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

Surveillance report Published: 11 April 2019

www.nice.org.uk

Contents

Surveillance decision	3
Reasons for the decision	3
Overall decision	8
How we made the decision	9
Evidence	9
Views of stakeholders	9

Surveillance decision

We will update the guideline on <u>surgical site infections</u>: prevention and treatment (NICE guideline NG125).

Reasons for the decision

Assessing the evidence

The purpose of this exceptional review was to examine any impact on the guideline of published evidence on the effectiveness of preoperative prophylactic antibiotics and/or mechanical bowel preparation on reducing surgical site infection (SSI) in adult patients undergoing elective colorectal surgery.

During <u>stakeholder consultation</u> on the draft 2019 guideline, stakeholders provided comments on areas that were outside the scope of the update, but had been considered in the original 2008 version of the guideline. This exceptional review considered evidence in response to comments from several stakeholders that preoperative oral antibiotics combined with mechanical bowel preparation significantly reduce the risk of SSI in adult patients undergoing elective colorectal surgery. A stakeholder also noted that surgeons in England are using various combinations of oral antibiotics following advice by some surgical expert groups; and that this has resulted in some conflict with antimicrobial stewardship teams.

The guideline currently recommends that mechanical bowel preparation is not routinely used to reduce the risk of SSI and does not mention using a combination of preoperative oral antibiotics combined with mechanical bowel preparation to reduce the risk of SSI.

We considered the following evidence on the effectiveness of antibiotic prophylaxis and/or mechanical bowel preparation on reducing the risk of SSI:

- systematic reviews and randomised control trials (RCTs) published between 18 January 2014 and 1 February 2019 identified through a search
- published evidence provided by stakeholders

• the findings of the previous surveillance review of the original 2008 version of NICE's guideline on surgical site infections.

See <u>appendix A</u>: summary of evidence from the exceptional surveillance review for details of all evidence considered and references.

Evidence summary

A stakeholder highlighted that the Global guidelines for the prevention of surgical site infections (<u>World Health Organisation [WHO] 2016</u>) recommends the following: 'The panel suggests 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'. It also 'recommends 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'.

The recommendations by the WHO were based on the findings of a systematic review that included RCTs comparing mechanical bowel preparation versus no mechanical bowel preparation (13 RCTs; n=4,869) or a combined intervention of mechanical bowel preparation and oral antibiotics versus mechanical bowel preparation and no oral antibiotics (11 RCTs; n=2,416). While all age groups were included in the search, only studies with adult patients undergoing colorectal surgical procedures were identified, and all patients in intervention and control arms received prophylactic intravenous (IV) antibiotics. The evidence was published between 1 January 1990 and 17 January 2014.

A meta-analysis of the 13 trials assessing mechanical bowel preparation versus no mechanical bowel preparation reported that there was no significant difference in SSI rate between the groups. The quality of the evidence was assessed as moderate (using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials; <u>Higgins et al.</u> <u>2011</u>). A meta-analysis of the 11 trials comparing mechanical bowel preparation and oral antibiotics with mechanical bowel preparation and no oral antibiotics reported a significant reduction in SSI in the oral antibiotics plus mechanical bowel preparation group, with the evidence assessed as moderate quality.

The WHO Guidelines Development Group recommendation on not providing mechanical bowel preparation alone is described as a 'strong recommendation', whereas the recommendation to provide oral antibiotics combined with mechanical bowel preparation is a 'conditional recommendation'. The latter decision was due to:

- none of the studies in the systematic review assessing the effect of oral antibiotics alone on SSI
- patients in control and intervention arms in all studies receiving standard IV antibiotic prophylaxis
- there being no difference in the occurrence of anastomatic leakage between those receiving mechanical bowel preparation and oral antibiotics versus those receiving mechanical bowel preparation and no oral antibiotics – this being described as important because 'concerns can be raised about the possible higher frequency of leakage if mechanical bowel preparation is not performed'.

The report also notes:

- the higher initial costs of providing oral antibiotics combined with mechanical bowel preparation
- that the included studies did not report on costs or cost-effectiveness
- side-effects such as gastrointestinal symptoms when given oral antibiotics or mechanical bowel preparation
- potential unintended consequence of an increase in antimicrobial resistance from routinely providing oral antibiotics in this scenario.

In response to the findings of the WHO report, it was decided that a focused literature search for systematic reviews and RCTs published since the end of the search period for the WHO systematic review should be undertaken to identify any further evidence on the effectiveness or cost-effectiveness of oral antibiotics and mechanical bowel preparation in reducing the risk of SSI in patients undergoing colorectal surgery. The search strategy from the WHO report was adapted and 5 databases were searched for relevant publications published between 18 January 2014 and 1 February 2019. Eight studies were identified, of which 6 systematic reviews and 4 RCTs were included. Details of the studies' findings are presented in <u>appendix A</u>: summary of evidence from this exceptional surveillance review.

New evidence from 5 of the systematic reviews, 3 of the RCTs and an observational study highlighted by a stakeholder, indicates that providing oral antibiotics in combination with mechanical bowel preparation (with or without IV antibiotics) significantly reduces the incidence of SSI from colorectal surgery when compared to mechanical bowel preparation (with or without IV antibiotics) and may be the best approach to reducing SSI in people

undergoing colorectal surgery.

The evidence from a network meta-analysis, an RCT and the observational study confirms that mechanical bowel preparation alone is no more effective than no preparation at reducing SSI in colorectal surgery.

