ELIMINATION OF SSI: USING SCIENCE TO OVERCOME BARRIERS AND BEHAVIOR

DEVERICK J. ANDERSON, MD, MPH, FIDSA, FSHEA
DIRECTOR, DUKE CENTER FOR ANTIMICROBIAL STEWARDSHIP AND INFECTION PREVENTION
WILLIAM A. RUTALA RETIREMENT SYMPOSIUM – APRIL 28, 2017
Disclosures

Grant funding
- AHRQ, NIH, CDC

Royalties
- UpToDate, Online
General Outline

Review of SSI
- Why is SSI important?
- Pathophysiology

Discuss 3 strategies to eliminate SSI
Review - Outcomes

Occurs following 2-5% of surgical procedures

Since 16 to 20 million procedures are performed each year:
- 300,000 to 1 million SSIs each year

SSIs lead to adverse patient outcomes
- Longer hospitalization
- Longer time in ICU
- Morbidity such as disability
- Increased risk of death

SSIs lead to adverse outcomes for healthcare
- $3.5 to $10 billion annually

www.cdc.gov/nhsn/pdfs; Anderson et al ICHE 2014
Review – Epidemiology

Most common and most costly HAI

- 38% of HAIs

Recent trends?

- SCIP let to improved adherence to performance measures
- Compared to 2008 baseline, NHSN data (2014) demonstrated 17% decrease in SSI
- Community hospitals had 10% decrease in SSI from 2008 to 2012
- BUT, progress may have stagnated
  - 5% increase in COLO SSI from 2013 to 2014

# Review – Common Organisms

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>CABG</th>
<th>Arthroplasty</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>Rank</td>
<td>No. (%)</td>
</tr>
<tr>
<td>Staphylococcus aureus*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Methicillin-sensitive S. aureus</td>
<td>616 (19)</td>
<td>1</td>
<td>904 (28)</td>
</tr>
<tr>
<td>- Methicillin-resistant S. aureus</td>
<td>550 (17)</td>
<td>3</td>
<td>634 (19)</td>
</tr>
<tr>
<td>Coagulase-negative staphylococci</td>
<td>573 (17)</td>
<td>2</td>
<td>512 (16)</td>
</tr>
<tr>
<td>Enterococcus species</td>
<td>193 (6)</td>
<td>6</td>
<td>240 (7)</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>223 (7)</td>
<td>4</td>
<td>116 (4)</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>197 (6)</td>
<td>5</td>
<td>117 (4)</td>
</tr>
<tr>
<td>Streptococcus species</td>
<td>66 (2)</td>
<td>11</td>
<td>212 (7)</td>
</tr>
<tr>
<td>Enterobacter species</td>
<td>142 (4)</td>
<td>8</td>
<td>88 (3)</td>
</tr>
<tr>
<td>Proteus species</td>
<td>131 (4)</td>
<td>10</td>
<td>75 (2)</td>
</tr>
<tr>
<td>Klebsiella pneumoniae, Klebsiella oxytoca</td>
<td>144 (4)</td>
<td>7</td>
<td>53 (2)</td>
</tr>
<tr>
<td>Serratia species</td>
<td>137 (4)</td>
<td>9</td>
<td>47 (1)</td>
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<tr>
<td>Candida albicans</td>
<td>52 (2)</td>
<td>12</td>
<td>6 (0)</td>
</tr>
<tr>
<td>Acinetobacter baumannii</td>
<td>29 (1)</td>
<td>13</td>
<td>23 (1)</td>
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<tr>
<td>Other Candida species or NOS</td>
<td>14 (0)</td>
<td>14</td>
<td>5 (0)</td>
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<tr>
<td>Other*</td>
<td>226 (7)</td>
<td>15</td>
<td>197 (6)</td>
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<tr>
<td>Total</td>
<td>3,316 (100)</td>
<td></td>
<td>3,258 (100)</td>
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</table>

