The effect of an evidence based bowel protocol on time taken to return to normal bowel function in post operative total hip and total knee replacement patients

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THE EFFECT OF AN EVIDENCE BASED BOWEL PROTOCOL ON TIME TAKEN TO RETURN TO NORMAL BOWEL FUNCTION IN POST OPERATIVE TOTAL HIP AND TOTAL KNEE REPLACEMENT PATIENTS

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Abstract

Total hip and knee replacement operations are one of the most commonly performed orthopaedic procedures in Australia. It is estimated however that up to 65% of patients will experience some degree of opioid-related bowel dysfunction in the post operative period. Often considered a mild and self-limiting problem, constipation can lead to significant morbidity and occasional mortality. Several clinical incidents and a lack of robust evidence to guide bowel management in this cohort was the impetus for this study.

This cluster randomised study sought to evaluate the Murdoch Bowel Protocol®, a simple nursing intervention based on the administration of polyethylene glycol (Movicol®) titrated to Bristol Stool Chart type. The Neuman Systems Model was the theoretical framework used to guide this study. The hypothesis was that patients who undergo a knee or hip replacement and receive the study bowel protocol will experience a statistically significant reduction in time taken to return to normal bowel function compared with patients who receive standard bowel management.

Three hundred and thirty one patients were recruited across seven hospitals in two Australian states over a 13 month period. Five hospitals were randomised as controls, two hospitals as interventions. Data was collected from all patients at three intervals: pre-admission, during admission and post discharge. Control participants (n = 171) received post operative bowel management as per that hospital or doctors usual regime whilst intervention participants (n = 160) received post operative bowel management as per the Murdoch Bowel Protocol®.

Inferential statistics confirmed several highly statistically significant results as well as clinically significant outcomes. Patients treated with the Murdoch Bowel Protocol® returned to normal bowel function more quickly than those
treated with ad hoc post operative bowel regimes ($p = 0.000$). In addition intervention patients were more than seven times more likely than controls to return to normal bowel function by day five post operatively ($p = 0.000$). Age, gender and length of pre-operative fasting were not found to influence this result. Type of anaesthetic was significant with patients who received combined regional and general anaesthesia returning to normal bowel function around two days less than those who received a general anaesthetic ($p = 0.014$). Type of operation was also significant with total knee replacement patients taking on average one extra day to return to normal bowel function ($p = 0.027$). Use of the generalised linear mixed model confirmed no cluster effect. These results confirm and support the study hypothesis.

These results support practice changes not only for hip and knee replacement patients but for other patient groups who experience opioid induced bowel dysfunction. Further research will determine whether the protocol is as efficacious in these patient groups.
Declaration

I certify that this thesis does not, to the best of my knowledge and belief:

i. Incorporate without acknowledgement any material previously submitted for a degree or diploma in any institution of higher learning;

ii. Contain any material previously published or written by another person except where the reference is made in the text; or

iii. Contain any defamatory material.

Signatur ________________________________

Gail Ross-Adjie

Date: 22 October 2012
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Chapter 1 - Introduction

Background and Context

Total hip and total knee replacements are one of the most commonly performed major orthopaedic procedures undertaken in Australia with over 80,000 operations performed in 2011 (Australian Orthopaedic Association, 2012). The Australian Orthopaedic Association (2011) reported the increasing numbers of procedures, having risen 7.9% from 2009 to 2010. Of these, over 60% were undertaken in private hospitals (Australian Orthopaedic Association, 2011). These patients are at very high risk for developing constipation for multiple reasons including a change in diet, reduced fluid intake, pre-operative fasting, the advanced age of many, reduced mobility, the administration of a general anaesthetic and the administration of opioid based analgesia both intravenously and orally (Ho, Kuhn, & Smith, 2008; Schmelzer, 1990; Stumm, Thomas, Coombes, Greenhill, & Hay, 2001).

In 2009 a clinical audit was undertaken at St John of God Murdoch Hospital (SJGMH) after some major joint replacement patients required extended inpatient stays for management of severe constipation, and some patients had returned to the emergency department following discharge for management of faecal impaction. Follow up phone calls revealed increasing numbers of patients were experiencing symptoms of severe constipation after discharge. Bowel management was ad hoc and largely dependent upon the experience and aperient preference of the nurse or medical practitioner. The audit was based on the Practical Application of Clinical Evidence System (PACES) from the Joanna Briggs Institute (JBI) Adelaide. The JBI is the world’s largest provider of evidence based guidelines for nurses and allied health professionals and is based at the University of Adelaide in South
Australia. The audit confirmed that opportunities for improvement existed in orthopaedic bowel management across all four audit criteria:

1. baseline assessment of usual bowel pattern;
2. monitoring of bowel habits whilst an inpatient using a validated tool;
3. ongoing evaluation and management of constipation whilst an inpatient;
4. education and written information on constipation for patients and their carers.

St John of God Murdoch Hospital is a large private teaching hospital with 363 beds. It is one of nine surgical hospitals within the national St John of God Health Care group of 15 hospitals. A nursing research council teleconference conducted in December 2009 with representatives from all of the groups 15 hospitals also identified that post-operative constipation in the orthopaedic patient cohort was a common problem across other St John of God surgical hospitals.

Whilst there is a significant body of evidence discussing the scope of constipation in orthopaedic patients, no evidence exists to guide bowel management in this cohort. In response to this, a multidisciplinary team developed the Murdoch Bowel Protocol© (the intervention protocol used for this study), a bowel management tool based on generic best practice guidelines for constipation and including the Bristol Stool Chart (BSC) (Heaton & Lewis, 1997) which is a standardised instrument used to record stool type (Appendix A). The intervention protocol is largely based on the titrated administration of polyethylene glycol (PEG) with electrolytes and marketed in Australia as Movicol®. The dose of Movicol® is increased, decreased or ceased depending on the post operative day and stool type as self described by the patient using the BSC. The BSC classifies stool as one of
seven types with stool types 1 and 2 indicating a hard, constipated stool; types 3 and 4 are considered normal stools; types 5 and 6 indicate a loose stool and type 7 a completely liquid stool.

Incidence of Constipation

General population.

Much has been written in the literature about the incidence of constipation in the general population. Estimates range from 2% (Ramkumar & Rao, 2005) to 27% (Belsey, Geraint, & Dixon, 2010) with best estimates around 12-19% in the United Kingdom (Belsey, et al., 2010). This concurs with a large Australian study (Chiarelli, Brown, & McElduff, 2000) which found the constipation rate in the 18-23 year old age group was 14.1% but increased to 27.7% in the 70-75 year old age group. Literature from the United States of America (McCrea, Miaskowski, Stotts, Macera, & Varma, 2009) cites constipation as a common problem affecting up to 28% of the general population with a larger increase after the age of 70 years. As well as the incidence increasing with age, constipation is also more prevalent in women (Belsey, et al., 2010; McCrea, et al., 2009; Norton, 1996; Ramkumar & Rao, 2005; Spinzi et al., 2009) possibly as a result of pelvic floor injury (McCrea, et al., 2009) or pelvic floor dysfunction (Glia & Lindberg, 1997).

Incidence in orthopaedic patients.

Whilst rates of constipation in the general population are discussed above the incidence is significantly higher in the orthopaedic patient cohort with up to 64% of patients thought to be affected (Ishihara et al., 2012). Constipation is one of the most common gastrointestinal complaints suffered by this group (Ho, et al., 2008) who are at particularly high risk for developing constipation due to the advanced age of many patients (Davies, Green, Mottran, & Pirmohamed, 2008), reduced mobility (Linari, Schofield, & Horrom, 2011),
altered diet and fluid intake (Linari, et al., 2011) and the administration of opioid analgesia (Ho, et al., 2008; Kurz & Sessler, 2003; Linari, et al., 2011; Madsen, Magor, & Parker, 2010).

Causes
Whilst a common problem constipation is often considered banal and self limiting. However, opioids administered after major surgery are commonly associated with debilitating bowel dysfunction with restoration of bowel function an important part of post operative care. Normal bowel function relies on several factors: the coordination of motility via continuous electrical activity, mucosal transport and defecation reflexes (Kurz & Sessler, 2003). Although well recognized as highly effective analgesics, opioids act on neural receptors in the stomach, small and large intestine with multiple clinical effects. In the stomach this results in decreased gastric motility and pyloric tone that can produce nausea, anorexia and vomiting (Kurz & Sessler, 2003). In the small intestine effects include decreased pancreatic and biliary secretion, reduced propulsion and increased fluid absorption which results in delayed absorption of medications, hard dry stool and delayed digestion. Large intestinal effects include straining, feelings of incomplete evacuation, bloating, abdominal distention, constipation and abdominal cramps (Kurz & Sessler, 2003).

Complications
Complications of constipation include abdominal discomfort, nausea, anorexia, urinary retention, faecal impaction and paralytic ileus (Davies, et al., 2008; Hall, Karstens, Rakel, Swanson, & Davidson, 1995; Linari, et al., 2011; Miaskowski, 2009; Schmelzer, 1990) which often necessitates use of laxatives, enemas and occasionally surgery. Length of stay may be increased to manage constipation with some patients requiring readmission to hospital
for management of faecal impaction and faecal incontinence (Kurz & Sessler, 2003; Madsen, et al., 2010; Pappagallo, 2001; Petticrew, Watt, & Sheldon, 1997; Schmelzer, 1990; Stumm, et al., 2001). Symptoms are often so severe that patients would rather tolerate severe pain than continue to take constipation causing analgesia (Camilleri, 2011; Holzer, 2008; Kurz & Sessler, 2003; Panchal, Muller-Schwefe, & Wurzelmann, 2007). Further, deaths have been reported in both adults and children as a result of complications arising from constipation induced faecal impaction and bowel obstruction (Chute, Cox, Archer, Bready, & Reiber, 2009; Government of Western Australia, 2009; Hibbard, Propst, Frank, & Wyse, 2009; Leven, Barrett, & Mendelowitz, 2002; Singh, Arbuckle, Little, & Manglick, 2004).

**Statement of Purpose**

Initially the primary purpose of the study was to investigate the effect of the Murdoch Bowel Protocol© on the time taken for patients who underwent a shoulder, knee or hip replacement to return to normal bowel function. However as only three patients who underwent a shoulder replacement operation were recruited, biostatistical advice was sought. This advice confirmed that inclusion of data from these participants would likely prevent the convergence of coefficients and cause spurious results. Further advice was to remove these participants from the total sample following baseline comparison of group variables and that doing so would have no impact on the final results. The study also sought to determine whether differences in the following variables influenced the time taken for these patients to return to normal bowel function: age; gender; length of pre operative fasting; anaesthetic type (general, regional; general + regional) and operation type.

**Hypotheses**

The hypotheses for this study reflect the revised Statement of Purpose.
Null hypothesis:
There is no difference in bowel function post knee or hip replacement between patients who receive the study bowel protocol and patients who receive standard bowel management.

Directional hypothesis:
Patients who undergo a knee or hip replacement and receive the Murdoch Bowel Protocol will experience a statistically significant reduction in time taken to return to normal bowel function compared with patients who receive standard bowel management.

Definition of Terms
Constipation. The Rome II diagnostic criteria for functional constipation uses the following definition (1999):
At least 12 weeks (which need not be consecutive in the preceding 12 months) of two or more of the following:
1. straining >1/4 of defaecations;
2. lumpy or hard stools >1/4 of defaecations;
3. sensation of incomplete evaluation >1/4 of defaecations;
4. sensation of anorectal obstruction/blockage >1/4 of defaecations;
5. manual manoeuvres to facilitate >1/4 of defaecations (e.g. digital evacuations, support of the pelvic floor); and/or
6. <3 defaecations per week.

The World Gastroenterology Organisation (2007) defines constipation using the Rome Criteria described below. Constipation must include two or more of the following:
- fewer than three bowel movements per week;
- hard stool in more than 25% of bowel movements;
• a sense of incomplete evacuation in more than 25% of bowel movements;
• excessive straining in more than 25% of bowel movements;
• a need for digital manipulation to facilitate evacuation.

Rome III diagnostic criteria for functional constipation (2006):

1. Must include two or more of the following:
   a. straining during at least 25% of defaecations;
   b. lumpy or hard stools in at least 25% of defaecations;
   c. sensation of incomplete evacuation for at least 25% of defaecations;
   d. sensation of anorectal obstruction/blockage for at least 25% of defaecations;
   e. manual manoeuvres to facilitate at least 25% of defaecations (e.g., digital evaluation, support of the pelvic floor);
   f. fewer than three defaecations per week.

2. Loose stools are rarely present without the use of laxatives;

3. Insufficient criteria for irritable bowel syndrome.

Bristol Stool Chart (BSC). A medical aid designed to classify the form of faeces into seven groups. It was developed by K. W. Heaton and S. J. Lewis at the University of Bristol and was first published in the Scandinavian Journal of Gastroenterology in 1997 (Heaton & Lewis, 1997). The form of the stool depends on transit time in the colon and ranges from type 1 (separate hard lumps which are hard to pass) to type 7 (watery with no solid pieces) (Appendix A). For the purpose of this study constipation was defined as a Bristol Stool Chart type 1 or 2, normal stool as types 3 or 4, and loose stool as types 5, 6 or 7.

Gold Standard. "Any standardised clinical assessment, method, procedure, intervention or measurement of known validity and reliability which is
generally taken to be the best available, against which new tests or results and protocols are compared.” (Segen’s Medical Dictionary, 2012).

**Arthroplasty.** Joint replacement with a prosthesis usually made of plastic and metal (Segen’s Medical Dictionary, 2012).

