Colorectal Surgery SSI Reduction Bundles and Prep: Does It Matter?

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New York State SSI Reduction Webinar
Disclosures

• None

Narayana Health Hospital, Bangalore, India
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)
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 infection accounting for 17% of all hospital acquired infections
  - In surgical patients, SSI are the most common healthcare associated infection (38%)
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”

http://www.uphs.upenn.edu/surgery/graphic2/images/colon_rectal_1.jpg
Surgical Site Infections (SSI)

• Implications of SSI
  • Increased length of hospital stay (2-4 days on average)
  • Increased costs
    • Mayo Clinic CRS data
      • Superficial SSI increased cost by $2,000 (median)
      • Deep wound SSI increased cost by $11,000 (median)
      • Organ space SSI increased cost by $14,000 (median)
  • Increased readmission rates
  • Increased patient morbidity, pain, and discomfort
  • Pose a risk to other patients
Traditional View of Surgical Systems and Outcomes

Making the assumption that only the surgical outcomes define quality

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

Operation Profile
- Procedures
- Operative events
- Anesthesia
- Communication
- Technical Skills
- Team Performance
- Decision-making
- Operative environment

Patient Factors
- Disease factors
- Individual factors
- SES factors

Hospital Profile
- Medical Services
- Nursing Services
- Pathology Services
- Radiology Services
- Hospital Infrastructure
- Communication
- Information Processing/Technology

Outcomes
- Mortality
- Morbidity
- Readmissions
- Patient experience
- Resource utilization
- Population health

Complex Interactions in CRS SSIs

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

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

**Surgical Factors**
- Emergent vs Elective
- Laparoscopic vs 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
The Role of Complexity in Changing SSI Outcomes

Multiple Contributing Factors

A SINGLE Intervention

Minimal Impact on SSI

* IV antibiotics had a significant impact
Looking for “Magic Bullets”

• Antiseptic surgery: Joseph Lister
  • August 12 1865, Glasgow Royal Infirmary
  • Clean instruments with phenol and aerosolized phenol into the operating theater
    • Reduced infections from 50% to 15%

• Antibiotics: Alexander Fleming
  • September 28, 1928, St. Mary’s Hospital in London
  • Identified Penicillin, “mold juice” that was highly effective against gram positive organisms

• Timing of antibiotic administration
  • Optimal timing of prophylactic antibiotic administration prior to surgical incision
The Role of Complexity in Changing SSI Outcomes

Multiple Contributing Factors + A SINGLE Intervention → Minimal Impact on SSI

* IV antibiotics had a significant impact
The Role of Complexity in Changing SSI Outcomes

Multiple Contributing Factors

Δ SSI
A “Bundle” Approach for CRS SSI Reduction

• Solutions to complex problems often 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

• Ideally, all elements should have some biologic or process evidence to support implementation

• Perform elements with high compliance
The Original SCIP Bundle

| SCIP INF 1 | Prophylactic antibiotic received within one hour prior to surgical incision |
| SCIP INF 2 | Prophylactic antibiotic selection for surgical patients |
| SCIP INF 3 | Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac patients) |
| SCIP INF 4 | Cardiac surgery patients with controlled 6 a.m. postoperative serum glucose |
| SCIP INF 6 | Surgery patients with appropriate hair removal |
| SCIP INF 7 | Colorectal surgery patients with immediate postoperative normothermia |
| SCIP Card 2 | Surgery patients on a beta-blocker prior to arrival that received a beta-blocker during the perioperative period |
| SCIP VTE 1 | Surgery patients with recommended venous thromboembolism prophylaxis ordered |
| SCIP VTE 2 | Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to surgery to 24 hours after surgery |

- Multi-hospital collaborative reported significant across the board reductions in SSIs, including CRS cases
- Despite reported high compliance nationally impact on SSIs was minimal
CRS Bundle Elements

• Appropriate antibiotic prophylaxis 60 minutes before incision

• Skin preparation
  • Prior to surgery
  • Sterile skin preparation

• Normothermia

• Optimal glycemic control

• Closing trays

• Hyper-oxygenation

• What about a bowel preparation???
Mayo Clin CRS SSI Reduction Bundle
Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients.

Tanner J¹, Padley W², Assadian O³, Leaper D³, Kiernan M⁴, Edmiston C⁵.