## Organism

<table>
<thead>
<tr>
<th>Organism</th>
<th>No. (%)</th>
<th>(n = 3,988)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus*</td>
<td>1,357 (34)</td>
<td></td>
</tr>
<tr>
<td>MSSA</td>
<td>683 (17)</td>
<td></td>
</tr>
<tr>
<td>MRSA</td>
<td>674 (17)</td>
<td></td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>482 (12)</td>
<td></td>
</tr>
<tr>
<td>Enterococcus spp.</td>
<td>467 (12)</td>
<td></td>
</tr>
<tr>
<td>Coagulase-negative staphylococci</td>
<td>340 (9)</td>
<td></td>
</tr>
<tr>
<td>Klebsiella spp.</td>
<td>246 (6)</td>
<td></td>
</tr>
<tr>
<td>Streptococcus spp.</td>
<td>242 (6)</td>
<td></td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>168 (4)</td>
<td></td>
</tr>
<tr>
<td>Enterobacter spp.</td>
<td>161 (4)</td>
<td></td>
</tr>
<tr>
<td>Fungi</td>
<td>121 (3)</td>
<td></td>
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<tr>
<td>Polymicrobial*</td>
<td>787 (20)</td>
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</tr>
<tr>
<td>No pathogen identified*</td>
<td>566 (14)</td>
<td></td>
</tr>
</tbody>
</table>

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Review – Pathophysiology

Microbial Characteristics
- Amount of contamination
- Virulence

Surgical Characteristics
- Foreign material
- Tissue damage

Patient Characteristics
- Immune status
- DM, others

Risk of SSI

Duke Center for Antimicrobial Stewardship and Infection Prevention
### Risk factor

<table>
<thead>
<tr>
<th>Intrinsic, patient related (preoperative)</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unmodifiable</strong></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>History of radiation</td>
<td></td>
</tr>
<tr>
<td>History of SSTIs</td>
<td></td>
</tr>
<tr>
<td><strong>Modifiable</strong></td>
<td></td>
</tr>
<tr>
<td>Glucose control</td>
<td></td>
</tr>
<tr>
<td>Control serum blood glucose levels for all surgical patients including patients without diabetes. For patients with diabetes mellitus, reduce glycosylated hemoglobin A1c levels to less than 7% before surgery, if possible. Increase dosing of prophylactic antimicrobial agent for morbidly obese patients. Encourage smoking cessation within 30 days of procedure. Avoid immune suppressive medications perioperatively, if possible. No formal recommendation. Although a noted risk factor, do not delay surgery for use of TPN.</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td></td>
</tr>
<tr>
<td>Smoking cessation</td>
<td></td>
</tr>
<tr>
<td>Intravenous medications</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
</tr>
</tbody>
</table>

**Extrinsic, procedure related (perioperative)**

| Preparation of patient                      |                   |
| Preoperative infections                     | Do not remove unless hair will interfere with the operation. If hair removal is necessary, remove outside the OR by clipping. Do not use razors.
| Operative characteristics                   |                   |
| Surgical scrub (surgical team members’ hands and forearms) | Use appropriate antiseptic agent to perform preoperative surgical scrub. For most products, scrub the hands and forearms for 2-5 minutes. |
| Skin preparation                           | Wash and clean skin around incision site. Use a sterile agent skin preparation containing alcohol, unless contraindications exist. |
| Antimicrobial prophylaxis                   | Administration only when indicated. Administer within 1 hour of incision to maximize tissue concentration. Blood transfusions increase the risk of SSI by decreasing macrophage function. Reduce blood loss and need for blood transfusion to the greatest extent possible. Select appropriate agents on the basis of surgical procedure, most common pathogens causing SSI for a specific procedure, and published recommendations. Stop agent within 24 hours after the procedure for all procedures. Handle tissue carefully and eradicate dead space. All members of the operative team should double glove and change gloves when perturbation is noted. Adhere to standard practices for OR asepsis. |
| Duration of prophylaxis                     |                   |
| Surgeon skill/technique                    |                   |
| Appropriate gloving                        |                   |
| Olfactory                                  |                   |

**Olfactory characteristics**

| Ventilation                               |                   |
| Traffic                                   |                   |
| Environmental stress                      |                   |
| Sterilization of surgical equipment       |                   |

Duke Center for Antimicrobial Stewardship and Infection Prevention

Anderson et al. ICHE 2014;35:605-627.
Risk Factors – Framework for Prevention

- Age
- Radiation
- Infection
- DM
- Obesity
- Smoking
- Nutrition

Pre-Op

Pre-Op Holding

Surgical Procedure

Post-Op Day 1

Post-Op

Peri-Op

- Hair
- Skin prep
- Surgeon prep
- AMP

- Hypoxemia
- Duration
- Hypothermia
- Transfusion

- Environment
- Sterile equip
- OR Traffic
- Technique

- Wound care
- DM
- Transfusion

Duke Center for Antimicrobial Stewardship and Infection Prevention
Quiz #1 – How frequently are wounds contaminated with bacteria during surgery?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2%</td>
<td>50%</td>
</tr>
<tr>
<td>15%</td>
<td>75%</td>
</tr>
<tr>
<td>40%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Wound Contamination is Universal

