Colorectal Surgical Site Infections
A Process Improvement Approach

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New York State Partnership for Patients
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Disclosures

• None
Agenda

• Colorectal surgery surgical site infection (SSI) problem
  • Scope
  • Impact
  • What we know or don’t know

• Quality improvement in Clinical Medicine
  • System improvement approach
  • Mayo Clinic CRS “bundle”
Defining Quality Healthcare

- The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
  - Institute of Medicine; *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001)

- The Six Aims of Quality Healthcare
  - *Safe*: Avoiding preventable injuries, reducing medical errors
  - *Effective*: Providing services based on scientific knowledge (clinical guidelines)
  - *Patient centered*: Care that is respectful and responsive to individuals
  - *Efficient*: Avoiding wasting time and other resources
  - *Timely*: Reducing wait times, improving the practice flow
  - *Equitable*: Consistent care regardless of patient characteristics and demographics
Traditional View of Surgical Outcomes

Making the assumption that only the surgical outcome defines quality

21st Century View of Surgical Quality
A Surgical “System of Care”

- Patient Factors
- Hospital Profile
- Operation Profile

Modified from Vincent et al. *Ann Surg* 2004
Surgical Site Infections (SSI)

• According to the CDC
  • 2.6% of 30 million operations per year are complicated by SSI
  • SSI are the second most common healthcare associated infections accounting for 17% of all hospital-acquired infections
  • In surgical patients, SSI are the most common healthcare associated infections (38%)
Hospital-Acquired Infections (HAI)

- 2 million American hospital patients develop HAI per year
- 90,000 deaths per year directly related to HAI
- Estimated direct costs of $5.7 billion dollars
- Top 4
  - Urinary catheter-associated infections (CA-UTI)
  - Surgical site infections (SSI)
  - Catheter-associated bloodstream infection (CA-BSI)
  - Ventilator-associated pneumonia (VAP)
Colon and Rectal Surgery SSI

- Colon and rectal surgery (CRS) is associated with the highest rate of SSI in the literature
  - Range 3-30%

- Multiple studies have identified
  - Patient specific risk factors
    - Malnutrition, DM, Obesity, Immuno-suppressed, Age
  - Disease specific risk factors
    - Inflammatory diseases, Cancer, Concurrent infections
  - Procedure specific risk factors
    - Emergent, Open v. minimally invasive, Duration, Surgeon

- Variable success of reduction efforts
  - No “Magic Bullet”
Colon and Rectal SSI

• Implications of SSI
  • Increased length of hospital stay
    • 2-4 days on average for superficial SSI
    • 1-2 weeks on average for organ space SSI
  • Increased costs
    • ~$600 per superficial SSI
    • ~$14,000 per organ space SSI
    • Surg Today 2012;42:639-645
  • Increased readmission rates
  • Increased patient morbidity, pain, and discomfort
  • Pose a risk to other patients
Complex Interactions in CRS SSIs

Patient Factors
- Weight
- Smoking
- Diabetes
- Heart disease
- Genetics
- Age
- Gender

Disease Factors
- Cancer
- Inflammatory bowel disease
- Infectious diseases
- Immunosuppressed states
- Chemo/XRT Treatment

Surgical Factors
- Emergent v Elective
- Laparoscopic v Open
- EBL
- Wound classification
- Site of resection and type of anastomosis
- Case duration
- Fluid status
- Body temperature
- Surgeon experience
- Team experience

System Factors
- Surgical Policies
- Medical Support
- Level of nursing care
- Radiology
- Pharmacy

SSI
The Role of Complexity in Changing SSI Outcomes

- Multiple Contributing Factors
- A Single Intervention

No Impact on SSI
Given the Complexity, What Do We Know Lowering CRS SSIs?

**SSI**

**Patient Factors**
- Weight
- Smoking
- Diabetes
- Heart disease
- Genetics
- Age
- Gender

**Disease Factors**
- Cancer
- Inflammatory bowel disease
- Infectious diseases
- Immunosuppressed states
- Chemo/XRT Treatment

**Surgical Factors**
- Emergent vs. Elective
- Laparoscopic vs. Open
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- Site of resection and type of anastomosis
- Case duration
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- Body temperature
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- Team experience

**System Factors**
- Surgical Policies
- Medical Support
- Level of nursing care
  - Radiology
  - Pharmacy
Focus Areas For CRS SSI Reduction

- Appropriate use of antibiotics
- Skin preparation
- Normothermia
- Hyper-oxygenation
- Mechanical bowel preps ± oral antibiotics
- Optimizing glucose control
Role of Pre-operative Antibiotics

- Penicillin discovered in 1926
- Process to mass produce it was not developed until early 1940s
- Hailed as the “end to surgical infections”
- Not so **FAST!!!!**

http://usermeds.com/static/penicillin-1.jpg
SSI in the Last Half of the 20th Century

• Introduction of antibiotics did significantly reduce the rate of death from septic complications after surgery

• Increasingly, institutions saw rapid development of bacterial antibiotic resistance even to newer and more powerful antibiotics

• SSI rates held pretty stable from 1970-2000 despite broad, aka indiscriminate, use of antibiotics
Role of Pre-operative Antibiotics

• By the end of the 1980s, 50% of all antibiotics in hospitals were used in surgical patients
• No one had any idea how to use them appropriately
• First “Burke’s Curve” published in 1961

![Graph showing infection rates](attachment:image.png)

Figure 1. Rates of Surgical-Wound Infection Corresponding to the Temporal Relation between Antibiotic Administration and the Start of Surgery.

NEJM 1992;326:281-286
Role of Pre-operative Antibiotics

- Update to “Burke’s Curve” from a population based study, the Basal Cohort (6,283 consecutive general surgical cases)
- Optimal timing to reduce SSI risk was 30-74 minutes before incision

Figure 1
Risk of surgical site infection by timing of surgical antimicrobial prophylaxis. The lowest risk of surgical site infection was observed when the antibiotics were administered between 74 and 30 minutes before surgery.