**Opiate.** Drugs derived from opium (Segen’s Medical Dictionary, 2012).

**Opioid.** Any synthetic narcotic that has opiate-like activities but is not derived from opium (Segen’s Medical Dictionary, 2012).

**Significance**

Post-operative analgesia-related constipation is a very common problem which may necessitate an increased length of stay and lead to significant morbidity and occasionally mortality. The challenge of preventing this complication has long been recognised in the clinical setting resulting in administration of ad hoc bowel interventions that are not supported by empirical evidence. The baseline work of the researcher conducted prior to this study resulted in the development of a novel and simple nursing intervention known as the Murdoch Bowel Protocol© (the Protocol). Although a clinical audit post development and implementation of the Protocol showed a reduction in morbidity related to opioid induced constipation in patients who had undergone major joint replacement surgery, the intervention has not been rigorously tested and there is a lack of empirical evidence to support its routine use in nursing practice. This study was the next logical step as it would complete the development, testing and evaluation cycle for the Protocol.

Nurses are in a key position to provide care that can minimise development of common complications such as post-operative constipation. Not only is this complication distressing and uncomfortable for patients, it has a number of nursing and other resource implications. The findings from this study will
have implications not only for nurses, but for clinical practice generally as the care of patients experiencing opioid-related constipation is not restricted to post-operative patients and has relevance to the care of patients who receive opioid analgesia for chronic conditions requiring short and longer term analgesia. As a consequence the study has significance across four main areas:

- minimising or preventing increased length of inpatient stay for the management of constipation in patients who undergo major joint replacement surgery;
- preventing readmission of these patients to hospital for management of faecal impaction;
- improved use of nursing resources currently used to manage analgesia related constipation; and
- improved education of patients, carers and health professionals regarding the prevention of analgesia-related constipation.

**Summary of the Chapter and Organisation of Thesis**

This initial chapter has provided the introduction, background, purpose, hypothesis and significance of the study. The relevant literature is discussed in Chapter 2, the frame of reference supporting this study is described in Chapter 3, methods and procedures are presented in Chapter 4 and data analysis and findings in Chapter 5. The discussion is presented in Chapter 6, followed by conclusions, recommendations and implications for practice and future research in Chapter 7.
Chapter 2 - Review of the Literature

A review of the published literature including the relevant medical subject headings (MeSH) and search strategy relating to constipation will be discussed in this chapter. The first part of the chapter will discuss the incidence of constipation in both the general population and post operative orthopaedic population, the causes and contributing factors for the development of constipation. It will also discuss the complications of constipation as well as different treatment modalities including natural therapies and new treatments. Recommendations for the management of constipation will also be discussed from both Australian and international perspectives.

The second part of the chapter will discuss the development of the Murdoch Bowel Protocol© and related clinical audit work that provided the impetus for this study.

This review will provide the background, theoretical and empirical support of the premise that: (a) constipation is a significant problem in the post operative orthopaedic patient cohort, (b) robust evidence is required to direct clinical nursing care in this area, and (c) early return to normal bowel function in this patient cohort can be positively influenced by use of the Murdoch Bowel Protocol©, a simple evidence-based nursing intervention. These factors form the theoretical basis that underpins the conceptual framework guiding this study.
Part One

Search Strategy
An extensive search of the relevant literature was conducted in the Medline, CINAHL, Scopus and PubMed electronic databases. MeSH terms used were: arthroplasty, hip replacement, knee replacement, analgesia, analgesic, narcotic, opioid, opiate, constipation, orthopaedic surgery, orthopedic surgery, gastrointestinal mobility and bowel dysfunction. The search was limited to English and included all years up to 2012 with an article from 1988 the earliest found. Most articles centred on constipation as a side-effect of opiates used for oncology patients and despite the scope and significance of constipation in orthopaedic patients, surprisingly few articles were retrieved. Of those that were, most were case studies or discussion papers with any research generally of poor quality with small sample sizes or demonstrating questionable academic rigor. The search results are summarised in Appendix B.

Best practice information was also sought from Australian Government websites including the Department of Health and Ageing and the National Health and Medical Research Council (NHMRC), as well as the Joanna Briggs Institute (JBI). International guidelines were sourced from the Cochrane Database of Systematic Reviews; the World Gastroenterology Association; the National Institute for Health and Clinical Excellence (NICE) (United Kingdom); the British Medical Journal’s Best Practice series and the American Gastroenterological Association.

Normal Bowel Function
Normal bowel function is the result of a complex set of coordinated reflexes, not all of which are completely understood: motility, mucosal transport and defaecation (Kurz & Sessler, 2003). Colonic motility involves both low
amplitude and high amplitude contractions. Low amplitude contractions are responsible for mixing the material within the colon and are most common after meals. These contractions expose the colon contents to a greater surface area hence promote the absorption of water. High amplitude contractions are responsible for the movement of large amounts of faecal matter through the colon. These contractions are most common in the morning after first waking and after meals (Lacy & Cole, 2004). The defaecation which follows is a complex, learned process which requires both an intact nervous system and normal muscle function. Once stool is pushed from the sigmoid colon into the rectum rectal distension is sensed and by assuming a squatting position the anorectal angle becomes straighter thus allowing ease of defaecation. The external anal sphincter must be voluntarily relaxed and intra-abdominal pressure is increased via a valsalva manoeuvre to facilitate stool evacuation (Lacy & Cole, 2004). The published literature will be divided into four broad sections: incidence, causes, complications and treatment modalities.

**Incidence of Constipation**

One of the difficulties when comparing the incidence of constipation reported in the literature is the range of definitions used. While some studies used the Rome I, II or III criteria (Drossman, 2006; Panchal, Muller-Schwefe, & Wurzelmann, 2007), others relied on patient self reporting which implies a significant degree of subjectivity. Other studies relied on more general measures such as laxative use, frequency of bowel actions per week or whether the patient had experienced a degree of incomplete evacuation. Although the cited incidence of constipation will be discussed, this limitation should be borne in mind.
Whilst often considered a mild self-limiting problem, constipation affects a large number of people from both general and hospital populations. Not only does it have a significant impact on quality of life but constipation may lead to significant morbidity and occasionally mortality with orthopaedic patients considered to be one of the highest risk cohorts (Davies, Green, Mottran, & Pirmohamed, 2008; Groth, 1988; Ho, Kuhn, & Smith, 2008; Kaçmaz & Kaşikçi, 2007; Linari, Schofield, & Horrom, 2011; Madsen, Magor, & Parker, 2010; Stumm, Thomas, Coombes, Greenhill, & Hay, 2001). In the general population the literature cites a wide range of incidence from 10% (Hindrichs & Huseboe, 2001; Norton, 1996) to 28% (Ho, et al., 2008) with up to 50% of elderly patients and those resident in aged care facilities (Bosshard, Dreher, Schnegg, & Bula, 2004) suffering from constipation.

A 2008 systematic review (Peppas, Alexiou, Mourtzoukou, & Falagas, 2008) of literature from seven European countries (Italy, France, Finland, Spain, The Netherlands, Sweden and Norway) found a mean incidence of 17.1% constipation and a mean incidence of 15.3% in Oceania (Australia and New Zealand) although one Sydney study cited in this review found a 30.7% incidence in adults aged 25-64 years. Chiarelli and colleagues’ (Chiarelli, Brown, & McElduff, 2000) study of over 41,000 Australian women found in a mailed survey that incidence increased with age with approximately 27% of older women (aged 70-75 years) reporting constipation compared with 14.1% of women aged 18-23 years. The authors claimed these results were consistent with the incidence in North America and noted the similarities between North America, and Europe and Oceania in terms of health care, dietary and lifestyle habits, exercise levels and socioeconomic level. McCrea and colleagues (McCrea, Miaskowski, Stotts, Macera, & Varma, 2009) found somewhat different results. Their 2009 review of the literature was specific to North America and reviewed 10 studies related to the incidence of
constipation in the United States of America (USA) and Canada. Their results found a range of 3.4% to 27.2% depending on the criteria used to define constipation. The lack of a consistent definition for constipation is a problem cited by numerous other authors (Bosshard, et al., 2004; Chiarelli, Brown, & McElduff, 2000; Lacy & Cole, 2004; Peppas, et al., 2008; Selby & Corte, 2010; Spinzi et al., 2009; World Gastroenterology Organisation, 2010).

As previously mentioned, orthopaedic patients are considered one of the highest risk patient groups for post operative constipation (Davies, et al., 2008; Groth, 1988; Ho, et al., 2008; Kaçmaz & Kaşikçi, 2007; Linari, et al., 2011; Madsen, et al., 2010; Schmelzer, 1990; Stumm, et al., 2001). The reasons are multiple and include the administration of an anaesthetic, reduced mobility, altered diet and fluid intake, pain and the use of opioid analgesia. Despite much being written about the high risk for constipation in this cohort, it is difficult to find accurate estimates of incidence in this particular population. Published estimates vary widely and range from 40% of orthopaedic patients in a small study in India (DeSousa, 2002) to 15-90% in patients receiving opioids for non-cancer pain (Panchal, et al., 2007) and 15%-64% as cited by Ishihara and colleagues’ (Ishihara et al., 2012) in their large 2011 multi-centre study. These estimates related to the use of opioids by patients with ‘non-cancer pain’, a broad term not specific to orthopaedic patients and for that reason they may not be generalisable to orthopaedic patients. Similarly, whilst Healey (2009) cited the incidence of constipation as up to 95% in patients taking opioids the specific patient group was not identified. However anecdotal reports gathered from orthopaedic nursing staff across multiple hospitals over the duration of this study support a significant incidence of post operative constipation associated with a major impact on the patient’s quality of life.
Role of opioid analgesia.

Opioid analgesics have long been recognised as the cause of a type of constipation referred to as opioid induced constipation (OIC), characterised by hard dry stools, straining, incomplete evacuation, bloating, abdominal distension and increased gastro-oesophageal reflux (Holzer, 2008; Kurz & Sessler, 2003). Healy (2009) cited the incidence of OIC to be as high as 95%, with this type of constipation considered one of the most distressing side effects of opioid analgesia. Camilleri (2011) reported incidence at a more modest 40% in the non oncology cohort while other studies reported a range from 15%-64% (Ishihara, et al., 2012). Despite these differences, the incidence of OIC is undoubtedly high with several studies (Camilleri, 2011; Hjalte, Berggren, Bergendahl, & Hjortsberg, 2010; Holzer, 2008; Ishihara, et al., 2012; Kurz & Sessler, 2003) reporting the gastrointestinal side effects of opioids dissuade some patients from accepting adequate analgesia as a consequence. As most studies relating to OIC have been conducted in oncology or palliative care settings, and as opioids are the most common form of analgesia in the early post operative period, orthopaedic patients are recognised as being at significant risk of developing OIC. The administration of opioids post operatively is a core component of nursing practice and their ability to cause constipation is well recognised. However, the mechanism of action in causing OIC is probably less well understood.

Mechanism of opioid action.

For centuries opioids have been used as antidiarrhoeal agents because of their mechanism of action. Opioids decrease gastrointestinal neural activity, inhibit gastric emptying, decrease rhythmic propulsive action, reduce mucosal secretions, delay the transit of gut contents and therefore increase gut fluid reabsorption (Healey, 2009; Panchal, et al., 2007). Ironically it is the antidiarrhoeal action of opioids which makes this effect so problematic in the
post operative cohort. Despite their use over centuries the mechanism of opioid action is still not entirely clear. What is clear is that three opioid receptor classes exist: mu - μ (further divided into μ1 and μ2), delta - δ and kappa - κ. These receptors mediate both the central and peripheral action of opioids and all three are associated with an analgesic action (Bryant, Knights, & Salerno, 1995). Bowel dysfunction is caused by the activation of μ2-receptors in the spinal cord and gastrointestinal tract (Kurz & Sessler, 2003) which results in decreased motility and increased tone in smooth muscle (Bryant, et al., 1995). As opioids are not fully selective in their action, analgesia is usually accompanied by unwanted side-effects such as OIC although these effects are dose-dependent (Kurz & Sessler, 2003). Analgesics are classified according to their action at these opioid receptors. This action is summarised in Table 2.1.
Table 2.1

Summary of Opioid Receptor Response

<table>
<thead>
<tr>
<th>Receptor</th>
<th>Drug Examples</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>mu - μ</td>
<td>Agonists:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• fentanyl, morphine,</td>
<td>analgesia, euphoria, respiratory</td>
</tr>
<tr>
<td></td>
<td>methadone,</td>
<td>depression, sedation, constipation,</td>
</tr>
<tr>
<td></td>
<td>hydromorphone</td>
<td>miosis</td>
</tr>
<tr>
<td>κ</td>
<td>Agonist:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• morphine,</td>
<td>analgesia, sedation, miosis,</td>
</tr>
<tr>
<td></td>
<td>β-endorphin</td>
<td>dysphoria, respiratory depression</td>
</tr>
<tr>
<td>δ</td>
<td>Agonist:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• *enkephalins,</td>
<td>analgesia, respiratory depression,</td>
</tr>
<tr>
<td></td>
<td>+β-endorphin</td>
<td>constipation</td>
</tr>
</tbody>
</table>

Note. *enkephalins are naturally occurring in the brain, spinal cord and gastrointestinal tract and have potent opiate-like effects; +β-endorphin is a naturally occurring opiate neurotransmitter released when the body is under stress.

Psychoactive drugs.

The use of psychoactive drugs, particularly the antipsychotic clozapine has been associated with significant rates of severe constipation. Some studies reported an incidence around 14% (Levin, Barrett, & Mendelowitz, 2002) while others (Hayes & Gibler, 1995) cited the incidence as up to 60% of patients taking this medication. Deaths from complications associated with psychoactive drugs are uncommon but not rare and will be discussed in more detail in the section Complications of Constipation to be presented later in this chapter.
Gender incidence.