Abstract

BACKGROUND: Care bundles are a strategy that can be used to reduce the risk of surgical site infection (SSI), but individual studies of care bundles report conflicting outcomes. This study assesses the effectiveness of care bundles to reduce SSI among patients undergoing colorectal surgery.

METHODS: We performed a systematic review and meta-analysis of randomized controlled trials, quasi-experimental studies, and cohort studies of care bundles to reduce SSI. The search strategy included database and clinical trials register searches from 2012 until June 2014, searching reference lists of retrieved studies and contacting study authors to obtain missing data. The Downs and Black checklist was used to assess the quality of all studies. Raw data were used to calculate pooled relative risk (RR) estimates using Cochrane Review Manager. The I² statistic and funnel plots were performed to identify publication bias. Sensitivity analysis was carried out to examine the influence of individual data sets on pooled RRs.

RESULTS: Sixteen studies were included in the analysis, with 13 providing sufficient data for a meta-analysis. Most study bundles included core interventions such as antibiotic administration, appropriate hair removal, glycemic control, and normothermia. The SSI rate in the bundle group was 7.0% (328/4,649) compared with 15.1% (585/3,866) in a standard care group. The pooled effect of 13 studies with a total sample of 8,515 patients shows that surgical care bundles have a clinically important impact on reducing the risk of SSI compared to standard care with a CI of 0.55 (0.39-0.77; P = .0005).

CONCLUSION: The systematic review and meta-analysis documents that use of an evidence-based, surgical care bundle in patients undergoing colorectal surgery significantly reduced the risk of SSI.

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Impact of CRS SSI Reduction Bundles

- Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients. Surgery 2015;158:66-77

Fig 2. Forest plot. Surgical care bundles to reduce the risk of surgical site infections.
  • 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
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<tr>
<td>Minimally invasive surgery</td>
<td>✔</td>
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<tr>
<td>Short duration of surgery</td>
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<tr>
<td>Silver dressings for 5 days</td>
<td>✔</td>
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<tr>
<td>Removal of sterile dressing within 48 h</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Postoperative washing of wound with CHG</td>
<td>✔</td>
<td>✔</td>
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</tbody>
</table>

*Omission of mechanical bowel preparation was revised during study to mechanical bowel preparation plus oral antibiotics.

BMI, Body mass index; CHG, chlorhexidine gluconate; SSI, surgical site infection.
Mayo Results of SSI Bundle

Tests performed with unequal sample sizes
Mechanical Bowel Preparation

• As intestinal surgery, colon surgery in particular, became more frequent in the 1930s the primacy of “cleansing the colon” became dogma
  • Commonly a multi-day mechanical bowel preparation (MBP)
  • Hospital based process

• As oral antibiotics became widely available in the early 1950’s, they were added to the mechanical bowel preparation (MBP + OA)
Rationale for Addition of OA

Antibiotic Protection of Colon Anastomoses

Isidore Cohn, Jr., M.D., and James D. Rives, M.D.
New Orleans, Louisiana

From the Department of Surgery, School of Medicine, Louisiana State University, New Orleans


The added risks of large bowel anastomosis are due chiefly to three factors:
1. The presence of solid feces and gas.
2. The vulnerable circulation.
3. The profuse bacterial flora.
Oral Antibiotics Alter Colonic Healing

- Purposely make a segment of colon ischemic
- Perform an anastomosis at one end of the ischemic segment
- Instill non-absorbable antibiotics into the ischemic segment
- Observe survival rates
Fig. 8. Survival in control and treated series.
Most Common MCP+OA of Latter 20th Century

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Diversity of MBP that has been used in those studies in which the oral antibiotic bowel preparation has been shown to be effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residue-free diet for 48 h before surgery</td>
<td>Day 1, low-residue diet; Bisacodyl, 1 capsule orally at 6 PM</td>
</tr>
<tr>
<td>Sodium phosphate and biphosphate 16 mL twice daily for 48 h before surgery</td>
<td>Day 2, continue low-residue diet; magnesium sulfate, 30 mL 50% solution (15 g) orally at 10:00 AM, 2:00 PM, and 6:00 PM; Saline enemas in evening until return clear</td>
</tr>
<tr>
<td>Two tap water enemas 2 d before surgery</td>
<td>Day 3 clear liquid diet; supplemental intravenous fluids as needed</td>
</tr>
<tr>
<td>Two tap water enemas each on the morning and afternoon of the day before surgery</td>
<td>Magnesium sulfate, at dose stated earlier, at 10:00 AM and 2:00 PM</td>
</tr>
<tr>
<td>500 mg neomycin and 250 mg tetracycline taken 4 times/d for 48 h before surgery</td>
<td>No enemas</td>
</tr>
<tr>
<td>Neomycin (1 g) and erythromycin base (1 g) at 1:00, 2:00, and 11:00 PM</td>
<td>Day 4, surgery scheduled at 8:00 AM</td>
</tr>
</tbody>
</table>