Swiss Med Wkly. 2012;142:w13616
Weight-based Dosing of Pre-op Antibiotics

- Weight-based dosing has been standard in pediatrics for years
- Adults are no longer the standard 70kg which was the “ideal” adult weight for dosing
- Serum concentration of antibiotics at incision and closure important determinants of SSI
- Force et al, reduced SSI rate from 16.5% to 5.6% by going from 1 gm to 2 gms of cefazolin

Surgery 1989;106:750-757
Antibiotic Choice is Important for Colectomy

- Until mid-2000s there were no standard pre-op prophylactic antibiotic regimens
- Population-based Michigan study evaluated SSI risk based upon antibiotic choice

Ann Surg 2013;257:469-475
Preoperative Skin Preparation

• Preoperative: body skin cleansing with antibacterial soap prior to and day of surgery (hygiene)
  • Chlorhexidine shower
• Surgical skin preparation
  • Anti-septic v. anti-septic plus alcohol based products for the operative skin preparation

http://t2.gstatic.com/images?q=tbn:ANd9GcSKO1vEOpg-Flvv9m_5vRXzdh08Cj4op_bXfhRlp-qK5tlFGDno
Chlorhexidine Showers

- 4% CHG showers day before and morning of surgery
- Mixed results on SSI rate
- When combined with MRSA nasal decontamination significant effect on SSI reduction
- Use of CHG cloths reduced SSI rate in select case types

AJIC 2013;41:167-173
## Operative Skin Preparation

### Characteristics of Antiseptic Solutions

<table>
<thead>
<tr>
<th>Antiseptic</th>
<th>Mechanism of Action</th>
<th>Antimicrobial Coverage</th>
<th>Onset</th>
<th>Duration</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous-iodophor</td>
<td>Free iodine – protein, DNA damage</td>
<td>Excellent for gram + bacteria, good for gram –, fungi, virus, Mtb</td>
<td>Intermediate</td>
<td>2 hours$^{19}$</td>
<td>2-step scrub and paint</td>
</tr>
<tr>
<td>Aqueous-CHG</td>
<td>Disrupts membranes</td>
<td>Excellent for gram +, good for gram – and virus, fair for fungus, poor for Mtb</td>
<td>Intermediate</td>
<td>6 hours$^{20}$</td>
<td>2-step scrub and dry, repeat</td>
</tr>
<tr>
<td>Alcohol-iodophor</td>
<td>Denatures protein, free iodine – protein, DNA damage</td>
<td>Improved gram –, Mtb activity</td>
<td>Rapid</td>
<td>48 hours (DuraPrep)$^{11}$, 96 hours (Prevail-FX)$^{21}$</td>
<td>1-step paint Dry time, minimum of 3 min on hairless surface</td>
</tr>
<tr>
<td>Alcohol-CHG</td>
<td>Denatures protein, disrupts membranes</td>
<td>Improved gram –, Mtb, fungal activity</td>
<td>Rapid</td>
<td>48 hours$^{22,23}$</td>
<td>Dry site: 30-sec scrub Moist site: 2-min scrub Dry time, minimum of 3 min on hairless surface</td>
</tr>
</tbody>
</table>

Operative Skin Preparation

- The preponderance of evidence supports use of:
  - Chlorhexidine-aqueous based over iodine-aqueous solutions
  - Alcohol-based preparations (chlorhexidine or iodine) are better than aqueous preparations
  - No studies directly comparing alcohol-based CHG v Iodine

What Do Gloves Have To Do With It

• William Halsted at the Johns Hopkin’s Hospital introduced wearing surgical gloves in American ORs in the late 1890s

• Using antiseptic skin preparation, meticulous surgical technique and surgical gloves, Halsted reduced SSI after hernia repair to <1%

• Now gloves play a role in protecting the patient from the surgical staff AND the surgical staff from the patient
What Do Gloves Have To Do With It

- 28% of gloves in thoracoscopic and 50% in open thoracotomy had unknown perforations after 2 hours

- Authors recommended glove change every two hours

Table 2. Glove Perforation Rate by the Length of Time Gloves Were Worn

<table>
<thead>
<tr>
<th></th>
<th>Endoscopic Procedure</th>
<th>Open Thoracotomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of gloves worn less than 2 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total gloves</td>
<td>33</td>
<td>32</td>
</tr>
<tr>
<td>Gloves with perforations (%)</td>
<td>1 (3%)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>10 (31%)</td>
</tr>
<tr>
<td>Number of gloves worn more than 2 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total gloves</td>
<td>18</td>
<td>34</td>
</tr>
<tr>
<td>Gloves with perforations (%)</td>
<td>5 (28%)</td>
<td>17 (50%)</td>
</tr>
</tbody>
</table>

<sup>a</sup> \( p < 0.01 \) vs gloves with perforations worn for more than 2 hours

What Do Gloves Have To Do With It

- University of Basal Hospital
- 4,147 surgical procedures
- Monitored unrecognized glove perforation at the end of procedure and SSI
- Perforation increased odds of SSI by 4 times in cases without antibiotic prophylaxis

Arch Surg 2009;144(6):553-558
Thermoregulation and SSI

- Keeping people warm makes physiological sense
  - Improves hemodynamics at the tissue level
  - Optimal range for immune function and tissue repair
- Kurz, et. 1996, 200 RCT with colorectal patients
  - Maintain temperature >36
  - 6% SSI rate in normothermic group; 19% in hypothermic group (p=0.009)
  - Numerous methodologic issues

Infect Control Hosp Epidemiol 2011;32:603-610
Thermoregulation and SSI

- Patients (524) after a trauma laparotomy with similar severity scores
- Treated in similar fashion in regards to antibiotics
- High baseline SSI rate
- Intraoperative hypothermia significantly associated with SSI

*FIGURE 2.** Patients with an intraoperative temperature nadir less than 35°C more often developed surgical site infections than patients with a temperature nadir of 35°C or more.

