

Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

Specific Care Question

In pediatric patients undergoing elective colon surgery what interventions, or surgical care bundles, prevent surgical site infections (SSI)?

Recommendations Based on Current Literature (Best Evidence) Only

Mechanical bowel preparation (MBP). *A conditional recommendation is made against the use of mechanical bowel preparation (MBP) in pediatric patients undergoing colon surgery. The overall certainty in the evidence is very low. Two systematic reviews (one adult and one pediatric) answered this question. Neither systematic review demonstrated lower rates of infection with MBP. Confidence in the evidence is low for the use of MBP in pediatric patients. The systematic review of pediatric patients only found two randomized control trials (RCT) and four cohorts that studied the use of MBP in pediatric patients.*

Oral plus intravenous (IV) antibiotics. *A conditional recommendation is made for the use of oral plus IV antibiotics in pediatric patients undergoing colon surgery. The overall certainty in the evidence is very low. One systematic review of adults and one cohort study of pediatric patients answered this question. The systematic review, which only included adults, demonstrated lower rates of infection in the oral plus IV antibiotics groups. The one cohort study for pediatric patients reported no difference in infection rates with oral plus IV antibiotics compared not IV antibiotics alone. While the confidence in the evidence is more certain adult patients, the confidence in the evidence of pediatric patients was very low.*

Surgical care bundles. *A conditional recommendation is made for the use of surgical care bundles in pediatric patients undergoing colon surgery. The overall certainty in the evidence is very low. Only four cohort studies were identified to answer this question, and three of the studies included adult patients only; all four studies used different bundle elements. Confidence in the evidence is very low for determining which bundle elements should be implemented in the pediatric population.*

Perioperative high inspired oxygen therapy. *No recommendation is made for the use of perioperative high inspired oxygen therapy in pediatric patients undergoing colon surgery. The overall certainty in the evidence is low. One systematic review of adult patients was identified. Four RCTs reported lower rates of surgical site infections in adult patients undergoing colon surgery. Confidence in the evidence is low for determining if oxygen therapy is effective in pediatric patients, as no studies were found.*

Literature Summary

Background. SSIs are the most common cause of hospital-acquired infections in the surgical population (Rangel et al., 2015). Colorectal procedures are responsible for a disproportionate burden of SSIs within pediatric surgery (Feng et al., 2015). SSIs occur in 13 to 25% in children undergoing colorectal surgery, resulting in significant morbidity for patients and costs to the healthcare system (Ares et al., 2018). Efforts to reduce SSIs in the pediatric population include SSI-reduction bundles and national networks sharing interventions (Children's Hospitals' Solutions for Patient Safety, 2019). Extensive literature on the efforts to reduce SSIs has been published on adults (Güenaga, Matos, & Wille-Jørgensen, 2011; Nelson, Gladman, & Barbateskovic, 2014; Rangel et al., 2015). Unfortunately, literature of the pediatric population has been limited (Rangel et al., 2015). This review will summarize identified literature for the interventions of MBP, oral plus IV antibiotics, care bundles, and perioperative high inspired oxygen therapy.

Study characteristics. The search for suitable studies was completed on February 14, 2019. L Harte, PharmD reviewed the 34 titles and/or abstracts found in the search and identified 24 articles believed to answer the question. After an in-depth review, 10 articles answered the question. The studies included five systematic reviews (Güenaga et al., 2011; Janssen Lok et al., 2018; Nelson et al., 2014; Rangel et al., 2015; Togioka et al., 2012) and five cohort studies (Bert et al., 2017; Bull et al., 2011; Jaffe et al., 2017; Janssen Lok et al., 2018; Nordin et al., 2018) (see Figure 1). The five systematic reviews included 34 randomized control trials (RCT) and four cohort studies.

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For the intervention “Bundles”, four cohort studies were analyzed. For the intervention “Oral Plus IV Antibiotics”, one systematic review (15 trials) and one cohort study was included. For the intervention of “MBP”, two systematic reviews (19 RCTs) were included. For the intervention of “Perioperative High Inspired Oxygen Therapy”, one systematic review (4 RCTs) was included. For the interventions of MBP, oral plus IV antibiotics, and perioperative high inspired oxygen therapy, this review was unable to create meta-analysis from previously published systematic reviews because new trials were not identified to add to the included meta-analysis. Meta-analysis was not created for the intervention of “Bundles” due to the heterogeneity of cohort studies.

Summary by Intervention

Mechanical Bowel Preparation. Two systematic reviews (Güenaga et al., 2011; Janssen Lok et al., 2018) found 19 studies which measured intra-abdominal infection and wound infections in patients that received MBP prior to colon surgery.

The systematic review by Janssen Lok et al. (2018) included two RCTs ($n = 76$) and four cohorts ($n = 2102$) that compared MBP versus no MBP in pediatric patients that underwent colon surgery. The summary of Jensen et al. (2018) meta-analysis is reported in Table 1. For intra-abdominal infection in pediatric patients that underwent colon surgery, the RCTs found that employing MBP was not different to not employing MBP, $OR = 1.08$, 95% CI [0.11, 10.74]. For wound infection in pediatric patients ($n = 76$) that underwent colon surgery, the RCTs found that employing MBP was not different to not employing MBP, $OR = 1.10$, 95% CI [0.22, 5.48]. The evidence was of low certainty based on serious risk of bias and serious imprecision. Risk of bias was serious due to deviation from intended interventions. Imprecision was serious due to the low number of SSIs.

For intra-abdominal infection in pediatric patients that underwent colon surgery, the cohort studies found that employing MBP was not different to not employing MBP, $OR = 0.91$, 95% CI [0.22, 5.48]. For wound infections in pediatric patients that underwent colon surgery, the cohort studies found that employing MBP was not different to not employing MBP, $OR = 1.39$, 95% CI [0.67, 2.90]. The evidence was of very low certainty based on serious risk of bias and serious imprecision. Risk of bias was serious due to confounding bias and imprecision was serious due to the low number of SSIs.

A systematic review by Güenaga et al. (2011) found 13 RCTs ($N = 4595$) that compared MBP versus no MBP in adult patients that underwent colon surgery. The summary of Güenaga et al. (2011) meta-analysis is reported in Table 1. For wound infection in adult patients that underwent colon surgery, the RCTs reported employing MBP was not different to not employing MBP, $OR = 1.16$, 95% CI [0.95, 5.48]. The evidence was of low certainty based on serious risk of bias and serious indirectness. Risk of bias was serious due to systematic differences in care provided (Güenaga et al. 2011). Indirectness was serious due to all the studies were adult not pediatric patients.

Oral plus IV antibiotics. One systematic review of adults (Nelson et al., 2014) and one cohort study of children (Xiaolong, Yang, Xiaofeng, Qi, & Bo, 2018) compared oral plus IV antibiotics versus IV antibiotics alone in patients undergoing colon surgery.

A systematic review by Nelson et al. (2014) found 15 RCTs ($N = 2929$) that compared oral plus IV antibiotics versus IV antibiotics alone in adult patients. The summary of Nelson et al. (2014) meta-analysis is reported in Table 2. The meta-analysis indicated fewer occurrences of SSI for adult patients who received oral plus IV antibiotics versus IV antibiotics alone, $OR = 0.50$, 95% CI [0.39, 0.65]. For adult patients undergoing colon surgery, there were 59 fewer SSIs per 1000 patients with a confidence interval of 74 few to 41 fewer. The evidence was of low certainty based on serious risk of bias and serious indirectness. Risk of bias was serious due to lack of allocation concealment, and there was serious indirectness due to all the studies were adult patients.

One cohort study (Xiaolong et al., 2018) compared oral plus IV antibiotics versus IV antibiotics alone in pediatric patients ($N = 564$). There was no difference in the occurrence of SSI in pediatric patients undergoing colon surgery, $OR = 1.08$, 95% CI [0.38, 3.07]. The evidence was of very low certainty due to serious risk of bias due to confound variables and serious imprecision due to a low number of SSIs.

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Bundles. Four cohort studies (Bert et al., 2017; Bull et al., 2011; Jaffe et al., 2017; Nordin et al., 2018), compared surgical bundles versus no surgical bundles in pediatric and adult patients who underwent gastrointestinal or colon surgery. A meta-analysis was not created for the four cohorts due to the heterogeneity of how the results were reported.

Nordin et al. (2018) implemented a surgical bundle in pediatric patients undergoing gastrointestinal surgery ($N = 1,474$). The bundle included a) perioperative MBP; b) perioperative abdomen surface cleansing, clean the abdomen with 2% chlorhexidine gluconate wipes for patients >2 months, clean the abdomen with antimicrobial wipes for patients <2 months; c) perioperative warming when temperatures are below 36.5°C , d) perioperative antibiotics, e) skin preparation with chlorhexidine for all patients >2 months or >1 kg, 10% povidone-iodine for patients <2 months or <1 kg; and f) closing procedures (change gloves, re-drape surgical field, and remove all dirty instruments). Post bundle implementation, SSI rates decreased from 7.1% to 4.7% despite an increase in surgical volume. Odds ratio (OR) and confidence intervals were not provided and could not be calculated as the pre-intervention number of patients was not provided.

Bert et al. (2017) implemented a surgical bundle in adult patients who underwent colon surgery ($N = 1,322$). The bundle included a) infection risk index calculator, b) pre-operative shower, c) trichotomy, d) antibiotic prophylaxis, and e) body temperature control. The OR indicated the intervention of this surgical bundle was protective against SSI for colon surgery, $OR = 0.55$, 95% CI [0.38, 0.78].

Bull et al. (2011) implemented a surgical bundle in adult patients who underwent colon surgery ($N = 275$). The bundle included a) maintenance of normothermia $\geq 36^{\circ}\text{C}$, b) oxygenation $\text{FiO}_2 \geq 0.8$, c) systolic blood pressure ≤ 90 mmHg, d) blood sugar level ≤ 10 mmol/L, and e) pre-operative antibiotics. Comparing pre- and post-bundle implementation, SSIs decreased from 15%, 95% CI [10.4, 20.2] to 7%, 95% CI [3.4, 12.6] after 12 months.

Jaffe et al. (2017) implemented a surgical bundle in adult patients who underwent colon surgery ($N = 3387$). The bundle included a) perioperative antibiotics, b) postoperative normothermia ($>96.8^{\circ}\text{F}$), c) oral antibiotics with bowel preparation, d) operative glycemic control, e) minimally invasive surgery, and f) short operative duration (<100 min). Rate of SSI was higher in the "low compliance bundle group" (0 to 2 items compliant) compared to the "high compliance bundle group" (3 to 6 items compliant), 17.9%, 95% CI [10.8, 27.0] and 0.9%, 95% CI [0, 3.0], respectively.

