A TAILORED KNOWLEDGE TRANSLATION STRATEGY TO INCREASE COMPLIANCE WITH GUIDELINE RECOMMENDATIONS FOR PREOPERATIVE BOWEL PREPARATION

By

Cagla Eskicioglu

A thesis submitted in conformity with the requirements for the degree of Master of Science (Clinical Epidemiology) Graduate Department of Health Policy, Management and Evaluation University of Toronto

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Abstract

A tailored knowledge translation strategy to increase compliance with guideline recommendations for preoperative bowel preparation

Cagla Eskicioglu  
Degree of Master of Science, 2009  
Department of Health Policy, Management and Evaluation, Division of Clinical Epidemiology  
University of Toronto, Toronto, Ontario, Canada

Background: There is strong level I evidence that in most patients, mechanical bowel preparation (MBP) is not required. Despite this, physician behaviour has been slow to change in favour of omitting preoperative MBP.

Methods: A knowledge translation strategy including: guideline development, consensus, education by opinion leaders, audit and feedback and reminder cards, was used in this study.

Results: Overall, 81.1% of patients in the “before” arm and 88.4% in the “after” arm received MBP in compliance with the guideline (p=0.038). Normal diet use was compliant with the guideline in 45.6% of the patients in the “before” arm and 55.8% in the “after” arm (p=0.080). The use of enemas was compliant with the guideline in 88.5% of “before” patients and 94.2% of “after” patients (p<0.001).

Conclusions: The results of this study reveal that a tailored, multi-faceted knowledge translation strategy can be used to change surgeon behavior in this clinical scenario.
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1.0 Introduction

1.1 Bowel Preparation

Bowel preparation before colorectal surgery has been engrained in standard surgical practice for over a century. Bowel preparation prior to elective colorectal surgery can include a variety or a combination of interventions, such as, preoperative dietary modifications, oral laxative solutions and the use of enemas. For the purposes of this manuscript, mechanical bowel preparation (MBP) refers to the use of an oral laxative solution used to cleanse the colon of fecal contents (e.g. polyethylene glycol, sodium phosphate, sodium picosulphate, magnesium citrate). It is believed that MBP decreases intra-luminal fecal mass and presumably decreases bacterial load in the bowel. It has been argued that this decrease in fecal load and bacterial contents reduces the rates of infectious postoperative complications such as surgical site infections, deep intra-abdominal infections and anastomotic dehiscence or disruption of the surgical anastomosis. These theories, however, have been based largely on clinical experience and expert opinion.\textsuperscript{1,2}.

For many years, the benefit of reducing postoperative infectious complications by prescribing MBP has been thought to greatly outweigh the risks of the preparation. However, MBP does have its own disadvantages. A randomized controlled trial (RCT) published by Bucher \textit{et al.}\textsuperscript{3} reported the histological changes in intestinal mucosa in 25 patients who had MBP with polyethylene glycol as compared to 25 patients who did not receive MBP. There was a significant difference in the loss of superficial mucous (p <0.001), loss of epithelial cells (p<0.01), edema of the lamina propria (p<0.01), lymphocyte infiltration (p <0.02) and polymorphonuclear cell infiltration (p<0.02) in patients who received MBP compared with those who did not.\textsuperscript{3} Although it is unclear if these morphological changes are clinically relevant, they
could potentially result in bacterial translocation and anastomotic disruption.\textsuperscript{4, 5} Furthermore, the process of bowel preparation, with the consumption of large volume laxative solutions, can be extremely unpleasant for patients. These solutions can also cause significant cramping, bloating, nausea and vomiting in some patients.

More importantly, MBP can lead to large volume and electrolyte disturbances which can result in death for a small proportion of patients with other co-morbidities (i.e. renal or cardiac disease). There have been many reports in the literature in the form of letters to the editor and case reports describing the adverse effects related to MBP. In brief, these case reports revealed that many of the different types of MBP such as sodium picosulfate, polyethylene glycol, sodium phosphate and magnesium citrate are associated with adverse effects.\textsuperscript{6-15} The primary adverse effects were related to electrolyte and volume disturbances in both healthy patients as well as patients with underlying cardiac or renal disease. Furthermore, these electrolyte disturbances led to seizures, syncope, coma and even death in some patients. There have also been reports of MBP associated ischemic colitis, pancreatitis and esophageal perforation.\textsuperscript{16-18} Finally, anecdotally patients who come to the operating room after receiving MBP arrive dehydrated and often require increased perioperative fluid. This, however, disagrees with recent evidence suggesting that restricted perioperative fluid regimes are associated with fewer cardiopulmonary and tissue healing complications in patients undergoing colorectal surgery.\textsuperscript{19}

More recently, research has shown that MBP with solutions such as, polyethylene glycol (PEG) do not change the bacterial concentration or the bacterial composition of stool.\textsuperscript{20} MBP can make the stool more liquid and therefore, may increase the risk of spillage and fecal contamination of
In a study by Zmora et al., 187 patients were randomized to receive MBP and 193 patients to receive no MBP. A significantly greater proportion of patients receiving MBP had liquid stool as compared to the patients in the non-prepared group (37.4% vs. 13.5% p=0.001). Furthermore, the authors reported that the rate of fecal spillage or contamination of the operative field in the prepared bowel group was 16.6% as compared to 9.3% in the non-prepared group (p = 0.046).

The first article to challenge the need for MBP was published in 1972. In this study, 46 patients who received MBP were compared to 51 patients who did not. Although this study was underpowered, there was no significant difference between the rates of wound infections, peritonitis or mortality between the two groups. Hughes concluded that “patients who underwent a mechanical bowel preparation fared no better than those who did not.” Since then, studies in emergency and trauma surgery have shown that there is no increased risk of anastomotic dehiscence in unprepared bowel. In one case series of 100 colorectal surgery cases that did not receive MBP from the United Kingdom, there was a 7% wound infection rate and a 1% anastomotic dehiscence rate.

Recently, a total of fourteen unique RCTs and eight systematic reviews, have shown that MBP does not reduce the rate of postoperative complications, including anastomotic dehiscence. The highest quality meta-analysis, which was published in 2005 as a Cochrane review, was based on 9 trials with a total of 1,592 patients. The results of this meta-analysis indicated that MBP is associated with higher rates of anastomotic leakage with an odds ratio of 2.03, 95% CI: 1.276 to 3.26 (p=0.003). However, since then a more recent meta-analysis was published by Slim et al.
in 2009 and included all 14 trials with a total of 4,859 patients. Two thousand four hundred and fifty two patients were randomized to the MBP group and 2,407 to the no MBP group. The pooled results of this meta-analysis yielded different results from the Cochrane review and revealed no statistically significant difference in anastomotic leakage rates between the two groups with narrower 95% confidence intervals (OR 1.12, 95% CI [0.82, 1.53], p=0.46). Although the results of these two meta-analyses differed, likely secondary to the increased sample size, both reviews concluded that there is no benefit to using MBP in patients undergoing elective colorectal surgery.

Unlike open colorectal surgical procedures, there is no evidence for the use or omission of MBP in patients undergoing laparoscopic colorectal procedures. In patients undergoing laparoscopic colon resection, there are additional factors to consider that influence the use or omission of MBP. MBP is used not only to cleanse the bowel contents in order to reduce infectious complications, but also to allow for easier handling of the colon and easier identification of the tumor or pathology to be resected. On the other hand, bowel preparation can make the colon quite distended and therefore, more difficult to manoeuvre intra-operatively. There have been no studies examining the need for MBP and its effect on anastomotic dehiscence rates specifically in patients undergoing laparoscopic colon resection. Currently, surgeons must extrapolate results from the open colorectal surgery population to these laparoscopic surgeries.

1.2 Utilization Data

Despite the plethora of Level I evidence on this topic, a survey of colorectal surgeons in the United States published in 2003, revealed that 99% of 515 responding surgeons prescribed MBP prior to surgery. A more recent survey published in 2005 reported responses from surgeons
from five northern European countries including the Netherlands, Scotland, Sweden, Norway and Denmark. This survey revealed variable rates of MBP use for an elective left-sided resection for cancer. Depending on the country, 52% to 95% of 200 respondents reported prescribing preoperative MBP to patients. In 2006, a multinational audit of 1082 patients in 295 hospitals from Europe and the United States revealed that 86% to 97% (mean 94%) of patients received preoperative MBP. Furthermore, this survey indicated that more than 80% of patients in Europe received the MBP in hospital. This highlights the additional costs of MBP (i.e. preadmission of patients, nursing care) which are completely independent of the risks and discomfort felt by patients.

Our research group administered an initial pilot survey of surgeons affiliated with 7 teaching hospitals in Toronto. Seventy two percent of 40 respondents replied that they were still using MBP for left-sided resections and 40% stated that they believed that there was research evidence to support this practice for the prevention of surgical site infections. This survey highlighted that the use of MBP in elective colorectal cases in Toronto parallels those results seen in the United States survey. This survey also indicated that many surgeons are aware of evidence regarding the omission of MBP prior to surgery but still have not changed their practices.

The surveys and audits described above provide evidence that a large gap exists between the evidence surrounding the use of MBP and the practice of surgeons. Although there is an abundance of evidence from the past thirty years, this evidence has not changed surgeon practices. Furthermore, there is enough evidence from well designed RCTs to develop a practice guideline. Currently, a practice guideline for bowel preparation prior to elective colorectal
surgery does not exist but was developed as part of this study. One important step in influencing change may be the development of a practice guideline into a concise review, which also provides opinion on the quality of the evidence. However, the larger hurdle is influencing surgeons to adopt the recommendations made by this guideline and requires a tailored knowledge translation strategy.

1.3 Knowledge Translation

Despite the abundance of evidence for the omission of MBP in patients undergoing elective colorectal surgery, surgeon practice is variable and reasons for not adopting this evidence is unclear. Furthermore, there remains a significant difference between the best evidence and the actual practice of medicine. This discrepancy between evidence and practice patterns has been termed the “clinical care gap” and has been identified as one of the disparities in health care. This gap has been well documented for various diseases in the different surgical specialties such as general surgery.

The Canadian Institutes of Health Research define knowledge translation as “the exchange, synthesis and ethically sound application of knowledge … to accelerate the capture of the benefits of research.” Knowledge translation has also been called implementation research in Europe and provider or quality improvement in the United States. Unfortunately, the process of knowledge translation can be slow, incomplete and faced with many barriers. Knowledge translation strategies can include knowledge syntheses such as systematic reviews, meta-analyses and evidence based guidelines as well as implementation strategies such as, educational meetings, opinion leader interventions, audit and feedback and reminders.
Clinical Practice Guidelines (CPGs) have emerged in a setting focused on improving quality of patient care based on the best available evidence. Furthermore, physicians are faced with an overwhelming abundance of literature that should influence their quality of care. CPGs have the potential to improve quality of patient care by supporting interventions that have been shown to be effective and discouraging interventions, which have been proven to be ineffective. CPGs are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.” CPGs, like systematic reviews and meta-analyses, are another method to consolidate evidence from a variety of sources as well as address conflicting or inconsistent evidence. They are designed to qualitatively combine a large body of literature on a given topic as well as draw upon clinical expertise and patient preferences. One advantage of these qualitative approaches is that guidelines can include evidence from a heterogeneous sample of studies and are not limited to clinical trials. Going one step further, authors of CPGs make recommendations based on the best evidence, considering both the expected benefits and harms of a given diagnostic test or treatment and the strength of the evidence.

CPGs are particularly useful in areas of clinical debate or even equipoise. When there is a large body of evidence, which may or may not be conflicting, CPGs are a useful technique to evaluate the quality and results of this evidence. Furthermore, CPGs can be helpful when there is a difference of opinion about care that should be provided, which can be evidenced by a large variation in practice patterns. Also, CPGs are needed in order to combine scientific knowledge
from research and expertise on a particular area, especially if the proposed interventions carry significant risks or cost.\textsuperscript{41} CPGs are less helpful when there is already consensus or very little variation around a given topic.

CPGs, like all other types of publications, can be biased. Therefore, a systematic approach to the development of CPGs is required in order to avoid conflicts of interest. Several bodies, such as the Canadian Task Force on Preventive Health Care (CTFPHC) and the US Preventive Services Task Force (USPSTF) have published their methods for guideline development.\textsuperscript{42-44} These methods emphasize a systematic, evidence based approach to guideline development in order to avoid bias.

The following steps are a summary of those described by the USPSTF.\textsuperscript{43,44} The first step of this rigorous approach is to define the scope of the guideline by clearly delineating the question(s) and target audience. A CPG may address a particular disease process, including diagnosis and treatment or it can focus on one particular aspect of a management strategy. Once the scope has been determined, authors must systematically review the literature to identify relevant studies that discuss the benefits as well as the potential harms of the strategy. This systematic review is ideally performed with the assistance of an information specialist and chosen articles should be based on pre-specified inclusion criteria.\textsuperscript{31} After articles have been identified, it is important to assess the quality and level of the available evidence. Like meta analyses, the quality of CPGs is influenced not only by methods of development but by the quality and level of the available evidence. Depending on the evidence available, authors can choose to include only the highest quality or highest level of evidence in the CPG. However, if the evidence for a particular topic is
sparse, authors may be forced to include all available evidence with a thorough discussion of the limitations of the included studies.