Despite the lack of a consistent definition of constipation, many studies cite an increased incidence in women (Belsey, Geraint, & Dixon, 2010; Hindrichs & Huseboe, 2001; Ho, et al., 2008; Joanna Briggs Institute, 2009; McCrea, et al., 2009; Nazarko, 1996; Norton, 1996; Peppas, et al., 2008; Petticrew, Watt, & Sheldon, 1997; Ramkumar & Rao, 2005; Selby & Corte, 2010; Spinzi, et al., 2009) with this incidence increasing with age. Chiarelli and colleagues’ (Chiarelli, et al., 2000) study of Australian women found constipation rates of 14.1% in the 18-23 year old age group increasing to 26.6% in the 45-50 age group and up to 27% in the 70-75 year old age group. One of the study limitations was the narrow range of ages reported which do not capture the incidence of constipation across the full age spectrum. McCrea and colleagues’ (McCrea, et al., 2009) review of the literature pertaining to gender and age differences in constipation rates in North America found that across all 11 studies which evaluated gender differences, women reported consistently higher levels of constipation with the female/male ratio ranging from 1.01 to 3.77 with a median of 2.0. The authors noted however that rates were higher when constipation was self-reported compared with the diagnosis being made using Rome II or Rome III criteria (McCrea, et al., 2009). Similarly a large British study found a peak prevalence in constipation amongst females in the 30-44 age group possibly reflecting an increased incidence during pregnancy (Schafe, Lee, Dalrymple, & Worwell, 2011). Cullen & O’Donoghue (2007) supported this finding with their review article reporting that up to 40% of women suffered symptoms of constipation during pregnancy although a small longitudinal study of 103 women (mean age 28 years SD ± 5 years) conducted in the United States of America (USA) in 2006 (Bradley, Kennedy, Turcea, Rao, & Nyaard, 2007) found a lower incidence. Using the Rome II criteria, women in their study experienced a 1st trimester incidence of 24%, a 2nd trimester incidence of 26% and a 3rd
trimester incidence of 16% with 24% of women reporting symptoms persisting into the post partum period. Results closer to those cited by Cullen & O'Donoghue (2007) were found in a small United Kingdom (UK) study by Derbyshire, Davies, & Costarelli (2006) which also used Rome II criteria. The authors reported a 1st trimester incidence of constipation at 35%, 2nd trimester incidence of 39%, 3rd trimester incidence of 21% and 17% at six weeks post partum. While these figures are largely based on small studies they report consistently high rates of constipation reflecting the commonly held belief that many pregnant women experience constipation.

Summary of Incidence
Whilst the reported incidence of constipation varies widely it is undoubtedly a significant problem in both the general and inpatient populations. Orthopaedic patients are at particularly high risk with estimates that up to 64% will develop post operative constipation. Women, the elderly, those taking psychoactive drugs and opiates suffer from higher rates of constipation.

Causes and Contributing Factors
While the incidence of constipation has been shown to be significant in both the general and orthopaedic populations, the causes and contributing factors for this will be explained further in this section.

Gender differences.
The increased incidence of constipation in women has already been discussed with studies confirming the influence of pregnancy and hormones on the gastrointestinal tract (Selby & Corte, 2010; World Gastroenterology Organisation, 2007). Damage to pelvic floor muscles (Chiarelli, et al., 2000; McCrea, et al., 2009) and pudental nerve damage (Chiarelli, et al., 2000; Lacy
are also cited as significant contributing factors to constipation in women. The causes of constipation in pregnancy are multifactorial and include the effect of hormones on the gastrointestinal tract, the effect of a growing foetus and placenta as well as dietary changes and often decreased levels of physical activity (Cullen & O’Donoghue, 2007). The higher incidence of constipation in the first trimester supports the theory that hormonal changes are the major contributing factor at this time and not the physical changes which occur later in pregnancy. Research in rats suggests that elevated levels of progesterone cause intestinal smooth muscle relaxation which contributes to both small and large bowel hypomotility yet human studies confirming this are contradictory (Cullen & O’Donoghue, 2007). Similarly it has been theorised that an increase in colonic water absorption during pregnancy is likely to increase the incidence of hard dry stools. Both oestrogen and progesterone increase the secretion of renin which converts angiotensinogen to angiotensin I, a weak vasoconstrictor. The angiotensin-converting-enzyme (ACE) converts angiotensin I to angiotensin II which acts on the adrenal cortex to stimulate the production of aldosterone. This increased level of aldosterone causes an increase in sodium, and water reabsorption from the renal tubules, an effect which increases as the pregnancy progresses. Whilst this physiological effect is not contested Cullen & O’Donoghue (2007) cited the findings of Derbyshire and colleagues’ small UK study (Derbyshire, Davies, & Costarelli, 2006) of 94 women which found that water consumption was inherently lower in pregnant women especially in the first trimester. Were these findings to be replicated in a larger, more robust study they may provide greater evidence to support another cause of hard dry stools in the pregnant population. As pregnancy progresses the increasing size and pressure exerted by the foetus and placenta may impede the movement of faecal matter and contribute to constipation. The external anal sphincter may also be damaged during
pregnancy and birth from a number of mechanisms including increased uterine weight, increased intra-abdominal pressure and injury sustained during the birth itself either from forceps delivery, high infant birth weight or prolonged second stage of labour (Cullen & O'Donoghue, 2007). The effect of dietary changes and exercise have also been considered a contributing factor although the simple addition of increased fibre to the diet was found to assist most women (Cullen & O'Donoghue, 2007). Light exercise was also found to be more beneficial than vigorous exercise as the latter causes a surge in progesterone leading to reduced intestinal transit times (Cullen & O'Donoghue, 2007) with resultant constipation.

**Age, fluid and fibre intake and exercise.**

While advanced age in both genders, decreased fluid intake and dietary fibre and lack of physical exercise are frequently discussed as causes of constipation the evidence surrounding these assumptions is inconsistent. Age is regularly cited as a cause of constipation although some authors (Bosshard, et al., 2004; Nazarko, 1996) believe that healthy older patients are no more likely to experience constipation than younger ones. A large study undertaken by the Division on Ageing at the Harvard Medical School (Harari, Gurwitz, Avorn, Bohn, & Minaker, 1996) studied data from 42,375 elderly patients. They sought to determine the relationship between advancing age and bowel habits and found no age related increase in the proportion of patients reporting infrequent bowel movements going on to conclude that constipation was not necessarily a consequence of ageing (Harari, et al., 1996). Whilst this is an old study its rigor and large sample size suggest the results are likely still generalisable particularly as they are supported by other authors in more recent studies (Bosshard, et al., 2004). Some authors (Joanna Briggs Institute, 2008; Nazarko, 1996; Norton, 1996) suggest the physical environment has much to do with constipation rates in
the elderly. As physical height declines some patients are unable to touch the floor, impeding their ability to effectively use their intra-abdominal muscles, needed for effective stool evacuation (Kyle, 2009). The provision of privacy is also an important consideration at any age.

The often cited trio of fluid, fibre and exercise continue to be regularly promoted as necessary for normal bowel function but once again, evidence remains contradictory with a systematic review in 2005 confirming that none of these measures had been validated in a rigorous controlled trial (Ramkumar & Rao, 2005). Lindeman and colleagues (Lindeman et al., 2000) interviewed and examined a randomly selected group of 883 volunteers in the United States of America (USA) (mean age 74.1 years). They found no evidence to support the guideline of drinking two litres of fluid per day finding that it may actually be dangerous for some elderly persons, especially those with congestive cardiac failure or renal disease. Further, their study found no evidence that ingesting this amount of fluid had any effect on the frequency of constipation, fatigue, tiredness, falls or blood pressure. They suggested that elderly patients drink at a level which is comfortable for them rather than feel pressured to consume the recommended two litres per day. A similar study assessing the impact of fibre, fluid intake and exercise on constipation was undertaken in an Australian setting in 2001 (Annells & Koch, 2003). This eight-month qualitative study of 90 community-dwelling older persons also found mixed results, however most patients were not convinced that fibre helped or prevented constipation. Some patients found that high fibre foods actually worsened symptoms of constipation or made them feel bloated and uncomfortable. Bran added to the diet of orthopaedic patients in a small study in the USA (Schmelzer, 1990) found no improvement in symptoms, a finding supported by Stumm and colleagues’ (Stumm, et al., 2001). Similarly
many patients were adamant they consumed ‘plenty of fluid’ yet were still constipated and none claimed that increasing fluid intake in isolation had any effect on overcoming constipation. The effect of exercise was also examined and although several patients reported a worsening of constipation during periods of immobility most were not convinced that a lack of exercise had any effect on their rates of constipation and were disillusioned with exercise as a preventative measure.

A systematic review examining the effectiveness of laxatives in the elderly (Petticrew, et al., 1997) conceded there had been few studies which examined the effect of low fluid intake on constipation which also controlled for other factors including age. Similarly Petticrew and colleagues (1997) found that although reduced physical mobility has been associated with constipation, bowel management programmes in the elderly which focus on exercise programmes have not been robustly evaluated. Bosshard and colleagues (2004) discussed the results of the Nurses’ Health study of 62,306 women aged 36-61 years. The study investigated the relationship between self-reported constipation and several health behaviours including fibre intake and physical activity. Whilst the study found a clear dose-response relationship between fibre intake, exercise and rates of constipation these results are not necessarily generalisable to an older patient cohort who suffer from post surgical constipation. Bosshard and colleagues (2004) went on to say that most evidence in support of physical activity was based on observational studies and that it was difficult to firmly conclude that elderly persons would gain any benefit from increasing their rate of exercise as a means of assisting constipation.

Other age-related factors associated with constipation include the higher use of constipation causing medications such as antidepressants and
antipsychotic agents; anti-Parkinsons medications; diuretics; analgesics including opiates; iron preparations; calcium channel blockers (Bosshard, et al., 2004; Chiarelli, et al., 2000; Dennison et al., 2005; Hindrichs & Huseboe, 2001; Ho, et al., 2008; Lacy & Cole, 2004; Nazarko, 1996; Petticrew, et al., 1997); metabolic conditions including diabetes (Lacy & Cole, 2004; Peppas, et al., 2008) and hypothyroidism (Bosshard, et al., 2004; Ho, et al., 2008; Nazarko, 1996); physiological changes to the colon and anorectum including haemorrhoids (Lacy & Cole, 2004; Petticrew, et al., 1997) and anal fissures (Bosshard, et al., 2004; Nazarko, 1996; Selby & Corte, 2010) and neurological conditions such as dementia and cerebrovascular disease (Bosshard, et al., 2004). As previously discussed, the lack of a consistent definition and validated screening tools for measuring constipation mean that much of the published data is based on self-reported incidence, something which multiple authors believe increases with age (Bosshard, et al., 2004; Petticrew, et al., 1997).

**Race and socioeconomic status.**

Lower socioeconomic class has also been claimed as a risk factor for the development of constipation with little evidence given for why this might be so (Hindrichs & Huseboe, 2001; Peppas, et al., 2008; Ramkumar & Rao, 2005; Spinzi, et al., 2009). However a robust Australian study (Bytzer et al., 2001) of more than 8,000 adults found a highly significant association between lower socioeconomic class and both the number and severity of upper and lower gastrointestinal symptoms (including constipation) with both measures increasing with social disadvantage ($p = <0.0001$). The authors discussed the uneven distribution of risk factors across social classes with the disadvantaged classes having a higher prevalence of risk. These risk factors included obesity, smoking, poor diet, lower levels of physical activity, higher rates of alcohol use and crowded living conditions, some factors which have
already been implicated in the development of constipation. These results were supported by a 2011 systematic review (Mugie & Benninga, 2011) which confirmed the relationship between individuals of lower social, economic and educational levels and higher rates of constipation.

An increased prevalence in those persons considered ‘non-white’ has also been described (Ho, et al., 2008; Ramkumar & Rao, 2005) but Mugie & Benninga (2011) found the data both scant and inconclusive with no convincing explanation for the higher cited prevalence.

**Summary of Causes and Contributing Factors**
The causes and contributing factors of constipation are many and varied. Significant causal factors are hormonal changes in women (particularly in pregnancy), constipating causing medications (especially opioids) and lower socioeconomic status. The evidence to support the role of increased fibre, fluids and exercise is less clear. Age in itself it not a cause of constipation although factors associated with ageing may contribute.

**Complications**

**Impact on quality of life.**
Much has been published about the impact of severe constipation on patients’ quality of life (QoL) as well as the increased morbidity and financial burden of severe constipation. Of note, while death due to complications of constipation is uncommon it is not unheard of. Quality of life has been reported as a measure in several studies (Bosshard, et al., 2004; Dennison, et al., 2005; Glia & Lindberg, 1997; Sun et al., 2011). Glia and Lindberg’s small 1997 Swedish study of 84 patients found that as stool frequency reduced to ≤2 bowel actions per week so did scores in five of six measures on the Psychological Well-Being Index (anxiety, depression, general well-being,
self-control, health) with $p < 0.05$ for all of these measures. Vitality as a measure was not found to be statistically significant. Similarly Dennison and colleagues’ (2005) summarised the literature for QoL outcomes in 10 studies conducted throughout the USA, Scotland, Sweden and Israel and found consistently higher rates of depression ($p = <0.01$) and psychological distress. Of note some studies were limited by small sample sizes however all studies except one sampled community dwelling and ambulatory patients, the other residential care patients. Data from the nationwide USA National Health and Wellness Survey in 2007 was published in 2011 (Sun, et al., 2011). Patients with chronic constipation ($n = 1430$) were score-matched to controls ($n = 1430$), with chronic constipation patients reporting significantly lower quality of life physical and mental scores ($p = <0.01$). Once again the lack of a consistent definition for constipation, the requirement to self-report symptoms as well as the subjective nature of quality of life mean that direct comparisons between studies is difficult.