Increased Inspired Oxygen and SSIs

- Concept is to “optimize” the microenvironment of the surgical wound right after the period of contamination,

- Wounds initially have poor perfusion and low oxygen tension,

- Immediate perioperative goals are to improve vascular perfusion of tissues as well as increase the oxygen tension to promote a more rapid and successful immune response both for bacterial clearance and initiating wound healing.
Increased Inspired Oxygen Concentration

- PROXI randomized control trial of 1400 patients undergoing laparotomy

- 80% versus 30% inspired O₂

- No impact

Table 3. Clinical Outcomes for Patients Scheduled for Laparotomy (N = 1386)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No. (%)</th>
<th>80% Oxygen (n = 685)</th>
<th>30% Oxygen (n = 701)</th>
<th>Univariate OR (95% CI)</th>
<th>P Value</th>
<th>Adjusted OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical site infection</td>
<td>131 (19.1)</td>
<td>141 (20.1)</td>
<td>0.94 (0.72 to 1.22)</td>
<td>.64</td>
<td>0.91</td>
<td>(0.69 to 1.20)</td>
<td>.51</td>
</tr>
<tr>
<td>Infection location</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Superficial</td>
<td>75 (57.3)</td>
<td>76 (53.9)</td>
<td>1.11 (0.75 to 1.66)</td>
<td>.60</td>
<td>1.13</td>
<td>(0.75 to 1.72)</td>
<td>.56</td>
</tr>
<tr>
<td>Deep</td>
<td>20 (15.3)</td>
<td>26 (18.4)</td>
<td>0.95 (0.61 to 1.48)</td>
<td>.82</td>
<td>0.95</td>
<td>(0.60 to 1.49)</td>
<td>.81</td>
</tr>
<tr>
<td>Organ/space</td>
<td>36 (27.5)</td>
<td>39 (27.7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASEPSIS score &gt;20³</td>
<td>32 (4.7)</td>
<td>36 (5.1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atelectasis</td>
<td>54 (7.9)</td>
<td>50 (7.1)</td>
<td>1.11 (0.75 to 1.66)</td>
<td>.60</td>
<td>1.13</td>
<td>(0.75 to 1.72)</td>
<td>.56</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>41 (6.0)</td>
<td>44 (6.3)</td>
<td>0.95 (0.61 to 1.48)</td>
<td>.82</td>
<td>0.95</td>
<td>(0.60 to 1.49)</td>
<td>.81</td>
</tr>
<tr>
<td>Health care–associated</td>
<td>30 (73.2)</td>
<td>30 (68.2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventilator-associated</td>
<td>7 (17.1)</td>
<td>9 (20.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspiration</td>
<td>2 (4.9)</td>
<td>1 (2.3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community-acquired</td>
<td>2 (4.9)</td>
<td>2 (4.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunocompromised</td>
<td>0 (0)</td>
<td>2 (4.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>38 (5.5)</td>
<td>31 (4.4)</td>
<td>1.27 (0.78 to 2.07)</td>
<td>.34</td>
<td>1.22</td>
<td>(0.74 to 2.03)</td>
<td>.44</td>
</tr>
<tr>
<td>Reoperation</td>
<td>104 (15.2)</td>
<td>104 (14.8)</td>
<td>1.03 (0.77 to 1.38)</td>
<td>.86</td>
<td>1.01</td>
<td>(0.75 to 1.37)</td>
<td>.93</td>
</tr>
<tr>
<td>Admission to ICU²</td>
<td>50 (7.3)</td>
<td>44 (6.3)</td>
<td>1.18 (0.77 to 1.79)</td>
<td>.45</td>
<td>1.21</td>
<td>(0.78 to 1.89)</td>
<td>.40</td>
</tr>
<tr>
<td>30–d mortality</td>
<td>30 (4.4)</td>
<td>20 (2.9)</td>
<td>1.56 (0.88 to 2.77)</td>
<td>.13</td>
<td>1.55</td>
<td>(0.86 to 2.85)</td>
<td>.15</td>
</tr>
<tr>
<td>Postoperative hospitalization</td>
<td>6 (1.34)</td>
<td>7 (2.36)</td>
<td>−0.69 (−2.3 to 0.93)</td>
<td>.09</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

JAMA 2009;302(14):1543-1550
Increased Inspired Oxygen Concentration

Can J Surg 2013;56:E82-E90
Sub-group analysis demonstrated SSI reduction 18.2% to 14.4% (p=0.05) in elective CRS with standardized antibiotic use.

Can J Surg 2013;56:E82-E90
Mechanical Bowel Preparation ± Oral Antibiotics

- Conflicting data in the literature
  - Cochrane Review 2011 showed no benefit to MBP as it relates to SSI

- Recent studies recommend oral antibiotics alone might be beneficial ± MBP

![Analysis 1.6. Comparison | Mechanical bowel preparation versus no preparation, Outcome 6 Wound infection.](image)
Improved Glucose Control

- Diabetes is one of the most commonly cited risk factors for SSI especially after colorectal surgery
- HbA1c is more sensitive for risk stratification prior to surgery for all postoperative complications
  - An indicator of poor overall glucose control pre-operatively
  - An indicator of more difficult glucose control post-operatively
  - Best to have HbA1c < 7-8 mg/dL
- Better overall postoperative outcomes if random BG < 180 mg/dL and fewer swings in BG
  - Need to AVOID hypoglycemia (BG < 70 mg/dL)
Improved Glucose Control