Antiseptics and antibiotics cannot eliminate all bacteria
- 20% of bacterial skin flora “hide” in skin appendages (e.g., sebaceous glands, hair follicles, sweat glands)

Experiments using human albumin microspheres prove that 100% of wounds are contaminated with particles from the patient
- Endogenous contamination

All surgical wounds are contaminated during the procedure
- Largest contamination at time of incision
- Wound contamination increases as the procedure progresses
- Contamination comes from the patient

IS THERE SOME WAY TO USE UNIVERSAL CONTAMINATION TO PROTECT AGAINST SSI?
STRATEGY 1 – CUTANEOUS MICROBIOME
Human Microbiome - What is it?

Community of microorganisms that share a location on the body

A few facts for you:
- By some estimates, the average human has ~3 pounds of bacteria in/out/on their body
- Microbial cells outnumber human cells 10:1
- Significant variation between individual people
- Important part of your health
- Dynamic – changes from infancy to old age
  - Higher level (phylum) taxonomic features display temporal stability at specific anatomic sites

The newest organ?

Description is based on DNA sequencing
Composition Depends on Location

Starts from Birth

Changes Over Time

Diet (your bacteria are what you eat)
- Meat predominant
  - Increased bile-tolerant bacteria (Alistipes, Bilophila, and Bacteroides)
  - Decreased Firmicutes
- Foodborne microbes from both diets transiently colonized the gut

Impact of lifestyle – some events can drastically change microbiome
- 10,000 longitudinal measurements of human wellness from 2 people over a year
- Microbial communities generally stable but abrupt changes evident
  - Travel
  - Enteric infection (Salmonella)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Disruption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psoriasis</td>
<td>Increased ratio of Firmicutes to Actinobacteria</td>
</tr>
<tr>
<td>Reflux esophagitis</td>
<td>Esophageal microbiota dominated by gram-negative anaerobes</td>
</tr>
<tr>
<td></td>
<td>Gastric microbiota with low or absent <em>H. pylori</em></td>
</tr>
<tr>
<td>Obesity</td>
<td>Reduced ratio of Bacteroidetes to Firmicutes</td>
</tr>
<tr>
<td>Childhood-onset asthma</td>
<td>Absent gastric <em>H. pylori</em> (especially cytotoxin-associated gene (cagA) genotype)</td>
</tr>
<tr>
<td>IBD</td>
<td>Increased Enterobacteriaceae</td>
</tr>
<tr>
<td>Functional bowel disease</td>
<td>Increased Veillonella and Lactobacillus</td>
</tr>
<tr>
<td>Colorectal carcinoma</td>
<td>Increased Fusobacterium spp.</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>Gut microbiota-dependent metabolism of phosphatidylcholine</td>
</tr>
<tr>
<td><em>C. difficile</em> colitis</td>
<td>Decreased Firmicutes and Bacteroidetes, increased Proteobacteria</td>
</tr>
</tbody>
</table>

Modify the Microbiome to Improve Health

Perhaps a future component of “Precision Medicine” or “Personalized Medicine”?  
- Cancer therapy based on genomic tests  
  - Classify subpopulations of patients that differ in susceptibility or response to disease or treatment  
  - Change to “of microbiome”?  

Right now, modifying with broad strokes  
- FMT for recurrent C. difficile
More Precise Manipulation

Use nontoxigenic *C. difficile* (NTCD-M3) to prevent *C. difficile* infection
- Phase 2, RCT, double-blind, placebo-controlled
- 173 patients enrolled, 157 completed therapy

Decrease in 6 week recurrence, particularly if remained colonized

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<table>
<thead>
<tr>
<th>Events in Intention-to-Treat Safety Population</th>
<th>Placebo (n = 43)</th>
<th>NTCD-M3 Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDI recurrence, No. (%)</td>
<td>13 (30)</td>
<td></td>
</tr>
<tr>
<td>Unadjusted comparison with placebo, P value*</td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td>Adjusted comparison with placebo*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odds ratio (95% CI)</td>
<td>0.4 (0.1-1.2)</td>
<td>0.1 (0.0-0.6)</td>
</tr>
<tr>
<td>P value</td>
<td>.11</td>
<td>.01</td>
</tr>
</tbody>
</table>

Gerding et al. JAMA 2015;313:1719.
Cutaneous Microbiome and Infection

Cutaneous microbiome is diverse

Surprisingly few studies on the impact of antibiotics

Disruptions lead to risk of infection

- Case-control study
  - 25 patients with skin abscess
  - 25 matched controls
- Cutaneous microbiome of patients with infection was different than uninfected controls, particularly if received antibiotic therapy BEFORE abscess
  - Decreased diversity
  - Increased metabolic markers

Horton et al. JID 2015;211:1895.
Cutaneous Microbiome and Infection

Horton et al. JID 2015;211:1895.
How Translate to SSI Elimination?