The evidence was of very low certainty due to serious risk of bias, serious imprecision, and serious indirectness. Risk of bias was high because only one study accounted for confounding variables (Bert et al., 2017). There was serious imprecision due to the low number of SSIs. There was serious indirectness because three of the four study populations were adult not pediatric patients and one study included gastrointestinal surgeries.

Perioperative high inspired oxygen therapy. One systematic review (Togioka et al., 2012) found four RCTs ($N = 1039$) comparing perioperative high inspired oxygen therapy versus no treatment in adults undergoing colon surgery. The summary of their meta-analysis is reported in Table 3. The OR indicated fewer occurrences of SSI in adult patients who received high inspired oxygen therapy versus patients who did not, $OR = 0.48$, 95% CI [0.32, 0.71]. There was 74 fewer SSI per 1000 patients with a confidence interval of 100 fewer to 40 fewer. The evidence was of low certainty based on serious indirectness due to all the studies were adult not pediatric patients. Also, there is serious imprecision due to the low number of SSIs.

Identification of Studies

Search Strategy and Results (see Figure 1)

PubMed

("Colorectal Surgery"[Mesh] OR "colorectal surgery"[tiab] OR "colon surgery"[tiab]) AND "Surgical Wound Infection/prevention and control"[Mesh] AND (pediatr* OR paediatr* OR child OR children OR infant OR adolescence) Filters: 10 years

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| CINAHL | | | | |
|---|--|---|--|---------|
| # | Query | Limiters/Expanders | Last Run Via | Results |
| S8 | S4 AND S6 | Limiters - Age Groups: Infant, Newborn: birth-1 month, Infant: 1-23 months, Child, Preschool: 2-5 years, Child: 6-12 years, Adolescent: 13-18 years, All Infant, All Child Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 15 |
| S7 | S4 AND S6 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 156 |
| S6 | S3 OR S5 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 9,256 |
| S5 | S1 AND S2 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 9,060 |
| S4 | (MH "Surgical Wound Infection/PC") | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 3,817 |
| S3 | "colon surgery" OR "colorectal surgery" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 2,528 |
| S2 | (MH "Colon+") OR "colorectal" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 34,645 |
| S1 | (MH "Surgery, Elective+") OR (MH "Surgery, Operative+") OR "surgery" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL | 682,605 |
| Records identified through database searching $n = 32$ Additional records identified through other sources $n = 2$ | | | | |
| <i>Studies Included in this Review</i> | | | | |

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| Citation | Study Type |
|------------------------------|------------|
| Authors (YYYY) | |
| Bert et al. (2017) | Cohort |
| Bull et al. (2011) | Cohort |
| Güenaga et al. (2011) | SR |
| *Bretagnol et al. (2010) | RCT |
| *Brownson (1992) | RCT |
| *Burke et al. (1994) | RCT |
| *Contant et al. (2007) | RCT |
| *Fa-Si-Oen et al. (2005) | RCT |
| *Jung et al. (2007) | RCT |
| *Mospiane et al. (2008) | RCT |
| *Miettinen et al. (2000) | RCT |
| *Pena-Soria et al. (2007) | RCT |
| *Ram et al. (2005) | RCT |
| *Santos Jr et al. (1994) | RCT |
| *Young Tabusso et al. (2002) | RCT |
| Jaffe et al. (2017) | Cohort |
| Janssen Lok et al. (2018) | SR |
| *Aldrink et al. (2015) | RCT |
| *Shah et al. (2016) | RCT |
| *Leys et al. (2005) | Cohort |
| *Breckler et al. (2010) | Cohort |
| *Serrurier et al. (2012) | Cohort |
| *Ares et al. (2018) | Cohort |
| Nelson et al. (2014) | SR |
| *Coppa et al. (1988) | RCT |
| *Espin-Basany et al. (2005) | RCT |
| *Ishibashi et al. (2009) | RCT |
| *Kaiser et al. (1983) | RCT |
| *Khubchandani et al. (1989) | RCT |
| *Kobayashi et al. (2007) | RCT |
| *Lau et al. (1988) | RCT |
| *Lazorthes et al. (1982) | RCT |
| *Lewis et al. (2002) | RCT |
| *McArdle et al. (1995) | RCT |
| *Peruzzo et al. (1987) | RCT |
| *Reynolds et al. (1989) | RCT |
| *Stellato et al. (1990) | RCT |
| *Takesue et al. (2000) | RCT |
| *Taylor et al. (1994) | RCT |
| Nordin et al. (2018) | Cohort |
| Rangel et al. (2015) | SR |

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| | |
|------------------------|--------|
| Togioka et al. (2012) | SR |
| *Belda et al. (2005) | RCT |
| *Bickel et al. (2011) | RCT |
| *Greif et al. (2000) | RCT |
| *Mayzler et al. (2005) | RCT |
| Xiaolong et al. (2018) | Cohort |

*References marked with an asterisk indicate studies included in the meta-analyses.

Studies Not Included in this Review with Exclusion Rationale

| Citation | Reason for exclusion |
|--------------------------------|---|
| Authors (YYYY) | |
| Ares et al. (2018) | Duplicate |
| Baracs et al. (2011) | Suture article |
| Breckler et al. (2010) | Survey |
| Eagye et al. (2011) | Did not look at oral plus IV antibiotics |
| Feng et al. (2015) | Survey |
| Fracalvieri et al. (2014) | Suture article |
| Govinda et al. (2010) | Measuring tissue oxygen |
| Hjalmarsson et al. (2015) | Did not look at oral plus IV antibiotics |
| Leng et al. (2014) | Only comparing IV antibiotics |
| Moghadamyeghaneh et al. (2015) | Adult cohort looking at MBP and antibiotics |
| Morse et al. (2018) | Review article |
| Palmer et al. (1994) | Adults, not an RCT |
| Pennington et al. (2014) | Infection rates not reported |
| Stewart et al. (1995) | Did not look at oral plus IV antibiotics |

Methods Used for Appraisal and Synthesis

^aRayyan is a web-based software used for the initial screening of titles and / or abstracts for this analysis (Ouzzani, Hammady, Fedorowicz & Elmagarmid, 2017).

^bReview Manager (Higgins & Green, 2011) is a Cochrane Collaborative computer program used to assess the study characteristics as well as the risk of bias and create the forest plots found in this analysis.

^cThe [GRADEpro Guideline Development Tool \(GDT\)](#) is the tool used to create the Summary of Findings table(s) for this analysis (see Tables 1).

^dThe Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram depicts the process in which literature is searched, screened, and eligibility criteria is applied (Moher, Liberati, Tetzlaff, & Altman, 2009).

^aOuzzani, M., Hammady, H., Fedorowicz, Z., & Elmagarmid, A. (2016). Rayyan-a web and mobile app for systematic reviews. *Systematic Reviews*, 5(1), 210. doi:10.1186/s13643-016-0384-4

^bHiggins, J. P. T., & Green, S. e. (2011). *Cochrane Handbook for Systematic Reviews of Interventions [updated March 2011]* (Version 5.1.0 ed.): The Cochrane Collaboration, 2011.

^cGRADEpro GDT: GRADEpro Guideline Development Tool (2015). McMaster University, (developed by Evidence Prime, Inc.). [Software]. Available from gradepr.org.

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^dMoher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 For more information, visit www.prisma-statement.org.

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Acronyms Used in this Document

| Acronym | Explanation |
|---------|--|
| ASA | American Society of Anesthesiologists |
| EBP | Evidence Based Practice |
| CI | Confidence interval |
| IV | Intravenous |
| MBP | Mechanical bowel preparation |
| OR | Odds ratio |
| RCT | Randomized control trial |
| RoB | Risk of bias |
| SSI | Surgical site infections |
| SR | Systematic review |
| SNICH | National System of Surveillance of Surgical Site Infection |

Date Developed/Updated

April 2019

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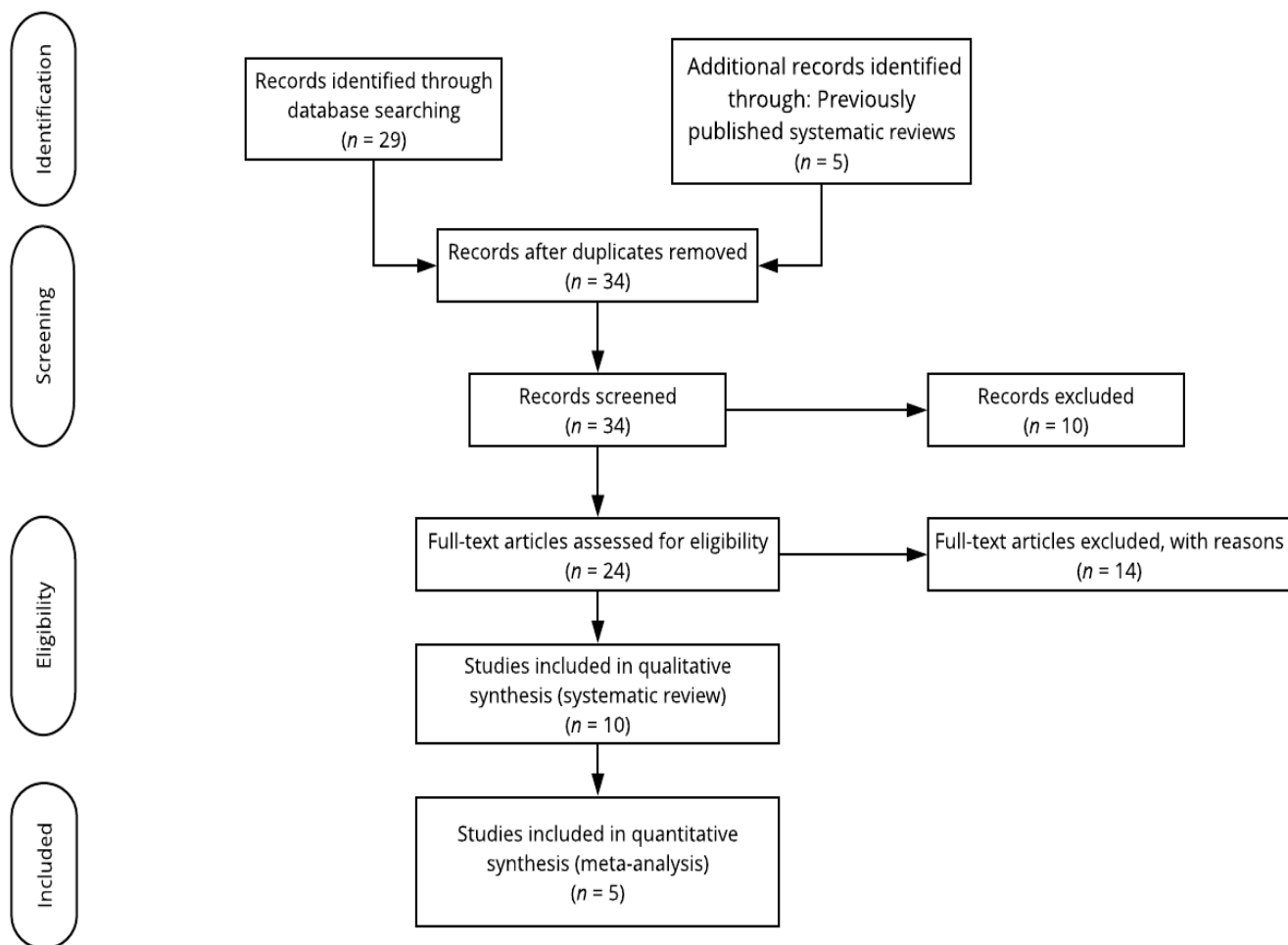