**Complications.**

Complications from constipation are numerous and range from common to rare and mild to life threatening. Common complications include bloating, anorexia, nausea, abdominal pain and distension and faecal soiling (Lacy & Cole, 2004; McCrea, et al., 2009; Norton, 1996; Spinzi, et al., 2009). Less common but more serious complications include rectal or uterine prolapse (Lacy & Cole, 2004), faecal impaction (Davies, et al., 2008; Levin, et al., 2002), urinary retention secondary to outflow obstruction (Davies, et al., 2008; McCrea, et al., 2009), ureteral dilatation, hydronephrosis and renal failure (Chute, Cox, Archer, Bready, & Reiber, 2009), diverticulitis (Lacy & Cole, 2004), paralytic ileus and intestinal obstruction (Davies, et al., 2008; Levin, et al., 2002) and bowel perforation (Dennison, et al., 2005; Spinzi, et al., 2009).
Fortunately deaths are rare but not unheard of and are discussed in more detail below.

**Reported deaths.**

While death as a complication of constipation has been reported it remains rare. Most of the published reports of death are as a result of faecal impaction and bowel perforation or faecal impaction with faecal aspiration and multiple organ failure in patients taking anti-psychotic medication, especially clozapine (Government of Western Australia, 2009; Hibbard, Propst, Frank, & Wyse, 2009; Levin, et al., 2002). These symptoms are due to the high likelihood of anticholinergic side effects from this particular medication (Muench & Hamer, 2010). A reported incidence of 60% constipation in clozapine-taking patients at one USA hospital (Hayes & Gibler, 1995) saw the development and introduction of a specific bowel protocol to ameliorate symptoms of this well known complication. At least eight cases of death related to clozapine induced constipation have been reported since 2001 with the Western Australian coroner reporting on a similar case in 2009 (Government of Western Australia, 2009). Sadly 2004 saw the reported death of a 12 year old boy in Sydney Australia who presented moribund to an emergency department and died after surgery for the treatment of a bowel obstruction (Singh, Arbuckle, Little, & Manglick, 2004). Whilst the child had a history of chronic constipation, an autopsy showed no underlying bowel abnormality. Anecdotally the author has been told of several Australian deaths in post operative orthopaedic patients as a result of severe constipation yet none of these deaths appear to have been reported in the academic literature.
Economic burden.

As well as the impact on a patient’s quality of life, the economic burden to both the patient suffering constipation and the health system are significant. In addition for some patients the economic burden of constipation extends to lost productivity and work absenteeism.

Spending on laxatives and doctors visits for the management of constipation has been estimated in several papers although Dennison and colleagues’ (2005) noted that economic studies are limited in terms of both their quality and recency with most papers published in the 1980s. Another limitation when comparing data is that costs associated with constipation are often collectively estimated for all constipation sufferers including long term opiate users, sufferers of chronic constipation and those suffering from intermittent or occasional symptoms. Other studies compare cancer and non-cancer patients making comparisons difficult.

Both prescription and over the counter medications are available to treat constipation. In the USA alone between 1980 and 1981 nearly five million prescriptions were written at a cost of $US22 million and in 1983 $US386 million was spent on over the counter treatments alone (Dennison, et al., 2005). The cost of laxatives is one of the largest expenses to the United Kingdom’s (UK) National Health Service costing more than antihypertensives, contraceptives and diabetes medications (Dennison, et al., 2005; Petticrew, et al., 1997). Annual expenditure on both prescription and over the counter laxatives in the UK was approximately £37 million in 1981-1982 (Dennison, et al., 2005) and increased to £43 million on prescription laxatives alone in 1996 (Petticrew, et al., 1997). The authors conceded this sharp rise in the cost to the NHS may reflect the prescribing of more
expensive laxatives and repeat prescriptions rather than a sole increase in the number of patients treated (Petticrew, et al., 1997). A more recent Belgian study sought to evaluate the cost of treating OIC in both cancer and non-cancer patients (Hjalte, et al., 2010) in Europe and the USA. The authors conceded the difficulties of doing so because of the paucity of quality literature, the differing costs of medications across countries and continents as well as the difference in labour costs for medical treatment (Hjalte, et al., 2010). Nevertheless they did conclude the costs were significant.

Despite the difficulties in quantifying the economic burden on health care systems, it is undoubtedly significant. In the USA, constipation was the primary reason for 17,000 inpatient stays during 1987 with a mean duration of stay of 4.7 days (Dennison, et al., 2005). Also in the USA, data from the 2001 National Ambulatory Medical Care Survey found that around 5.7 million people sought care for constipation during that year at a cost of US$235 million (Martin, Barghout, & Cerulli, 2006). In the UK during 1981-1982 an estimated 450,000 visits were made to general practitioners for management of constipation with Spinzi and colleagues (2009) suggesting this figure had increased to around 500,000 by 1991-1992 at a cost of approximately £4.5 million (Dennison, et al., 2005). A more recent UK cohort study examined the prescribing trends for laxatives during the period of 2005-2009 (Schafe, et al., 2011). The study examined the records of over 3.8 million patients in the UK and found that in 2007 19% of patients sought medical assistance for constipation at least once, a figure which remained reasonably constant over the study period. Despite this high proportion, the authors believed that it was a considerable underestimation of the real prevalence of the problem due to many patients self managing their symptoms and not seeking medical advice.
Information about the economic burden of constipation in Australia is scant. A large report by Deloitte Access Economics for the Continence Foundation of Australia (2011) addressed the economic impact of both faecal and urinary incontinence but not constipation. A review of Australian Government, National Health and Medical Research Council (NHMRC) and Australian Bureau of Statistics websites found no information about the cost of constipation to the Australian community. However a Pharmaceutical Industry of Australia working paper (Sweeny, 2007) found prescribed laxatives fourteenth of fifteen classes of medication ranked in order of the number of patients taking that medication. This does not take into account the fact that most laxatives in Australia are sold over-the-counter and a prescription is not required hence the result is unlikely to reflect the magnitude of spending on laxatives in this country.

In addition to the direct costs of medication, investigations and medical treatment, indirect costs include absenteeism and impaired work function as a consequence of constipation. An analysis of the large UK National Health and Wellness Survey (Sun, et al., 2011) found a statistically significant difference between constipated patients and controls on the outcomes absenteeism, presenteeism (an inability to perform all work duties while present at work due to health or personal problems), overall work impairment and activity impairment ($p < 0.01$) as well as reporting higher rates of medical visits and emergency department visits ($p < 0.01$). Similarly Dennison and colleagues (2005) reported a survey from the USA which found that each constipated patient was absent from work for 0.4 days annually with constipation causing 13.7 million days of restricted activity and 3.4 million days of bed disability across the entire population annually. Once again no Australian data was found to compare the economic burden of constipation across continents although the high incidence of constipation
in Australia suggests that our economic burden is likely to be similar to that found in both the UK and the USA.

Summary of Complications
Complications from constipation range from mild to severe and while deaths are not common multiple cases have been reported. Constipation can have a significant impact on not only the patient’s quality of life but is responsible for a significant economic burden both in terms of the costs of laxatives, medical treatment and lost productivity.

Treatment Modalities
Treatment modalities will be discussed according to traditional laxative use, alternative laxative therapies and newer laxative treatments.

Traditional laxatives.
Many articles and guidelines discuss the different treatment options for patients suffering from constipation with most advocating a stepped approach using general measures like a high fibre diet, adequate fluid intake and encouraging physical activity when possible. Laxative use also follows a stepped approach with one agent advocated prior to the next recommended level or agent.

Traditional laxatives are commonly classified into five broad classes:

- fibre and bulk-forming laxatives: bran, psyllium (Metamucil®), isphaghula husk (Fybogel®), sterculia (Normacol®), inulin (Benefibre®);
- iso-osmotic laxatives (also known as macrogols): polyethylene glycol (PEG) + electrolytes (Movicol®);
- osmotic laxatives: lactulose, sorbitol, magnesium sulphate (Epsom salts), sodium phosphate enema (Fleet Ready-to-Use® enema), Microlax® enema;
- stool softeners: docusate sodium (Coloxyl®), liquid paraffin (Agarol®, Parachoc®);
- stimulant laxatives: bisacodyl tablets (Dulcolax®), senna (Laxettes®, Senokot®, Sennetabs®), sennosides + docusate sodium (Coloxyl® with Senna).

The use of traditional laxatives and dietary supplements remain a mainstay of treatment despite the lack of evidence to support some agents. The addition of fibre supplements to the inpatient diet of orthopaedic patients has been reported in several studies although all were small and of poor design and rigor. Groth (1988) studied the effect of wheat bran versus Metamucil® (a bulk forming laxative with psyllium husks as the main ingredient) in 22 matched pairs of post operative orthopaedic patients. The researcher acknowledged that patients were assigned to groups depending on their preference i.e. bran or Metamucil® and the need to match pairs within the sample. The results were confusing. Groth claimed statistical significance in the outcome measure `days to spontaneous bowel movement’ but quoted the result as \( p = 0.5 \). Other results quoted provided no justification or were based on subjective assessments by the patients.

Another small study by Schmelzer (1990) investigated the addition of high fibre supplements in eight matched pairs (\( n = 16 \)) of post surgical orthopaedic patients. Those in the intervention group received high fibre cookies and muffins while those in the control group received similar foods but made with white flour. No statistically significant difference between the two groups on the incidence of constipation was found (\( p= 0.12 \)) and the author admitted the fibre content in the foods was reduced for the last four participants in the intervention group after complaints about palatability.
An Australian randomised controlled trial (RCT) of 89 elderly orthopaedic patients (Stumm, et al., 2001) sought to compare the effect of pear juice and a fibre supplement on the laxative requirements and bowel function of elderly orthopaedic patients. The authors acknowledged that bran alone had not been proven helpful in patients suffering from OIC and that increasing dietary fibre without increasing fluid intake may cause faecal impaction. Their RCT saw the treatment group \((n = 32)\) receive a 150ml glass of pear juice twice daily while the fibre supplement group \((n = 24)\) received a 'fibre ball' consisting of bran, oats, prunes, apple and coconut. Thirty three patients comprised the control subjects. Their study found no difference in time to first bowel action, overall rate of bowel actions or requirements for laxatives between the fibre ball or pear juice groups (no actual result given), but reported an increased rate of bowel opening in the pear juice group after seven inpatient days \((p = 0.045)\). Once again there were numerous limitations to this study including poor compliance with the fibre ball consumption, incomplete fluid and bowel data, a deviation from the set study protocol and ad hoc use of laxatives.

In the USA, a quality improvement initiative conducted over three years in a single hospital setting (Hall, Karstens, Rakel, Swanson, & Davidson, 1995) examined the addition of high fibre foods and increased fluid on elderly hospitalised patients. Hall and colleagues (1995) also reported the two findings discussed above and hypothesised that in addition to high fibre supplementation, ensuring privacy, encouraging fluid intake between 1500-2000ml daily, placing patients in an upright position for toileting and using abdominal strengthening muscles to assist defaecation would improve bowel outcomes for their patients. Baseline bowel data was collected from 16 patients and self reported rates of constipation, faecal impaction and requests for laxatives were monitored over a three year period \((n = 69)\) and reported
quarterly (i.e. every three months). The authors reported a reduction in the incidence of constipation from 59% to 9%, laxative use from 59% to 8% as well as the elimination of any reports of faecal impaction. Whilst these figures seem impressive the study had a number of limitations. The study sample was small and because of small patient numbers in one particular quarter, the results were eliminated when analysing outcomes; results were analysed quarterly for the first year then annually for years two and three; the outcomes relied on patient self-reporting; a validated tool was not used; no discussion was made about the elderly patient’s ability to use the abdominal strengthening muscle exercises and no attempt was made to control for other variables which may have influenced the outcome.

A more recent smaller study of elderly orthopaedic patients was undertaken in 2006 in Turkey (Kaçmaz & Kaşıkçı, 2007). The study sought to evaluate the effectiveness of a bran supplement in 60 volunteer patients. The patients were non-randomly assigned to either an intervention group who received a `packet’ of fibre to be ingested over one day or a control group who received only routine nursing care. Patients used a Constipation Following Form developed by the researchers that was apparently based on previous literature. The tool used an outcome measure for amount: none, small, normal or much as well as measures not normally used in constipation tools including colour (light, normal, dark), duration (normal or long), time (same time, changed time) and intensity (watery, normal, hard). In addition patients were asked whether they were `considering’ defaecation or were `anxious’ about it. The authors found a statistically significant difference between groups on the `no defaecation’ outcome on days one and five ($p = 0.016$) although the amount (small, normal, much) was not discussed and may therefore not represent an effective bowel motion. Despite the poor quality of the above studies and the inability to be able to generalise the
results beyond the study groups, the need for adequate fibre is cited in virtually all studies and guidelines which relate to constipation.

In 2005 Ramkumar and Rao published a systematic review of the literature in relation to the efficacy and safety of traditional medical therapies for chronic constipation. The authors discussed the paucity of literature available to support the use of many commonly used laxatives such as senna and bisacodyl with polyethylene glycol (PEG) the only laxative to be supported by level 1 evidence and a grade A recommendation. It was consistently found to be more effective than lactulose and despite being more expensive was found to be more cost effective due to its efficacy (Ramkumar & Rao, 2005). A summary of their results is shown in Table 2.2.