Turn of the Century Reports MBP v. None

**Table 3** Prospective randomized trials of no MBP versus patients receiving MBP in elective colon surgery from 2000 through 2010

<table>
<thead>
<tr>
<th>Study</th>
<th>No mechanical preparation</th>
<th>With mechanical preparation</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of patients</td>
<td>Infections</td>
<td>Number of patients</td>
</tr>
<tr>
<td>Miettinen, 2000*</td>
<td>129</td>
<td>10 (8%)</td>
<td>136</td>
</tr>
<tr>
<td>Bucher, 2005*</td>
<td>75</td>
<td>6 (8%)</td>
<td>78</td>
</tr>
<tr>
<td>Fa-Si-Oen, 2005*</td>
<td>125</td>
<td>13 (10%)</td>
<td>125</td>
</tr>
<tr>
<td>Ram, 2005†</td>
<td>165</td>
<td>10 (6%)</td>
<td>164</td>
</tr>
<tr>
<td>Zmora, 2006*</td>
<td>129</td>
<td>17 (13%)</td>
<td>120</td>
</tr>
<tr>
<td>Jung, 2006*</td>
<td>657</td>
<td>106 (16%)</td>
<td>686</td>
</tr>
<tr>
<td>Contant, 2007†</td>
<td>684</td>
<td>96 (14%)</td>
<td>670</td>
</tr>
<tr>
<td>Pena-Soria, 2008*</td>
<td>64</td>
<td>11 (17%)</td>
<td>65</td>
</tr>
<tr>
<td>Van’t Sant, 2010†</td>
<td>213</td>
<td>36 (17%)</td>
<td>236</td>
</tr>
</tbody>
</table>

Only 1 article concluded a statistically significant difference in infection rates.

*Reports include all SSIs.
†Reports include only surgical incision infections.
Need to Read More Than the Abstract

Colon and Rectal Surgery Without Mechanical Bowel Preparation
A Randomized Prospective Trial

Oded Zmora, MD, Ahmad Mahajna, MD, Barak Bar-Zakai, MD, Danny Rosin, MD, Dan Hershko, MD, Moshe Shabtai, MD, Michael M. Krausz, MD, and Amram Ayalon, MD

From the Departments of Surgery, Sheba Medical Center and Sackler School of Medicine, Tel Aviv, and Rambam Medical Center and Rappaport School of Medicine, Haifa, Israel
Need to Read More Than the Abstract

- OA were given in many of the reports
OA + IV Antibiotics versus IV Alone

- At the same time there were a number of studies that evaluated the role of OA + IV versus IV prophylaxis alone

- Nearly all demonstrated a benefit for the combined antibiotic prophylaxis therapy in reducing SSI
MBP Falls Out of Favor

• Cochrane Reviews in 2005 and 2011 report MBP not effective

  Despite the inclusion of more studies with a total of 5805 participants, there is no statistically significant evidence that patients benefit from mechanical bowel preparation, nor the use of rectal enemas. In colonic surgery the bowel cleansing can be safely omitted and induces no lower complication rate. The few studies focused in rectal surgery suggested that mechanical bowel preparation could be used selectively, even though no significant effect was found. Further research on patients submitted for elective rectal surgery, below the peritoneal verge, in whom bowel continuity is restored, and studies with patients submitted to laparoscopic surgeries are still warranted.