Both the USPSTF and CTFPHC have outlined a number of criteria that can be used to assess the quality of different publication types. These criteria are general but can be modified to reflect the types of literature being reviewed for a particular CPG. However, these quality criteria should be determined a priori to avoid bias in the quality assessment stage. Using the predefined criteria, studies are given quality ratings of “good”, “fair” or “poor”. Studies of “good” quality meet all of the predetermined criteria, whereas studies of “poor” quality have flaws in study design and therefore, fail to meet some of the quality criteria. Some examples of quality criteria include: allocation concealment, use of validated measurement tools, minimal loss to follow-up and use of intention-to-treat analysis.

The level of evidence from a publication is also an important consideration in guideline development. Many organizations, including the USPSTF, have described a hierarchy of evidence from different publication types. Meta analyses and RCTs are at the top of the hierarchy with the highest level of evidence. Cohort studies, case-control studies, case reports and finally, expert opinion represent other levels of evidence with decreasing strength in that order.

Once the evidence has been collected and quality has been assessed, recommendations are formulated by weighing the net benefits and harms of the strategy. Furthermore, the strength of the recommendation is based on both the levels and quality of the available evidence. This step
can be particularly influenced by bias and it is crucial to be transparent in the description of how recommendations were made. Using USPSTF methodology, recommendations are given a grade from grade “A” to “D” or “I” depending on the strength of the recommendation; with a grade “A” recommendation suggesting a strong recommendation to provide a service and a grade “D” recommendation suggesting a strong recommendation against the provision of a service. A recommendation given a grade “I” indicates that there is insufficient evidence to support or refute the use of a particular intervention.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group has described another method of grading recommendations. The GRADE system reports the strength of a recommendation based on the magnitude of the benefit and the quality of the evidence. These recommendations are described as “strong” or “weak” by the GRADE system.

After recommendations have been developed, these recommendations can be simplified into “actionable messages” in order to aid in implementation and guideline uptake. It is also important to have a newly developed CPG reviewed by relevant stakeholders to ensure consensus and avoid potential barriers to implementation. Furthermore, it may also be advantageous to obtain endorsement for the guideline by a well known, reputable society. Finally, guidelines should be updated at regular time intervals to reflect the most recent available evidence.
Since CPGs are greatly influenced by the quality and level of the available evidence, there is a spectrum of developed guidelines. Broadly, they can fall under two categories resulting from their development method and the available evidence.\textsuperscript{40} Firstly, CPGs can be consensus statements based largely on clinical expertise and expert opinion in areas where there is not a large body of evidence. In controversial areas where evidence is lacking, a CPG derived by expert consensus may be useful. Alternately, CPGs can be evidence-based guidelines which are developed by drawing on evidence from well designed RCTs and meta-analyses. Evidence-based CPGs can include evidence from only RCTs if this level of evidence is available for the particular topic. However, if evidence from only cohort studies, case-control trials or even case series is available, then the CPG is based on this evidence. These two different types of CPGs represent two ends of a spectrum with most CPGs falling at some point along this continuum.\textsuperscript{40}

Development of an evidence based guideline, however, is only one part of the knowledge translation pathway. A larger hurdle is disseminating and implementing the guideline with the final goal of changing physician behavior. Therefore, the implementation should also involve a strategy to evaluate the result of the knowledge translation intervention. It has been suggested that passive dissemination of CPGs alone is less effective at changing physician behavior than dissemination of educational materials plus reminders, outreach or audit and feedback.\textsuperscript{37} This indicates that dissemination of CPGs paired with a tailored knowledge translation intervention may improve adherence to the recommendations put forth by the guideline.
1.3b Opinion leaders

One particularly useful strategy to increase adoption of new evidence is the use of opinion leaders. A survey of Australian surgeons revealed that opinion leaders were more likely to be “very influential” in promoting behavioral change as compared to clinical practice guidelines.46

Opinion leaders are those perceived by their colleagues as “educationally influential”.47 Based on the theory of diffusion of innovations and social influence research, it is believed that opinion leaders can facilitate research transfer by increasing awareness and improving communication between professionals.46 Opinion leaders have been identified in many clinical disciplines, including general surgery, and have been shown to influence change in this population.46-48

Opinion leaders can be identified using various models that can be classified into the following categories: the observation method, self-designating method, sociometric method and the informant method.49 In the observation method, an independent observer is used to identify opinion leaders from a group of professionals interacting in a work setting. Individuals report their own roles as opinion leaders in the self-designating model. The sociometric model asks professionals to judge individuals according to the extent to which they are “educationally influential”, “knowledgeable” and “humanistic”. Finally, the informant method relies on other professionals to identify individuals who act as primary sources of influence.49 The method used to designate opinion leaders can have a large effect on the impact of opinion leaders in influencing change. In both the observation and self-designating models, opinion leaders are chosen by individuals who will not be downstream from the influence of the designated opinion leader. This may lead to a dampened effect of the opinion leader in influencing change. Furthermore, it has been shown that opinion leaders chosen using the
informant model are more likely to influence their colleagues than opinion leaders chosen using the sociometric method.\textsuperscript{36}

\textit{1.3c Audit and Feedback}

Audit and feedback has been defined as “any summary of clinical performance of health care over a specified period of time, given in written, electronic or verbal format”.\textsuperscript{50} The use of audit and feedback as a knowledge translation strategy is based on the logic that physicians may want to change practice if they are shown that their practices are not in keeping with their peers or with published guidelines.\textsuperscript{50} It has been used in a variety of settings as a method to improve physician practice.\textsuperscript{50}

In an early review of audit and feedback studies, Mugford \textit{et al.} showed that audit and feedback may be more effective if provided close to the time of decision making and if physicians had agreed to review their practice.\textsuperscript{51} Furthermore, this review also categorized feedback as being passive or active; with passive feedback being unsolicited and with no proposed requirement for action whereas active feedback is provided to clinicians who are aware of the particular topic and whose interest in the topic has been engaged.\textsuperscript{51} Examples of active feedback are when feedback is provided as part of continuing education, when standards have been agreed upon, or when feedback is used as a source for further discussion.\textsuperscript{51}

In a more recent review, 118 RCTs were evaluated; in 72 of these studies, audit and feedback as either the intervention or a component of the intervention was compared to no intervention. The main outcome measured in these studies was difference in compliance and this ranged from a 10% decrease in compliance to a 70% increase in compliance.\textsuperscript{50} Factors such as low baseline compliance
and the intensity of the audit and feedback intervention were associated with greater effectiveness.\textsuperscript{50} Furthermore, in the review by Grimshaw \textit{et al.}, 5 cluster RCTs including audit and feedback showed improvements with an absolute improvement of +7.0\% (range +1.3\% to +16.0\%).\textsuperscript{37}

\textit{1.3d Reminders}

In the comprehensive review by Grimshaw \textit{et al.}, reminders were the most frequent single intervention evaluated. Reminders were compared to no intervention for guideline dissemination in 38 of 309 comparisons (13\%).\textsuperscript{37} Furthermore, they were included as part of a multifaceted intervention in 95 of 309 comparisons (31\%).\textsuperscript{37} In 12 of 14 cluster randomized trials evaluating reminders as a single intervention, reminders were associated with improvements in care with a median effect of +14.1\% (range -1.0 to +34.0\%) absolute improvement in performance.\textsuperscript{37} This review indicates that reminders are a “potentially effective intervention and are likely to result in moderate improvements in process of care.”\textsuperscript{37}

\textit{1.3e Single vs. Multi faceted interventions}

The field of knowledge translation is diverse and heterogeneous. There are many potential interventions, including the ones discussed above, which can be used as strategies to change physician behavior. Individually, most interventions have been shown to have a small to modest benefit in terms of influencing change.\textsuperscript{37} However, one knowledge translation strategy has not consistently been shown to be superior to others. Often times, these interventions are used in combination in an effort to maximize the potential modification of physician behavior. Research in CPG implementation or knowledge translation is continually evolving and growing. However, at times this body of literature can be difficult to interpret since it is based in
heterogeneous settings and often involves a variety of clinical problems.\textsuperscript{31} An extensive review of knowledge translation interventions concluded that “the majority of interventions observed modest to moderate improvements in care”; however, there was “considerable variation in the observed intervention both within and across interventions”.\textsuperscript{37}

One area examined in this review of guideline dissemination strategies focused on the number of interventions used in knowledge translation strategies. This review included 235 studies reporting 309 interventions.\textsuperscript{37} Seventy-three percent of these comparisons examined multifaceted interventions but there was significant heterogeneity in the interventions and few multifaceted interventions were replicated. Educational materials were most frequently evaluated as a component of multifaceted interventions (48\% of studies) followed by educational meetings (41\%) and reminders (31\%).\textsuperscript{37} The authors concluded that multifaceted interventions were not more effective than single interventions; however, they also recognized the difficulty in drawing “generalizable conclusions” from these data.\textsuperscript{37} Furthermore, the results did not indicate an increased effectiveness in promoting change with a greater number of components in the intervention strategy.\textsuperscript{37}
2.0 Theoretical Framework

The framework for this study is based on the model of knowledge translation, as outlined by Pathman. The awareness-to-adherence model describes four key steps to knowledge translation or specifically guideline dissemination, which include awareness, agreement, adoption and adherence. For each step, a different educational approach can be used to influence change. This model, described in 1996, was tested on pediatric vaccine recommendations. The authors hypothesized that progression along the path could stop at any stage and this would ultimately result in guideline noncompliance. They concluded that physician compliance with guidelines generally occurs sequentially through the four stages listed above and that guideline dissemination should be targeted to particular stages in the model.

In particular clinical scenarios, continuing medical education and continuing professional development strategies are not able to bridge this gap between best evidence and actual practice. Therefore, other strategies including the ones discussed above are necessary to engage clinicians and lead them through the steps of knowledge translation. In order to increase awareness regarding a particular topic, physician education is important. Education can be accomplished by educational materials in the form of knowledge syntheses, such as guidelines or reviews, as well as by educational meetings and presentations. Although educational strategies can raise awareness about evidence-based practice, they may not be as successful in the agreement, adoption of and adherence to that practice. To move physicians into the agreement phase of change, consensus meetings and small group discussions can be used. Once physicians are aware and agree with the evidence, the next hurdle is adoption of the evidence. Considerable research has shown that strategies designed to promote behavior change either through incentives
(pay-for-practice, public performance reporting) or social influence (opinion leaders, audit and feedback) have been able to influence change; however, the effect size of these interventions varies greatly between different settings. Finally, after adopting a change in practice, the key is to adhere to this practice on a regular basis. There are many different knowledge translation strategies such as the use of reminders and audit and feedback that can be used to promote adherence to a newly adopted strategy. Table A describes the specific components that are included in the tailored, knowledge translation, which is utilized in this study. It also outlines the Pathman stage, which is targeted by each component.

Table A: Knowledge translation strategies used to target Pathman stages

<table>
<thead>
<tr>
<th>Pathman Stage</th>
<th>Knowledge Strategy Employed</th>
</tr>
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<tbody>
<tr>
<td>Awareness</td>
<td>• Educational seminar</td>
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<tr>
<td></td>
<td>• Interactive question &amp; answer</td>
</tr>
<tr>
<td>Agreement</td>
<td>• Consensus with opinion leaders</td>
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<td></td>
<td>• Endorsement by CSCRS</td>
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<tr>
<td>Adoption</td>
<td>• Opinion leader involvement in CPG development</td>
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<tr>
<td></td>
<td>• Audit and feedback</td>
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<tr>
<td>Adherence</td>
<td>• Reminder cards</td>
</tr>
<tr>
<td></td>
<td>• Quantitative evaluation of compliance (Future directions)</td>
</tr>
<tr>
<td></td>
<td>• Qualitative assessment of the impact of each strategy (Future directions)</td>
</tr>
</tbody>
</table>
3.0 Rationale

Although there is little evidence supporting its use, surgeons performing colorectal surgery have been using bowel preparation for many years. This practice has become surgical tradition and has been passed from mentor to student. Currently, level I evidence indicates that the use of MBP is not associated with reduced post-operative infectious complications and that the omission of MBP is not associated with increased anastomotic leakage. However, the lack of adoption of this evidence indicates that there are significant barriers to changing bowel preparation practices amongst general surgeons.

It was hypothesized that an evidence based guideline regarding the use and omission of MBP, dietary restrictions and the use of enemas in patients undergoing elective colorectal surgery was needed in order to consolidate, synthesize and appraise the available literature. Promoting awareness of the evidence as well as achieving consensus and agreement to the guideline would be necessary steps in the implementation of this guideline. Furthermore, these steps would be required before surgeons would adopt and adhere to the recommendations outlined by the guideline and the guideline can start influencing change in surgeon behavior. Finally, it was felt necessary to evaluate the impact and reach of this tailored knowledge translation strategy involving development and consensus of the guideline and education of local surgeons to promote the MBP guideline. This study sought to increase awareness of the evidence and then, to convince surgeons that it is time to change. Most importantly, it was felt that there was an opportunity to change physician practices with the ultimate goal of improving quality of care and outcomes for patients.
4.0 Objectives

4.1 Guideline Development and Knowledge Translation Strategy

1. To develop and disseminate an evidence based guideline regarding bowel preparation in patients undergoing elective colorectal surgery by:

   a. Synthesizing the available literature and formulating recommendations in the form of a guideline

   b. Achieving consensus and agreement with the recommendations set out by the guideline amongst local colorectal surgeon opinion leaders and receiving endorsement from the CSCRS

   c. Using a tailored knowledge translation strategy, which includes educational lectures, audit and feedback and reminder cards to facilitate awareness, agreement, adoption of and adherence to the guideline by general surgeons and general surgery residents at the University of Toronto

4.2 Before-After Evaluation of MBP Practices

1. To measure compliance with the evidence based guideline regarding three bowel preparation components (MBP, dietary restrictions, enemas) before and after a tailored knowledge translation intervention

2. To measure the change in the proportion of patients receiving MBP, normal diet and enemas preoperatively prior to colorectal surgery before and after a tailored knowledge translation intervention
5.0 Methods

This study included the development of a tailored knowledge translation strategy in order to disseminate recent changes in evidence regarding the use and omission of MBP in patients undergoing elective colorectal surgery. The tailored knowledge translation strategy involved the development of an evidence based guideline followed by consensus to the guideline by opinion leaders in colorectal surgery. The guideline was modified as a result of this consensus meeting and this revised guideline was distributed to general surgeons in Toronto by educational meetings involving audit and feedback and distribution of reminder cards. Finally, this study also assessed the change in practice patterns of general surgeons in Toronto regarding the use of bowel preparation in patients undergoing elective colorectal surgery. These practice patterns were evaluated by prospectively collecting and comparing data about the use of MBP in these patients, before and after the multifaceted knowledge transfer intervention. The primary question addressed by this study was: can we increase compliance with the guideline recommendations regarding three bowel preparation components (MBP, dietary restrictions, enemas) using a tailored knowledge translation intervention?