Table 2.2

<table>
<thead>
<tr>
<th>Class of Agent</th>
<th>Name</th>
<th>Evidence</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>bulk forming</td>
<td>bran</td>
<td>Level III – poor</td>
<td>C</td>
</tr>
<tr>
<td>bulk forming</td>
<td>psyllium</td>
<td>Level II - fair</td>
<td>B</td>
</tr>
<tr>
<td>iso-osmotic</td>
<td>PEG</td>
<td>Level I – good</td>
<td>A</td>
</tr>
<tr>
<td>osmotic</td>
<td>lactulose</td>
<td>Level II – fair</td>
<td>B</td>
</tr>
<tr>
<td>stimulant</td>
<td>senna</td>
<td>Level III - poor</td>
<td>C</td>
</tr>
<tr>
<td>stimulant</td>
<td>bisacodyl</td>
<td>Level III - poor</td>
<td>C</td>
</tr>
</tbody>
</table>

Spinzi and colleagues’ (2009) discussion article aimed to identify evidence-based interventions for the management of constipation. They confirmed that few high quality trials have been conducted on commonly used laxatives but confirmed the importance of clean and private toileting and where
possible the need to avoid bedpans. The authors also discussed the inconsistent evidence for fibre despite being commonly recommended. The authors also highlighted that few studies have been able to correlate poor hydration or exercise levels with constipation (Spinzi, et al., 2009). This study will make a valuable contribution to this paucity of literature.

Belsey and colleagues (2010) undertook a systematic review to assess the efficacy of PEG with other classes of laxatives. The authors reviewed 20 studies and found that PEG use resulted in a highly significant increase in defaecations per week when compared with lactulose ($p = 0.021$) and isphaghula ($p < 0.001$). These findings are interesting in light of the data published from the Laxative Usage in Constipation in the UK (LUCK) study (Schafe, et al., 2011). This epidemiological study investigated the prescribing trends for laxatives in the UK during 2005-2009. Findings showed that although senna and lactulose were the most commonly prescribed laxatives in the UK in 2005, by 2009 PEG was the most commonly prescribed agent and senna use had declined significantly. These findings were echoed by a Cochrane intervention review (Lee-Robichaud, Thomas, Morgan, & Nelson, 2011) which also concluded that PEG should be used in preference to lactulose for the treatment of chronic constipation. The review reported that PEG is better than lactulose for the outcomes of stool frequency per week, form of stool, relief of abdominal pain and the need to use other products. Of particular note, the LUCK study (Schafe et al., 2011) also found that macrogols (including Movicol®) were being increasingly prescribed by general practitioners for the management of pregnancy related constipation. This finding was of interest given that pregnancy and breastfeeding are listed contraindications in early versions of the product literature. More recent product information does not consider pregnancy or breastfeeding to be contraindications to use but recommends taking Movicol® on medical advice.
(Therapeutic Goods Administration, 2011). Movicol® was the laxative chosen for the Murdoch Bowel Protocol© used in this study.

Despite the acknowledgement that orthopaedic patients are at very high risk for developing OIC only one article that reviewed the effectiveness of PEG in this group was found. A small, single site study \( (n=31) \) conducted in Adelaide Australia (Madsen, et al., 2010) sought to compare the effectiveness of PEG (Movicol®) with a standard bowel treatment. The control group \( (n = 16) \) received the standard bowel management protocol which consisted of Coloxyl and Senna®, sorbitol and a Microlax® enema. The intervention group \( (n = 15) \) received Movicol® 1-2 sachets per day from day 1 post operatively. Only 28 patients completed the study. A statistically significant difference in time to first bowel motion \( (p = 0.001) \) was found in those patients who took Movicol® and although the intervention group did experience nausea more often the difference between groups was not statistically significant \( (p = 0.14) \). Similarly the intervention group reported passing more flatus although this difference was not statistically significant \( (p = 0.12) \).

The inconsistent advice and lack of robust evidence to support the use of some common laxatives may cause some patients to seek alternative therapies for the management of constipation.

**Alternative therapies.**

Alternative therapies for constipation include acupuncture, Chinese herbs (usually taken as herbal teas), reflexology, colonic irrigation and abdominal massage.
Whilst much has been written about the effect of acupuncture and Chinese herbs for the treatment of constipation, many of the articles are not published in English. However the effect of acupuncture and Chinese herbs for constipation was evaluated in a systematic review published in 2009 (Lin et al., 2009). The authors found that Chinese herbal medicines had been evaluated in many high-quality trials and they were found to be significantly more effective for the treatment of constipation than conventional medicine. However the authors went on to add the differences in constipation definition and reporting criteria between studies made direct comparisons difficult. Whilst not specifically related to constipation a randomised controlled trial published in 1998 evaluated the efficacy of Chinese herbal medicine for the treatment of irritable bowel syndrome ($n = 119$). The authors found statistically significant results in the outcomes measures of symptom relief ($p = 0.001$) and symptom interference with lifestyle ($p = 0.03$). Only three trials using acupuncture were evaluated; acupuncture versus lactulose, acupuncture versus senna and traditional acupuncture versus deep acupuncture. While all three studies showed positive results on the cited Cleveland Constipation Score, the authors recommend caution as the acupuncture procedures were different in all three studies making comparisons difficult. A systematic review of previously reported systematic reviews of acupuncture was published by Bandolier, the University of Oxford evidence based medicine website. They found that over a large range of conditions and outcomes acupuncture could not be shown to be effective based on the studies published to date (University of Oxford, n.d.). No date has been provided by the authors.

Whilst reflexology is widely practised in Australia, robust studies relating to its use for constipation are scant. The Australian Reflexology Association defines reflexology as the application of digital pressure to various points on
the feet which correspond to a particular body part, pressure on which stimulates the body’s own healing process. A small UK study (n = 50) looked at the effectiveness of reflexology in children suffering faecal soiling and chronic constipation (Bishop, McKimmon, Weir, & Brown, 2003). Children in this observational study were treated with a 30 minute reflexology session weekly for six weeks with the study finding an increase in the number of spontaneous bowel movements with a decrease in the amount of faecal soiling experienced. A UK pilot study (Woodward, Norton, & Barriball, 2010) of women with chronic idiopathic constipation (n = 19) were treated with a 35-45 minute reflexology session per week for six weeks. Analysis of participants’ self-reported bowel diaries found that 79% (n = 15) of women reported either cessation or a significant reduction in laxative use after six weeks. Whilst these two small studies yielded positive results, both authors recommended that more research was warranted. Until then reflexology as a treatment for constipation was not supported by robust evidence.

Colonic irrigation is also widely practised with the procedure reputed to assist with the elimination of toxins, gas blockages and undigested food. Eradication of these problems can allegedly assist with many symptoms including constipation, diarrhoea, irritable bowel syndrome, depression, backache, headaches and liver overload. A review of the literature found evidence of these claims to be sorely lacking. Whilst articles do exist on the use of colonic irrigation they relate to its use for patients with faecal incontinence or obstructed defaecation after obstetric injury, anorectal surgery or with neurological disorders (Koch, Melenhorst, Gemert, & Baeten, 2008). Colonic irrigation in these patients has been found to be highly beneficial although its use as a general tonic in those without significant underlying pathology is not supported.
Abdominal massage as a treatment modality for constipation has also been evaluated by Bandolier (University of Oxford, 1997) who reviewed four trials. There was insufficient evidence of the benefit of abdominal massage for chronic constipation with all trials being small and of poor methodological quality.

**New treatments.**

New treatments for constipation revolve around the use of several agents: misoprostol a synthetic prostaglandin analogue; tegaserod a serotonin receptor agonist; methylnaltrexone an opioid receptor antagonist and alvimopan. Only methylnaltrexone is registered by the Therapeutic Goods Administration (TGA) for use in Australia and will be discussed here. The combination analgesic Targin (oxycodone and naloxone) was approved by the TGA for use in Australia in 2010 and will also be discussed here because of its prophylaxis of OIC.

Methylnaltrexone is a derivate of naltrexone and classified as a mu-opioid receptor antagonist. It has only recently been approved for use in Australia for OIC in patients receiving palliative care (Therapeutic Goods Administration, 2012). Methylnaltrexone reverses unwanted opioid side-effects in the gut without compromising analgesia or precipitating symptoms of withdrawal (Camilleri, 2011; Holzer, 2008). It has been used in the USA, Canada and Europe for some years with studies confirming its efficacy. A Cochrane Intervention Review (McNicol, Boyce, Schumann, & Carr, 2011) of 23 studies which investigated four opioid antagonists (including methylnaltrexone) found that methylnaltrexone was better than a placebo in reversing OIC with the incidence of adverse effects considered mild to moderate.
Targin, a combination of oxycodone and naloxone was approved by the TGA for the management of moderate to severe pain and/or prophylaxis of OIC. It was designed to reduce (but not eliminate) the duration and severity of OIC without compromising the analgesic properties of oxycodone. Trials on the efficacy of this drug found a 25% reduction in the incidence of OIC amongst people with pre-existing constipation and a 7% reduction in those without a pre-existing history ("Oxycodone-with-naloxone controlled-release tablets (Targin)," 2011).

**Summary of Treatment Modalities**

Robust evidence to support many common laxatives and lifestyle changes is contradictory yet they remain the mainstay of first line treatment. Systematic reviews have found PEG, the laxative used in the protocol for this study, to be more efficacious than other laxatives and its use is increasing and whilst alternative therapies are commonly employed none are supported by empirical evidence. Methynaltrexone is the only opioid antagonist approved for use in Australia although only for palliative care patients. Targin, an oxycodone and naloxone compound has been used with good effect in reducing the incidence of OIC.

**Local, National and International Constipation Guidelines**

As demonstrated above there is still a lack of evidence to support some long held beliefs about the best way to manage constipation. The issue of OIC has not been specifically addressed in any published guidelines with general guidelines being used.

**Local guidelines.**

Despite conceding the scope of the problem, a review of major teaching hospitals in Perth failed to reveal any evidence of standardised bowel care
guidelines across all hospitals. One large teaching hospital uses a constipation algorithm based on the administration of Pikoprep®, an osmotic laxative with an action similar to that of PEG (Hoy, Scott, & Wagstaff, 2009) and a Durolax® (bisacodyl) stimulant suppository. This regime is not specific to orthopaedic patients. Other hospitals use varying guidelines across different ward areas with no standard protocol. The sole paediatric teaching hospital is currently evaluating a protocol similar to that tested herewith and based on the administration of PEG in post operative orthopaedic patients. This trial is in its infancy and results are not available.

National guidelines.
National guidelines for the management of constipation have either been published by the Australian Government’s Department of Health and Ageing or other agencies who have been funded by the Department. The Department of Health and Ageing’s brochure ‘Help patients win the constipation battle’ (2003) was published as part of the National Continence Management Strategy, now the National Continence Program and despite its publication date is still in wide circulation. This brochure was aimed at health professionals and aimed to provide best practice information on the prevention and treatment of constipation. The brochure advocated general measures such as correct toilet positioning, 30 minutes of walking per day, eight glasses of water and 25-35 grams of fibre daily. The laxative guidelines for general practitioners advocated a stepwise approach starting with bulk-forming laxatives, then faecal softeners, stimulant laxatives and finally osmotic laxatives such as lactulose or PEG. The brochure grudgingly advises “There is no compelling evidence that one laxative is better than another so the cheapest alternative should be tried first” (Wallis et al., 2003).
The follow-up brochure 'Looking after your bowel: A guide to improving bowel function' (2008) aimed to improve awareness and prevention of continence issues and was designed for patients. The brochure is a 19 page guide covering general topics such as normal bowel function, good toileting habits, pelvic floor training, diet, constipation and faecal incontinence. It does not discuss the use of laxatives in any detail and advises readers to seek advice from a continence nurse, physiotherapist or doctor.

The Joanna Briggs Institute (JBI) based at the University of Adelaide produces best practice guidelines for health professionals. Their information sheet 'Management of constipation in older adults' (Joanna Briggs Institute, 2008) cites opioid analgesics as a risk factor for constipation although the information is not specific to OIC. The sheet confirms the efficacy of PEG and recommends that in moderate to severe acute constipation osmotic laxatives should be used to empty the rectum followed by preventative measures such as adequate fibre and fluid intake. Further, JBI stress the importance of determining individual requirements.

Australia’s National Health and Medical Research Council (NHMRC) website has four links to evidence based guidelines for constipation. One is specific to urinary incontinence; one links to the JBI 'Managing constipation in older adults' guidelines discussed above; one is specific to palliative care and the fourth is written by Selby and Corte (2010) and has already been discussed within the body of this literature review.

In addition brochures are often available at pharmacies and in primary care waiting rooms which provide generic information for the management of constipation. Their content varies and the information provided may not
reflect best practice. No attempt was made to evaluate them due to the scope of this thesis.

**International guidelines.**

International guidelines for the management of constipation have been produced by multiple groups.

The World Gastroenterology Organisation published ‘Constipation: a global perspective’ in 2010. Once again these guidelines do not address the issue of OIC specifically and aim to provide guidelines which can be translated across multiple cultures and demographic groups. Of interest they recommend use of the Bristol Stool Chart to standardise stool recording and note that stool consistency is a better indicator of colon transit time than stool frequency. When discussing treatment for constipation they advocate a stepwise approach:

1. increasing fibre (either dietary or as a bulk-forming laxative);
2. adding an osmotic laxative (lactulose or PEG). They add that the best evidence points to the use of PEG over lactulose but availability may determine which agent is used; and
3. then bisacodyl or sodium picosulfate as stimulant laxatives if required.

It is worth noting these guidelines are written for worldwide use and the authors acknowledge that not all agents may be available in all countries. For that reason JBI also provide cascade options according to the availability of resources (limited, medium or extensive).