• In colorectal surgery even in “non-diabetic” patients, hyperglycemia is associated with worse clinical outcomes including SSI

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**TABLE 2. Outcome Variables for Nondiabetic Patients**

<table>
<thead>
<tr>
<th>Level of Glycermia (mg/dL)</th>
<th>Overall</th>
<th>Normoglycemia (&lt;125)</th>
<th>Mild HG (126-200)</th>
<th>Severe HG (&gt;200)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intraoperative</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. patients</td>
<td>2447</td>
<td>342 (14%)</td>
<td>212 ± 282</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>EBL</td>
<td>166 ± 1</td>
<td>12 (1.5%)</td>
<td>9 (2.6%)</td>
<td>0.022</td>
<td></td>
</tr>
<tr>
<td>Transfusion (no. patients)</td>
<td>234 (9.6%)</td>
<td>15 (4.4%)</td>
<td>18 (1.4%)</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>Length of surgery (min)</td>
<td>158.2 ± 180.7 ± 104.0</td>
<td></td>
<td>24.3%</td>
<td>&lt;0.001*</td>
<td></td>
</tr>
<tr>
<td>Dextrose infusion (%)</td>
<td>21.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Postoperative</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute renal failure (%)</td>
<td>24 (1.4%)</td>
<td>12 (1.5%)</td>
<td>18 (1.4%)</td>
<td>12 (3.5%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Anastomotic leak (%)</td>
<td>60 (2.5%)</td>
<td>17 (0.6%)</td>
<td>24 (0.9%)</td>
<td>0.032</td>
<td></td>
</tr>
<tr>
<td>Arrhythmia (%)</td>
<td>5 (0.2%)</td>
<td>7 (0.86%)</td>
<td>3 (0.23%)</td>
<td>2 (0.58%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Myocardial infarction (%)</td>
<td>23 (0.9%)</td>
<td>15 (5.4%)</td>
<td>16 (0.78%)</td>
<td>7 (2.0%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Pneumonia (%)</td>
<td>9 (0.37%)</td>
<td>1 (0.12%)</td>
<td>3 (0.23%)</td>
<td>5 (1.5%)</td>
<td>0.006</td>
</tr>
<tr>
<td>Sepsis (%)</td>
<td>12 (0.49%)</td>
<td>5 (0.61%)</td>
<td>28 (2.3%)</td>
<td>12 (3.5%)</td>
<td>0.005</td>
</tr>
<tr>
<td>SSI deep (%)</td>
<td>25 (1.0%)</td>
<td>10 (1.2%)</td>
<td>40 (3.8%)</td>
<td>21 (6.1%)</td>
<td>0.046</td>
</tr>
<tr>
<td>SSI superficial (%)</td>
<td>107 (4.4%)</td>
<td>24 (2.9%)</td>
<td>56 (4.3%)</td>
<td>26 (7.7%)</td>
<td>0.025</td>
</tr>
<tr>
<td>SSI organ/space (%)</td>
<td>96 (3.9%)</td>
<td>24 (2.9%)</td>
<td>56 (4.3%)</td>
<td>26 (7.7%)</td>
<td>0.025</td>
</tr>
<tr>
<td>UTI (%)</td>
<td>95 (3.9%)</td>
<td>25 (3.1%)</td>
<td>40 (3.8%)</td>
<td>21 (6.1%)</td>
<td>0.046</td>
</tr>
<tr>
<td>DVT (%)</td>
<td>65 (2.6%)</td>
<td>10 (1.2%)</td>
<td>37 (2.9%)</td>
<td>18 (5.3%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Length of stay (d)</td>
<td>8.2 ± 7.1</td>
<td>6.8 ± 5.6</td>
<td>8.4 ± 6.45</td>
<td>11.1 ± 10.8</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Readmission (%)</td>
<td>285 (12.1%)</td>
<td>88 (10.8%)</td>
<td>165 (12.8%)</td>
<td>42 (12.3%)</td>
<td>0.38</td>
</tr>
<tr>
<td>Reoperation (%)</td>
<td>114 (4.7%)</td>
<td>25 (3.1%)</td>
<td>64 (5.0%)</td>
<td>25 (7.3%)</td>
<td>0.006*</td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>9 (0.37%)</td>
<td>1 (0.12%)</td>
<td>2 (0.23%)</td>
<td>5 (1.5%)</td>
<td>0.006*</td>
</tr>
</tbody>
</table>

Outcome variables stratified by level of glycermia. P values indicate probabilities of significant differences found by analysis of variance testing, and footnote symbols (*, †, or ‡) indicate the group(s) that differ from normoglycemia as reference.

*Indicates significant difference between normoglycemia (N) and mild or severe hyperglycemia.
†Indicates significant difference between normoglycemia and severe hyperglycemia.
‡Indicates significant difference between mild and severe hyperglycemia.
DVT indicates deep venous thrombosis; EBL, estimated blood loss; HG, hyperglycemia; UTI, urinary tract infection.