5.1 Guideline Development

Definitions

Bowel preparation prior to elective colorectal surgery can include a variety or combination of interventions. For the purposes of this guideline, MBP refers to the use of an oral laxative solution used to cleanse the colon of fecal contents (e.g. polyethylene glycol, sodium phosphate, sodium picosulphate, magnesium citrate). Preoperative dietary modifications and the use of enemas are also addressed as separate components of bowel preparation. The use of a normal
diet refers to allowing patients a regular, unrestricted diet on the day prior to surgery. This can be replaced with a clear fluid diet, which restricts patients from eating solid food. An enema is the administration of liquid per rectum used to evacuate stool from the rectum.

Literature Review

Two searches were performed with the assistance of a medical librarian to identify relevant articles to address the questions outlined in the analytic framework (APPENDIX 1). The first search identified articles evaluating postoperative complications in patients who did and did not receive MBP. The second search identified articles describing adverse effects related to the use of MBP. These search strategies complete with Medical Subject Headings (MeSH) are outlined in Table B. A search of the medical literature using MEDLINE, EMBASE and Cochrane databases was performed to identify relevant articles published between January 1950 and February 2009 that compared adult, human subjects who received MBP or no MBP and reported postoperative infectious complications as an outcome (Search #1). The search was limited to RCTs involving adult human subjects using the Robinson & Dickersin Sensitivity Strategy. Non-randomized controlled trials or studies including patients undergoing emergency colorectal surgery were excluded.

A second search using MEDLINE, EMBASE and Cochrane databases was performed to identify relevant articles pertaining to search strategy #2. This search strategy was not limited to publication type. A manual search of the reference lists of selected manuscripts from each literature search was also performed in order to further identify relevant research studies. Two
reviewers independently assessed all titles and abstracts in order to select the studies to be included in this guideline. Disagreement on selection was resolved in a consensus meeting.
Table B: Search strategy used for systematic review of literature for evidence on mechanical bowel preparation and postoperative complications and mechanical bowel preparation and adverse effects

<table>
<thead>
<tr>
<th>MEDLINE/COCHRANE</th>
<th>EMBASE</th>
</tr>
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<tbody>
<tr>
<td><strong>Search #1 - MBP and Postoperative Complications</strong></td>
<td><strong>Search #1 - MBP and Adverse Effects</strong></td>
</tr>
<tr>
<td>1. (mechanical adj2 bowel adj2 prepar:).ti,ab. OR exp cathartics/ OR laxatives/</td>
<td>1. (Bowel adj5 Prepar:).mp.</td>
</tr>
<tr>
<td>2. exp Colorectal Neoplasms/ OR exp Colonic Neoplasms/</td>
<td>2. exp Intestine Preparation/ OR exp Laxative/</td>
</tr>
<tr>
<td>3. exp Colorectal Surgery/ or exp Surgery/ OR exp Colorectal Neoplasms/su or exp Colonic Diseases/su or exp Rectal Diseases/su or Anastomosis, Surgical/ or Colorectal Surgery</td>
<td>3. 1 AND 2</td>
</tr>
<tr>
<td>4. 1 AND 2 AND 3</td>
<td>4. exp PELVIS SURGERY/ or exp MAJOR SURGERY/ or exp MINIMALLY INVASIVE SURGERY/ or exp LAPAROSCOPIC SURGERY/ or exp ANUS SURGERY/ or exp COLON SURGERY/ or exp INTESTINE SURGERY/ or exp GASTROINTESTINAL SURGERY/ or exp RECTUM SURGERY/ or exp COLORECTAL SURGERY/ or exp ABDOMINAL SURGERY/ or exp SURGERY/ or exp CANCER SURGERY/ or exp GENERAL SURGERY/ or exp ELECTIVE SURGERY/</td>
</tr>
<tr>
<td>5. 6 AND Robinson &amp; Dickersin Sensitivity Strategy</td>
<td>5. exp Intestine Tumor/ OR exp Large Intestine Disease/</td>
</tr>
<tr>
<td>7. 4 AND 6</td>
<td>7. exp Postoperative Complication</td>
</tr>
<tr>
<td>8. Robinson &amp; Dickersin Sensitivity Strategy</td>
<td>8. 6 AND 7</td>
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<td>10. 8 AND 9</td>
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Quality Assessment

Quality appraisal was performed independently by two authors. The selected manuscripts were reviewed and a quality assessment was performed using the criteria of the USPSTF. RCTs were given a GOOD rating, provided patients in the intervention and control groups were comparable at the start of the trial, there was no crossover between the two groups, minimum follow-up of 80% was reported, interventions were clearly defined, well-defined and reproducible outcome assessments were applied equally in both groups, outcome assessors were blinded, intention-to-treat analysis was employed and appropriate attention was given to confounders in the analysis. Studies were deemed to be of POOR quality if they had any one of the following: gross differences between the intervention and control groups at the start of the study, greater than 10% crossover between the two groups, significant (>20%) loss to follow-up, lack of a power calculation or the interventions were not clearly defined. Studies with minor methodological flaws were given a FAIR rating. Meta-analyses were given a GOOD rating if they were published within the last 4 years, included a comprehensive literature search, had duplicated study selection and/or data extraction, utilized relevant selection criteria, provided characteristics of the included studies, documented and used a quality assessment to formulate conclusions, used statistical methods to combine study findings described (pooled analysis, tests for heterogeneity), assessed the likelihood of publication bias and stated conflicts of interest.

Recommendations

After critical appraisal of the methodology and evidence of the included studies, recommendations were made using the criteria established by the USPSTF. Outcomes assessed included anastomotic dehiscence and superficial surgical site infections. These outcomes were
reviewed for all patients undergoing elective colorectal surgery as well as for the following subgroups: patients undergoing low anterior resections with or without diverting ileostomies and patients undergoing laparoscopic colorectal surgery. Finally, recommendations were also made regarding preoperative dietary modifications and the use of preoperative enemas.

*Endorsement of Guideline*

The Canadian Society of Colon and Rectal Surgeons (CSCRS) was approached to endorse of the guideline. The guideline was first presented briefly to the members of the Society at an annual meeting in September 2008. At that time, a short, ten minute presentation was made by the principal investigator outlining the recommendations described in the guideline. This presentation generated a great deal of interest as well as disagreement and indicated a more thorough and transparent presentation of the evidence and the recommendations were required. At this meeting, it was decided that the principal investigator would formally distribute the guideline to the members of the CSCRS through the Executive Director of the Society. After distribution, the members would be asked to vote as to whether the Society should endorse the guideline.

*5.2 Knowledge Transfer Strategy*

Following development of the bowel preparation guideline, a multifaceted knowledge translation strategy was used to raise awareness and implement the guideline. This strategy involved achieving consensus to the developed guideline and dissemination of the guideline using educational lectures by opinion leaders, audit and feedback, and reminder cards.
Setting/Sample

This strategy was designed to target practicing general surgeons working at seven adult teaching hospitals affiliated with the University of Toronto in Toronto. The hospitals included: Mount Sinai Hospital, Toronto General Hospital, Toronto Western Hospital, Sunnybrook Health Sciences Centre, St. Michael’s Hospital, Toronto East General Hospital and St. Joseph’s Health Centre. The population of interest in this study was all practicing general surgeons affiliated with the seven hospitals. All general surgeons, who are certified by the Royal College of Physicians and Surgeons of Canada, were eligible for the study. Surgeons were excluded from this study if they are 1) retired, 2) not performing any elective colorectal surgery, or 3) practicing only another surgical sub-specialty (i.e. cardiac, vascular, and thoracic).

Consensus Meeting

A consensus meeting was called to evaluate and reach agreement on the guideline developed regarding bowel preparation practices. All surgeons who were considered opinion leaders at University of Toronto hospitals in the field of colorectal surgery were invited to attend the meeting. Opinion leaders were chosen using the observant method by the principal investigator and Dr. Robin McLeod. The guideline was distributed to participating surgeons prior to the meeting and surgeons were asked to review the guideline and attend the meeting ready to discuss concerns and disagreements. This consensus meeting was held over dinner on October 2, 2008 and was chaired by Dr. Robin McLeod, an opinion leader in the field of colorectal surgery. At the meeting, the principal investigator made a presentation outlining the evidence and the recommendations discussed in the guideline. This presentation was followed by a question period and discussion. This meeting allowed participating surgeons, who are the key
stakeholders, to be involved in finalizing the guideline and promoted discussion of the sources of contention for the guideline.

*Educational Rounds and Audit and Feedback by Opinion Leaders*

Following consensus and guideline revision, the finalized guideline was presented to all eligible surgeons and general surgery residents over the month of October 2008. A presentation was made at each of the seven participating centers by the principal investigator with the support and supervision of Dr. McLeod. This educational lecture was usually held during weekly hospital general surgery rounds. Furthermore, a presentation was made to all the general surgery residents during weekly general surgery teaching on October 23, 2008. This teaching is protected time for residents and all residents in the general surgery training program are expected to attend. Dr. McLeod was present at all of the educational rounds as a content expert and opinion leader in the field of colorectal surgery and MBP. Each presentation was approximately forty minutes long and was followed by fifteen minutes of questions and discussion. During the presentation, the evidence as well as the recommendations that are outlined in the guideline were presented. Furthermore, the results from the pre intervention audit were presented and suggestions for changing practice were made. This audit captured MBP, diet and enema instructions for patients undergoing elective colorectal surgery.

*Distribution of Reminder Cards*

Laminated cards designed to be carried in a lab coat pocket were made outlining the specific recommendations described in the complete guideline (APPENDIX 2). These cards were intended to be a brief summary and reminder of the recommendations made in the guideline.
These cards were distributed to all of the residents at the time of the educational lecture at general surgery teaching. The reminder cards were also provided to all general surgery attending surgeons either at the time of the educational lecture at their hospital or at a later date through their offices.

5.3 Before-After Evaluation of MBP Practices

A multi-centre before-after study design was used to evaluate change in surgeon practice with respect to bowel preparation after the implementation of a tailored knowledge translation strategy targeting general surgeons. It was conducted at 7 adult teaching hospitals affiliated with the University of Toronto. Bowel preparation practice patterns were measured prospectively three months before the knowledge translation intervention in order to gather appropriate baseline information. Adoption of the guideline recommendations were measured for three months following the tailored intervention.

Population

The intervention was designed to target general surgeons at the participating hospitals. However, the data collection was at the patient level. The population of patients who were approached for inclusion were all adult patients (≥18 years of age), who had an elective, open or laparoscopic, colon or rectal resection. This included all patients regardless of indication for surgery (e.g. colon cancer, inflammatory bowel disease, diverticulosis, etc.). Those patients who had a colon resection for any emergent cause were excluded.
Outcome Measures

The primary outcome measure was compliance with the recommendations presented in the guideline regarding MBP, diet and enema use. These data reflect a measure of actual adoption of the guideline in patients undergoing elective colorectal surgery. Secondary outcomes were the proportion of patients who received MBP, were prescribed a normal diet on the preoperative day and prescribed enemas. As determined during the development of the guideline, bowel preparation recommendations differed based on whether the surgery to be performed was: 1) an open low anterior resections (LAR) with/without diverting stoma, 2) any other open procedures (including segmental resections, APR, TPC, IPAA, etc…) or 3) any laparoscopic procedures. Therefore, each outcome would be examined overall and subsequently within each surgery type.

These outcome data were collected prospectively directly from patients because there is literature to support the collection of adherence data as opposed to self-reported data, which may be biased or overestimated. From a recent chart review performed by our research group for another study, we revealed that information regarding the administration or prescription of MBP and the type of MBP is poorly documented in the hospital charts.

Data Collection

Data on the use of bowel preparation for patients undergoing elective colorectal surgery were collected for consecutive, consenting patients at each hospital. Data were collected over three months prior to completion of the educational seminar on guidelines for bowel preparation (baseline) and again for three months post-intervention. Baseline data collection occurred from July 2008 until September 2008 and post-intervention data was collected from December 2008
until February 2009. Data collection included: name of surgeon, type of procedure and use of MBP, type of diet (unrestricted or clear fluids) and enemas as well as patient demographics such as age and gender.