Contamination is universal, so use to our benefit

Microbiome-precision medicine

Screen cutaneous microbiome composition

- If not “acceptable”
  - Eliminate or decrease pathogenic organisms
  - Increase (or add) “helpful” (non-pathogenic) organisms
STRATEGY 2
QUIZ #2 – BIGGEST Risk Factor?

- Age
- Obesity
- DM
- Smoking
- Hair removal
- Skin prep

- AMP
- Hypoxemia
- Hypothermia
- Sterile equipment
- Surgeon technique
- Wound care
Technique = Holy Grail of SSI Prevention

Believed to be the most important aspect of SSI prevention

Why important for SSI?
- Duration
- Tissue handling/trauma/dead space
- Hemostasis/hematomas
- Tissue debridement/necrosis/hypoxemia

Inevitable that some surgeons are better than others

No way to study “technique”
- No controlled experiments

Some studies on specific components, but not convincing evidence
- Diathermy vs. scalpel
- Suture technique

Technique Matters – Indirect Evidence

Surgeons who perform fewer procedures typically have worse outcomes
- 4552 patients with traumatic femoral fx
- 10 hospitals
- Decreased rates in
  - High volume hospitals
  - Trauma surgeons (vs. general surgeons)

Hospitals that perform fewer procedures typically have worse outcomes
- 18 hospitals
- Small hospitals (<1500 procedures/yr) had worse rates of SSI

Emergence of “Centers of Excellence”
- Movement of complicated care to specific locations

SO HOW CAN WE MAKE SYSTEMATIC IMPROVEMENT IN SURGICAL TECHNIQUE?
STRATEGY 2 - ROBOTIC-ASSISTED SURGERY
What is it?
What is it?

Computer-controlled device that can be programmed to aid in the positioning and manipulation of instruments
- 3-dimensional camera system
- Better ergonomics
- Expensive, but increasing used

Minimally invasive technique

Strategy increasingly used in multiple types of surgery
- Colorectal, ENT, urologic, CT, breast, GYN, thyroid

Associated with better patient outcomes and satisfaction
- Decreased pain
- Less blood loss
- Shorter recovery time
- Shorter hospitalization
Different Functions

PASSIVE

Autonomous
- Pre-programmed movements

Supervisory
- Positioning system

ACTIVE

Immersive

Haptics (tactile feedback)
- Learn visual cues

Teleoperated - Not at the table

Telepresence - Not in the OR

Telestration - Teaching

Dual-console
- Multiple surgeons
Example 1

Lobectomy

Several methods of port placement can be utilized.

In general, place camera port approximately 15-20 cm away from surgical site.

In general, instrument ports (#s 1 & 2) must be a 8-10 cm away from the camera port.

Can setup the 4th arm (robot arm #3) to perform retraction.

Slides courtesy of Dr. Matthew Hartwig
Port Placement

Camera port placed in the 8th-9th intercostal space in the posterior axillary line.

One robot port placed one hands-breadth anteriorly in the 5th-6th intercostal space.

Second robot port placed one hands-breadth posteriorly and superiorly in approximately the seventh intercostal space.

12 step port placed between the anterior incision and the camera in the 8th-10th intercostal space.

Slides courtesy of Dr. Matthew Hartwig
System Position

Slides courtesy of Dr. Matthew Hartwig
Example 2

Robotic Thymectomy

Slides courtesy of Dr. Matthew Hartwig
Example 2

Robotic Thymectomy

- Position patient on edge of table
- Insert roll sub-scapularly to allow patient shoulder to drop.
- Arm of patient positioned below table in a sling.
- Roll table to provide proper exposure of chest wall (Approximately 30°)
- Bring Robot in from opposite side

Slides courtesy of Dr. Matthew Hartwig
Left Side Approach

Instrument Ports

Xiphoid Process

Sternal Notch

6th/7th ICS

2nd/3rd ICS

4th/5th ICS

6th/7th ICS

2nd/3rd ICS

4th/5th ICS

AAL

MCL

Slides courtesy of Dr. Matthew Hartwig
Impact on SSI?