The UK National Health Service (NHS) produces a comprehensive range of health care resources with most information available online. Some
professional-only content is restricted to residents of Wales or England and as such was not available for review. Their Constipation Treatment website advocates increasing dietary fibre and using a bulk-forming laxative followed by an osmotic laxative such as lactulose or PEG. If required the addition of a stimulant laxative may be required as the third step. These guidelines reflect those of the World Gastroenterology Organisation discussed previously.

The British Medical Journal’s Best Practice series has an extensive web based resource for the definition, aetiology, diagnosis, management and prognosis of constipation (British Medical Journal, 2012). This resource provides a step-by-step treatment approach for both acute and chronic constipation but is one of the few guidelines which specifically addresses the issue of OIC. The series recommends lactulose, PEG, and senna as the only agents of use in patients taking opioids and cite ‘unknown effectiveness’ for bisacodyl, docusate, magnesium salts, sodium picosulfate, liquid paraffin and isphaghula husk (British Medical Journal, 2012).

The American Gastroenterological Association’s ‘Medical position statement: guidelines on constipation’ was last published in 2000. Their guidelines for medical management advocate a gradual increase in fibre both via the diet and as dietary supplements (e.g. bran). If more treatment is required an inexpensive agent such as milk of magnesia, followed by a stimulant such as dulcolax then an osmotic agent, either lactulose or PEG (Locke, Pemberton, & Phillips, 2000) is recommended. The use of an agent such as milk of magnesia which is not recommended by other credible sources may reflect the age of the guidelines. These guidelines do not specifically mention OIC only that a full record of prescription and over the counter medications should be obtained.
In 2011 an article describing the European perspective on the diagnosis and treatment of chronic constipation was published (Tack et al., 2011). Whilst not purporting to be clinical guidelines per se the article presented a comprehensive overview of current diagnosis and management guidelines in Europe. This is one of the few articles to address the issue of drug-induced constipation (although its treatment is similar to that of chronic constipation).

Of interest the authors noted that although a number of groups have provided recommendations for the diagnosis and treatment of constipation no standardised guidelines exist (Tack, et al., 2011). Further, the authors reiterated that although the evidence for diet and lifestyle interventions was either weak or contradictory they continue to be recommended. In light of this recommendations include diet and lifestyle adjustments; osmotic laxatives, stool softeners or bulk forming laxatives (no consensus on the order to be tried) then stimulant laxatives, suppositories or enemas. Of note, the World Health Organisation (WHO) has not produced specific guidelines on the management of constipation.

**Summary of Guidelines**

Constipation guidelines have been published by many organisations, some of which still in use are more than 10 years old. Despite the lack of robust evidence to support them, increasing dietary fibre and fluid and exercising moderately remain the first line of treatment. Older guidelines recommend the administration of faecal softeners or stimulants while more recent guidelines recommend the use of PEG or other osmotic laxatives. None of the guidelines discuss the management of OIC specifically. A review of bowel management procedures across major Perth hospitals found a lack of standardisation in terms of post operative bowel management.
Summary of Literature Review

This extensive review of the published literature confirms that while constipation is a significant problem there remains a lack of consensus about how best to treat the condition. Commonly cited measures such as increasing fibre and fluid intake and exercising moderately are not supported by robust evidence although continue to be the mainstay of constipation advice and treatment. The high risk of constipation in orthopaedic patients is also acknowledged although studies within this cohort are few, of poor methodological design and have not yielded results which are generalisable. This large gap in our knowledge base and the lack of clear guidelines for the management of post operative constipation in orthopaedic patients was the primary driver behind the development of the Murdoch Bowel Protocol©. The aim was to develop a gold standard treatment protocol for the prevention of constipation in this group. Part Two details how this was achieved.
Part Two

Baseline Audit

In 2008 several adverse constipation-related clinical incidents occurred at the researcher’s hospital prompting a review of the way post operative orthopaedic bowel care was managed. In addition anecdotal reports from the emergency department reported a significant increase in the number of post operative orthopaedic patients returning for management of severe constipation or faecal impaction post discharge. Further ward staff reported occasional increased lengths of stay to manage constipation and staff making follow up phone calls to the patient approximately one week after discharge found that many were reporting significant problems with constipation. Some of these patients reported the need to see their general practitioner or seek pharmacy advice for their symptoms. An initial meeting with orthopaedic nurses to discuss inpatient bowel management found an ad hoc approach was used which varied according to: the knowledge, experience and aperient preference of the nurse; the preference of the surgeon, anaesthetist or patient; and the availability of aperients at that particular time. Discussions with colleagues at both public and private hospitals within Western Australia and interstate revealed this problem was not unique to our hospital with all centres experiencing similar clinical issues. This haphazard approach prompted a clinical audit of bowel management using the Joanna Briggs Institute Practical Application of Clinical Evidence System (PACES) audit tool. As previously stated the Joanna Briggs Institute (JBI) is an internationally recognised leader in the development of evidence based guidelines for nurses and allied health professionals and is based at the University of Adelaide in South Australia. As no orthopaedic-specific bowel audit tool was found, the more generic JBI audit tool `Constipation associated with analgesia’ was considered the most appropriate for the baseline audit since patients who undergo major joint replacements such as
hip and knees are administered large quantities of opioid analgesia. As discussed in part I, the administration of large quantities of opioid analgesia is a significant contributing factor in the development of severe constipation hence the relevance of this topic. Four audit criteria existed for this topic:

- Criteria 1. a baseline assessment of usual bowel patterns is documented prior to constipation occurring;
- Criteria 2. the severity of constipation is evaluated and documented using a standardised grading tool;
- Criteria 3. there is documented evidence that patients with constipation are monitored for improvements or progression of constipation; and
- Criteria 4. there is documented evidence that patients and their carers (if applicable) have been educated and given information regarding measures to prevent constipation.

A baseline audit of 30 total hip and total knee replacement patients was undertaken in September 2009 using this JBI tool with the results shown in Figure 2.1. This number was chosen for convenience as each of our two orthopaedic wards have 30 inpatient beds. As this was a baseline audit it was not considered necessary to undertake a sample size calculation.

The baseline bowel audit identified areas for improvement across all four criteria. The first criteria, that a baseline assessment of usual bowel patterns be recorded scored poorly with only 10% (n = 3) of 30 patients having this undertaken. A review of the hospital Nursing Admission Form found that no trigger questions were included in the Elimination heading section and that the space for writing was so small as to discourage the recording of any detail. This form has since undergone extensive review with the addition of trigger questions and adequate space for recording.
The second criteria, that the severity of constipation is evaluated and documented using a standardised grading tool, scored poorly with no documented evidence for any of the 30 patients. This poor result reflected the lack of a standardised tool for documenting the patient’s bowel status and was addressed by the bowel protocol which is discussed in more detail later in this chapter.

The third criteria documented evidence that patients with constipation are monitored for improvements or progression of constipation, scored better with 63% (n = 19) of 30 patients having this criteria documented in their nursing care notes. We were cautious about this result which we considered potentially misleading as nurses relied on the patient to self report their bowel actions and used terms such as BO (bowels open) or BNO (bowels not open) on observation charts. The abbreviation BO provided no detail about stool type or size given the potential that many patients recorded as BO may have only been passing small quantities of constipated stool yet were considered constipation free. This problem was also addressed with the development of the Murdoch Bowel Protocol© and is discussed in more detail later in this chapter.

Criteria four documented evidence that patients and their carers (if applicable) have been educated and given information regarding measures to prevent constipation, also scored poorly with only 17% (n = 5) of patients having this recorded in their nursing care notes. At the time of the baseline audit no written information about the risks and management of constipation was given to patients with verbal advice the only information relayed to patients or carers.
These poor results highlighted a significant gap in how we managed postoperative constipation in the orthopaedic patient cohort and prompted a collaborative approach to the problem.

Figure 2.1

Baseline Clinical Audit Results

Development of the Murdoch Bowel Protocol©

A working party consisting of a clinical dietician, continence nurse specialist, orthopaedic learning and development nurse and coordinator of nursing research was convened and met regularly over a period of several months to seek a solution to the problem. These people were recruited because of their expertise in specific areas relevant to the development of a solution. A discussion with colleagues from other surgical hospitals within the St John of God group confirmed that our poor audit result would likely be replicated at other sites as the problems we identified were common to all divisions, i.e. the ad hoc management and a lack of standardised orthopaedic bowel care. Other divisions also reported details of clinical incidents concerning faecal
impactation and associated complications. Hence the scope of the problem was larger than initially thought even at the preliminary phase.

A review of the literature was undertaken to determine best practice for orthopaedic bowel management. As discussed in part I of this chapter, whilst much is written about the scope of this problem, no robust evidence exists to guide clinical management. This lack of evidence was the primary impetus for the development of the bowel intervention protocol.

Having determined that no guidelines existed for the management of constipation in orthopaedic patients we sought more general best practice guidelines for the management of constipation. As discussed in part I, a paucity of literature exists to guide such a common problem with much of it conflicting, of poor quality or the result of questionable research rigor. However a systematic review by (Ramkumar & Rao, 2005), guidelines from an internationally recognised authority (World Gastroenterology Organisation, 2007) and Australian evidence based guidelines (Joanna Briggs Institute, 2008) confirmed the use of polyethylene glycol with electrolytes as the agent of choice for functional constipation. Polyethylene glycol (PEG) with electrolytes is produced by Norgine Pty Ltd and marketed in Australia as Movicol®. It is an inert iso-osmotic agent which works by attracting water into the gut which increases stool volume, softens stool consistency and facilitates stool passage. The addition of the electrolytes sodium bicarbonate, sodium chloride and potassium chloride ensure no net loss of electrolytes. Movicol® is supplied as a powder in individual sachets which are dissolved in 125ml of water and taken straight away. The dose recommended from the manufacturer is up to three sachets daily although it can be given in doses of up to eight sachets daily for the treatment of faecal impaction. This wide dosage margin reflects the inherent safety of the
medication with the only absolute contraindications being gut obstruction and perforation or inflammatory bowel disease (ulcerative colitis or Crohn’s disease). Whilst the manufacturers advise the safety of Movicol® during pregnancy and breastfeeding has not been established it has been used safely and with good effect in this cohort (Neri et al., 2004) as well as being considered safe for pregnant or breastfeeding mothers by the United Kingdom’s National Health Service in their constipation guidelines (National Health Service, 2012).

Movicol® is non-scheduled meaning it is freely available over-the-counter at both chemists and in supermarkets in Australia. Multiple factors influence the scheduling of medications in Australia including the potential for abuse, the need for the substance, the purpose of use and the inherent safety of the medication. Medications are classified in nine schedules according to the degree of control required over their availability, with progression through the schedules signifying increased control (Therapeutic Goods Administration, 2008). Movicol® is non-scheduled signifying the Australian Therapeutic Goods Administration has found it to be inherently safe. Whilst generic evidence supported the administration of Movicol® as an aperient for our orthopaedic patients the working party identified the lack of standardised tool to identify stool type as a significant problem. Stool description and constipation is inherently subjective and a clear tool was required to ensure consistent recording. The Bristol Stool Chart (Figure 2.2) was developed by Heaton and Lewis at the University of Bristol and first published in 1997 (Heaton & Lewis, 1997). It classifies faeces into one of seven types depending on the time taken for the faecal mass to pass through the gut. Fast transit time decreases the absorptive function in both the large and small bowel whilst slow transit time leads to hard stool and symptoms of constipation (Heaton & Lewis, 1997). Their research confirmed that stool
form (type) was a better predictor of intestinal transit time than stool frequency (Heaton & Lewis, 1997).

Figure 2.2
Bristol Stool Chart

From About bladder and bowel health, 2010, Continence Foundation of Australia

Heaton and Lewis (1997) were committed to developing a tool with stool descriptions in ‘everyday language’. The Bristol Stool Chart is a simple, visual tool that is widely used and has been validated through repeated use over many studies (Heaton & Lewis, 1997). For this reason it was included as part of the bowel intervention protocol.
According to the Bristol Stool Chart (BSC) types 1 (separate hard lumps) and 2 (sausage shaped but lumpy) indicate a constipated stool, types 3 (like a sausage or snake but with cracks on the surface) and 4 (like a sausage or snake but smooth and soft) most closely resemble normal stool, types 5 (soft blobs with clear cut edges) and 6 (fluffy and mushy) represent a soft stool and type 7 is an entirely liquid stool. Whilst patients may consider their usual stool to differ from BSC types 3 or 4, normal gut transit time determines stool type. Consequently BSC 3 and 4 are considered ‘normal’ and therefore ‘usual’ may differ from ‘normal’ in some patients.

Consensus amongst the working party deemed the titrated use of Movicol® according to BSC type and post operative day should be trialled. Patients often report nausea on the first day post operatively so it was felt that Movicol® was best commenced on day two with the ongoing dose range of one or two sachets depending on BSC type and day. Whilst there is conflicting evidence about the effect of diet, fluid intake and exercise on the management of constipation (Annells & Koch, 2003; Kurz & Sessler, 2003; Lindeman, et al., 2000; Spinzi, et al., 2009), they are largely cited as important and were included as part of the general measures in the tool. Whilst opioid analgesia is a mainstay of post operative care for major joint replacement patients its role in causing constipation is undisputed (Ahmedzai & Boland, 2009; Camilleri, 2011; Davies, et al., 2008; DeLuca & Coupar, 1996; Ishihara, et al., 2012; Kurz & Sessler, 2003; Miaskowski, 2009; Panchal, et al., 2007; Pappagallo, 2001). These drugs are usually administered intravenously, intramuscularly and/or orally. Whilst acknowledging the importance of adequate analgesia post operatively encouraging the use of non-opioid analgesia is well recognised and is routinely ordered by medical staff. For this reason the intervention also reminds nursing staff to ‘consider reducing constipation causing medications if possible e.g. opioids’. The continence specialist nurse advised that if patients were still experiencing symptoms of
constipation (BSC type 1 or 2) by day six post operatively despite using the protocol a referral should be made for the patient to be seen by this specialist nurse. In addition if constipation, a loose stool or diarrhoea (BSC 5, 6 or 7) were observed in a patient closer to discharge, the continence specialist nurse should also be contacted. This action was included in the protocol to ensure that a patient suffering from constipation with faecal overflow was identified and appropriately managed prior to discharge.