In an effort to be minimally intrusive to surgeons, information regarding the prescription of bowel preparation was collected directly from patients undergoing elective colorectal surgery by a research assistant during the in-hospital postoperative period. If data collection is intrusive to surgeons, it may change surgeons’ behavior and thus potentially bias the final results of the study. Although asking patients may raise concern about recall, the outcome measurement is occurring just a few days after surgery. Furthermore, we asked only yes/no questions about whether they received MBP, dietary restrictions or enemas. Due to the short time interval between the bowel preparation and surgery and the unpleasant side effects of MBP, patients would likely be able to accurately answer this question. In order to cause minimal disturbance to the patient, the surgeon and the surgical team, the patients were approached on the ward on postoperative day 2 or 3.

Data were collected by two individuals both before and after the intervention. Baseline data were collected by a medical student who was hired for the summer of 2008 as a research assistant and the principal investigator. Post-intervention data collection was performed by a research nurse and principal investigator. All data collectors were provided with an operating room schedule for every week. Every day, outcome assessors went to the surgical ward and identified patients who were early in their postoperative course. Written consent was then obtained from each patient prior to the short interview. At the time of the patient interaction, a simple data extraction form
was completed. Data from these data extraction forms were then entered into a Microsoft Excel spreadsheet weekly.

Sample Size

Prior to completion of the guideline and before starting the baseline audit, a sample size was calculated for the before-after study. Based on clinical experience, it was thought that only 30% of patients undergoing elective colorectal surgery were not receiving MBP prior to surgery. In other words, approximately 30% of cases were in adherence to the MBP guideline. Therefore, sample size calculations were performed based on detecting a clinically significant increase of MBP omission or compliance with the guideline from 30%, to 60%. Since, there are no previous studies measuring the change in physician behavior for this particular clinical scenario, we hypothesized that this would be a clinically significant and a feasible change in physician behavior. Sample size calculations were based on a power of 80% and two-tailed type I error rate of 5%; this resulted in a sample size of 42 patients per intervention arm. In order to perform statistical analysis separately for each of the seven participating hospitals after taking into account a conservative 15% incomplete recruitment, post-recruitment exclusion, or post-recruitment refusal, we aimed to recruit 50 patients from each hospital for both the “before” intervention arm and “after” intervention arm of the study.

Recruiting 50 patients from each hospital before and after the intervention would allow us to analyze the results and make conclusions based on 80% power for each individual site. Furthermore, when combined we could evaluate changes in behavior across all 7 hospitals with 350 patients before the intervention and 350 patients after the intervention. However, given that
surgical practices within hospitals and surgeons are likely to be correlated, we accounted for this clustering effect when determining the minimum significant difference detectable with 350 patients prior to and following intervention. After assuming a liberal clustering design effect of 2.0, we would have 80% power to detect an overall 15% change in patients not receiving bowel preparation (e.g. from 30% to 45%) assuming a two-tailed type I error rate of 5%.

Data Analysis

Descriptive statistics (means, medians, standard deviations, and proportions) were calculated for all variables. Student’s t-tests and chi-squared tests were used to compare continuous and categorical variables respectively; these comparisons were made between the “before” intervention group and the “after” intervention group. Furthermore, compliance with the recommendations presented by the guideline was also compared for MBP, diet and enema “before” and “after” the intervention. For the final analysis of the hospitals overall or the “pooled” analysis, a design-adjusted chi-squared test was used to compare the “before” and “after” proportions. The purpose of the design-adjusted chi-squared test is to take into account the effect of clustering. For the secondary analyses, the results were stratified by type of surgery. Due to small numbers at the individual hospital level, this stratification was performed once the data from each of the seven hospitals were pooled for an overall analysis. All statistical analyses were carried out using SAS version 9.1 (Cary, NC). A p-value of 0.05 or smaller was considered statistically significant.
5.4 Ethics

Ethics approval was obtained from the Research Ethics Board of each of the following hospitals: Mount Sinai Hospital, University Health Network (Toronto General Hospital and Toronto Western Hospital), Sunnybrook Health Sciences Centre, St. Michael’s Hospital, Toronto East General Hospital and St. Joseph’s Health Centre). Furthermore, ethics approval was granted by the University of Toronto Research Ethics Board. Informed consent was obtained from patients in order to ask them details regarding their bowel preparation before surgery. Since the outcome assessment from the patient standpoint was simply a short interview, this consent was obtained before beginning the interview and after a brief description of the study including the potential risks and benefits of being involved in the study. Patient confidentiality was respected throughout the entire study and only research personnel had access to the data. All data were stored and reported without personal identifying information.
6.0 Results

6.1 Guideline Development

Fourteen unique RCTs were identified.\(^2\)\(^1\), \(^5\)\(^5\)-\(^6\)\(^7\) One trial was published twice but was included only once.\(^5\)\(^8\) Another trial was published as both an interim and final analysis; only the final analysis was included.\(^6\)\(^7\) Two trials published subgroup analyses as a separate manuscript and were excluded from further review to eliminate duplicate results.\(^2\)\(^1\), \(^6\)\(^2\) A summary of the quality assessment of the fourteen trials is shown in APPENDIX 3. Two trials were not given a quality assessment as they were not published in English.\(^5\)\(^8\), \(^6\)\(^0\)

The literature review identified eight meta-analyses that were reviewed for this guideline.\(^2\)\(^5\), \(^2\)\(^6\), \(^6\)\(^8\)-\(^7\)\(^3\) These meta-analyses reported different combinations of the fourteen published RCTs. The largest meta-analysis published in 2009 combines the results of all 14 RCTs.\(^2\)\(^6\) The Cochrane review was published in 2003 and was updated in 2005.\(^2\)\(^5\) The most current version was included. The Cochrane review was also published in another source separately by the same authors and therefore, this duplicate publication was excluded. A summary of the quality assessment of these seven meta-analyses is shown in APPENDIX 4.

Mechanical Bowel Preparation

I. Patients Undergoing Open Elective Colorectal Surgery - Anastomotic Leaks

All fourteen trials compared anastomotic leak rates in patients receiving MBP and those not receiving MBP. The results for anastomotic leaks are summarized in APPENDIX 5. Two of the fourteen trials found significant differences in anastomotic leak rates in favor of omission of MBP.\(^5\)\(^6\), \(^6\)\(^0\) The other twelve trials found no significant differences in the anastomotic leak rates.
Two of these trials were large and are described in further detail below. The main flaw in the other trials was that they were underpowered.

A RCT by Contant et al. published in 2007 was a multi-centre trial where investigators from 13 hospitals in the Netherlands randomized 670 patients to receive MBP and 684 patients to no MBP. Those patients receiving a MBP were prescribed either polyethylene glycol with bisacodyl or a sodium phosphate solution. There was no significant difference in anastomotic leaks (difference 0.6%, 95% CI [-1.7%, 2.9%], p=0.69). This was a FAIR quality RCT with one of its strengths being its large sample size. However, like many of the RCTs performed on this topic, outcome assessment was not blinded. Furthermore, the two groups were not comparable at the beginning of the trial with a larger proportion of smokers and patients with inflammatory bowel disease in the MBP group.

In another RCT, published by Jung et al., all Swedish colorectal units and one German colorectal unit participated. Six hundred and eighty-six patients were randomized to receive MBP and 657 were randomized to no MBP. Forty seven percent of patients in the MBP group were prescribed a polyethylene glycol preparation and 48.5 % received a sodium phosphate preparation. There were no significant differences between the two groups for the primary outcomes of cardiovascular, general infectious and surgical-site complications. Specifically, anastomotic dehiscence was seen in 2.3% of patients in the MBP groups and 2.6% of patients in the no MBP group. Six patients in each group died (p=0.94).

Jung et al. also examined the generalizability of the results and potential selection bias by comparing the randomized patients to those patients who where not enrolled in the study at 3 participating centers. They found no statistically significant differences in the demographics or
the outcomes between these two cohorts. This study did not show a significant difference but was also underpowered in that it was powered to detect a 50% difference in complication rates. However, it is unlikely that the addition of 57 patients (for a total of 1400 patients as estimated by the reported sample size calculation) would change the conclusion.\textsuperscript{66} For these reasons, this was not deemed a fatal flaw and the trial was given a FAIR rating.

Review of the included meta-analyses revealed that one meta-analysis provided no pooled data and reported only a descriptive analysis of the included studies.\textsuperscript{71} Of the remaining 7 meta-analyses, 4 meta-analyses reported statistically significant differences in the pooled results for anastomotic leakage.\textsuperscript{25, 69-71} Of these 4 meta-analyses showing a difference, the largest and most recent was the Cochrane review published in 2005.\textsuperscript{25} Three of the 7 meta-analyses found no significant difference between the MBP and the no MBP group with regards to anastomotic leaks.\textsuperscript{26,72,73} Of the 3 meta-analyses that reported no difference in anastomotic leak rates, one of these meta-analyses was the oldest review\textsuperscript{73}, including only 3 trials and the other two\textsuperscript{26,72} were the most recent reviews.

The highest quality systematic review was published by Guenaga and colleagues in 2005 as a Cochrane Systematic Review.\textsuperscript{25} This GOOD quality review was an update of the first Cochrane Review published in 2003. Guenaga et al. included 9 trials with a total of 1,592 patients.\textsuperscript{25} Of these patients, 789 were allocated to the MBP group and 803 to the no MBP group. The main outcome was anastomotic leakage; other outcomes evaluated included mortality, wound infection, peritonitis and re-operation. Overall MBP was associated with a higher rate of anastomotic leakage (OR 2.03, 95% CI [1.276, 3.26], p=0.003).\textsuperscript{25} The authors of this review concluded that MBP for patients undergoing elective colorectal surgery has not “proven
valuable” and the procedure should be omitted as it may increase the risk of anastomotic dehiscence. The primary strength of this meta-analysis was the thorough discussion of the quality and methodology of the included articles.

The largest meta-analysis, which was published by Slim et al. in 2009, included 14 trials with a total of 4,859 patients and provided different results.26 This meta-analysis included substantially more patients because of the inclusion of the trials by Jung et al.66 and Contant et al.65 which were published after the meta-analysis by Guenaga.25 This meta-analysis was given a FAIR quality rating because conflicts of interest were not stated. Two thousand four hundred and fifty-two patients were randomized to the MBP group and 2,407 to the no MBP group. The outcomes reported were rates of anastomotic leakage and wound infection. The pooled results revealed no significant difference in anastomotic leakage rates between the two groups with a fairly narrow 95% confidence intervals (OR 1.12, 95% CI [0.824, 1.532], p=0.46).26 Although these results differed from the results of the Cochrane review, these authors again concluded that there is no benefit to using MBP in patients undergoing elective colorectal surgery.25,26

II. Patients Undergoing Open Elective Colorectal Surgery - Surgical Site Infections (SSIs)

All fourteen RCTs included superficial SSIs as another endpoint and these results are summarized in APPENDIX 6. In all fourteen trials, there was no statistically significant differences in the rates of superficial SSIs in the MBP and no MBP groups.21, 55-67 One of the 7 meta-analyses reported a statistically significant difference in superficial SSIs between the two groups, with an increased rate of superficial SSIs in patients who received MBP (difference 3.4%, 95% CI [-1.6%, 8.4%], p=0.002).73 The other 6 meta-analyses found no difference in the rates of superficial SSIs when comparing patients who did and did not receive MBP.25, 26, 68-70,72
Guenaga et al. reported rates of superficial SSIs as 7.4% (59/789) in the MBP group and 5.4% (43/803) in the no MBP group (OR 1.46, 95% CI [0.97, 2.18], p=0.07). In the meta-analysis by Slim et al., the rate of superficial SSI in the MBP group was 9.5% as compared to 8.3% in the no MBP group (OR 1.17, 95% CI[0.96, 1.44], p=0.11).

III. Patients Undergoing Low Anterior Resections (LAR) with Diverting Ileostomy

It has been well documented that the risk of anastomotic dehiscence is higher following low colorectal or coloanal anastomoses and these low anastomoses have been associated with high rates of morbidity and mortality. For this reason, many surgeons performing these operations opt to protect the anastomosis with a diverting stoma. The use or omission of MBP in patients undergoing this particular operation (LAR with diverting stoma) poses a difficult dilemma and raises important concerns. Surgeons may hesitate to omit MBP in these patients because it would leave a column of stool between the stoma and the anastomosis. In the event that this patient developed an anastomotic leak, there would still be a risk of fecal contamination, despite the fact the anastomosis had been protected. In patients who do not receive a diverting stoma, surgeons may also be concerned with the potentially increased morbidity associated with an anastomotic leak.

Patients undergoing a LAR with or without a diverting ileostomy were poorly represented in the fourteen trials included in this guideline for two reasons. Some trials (2 of 14) excluded patients who underwent LAR or LAR with anastomoses below the peritoneal reflection. Other trials (5 of 14) excluded patients who had planned diverting stomas. Finally, in some trials (3
Five trials included patients undergoing LAR and the results of four of these RCTs were included in a subgroup analysis reported in the Cochrane review. In one of these trials, whether patients received diverting stomas is not mentioned. In another, patients with diverting stomas were excluded and the other two studies clearly state that patients did not receive diverting stomas. When the results of this subgroup of LAR patients from these four trials were pooled in the Cochrane review, the rate of anastomotic leakage for low anterior resections was 9.8% (11/112) in patients in the MBP group compared to 7.5% (9/119) in patients in the no MBP group. The OR was 1.45 (95%CI [0.57, 3.67], p=0.4) and was not statistically significant, with wide 95% confidence intervals, likely because of the small sample size.