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)^d

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Table 1

Summary of Findings Table^c: Mechanical Bowel Preparation Compared to No Mechanical Bowel Preparation for Pediatric Colon Surgery Patients

| Certainty assessment | | | | | | | Summary of findings | | | | |
|---|----------------------|---------------|--------------|----------------------|------------------|-------------------------------|--------------------------------------|-----------------------------------|-----------------------------------|---|---|
| Nº of participants (studies) Follow-up | Risk of bias | Inconsistency | Indirectness | Imprecision | Publication bias | Overall certainty of evidence | Study event rates (%) | | Relative effect (95% CI) | Anticipated absolute effects | |
| | | | | | | | With No Mechanical Bowel Preparation | With Mechanical Bowel Preparation | | Risk with No Mechanical Bowel Preparation | Risk difference with Mechanical Bowel Preparation |
| <i>Intra-abdominal infection in pediatric patients</i> | | | | | | | | | | | |
| 76 (2 RCTs) | serious ^b | not serious | not serious | serious ^c | none | ⊕⊕○○ LOW | 3/42 (7.1%) | 2/34 (5.9%) | OR 1.08 (0.11 to 10.74) | 71 per 1,000 | 5 more per 1,000 (63 fewer to 381 more) |
| <i>Wound infections in pediatric patients</i> | | | | | | | | | | | |
| 76 (2 RCTs) | serious ^b | not serious | not serious | serious ^c | none | ⊕⊕○○ LOW | 5/34 (14.7%) | 7/42 (16.7%) | OR 1.10 (0.22 to 5.48) | 147 per 1,000 | 12 more per 1,000 (111 fewer to 339 more) |
| <i>Intra-abdominal infection in pediatric patients</i> | | | | | | | | | | | |
| 415 (2 observational studies) | serious ^d | not serious | not serious | serious ^c | none | ⊕○○○ VERY LOW | 1/118 (0.8%) | 2/297 (0.7%) | OR 0.91 (0.08 to 10.15) | 8 per 1,000 | 1 fewer per 1,000 (8 fewer to 71 more) |
| <i>Wound infections in pediatric patients</i> | | | | | | | | | | | |

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| Certainty assessment | | | | | | | Summary of findings | | | | |
|---|----------------------|-------------|----------------------|----------------------|------|---------------------|---------------------|--------------------|-------------------------------------|--------------------|--|
| 2102 (4 observational studies) | serious ^d | not serious | not serious | serious ^c | none | ⊕○○○ VERY LOW | 44/1133 (3.9%) | 64/969 (6.6%) | OR 1.39 (0.67 to 2.90) | 39 per 1,000 | 14 more per 1,000 (12 fewer to 66 more) |
| Wound infections in adult patients | | | | | | | | | | | |
| 4595 (13 RCTs) | serious ^a | not serious | serious ^e | not serious | none | ⊕⊕○○ LOW | 196/2290 (8.6%) | 223/2305 (9.7%) | OR 1.16 (0.95 to 1.42) | 86 per 1,000 | 12 more per 1,000 (4 fewer to 32 more) |

Notes:

- a. Systematic differences in care provided, apart from the intervention being evaluated.
- b. Bias from the randomization process and deviation from intended interventions
- c. Low number of SSIs
- d. Serious confounding bias
- e. Adult patients

Table 2

Summary of Findings Table^c: Oral + IV Antibiotics compared to IV Alone for Pediatric Colon Surgery Patients

| Certainty assessment | | | | | | | Summary of findings | | | | |
|--|----------------------|---------------|----------------------|-------------|---------------------|--|--------------------------|----------------------------------|-------------------------------------|---------------------------------|---|
| Nº of participants (studies) Follow-up | Risk of bias | Inconsistency | Indirectness | Imprecision | Publication bias | Overall certainty of evidence | Study event rates (%) | | Relative effect (95% CI) | Anticipated absolute effects | |
| | | | | | | | With IV alone | With Oral + IV antibiotics | | Risk with IV alone | Risk difference with Oral + IV antibiotics |
| Surgical site infections adult patients | | | | | | | | | | | |
| 2929 (15 RCTs) | serious ^d | not serious | serious ^a | not serious | none | ⊕⊕⊕○ MODERATE | 188/1473 (12.8%) | 100/1456 (6.9%) | OR 0.50 (0.39 to 0.65) | 128 per 1,000 | 59 fewer per 1,000 (74 fewer to 41 fewer) |
| Surgical site infections pediatric patients | | | | | | | | | | | |

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| Certainty assessment | | | | | | | Summary of findings | | | | |
|--------------------------------|----------------------|-------------|-------------|----------------------|------|------------------|---------------------|-----------------|----------------------------------|--------------|--|
| 564 (1 observational study) | serious ^b | not serious | not serious | serious ^c | none | ⊕○○○ VERY LOW | 9/348 (2.6%) | 6/216 (2.8%) | OR 1.08 (0.38 to 3.07) | 26 per 1,000 | 2 more per 1,000 (16 fewer to 50 more) |

Notes:

- a. Adult patients
- b. Serious confounding bias
- c. Low number of SSIs
- d. Lack of allocation concealment

Table 3

Summary of Findings Table^c: Hyperoxia compared to No Hyperoxia for Colon Surgery Patients

| Certainty assessment | | | | | | | Summary of findings | | | | |
|--|--------------|---------------|----------------------|----------------------|------------------|-------------------------------|-----------------------|------------------|----------------------------------|------------------------------|--|
| Nº of participants (studies) Follow-up | Risk of bias | Inconsistency | Indirectness | Imprecision | Publication bias | Overall certainty of evidence | Study event rates (%) | | Relative effect (95% CI) | Anticipated absolute effects | |
| | | | | | | | With no Hyperoxia | With Hyperoxia | | Risk with no Hyperoxia | Risk difference with Hyperoxia |
| Surgical site infections adult patients | | | | | | | | | | | |
| 1039 (4 RCTs) | not serious | not serious | serious ^a | serious ^b | none | ⊕⊕○○ LOW | 80/515 (15.5%) | 43/524 (8.2%) | OR 0.48 (0.32 to 0.71) | 155 per 1,000 | 74 fewer per 1,000 (100 fewer to 40 fewer) |

Notes:

- a. Adult patients
- b. Low number of SSIs

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Characteristics of Studies

Bert 2016

| | |
|----------------------|--|
| Methods | Retrospective Cohort |
| Participants | <p>Participants: Hip or colon operations performed between January 1 - December 31, 2012</p> <p>Setting: 37 hospitals in the Piedmont region of Turin, Italy</p> <p>Number enrolled: <i>N</i> = 3314</p> <ul style="list-style-type: none"> • Group 1 (<i>National System of Surveillance of Surgical Site Infection</i> (SNICH) + bundle): <i>n</i> = 1785 • Group 2 (SNICH alone): <i>n</i> = 1529 <p>Number complete: <i>N</i> = 3314</p> <ul style="list-style-type: none"> • Group 1 (SNICH + bundle): <i>n</i> = 1785 • Group 2 (SNICH alone): <i>n</i> = 1529 <p>Gender, males: <i>N</i> = 44%</p> <ul style="list-style-type: none"> • Group 1 (SNICH + bundle): <i>n</i> = 44.5% • Group 2 (SNICH alone): <i>n</i> = 43.4% <p>Age, years (mean): adult, the SNICH alone group was</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Hip or colon surgery <p>Exclusion criteria: Not reported</p> <p>Covariates identified:</p> <ul style="list-style-type: none"> • Total number who received either therapy is not known, mortality is not reported. • Length and complexity of surgery • ASA (American Society of Anesthesiologists) score • Period of hospital stay prior to operation • Age • Number of contamination cases |
| Interventions | <ul style="list-style-type: none"> • Group 1 (SNICH + bundle) • Group 2 (SNICH alone) |
| Outcomes | To determine the effectiveness of the surgical bundle to reduce the incidence of SSIs in the main 2 surgical categories of 2012 regional surveillance: hip replacement and colon surgery |

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| Notes | |
|-------|--|
| | <p>Univariate analysis - the surgical bundle was protective against SSI for colon surgery. For those whose care included the bundle for the outcome SSI, <i>OR</i> = 0.56, 95% CI [0.39, 0.80].</p> <p>The following were associated with increased risk of SSI in colon surgery</p> <ul style="list-style-type: none">• Intervention technique, <i>OR</i> = 2.07, 95%CI [1.25, 3.62]• ASA score ≥ 3, <i>OR</i> = 1.8, 95%CI [1.26, 2.57]• Urgent procedures, <i>OR</i> = 1.81, 95%CI [1.22, 2.66]• Contamination class ≥ 3, <i>OR</i> = 2.32, 95%CI [1.62, 3.31] <p>Multivariate analysis - the surgical bundle was protective against SSI for colon surgery and confirmed the univariate analysis. For those whose care included the bundle, the odds ratio for a SSI, <i>OR</i> = 0.55, 95% CI [0.38, 0.78].</p> <p>The following were continued to be associated with increased risk of SSI in colon surgery</p> <ul style="list-style-type: none">• ASA Score ≥ 3• Contamination class ≥ 3 <p>SSI surveillance bundle:</p> <ul style="list-style-type: none">• Infection risk index calculation• Perioperative shower• Trichotomy• Antibiotic prophylaxis• Body temperature control <p>National System of Surveillance of Surgical Site Infections (SNiCh)</p> <p>Results: see table.</p> |

Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

Bull 2011

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| Methods | Cohort study to evaluate the feasibility of implementing a bundle of care for patients undergoing colorectal surgery |
| Participants | <p>Participants: All patients undergoing a colorectal procedure included in the National Health and Safety Network (NHSN) colon or rectal procedure groups during the study periods included.</p> <p>Setting: The Colorectal Surgical Unit at Dandenong Hospital, Melbourne, Victoria</p> <p>Number enrolled: $N = 275$</p> <p>Number completed: $N = 275$</p> <p>Gender, males: 55% male</p> <p>Age, years median [range] 66 years [18-90 years]</p> <p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Listed under participants <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • None listed. |
| Interventions | <p>Bundle included:</p> <ul style="list-style-type: none"> • Maintenance of normothermia $\geq 36^{\circ}$ C. Recommendations included documentation of temperature, use of warmed blankets pre- and postoperatively, use of Bair Huggers and warmed fluids intra-operatively. • Oxygenation $FiO_2 \geq 0.8$. Adequate postoperative oxygenation was defined initially as administration of at least 6L oxygen/min and regular monitoring of oxygen saturation. Later in the project, this was changed to use of high-flow non-rebreathing mask for 4 hours postoperatively. • Blood Pressure Systolic ≥ 90 mmHg intra- and postoperatively. • Blood sugar level ≤ 10 mmol pre-and intra-operatively. • Antibiotic prophylaxis appropriate choice, timing and second dose for prolonged procedures > three hours. |
| Outcomes | <ul style="list-style-type: none"> • Overall compliance to the bundle • Surgical site infections (SSIs) during the implementation phase • SSIs during the sustainability phase. • Infection rate for those patients receiving optimal prophylactic antibiotic |
| Notes | <p>Results:</p> <p>Overall</p> <ul style="list-style-type: none"> • Overall compliance with the elements of bundled care was 21% at the end of the project. • Twelve Surgical site infections (SSIs) were identified during the implementation phase. • Ten SSIs were identified during the sustainability phase. • The infection rate for those patients receiving optimal prophylactic antibiotic administration was 5% compared with 10% in patients who did not receive optimal prophylactic antibiotic administration. <p>By bundle element</p> <ul style="list-style-type: none"> • Maintenance of normothermia: <ul style="list-style-type: none"> ○ 77% of patients had a temperature of $\geq 36^{\circ}$ before leaving the ward. ○ 61% of patients had a temperature of $\geq 36^{\circ}$ by the time they reached the operating theatre. |

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| | <ul style="list-style-type: none">○ Patients whose temperature was measured and recorded were much more likely to be given a blanket than patients whose temperature was not measured. (odds ratio 14.8, 95% CI 3.3-66.9)• Oxygenation<ul style="list-style-type: none">○ Patients receiving $FiO_2 \geq 0.8$ had a had a mean lowest recorded intraoperative oxygen saturation of 98%.○ Patients who did not receive $FiO_2 \geq 0.8$ had a mean lowest intraoperative oxygen saturation of 97%○ There was no discussion of postoperative oxygen saturation levels.• Blood Pressure<ul style="list-style-type: none">○ Systolic blood pressure was maintained at ≥ 90 mmHg in 98% of patients.• Blood sugar levels<ul style="list-style-type: none">○ This was monitored for diabetic patients. During the study period 96% of diabetic patients had a blood sugar level recorded preoperatively.○ Intraoperative maintenance at < 10 mmol/L dropped from 94% in the implementation phase to 56% in the sustainability phase.• Antibiotic prophylaxis<ul style="list-style-type: none">○ 41% of the patients received optimal prophylactic antibiotic administration.○ 59% of the patients did not receive optimal prophylactic antibiotic administration. The poorest results were related to the administration of a second dose of antibiotic for procedures $>$ three hours. Only 32 of 144 patients received the second dose. |
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Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

Guenaga, 2011

| Design | Quantitative Synthesis (meta-analysis) | | | | | | | | | |
|------------------|---|--------------|--------|------------|-----|--------|--------|-----|--------|--------------|
| Objective | <p>To determine the security and effectiveness of Mechanical Bowel Preparation (MBP) on morbidity and mortality in colorectal surgery.</p> <p>Patients (adults and children) undergoing elective colorectal surgery.</p> <table border="1" style="width: 100%; margin: 10px 0;"> <thead> <tr> <th style="width: 30%; text-align: center;">Intervention</th> <th style="width: 10%; text-align: center;">versus</th> <th style="width: 60%; text-align: center;">Comparison</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">MBP</td> <td style="text-align: center;">versus</td> <td style="text-align: center;">No MBP</td> </tr> <tr> <td style="text-align: center;">MBP</td> <td style="text-align: center;">versus</td> <td style="text-align: center;">Rectal enema</td> </tr> </tbody> </table> <p>Outcomes:</p> <ul style="list-style-type: none"> • Primary: Anastomotic leakage • Secondary: <ul style="list-style-type: none"> ○ Mortality: number of postoperative deaths related to the surgery. ○ Peritonitis: presence of postoperative infections in the abdominal cavity, localised (abscess) or not. ○ Reoperation: surgical re-intervention for anastomotic complication or peritonitis. ○ Wound infection: defined as a discharge of pus from the abdominal wound. ○ Infectious extra-abdominal complication: postoperative infectious complication at extra-abdominal site. ○ Non-infectious extra-abdominal complication (e.g. deep venous thrombosis, cardiac complications, wound rupture). | Intervention | versus | Comparison | MBP | versus | No MBP | MBP | versus | Rectal enema |
| Intervention | versus | Comparison | | | | | | | | |
| MBP | versus | No MBP | | | | | | | | |
| MBP | versus | Rectal enema | | | | | | | | |
| Methods | <p>Protocol and registration.</p> <ul style="list-style-type: none"> • Did not disclose <p>Eligibility Criteria.</p> <ul style="list-style-type: none"> • All three criteria must be met for inclusion of a trial: <ul style="list-style-type: none"> ○ Randomized clinical trials comparing preoperative MBP versus no preparation and/or rectal enema (or placebo) ○ Participants undergoing elective colorectal surgery ○ The primary outcome (anastomotic leakage) is clearly stated in both treatment arms. • Exclusion criteria: <ul style="list-style-type: none"> ○ Studies which had more than one cleansing method in the protocol ○ Studies that included emergency surgery participants <p>Information sources.</p> <ul style="list-style-type: none"> • Cochrane Colorectal Cancer Group Specialized Register • Cochrane Central Register of Controlled Trials • MEDLINE • EMBASE • CINAHL • LILACS • IBECs • SCISEARCH | | | | | | | | | |

Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

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| | <ul style="list-style-type: none"> • Controlled Clinical Trials Database. • Searches for additional trials included: <ul style="list-style-type: none"> ○ Checking reference lists of relevant papers ○ Writing to experts in the field ○ Handsearching journals ○ Contacting the authors of relevant trial papers ○ Conference proceedings from major gastrointestinal conferences (World Congress of Gastroenterology, annual meetings of the American Society of Colon and Rectal Surgery, annual meetings of the Association of Coloproctology of Great Britain and Ireland, annual meetings of the European Association of Coloproctology, and the Tripartites meetings) were reviewed from 1994 (last possible retrieval of abstract material) through December 1, 2010. <p>Search. See study for search strategy</p> <p>Study Selection.</p> <ul style="list-style-type: none"> • At least two of the authors assessed and selected the trials to be included in this review independently. • Disagreements about selection were resolved by consensus (via e-mail correspondence). • Sometimes unpublished studies were identified through personal contact with the authors and thus were included. <p>Data collection process.</p> <ul style="list-style-type: none"> • The methodological quality of each trial was assessed by at least two of the authors. • Details of the randomization method, blinding, and whether an intention-to-treat analysis was done, and the number of participants lost to follow up was recorded. • The external validity of the studies was assessed by analysis of the characteristics of participants and the interventions. • Disagreements were solved by consensus. • Review Manager 5 (version 5.0.25) was used for data collection employing the following protocol: single data-entry, with the consent of an author; all data-entries were controlled by a second author. <p>Risk of bias (RoB) across studies.</p> <ul style="list-style-type: none"> • Risk of bias occurred as each study was assessed for selection, performance, blinding, attrition, and detection bias • Potential publication bias in the results of the meta-analysis was assessed both by inspection of graphical presentations (by means of a funnel plot: plotting the study weight or sample size [on the Y axis] against the OR [on the x axis]), and by calculating a test of heterogeneity (standard chi-squared test on N degrees of freedom where N equals the number of trials contributing data minus one). <p>Summary measures.</p> <ul style="list-style-type: none"> • For dichotomous outcomes, the default measurement was Peto-Odds Ratio (OR) with the fixed-effect model • A test for heterogeneity occurred. When heterogeneity was identified the authors calculated an Odds Ratio with random-effects modelling • Sensitivity analysis was performed for anastomotic leakage and wound infection in studies with adequate randomization and studies in which bowel continuity was restored. <p>Synthesis of results.</p> <ul style="list-style-type: none"> • Confidence intervals were at 95% • Random-effects modelling provides a more conservative estimate of overall effect, therefore it was used as the default model |
| Results | Study Selection. |