First reports – NOT GOOD
- Rates of SSI actually higher with RAS
- Tertiary care center described first 273 uses – 16 (6%) SSIs
  - GU/Prostate – 5.7 vs. 0.85
  - GYN – 10 vs. 1.7
  - COLO – 33 vs. 6

Recent data suggests improves rates of SSI

Hermsen ED et al. ICHE 2010; 31:822.
Decreased SSI

Obese patients undergoing pancreaticoduodenectomy
- N=474 in cohort
- 70% lower rates of SSI (adjusted) and other improved outcomes

Case-control study of laparoscopic procedures
- 26 Robot vs. 23 conventional
- >50% reduction in SSI (unadjusted)

Radical prostatectomy
- N=5908
- 4824 retropubic
- 1084 RA radical prostatectomy
- 80% reduction in SSI (unadjusted)

Meta-analysis of technique for kidney transplant (n=18)
- Overall, minimally invasive techniques had lower rates of SSI
- RA kidney transplant rates practically zero

Decreased SSI

Cohort detailing the implementation of robotic colorectal surgery in a community hospital

- 41 patients with open COLO and 38 RCS
- Comparable patients

Robotic colorectal surgery took longer (222 vs. 141 min)
Hospital stay shorter after RCS (5.7 v. 6.7 days)
Significantly lower rates of SSI (11% vs. 29%, p=0.04)

Zawadzki M et al. Dig Surg 2017;epub ahead of print
How Translate to SSI Elimination?

Make surgical technique more systematic

Robotic approach can improve outcomes
  - More systematic approach to surgical technique
  - Less invasive
  - Ceiling is unknown (or ROOF?)

Barriers remain, but can be overcome
  - Learning curve
    - Additional training required (and credentialing?)
      - Both surgeons and nurses
  - No high quality data
  - Costs
STRATEGY 3
Risk Factors – Framework for Prevention

- Pre-Op
- Pre-Op Holding
- Surgical Procedure
- Post-Op Day 1
- Post-Op

Peri-Op
Additional (Important) Component
SENIC – Classic Study for IC

Series of publications
- Early risk adjustment

Infection prevention program that includes feedback of SSI rates to surgeons
- Lower rate of SSI by 35%

Why does surveillance and feedback work?
- Increased awareness
- Anxiety
- Introspection concerning systematic, procedural, or technical errors

Traditional approach
- Provide summary data 1 or 2 times each year

Table. Stratified SSI data for Hospital A compared to DICOM hospitals with greater than 4,000 total procedures.

<table>
<thead>
<tr>
<th>NHSN RI</th>
<th>SSIs</th>
<th>Procedures</th>
<th>Rate at Hospital A</th>
<th>DICOM Mean</th>
<th>P.Value</th>
<th>DICOM Median</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colon Surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>300</td>
<td>2.33</td>
<td>2.78</td>
<td>0.85</td>
<td>3.21</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>58</td>
<td>0.00</td>
<td>2.17</td>
<td>-</td>
<td>0.93</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>193</td>
<td>2.59</td>
<td>2.22</td>
<td>-</td>
<td>2.38</td>
</tr>
<tr>
<td>&gt;=2</td>
<td>2</td>
<td>49</td>
<td>4.06</td>
<td>4.48</td>
<td>-</td>
<td>5.99</td>
</tr>
<tr>
<td><strong>Total Knee Replacement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>610</td>
<td>0.66</td>
<td>0.41</td>
<td>0.33</td>
<td>0.43</td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td>127</td>
<td>1.57</td>
<td>0.13</td>
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<tr>
<td>1</td>
<td>1</td>
<td>442</td>
<td>0.23</td>
<td>0.45</td>
<td>-</td>
<td>0.49</td>
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<tr>
<td>&gt;=2</td>
<td>1</td>
<td>41</td>
<td>2.44</td>
<td>1.47</td>
<td>-</td>
<td>1.60</td>
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<tr>
<td><strong>Total Hip Replacement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>356</td>
<td>0.56</td>
<td>0.76</td>
<td>1</td>
<td>0.64</td>
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<tr>
<td>0</td>
<td>1</td>
<td>67</td>
<td>1.49</td>
<td>0.41</td>
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<tr>
<td>1</td>
<td>1</td>
<td>265</td>
<td>0.30</td>
<td>0.85</td>
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<td>0.66</td>
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<tr>
<td>&gt;=2</td>
<td>0</td>
<td>24</td>
<td>0.00</td>
<td>1.61</td>
<td>-</td>
<td>1.40</td>
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<tr>
<td><strong>Vaginal Hysterectomy</strong></td>
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<td></td>
</tr>
<tr>
<td>Total</td>
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<td>176</td>
<td>0.57</td>
<td>0.98</td>
<td>1</td>
<td>0.48</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>94</td>
<td>0.00</td>
<td>0.56</td>
<td>-</td>
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<td>1.22</td>
<td>1.56</td>
<td>-</td>
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Quiz #3

Was the new protocol effective in reducing deaths?