There is one RCT published by Platell and colleagues which included a substantial proportion of patients having LAR with diverting stomas. This trial was underpowered to show equivalence, although it did reveal statistically significant differences in some secondary outcomes. Therefore, this study was given a FAIR rating. Patients were randomized to receive oral MBP (polyethylene glycol) or a single phosphate enema only. For the purpose of this review, the enema group was considered the no MBP group because none of these patients received an oral MBP. One hundred forty seven patients were randomized to MBP group and 147 patients to no MBP group.

Sixty-four percent (94 of 147) of patients in the MBP group and 55% (81 of 147) of patients in the no MBP group underwent an anterior resection. Furthermore, 39% (57/147) of patients in the MBP group and 32% (47/147) of patients in the no MBP group had a diverting stoma.
authors stated that patients undergoing a low or ultralow anterior resection were “routinely covered with a defunctioning loop ileostomy”. There were three anastomotic leaks in the MBP group and seven in the no MBP group (2% and 4.8% respectively, p=0.198). However, none of the patients in the MBP group compared to 6 patients in the no MBP group required reoperation (0% and 4.1% respectively, p=0.013). These results led to the trial being closed prematurely. The mortality rate in the MBP group was 2.7% as compared to 0.7% in the no MBP group with an OR of 1.62 (95%CI [0.45, 36.98], p=0.176). There was no statistically significant difference in the rate of superficial SSIs between the MBP and no MBP groups.

These results are in contrast to all the other trials and meta-analyses. However, this trial differs in that patients in the no MBP group received an enema. In order to make further conclusions about the use of enemas in the preoperative preparation of patients undergoing elective colorectal surgery, a RCT examining only the enema intervention would be required. This trial was included in this systematic review because many surgeons who disagree with the omission of MBP cite this article as an example of increased complications when no MBP is prescribed. However, as demonstrated above, it is important to distinguish this study from the others as it compares a different intervention in addition to comparing MBP versus no MBP.

IV. Patients Undergoing Laparoscopic Colorectal Resections

Although there are no studies examining the effect of MBP in patients undergoing elective laparoscopic surgery, the evidence presented in this guideline likely can be extrapolated to this population. There is no clinical reason why patients having laparoscopic colorectal surgery should have a different rate of postoperative infectious complications based on type of bowel preparation. Some argue that MBP may be required in patients with small tumors that may not be
appreciated laparoscopically, thus requiring intra-operative colonoscopy, but preoperative
tattooing of the lesion would obviate such a need. Some surgeons have also indicated that the
unprepared colon may be slightly heavier and thus, difficult to manipulate laparoscopically.

V. Adverse Events Associated with MBP

The search strategy identified one RCT of FAIR quality that examined the adverse histological
effects of mechanical bowel preparation. Many other citations in the form of letters to the editor
and case reports describing the adverse effects related to mechanical bowel preparation were
obtained. This RCT published by Bucher et al. \(^3\) reported the histological changes in intestinal
mucosa in 25 patients who had MBP with polyethylene glycol as compared to 25 patients who
did not receive MBP. There was a significant difference in the loss of superficial mucous (\(p <0.001\)), loss of epithelial cells (\(p<0.01\)), edema of the lamina propria (\(p<0.01\)), lymphocyte
infiltration (\(p <0.02\)) and polymorphonuclear cell infiltration (\(p<0.02\)) when the two groups were
compared. These changes were all more frequent in those patients who had taken a MBP.
Although it is unclear if these morphological changes are clinically relevant, they could
potentially result in bacterial translocation and anastomotic disruption. \(^4,5\)

Thirteen other selected articles describing the adverse effects of MBP were reviewed. \(^6-18\) The
details of these manuscripts can be seen in APPENDIX 7. In brief, these case reports revealed
that many of the different types of MBP such as sodium picosulfate, polyethylene glycol, sodium
phosphate and magnesium citrate are associated with adverse effects. \(^6-15\) The primary adverse
effects were related to electrolyte and volume disturbances in both healthy patients as well as
patients with underlying cardiac or renal disease. Furthermore, these electrolyte disturbances led
to seizures, syncope, coma and even death in some patients. Finally, there have also been reports of MBP associated ischemic colitis, pancreatitis and esophageal perforation.16-18

**Dietary Modifications**

None of the fourteen trials included in this review performed a direct comparison of different dietary modifications prior to surgery. APPENDIX 8 describes the specific MBP, dietary modifications and enemas which were used in each group in each trial. Nine of the fourteen trials stipulated no dietary restrictions prior to surgery and patients in the no MBP arm received a normal or low-residue diet on the day prior to surgery. Since the majority of these trials allowed patients in the no MBP arm to have a normal diet prior to surgery and these patients did not have increased postoperative infectious complications, it is likely safe to omit dietary modifications in the preoperative management of patients undergoing elective colorectal surgery.

**Enemas**

Again, none of the fourteen trials included in this review performed a direct comparison of enema versus no enema prior to surgery. Three of the fourteen trials prescribed enemas for left-sided or rectal resections in patients in the no MBP group.21, 61, 64 Also, in five of the fourteen trials, patients in the MBP group also had an enema.21, 55, 61, 66, 67 Applying this evidence, it is difficult to draw conclusions and make recommendations regarding the use or omission of enemas in patients undergoing elective colorectal surgery.

**Summary of the Evidence**

The majority of the evidence supports the omission of MBP and reveals that MBP is not associated with an increased risk of anastomotic dehiscence. Furthermore, there appears to be no difference in other postoperative complications such as superficial SSIs, intra-abdominal
infections and mortality. Based on the population of patients in these trials, these results can be applied to patients undergoing elective, open right-sided and/or left-sided colorectal resections (excluding LAR). MBP is generally safe but has been associated with serious complications in patients with existing cardiac and renal disease as well as previously healthy patients. Furthermore, most patients find taking a MBP to be unpleasant. Thus, the use of MBP has not been shown to be beneficial, but has been shown to be associated with rare but serious adverse effects.

There is less evidence regarding patients undergoing low anterior resections with a diverting ileostomy. After thorough assessment of the included trials, only one trial provided a comparison of MBP and no MBP in this specific population and all others excluded this group of patients. This fair quality RCT revealed that patients receiving MBP had lower rates of anastomotic dehiscence but this was not statistically significant. This study was designed to be an equivalence study but was terminated early due to the increased need for reoperations in patients who developed a leak. However, all patients in the no MBP group received a phosphate enema which might account for the differences observed between the two groups.

Patients undergoing laparoscopic colorectal resections are not included in any of the trials discussed in this guideline. The results from the included trials where patients underwent open procedures, however, likely can be generalized to this patient population.

**Recommendations**

A synthesis of the level I evidence reveals that there is good evidence supporting the omission of MBP in the preoperative management of patients undergoing elective right-sided and/or left-sided colorectal surgical resections (Grade A recommendation). Examining the data
specifically for patients undergoing low anterior resections with or without planned diverting stomas has revealed that there is insufficient evidence to support or refute the omission of MBP in the preoperative management of these patients (Grade I recommendation). There is no specific evidence regarding patients undergoing laparoscopic colorectal surgery but the recommendations can be reasonably extrapolated to this population. However, by adopting a conservative approach, there is insufficient evidence to support or refute the omission of mechanical bowel preparation in the preoperative management of patients undergoing elective laparoscopic colorectal surgery (Grade I recommendation).

Although there is some heterogeneity when evaluating dietary modifications prior to elective colorectal surgery, most trials allowed patients in the no MBP group to consume a regular diet until midnight prior to surgery. These interventions have revealed that there is fair evidence to recommend normal diet until midnight prior to surgery in the preoperative management of patients undergoing elective colorectal surgery (Grade B recommendation). Finally, There is insufficient evidence to support or refute the use of enemas in the preoperative management of patients undergoing elective colorectal surgery (Grade I recommendation).

These recommendations are driven mostly by the two large RCTs, the highest quality and the most recent meta-analyses. Although the primary RCTs have not shown a statistically significant difference in postoperative complications when comparing the MBP to no MBP group, the common flaw in these studies is inadequate sample size and power. The utility of the meta-analyses is directed at this particular problem. Furthermore, the reports surrounding adverse effects of MBP reveal that although complications are rare and more common in individuals with underlying cardiac and renal disease, these complications are extremely serious.
Taking into account the lack of difference in postoperative infectious complication rates with the use or the omission of MBP and the adverse effects of MBP, we believe that we are justified in making a strong recommendation based on this literature.

The guideline was then distributed to the members of the CSCRS for review and voting to support endorsement. The guideline received support from greater than two-thirds of CSCRS members and the guideline was thus, formally endorsed by the Society (APPENDIX 9). However, this endorsement was received after the knowledge translation strategy had been implemented at the University of Toronto. The guideline was also distributed and discussed at the consensus meeting involving local colorectal opinion leaders. At this meeting, each recommendation was discussed specifically and participants voiced agreement or concerns. Following this meeting, minor modifications were made to the guideline to reflect and address the points brought up during this meeting.

During the process of endorsement by the CSCRS and of consensus with local opinion leaders it was suggested that the recommendations were further outlined for three categories of surgery, which included: 1) open low anterior resections (LAR) with/without diverting stoma, 2) all other open procedures (including segmental resections, APR, TPC, IPAA, etc…) and 3) all laparoscopic procedures. After final endorsement and consensus, these more specific recommendations were presented and distributed on reminder cards (APPENDIX 2) as part of the knowledge translation intervention.
6.2 Before-After Evaluation of MBP Practices

One hundred and eleven patients were entered into the study for the “before” intervention arm between July 2008 and September 2008. One hundred and seventy one patients were enrolled for the “after” intervention arm between December 2008 and February 2009. The patients in the “before” and “after” arms were similar with regards to age and sex. The location of anastomosis was evenly distributed amongst both study arms, with left-sided and rectal resections being well represented. Finally, approximately two-thirds of cases in both arms were performed open and one-third performed laparoscopically. The specific break down of these demographic and clinical characteristics can be seen in Table 1.

Table 1: Demographic and clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Before (n=111)</th>
<th>After (n=171)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (std)</td>
<td>58.1 (17.9)</td>
<td>56.3 (18.1)</td>
</tr>
<tr>
<td>Male</td>
<td>51.4% (57)</td>
<td>53.4% (92)</td>
</tr>
<tr>
<td>Female</td>
<td>48.7% (54)</td>
<td>46.5% (80)</td>
</tr>
<tr>
<td>Location of Anastomosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R-sided resections</td>
<td>27.0% (30)</td>
<td>31.4% (54)</td>
</tr>
<tr>
<td>L-sided resections</td>
<td>28.8% (32)</td>
<td>18.6% (32)</td>
</tr>
<tr>
<td>Rectal + Other</td>
<td>29.7% (33)</td>
<td>30.8% (53)</td>
</tr>
<tr>
<td>LAR</td>
<td>14.4% (16)</td>
<td>19.2% (33)</td>
</tr>
<tr>
<td>Type of Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open</td>
<td>65.8% (73)</td>
<td>60.5% (104)</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>28.8% (32)</td>
<td>32.6% (56)</td>
</tr>
<tr>
<td>Lap to Open</td>
<td>5.4% (6)</td>
<td>7.0% (12)</td>
</tr>
</tbody>
</table>
Table 2: Distribution of patients by hospital

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Before (n=111)</th>
<th>After (n=171)</th>
<th>Total (n=282)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>46 (41.4%)</td>
<td>48 (28.0%)</td>
<td>94</td>
</tr>
<tr>
<td>Hospital B</td>
<td>14 (12.6%)</td>
<td>28 (16.4%)</td>
<td>42</td>
</tr>
<tr>
<td>Hospital C</td>
<td>24 (21.6%)</td>
<td>46 (26.9%)</td>
<td>70</td>
</tr>
<tr>
<td>Hospital D</td>
<td>12 (10.8%)</td>
<td>28 (16.4%)</td>
<td>40</td>
</tr>
<tr>
<td>Hospital E</td>
<td>15 (13.5%)</td>
<td>8 (4.7%)</td>
<td>23</td>
</tr>
<tr>
<td>Hospital F</td>
<td>0 (0%)</td>
<td>14 (8.2%)</td>
<td>14</td>
</tr>
</tbody>
</table>

Table 2 shows the proportion of patients recruited from each of the hospitals. For Hospital F, patients were only enrolled in the “after” intervention arm due to delays in securing REB approval. There is some variation in the numbers of patients recruited from each site and this mostly represents case load as well as the number of colorectal surgeons practicing at each site. Since the number of recruited patients from each hospital is so small, comparison of the “before” and “after” data at the hospital level was not performed. The results presented below are based on the data compiled from the six individual hospitals.

Bowel preparation practices were analyzed in accordance with the evidence based guideline, which was written and presented as part of the knowledge translation intervention. Overall, 81.1% of patients in the “before” arm and 88.4% of patients in the “after” arm received MBP in compliance with the guideline (p=0.038). Normal diet was encouraged in concordance with the guideline in 45.6% of the patients in the “before” arm and 55.8% of patients in the “after” arm (p=0.080). The use of enemas was compliant with the guideline in 88.5% of “before” patients and 94.2% of “after” patients (p<0.001).
These results were also analyzed according to the type of surgery, which was divided into three surgical categories based on the guideline including: 1) open LAR with/without diverting stoma, 2) all other open procedures (including segmental resections, APR, TPC, IPAA, etc…) and 3) all laparoscopic procedures. For patients having other open procedures, the recommendations presented in the guideline suggested, no dietary restrictions, no MBP and enemas at the discretion of the surgeon only for patients having left-sided resections. Compliance with the guideline recommendations increased for all three components when results in the “before” and “after” arms were compared and are shown in Table 3. There was a 10% increase in compliance with MBP recommendations (p=0.257), a 15% increase in compliance with dietary recommendations that was statistically significant (p=0.006) and a 10% increase in compliance with enema recommendations that was again statistically significant (p=0.005).