Ann Surg 2013;258:599-605
The Role of Complexity in Changing SSI Outcomes

Multiple Contributing Factors

A Single Intervention

No Impact on SSI
The Role of Complexity in Changing SSI Outcomes

Multiple Contributing Factors

Δ SSI
SSI Reduction Efforts

• Facts:
  • Numerous elements contribute to SSI development
  • Relative contribution of each element to SSI development is unknown
  • The influence of each element to SSI development is not constant
  • SSI occurrence for an individual patient is unpredictable

• Conclusion
  • No single intervention will have a significant impact on SSI
  • The optimal approach is to consistently apply multiple interventions
A “Bundle” Approach for CRS SSI Reduction

• Solutions to complex problems require multi-phased (multiple element) solutions

• Numerous “bundles” of interventions have been used to address colorectal SSI with favorable results

• Not all the bundles have all the same elements

• The goal is to reduce variation at every step and perform all interventions for every patient
Waits, et al. (2014): 6 elements in the bundle
• Just one element = 17.5% SSI rate
• All six elements = 2% SSI rate

Crolla, et al. (2012): 4 elements in bundle
• Compliance with bundle elements increased from 10% to 60%
• Within increased element compliance there was a significant decrease in SSI

Figure 2. Annual changes in the surgical site infection (SSI) rate and bundle compliance and the 95% confidence interval. Footnote: 2008 was taken as the reference year for SSI and the relative changes after adjustment for confounding variables are provided. doi:10.1371/journal.pone.0044599.g002
Mayo Clinic CRS SSI Reduction Bundle
Applying Evidence Into Clinical Process Improvement

- Not all evidence can be Grade 1A

Next steps
- Is there reasonable evidence to support the practice?
- Is it safe for the patient and the staff?
- Can it be implemented and sustained with minimal disruption to existing processes?
- Does it make economic sense?
- Can it be reversed easily if new evidence becomes available?
Essential Health Care Quality Improvement Concept

• Health care outcomes are the result of an interaction between natural and health care delivery processes

  • **Common cause variation**
    • Phenomena constantly active within the system
    • Variation predictable
    • Irregular variation within a historical experience base
    • Lack of significance in individual high or low values

  • **Special cause variation**
    • Stems from external sources that influence the process
Complexity, Quality Improvement, and SSI Reduction

• In any complex system, successful QI requires reducing process variation as much as possible.

Uniformity leads to predictability, improved process control, and more predictable outcomes.
The Beginnings of SSI Reduction Process Improvement

• Multi-disciplinary team
  • Multiple contributing factors need multiple experts to understand how we can address these factors

• Define the *Current State* across the *Entire Process*
  • What is current performance?
  • What is/are the current process(es)?
SSI Reduction Process Improvement Effort

• Construct a Value Stream Map (VSM) of the processes across the episode of care
  • Identify steps/interventions that can add “value” to the outcome
    • Known interventions that are associated with SSI reductions
      • Appropriate, weight based antibiotics administered at the correct time
    • Possible interventions that might contribute to reducing SSI if they are
      • Easily placed into the system
      • Can be done with high compliance
      • Make economic sense
What Does Process Improvement for SSI Reduction Really Mean

• Gain consensus on those VSM elements that all stakeholders agree to implement
• Design processes to ensure a high level of compliance with each implementation element
• Actively monitor compliance with the process steps and provide feedback on compliance
• Long and short:
  • Develop a “bundle” of interventions and make sure everyone does what they are supposed to do
Mayo Colorectal Surgery Practice

• Full spectrum of CRS
  • Benign anorectal to recurrent rectal cancers
  • > 50% of colectomies performed using a minimally invasive approach

• Eight board certified colorectal surgeons
  • General surgery residents
  • 4 colorectal surgery fellows

• Dedicated CRS operating rooms and allied health staff

• Two dedicated CRS post-operative nursing floors
Quality Improvement as a Process

DMAIC Method: process improvement based upon a Lean/Six Sigma approach
Where were we starting?

• We knew we needed SSI rates but which data was the one to base the reduction effort?
  • Institutional IPAC data
    • Quarterly evaluation
    • Culture-based
    • Follow-up requires notification
    • Weighted toward deep infections
  • National Surgical Quality Improvement Program (NSQIP)
    • Chart abstraction by trained abstractors
    • Mandated 30 day follow-up with active outreach to patient
SSI Surveillance Systems

- **IPAC triggers**
  - Positive culture
  - Readmission to hospital with diagnosis implying a wound or organ space infection
  - Return to the OR with pre-op diagnosis of wound or organ space infection
  - Call from provider indicating a SSI
  - NHSN definition and risk adjustment
    - Superficial SSI
    - Deep incisional SSI
    - Organ / Space SSI

- **NSQIP abstraction guidelines**
  - Only *sample* of patients
  - 30 day post-op follow up
  - Standard definitions
    - Wound cellulitis
    - Superficial SSI
    - Deep incisional SSI
    - Organ / Space SSI
Comparison of CRS SSI Events

To verify the representation of the sample in both the groups
Time Frame: Jan 2009 to April 2010
IPAC data identified 79 SSI
NSQIP data identified 45 SSI
“As Expected” in NSQIP CRS SSI
Define Phase

- **Goal:** Reduce colorectal surgical site infections by 50% and improve OE ratio from 4\(^{th}\) decile to 2\(^{nd}\) decile by December 2011. 2009 overall SSI rate was 10.5%.

- **Unit of Improvement:** Colorectal Surgical Procedures
  - All patients undergoing colorectal surgery (emergency and elective) at Rochester Methodist Hospital. NSQIP CPT codes for colorectal surgery.
  - All types of Surgical Site Infections (Superficial Incisional, Deep Incisional, and Organ/Space).
  - Excludes: Trauma and Primary Transplant patients. Patients under 18 years of age.
  - **Defect:** Any Surgical Site Infections  
    **Data source:** NSQIP Data Set
Measure Phase
Already done thanks to NSQIP
Analyze Phase

![Bar graph showing SSI Type and Percentage]
Analyze Phase
Important MCR Variables

130+ NSQIP Variables

40 NSQIP Variables
Age
Gender
BMI
Wound Class
Diabetes
Transfusion
Various Labs
CPT4 Codes
Disease

Significant Variables
Age (p = .0002)
BMI (p = .0495)
Wound Class (p = .0004)
Diabetes (p = .046)
Laparscopic (p = .0005)
Open (p = .0005)
Intra-op Blood (p = .0024)
Duration (p = .0005)
Sepsis (p = .026)
Steroid use (p = .001)
CPT-4 code (p = .024)
Analyze Phase
Major Variables for Mayo CRS SSI

- Diagnosis
  - Crohn's Disease
  - Diverticular disease
  - Ulcerative Colitis
    - Represented over half of all identified NSQIP Mayo Clinic SSIs

- BMI

- Operative time

Diagnoses Influence Surgical Site Infections (SSI) in Colorectal Surgery: A Must Consideration for SSI Reporting Programs?
## What About the Surgeon?