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| | <p>Number of articles identified: $N = 20$ (one unpublished study and 19 published studies) Full-text articles assessed for eligibility: $n = 20$</p> <ul style="list-style-type: none"> ○ Studies included in Comparison 1 quantitative synthesis: $n = 15$ ○ Studies included in Comparison 2 quantitative synthesis: $n = 5$ <p>Synthesis of results. Comparison 1 Mechanical bowel preparation versus no preparation</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Outcome</th> <th style="text-align: center;">Number of Studies</th> <th style="text-align: center;">Number of Subjects</th> <th style="text-align: center;">Results OR [95% CI]</th> <th style="text-align: center;">I₂</th> </tr> </thead> <tbody> <tr> <td>Wound Infection</td> <td style="text-align: center;">13</td> <td style="text-align: center;">4595</td> <td style="text-align: center;">1.16 [0.95, 1.42]</td> <td style="text-align: center;">0%</td> </tr> </tbody> </table> <p>Comparison 2 Mechanical bowel preparation versus rectal enema</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Outcome</th> <th style="text-align: center;">Number of Studies</th> <th style="text-align: center;">Number of Subjects</th> <th style="text-align: center;">Results OR [95% CI]</th> <th style="text-align: center;">I₂</th> </tr> </thead> <tbody> <tr> <td>Wound Infection</td> <td style="text-align: center;">5</td> <td style="text-align: center;">1210</td> <td style="text-align: center;">1.26 [0.85, 1.88]</td> <td style="text-align: center;">0%</td> </tr> </tbody> </table> <p>Risk of bias across studies. See risk of bias section within the review.</p> | Outcome | Number of Studies | Number of Subjects | Results OR [95% CI] | I ₂ | Wound Infection | 13 | 4595 | 1.16 [0.95, 1.42] | 0% | Outcome | Number of Studies | Number of Subjects | Results OR [95% CI] | I ₂ | Wound Infection | 5 | 1210 | 1.26 [0.85, 1.88] | 0% |
|-------------------|--|--------------------|---------------------|--------------------|---------------------|----------------|-----------------|----|------|-------------------|----|---------|-------------------|--------------------|---------------------|----------------|-----------------|---|------|-------------------|----|
| Outcome | Number of Studies | Number of Subjects | Results OR [95% CI] | I ₂ | | | | | | | | | | | | | | | | | |
| Wound Infection | 13 | 4595 | 1.16 [0.95, 1.42] | 0% | | | | | | | | | | | | | | | | | |
| Outcome | Number of Studies | Number of Subjects | Results OR [95% CI] | I ₂ | | | | | | | | | | | | | | | | | |
| Wound Infection | 5 | 1210 | 1.26 [0.85, 1.88] | 0% | | | | | | | | | | | | | | | | | |
| Discussion | <p>Summary of evidence. Prophylactic mechanical bowel preparation prior to colonic surgery was not proven to be decrease the risk of surgical wound infections. This review suggested that in cases of well-defined location and size of the lesion, the surgeon and his patient are free to choose. Bowel cleansing should be considered when a surgeon needs to identify pathology - for example, a small tumor - or when an intra-operative colonoscopy might be performed.</p> <p>Limitations.</p> <ul style="list-style-type: none"> • Review included studies where bowel continuity was not restored • One trial included children ($n = 149$) | | | | | | | | | | | | | | | | | | | | |
| Funding | <p>Funding.</p> <ul style="list-style-type: none"> • Clinical Trials and Meta-analyses Unit, Federal University of São Paulo, Brazil. • Surgical Gastroenterology Department, Federal University of São Paulo, Brazil. • Cochrane Colorectal Cancer Group, Denmark. External sources • The Valerie Jefferson Fund, UK. • SanMed - Materiais Médicos Hospitalares Ltda., Brazil. | | | | | | | | | | | | | | | | | | | | |

Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

Jaffe 2017

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| Methods | Retrospective Cohort: Data from a QI project on perioperative practices |
| Participants | <p>Setting: USA, Michigan Surgical Quality Collaborative (MSQC) group (73 hospitals in Michigan), 2012-2015</p> <p>Number in Study: $n = 3387$</p> <p>Gender: no breakdown</p> <p>Age, years: 18+</p> <p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Age 18+ • Patient insured by BCBS of Michigan • Current Procedural Terminology (CPT) codes: <ul style="list-style-type: none"> 44204 $n = 1482$ (laparoscopy, surgical; colectomy, partial, with anastomosis) 44205 $n = 418$ (laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy) 44140 $n = 1050$ (open colectomy, partial; with anastomosis) 44160 $n = 437$ (open colectomy, partial, with removal of terminal ileum with ileocolostomy) <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Patients with missing outcome data (Surgical Site Infection (SSI) or cost) • Patients missing key explanatory variables (perioperative care processes) <p>Power analysis not done, this is data from a QI project</p> |
| Interventions | <p>Use of a six element bundle:</p> <ul style="list-style-type: none"> • Appropriate Surgical Care Improvement Project-2 antibiotics (study does not say what these are) administered within 60 minutes of surgical incision • Postoperative normothermia ($T > 96.8F$) • Oral antibiotics with bowel preparation ("Nichols prep") • Peri (post? it says 2 different things in 2 different sections) operative glycemic control (post-operative day 1 glucose $</+ 140$ mg/dL) • Minimally invasive surgery • Short operative duration (incision to closure < 100 minutes) |
| Outcomes | <ol style="list-style-type: none"> 1. Number of SSI 2. Cost for SSI within 30 days of surgery 3. 30-day episodic cost (compares laparoscopic to open surgery) |
| Notes | <p>SSI defined as superficial, deep, and/or organ space SSI</p> <p>There is no breakdown of SSI for each CPT code</p> <p>Results:</p> <p>Outcome 1. Rate of SSI:</p> <p>Low compliance with bundle (0-2 items compliant): 17.9%, 95% CI, [10.8, 27.0%]</p> <p>High compliance with bundle (3-6 items compliant): 0.9%, 95% CI, [0, 3.0%]</p> <p>Outcome 2. Total Payment (not cost) for SSI within 30 days of surgery:</p> <p>Low compliance with bundle (0-2 items compliant): \$20,046</p> <p>High compliance with bundle (3-6 items compliant): \$15,272</p> <p>Outcome 3. Episodic Total Payment (not cost)</p> |

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| | <ul style="list-style-type: none">• Open surgical cases: Low compliance with bundle (0-2 items compliant): \$20,097 High compliance with bundle (3-6 items compliant): \$17,284• Laparoscopic cases: Low compliance with bundle (0-2 items compliant): \$16,493 High compliance with bundle (3-6 items compliant): \$15,155 |
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Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

Janssen 2018

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| Design | Quantitative Synthesis (meta-analysis) |
| Objective | To systematically review and analyze the effect of mechanical bowel preparation (MBP) on the incidence of postoperative complications; anastomotic leakage; intra-abdominal infection and wound infection following colorectal surgery in pediatric patients. |
| Methods | <p>Protocol and registration: n/a</p> <p>Eligibility Criteria:</p> <p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Pediatric patients 0-21 years • Patients underwent elective colorectal surgery • Patients received a form of MBP • The study reports > 1 of the outcomes: anastomotic leakage, intra-abdominal infection, wound infection • All languages <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Letter to Editor, response, conference abstracts and other non-full text reports • MBP for colonoscopy in children • Review articles <p>Information sources: Embase, MEDLINE, Web of Science, CINAHL databases for studies published until January 10th, 2018.</p> <p>Search:</p> <ul style="list-style-type: none"> • Search terms (or combination of); colorectal surgery, bowel, gut, intestine, preparation, lavage, cleansing, irrigation • A manual search of the references within retrieved articles was performed <p>Study Selection:</p> <ul style="list-style-type: none"> • 1731 papers retrieved • Of the 1731 articles, 94 potentially relevant articles were selected • Subsequently, these 94 full text articles were independently assessed, and six articles were identified that met eligibility criteria • Of the six articles, two were randomized controlled trials • Of the six articles, four were retrospective cohort studies <p>Data collection process:</p> <ul style="list-style-type: none"> • After removing duplicates, two reviewers independently screened titles and abstracts while taking all eligibility into account. • All articles identified underwent an independent full text review, in which data were collected using a pre-designated and pre-specified extractions form. • Information collected from each article included; first author, year of publication, country of origin, study design, sample size, gender, age of patients, detail of MBP, administration of oral and/or intravenous antibiotics, characteristics of no MBP management and postoperative complications. • Authors were contacted if they did not clearly report details of oral and/or intravenous antibiotic administration. <p>Risk of bias (RoB) across studies:</p> <ul style="list-style-type: none"> • Risk of Bias 2.0 tool (RoB 2.0) was used for randomized studies • Risk of Bias in Non-Randomized Studies of Interventions tool (ROBINS-I) was used for non-randomized studies |

Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

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| | <ul style="list-style-type: none"> Grading of Recommendations and Assessment, Development, and Evaluation (GRADE) assessment was used to evaluate the quality and certainty of evidence. <p>Summary measures:</p> <ul style="list-style-type: none"> Anastomotic leakage Intra-abdominal infection Wound infection <p>Synthesis of results:</p> <ul style="list-style-type: none"> Overall quality of evidenced is low MBP before colorectal surgery did not significantly decrease the occurrence of anastomotic leakage, intra-abdominal infection, or wound infection compared to no MBP <p>Additional analysis:</p> <ul style="list-style-type: none"> Pooled estimates of odds ratios and their 95% confidence intervals were calculated using random-effects model according to Mantel-Haenszel method. Review Manage 5.3 analysis was used. Inter-study heterogeneity was assessed using the inconsistency score and was considered substantial if above 50% |
| <p>Results</p> | <p>Study Selection.</p> <p>Number of articles identified: $N = 1731$</p> <ul style="list-style-type: none"> Full-text articles assessed for eligibility: $n = 94$ Studies included in qualitative synthesis: $n = 6$ <p>Synthesis of results:</p> <ol style="list-style-type: none"> Postoperative complications in RCT studies. <ol style="list-style-type: none"> The incidence for intra-abdominal infection was 7.1% (3/42) in the MBP group versus 5.9% (2/34) in the no MBP group, $OR = 1.10$, 95% CI [0.22, 5.48]. The incidence of wound infection was 16.7% (7/42) in MBP group versus 14.7% (5/34) in the no MBP group, $OR = 1.10$, 95% CI [0.22, 5.48]. Postoperative complications in non-randomized studies. <ol style="list-style-type: none"> The incidence for intra-abdominal infection was 0.7% (2/297) in the MBP group versus 0.8% (1/118) in the no MBP group, $OR = 0.91$, 95% CI [0.08, 10.15]. The incidence of wound infection was 6.6% (6/969) in MBP group versus 3.9% (44/1133) in the no MBP group, $OR = 1.39$, 95% CI [0.67, 2.90]. <p>Risk of bias across studies:</p> <ol style="list-style-type: none"> Risk of Bias in RCT studies (RoB 2.0) <ol style="list-style-type: none"> Shah et al. (2005) did not report details of the randomization process. It was not clear how mechanical bowel preparation was assigned. "Some concerns" arising from randomization process. Aldrink et al. (2015) Reported that 39% of the patients received a different dose of intravenous antibiotics due to surgeons deviating from study protocol, possibly affecting the incidence of postoperative infectious complications. The overall risk of bias was rated as "some concerns" for all postoperative outcomes. Risk of Bias in non-randomized studies (ROBINS-I) <ol style="list-style-type: none"> The type of surgery conducted varied among the retrospective studies. Leyes et al. Reported colostomy, proctectomy with pull-through, colon resection, ileocectomy and ileal resection. |