In patients undergoing LAR with or without diverting stomas, the guideline recommends no dietary restrictions and leaves MBP and enema use to the discretion of the surgeon. Compliance with the dietary recommendations for patients having LAR was similar “before” and “after” the intervention, 16.7% and 20.0% respectively, (p=0.830). Since MBP and enema use were left to surgeons’ discretion, there was 100% compliance for both strategies in the “before” and “after” arms.

Finally, for patients undergoing any laparoscopic procedure, the guideline leaves all three components of preoperative bowel preparation to the discretion of the surgeon, with enemas at the discretion of the surgeon only in patients undergoing left-sided resections. Compliance with
the MBP and dietary recommendations was therefore 100% in both the “before” and “after” arms. Compliance with enema recommendations for patients having laparoscopic surgery was similar in both the “before” and “after” groups with 94.6% and 95.6% compliance respectively.

Table 3: Compliance with guideline before/after intervention - % of patients receiving bowel preparation according to the guideline

<table>
<thead>
<tr>
<th></th>
<th>Before (n=111)</th>
<th>After (n=171)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MBP (overall)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other OPEN</td>
<td>65.0% (39)</td>
<td>74.7% (59)</td>
<td>0.257</td>
</tr>
<tr>
<td>LAR</td>
<td>100.0% (13)</td>
<td>100.0% (25)</td>
<td>-</td>
</tr>
<tr>
<td>Lap</td>
<td>100.0% (38)</td>
<td>100.0% (68)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Normal Diet (overall)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other OPEN</td>
<td>14.8% (8)</td>
<td>29.1% (23)</td>
<td>0.006</td>
</tr>
<tr>
<td>LAR</td>
<td>16.7% (2)</td>
<td>20.0% (5)</td>
<td>0.830</td>
</tr>
<tr>
<td>Lap</td>
<td>100.0% (37)</td>
<td>100.0% (68)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Enema (overall)</strong></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other OPEN</td>
<td>81.8% (45)</td>
<td>91.1% (72)</td>
<td>0.005</td>
</tr>
<tr>
<td>LAR</td>
<td>100.0% (12)</td>
<td>100.0% (25)</td>
<td>-</td>
</tr>
<tr>
<td>Lap</td>
<td>94.6% (35)</td>
<td>95.6% (65)</td>
<td>0.849</td>
</tr>
</tbody>
</table>

Compliance with all three of the recommendations for each type of surgery was also analyzed. For example, for patients undergoing open procedures (other than LAR), compliance with the recommendations of 1) normal diet preoperatively, 2) no MBP and 3) no enema (expect for patients undergoing left-sided colorectal surgery), was compared “before” and “after” the intervention. In the “before” group, there was compliance with all three of these recommendations in 9.3% of patients. This compliance increased significantly to 24.1%
following the tailored knowledge translation intervention (p=0.035). Compliance for all three components also increased for in patients having open LAR procedures and laparoscopic procedures; however, this change was not statistically significant (Table 4).

Table 4: Compliance with ALL three of the guideline components before/after intervention

<table>
<thead>
<tr>
<th>Type of Surgery</th>
<th>Before n=103</th>
<th>After n=171</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>40.8 (42)</td>
<td>51.7 (89)</td>
<td>0.097</td>
</tr>
<tr>
<td>All other OPEN procedures (including segmental resections, APR, TPC, IPAA, etc…)</td>
<td>9.3 (5)</td>
<td>24.1 (19)</td>
<td><strong>0.035</strong></td>
</tr>
<tr>
<td>OPEN LAR with/without diverting stoma</td>
<td>16.7 (2)</td>
<td>20.0 (5)</td>
<td>0.830</td>
</tr>
<tr>
<td>All LAPAROSCOPIC procedures</td>
<td>94.6 (35)</td>
<td>95.6 (65)</td>
<td>0.849</td>
</tr>
</tbody>
</table>

Overall, 36% of patients in the “before” arm received MBP prior to surgery as compared to 33.7% in the “after” arm (p=0.708). For further analysis of this secondary outcome, the results were again divided into the three surgical categories that were outlined above. Table 5 demonstrates the usage of MBP, dietary restrictions and enemas in patients undergoing elective colorectal surgery according to the type of surgery received. For patients undergoing open LAR with/without diverting stomas, the use of MBP doubled from 23.1% in the “before” arm to 56.0% in the “after” arm (p=0.103). In both the other groups, all other open procedures and all laparoscopic procedures, MBP usage decreased when the “before” and “after” arms were compared.

With regards to the secondary outcome of normal diet, 16.5% of patients in the “before” arm were encouraged to eat a normal diet on the day prior to surgery as compared to 32.7% of
patients in the “after” arm (p<0.001). Those patients who did not receive a normal diet were prescribed a clear fluid diet for twenty four hours; this included 83.5% of patients in the “before” arm and 67.3% of patients in the “after” arm. When analyzing patients who had other open procedures or laparoscopic procedures, there was again a significant increase in the use of a regular diet on the day prior to surgery. For patients having open procedures (other than LAR), this increase was from 14.8% in the “before” group to 29.1% of patients in the “after” group (p=0.006). For patients having laparoscopic surgery, normal diets increased from 18.9% to 41.8% when comparing the “before” and “after” groups (p=0.021). In patients having LAR, the prescription of a normal diet increased from 16.7% to 20% in the “before” and “after” arms, respectively (p=0.830).

Another secondary outcome was change in enema use for patients undergoing elective colorectal surgery “before” and “after” the knowledge translation intervention. Overall, enemas were used in 17.3% of patients in the “before” arm and 14.0% of patients in the “after” arm (p=0.202). Furthermore, there was a significant decrease in the proportion of enemas used for patients undergoing LAR, 41.7% to 20.0% (p=0.020). For patients having open procedures (other than LAR) and patients having laparoscopic surgery, enema usage decreased in the “after” group; but, these changes were not statistically significant.
Table 5: Bowel preparation practices before/after intervention - % of patients receiving mechanical bowel preparation, normal diet, enema

<table>
<thead>
<tr>
<th></th>
<th>Before (n=111)</th>
<th>After (n=171)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MBP Given (overall)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Other OPEN</td>
<td>35.0% (21)</td>
<td>25.3% (20)</td>
<td>0.257</td>
</tr>
<tr>
<td>• LAR</td>
<td>23.1% (3)</td>
<td>56.0% (14)</td>
<td>0.103</td>
</tr>
<tr>
<td>• Lap</td>
<td>42.1% (16)</td>
<td>35.3% (24)</td>
<td>0.110</td>
</tr>
<tr>
<td><strong>Normal Diet Given (overall)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Other OPEN</td>
<td>14.8% (8)</td>
<td>29.1% (23)</td>
<td><strong>0.006</strong></td>
</tr>
<tr>
<td>• LAR</td>
<td>16.7% (2)</td>
<td>20.0% (5)</td>
<td>0.830</td>
</tr>
<tr>
<td>• Lap</td>
<td>18.9% (7)</td>
<td>41.8% (28)</td>
<td><strong>0.021</strong></td>
</tr>
<tr>
<td><strong>Enema Given (overall)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Other OPEN</td>
<td>18.2% (10)</td>
<td>12.7% (10)</td>
<td>0.106</td>
</tr>
<tr>
<td>• LAR</td>
<td>41.7% (5)</td>
<td>20.0% (5)</td>
<td><strong>0.020</strong></td>
</tr>
<tr>
<td>• Lap</td>
<td>8.1% (3)</td>
<td>13.2% (9)</td>
<td>0.449</td>
</tr>
</tbody>
</table>

The use of the three preoperative bowel preparation components and compliance with the recommendations were also analyzed according to colorectal and minimally invasive surgery training. Colorectal surgeons were significantly less likely to prescribe MBP to patients undergoing elective colorectal surgery as compared to surgeons who did not have colorectal fellowship training; in the “before” arm, 28.4% of patients of surgeons with colorectal fellowship training as compared 56.7% of patients of non-colorectal surgeons received a MBP prior to surgery (p=0.002). When comparing the “before” and “after” patients for colorectal surgeons, there was no difference in MBP use. However, surgeons without colorectal training decreased their use of MBP from 56.7% to 40.8% (p=0.089). Conversely, surgeons without colorectal fellowship training were more likely to allow patients to have a normal diet on the day prior to...
surgery as compared to colorectal trained surgeons. In the “before” arm, normal diet was used in 8.1% of patients of colorectal specialists as compared to 37.9% of patients of non-colorectal surgeons (p=0.001).

Furthermore, there was no effect of colorectal fellowship training on compliance with the guideline with regards to MBP and enema use. As reflected by the usage data presented above, colorectal trained surgeons were less likely to prescribe a normal diet on the day prior to surgery when compared to their non-colorectal trained counterparts. Accordingly, colorectal trained surgeons were significantly less likely to be compliant with the diet recommendation as compared to non-colorectal trained surgeons (p<0.001). However, when compliance with the diet recommendation presented in the guideline was compared in the “before” and “after” arms for each of these two groups, the compliance of colorectal trained surgeons increased significantly from 39.2% to 55.2% as compared to the compliance of non-colorectal trained surgeons, which actually decreased from 62.1% to 44.8% (p=0.005).

There was no statistically significant difference in the use of MBP for patients between surgeons who did and did not have minimally invasive fellowship training. However, surgeons with minimally invasive training were more likely to allow patients a normal diet on the day prior to surgery as compared to surgeons without minimally invasive training (63.6% vs. 10.9%, p<0.001). Finally, there was no significant difference in the use of enemas between surgeons with and without minimally invasive fellowship training.
Similar to the comparison between colorectal and non-colorectal trained surgeons, there was no significant difference in the compliance with the MBP recommendation and the change in compliance according to the recommendation between the “before” and “after” groups when minimally invasive trained surgeons and non-minimally invasive trained surgeons were compared. When compliance with the diet recommendation was measured, minimally invasive trained surgeons were significantly more likely to comply as compared to the non-minimally invasive trained surgeons (p=0.001).
7.0 Discussion

Previous studies have shown that bowel preparation practices for patients undergoing elective colorectal surgery are not in keeping with the recent Level I evidence in this field. The purpose of this research study was first to develop and disseminate an evidence based guideline regarding bowel preparation and then to measure compliance with the guideline recommendations with respect to three aspects of bowel preparation practices including the use or omission of MBP, the prescription of a normal diet on the day preoperatively instead of a restricted, clear fluid diet and the use or omission of enemas. Considering compliance with the guideline recommendations regarding the three components of bowel preparation as the primary outcome, this knowledge translation strategy was able to change two of the three components. There was a 7.3% increase in compliance with recommendations specific to MBP (p=0.038) and a 5.7% increase in compliance with recommendations for enemas (p<0.001). There was an increase in compliance with recommendations for the use of normal diet prior to surgery; however, this increase was not statistically significant.

When evaluating compliance with all three components of the guideline, there was a 10% increase in compliance; however, this increase was not significant likely because the study was underpowered to detect such a difference. In the “before” arm, compliance with all three components was 40.8%, whereas in the “after” arm, compliance was increased to 51.7% (p=0.097). When the data were divided into the three subgroups of surgery as presented by the guideline, there was a significant increase in compliance with all three bowel preparation components (MBP, diet, enema) from 9.3% in the “before” arm to 24.1% in the “after” arm (p=0.035) in patients having open procedures other than LAR. These results are especially
reassuring as the recommendations for this surgical group were the most prescriptive because of the stronger evidence. For patients having open procedures (other than LAR), the recommendations in the guideline were specific, prescriptive and left only the use of enemas in left-sided resections at the discretion of the surgeon. It was for this largest group of patients that compliance with all three aspects of bowel preparation increased significantly. This may also indicate that surgeons are more likely to comply with prescriptive recommendations once they are aware and agree with the evidence. Furthermore, there were variable bowel preparation practices amongst surgeons with and without colorectal fellowship training and this suggests that surgeons with colorectal training prescribe less MBP but are also less likely to change their practices.

Although there was an increase in compliance with all three components of the guideline recommendations in patients undergoing all laparoscopic procedures or open LAR procedures with or without ileostomy, this increase was not statistically significant. The non-significant change in compliance for patients undergoing elective laparoscopic surgery was not surprising. Since there is no Level I evidence for bowel preparation for patients undergoing laparoscopic colorectal surgery, the recommendations presented in the guideline leave the use of MBP, the prescription of a normal diet and the use of enemas in patients having left sided laparoscopic colorectal surgery up to the discretion of the surgeon. Therefore, compliance with all three components of the guideline in these patients was quite high, 94.6%, in the “before” intervention arm. As a result, it was difficult to increase compliance with a value much higher than this in the “after” intervention arm.
Patients undergoing LAR with or without ileostomy represent a unique group of patients when considering preoperative bowel preparation. There is considerable controversy regarding bowel preparation for these patients as they have a higher rate of anastomotic dehiscence due to the low level of the anastomosis as well as potentially more disastrous consequences if anastomotic dehiscence occurs when compared to patients having right sided resections. Furthermore, these patients have not been well represented in the RCTs published on MBP because they were often excluded from enrollment. Moreover, the little data that are available for patients having LAR is inconsistent.