There is also evidence from 3 systematic reviews and the observational study to suggest that oral antibiotics alone significantly reduce SSI in colorectal surgery; and a network meta-analysis indicates that the provision of oral antibiotics is the second-best approach for reducing SSI (with oral antibiotics plus mechanical bowel preparation being the best approach). However, there remains a lack of data on the use of preoperative oral antibiotics alone for reducing SSI and no studies on the cost-effectiveness of the different potential strategies for reducing SSI in colorectal surgery were identified.

Guideline development

A literature search was undertaken for systematic reviews and RCTs published between 1950 and October 2007. The guideline's recommendation, 'Do not use mechanical bowel preparation routinely to reduce the risk of surgical site infection' was based on the findings of a meta-analysis of 12 RCTs (n=5,383) that assessed whether mechanical bowel preparation reduces the rate of SSI in patients undergoing colorectal surgery. Different mechanical bowel preparation solutions were administered in the studies: polyethylene glycol, mannitol, sodium picosulfate, laxative/enema/mannitol and in 2 studies the solution was not reported. There was no heterogeneity and no statistically significant difference in SSI incidence between the treatment and control groups (who received no mechanical bowel preparation).

The recommendations in the guideline to 'Give antibiotic prophylaxis to patients before ... clean-contaminated surgery, contaminated surgery' are also relevant to the findings concerning the use of prophylactic oral antibiotics and mechanical bowel preparation for colorectal surgery to reduce SSI. The type of antibiotic prophylaxis (administration route) is not mentioned in the guideline, although it is recommended to 'consider giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia' and to 'use the local antibiotic formulary and always consider potential adverse effects when choosing specific antibiotics for prophylaxis'. There is no specific mention of providing oral antibiotics. These recommendations were made in response to evidence identified to answer the review question 'What is the clinical effectiveness of parenteral or oral antibiotic prophylaxis for the prevention of surgical site infection compared with placebo or no antibiotic in patients

undergoing surgery involving a skin incision?' Systematic review and RCT evidence in relation to location of surgery and surgery type was reviewed. For colorectal surgery a systematic review and 4 RCTs were included that compared patients receiving antibiotic prophylaxis for colorectal surgery with a control group not given antibiotics. The antibiotics used prophylactically in these 4 trials were gentamicin plus metronidazole, metronidazole alone or metronidazole plus ampicillin, mezlocillin plus oxacillin, and cefoxitin. SSI was significantly lower in the antibiotic groups than in the control groups.

Previous surveillance

A surveillance review of the original 2008 version of the guideline was undertaken in January 2017. No new evidence relevant to the recommendation on bowel preparation was identified. The cumulative evidence from previous surveillance reviews was considered, and it was concluded that overall, the evidence supported the recommendation to not routinely use mechanical bowel preparation in order to reduce SSI (see <u>appendix A</u>).

Views of topic experts

In this exceptional review we contacted 8 topic experts who helped develop the 2019 guideline update. We received feedback from 3 topic experts, all of whom felt that the guideline should be updated to consider evidence on the use of oral antibiotics and mechanical bowel preparation on preventing SSI in adults undergoing colorectal surgery.

Topic experts were also asked about current practice. One topic expert responded that it is not generally current practice to use oral antibiotics before colorectal surgery, but that this does occur in a few centres.

Topic experts raised concerns that the use of oral antibiotics could lead to antimicrobial resistance and that this would need to be considered alongside the evidence of effectiveness at reducing SSI.

Impact

The evidence is directly relevant to the recommendation 'Do not use mechanical bowel preparation routinely to reduce the risk of surgical site infection' and of relevance to recommendations on providing antibiotic prophylaxis in the guideline.

The new evidence confirmed that mechanical bowel preparation alone should not be used

routinely for the purpose of reducing SSI in adult patients undergoing elective colorectal surgery. It also indicates that the most effective approach to reducing SSI in adult patients undergoing colorectal surgery is to provide a combination of preoperative oral antibiotics and mechanical bowel preparation, which was consistently found to be significantly more effective than mechanical bowel preparation with or without IV antibiotics at reducing SSI. There was also evidence indicating that preoperative oral antibiotics alone are effective at reducing SSI in patients undergoing elective colorectal surgery, however there remains a paucity of evidence on the effectiveness of oral antibiotics alone in reducing SSI for this group. There is also concern about the emergence of antimicrobial resistance, which should be considered in an update.

After taking into account the new evidence and views of topic experts, we have concluded that the new evidence does have an impact on the recommendations within the guideline. For this reason, we are recommending an update.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering the impact of the evidence on current recommendations, we decided that the guideline should be updated to consider evidence concerning whether oral antibiotics alone or a combination of oral antibiotics and mechanical bowel preparation should be provided to people undergoing colorectal surgery in order to reduce the incidence of SSI.

See how we made the decision for further information.

How we made the decision

Exceptionally, significant new evidence may mean an update of a guideline is agreed before the next scheduled check of the need for an update. The evidence might be a single piece of evidence, an accumulation of evidence or other published NICE guidance.

For details of the process and update decisions that are available, see <u>ensuring that</u> <u>published guidelines are current and accurate</u> in developing NICE guidelines: the manual.

Evidence

This surveillance report provides an overview of 1 report, 6 systematic reviews, 4 randomised control trials and an observational study. The results of this evidence, and previous surveillance evidence, were considered in detail to determine if there was an impact on the recommendations within the guideline.

Views of stakeholders

Because this was an exceptional surveillance review, we did not consult on the decision.

ISBN: 978-1-4731-3357-0