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| | <ul style="list-style-type: none"> b. The remaining retrospective studies reported colostomy closure only or colonic anastomoses with colostomy closure specifically in most of the patients. c. Leys et al. compared a single surgeon that routinely omitted MBP to multiple surgeons who always administered MBP which also contributed to a serious confounding bias for all three outcomes. d. Group size and distribution of participants were skewed and different manners of MBP administration were included in this study. e. The overall risk of bias was rated as “serious” for all postoperative outcomes. <p>3. Assessment of quality of evidence using GRADE</p> <ul style="list-style-type: none"> a. Inconsistency was low to moderate as heterogeneity was below 50%. b. Indirectness was also considered not serious. c. Imprecision was considered serious for all outcomes because of small sample size. d. Overall the quality of the evidenced was considered “low” for RCT’s and “very low” for non-RCT's for all outcomes. |
| Discussion | <p>Summary of evidence:</p> <ul style="list-style-type: none"> • 1731 papers retrieved: 2 RCT’s and 4 retrospective cohort studies met inclusion criteria. • The overall quality of evidenced was low. • MBP before colorectal surgery did not significantly decrease the occurrence of anastomotic leakage, intra-abdominal infection, or wound infection compared to no MBP. <p>Limitations:</p> <ul style="list-style-type: none"> • The risk of bias in RCT’s for all outcomes was mainly caused by unclear randomization processes and due to deviations from intended interventions. • In the retrospective studies, there was serious risk of confounding bias for all outcomes caused by including multiple types of colorectal surgery and the comparison of surgeon that routinely omitted MBP in one study. • Oral and IV antibiotics prophylaxis complicated a reliable comparison. • Age at enrollment varied across the included studies, possibly confounding the results. <p>Conclusions:</p> <ul style="list-style-type: none"> • On the basis of existing evidence, MBP may safely be omitted prior to colorectal surgery in children. • To overcome confounding factors such as treatment allocation in RCT’s and other factors in retrospective studies such as variation in type of surgery, administration of oral intravenous antibiotics, and comparison of individual’s surgeon’s practices, a large prospective RCT is needed to validate these results. |
| Funding | <p>Funding: Robert M. Filler, Chair of Surgery at the Hospital for Sick Children. The authors have no financial relationships relevant to disclose.</p> |

Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Interventions to Decrease Surgical Site Infections in Colon Surgery

Nelson 2015

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| Design | Quantitative Synthesis (meta-analysis) |
| Objective | <p>To establish the effectiveness of antimicrobial prophylaxis in colorectal patients to mitigate surgical wound infection with specific attention paid to:</p> <ol style="list-style-type: none"> 1. Measuring if antimicrobial prophylaxis reduces the risk of surgical wound infection. 2. The target spectrum of bacteria (aerobic or anaerobic bacteria, or both). 3. The best timing and duration of antibiotic administration. 4. The most effective route of antibiotic administration (intravenous, oral or both). 5. Whether any antibiotic regime is more effective than the currently recommended published guidelines. 6. Whether antibiotics should be given before or after surgery. |
| Methods | <p>Protocol and registration. The protocol was published in <i>The Cochrane Library</i> (1998, Issue 2).</p> <p>Eligibility Criteria.</p> <ul style="list-style-type: none"> • Randomized controlled trials that assessed the effectiveness of antimicrobial prophylaxis in the prevention of postoperative surgical wound infections • The study included patients undergoing colorectal surgery • Surgical wound infections were measured • Patients (adults and children) undergoing either elective or emergency colorectal surgery, in which sepsis was not suspected preoperatively. • All antimicrobial prophylaxis regimens delivered orally, intravenously or by intramuscular injection that were used to prevent postoperative infection. • Antibiotics had to be administered before the onset of infection. <p>Eligibility Exclusion.</p> <ul style="list-style-type: none"> • If antibiotics were given before surgery for suspected appendicitis or diverticulitis the study was excluded because the antibiotics are treating an established infection for which surgery was required. • If topical antibiotics were used. <p>Information sources.</p> <ul style="list-style-type: none"> • MEDLINE (1954 to January 7, 2013) • EMBASE (1974 to January 7, 2013) • CENTRAL (1954 to January 7, 2013) • The references of the identified trials were also searched to identify further relevant trials <p>Study Selection. Due to the large number of studies published in this area, once the decision had been made to include a study, the methodological quality (validity) of the study was assessed by one review author, and validated by another review author, using the following check-points:</p> <ul style="list-style-type: none"> • Was the assignment to the treatment groups really random (versus quasi-randomized by birth dates or hospital numbers etc.)? • Were those assessing outcomes blind to the treatment allocation? • Were the control and treatment groups comparable at entry, i.e. were there significant differences in clinical parameters such as age/gender/diagnosis? • Were the groups treated the same other than for the named interventions? |

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| | <ul style="list-style-type: none"> • Were the operative procedures defined and described? • Did the study include a definition of wound infection and were all other outcome measures reported? • Was relatively complete follow-up achieved (i.e. greater than 90%)? • Were the outcomes of people who withdrew described and included in the analysis? • Was the outcome assessor blind as to treatment group assignment? • Disagreements arising at this stage were resolved through study team discussion <p>Data collection process.</p> <ul style="list-style-type: none"> • Data were extracted from included trials by one review author and checked by another using a data abstraction form (form shared in review, Appendix 2) <p>Risk of bias (RoB) across studies.</p> <ul style="list-style-type: none"> • Quality of evidence was assessed using GRADE methods • A RoB table for each article was provided in review <p>Summary measures.</p> <ul style="list-style-type: none"> • For the dichotomous outcome of Surgical Wound Infections, risk ratios were reported <p>Synthesis of results.</p> <ul style="list-style-type: none"> • Statistical heterogeneity was assessed with the Chi² test and the I² statistic • If heterogeneity existed, the authors investigated using a sub-group analysis • 95% Confidence Intervals were employed along with random-effects analysis | | | | | | | | | | | | | | | |
|---|---|--------------------|---------------------|----------------|---------------------|----------------|-----|----|------|-------------------|----|---|--|--|--|--|
| Results | <p>Study Selection.</p> <p>Number of articles identified: <i>N</i> = Not stated</p> <p>Full-text articles assessed for eligibility: <i>n</i> = 260</p> <ul style="list-style-type: none"> ○ Studies included in qualitative synthesis: <i>n</i> = 260 <p>Synthesis of results.</p> <ul style="list-style-type: none"> • Statistically significant improvements in the reduction of surgical wound infection rates occurred when combined oral and intravenous antibiotic prophylaxis were compared to oral alone (see following table) <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="border-top: 1px solid black; border-bottom: 1px solid black;">Outcome Comparison</th> <th style="border-top: 1px solid black; border-bottom: 1px solid black;">Number of studies</th> <th style="border-top: 1px solid black; border-bottom: 1px solid black;">Total subjects</th> <th style="border-top: 1px solid black; border-bottom: 1px solid black;">Risk Ratio [95% CI]</th> <th style="border-top: 1px solid black; border-bottom: 1px solid black;">I²</th> </tr> </thead> <tbody> <tr> <td style="border-bottom: 1px solid black;">SWI</td> <td style="border-bottom: 1px solid black;">15</td> <td style="border-bottom: 1px solid black;">2929</td> <td style="border-bottom: 1px solid black;">0.55 [0.43, 0.71]</td> <td style="border-bottom: 1px solid black;">9%</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Combined oral / IV antibiotics versus IV only</td> <td style="border-bottom: 1px solid black;"></td> <td style="border-bottom: 1px solid black;"></td> <td style="border-bottom: 1px solid black;"></td> <td style="border-bottom: 1px solid black;"></td> </tr> </tbody> </table> <p>Risk of bias across studies.</p> <ul style="list-style-type: none"> • The authors of the SR identified that the biggest risk of bias was participant attrition however, in analyzing the attrition bias for the comparison of interest the 15 included studies had only 8% attrition bias with a range of 0% to 34%. Five of the 15 included studies exceeded the authors established threshold of greater than 10% attrition. | Outcome Comparison | Number of studies | Total subjects | Risk Ratio [95% CI] | I ² | SWI | 15 | 2929 | 0.55 [0.43, 0.71] | 9% | Combined oral / IV antibiotics versus IV only | | | | |
| Outcome Comparison | Number of studies | Total subjects | Risk Ratio [95% CI] | I ² | | | | | | | | | | | | |
| SWI | 15 | 2929 | 0.55 [0.43, 0.71] | 9% | | | | | | | | | | | | |
| Combined oral / IV antibiotics versus IV only | | | | | | | | | | | | | | | | |
| Discussion | <p>Summary of evidence. This review included 15 studies in which a combination of oral and intravenous antibiotics versus intravenous only was compared. The analysis indicates a statistically significant benefit when a combination of oral and</p> | | | | | | | | | | | | | | | |

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| | intravenous antibiotics are used for colorectal surgery to reduce the risk of surgical wound infection. None of the included trials measured the outcome of interest in the pediatric population. |
| Funding | Funding. Not stated |

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| Methods | Before / After cohort study with a matched cohort analysis occurring with 53 patients after bundle implementation occurred |
| Participants | <p>Participants: Pediatric patients undergoing GI surgery baseline data collected from January to October 2014 and with bundle implementation prospective data collected from November 2014 to September 2016</p> <p>Setting: Tertiary care free-standing pediatric hospital</p> <p>Number completed:</p> <ul style="list-style-type: none"> • Prior to bundle implementation <ul style="list-style-type: none"> ○ Total number not disclosed, the authors report an average of 55 GI operations performed per month • Post bundle implementation <ul style="list-style-type: none"> ○ <i>N</i> = 1474 patients <ul style="list-style-type: none"> ▪ Elective: <i>n</i> = 1328 (83.2%) ▪ Urgent: <i>n</i> = 151 (9.5%) ▪ Emergent cases: <i>n</i> = 105 (6.6%) <p>Gender: (% male)</p> <ul style="list-style-type: none"> • Prior to bundle implementation data was not reported • Post bundle implementation <ul style="list-style-type: none"> ○ Overall: <ul style="list-style-type: none"> ▪ Without SSI: 46.7% ▪ With SSI: 34% ○ Foregut: <ul style="list-style-type: none"> ▪ Without SSI: 42.9% ▪ With SSI: 0% ○ HPB: <ul style="list-style-type: none"> ▪ Without SSI: 53.3% ▪ With SSI: 0% ○ Midgut/Hindgut: <ul style="list-style-type: none"> ▪ Without SSI: 33.3% ▪ With SSI: 37.5% ○ Stoma Closure: <ul style="list-style-type: none"> ▪ Without SSI: 59.4% ▪ With SSI: 38.9% <p>Age, years:</p> <ul style="list-style-type: none"> • Prior to bundle implementation data was not reported • Post bundle implementation <ul style="list-style-type: none"> ○ Overall: <ul style="list-style-type: none"> ▪ Without SSI: 7.26 ▪ With SSI: 8.33 ○ Foregut: <ul style="list-style-type: none"> ▪ Without SSI: 8.75 ▪ With SSI: 13.67 ○ HPB: <ul style="list-style-type: none"> ▪ Without SSI: 13.72 |