The subgroup analysis of patients having LAR presented in the Cochrane review, which included 231 patients from 4 studies, revealed no significant difference in the rate of anastomotic dehiscence when comparing patients who did and did not have MBP, with an OR of 1.45 (95%CI [0.57, 3.67], p=0.4).25 In contrast, in the RCT by Platell et al., 3 of 147 patients developed anastomotic leaks in the MBP group compared to 7 of 147 in the no MBP group (p=0.198).64 However, none of the patients in the MBP group compared to the 6 patients (6 of 147) in the no MBP group required reoperation (p=0.013).64 This resulted in early closure of the trial, which concluded that patients undergoing LAR without MBP were at increased risk for severe anastomotic leaks.

For these reasons, it is not surprising that surgeons may feel more comfortable operating on patients who have received MBP. Compliance with all three components of bowel preparation as presented by the guideline in this group of patients was 16.7% in the “before” arm and increased to only 20.0% in the “after” arm and this was not statistically significant. The recommendations
in the guideline for LAR patients suggested that they should receive a normal diet and the use of MBP and enemas were left at the discretion of the surgeon. Nearly 100% compliance was expected for MBP and enema use since these components were left to the discretion of the surgeon. Such low values for overall compliance both “before” and “after” the intervention are likely reflective of poor compliance with the dietary recommendations. Most patients undergoing LAR with or without ileostomy did not receive a normal diet on the day preoperatively and instead were instructed to follow a clear fluid diet for 24 hours. Poor compliance with the recommendations seen in these patients may represent the controversy in the preoperative bowel preparation management of patients undergoing LAR with or without diverting ileostomy.

Analyzing the overall results in terms of actual bowel preparation practices, there were minimal changes in the use and/or omission of MBP in patients undergoing elective colorectal surgery. When MBP use was divided by type of surgery, there was a 10% decrease in the use of MBP in patients having open surgery (except LAR) and a 7% decrease in MBP use in patients having laparoscopic surgery. Although these changes can represent clinically significant changes in behavior, they were not statistically significant. Overall, it appeared that there was a minimal change in MBP prescription practices. However, in fact, there was a 25% increase in MBP usage in patients undergoing LAR with or without ileostomy. Thus, when analyzed in detail depending on the type of surgery, the results show that the knowledge translation strategy was able to change the proportion of patients receiving MBP; although these changes were not statistically significant due to small sample size.
For the outcome of normal diet, there was a significant increase of 16% in the overall prescription of normal diet on the day preoperatively as opposed to a clear fluid diet. This increase was seen in all patients having elective colorectal surgery except for those patients having a LAR with or without ileostomy. This may be reflective of surgeons combining MBP use and clear fluid use as the bowel preparation prior to surgery. For example, most surgeons who prescribed MBP for a patient undergoing elective colorectal surgery also may have prescribed a clear fluid diet. Since there was an increase in the use of MBP for patients undergoing LAR, this may also explain the minimal change in normal diet prescription for these patients.

In the early phases of study design, the goal and primary objective of this study was to reduce the use of MBP in all patients undergoing elective colorectal surgery using a tailored knowledge translation strategy. The sample size and power calculations were based on this primary objective. We hypothesized that approximately 30% of patients undergoing any type of elective colorectal surgery would not be receiving a MBP and our aim was to increase this proportion to 60% of patients not receiving MBP. With these estimates, the sample size was originally calculated to be 350 patients required “before” the intervention and 350 patients “after” the intervention.

During the process of guideline development and consensus, it became clear that this component of the knowledge translation strategy was complex. The first iteration of the guideline recommended that MBP be omitted for all patients undergoing elective colorectal surgery and these recommendations were presented to the Canadian Society of Colon and Rectal Surgeons at
the annual meeting. There was tremendous concern with the recommendations and important
discussion points were raised. One of the most important concerns was that all patients
undergoing elective colorectal surgery should not be grouped together but rather categorized
specifically depending on the type of surgical procedure. Furthermore, the exact definition of
bowel preparation was questioned and suggestions were made to make individual
recommendations on MBP, diet and enema use. As a result of this meeting, the guideline was
reorganized and modified: the recommendations were divided into three components including
MBP use, normal diet on the day prior to surgery and enema use. Furthermore, recommendations
were made based on specific types of surgery.

Once these major modifications were made, the CSCRS endorsed the guideline and consensus
with local opinion leaders was facilitated. After the consensus meeting, there were minor
modifications relating mostly to patients having laparoscopic surgery but in general the changes
were small. The process of guideline development and consensus was iterative and an integral
component of the knowledge translation strategy. This process allowed national colorectal
surgeons and local opinion leaders to be involved in formulating recommendations and may have
resulted in increased compliance with the guideline recommendations after its dissemination and
implementation with educational lectures, audit and feedback and reminder cards. Increasing the
formal involvement of the opinion leaders at the hospital level could potentially have increased
the magnitude of the change in compliance by further improving adoption.

Based on the finalized guideline, it would have been difficult to achieve our primary objective of
reducing MBP use in all patients undergoing elective colorectal surgery. After further review of
the literature and the consensus process, it became evident that the evidence supporting the omission of MBP in patients having LAR with or without ileostomy is sparse. The few trials, which do include this patient population, are small and reveal conflicting results as discussed previously. Surgeons were particularly concerned about the significantly increased need for reoperation in this subgroup of patients without MBP. Therefore, the use of MBP in these patients was left to the discretion of the surgeon as the evidence from RCTs was insufficient to make strong recommendations for or against MBP use.

In light of the recommendations outlined in the guideline, it was believed it would be more appropriate to measure compliance with the guideline recommendations “before” and “after” the intervention as the primary outcome assessing the effectiveness of the tailored knowledge translation intervention. For this reason, we chose to change the primary research question to: can compliance with the three separate components of the guideline be increased using a tailored knowledge translation intervention including, guideline development and consensus, educational lectures, audit and feedback and reminder cards? This change in the research question, however, occurred after the “before” intervention data collection and more specifically, during the intervention.

Due to the change in the research question, the sample size calculation was no longer reflective of the study. Regardless of the sample size calculations, the number of patients enrolled in the study for both the “before” and “after” arms was much lower than was anticipated. The a priori sample size calculations required 50 patients from each of the seven hospitals both “before” and “after” the intervention, for a total of 350 patients “before” and 350 patients “after”. There were
two main challenges which affected recruitment. Firstly, ethics approval for two of the seven sites was delayed and therefore, data collection “before” the intervention did not occur at these hospitals. Furthermore, the volume of elective colorectal surgery was variable across the hospitals. The reason for small numbers at particular hospitals was not due to difficulties in patient consent and recruitment but due to small number of elective cases performed. It was anticipated that 50 patients could be recruited at each hospital over a three month period and this was true in the minority of hospitals.

This study has several other limitations which could have influenced the results. One important limitation of the study was the timeline of the project. Guideline consensus and guideline distribution with educational seminars occurred over one month. Surgeons were then given one month to change practice prior to the beginning of the “after” data collection. Some surgeons may see patients in clinic for consent and preoperative assessment more than one month before surgery and therefore, preoperative bowel preparation management of these patients would not have changed even though they were included in the “after” group. Also, one month may be a short time to expect surgeons to change practices that are controversial and have been engrained in colorectal surgery for over a century. Furthermore, one hospital in particular bases its bowel preparation practices on standardized orders sheets as well as recommendations in resident handbooks. Over the one month intervention period in this study, neither the standardized orders nor the resident handbook were changed.

This study is also limited by study design. Like all before-after studies, it can be difficult to assume changes and results were solely due to the intervention being studied as a variety of
external factors could also be involved. For example, preoperative bowel preparation for patients undergoing elective colorectal surgery has been a prominent topic of discussion at national and international conferences. Furthermore, in light of recent Level I evidence some surgeons have independently started to change their practice and this is reflected in the education of general surgery resident trainees. This study was not adequately controlled and ideally, this research question would be answered using a cluster RCT.

Finally, this before-after study evaluated a multifaceted knowledge translation strategy to change surgeon behavior. The knowledge translation strategy included 1) the development of a guideline based on the best available evidence, 2) the achievement of consensus to the guideline by local colorectal opinion leaders, 3) active distribution of the guideline and the evidence using educational rounds, 4) audit and feedback of current bowel preparation practices and 5) the distribution of reminder cards outlining the recommendations presented in the guideline. From the results of this study it is difficult to draw conclusions regarding the effectiveness of the individual strategies in changing surgeon behavior for this particular clinical scenario since it did not evaluate the individual knowledge translation components. The results of this study may support evidence that multifaceted knowledge translation strategies can be effective in influencing change. Although the intended outcome of study was physician compliance, which was a measure of physician behavior, the actual outcome was measured at the patient level. Analysis of guideline compliance at the surgeon level would have been interesting but was not feasible due to small sample size.
This knowledge translation intervention along with the before-after study took place over an eight month time period. The intervention was multi-faceted and labor intensive; however, using multiple interventions allowed for surgeons in different phases of change according to the Pathman model to be targeted. This intervention essentially led to a 7% increase in compliance with MBP recommendations and a 5% increase in compliance with enema recommendations. These changes are in keeping with 5-10% changes reported by most knowledge translation strategies.

These limitations aside, the knowledge translation strategy evaluated in this study was effective in influencing change for particular scenarios. These likely represent scenarios where surgeons are more comfortable in terms of risk of post-operative infectious complications such as anastomotic dehiscence. For patients undergoing open colorectal procedures (excluding LAR), this intervention was able to increase compliance with all three components of the guideline by 15%. This is a substantial increase, which is a clinically and statistically significant change in surgeon behavior that occurred over a short period of time. Areas where there is more controversy such as in patients having LAR, compliance and change in behavior was more subtle. Furthermore, change in physician behavior likely occurs in gradual steps. For example, once surgeons are comfortable omitting MBP for open cases and proximal colon resections, they may be more likely to start omitting MBP for laparoscopic cases and left-sided resections.

It is interesting to speculate whether the amount and strength of evidence required to change physician behavior differs depending on whether the change in behavior is in adopting a new practice or stopping a pre-existing practice; and furthermore, whether different knowledge
translation strategies are required in these two scenarios. Currently, there is no literature on these topics. It can be hypothesized that physicians might require a greater amount of strong level I evidence in order to stop a pre-existing standard practice as compared to that required to adopt a new practice. Physicians might require more convincing that there is no harm if the previously held practice is discontinued.

MBP has been used in the preoperative management of patients undergoing colorectal surgery for many years. The major concern for surgeons when omitting MBP is that the risk of infectious complications might be increased. The first RCT showing no increase in the risk of anastomotic leaks or SSI was published in 1992 and since then there has been mounting evidence in this field.56 Seventeen years after the publication of this first RCT, this current study was able to demonstrate a shift in MBP practices after the implementation of a tailored knowledge translation strategy. While the delay is significant, others have shown that it takes approximately this length of time for the adoption of new treatments to become part of routine practice following the first RCT.75

Since there are no studies evaluating the effectiveness of different strategies to either adopt or stop a practice, it was decided to tailor the knowledge translation strategy to the clinical problem. The strategies used in this study were chosen in order to target surgeons in all four phases of change as described by the Pathman model of change.52 Educational seminars, consensus with guideline recommendations and endorsement by CSCRS were used to increase awareness and agreement to the evidence. Opinion leader involvement in CPG development, presentation of
audit and feedback data and reminder cards were intended to increase adoption and adherence with the recommendations outlined in the guideline.