Survey of surgeon practices for “relevant” items

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Do you routinely order a bowel preparation?</td>
</tr>
<tr>
<td>2.</td>
<td>If you use a bowel preparation, do you order oral antibiotics with the bowel preparation?</td>
</tr>
<tr>
<td>3.</td>
<td>If you do not use a bowel preparation, do you still order oral antibiotics?</td>
</tr>
<tr>
<td>4.</td>
<td>Do your patients routinely receive an enema prior to arriving in the operating room?</td>
</tr>
<tr>
<td>5.</td>
<td>Do you routinely provide your patients with a medicated soap (antibacterial) to shower with prior to surgery?</td>
</tr>
<tr>
<td>6.</td>
<td>For left-sided colectomies/rectal surgery, do you irrigate the rectum?</td>
</tr>
<tr>
<td>7.</td>
<td>What skin preparation do you routinely use?</td>
</tr>
<tr>
<td>8.</td>
<td>Do you routinely use an Ioban type drape over the prepared abdomen during your procedures?</td>
</tr>
<tr>
<td>9.</td>
<td>Do you routinely use wound protectors during the operation? (ie sponges under fixed retractors or a wound protector product)</td>
</tr>
<tr>
<td>10.</td>
<td>Do you routinely use saline or antibiotic irrigation of the abdomen?</td>
</tr>
<tr>
<td>11.</td>
<td>Do you routinely air test all colorectal anastomoses?</td>
</tr>
<tr>
<td>12.</td>
<td>For small bowel or colon anastomoses, what type anastomosis do you routinely perform?</td>
</tr>
<tr>
<td>13.</td>
<td>Do you routinely have antibiotics re-dosed at four hours for your longer cases?</td>
</tr>
<tr>
<td>14.</td>
<td>Your routine fascial closure is what style?</td>
</tr>
<tr>
<td>15.</td>
<td>Do you use fresh clean instruments that had not been on the table during the case to close the abdomen?</td>
</tr>
<tr>
<td>16.</td>
<td>Do you have the team members change gloves and/or gowns just prior to abdominal closure?</td>
</tr>
<tr>
<td>17.</td>
<td>Do you routinely irrigate the subcutaneous space prior to skin closure with saline and/or antibiotic irrigation?</td>
</tr>
<tr>
<td>18.</td>
<td>Do you routinely use a subcutaneous drain at the site of the primary incision closure?</td>
</tr>
<tr>
<td>19.</td>
<td>Do you routinely use a subcutaneous drain at the site of an ostomy?</td>
</tr>
<tr>
<td>20.</td>
<td>When do you remove the dressing applied in the operating room if it is not soiled?</td>
</tr>
<tr>
<td>21.</td>
<td>Do you have your patients shower/bathe with medicated (antibacterial) soap while in the hospital?</td>
</tr>
</tbody>
</table>
Surgeon Survey Results

• Demonstrated
  • Wide variability amongst the surgeons on most elements (28% 100% concordance)
    • We all trained at the Mayo Clinic but all do something different
  • Started a conversation on the “best” practice
  • Gained consensus to move towards more standardization on specific surveyed items
Principles of Our Reduction Effort

• Interventions across the episode of care
  • Pre-op, Intra-op, Post-op

• Multi-disciplinary

• Engage staff, patient, and families

• Standardize as many processes as possible

• Ensure high compliance with elements
  • Quick audits

• Build the elements into the system

• Frequent feedback and communication
The Team

• Gene Dankbar, Black Belt Lead, Systems and Procedures
• Kimberly Aronhalt, R.N., Infection Control and Prevention
• Diane Foss, R.N., Kim Gaines, R.N., Nursing, Pamela Grubbs, R.N.,
• Pamela Maxson, R.N., Ph.D., Jennifer Wolforth, R.N., Nursing
• Sharon Nehring, R.N., Roxanne Hyke, R.N., Diane Tyndale, R.N., NSQIP
• Jenna Lovely, Pharm.D., Pharmacy Services
• Sarah Pool, R.N., Surgical Services, Lynn Quast, R.N., Surgical Services
• Jim Rogers, Systems and Procedures
• Rajesh Pendlimari, MBBS, Research Fellow, CRS
• Karen Piotrowicz, R.N., Mid-level Provider, CRS
• Robert Cima, M.D., Project lead
Critical to Quality Tree: Surgical Site Infections for Colorectal Surgery

Pre-operative Processes

- Patient Skin Cleansing
  - 2% Chlorhexidine Cloths @ AM admission
  - Hibiclens® shower right before and day of surgery
  - Ensure patient understanding by reading pamphlet “Preventing SSI”

Antibiotic Administration

- Ensure SCIP® compliance
  1. Right antibiotics
  2. Administer 60 min prior to incision
  3. Discontinued within 24 hours
- Ensure re-dose of cefazolin within 3-4 hours after incision

Intra-operative Processes

- Chloraprep® applied – use appropriate amount to ensure complete coverage of incisional area
- Use closing tray for closure of fascia and skin
- Glove change by staff before closure of fascia
- Hand hygiene education – Patient, Visitor, and Staff
- Patient shower with Hibiclens® following dressing removal

Post-operative Process

- Patient, Visitor and Staff Hand Hygiene
  - Hand cleansing agent readily available – Patient and Staff
  - Place sign for Moments of Hand Hygiene
  - Purell® hand wipes made available to patients
  - Ensure dressing removal within 48 hours