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| | <ul style="list-style-type: none"> ▪ With SSI: 14.50 ○ Midgut/Hindgut: <ul style="list-style-type: none"> ▪ Without SSI: 6.40 ▪ With SSI: 7.73 ○ Stoma Closure: <ul style="list-style-type: none"> ▪ Without SSI: 6.66 ▪ With SSI: 4.87 <p>Inclusion Criteria: All patients undergoing GI surgeries Exclusion criteria: Appendectomies and trauma operations Covariates identified: age, sex, body mass index (BMI), ASA class, pre-operative location, procedure performed, total hospital LOS, intensive care unit (ICU) LOS, number of ICU admissions, total number of GI operations, and total 30-day inpatient charges, surgical procedures categorized as either elective, urgent, or emergent.</p> |
| <p style="text-align: center;">Interventions</p> | <ul style="list-style-type: none"> • Implementation of perioperative bundle for all GI procedures. <p>Bundle components:</p> <ol style="list-style-type: none"> 1. Preop Bowel Prep: <ul style="list-style-type: none"> • GoLytely 25 ml/kg/h x 4h • Neomycin 15 mg/kg/dose (x 3 doses) • Erythromycin 20 mg/kg/dose (x 3 doses) 2. Preop cleansing: <ul style="list-style-type: none"> • Patients >2 months: clean the abdomen with 2% chlorhexidine gluconate wipes • Patients <2 months: clean the abdomen with antimicrobial wipes 3. Preop warming: <ul style="list-style-type: none"> • Measure pt temperature 1 h prior to operation • Apply convection warming blanket for all patients with initial temperature <36.5° C • Recheck temperature every 30 min 4. Preop antibiotics: <ul style="list-style-type: none"> • Administer appropriate antibiotic to finish within 60 minutes of incision <ul style="list-style-type: none"> ○ Cefazolin for foregut and HPB procedures. Redose as needed ○ Cefoxitin for midgut/hindgut procedures. Redose as needed <ul style="list-style-type: none"> ▪ Gentamicin/clindamycin for patients with penicillin allergies ▪ Ampicillin/gentamicin acceptable for neonates within first week of life; add clindamycin after first week • If pt is on adequate systemic antibiotics prior to procedure, no additional antibiotics are needed. Redose as needed. 5. Skin prep: <ul style="list-style-type: none"> • Chlorhexidine for all patients > 2 months or > 1 kg • 10% povidone-iodine for patients <2 months or <1 kg 6. Closing procedures: <ul style="list-style-type: none"> • Prior to fascial closure: <ul style="list-style-type: none"> ○ All staff change gloves ○ Re-drape the surgical field ○ Remove all dirty instruments; use clean instruments for fascia and wound closure |

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| Outcomes | <p>Primary outcomes: Surgical Site Infections (SSI) rates</p> <ul style="list-style-type: none"> • SSI rates were calculated as the number of infections divided by the total number of GI procedures for each month. • Separate SSI rates were calculated for each procedure category with special attention to midgut/hindgut procedures and stoma closures, since these groups generally have higher reported SSI rates. |
| Notes | <p>Results: (Description of SSI occurrence and bundle implementation)</p> <ul style="list-style-type: none"> • Prior to bundle implementation: <ul style="list-style-type: none"> ○ There was an average of 55 GI operations performed every month. ○ The initial SSI rate was 3.4%, which increased to 7.1% by the end of this time period. • After bundle implementation <ul style="list-style-type: none"> ○ Monthly data analysis and ongoing feedback was provided to improve compliance with all bundle components ○ There was a total of 1595 GI operations performed on 1474 patients (an approximate increase of 15 cases per month). See above "number completed" for further break down of surgical types after bundle implementation. ○ Overall 30-day mortality following bundle implementation was 1.15% ($n = 17$ patients) and only 0.11% in planned elective cases ($n = 1$ patient) ○ SSI rate <ul style="list-style-type: none"> ▪ decreased to 4.7% despite an increase in surgical volume ▪ for midgut/hindgut procedures decreased from 11.3% to 8.0% and remained stable for over 12 months ▪ for stoma closure decreased from 21.4% to 7.9% ▪ for foregut and HPB were 2.3% to 1.1% and did not significantly change after bundle implementation. ○ Bundle compliance increased from 43% to 80% since the bundle was first introduced. (Above rates only represent fully compliant cases only, in which all bundle elements were performed). ○ There was no significant difference in age, BMI, or ASA class between patients that did and did not develop SSI, however a higher number of female patients developed SSI's. ○ Patients who did not develop an SSI had a shorter length of stay (LOS) (8.3 days versus 13.9 days) and incurred fewer charges (\$80,997 versus \$131,897). ○ Bundle control charts were developed to demonstrate the direct effects of bundle implementation. In all populations, use of the bundle did not result in significant changes in LOS, however in midgut/hindgut procedures LOS decreased from 20.3 days to 13.6 and from 12.6 to 7.9 in stoma closures. <p>The authors performed a matched cohort analysis, in which 53 patients who developed an SSI (after an elective procedure) were compared with 106 similar patients who did not develop an SSI. The authors report there were no significant differences in age, BMI, or ASA class; however there was a significant higher number of female patients with a reported SSI. Midgut/hindgut procedures, including stoma closures, showed a significant increase in additional GI operations, ICU LOS, ICU admissions, and total average charges for the patients with an SSI.</p> |

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Rangel 2014

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| Design | Quantitative Synthesis (meta-analysis) |
| Objective | <p>Objective: To examine the available evidence regarding interventions (and combinations of interventions when available) and to propose recommendations based on the strength of available data.</p> <ol style="list-style-type: none"> 1. Utilization of systemic antibiotic prophylaxis before, during and after operative procedures. 2. Reduction of stool burden through the use of mechanical bowel preparation. 3. Use of enteral nonabsorbable antibiotics in colon and rectum for decontamination. |
| Methods | <p>Protocol and registration. Not reported</p> <p>Eligibility Criteria.</p> <ul style="list-style-type: none"> • Met either Class I or Class II evidence as defined by the Oxford Centre for Evidence-Based Medicine. • Adult-focused studies included because of lack of pediatric studies and similarities in fecal bacterial concentrations between adults and children. • Outcomes of interest included <ol style="list-style-type: none"> 1. Infectious and mechanical complications plausibly related to stool burden 2. Intraluminal bacterial concentration <p>Information sources: English language publications in Medline, PubMed, Cochrane reviews.</p> <p>Search: Medical subject headings and keywords used: colorectal surgery, antibiotic prophylaxis, infection control and prevention, mechanical bowel preparation, surgical site infection, anastomotic leakage, intraabdominal abscess and deep-space infection.</p> <p>Study Selection. The American Pediatric Surgery Association Outcomes and Trails Committee selected eight questions to address this topic. There was limited pediatric evidence, therefore by consensus, studies with adult subjects were accepted. Accepted English language only.</p> <p>Data collection process. Not reported</p> <p>Risk of bias (RoB) across studies. Oxford Center for Evidence Based Medicine classification system www.cebm.net The accepted Class I or Class II evidence, which are defined as systematic reviews of RCTs or a single RCT with narrow confidence intervals; or cohort studies, low quality RCTs, or outcomes research, respectively.</p> <p>Summary measures.</p> <ol style="list-style-type: none"> 1. Prophylactic antibiotic use, which kind and dose? 2. Prophylactic antibiotic use when should it be administered? 3. How often should parenteral antibiotics be re-dosed during colorectal procedure? 4. How long parenteral antibiotics should be continued after procedure? |

