

## **Appendix A: Summary of evidence from exceptional surveillance review**

### **2019 surveillance of surgical site infections: prevention and treatment (2019) NICE guideline NG125**

#### **Summary of evidence from exceptional surveillance review**

Studies identified from a search are summarised from the information presented in their abstracts.

Feedback from topic experts, was considered alongside the evidence to reach a view on the need to update.

Feedback from stakeholders on the draft 2019 NICE guideline NG125 was also considered alongside the evidence to reach a view on the need to update.

#### **Relevant recommendation**

##### **Mechanical bowel preparation**

1.2.8 Do not use mechanical bowel preparation routinely to reduce the risk of surgical site infection.

#### **Surveillance proposal**

This recommendation should be updated.

#### **Editorial amendments**

None.

#### **Previous surveillance reviews**

In previous surveillance of this guideline, evidence at 3 years (2011) included a Cochrane review, 4 systematic reviews, 1 RCT and a post-hoc analysis of an RCT. [1-7] One systematic review was identified at the 6-year surveillance review (2014); [8] and no studies relevant to this recommendation were identified at the 8-year surveillance review (2017). The

evidence generally supported the guideline recommendation to not use mechanical bowel preparation (MBP) routinely to reduce the risk of surgical site infections (SSI). While 1 trial suggested possible differences between bowel preparation with sodium phosphate compared with polyethylene glycol, this was a post-hoc subgroup analysis of a trial designed to

compare antibiotic regimens, not MBP *per se*. [7] Therefore, the findings of this trial were deemed as not sufficient to outweigh the evidence from the many other studies that indicated there was no effect of MBP on surgical site infection when it was compared with no MBP. In general, the studies did not compare the effects of MBP with and without oral antibiotic prophylaxis.

### 2019 surveillance summary

A network meta-analysis of 38 RCTs (n=8,458) compared all 4 preoperative approaches to elective colorectal surgery: MBP with oral antibiotics, oral antibiotics only, MBP only, or no preparation. There were 4 direct comparisons and 2 indirect comparisons for 8 outcome measures. Bayesian analysis indicated that MBP with oral antibiotics was significantly associated with reduced SSI (total, incisional, and organ/space SSI rates) when compared with MBP only. There were no other significant differences between groups on measures of SSI, except for a risk reduction in organ/space SSI for oral antibiotics only when indirectly compared with no preparation. Oral antibiotics only was ranked as the second-best approach for reducing SSIs, but the authors noted that 'the data available on this approach were limited'. The authors also reported that there were no differences in the rates of anastomotic leak, readmissions, or reoperations between any groups. [9]

A systematic review included 12 RCTs, 22 cohort studies, and 5 meta-analyses in order to assess the relative effectiveness of MBP, antibiotic preparation, combined antibiotic and MBP or no preparation on the incidence of SSI in colorectal procedures. The authors reported that

there is a 'consistent trend towards lower infection rates and anastomotic leak rates with the use of oral antibiotics', which is 'often statistically significant' (data and statistics= not reported (NR)). They concluded that 'the use of oral antibiotics with or without mechanical bowel preparation consistently reduces the incidence of SSI compared to non-use of oral preparation'. [10]

### Oral antibiotics (with or without MBP) compared to MBP

A meta-analysis of 28 RCTs (n=6,437) and 12 cohort studies (n=63,080) compared the impact of oral antibiotics with or without MBP on outcomes in elective colorectal surgery. Results indicated that there was a significant reduction in SSI when oral antibiotics plus MBP was used compared with MBP alone. There was no significant difference in SSI when oral antibiotics plus MBP was compared with oral antibiotics alone. It was noted that there was a significant reduction in 30-day mortality, and incidence of postoperative ileus with the oral antibiotics plus MBP combination when compared with oral antibiotics alone. [11]

### Oral antibiotics with MBP compared to MBP (with or without IV antibiotics)

A systematic review included 14 RCTs and 8 observational studies (n=57,207) that evaluated the effect of preoperative oral antibiotic prophylaxis in combination with intravenous (IV) antibiotic prophylaxis and MBP versus IV antibiotic prophylaxis with MBP on SSI rates following colorectal surgery. A meta-analysis of the data indicated that the combination of oral and IV antibiotics and MBP were associated with significantly lower rates of SSI than

the combination of IV antibiotics and MBP across RCTs and cohort studies. [12]

A meta-analysis included 7 RCTs (n=1,769) comparing the efficacy of combined oral and systemic antibiotics and MBP with systemic antibiotics and MBP in colorectal surgery in preventing bacterial infection. Results indicated that total SSI and incisional SSI were significantly reduced in patients receiving combined oral and systemic antibiotics and MBP compared with those receiving systemic antibiotics and MBP; but that there was no significant difference in the rate of organ/space SSI between the groups. The authors noted that there was a risk of bias due to the majority of the RCTs not using blinding. [13]

A prospective RCT (n=190) assessed the efficacy of preoperative MBP compared with MBP plus oral antibiotics in preventing SSIs in clean contaminated, contaminated, and dirty colorectal procedures in adult patients undergoing abdominal surgery. There were significantly less SSIs in the MBP plus oral antibiotics group compared to the MBP only group. Multivariable analysis also indicated that blood loss  $\geq 500$  mL, ASA score  $\geq 3$ , contaminated types and administration of preoperative oral antibiotics independently affected the incidence of SSI. [14]