Post-hospitalization Process

- Dismiss patient with 4 oz. bottle of Hibiclens®
- Patient education on wound care and recognizing infection symptoms
- Follow-up phone call from nurses

Reduce SSI by 50%
(10% → 5%)

SCIP – Surgical Care Improvement Project

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Improve Phase
Preoperative Elements

• Pre-operative Chlorhexidine packets
  o Provided to all patients preoperatively with instructions
  o Use monitored morning of admission
  o If not reported as not being used, SAGE wipes used on the entire body

• Patients with BMI > 30
  o SAGE wipes applied even if preoperative bath performed
  o Procedure listing software automatically identifies patients with BMI > 30
Improve Phase
BMI Trigger for Admissions Unit

Additional Instructions
Height recorded upon admission
Weight recorded upon admission
UCI in OR
Sequential Compression Devices bilateral lower extremity placed in OR

BMI is > 30, Cleanse total body w/chlorhexidine 2% cloths upon admission

Skin Preparations
Clip nipples to pubis
Improve Phase
Pre-operative Elements

• Pre-op antibiotic ordering

• Procedure scheduling software automatically provides SCIP appropriate choices

• Weight-based dosing

• Software automatically orders intra-operative re-dosing dose if historical data for the specific procedure and surgeon demonstrated an average case duration >3 hours
Surgical Hospital Assignment System

Improve Phase

Surgery Information
Clinic Nr: [Redacted] Surgery Date: Jan 17 2011
Patient Name: [Redacted] Time to Report: 07:15 AM
Sex/Age/DOB: [Redacted] First Case: YES - 08:15
Type of Admission: Routine "OCC" Location: Gonda 15 - OR 04
Patient Admission: Outpatient, Same Day (OP-RMH) Listing Status: Finalized By SGL
Planned Post Op Level of Care: No Information
Listing Completed by: Schilling, Aaron C. on Jan 14 2011 7:41AM

Surgeon Information (CRA Supervisor) * indicates the primary physician
Surgeon: *KAKAR, SAMUE - ORTS/46101

Surgery Description
Diagnosis: left carpil tunnel.
Indication: pain relief.
Procedure: Left wrist carpil tunnel open; left open carpil tunnel release.
(Estimated OR Time: 0:43 + 0:20 = 1:03)

Anesthesia
Anesthesia Approval: No PAHE - Anesthesia Review
Anesthesia Type: Monitored Anes. Care (Attd. Local)

Transfusion Medicine
Transfusion: No Transfusion

Preoperative Surgical Orders
Preop Orders: Completed by Schilling, Aaron (Pager: ) on Jan 14 2011 7:41AM
Preop NPO After: 12:00 AM
Enema: Enema Not Required

Medication(s)
Cefazolin (Ancef) IV IN OR within 60 minutes prior to incision, repeat in 3 hours: 40 - 79 Kg 1 gram with 1 gram repeat; 80 - 119 Kg 2 gram with 2 gram repeat; 120 Kg and above 3 gram with 2 gram repeat.

Lidocaine 1% Bupivacaine 0.25% INJECTION IN OR used as local anesthetic (Dispense Unit 30 mL vial)

Medical Condition
Diabetes
Pacemaker: Manufacturer-Guidant; Model#: 1290
Call Heart Rhythm Services to determine if HRS Nurse is required.

Drug Allergies: See MICS Allergies Module for allergy information.
Improve Phase
Intra-operative Elements

• Hair removal by electric clipper
  • Outside of the operating room

• Standardized to Chlorhexidine-Alcohol (Chloraprep™) skin preparation for all abdominal cases
  • Surgical assistant applies skin preparation
    • All in-serviced on appropriate application
  • Must dry for 3 minutes before drapes applied
Improve Phase
Intraoperative Elements

• Pre-procedural pause includes confirming appropriate timing of antibiotics administered and documented

• Re-dosing of cefazolin for cases longer than 3 hours
  • Circulating nurse has the pre-op order and pulls medication at the beginning of the case
  • Reminder window on anesthesia provider’s computer screen
    • Triggered off time of first dose administration
  • Appropriate weight-based dosing
Improve Phase
Anesthesia Antibiotic Reminder Screen

For example:
- The initial Cefazolin dose was documented at 11:00, current time is 14:00
- The reminder window appears, prompting re-dosing of “Cefazolin”
- The reminder can be delayed up to 30 minutes
- The reminder resets to 3 hours once the dose is charted
Improve Phase
Intraoperative Elements

• “Closing” Process
  • At the time of fascia closure
    • All staff change gloves
      • Gowns if soiled
    • Field re-blocked with fresh sterile towels
  • Instruments used during case removed and “closing tray” brought onto the field
Closing Process
Improve Phase
Postoperative Elements

• All order-sets discontinue SCIP compliant antibiotics after two postop doses or single dose when appropriate
  • Pharmacist part of team and queries service

• Hand hygiene essential on floor
  • Physician/Nursing initiative
  • Patient and Family initiative

• Sterile dressing on until morning of POD 2
  • Document removal in nursing flow sheet; electronic audits

• Chlorhexidine shower/wipes daily after dressing removal

• Standard post-op order-sets orders urinary catheter removal at 8am the morning after surgery

• Dismiss with chlorhexidine soap bottle for use at home
Improve Phase
Process audits

• Audits of elements to determine compliance
  • Use different data sources
    • SCIP UHC data
    • Institutional hand hygiene compliance
    • OR process data

• Assess counterbalance effects
  • Does closing process increase operative times?
Improve Phase
Process audits

- Cefazolin re-dose after 3-4 hours if Op time > 3 hours
- Antibiotic “watcher” effective after 1/1/11
- Re-dosing after 4 hour improved from 8/12 (66%) in 2/2010 to 17/17 (100%) in 2/2011
Improve Phase
Process audits