This research is an important step in the evaluation of knowledge translation and compliance with guidelines recommendations regarding bowel preparation. It would also be interesting to evaluate the multifaceted strategy and compliance with the guideline in a more qualitative manner. For example, it would be important to note why surgeons changed or did not change their practices for particular components or for particular surgeries. Moreover, to add further to the field of knowledge translation research, investigating which part of the strategy surgeons deemed influential would be necessary. The before-after component of this study was designed to assess adoption of the recommendations in the guideline. In the future, it would be useful to investigate if the change in surgeon behavior, which occurred as a result of our multifaceted intervention, will be sustained. This would address the adherence stage of physician behavior as described in Pathman’s awareness-to-adherence model. Finally, a large, well-designed randomized controlled trial evaluating postoperative infectious complications in patients receiving and not receiving MBP in patients undergoing LAR with and without diverting ileostomies would be invaluable.
8.0 References


9.0 Appendices

APPENDIX 1: Analytic framework for omission of mechanical bowel preparation prior to elective colorectal surgery

1. Among patients undergoing elective colorectal surgery, does the omission of mechanical bowel preparation (MBP) increase the rate of post-operative infectious complications such as anastomotic dehiscence, superficial wound infections and deep intra-abdominal infections?
   a. Is there a difference when mechanical bowel preparation is omitted in open vs. laparoscopic colorectal surgeries?
   b. Is there a difference when mechanical bowel preparation is omitted in right colonic vs. left colonic vs. rectal resections?
2. What is the proportion of patients undergoing elective colorectal surgery who are prescribed a mechanical bowel preparation prior to surgery?
3. Does the use of mechanical bowel preparation in patients undergoing elective colorectal surgery result in adverse effects?
Guideline #2
Mechanical Bowel Preparation Strategies for Patients Undergoing Elective Colorectal Surgery

Recommendations

1. **OPEN low anterior resections (LAR) with/without diverting stoma**
   - No dietary restrictions
   - Mechanical bowel preparation (MBP) at the discretion of the surgeon
   - Enema at the discretion of the surgeon

2. **All other OPEN procedures (including segmental resections, APR, TPC, IPAA, etc…)**
   - No dietary restrictions
   - No MBP
   - Enema at the discretion of the surgeon for left-sided resections

3. **All LAPAROSCOPIC procedures**
   - Dietary restrictions (clear fluids or unrestricted diet) at the discretion of the surgeon
   - MBP at the discretion of the surgeon
   - Enema at the discretion of the surgeon for left-sided resections

*Although there are no studies examining the effect of MBP in patients undergoing elective laparoscopic surgery, the evidence can likely be extrapolated to this population and the above recommendations for OPEN procedures can be followed. However, some argue that MBP may be required in patients with small tumors that may not be appreciated laparoscopically, in those requiring intra-operative colonoscopy or for ease of handling the bowel. Thus, the preoperative bowel preparation is left to the discretion of the surgeon.*
Guideline #2
Mechanical Bowel Preparation Strategies for Patients Undergoing Elective Colorectal Surgery

Summary of Evidence

1. MBP should be omitted in patients undergoing all elective OPEN colorectal procedures (including segmental resections, abdominal perineal resections, total proctocolectomy, ileal pouch anal anastomosis, etc…) with the exception of LOW ANTERIOR RESECTIONS with/without DIVERTING ILEOSTOMY (Grade A recommendation)

2. There is insufficient evidence to support or refute the omission of MBP in the pre-operative management of patients undergoing elective LOW ANTERIOR RESECTIONS with/without DIVERTING ILEOSTOMY (Grade I recommendation)

3. There is insufficient evidence to support or refute the omission of MBP in the pre-operative management of patients undergoing elective LAPAROSCOPIC colorectal surgery (Grade I recommendation)*

4. Patients undergoing elective colorectal surgery should receive DAT until midnight the day prior to surgery (Grade B recommendation)

5. There is insufficient evidence to support or refute the use of enemas in the pre-operative management of patients undergoing elective colorectal surgery (Grade I recommendation)
APPENDIX 3: Quality table – randomized controlled trials

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<th>Lack of Contamination</th>
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APPENDIX 5: Results table – anastomotic leaks (randomized controlled trials)

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<td>294</td>
<td>3/147 (2.0%)</td>
<td>7/147 (4.8%)</td>
<td>0.198</td>
</tr>
<tr>
<td>Contant 2007</td>
<td>1354</td>
<td>32/670 (4.8%)</td>
<td>37/684 (5.4%)</td>
<td>0.596</td>
</tr>
<tr>
<td>Jung 2007</td>
<td>1343</td>
<td>13/686 (1.9%)</td>
<td>17/657 (2.6%)</td>
<td>0.39</td>
</tr>
<tr>
<td>Pena-Soria 2007</td>
<td>97</td>
<td>4/48 (8.3%)</td>
<td>2/49 (4.1%)</td>
<td>0.44</td>
</tr>
</tbody>
</table>
## APPENDIX 6: Results table – surgical site infections (randomized controlled trials)

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>MBP</th>
<th>No MBP</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brownson 1992</td>
<td>179</td>
<td>5/86 (5.8%)</td>
<td>7/93 (7.5%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Burke 1994</td>
<td>169</td>
<td>4/82 (4.9%)</td>
<td>3/87 (3.5%)</td>
<td>0.71</td>
</tr>
<tr>
<td>Santos 1994</td>
<td>149</td>
<td>17/72 (24%)</td>
<td>9/77 (12%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Fillmann 1995</td>
<td>60</td>
<td>1/30 (3.3%)</td>
<td>2/30 (6.7%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Miettinen 2000</td>
<td>267</td>
<td>5/138 (4%)</td>
<td>3/129 (2%)</td>
<td>0.72</td>
</tr>
<tr>
<td>Tabusso 2002</td>
<td>47</td>
<td>2/24 (8.3%)</td>
<td>0/23 (0%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Fa-Si-Oen 2003</td>
<td>250</td>
<td>9/125 (7.2%)</td>
<td>7/125 (5.6%)</td>
<td>0.61</td>
</tr>
<tr>
<td>Zmora 2003</td>
<td>380</td>
<td>12/187 (6.4%)</td>
<td>11/193 (5.7%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Bucher 2005</td>
<td>153</td>
<td>10/78 (13%)</td>
<td>3/75 (4%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Ram 2005</td>
<td>329</td>
<td>16/164 (9.8%)</td>
<td>10/165 (6.1%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Platell 2006</td>
<td>294</td>
<td>19/147 (12.9%)</td>
<td>21/147 (14.3%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Contant 2007</td>
<td>1354</td>
<td>90/670 (13.4%)</td>
<td>96/684 (14.0%)</td>
<td>0.82</td>
</tr>
<tr>
<td>Jung 2007</td>
<td>1343</td>
<td>54/686 (7.9%)</td>
<td>42/657 (6.4%)</td>
<td>0.29</td>
</tr>
<tr>
<td>Pena-Soria 2007</td>
<td>97</td>
<td>6/48 (12.5%)</td>
<td>6/49 (12.2%)</td>
<td>0.97</td>
</tr>
</tbody>
</table>
## APPENDIX 7: Case reports reporting adverse events associated with mechanical bowel preparation

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Type of Preparation Used</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gray (2005)</td>
<td>Review</td>
<td>Polyethylene glycol</td>
<td>Spontaneous rupture of the esophagus</td>
<td>- 4 case reports; 3 patients survived after surgical intervention, 1 mortality</td>
</tr>
<tr>
<td>Frizelle (2005)</td>
<td>Case Report - 3 patients</td>
<td>1) Sodium phosphate  2) Sodium picosulfate/magnesium citrate  3) Sodium Phosphate</td>
<td>Grand mal seizure activity, hyponatremia</td>
<td>-1/3 has gone on to develop epilepsy</td>
</tr>
</tbody>
</table>
| Ayus (2003) | Case Report - 4 patients | Polyethylene glycol      | 1-2) hyponatremia  3-4) hypernatremia                   | 1) status epilepticus – complete recovery  
2) grand mal seizures – cardiac arrest, death  
3) metabolic alkalosis - respiratory arrest, death  
4) seizures, aspiration - cardiac arrest, death |
| Mackey (2002) | Letter to Editor | Sodium phosphate         | 4 cases of tonic-clonic seizures                                         | - 4 patients with no history of seizure or electrolyte abnormalities  
- attributed to electrolyte imbalance resulting in seizures                                                                                                                                              |
| Hookey (2002) | Review – 20 publications describing adverse events in 29 patients | Sodium phosphate         | Hypocalcemia, hypotension, hypernatremia, hypokalemia, renal failure, hypovolemia, hyperphosphatemia | - many of these adverse events are attributed to inappropriate dosing, pre-existing renal impairment  
- 4/29 patients did not have any clear or probable predisposing factors (dose or relative contra-indication)                                                                                             |
| Tan (2002)  | Case Report - 6 patients | Sodium phosphate         | 1-2) delayed awakening from general anaesthesia 3-6) severe electrolyte abnormalities | 1) baseline CFR – developed hypocalcemia, hypokalemia, hypernatremia, hyperphosphatemia – eventually required long term hemodialysis  
2) healthy – developed metabolic and respiratory acidosis with ARF – completely recovery  
3) dehydration, breathlessness, complete recovery  
4) coma, complete recovery  
5) tonic/clonic seizures, death  
6) seizures, central pontine myelinos, death |
<p>| Ullah (2002) | Case Report      | Sodium phosphate         | Severe hyperphosphatemia, acute pulmonary edema, cardiorespiratory arrest | - 55 M with diabetes, hypertension, and end-stage renal disease                                                                                                                                           |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Type of Preparation Used</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADRAC (2002)</td>
<td>Case Report - 16 reports</td>
<td>Sodium picosulfate</td>
<td>Hyponatremia with seizures, hyponatremia/ hypokalemia with syncope, unconsciousness, metabolic acidosis</td>
<td>- 4 reports of syncope and dehydration without concomitant electrolyte abnormalities</td>
</tr>
</tbody>
</table>
| Franga (2000)      | Case Report      | Polyethylene glycol      | Pancreatitis                                                            | - 75F with history of hypertension, COPD, peripheral vascular disease; no prior history of pancreatitis  
- Progressed to develop pancreatic pseudocysts                                                  |
| Boivin (1998)      | Case Report - 2 patients | Sodium phosphate         | 1) hypocalcemia with severe tetany                                      | 1) attributed to chronic renal failure                                                    |
|                    |                  |                          | 2) hypocalcemia with perioral numbness/tingling                        | 2) no history of renal disease; attributed to magnesium depletion                           |
| Oh (1997)          | Case Report - 2 patients | 1) Magnesium citrate 2) Sodium phosphate | 1) ischemic colitis – patchy submucosal hemorrhage and mucosal denudation  
2) ischemic colitis – friable mucosa, submucosal hemorrhage with ulceration | 1) took magnesium citrate in preparation for a screening sigmoidoscopy  
2) previously had 5 colonoscopies with PEG or sodium phosphate preparations and had no adverse reactions |
| Vukasin (1997)     | Case Report      | Sodium phosphate         | Severe hyperphosphatemia and hypocalcemia with tetany                   | - otherwise healthy patient, no renal failure  
- all lab values returned to normal by 2 weeks                                               |
| ADRAC (1997)       | Case Report - 3 reports | Sodium phosphate         | 1) hyperphosphatemia/ hypocalcemia                                      | 1) followed by renal failure and death; (90M with no history of renal failure)  
2) hypocalcaemia, hyponatremia and hypokalemia  
3) hyperphosphatemia, hypocalcaemia, paraesthesia, carpal spasm and QT prolongation     |
|                    |                  |                          |                                                                         | 2) dehydration and subsequent death; (70F with no history of renal failure)  
3) required hemodialysis; patient had history of renal failure                                |
APPENDIX 8: Description of bowel preparation interventions used in each randomized controlled trial included in guideline

<table>
<thead>
<tr>
<th>Study</th>
<th>MBP Intervention</th>
<th>No MBP Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brownson (1992)</td>
<td>PEG</td>
<td>-</td>
</tr>
<tr>
<td>Burke (1994)</td>
<td>Sodium picosulphate, CF x 24h</td>
<td>DAT</td>
</tr>
<tr>
<td>Santos (1994)</td>
<td>Mineral oil TID x 5d, enema OD x 2 d, CF x 24h</td>
<td>LRD x 24h</td>
</tr>
<tr>
<td>Fillmann (1995)</td>
<td>Mannitol + orange juice</td>
<td>Orange juice</td>
</tr>
<tr>
<td>Miettinen (2000)</td>
<td>PEG, no solid food</td>
<td>DAT</td>
</tr>
<tr>
<td>Tabusso (2002)</td>
<td>Mannitol OR PEG, CF x 48h</td>
<td>CF x 48h</td>
</tr>
<tr>
<td>Fa-Si-Oen (2003)</td>
<td>PEG</td>
<td>DAT until 10 hrs prior to OR</td>
</tr>
<tr>
<td>Zmora (2003)</td>
<td>PEG, DAT, enema for rectal resections</td>
<td>DAT, enema for rectal resections</td>
</tr>
<tr>
<td>Bucher (2005)</td>
<td>PEG, DAT, enema for anterior resections</td>
<td>DAT, enema for anterior resections</td>
</tr>
<tr>
<td>Ram (2005)</td>
<td>Sodium phosphate, LRD</td>
<td>LRD x 24h</td>
</tr>
<tr>
<td>Platell (2006)</td>
<td>PEG, CF x 24h</td>
<td>Enema, CF x 24h</td>
</tr>
<tr>
<td>Contant (2007)</td>
<td>PEG OR Sodium phosphate, FF x 24h</td>
<td>DAT</td>
</tr>
<tr>
<td>Jung (2007)</td>
<td>PEG, Sodium phosphate OR Enema</td>
<td>DAT</td>
</tr>
<tr>
<td>Pena-Soria (2008)</td>
<td>PEG +enemas, dietary restrictions x 24h</td>
<td>DAT</td>
</tr>
</tbody>
</table>
APPENDIX 9: Endorsement from Canadian Society of Colon Rectal Surg

Dec. 17th, 2008

Dr. Çağla Eskicioglu
55 Maidland St., Apt. 608
Toronto, ON M4Y 1C9

Dear Dr. Eskicioglu,

The Canadian Society of Colon and Rectal Surgeons is pleased to provide you with this letter of endorsement toward your proposed guideline on ‘Mechanical Bowel Preparation’ (MBP).

The proposed MBP Guideline was sent electronically to all CSCRs Fellows for revision and I am happy to inform you that over 66% of Fellows responded with approval, which was the criterion set by the Executive to reach endorsement. This overwhelming support for the information contained in the guideline is an indication of how critically important it is to the future practice of colorectal surgery.

On behalf of the CSCRs, I congratulate you on your quality research and we wish you the best both personally and professionally in the future.

Sincerely,

[Signature]

Dr. Cliff Yaffe,
President
Canadian Society of Colon and Rectal Surgeons

774 promenade Echo Drive, Ottawa, ON, K1S 5N8
Tel. / tél. : (613) 730-6210  ●  Fax /téléc. : (613) 730-1116
cscrs@rcpsc.edu  ●  colon-rectalsurgery.org