An RCT (n=310) assessed the effectiveness of oral antibiotics and probiotics in preventing postoperative infection in elective colon cancer procedures. All patients underwent MBP and received IV antibiotics (flomoxef); they were randomised to also receive either probiotics, oral antibiotics or nothing (control). The rate of incisional SSIs was

significantly lower in the oral antibiotics group compared with the probiotics and control group. [15]

A prospective RCT (n=335) assessed the efficacy of oral antimicrobial prophylaxis in patients undergoing surgery for Crohn disease. All patients underwent MBP and were then randomised to receive either IV antimicrobial prophylaxis or preoperative oral and IV antimicrobial prophylaxis. Patients in the combined oral and IV antibiotic group had a significantly lower incidence of incisional SSI than the IV antibiotic group, and multivariate analysis indicated that the absence of oral antibiotic prophylaxis was an independent risk factor for incisional SSI. There was however no difference between the groups in the incidences of overall and organ/space SSI. [16]

### **Antibiotics compared to MBP**

A systematic review included 23 RCTs and 8 observational studies (n=not reported in abstract (NR)) that evaluated the effectiveness of oral antibiotic prophylaxis and/or MBP in preventing SSIs in elective colorectal surgery. The authors reported that the combination of oral and systemic antibiotic prophylaxis resulted in a 'statistically significant advantage in preventing SSIs' (data and statistics = NR) and that their 'analysis of the cohort studies shows no benefits in the use of MBP in prevention of SSIs'. [17]

### **MBP compared to no preparation**

A prospective RCT (n=202) assessed whether elective colorectal surgeries can be performed safely without preoperative MBP by comparing SSIs in patients given preoperative MBP versus those receiving no MBP. All patients also received broad-

spectrum IV antibiotics before the start of procedure. At 2 months follow-up there was no significant difference in SSIs between the groups. [18]

## Intelligence gathering

There is a NICE [Quality and Productivity case study](#) published April 2017 assessing the impact of a Cochrane review ([1]) on MBP for elective colorectal surgery. This concluded that MBP 'is not effective for improving outcomes in patients undergoing elective colorectal surgery and should not be used routinely. It should be reserved for procedures in which intraoperative colonoscopy might be performed or close visualisation of the bowel mucosa is needed.

Stopping or reducing the routine use of MBP in patients undergoing elective colorectal surgery is likely to lead to improved quality of patient care, improved patient experience and productivity savings. MBP should still be used at the surgeon's discretion during procedures to identify pathology or when intraoperative colonoscopy might be performed.'

Stakeholders who commented on the draft NICE guideline NG125 identified that the World Health Organization (WHO) [Global guidelines for the prevention of surgical site infections](#) recommend that 'preoperative oral antibiotics combined with mechanical bowel preparation should be used to reduce the risk of SSI in adult patients undergoing elective colorectal surgery' and that 'mechanical bowel preparation alone (without administration of oral antibiotics) should not be used for the purpose of reducing SSI in adult patients undergoing elective colorectal surgery.'

Stakeholders also highlighted [Meta-analysis of oral antibiotics, in combination with preoperative intravenous antibiotics and mechanical bowel preparation the day before surgery, compared with intravenous antibiotics and mechanical bowel preparation alone to reduce surgical-site infections in elective colorectal surgery](#), which was identified in the literature search [12]; and an observational study: [Comparative Effectiveness and Risks of Bowel Preparation Before Elective Colorectal Surgery](#) which reported that MBP alone did not reduce SSI, but that oral antibiotics alone and MBP plus oral antibiotics were associated with a significant decrease in the risk of SSI when compared with patients who received no bowel preparation; and there was no significant difference in SSI risk reduction between the oral antibiotics alone and MBP plus oral antibiotics groups.

## Impact statement

New evidence from 5 systematic reviews and 3 RCTs indicates that providing prophylactic oral antibiotics in combination with MBP (with or without IV antibiotics) significantly reduces the incidence of SSI from colorectal surgery when compared to MBP (with or without IV antibiotics) and may be the best approach to reducing SSI in people undergoing colorectal surgery. [9-16] This is also supported by the findings of the observational study highlighted by a stakeholder.

The evidence from a network meta-analysis, an RCT and the observational study also indicates that there is no difference in SSI between patients receiving MBP compared to no

preparation prior to colorectal surgery. [9, 18]

There is also evidence that suggests the provision of prophylactic preoperative oral antibiotics alone significantly reduces the risk of SSI in this population. The findings from 3 systematic reviews, 1 meta-analysis and the observational study indicate that oral antibiotics without MBP significantly reduce SSI, but it remains unclear whether or not the addition of MBP leads to a further significant reduction in SSI; it should be noted that there is limited data on the use of oral antibiotics alone on reducing SSI. [9-11, 17]

Overall, the evidence is in line with the recommendations of the WHO reported in [Global guidelines for the prevention of](#)

[surgical site infections](#). The evidence indicates that while the recommendation in NICE guideline NG125 to not use MBP alone is warranted, consideration should be made as to whether an additional recommendation is needed concerning the provision of prophylactic oral antibiotics plus MBP for colorectal surgery in order to reduce SSI. However there remains uncertainty concerning the comparative effectiveness of oral antibiotics alone versus oral antibiotics plus MBP on reducing SSI in patients undergoing colorectal surgery.

**New evidence identified that may change current recommendations.**

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