention and control groups, respectively. By October 2011, the infection rate declined to 1.33 in the intervention group compared to 2.16 in the control group (adjusted incidence rate ratio 0.19; \( p = .003 \); 95% confidence interval 0.06–0.57).
Prevention of hospital infections by intervention and training (PROHIBIT): results of a pan-European cluster-randomized multicenter study to reduce central venous catheter-related bloodstream infections

Tjallie van der Kooi, Hugo Sax, Didier Pittet, Jaap van Dissel, Birgit van Benthem1, Bernhard Walder4

Abstract

Purpose: To test the effectiveness of a central venous catheter (CVC) insertion strategy and a hand hygiene (HH) improvement strategy to prevent central venous catheter-related bloodstream infections (CRBSI) in European intensive care units (ICUs), measuring both process and outcome indicators.

Methods: Adult ICUs from 14 hospitals in 11 European countries participated in this stepped wedge cluster randomized study. 25,348 patients with 35,831 CVCs were included. CRBSI incidence density decreased from 2.4/1000 CVC-days at baseline to 0.9/1000 (p < 0.0001). When adjusted for patient and CVC characteristics all three interventions significantly reduced CRBSI incidence density.

Conclusions: This study demonstrates that multimodal prevention strategies aiming at improving CVC insertion practice and HH reduce CRBSI in diverse European ICUs. Compliance explained CRBSI reduction and future quality improvement studies should encourage measuring process indicators.

Keywords: Catheter-related bloodstream infection, Bundle, Hand hygiene, Europe, Multicentre, PROHIBIT, Behavioural change, Multimodal strategy

Limitations

- Could not evaluate effect of individual components of intervention
- Could not evaluate compliance with intervention
- No CRBSI data from non-participating ICUs in MI
- 30 of 103 (29%) of ICUs did not report complete data
  - missing data for 5% of 2,216 potential ICU months

Unfunded pragmatic studies must have feasible data collection