- All CPT-4 Codes in project
- No differences in operative times
## Improve Phase
### Comparison 2009/2010 to 2011 Demographics

<table>
<thead>
<tr>
<th></th>
<th>2009-2010 (Baseline)</th>
<th>2011</th>
<th>Total / Overall</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sampled Cases</strong></td>
<td>532</td>
<td>199</td>
<td>731</td>
<td></td>
</tr>
<tr>
<td><strong>Number of Infections</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Superficial</td>
<td>28 (5.3%)</td>
<td>3 (1.5%)</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Organ Space</td>
<td>28 (5.3%)</td>
<td>5 (2.5%)</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Deep</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>57.3 +/- 17.1</td>
<td>56.8 +/- 18.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age &gt; 60</strong></td>
<td>255 (47.9%)</td>
<td>97 (48.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td>260 (48.9%)</td>
<td>91 (45.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td>27.1 +/- 6.1</td>
<td>26.9 +/- 5.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI ≥ 30</td>
<td>145 (27.4%)</td>
<td>50 (25.1%)</td>
<td>195 (26.7%)</td>
<td>0.544</td>
</tr>
<tr>
<td>BMI ≥ 40</td>
<td>20 (3.8%)</td>
<td>7 (3.5%)</td>
<td>27 (3.7%)</td>
<td>0.877</td>
</tr>
</tbody>
</table>
# Improve Phase
Comparison 2009/2010 to 2011 Demographics

<table>
<thead>
<tr>
<th></th>
<th>2009-2010 (Baseline)</th>
<th>2011</th>
<th>Total / Overall</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18.5</td>
<td>20 (3.8%)</td>
<td>6 (3%)</td>
<td>26 (3.6%)</td>
<td>0.677</td>
</tr>
<tr>
<td>18.5 – 24.9</td>
<td>185 (34.9%)</td>
<td>79 (39.7%)</td>
<td>264 (36.1%)</td>
<td></td>
</tr>
<tr>
<td>24.9 – 29.9</td>
<td>179 (33.8%)</td>
<td>63 (31.7%)</td>
<td>242 (33.1%)</td>
<td></td>
</tr>
<tr>
<td>&gt;30</td>
<td>146 (27.6%)</td>
<td>51 (25.6%)</td>
<td>197 (27%)</td>
<td></td>
</tr>
<tr>
<td><strong>Wound Class:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean Contaminated</td>
<td>465 (87.4%)</td>
<td>155 (77.9%)</td>
<td>620 (84.8%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Contaminated</td>
<td>16 (3%)</td>
<td>18 (9%)</td>
<td>34 (4.6%)</td>
<td></td>
</tr>
<tr>
<td>Dirty / Infected</td>
<td>51 (9.6%)</td>
<td>26 (13.1%)</td>
<td>77 (10.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>ASA Class</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA 1 - No Disturb</td>
<td>23 (4.3%)</td>
<td>10 (5%)</td>
<td>33 (4.5%)</td>
<td>0.013</td>
</tr>
<tr>
<td>ASA 2 - Mild Disturb</td>
<td>333 (62.2%)</td>
<td>127 (63.8%)</td>
<td>458 (62.6%)</td>
<td></td>
</tr>
<tr>
<td>ASA 3 - Severe Disturb</td>
<td>177 (33.3%)</td>
<td>57 (28.6%)</td>
<td>234 (32%)</td>
<td></td>
</tr>
<tr>
<td>ASA 4 - Life Threat</td>
<td>1 (0.2%)</td>
<td>5 (2.5%)</td>
<td>6 (.8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>20 (3.8%)</td>
<td>6 (3%)</td>
<td>26 (3.6%)</td>
<td>0.24</td>
</tr>
<tr>
<td>No</td>
<td>484 (91%)</td>
<td>176 (88.4%)</td>
<td>660 (90.3%)</td>
<td></td>
</tr>
<tr>
<td>Non-Insulin</td>
<td>28 (5.3%)</td>
<td>17 (8.5%)</td>
<td>45 (6.2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Operative Duration (minutes)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>203.1 +/- 93.1</td>
<td>191.5 +/- 88.5</td>
<td>0.12</td>
<td></td>
</tr>
</tbody>
</table>
Control Phase
Results

P Chart of Total Observed SSI by Phase

Tests performed with unequal sample sizes

Proportion

Month and Year

2009 2010 2011

UCL=0.1837
P=0.0388
LCL=0

Jan-09 May-09 Sep-09 Jan-10 May-10 Sep-10 Jan-11 May-11 Sep-11 Jan-12

2009 2010 2011
Control Phase

Results

P Chart of Superficial SSI by Phase

Tests performed with unequal sample sizes

\( \bar{p} = 0.0146 \)

\( UCL = 0.1044 \)

\( LCL = 0 \)
Control Phase Results

Tests performed with unequal sample sizes
SSI Reduction in Colorectal Surgery

- SSIs in colorectal surgery is a complex, multifactorial problem
- Reduction efforts require multiple intervention across the surgical episode
- Development of a “bundle” of interventions will help to reduce variation
  - Stakeholder buy-in is essential
  - Designing into the system of care is essential to ensure compliance
  - Monitoring compliance is essential
Lessons Learned

- **Multidisciplinary** approach is essential
  - Engage all staff
- Reliable, timely, actionable data
- **Data in depth**
  - Details to be readily available
- **Walk the process; make no assumptions**
  - Policies and practice are not the same
- Look at the entire episode
  - Pre, intra, and postoperative elements may influence SSI rates
  - Interventions designed for each phase
- Introduce multiple elements of change and **audit compliance**
- Build improvements **into the system** to increase compliance
The Needs of the Patient Come First - W.J. Mayo

Questions & Discussion