**Validity of the Murdoch Bowel Protocol©**

All of the detail discussed above was translated into the Murdoch Bowel Protocol© shown in Figure 2.3. Following this initial developmental stage, the protocol was then discussed at both the physicians’ craft group and orthopaedic craft group. These forums allowed for analysis and discussion of the protocol and both groups ratified its use without recommending any changes. Despite being ratified at the orthopaedic craft group every orthopaedic surgeon who practised within the hospital was contacted in writing and asked for their written permission to manage their post operative major joint replacement patients using this formal protocol. Every surgeon agreed in writing. In addition the protocol was tabled at the hospitals’ Clinical Risk Meeting for discussion. This multidisciplinary forum meets monthly and includes representatives from across all hospital departments including medical, nursing, legal and pharmacy. The Clinical Leadership Council also meets monthly and is a forum for nursing and midwifery staff to discuss clinical matters and new interventions. Both of these senior hospital groups also ratified the protocol for use without any recommendations for change.
Days 2 and 3

**Type, 1 or 2 (constipation)**
- High fibre diet, increased fluids & exercise
- Encourage mobilisation if appropriate
- Commence Movicol® one sachet BD
- Consider reducing specific medications (eg. opioids)

**Type, 3 or 4 (normal stool)**
- Diet, fluids & exercise as above
- Continue Movicol® one sachet BD

**Type, 5, 6 or 7 (loose stool or diarrhoea)**
- Diet, fluids & exercise as above

Days 4 and 5

**Type, 1 or 2 (constipation)**
- High fibre diet, increased fluids & exercise as per Day 2
- Continue Movicol® one sachet BD
- Administer Microlax® enema

**Type, 3 or 4 (normal stool)**
- Diet, fluids & exercise as above
- Continue Movicol® one sachet daily

**Type, 5, 6 or 7 (loose stool or diarrhoea)**
- Diet, fluids & exercise as above
- Cease Movicol®

Days 6 and 7

**Type, 1 or 2 (constipation)**
- High fibre diet, increased fluids & exercise as per Day 2
- Continue Movicol® one sachet BD
- Refer to Continence Nurse Specialist

**Type, 3 or 4 (normal stool)**
- Diet, fluids & exercise as above
- Continue Movicol® one sachet daily

**Type, 5, 6 or 7 (loose stool or diarrhoea)**
- Diet, fluids & exercise as above
- Cease Movicol®

* If patient has had past bowel surgery please contact Dr prior to commencing any laxatives

References:
- Bristol Stool Chart (K. W. Heaton and S. J. Lewis 1997)
- Joanna Briggs Institute Best Practice Information Sheet “Management of Constipation in Older Adults” (2008)
- Efficacy & safety of traditional medical therapies for chronic constipation: systematic review (Ramkumar & Rao 2005)
Having been endorsed for use within the hospital significant education of orthopaedic nursing staff began in early 2009. This comprehensive education included information about the incidence, causes, complications and management of constipation as well as instructions about how to conduct a baseline bowel assessment, an issue which had been highlighted in the baseline audit. Education took the form of storyboards, Stop Think posters, didactic forums, quizzes and questionnaires and was undertaken by multiple caregivers including the dietician, orthopaedic learning and organisational development nurses, continence nurse specialist and coordinator of nursing research. In May 2009 the protocol was trialled on two, 30 bed orthopaedic wards. Feedback was sought from orthopaedic nursing staff approximately one month after the trial commenced and again three months after implementation. In addition, medical staff took the opportunity to comment and changes were made to the protocol in response to this feedback. One change requested by nursing staff was the administration of a Microlax® enema if the patient recorded BSC type 1 or 2 by post operative days four or five. Microlax® enemas contain a 5ml volume of sodium citrate, sodium lauryl sulfoacetate and sorbitol and are classified as a stool softener. Whilst the clinical wisdom of expert nurses is acknowledged there was no robust evidence to either support or decline this addition to the protocol, largely a reflection of the poor quality of literature published on the subject.

Following considered discussion, the opinion of the working party was to include administration of a Microlax® enema in the protocol with the proviso that it could be withheld by the nurse or refused by the patient if necessary. Its inclusion was likely a reflection of embedded nursing practice rather than being evidence based.
A formal evaluation of the protocol was undertaken one year after implementation using the same JBI PACES tool used for baseline auditing. The comparative results are shown in Figure 2.4. Significant improvements were made across all audit criteria except the first as review of the Nursing Admission Form had not been completed by this time. This has since been undertaken and the new form is in use.

Figure 2.4

Comparison of Clinical Audit Results at Baseline and One Year Post Implementation of the Murdoch Bowel Protocol©

As no records about discharge phone calls are routinely kept only anecdotal evidence was available to compare patient satisfaction post discharge. Staff who undertook these phone calls reported a significant improvement in patient satisfaction pre and post implementation of the protocol with drastically smaller numbers reporting problems with constipation or needing to seek assistance for this problem. Similarly despite attempts to quantify the number of patients who return to our emergency department seeking assistance for post operative constipation, no reliable data could be found.
either pre or post intervention. These patients may present with common symptoms including abdominal pain, nausea, urinary retention or constipation making their attendance difficult to link with an orthopaedic discharge. Despite attempting to cross reference admissions or treatment with orthopaedic surgeons the results were not reliable. Once again, anecdotal reports from emergency department nursing staff report a significant reduction in the number of patients returning to the department post major joint replacement with symptoms of severe constipation or faecal impaction. Whilst length of stay data is collected once again it is difficult to isolate specific patients whose discharge has been prolonged due to the management of a complication such as constipation. As the increase of one or two days may still reflect the normal range of inpatient days a reliance on anecdotal data from staff was necessary and they reported no episodes of increased lengths of stay due to constipation since the introduction of the protocol.

The major improvement in three of the four audit criteria, along with anecdotal reports of significant reductions in both emergency presentations, increased patient satisfaction post discharge and no episodes of extended length of stay for management of constipation prompted one senior surgeon to seek the protocol for use at other metropolitan hospitals at which he worked. As a result the protocol is now widely used at multiple metropolitan hospitals in Perth. This success and improvement in patient outcomes prompted discussion about the protocol at several conferences around Australia. The intervention was named the Murdoch Bowel Protocol®. Interest in the protocol is increasing significantly and its use now extends to hospitals around Australia and New Zealand. This widespread interest reflects the scope of the problem and confirmed the urgent need for
an evidence based tool to guide management in this common but poorly managed area of clinical nursing practice.

The Murdoch Bowel Protocol© was developed to provide robust clinical guidelines for the management of constipation in post operative orthopaedic patients. This group is recognised as one of the highest risk cohorts for the development of post operative constipation yet many nurses continue to provide ad hoc bowel care in the absence of good, clear evidence to guide their clinical decision making. For patients constipation may lead to extended lengths of hospital stay and unnecessary discomfort from inadequate analgesia or the symptoms of constipation itself. Inadequate or ineffective treatment may lead to increased morbidity and occasional mortality all of which can be avoided with diligent bowel care.

The Murdoch Bowel Protocol© is a clear, easy to use protocol which uses a validated tool, the Bristol Stool Chart (BSC) to standardise stool type. As demonstrated in the literature review PEG has been found to be the most efficacious agent to treat constipation and its use is supported by Level I evidence. As such it was the agent of choice to administer to patients in a titrated dose depending on the post operative day and BSC type. The Murdoch Bowel Protocol© has been embedded in clinical practice at the researcher’s hospital for over two years. In this time patient satisfaction has increased significantly, medical staff have fully supported the implementation of the protocol and nursing staff enjoy having a clear protocol to guide orthopaedic bowel care. It was anticipated that evaluating the Murdoch Bowel Protocol© in this multi centre study would provide the empirical evidence required for nurses around the world to use this protocol knowing their patients would be the beneficiaries of a robust and effective intervention.
Summary of Development of the Murdoch Bowel Protocol©

The Murdoch Bowel Protocol was developed in response to poor clinical audit results and a lack of evidence based guidelines to manage post operative constipation in the orthopaedic patient cohort. The protocol is based on the titrated use of polyethylene glycol (Movicol®) according to Bristol Stool Chart type. Follow up audit results and anecdotal reports at the researcher’s hospital showed significant improvements in patient outcomes. These results as well as requests to use the protocol at both private and public hospitals across Australia and New Zealand prompted a robust study to empirically evaluate the protocol.

The theoretical model used to guide this study was based on the Neuman Systems Model and will be discussed in more detail in Chapter 3.
Chapter 3 - Frame of Reference

This chapter will discuss and present the theoretical framework which underpinned this study.

The theoretical framework for this study was based on the Neuman Systems Model (NSM). This model was developed by Dr Betty Neuman and first published in 1972 in an article entitled “A model for teaching total person approach to patient problems” (Neuman & Young, 1972). The NSM was developed in response to a perceived need to assist University of California, Los Angeles (UCLA) nursing students conceptualise a systems approach to patient care (Fitzpatrick & Whall, 2005). Neuman initially developed the model as a teaching aid and not as a specific conceptual model of care (Fawcett, 2001) however she cited multiple influences in her development of the Systems Model including de Chardin’s philosophic beliefs about the wholeness of life (1955); von Bertalanffy’s (1968) description of a general system theory; Caplan’s (1964) work on the development of primary, secondary and tertiary prevention strategies (common in a public health context); Gestalt psychology which looks at the human mind and behaviour as a whole entity and Selye’s Theory of Stress which was based on scientific work by the Hungarian endocrinologist Hans Selye (1950).

Whilst the NSM has remained essentially unchanged, the ten underlying assumptions which underpin the model have been more clearly articulated to ensure they remain relevant to current nursing practice (Fitzpatrick & Whall, 2005):

1. Each individual is unique with composite innate characteristics and possess a normal range of responses.

2. The client as a system constantly changes energy with the environment.
3. There are many types of known, unknown and universal stressors which may upset a client’s equilibrium (normal line of defence). The interrelationship of the five client variables determines the degree of protection offered by the flexible line of defence.

4. Over time each client develops a normal range of responses called the client’s normal lines of defence.

5. The cushioning, accordion-like flexible line of defence protects the client against stressors. When it cannot, the stressor upsets the client system equilibrium and interrelationships among the five variables determine the degree of reaction.

6. Wellness is a dynamic composite of the interrelationship of the five client variables and represents a continuum of available system energy.

7. Following a stressor reaction, internal resistance lines attempt to stabilise the client by returning to a normal or enhanced wellness state.

8. Primary prevention assessment and intervention identifies and allays risk factors associated with stressors. Included in primary prevention is health promotion.

9. Secondary prevention relates to symptom identification and implementation of interventions to deal with system disruption.

10. Tertiary prevention assists client adjustment as reconstitution is initiated and maintenance factors move the client back toward primary prevention (Fitzpatrick & Whall, 2005)

The NSM encompasses a holistic approach to patient care where the nurse and patient work in partnership to achieve optimal health retention, restoration and maintenance (Fitzpatrick & Whall, 2005). It has two primary areas of focus: how a patient responds to stressors and the nurse’s
interventions to assist the patient cope with these stressors. The NSM defines a stressor as something which has the potential to impact on the patient’s `steady state’ and may be positive or negative. Positive stressors may increase self-awareness or assist personal growth or development whereas negative stressors may result in deleterious outcomes and a deviation from wellness (Fitzpatrick & Whall, 2005). The nursing process within the NSM consists of three components: a nursing diagnosis based on a nursing assessment; goals based on active patient participation and outcomes related to mutually set goals (Fitzpatrick & Whall, 2005). This collaborative approach to optimising health outcomes is one of the reasons the NSM is so widely used not only by nurses but by other multidisciplinary teams (Memmott, Marett, Bott, & Duke, 2000).

Within the NSM the client (patient) can be defined as both an individual or group of people (i.e. family) consisting of five interacting variables:

1. physiological (bodily structure and internal function);
2. psychological (mental processes and interactive environmental effects both internal and external);
3. sociocultural (combined effects of social-cultural conditions and influences);
4. developmental (age-related development processes and activities); and
5. spiritual (spiritual beliefs and influences).

The Neuman Systems Model is reproduced in Figure 3.1. The model describes the patient as the central core consisting of basic survival factors (normal temperature range, genetic structure, response pattern, organ strength/weakness, and ego structure). The patient is surrounded by both solid and flexible lines. The flexible line of defence acts as a protective buffer to
prevent stressor invasion of the patient’s normal line of defence (or wellness state). Stressors may be intra, inter or extra personal and regular exercise, adequate sleep and good nutrition are examples of practices that will expand the flexible line of defence (Memmott, et al., 2000).