• No mention of the role of OA in the studies

• Other Drivers
  • Hospital length of stay reduction efforts
  • Morning of admission for elective surgery
  • No hospital stay for “complex bowel prep”
There Were Continued “Warnings”

- Intermittent reports of benefits from MBP + QA+ IV

Oral versus systemic antibiotic prophylaxis in elective colon surgery: a randomized study and meta-analysis send a message from the 1990s

Ronald T. Lewis, MB BS*

21st Century: Age of the Human **Microbiome**

- **Microbiota**: a collection or community of microbes
- The human microbiota consists of 10-100 trillion symbiotic microorganisms
- Majority are in our gut

- **Microbiome**: the full collection of genes in all of the microbes in our human community. The genes in our microbiome outnumber our own human genome by greater than 100 to 1
Microbiome in Health and Disease

- Numerous disturbances in microbiome are linked to health issues.
- Targeted alterations in microbiome are in place and many more are being developed:
  - Fecal transplant
  - Obesity treatment

Figure 1. Some Functions of the Gut Microbiota and Disease Associations.

*Notes:
- Influences: Immune maturation and homeostasis, Host cell proliferation, Vascularization, Neurologic signaling, Pathogen burden, Intestinal endocrine functions, Bone density, Energy biogenesis.
- Disease Indications: Neurologic, Psychiatric, Respiratory, Cardiovascular, Gastrointestinal, Hepatic, Autoimmune, Metabolic, Oncologic.

*Source:
*n engl j med 375;24 nejm.org December 15, 2016*
Colon Anastomosis Alters Microbiome at the Anastomosis

Figure 3 Comparative analysis of bacterial abundance in anastomotic tissues at POD0 and POD6. The analysis is presented at phylum, order, class, family, and genus levels.

Shogan et al. Microbiome 2014, 2:35
http://www.microbiomejournal.com/content/2/1/35
Microorganisms at the Anastomosis
Change in Composition and Virulence

• At the site of the anastomosis certain organisms can become more virulent
  • Intestinal Tissues Induce an SNP Mutation in *Pseudomonas aeruginosa* That Enhances Its Virulence: Possible Role in Anastomotic Leak
    • PLoS ONE 7(8): e44326. doi:10.1371/journal.pone.0044326
  • Select for organisms with higher collagenase activity

• Anastomotic leaks, both small and large, might not just be technical, tissue quality, blood supply or tension issues but perhaps a complex interaction between the local microbiome and the above elements
So Where Are We Now?

- We have rediscovered the MBP + OA + IV
MBP + OA + IV Reboot

**CURRENT STATUS**

Comparing Mechanical Bowel Preparation With Both Oral and Systemic Antibiotics Versus Mechanical Bowel Preparation and Systemic Antibiotics Alone for the Prevention of Surgical Site Infection After Elective Colorectal Surgery: A Meta-Analysis of Randomized Controlled Clinical Trials

Min Chen, M.D.¹ • Xue Song, M.D.¹ • Liang-zhou Chen, M.D.¹ • Zhi-dong Lin, M.D.¹
Xue-li Zhang, M.D.²


- Multiple contemporary trials and meta-analyses now support the combination of MBP+OA+IV

**CONCLUSIONS:** Oral systemic antibiotics and mechanical bowel preparation significantly lowered the incidence of surgical site infection after elective colorectal surgery compared with systemic antibiotics alone and mechanical bowel preparation.

**FIGURE 2:** Forest plot for total surgical site infection (SSI) after surgery. A Mantel-Haenszel fixed-effects model was used for meta-analysis. Risk ratios are shown with 95% CIs. o = oral antibiotics; s = systemic antibiotics; df = degrees of freedom.
NSQIP CRS Specific Data

• Analysis of the targeted colectomy NSQIP also supports the use of MBP+OA + IV

Combined Preoperative Mechanical Bowel Preparation With Oral Antibiotics Significantly Reduces Surgical Site Infection, Anastomotic Leak, and Ileus After Colorectal Surgery

Ravi Pokala Kiran, MBBS, MS, FRCS, FACS, MSc (EBM), FASCRS,* † Alice C. A. Murray, BSc, MBBS, MRCS,* Cody Chiu, PhD, † David Estrada, MD,* and Kenneth Forde, MD*


Conclusions: These data clarify the near 50-year debate whether bowel preparation improves outcomes after colorectal resection. MBP with oral antibiotics reduces by nearly half, SSI, anastomotic leak, and ileus, the most common and troublesome complications after colorectal surgery.