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| | <p>5. Does the use of enteral, nonabsorbable antibiotic with mechanical bowel preparation reduce infectious complications?</p> <p>6. Does mechanical bowel preparation without enteral, nonabsorbable antibiotic reduce infectious complications?</p> <p>7. Does the use of enteral, nonabsorbable antibiotic without mechanical bowel preparation reduce infectious complications?</p> <p>8. Does preoperative enema reduce infectious complications?</p> <p>Synthesis of results. Did not report</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|-------------------|--|------------------|--|--|--|--|-----------------------|----|-----------|-------------------|-------------------|----|-----------|-------------------|--------------------|----|-----------|-------------------|----------------------|----|-----------|-------------------|---------|------------------|--|------------------|--|--|--|--|----------------------|----|-----------|-------------------|---------------------|----|----------|-------------------|-----------------------|----|-----------|-------------------|
| Results | <p>Study Selection. - Did not report process of study selection</p> <p>Number of articles identified: <i>N</i> = Not reported</p> <p>Full-text articles assessed for eligibility: <i>n</i> = Not reported</p> <ul style="list-style-type: none"> ○ Studies included in qualitative synthesis: <i>n</i> = Not reported <p>Synthesis of results.</p> <p>Overview of meta-analyses comparing pre-operative MBP vs. no MBP for the outcomes, anastomotic leak, wound or surgical site infection, and intra-abdominal abscess.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Outcome</th> <th style="text-align: center;">Number of trials</th> <th style="text-align: center;">MBP (<i>n</i>)/ no MBP (<i>n</i>)</th> <th style="text-align: center;">Peto OR [95% CI]</th> </tr> </thead> <tbody> <tr> <td colspan="4">Wound infection or surgical site infection</td> </tr> <tr> <td style="padding-left: 20px;">Guenaga et al. (2003)</td> <td style="text-align: center;">13</td> <td style="text-align: center;">2305/2290</td> <td style="text-align: center;">1.16 [0.95, 1.42]</td> </tr> <tr> <td style="padding-left: 20px;">Cao et al. (2009)</td> <td style="text-align: center;">14</td> <td style="text-align: center;">2682/2691</td> <td style="text-align: center;">1.26 [0.94, 1.68]</td> </tr> <tr> <td style="padding-left: 20px;">Slim et al. (2004)</td> <td style="text-align: center;">14</td> <td style="text-align: center;">2452/2407</td> <td style="text-align: center;">1.40 [1.05, 1.87]</td> </tr> <tr> <td style="padding-left: 20px;">Pineda et al. (2008)</td> <td style="text-align: center;">13</td> <td style="text-align: center;">2304/2297</td> <td style="text-align: center;">1.16 [0.95, 1.41]</td> </tr> </tbody> </table> <p>Overview of meta-analyses comparing enteral antibiotic plus MBP versus enteral antibiotics alone for the identified outcomes, anastomotic leak, wound or surgical site infection, and intra-abdominal abscess.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Outcome</th> <th style="text-align: center;">Number of trials</th> <th style="text-align: center;">Enteral + MBP (<i>n</i>)/ IV alone (<i>n</i>)</th> <th style="text-align: center;">Peto OR [95% CI]</th> </tr> </thead> <tbody> <tr> <td colspan="4">Wound infection or surgical site infection</td> </tr> <tr> <td style="padding-left: 20px;">Nelson et al. (2009)</td> <td style="text-align: center;">13</td> <td style="text-align: center;">1176/1186</td> <td style="text-align: center;">0.55 [0.41, 0.74]</td> </tr> <tr> <td style="padding-left: 20px;">Lewis et al. (2002)</td> <td style="text-align: center;">13</td> <td style="text-align: center;">988/1077</td> <td style="text-align: center;">0.56 [0.26, 0.86]</td> </tr> <tr> <td style="padding-left: 20px;">Bellows et al (2011),</td> <td style="text-align: center;">16</td> <td style="text-align: center;">1352/1317</td> <td style="text-align: center;">0.57 [0.43, 0.76]</td> </tr> </tbody> </table> <p>Risk of bias across studies. Unclear</p> | Outcome | Number of trials | MBP (<i>n</i>)/ no MBP (<i>n</i>) | Peto OR [95% CI] | Wound infection or surgical site infection | | | | Guenaga et al. (2003) | 13 | 2305/2290 | 1.16 [0.95, 1.42] | Cao et al. (2009) | 14 | 2682/2691 | 1.26 [0.94, 1.68] | Slim et al. (2004) | 14 | 2452/2407 | 1.40 [1.05, 1.87] | Pineda et al. (2008) | 13 | 2304/2297 | 1.16 [0.95, 1.41] | Outcome | Number of trials | Enteral + MBP (<i>n</i>)/ IV alone (<i>n</i>) | Peto OR [95% CI] | Wound infection or surgical site infection | | | | Nelson et al. (2009) | 13 | 1176/1186 | 0.55 [0.41, 0.74] | Lewis et al. (2002) | 13 | 988/1077 | 0.56 [0.26, 0.86] | Bellows et al (2011), | 16 | 1352/1317 | 0.57 [0.43, 0.76] |
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| Wound infection or surgical site infection | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Wound infection or surgical site infection | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Discussion | <p>Summary of evidence.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Question</th> <th style="text-align: left;">Recommendations</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"></td> <td></td> </tr> </tbody> </table> | Question | Recommendations | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Question | Recommendations | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| | <p>Prophylactic antibiotic use which kind and dose?</p> | <p>Parenteral antibiotic prophylaxis should include one of the SCIP (Surgical Care Improvement Project)-approved agents. For children undergoing elective colorectal procedures: Cefazolin + metronidazole is recommended when no allergies are present.</p> |
| | <p>Prophylactic antibiotic use when should it be administered?</p> | <p>Recommendation is dosing within one hour of incision until further data is available.</p> |
| | <p>How often should parenteral antibiotics be re-dosed during colorectal procedure?</p> | <p>Recommendation is in children with normal renal function follow the ASHP guidelines for redosing.</p> |
| | <p>How long parenteral antibiotics should be continued after procedure?</p> | <p>Prophylaxis antibiotic should be discontinued within 24 hours of the end of surgery.</p> |
| | <p>Does the use of enteral, nonabsorbable antibiotic with mechanical bowel preparation reduce infectious complications?</p> | <p>No recommendation in children, more studies needed.</p> |
| | <p>Does mechanical bowel preparation without enteral, nonabsorbable antibiotic reduce infectious complications?</p> | <p>The use of mechanical bowel preparation (MBP) alone is not recommended.</p> |
| | <p>Does the use of enteral, nonabsorbable antibiotic without mechanical bowel preparation reduce infectious complications?</p> | <p>Patients with only enteral antibiotics without MBP had a greater reduction in the odds of SSI (OR 0.33; 95% CI 0.21-0.50) than those receiving both antibiotics and MBP (OR 0.43; 95% CI 0.34-0.55). No recommendation, further evidence needed.</p> |
| | <p>Does preoperative enema reduce infectious complications?</p> | <p>No recommendation, further data needed.</p> |

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| | Limitations. Evidence is drawn predominantly from adult trials. Caution should be used when using recommended as guidelines. |
| Funding | Funding. Not reported |

Togioka 2012

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| Design | Quantitative Synthesis (meta-analysis) |
| Objective | To determine whether perioperative hyperoxia reduces surgical site infection (SSI) |
| Methods | <p>Protocol and registration: n/a</p> <p>Eligibility Criteria:</p> <p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Human adults • Randomized controlled trials • Clearly defined comparison of high oxygen verses low oxygen or control • Documented assessment for perioperative infection • All languages <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Hyperventilation studies • Case reports • Review articles • Editorials • Comments • Abstracts without sufficient detail for analysis <p>Information sources: MEDLINE, CENTRAL, EMBASE databases and authors’ own personal files were searched for studies published</p> <p>Search:</p> <ul style="list-style-type: none"> • Search terms (or combination of); oxygen, infection, human • The search process was conducted iteratively, until no duplicate citations were found in the reference lists of the included articles <p>Study Selection:</p> <ul style="list-style-type: none"> • 658 articles retrieved • Of the 658 articles, nine potentially relevant articles were selected • Subsequently, these nine full text articles were independently assessed and seven articles were identified that met eligibility criteria • All seven of the included studies were randomized controlled trials <p>Data collection process:</p> <ul style="list-style-type: none"> • Data extraction was completed by 2 independent reviewers (BT and SS) who were given full-text versions of each article. • Data was extracted using a standard scoring sheet that was created before the literature search was completed. • Study quality was assessed for all articles by scoring each trial for both a Cochrane Quality and Jadad Score. |

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| | <p>Risk of bias (RoB) across studies:</p> <ul style="list-style-type: none"> • Authors did not discuss <p>Summary measures:</p> <ul style="list-style-type: none"> • Surgical site infections <p>Additional analysis:</p> <ul style="list-style-type: none"> • Pooled estimates of odds ratios and their 95% confidence intervals were calculated using a random effects model. • Cochrane Collaboration’s RevMan version 5.0.25 was used. • Heterogeneity was assessed by Cochrane Q statistic and calculation of I² value with thresholds for low (25%-49%), moderate (50%-74%), and high (>75%) levels. |
| Results | <p>Study Selection.</p> <p>Number of articles identified: <i>N</i> = 658</p> <ul style="list-style-type: none"> • Full-text articles assessed for eligibility: <i>n</i> = 9 • Studies included in qualitative synthesis: <i>n</i> = 7 <p>Synthesis of results:</p> <ol style="list-style-type: none"> 1. The pooled infection rate in the hyperoxia group was 15%. 2. The pooled infection rate for the control group was 17.5%. 3. OR = 0.85 [95% CI: 0.52, 1.38] <p>Risk of bias across studies: Authors did not discuss risk of bias.</p> |
| Discussion | <p>Summary of evidence</p> <p>The meta-analysis of all trials that met inclusion criteria did not show that high inspired perioperative oxygen therapy is beneficial for preventing surgical site infections.</p> <p>Limitations</p> <ul style="list-style-type: none"> • Inability to control for differences among studies including variables such as perioperative antibiotic use, surgical operations, absence or presence of neuraxial anesthesia, use of nitrous oxide, et cetera. |
| Funding | <p>Funding Authors did not disclose</p> |

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| Methods | Retrospective cohort study |
| Participants | <p>Participants: Children (0 to 14 years) who underwent elective colorectal surgery between January 2010 and December 2016</p> <p>Setting: West China Hospital of Sichuan University</p> <p>Number completed: $N = 564$ (OA, Oral nonabsorbable antibiotics + IV antibiotics = 216; A, IV antibiotics only = 348)</p> <p>Gender, males (%):</p> <ul style="list-style-type: none"> • Group 1 (OA): $n = 148$ (68.52) • Group 2 (A): $n = 244$ (70.11) <p>Age, median in months [interquartile range]:</p> <ul style="list-style-type: none"> • Group 1 (OA): 29.0 [8.0-48.0] • Group 2 (A): 27.0 [8.0-48.0] <p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Pediatric patients 0-14 years old • Underwent elective colorectal surgery <p>Covariates identified:</p> <ul style="list-style-type: none"> • Demographic data, diagnosis, procedure being performed, and operative time |
| Interventions | <p>Both groups (OA & A): Received mechanical bowel preparation with 25 ml/kg/hr of polyethylene glycol 12-16 hours before surgery. Also received 1 pre-operative dose of intravenous cefotaxim 30 mg/kg, up to 2 gm administered 30 minutes before skin incision, and 1 postoperative dose administered 8 hours from the first dose. For patients with a penicillin or cephalosporin allergy, gentamicin 2.5 mg/kg and clindamycin 10 mg/kg were administered at equivalent time points. Surgeons were able to administer prophylactic antibiotics for more than 1 day if necessary.</p> <ul style="list-style-type: none"> • Group 1 – (OA): Combination of oral non-absorbable and intravenous antibiotics; neomycin combined with erythromycin (1 gm neomycin and 1 gm erythromycin) were given 3 times after bowel preparation the day before surgery. • Group 2 – (A): Intravenous antibiotics alone, which is presumed to be 1 gm erythromycin 3 times after bowel preparation the day before surgery. |
| Outcomes | <p>Primary outcome(s): Post-operative infectious complications, which are defined as:</p> <ul style="list-style-type: none"> • Wound infection • Intra-abdominal abscess • Anastomotic leak <p>Secondary outcome(s)</p> <ul style="list-style-type: none"> • None reported <p>Safety outcome(s):</p> <ul style="list-style-type: none"> • None reported |
| Notes | Results: |

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| | <ul style="list-style-type: none">• The comparison of post-operative infectious complications between the two groups proved to be insignificant:<ul style="list-style-type: none">○ Wound infection: OA: $n = 6$ (2.78%), A: $n = 9$ (2.59%), $p = 0.89$○ Intra-abdominal abscess: OA: $n = 5$ (2.31%), A: $n = 11$ (3.16%), $p = 0.557$○ Anastomotic leak: OA: $n = 5$ (2.31%), A: $n = 13$ (3.74%), $p = 0.352$ |
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