Limitations of Standard Surveillance

Requires aggregation
- Trends often missed
- Dilution of increases

Delay in detection of increases

SSI increases identified by
- Surgeon
- IP
- ID or other physician
- Micro lab


Post-CABG mortality

Duke Center for Antimicrobial Stewardship and Infection Prevention
STRATEGY 3 – STATISTICAL PROCESS CONTROL (SPC) CHARTS
SPC Approach

Branch of statistics that uses time series analysis

Commonly utilized in manufacturing

Analyzes variation in a process, i.e., separates “signal from noise”
  “Common cause” natural variation
  “Special cause” unnatural variation

Detects when process is “out of control” or is demonstrating improved control

Prior studies demonstrate can identify important increases prior to standard surveillance

KQC = Key Quality Characteristic
UCL = Upper Control Limit
LCL = Lower Control Limit
$\bar{X} = \text{Mean Score}$

An indication of a special cause

Duke Center for Antimicrobial Stewardship and Infection Prevention
Outbreak of PA in Norway (2002)

231 patients from 24 hospitals had outbreak strain
- 39 patients had BSI
- 71 died

Institute of Public Health alerted all hospitals in Norway

Outbreak declared monoclonal and national

Contaminated mouth swabs identified as source of outbreak

February 2011: Out of control signal
1 signal above UCL

January 11, 2002: Out of control signal

7th consecutive observation below the mean

Outbreak of PA in Norway (2002)

231 patients from 24 hospitals had outbreak strain
- 39 patients had BSI
- 71 died

Outbreak recognized by Shewhart control chart
Outbreak declared monoclonal and national

January
February
March
April

Outbreak recognized by G-type control chart
Institute of Public Health alerted all hospitals in Norway
Contaminated mouth swabs identified as source of outbreak

Outbreak Response

TOTAL SSIs= 66
Outbreak Period = 8 months

Post-Intervention Duration (4 months)
Use SPC Surveillance – Close the Loop

Identify by SPC

Outbreak Begins

Post-Intervention Duration (4 months)

TOTAL SSIs= 45
Outbreak Period = 5 months
Applied to Real Data
Optimized SPC Methods

Goal: identify charts with high sensitivity and acceptable specificity

Retrospective review of 12 years of data from 49 hospitals
- >1.2 million procedures

Evaluated using 50 different SPC charts
- Weighted average, baseline window, lag, etc.
- 3,600 variations

Compared ability of SPC chart(s) to identify important increases in SSI compared to “gold standard” (review by epidemiologist)
- Reviewed 2,711 signals in derivation and validation phases
**Final Optimized Approach**

Combination of two charts – look for signal generated by EITHER (“OR”) chart

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In preliminary application to retrospective data, found 80% of “important increases” prior to standard surveillance

As of March 2017, we began a RCT with stepped-wedge design in 29 DICON hospitals
How Translate to SSI Elimination?

CLOSE THE LOOP
- Identify important increases earlier = Start improvement processes earlier = Decrease in SSI

Some technical challenges, but not many
- SPC alerts can be automated

Uncertain of “acceptable” rate of false positive signals
- Time and effort required to investigate signals

Can be coupled with other strategies to improve detection and surveillance
- Coded data
- Clinical data
Take Home Points

1. Pre-Op
2. Pre-Op Holding
3. Surgical Procedure
4. Post-Op Day 1
5. Post-Op

Peri-Op
Take Home Points

We may have plateaued with current approaches to SSI prevention
- Perhaps rates are improved, but still too common (and not ZERO)
- Need to pursue new ideas

I believe these three novel strategies are promising and worth pursuing
- I don’t know if they will pan out
  - FAIL vs. superceded
- I don’t know how long it will take for them to become widespread

Regardless, it will be an interesting ride!
QUESTIONS?

dicon.medicine.duke.edu
dason.medicine.duke.edu