FIGURE 1. Postoperative complications according to type of bowel preparation. *Statistical significance, P < 0.0001.
Mayo SSI Reduction Effort Update

• Automatic distribution process of monthly NSQIP occurrence submission data to division membership (consultants, residents and fellows, clinic, OR, floor nursing staff, CRS pharmacy teams, administrative leadership)

• Monthly control chart distribution

• Quarterly review by practice review multidisciplinary team to assess and consider new changes
  • Group decided to implement mechanical bowel preparation with oral antibiotics for 18 month observation period
  • Started November 2015
Impact Update

Introduction of mechanical bowel prep with oral antibiotics
Pre-Operative Bowel Preparation Instructions for Colon and Rectal Surgery

Your surgeon has asked you to cleanse your bowels before your operation. The process includes two types of laxative agents, two types of oral antibiotics, and a medicine to help you with any associated nausea.

You will need to purchase the following items at your local pharmacy or store:

**The laxative agents** (NO prescriptions are required)
- 238 gram bottle of MiraLAX™
- 4 bisacodyl (Dulcolax™) **laxative** tablets (The store package may contain more than 4 tablets)
- Two 32 oz. Gatorade™ (if you are diabetic or do not like regular Gatorade™, you may substitute another clear liquid drink, such as Gatorade 2™, Crystal Light™, Propel™, etc.)

**Antibiotics:** (A prescription is required)
- 6 neomycin (500 mg tablets)
- 3 metronidazole (500 mg tablets)

**Anti-nausea medication:** (A prescription is required)
- 3 ondansetron (Zofran™) (4 mg tablets)

**Facts about the bowel preparation experience**:

- Clear liquids should be actively ingested throughout the day that you are doing your bowel preparation. Examples are: water, clear fruit juices (apple, grape, cranberry), Gatorade-like sports drinks, bouillon, Jell-O™ (no fruit), flavored ices, tea, and black coffee (it is okay to add sugar but no dairy products)
- This bowel prep will dehydrate you. It is **important to drink plenty of clear fluids in addition to the MiraLAX™ mixture on the day of the bowel preparation**.
- You will experience periods of abdominal bloating, cramps, and frequent liquid bowel motions. All of this is expected and will resolve. If you experience severe abdominal pain, fever, or persistent vomiting stop your preparation and call the surgeon contact information provided in your scheduling packet.
- The commercially available sports drinks are ideal because they provide sugar and salts to replace fluid losses you experience with the bowel preparation.
Instructions for your bowel preparation the day before surgery

- You may have a light breakfast of regular food as long as it is completed before 9 am.
- After 9 am, no solid foods or milk products are allowed.
- Drink only clear liquids for the remainder of the day including at lunch and dinner times.
- Take the number of tablets noted in the box at the specified time with an 8 oz. glass of any clear liquid.

<table>
<thead>
<tr>
<th>Time</th>
<th>Bisacodyl (4 tablets total)</th>
<th>Neomycin (6 tablets total)</th>
<th>Metronidazole (3 tablets total)</th>
<th>Ondansetron (3 tablets total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 am</td>
<td>2 tablets</td>
<td></td>
<td></td>
<td>1 tablet</td>
</tr>
<tr>
<td>12 pm</td>
<td></td>
<td>2 tablets</td>
<td>1 tablet</td>
<td></td>
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<tr>
<td>2 pm</td>
<td>Mix the 238-gram bottle of MiraLAX™ in 64 oz. of clear liquid. Shake the solution until the MiraLAX™ is dissolved. Drink an 8 oz. glass every 15-20 minutes until the solution is gone.</td>
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<tr>
<td>5 pm</td>
<td>2 tablets</td>
<td>1 tablet</td>
<td></td>
<td></td>
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<tr>
<td>6 pm</td>
<td>2 tablets</td>
<td>1 tablet</td>
<td>1 tablet</td>
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<tr>
<td>For the rest of the evening, drink four additional 8 oz. glasses of clear liquids</td>
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<tr>
<td>9 pm</td>
<td>2 tablets</td>
<td>1 tablet</td>
<td>1 tablet</td>
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</table>
Summary

• Colorectal SSIs continue to be a major problem in the US

• There is no single intervention that can prevent them from occurring

• Bundles of intervention used with high compliance can significantly reduce SSIs

• Addition of MBP+OA+IV prophylaxis is an important component of SSI reduction

• Future studies and possible interventions of the microbiome might further assist in reducing SSI incidence
The Needs of the Patient Come First - W.J. Mayo
Questions & Discussion