The integrity of the normal line of defence is crucial to maintaining wellness with a variance from wellness occurring when it is penetrated. The flexible lines of resistance are denoted as ‘accordion-like’ because they move towards and away from the normal line of defence. When they are expanded greater protection is provided to the patient and when they move closer to the normal line of defence their ability to provide protection is decreased. When the normal line of defence is penetrated the lines of resistance are reactions that occur within the patient and serve to stabilise and return the patient to a state of equilibrium and good health. Neuman advocates interventions either before or after the lines of resistance are penetrated. Reconstitution represents the return and maintenance of system stability following treatment for stressor reactions. It is important to remember that reconstitution may vary depending on the patient’s reaction (influenced by individual variables including basic structure differences, natural and learned resistance and time exposed to the stressor) and whilst the goal is to return the patient to their usual wellness state, they may actually return to a higher or lower level of wellness after their illness (Neuman, 2002). Neuman sees the nurse as an intervener whose role is to reduce or mitigate stressors. This can be undertaken by appropriate prevention at the primary, secondary or tertiary level (Neuman, 2002).

A model of nursing care based on the NSM was developed to guide this study and is conceptualised in Figure 3.2. The post operative orthopaedic patient
(central core), represented in the inner circle is influenced by both intrapersonal, extrapersonal and interpersonal stressors described in more detail in Table 3.1. Interventions are included within primary and secondary prevention i.e. identifying, reducing or eliminating actual or potential risks of constipation and early identification and treatment of symptoms. Acknowledgement of made of the fact that patients respond differently to stressors and that reconstitution aims to return the patient to their usual wellness state. For this study the stressors and the variables which influence them have been summarised in Table 3.1.
<table>
<thead>
<tr>
<th>Stressor</th>
<th>Definition</th>
<th>Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrapersonal</td>
<td>Forces external to the patient</td>
<td>- Hospitalisation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Constipation-causing medications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Reduced mobility</td>
</tr>
<tr>
<td>Interpersonal</td>
<td>Forces occurring between one or more individuals (i.e. nursing care)</td>
<td>- Privacy concerns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Embarrassment about bowel management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Variable bowel management according to different views and practices amongst medical and nursing staff</td>
</tr>
<tr>
<td>Intrapersonal</td>
<td>Forces occurring within a patient</td>
<td>- Reduced gut transit time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Response to anaesthetics, opioids and other medications known to cause constipation</td>
</tr>
</tbody>
</table>
Figure 3.1

*The Neuman Systems Model.* (Original diagram copyright© 1970 by Betty Neuman.)

- **Primary prevention**
  - Reduce possibility of encounter with stressors
  - Strengthen flexible line of defence

- **Secondary prevention**
  - Early case-finding
  - Treatment of symptoms

- **Tertiary prevention**
  - Readaptation
  - Re-education to prevent future occurrences
  - Maintenance of stability

- **Stressors**
  - Identified
  - Classified as to knowns or possibilities:
    - Loss
    - Pain
    - Sensory deprivation
    - Cultural change

- **Basic structure**
  - Basic factors common to all organisms:
    - Normal temperature range
    - Genetic structure
    - Response pattern
    - Organ strength or weakness
    - Ego structure
    - Known commonalities

- **Stressors**
  - More than one stressor could occur simultaneously
  - Same stressors could vary as to impact or reaction
  - Normal defence line varies with age and development

- **Reaction**
  - Individual intervening variables:
  - Basic structure idiosyncrasies
  - Natural and learned resistance
  - Time exposed to stressor

- **Reaction**
  - Could begin at any degree or level of reaction
  - Range of possibility may extend beyond normal line of defence

- **Interventions**
  - Can occur before or after resistance lines are penetrated in both reaction and reconstitution phases
  - Interventions are based on:
    - Degree of reaction
    - Resources
    - Goals
    - Anticipated outcome

**NOTE:**
- Physiological, psychological, socio-cultural, developmental and spiritual variables are considered simultaneously in each client concentric circle.
Figure 3.2

Model of Nursing Care for the Management of Constipation in Post Operative Arthroplasty Patients (adapted from Neuman, 1989)

**Primary Prevention**
Prevent opioid induced constipation by:
1. Increased fluid and dietary fibre
2. Ensuring private toileting facilities
3. Daily monitoring of bowel habits to identify early signs of constipation
4. Adequate analgesia to ensure early mobilisation

**Secondary Prevention (Interventions)**
1. Early identification of constipation
2. Interventions as per Murdoch Bowel Protocol

**Outcomes (Reactions)**
Return to normal bowel function whilst still hospitalised

**Stressors**
1. Opioid use
2. Anaesthetic administration
3. Altered diet and fluid intake
4. Decreased mobility

**Flexible Line of Defence**

**Normal Line of Defence**

**Lines of Resistance**

**Post operative arthroplasty**

**Tertiary Prevention**
1. Education re ongoing risk of constipation related to opioid analgesia post discharge
2. Recommend Movicol® after discharge as required

**Outcome (Reaction)**
Maintain normal bowel function post discharge whilst still using opiate analgesia

**Intra**

**Inter**

**Extra**

**Personal factors**
The *lines of resistance* surrounding the patient represent interventions which aimed to protect against stressors and maintain a healthy existence. In this study, examples of such nursing interventions included encouraging early mobilisation, ensuring privacy for toileting, decreasing or ceasing constipation-causing medications (where appropriate) and administering aperients as per the Murdoch Bowel Protocol.

The *normal line of defence* represents the patient’s normal state of wellness which is considered dynamic because of the way it changes over time. The normal line of defence is influenced by many factors including coping mechanisms, lifestyle factors, developmental, spiritual and cultural influences (Ume-Nwagbo, DeWan, & Lowry, 2006). The *flexible line of defence* moves both towards and away from the normal line of defence and serves as a protective buffer. In this study examples of stressors which may have compromised the flexible line of defence included the administration of an anaesthetic agent and opioid medications, altered diet and fluid intake and reduced mobility. These factors served to draw the flexible line of defence closer to the normal line of defence providing reduced protection against stressors.

Neuman proposed that nurses ‘enter into the patient’s world’ to promote stability and balance (Ume-Nwagbo, et al., 2006) while the NSM emphasises primary, secondary and tertiary prevention as key concepts (Memmott, et al., 2000).

In this study, primary level interventions which aimed to strengthen the flexible line of defence and reduce risk factors included:
• maintaining a high fibre diet;
• ensuring adequate fluid intake;
• ensuring private toilet facilities;
• ensuring daily monitoring of bowel habits to identify early signs of constipation; and
• ensuring adequate analgesia to encourage early mobilisation and resumption of normal activities.

At a secondary level, interventions which aimed to restore the patient to a state of equilibrium by treating symptoms which occurred after the line of defence was penetrated included:

• early identification of constipation; and
• bowel management as per the Murdoch Bowel Protocol®.

At a tertiary level interventions which aimed to support and educate the patient so that they could readapt and resume wellness included:

• providing education about the ongoing risk of constipation associated with opioid medication post discharge; and
• ensuring continued use of Movicol® as required post discharge.

Whilst working collaboratively with the patient to ensure a successful return to wellness, it was important that nurses assessed each of the five variables: physiological, psychological, sociocultural, developmental and spiritual to ensure targeted, holistic nursing care which would achieve the best possible patient outcome. ‘One size’ does not fit all patients thus primary, secondary and tertiary interventions needed to be tailored to each patient’s individual lifestyle and circumstances.
Summary of the Chapter

This chapter has provided an overview of the Neuman Systems Model, a theoretical framework for explaining and supporting the study hypothesis that opioid related post operative constipation may be prevented or treated with primary, secondary and tertiary prevention measures.

The framework supported the hypothesis for the study: that patients who undergo a knee or hip replacement and receive the study bowel protocol will experience a statistically significant reduction in time taken to return to normal bowel function compared with patients who receive standard bowel management.
Chapter 4 - Method

In this chapter the methods and procedures used to conduct the study will be discussed. The following sections will be presented: design, sample, setting, instruments and materials, training of research assistants, procedure and ethical considerations.

Design

It was not possible to conduct a randomised controlled trial (RCT) at a single hospital due to the significant risk of data contamination and confusion if patients were randomised to either a control or intervention group. For that reason a cluster randomised trial, a legitimate form of RCT, was conducted with the seven participating hospitals randomly assigned as either control or intervention hospitals. Whilst St John of God Health Care operates 15 hospitals across Australia and New Zealand only surgical hospitals who undertake major joint replacement surgery were invited to participate. Randomisation was controlled by the study’s biostatistician with each hospital having an equal chance of being selected into either group. St John of God (SJG) hospitals in Ballarat, Bendigo, Warrnambool, Geelong (all in regional Victoria) and Bunbury (regional Western Australia) were randomised as control hospitals while SJG Berwick (outer Melbourne) and Subiaco (suburban Perth) were randomised as intervention hospitals.

Inpatient recording of stool type was recorded by registered or enrolled nursing staff from the orthopaedic ward at each hospital. This was done to ensure that the researcher was blinded to and independent of the data collection.
Patients at control hospitals received post operative bowel management as per the usual regime for their doctor or hospital. Patients at intervention hospitals received post operative bowel management as per the study protocol. The independent variable was the type of bowel protocol and the dependent variable was time taken to return to normal bowel function post operatively, described as a score of three or four on the Bristol Stool Chart. Figure 4.1 shows a flowchart of the study design. The numbers of participants are presented and discussed later in the chapter. The study CONSORT diagram will be presented in chapter five.
Seven participating hospitals randomised as either control or intervention sites

Patients suitable for possible inclusion assessed at pre-admission clinic (total hip and total knee and replacements)

Informed written consent obtained from suitable patients

Baseline demographic data obtained (age, gender, operation, use of constipating drugs pre-operatively, baseline bowel assessment)

All patients had information recorded by ward based RN or EN about duration of pre-operative fasting, time of commencement of solid food and date and time first mobilised

Bristol Stool Chart type recorded at 1000 hrs daily for all patients

Control hospitals
Aperients as per hospital or doctor’s individual regime

Telephone follow-up one week post discharge

Returned to normal bowel function?

Not yet returned to normal bowel function?

No further follow up

Final follow up phone call one week later

Intervention hospitals
Aperients as per intervention protocol
Setting

St John of God Health Care is the third largest private health care operator in Australia and the largest not-for-profit health care group in Australia.

The study took place on the orthopaedic wards of the following St John of God hospitals in Victoria and Western Australia.

- St John of God Subiaco Hospital, a 548 bed hospital in the western suburbs of Perth, Western Australia which undertakes approximately 120 joint replacements per month;
- St John of God Bunbury Hospital, a 126 bed hospital located in regional Western Australia which undertakes approximately 50 joint replacements per month;
- St John of God Berwick Hospital, a 70 bed hospital located in the outer eastern suburbs of Melbourne which undertakes approximately five joint replacements per month;
- St John of God Geelong Hospital, a 184 bed hospital located in regional Victoria which undertakes approximately 40 joint replacements per month;
- St John of God Bendigo Hospital, a 117 bed hospital located in regional Victoria which undertakes approximately 50 joint replacements per month;
- St John of God Ballarat Hospital, a 194 bed hospital located in regional Victoria which undertakes approximately 50 joint replacements per month;
- St John of God Warrnambool Hospital, a 74 bed hospital located in regional Victoria which undertakes approximately five joint replacements per month.
Due to the diverse patient populations between these small regional and large metropolitan hospitals, it was felt the patient cohort provided a sufficiently broad and representative sample of patients undergoing major joint replacement. For this reason no other hospitals were considered for inclusion in the cluster samples.

**Sample**

Prior data from a small pilot study ($n = 12$) conducted at the researcher’s hospital was used to assist with calculating the sample size. Sample size calculation found that 97 control and 97 intervention patients needed to be recruited into the study to be able to reject the null hypothesis, that the intervention and control survival curves are equal with probability (power) of 80%. The type 1 error probability associated with this test of the null hypothesis was 0.05 (Dupont & Plummer, 1998). Difference in variance is known as the variance inflation factor (VIF): $1 + (k-1)\times ICC$, where $k$ = number of members in each cluster and ICC = degree of resemblance between members of the same cluster. For our calculation, $k = 50$ and ICC = 0.1 (our ICC value is similar to published ICC values (Smeeth & Ng, 2002) hence the VIF is 1.5 (Donner, Birkett, & Buck, 1981; Donner & Klar, 2000) meaning 146 experimental subjects and 146 control subjects were required (Donner, Birkett, & Buck, 1981; Donner & Klar, 2000). As a contingency to account for drop-outs a minimum of 160 patients in each arm were recruited. The loss of statistical efficiency for this design is justified as it reduced experimental contamination, (as individual hospitals have different post operative bowel protocols) and it avoids potential logistical or methodological problems. Proportional sampling provided the minimum proportion of patients to be recruited from each participating hospital (based on the average number of major joint replacement operations conducted monthly). This information is summarised in Table 4.1.
### Table 4.1

*Pre-Study Estimation of Minimum Proportion of Patients Required for Sampling*

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Approximate number of joint replacements per month</th>
<th>Minimum number to be recruited</th>
<th>Expected proportion %</th>
<th>Randomised group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berwick</td>
<td>5</td>
<td>5</td>
<td>1.56</td>
<td>Intervention</td>
</tr>
<tr>
<td>Subiaco</td>
<td>120</td>
<td>151</td>
<td>47.04</td>
<td>Intervention</td>
</tr>
<tr>
<td><strong>Total Intervention</strong></td>
<td><strong>125</strong></td>
<td><strong>156</strong></td>
<td><strong>48.60</strong></td>
<td></td>
</tr>
<tr>
<td>Ballarat</td>
<td>50</td>
<td>47</td>
<td>14.64</td>
<td>Control</td>
</tr>
<tr>
<td>Bendigo</td>
<td>40</td>
<td>38</td>
<td>11.84</td>
<td>Control</td>
</tr>
<tr>
<td>Geelong</td>
<td>50</td>
<td>47</td>
<td>14.64</td>
<td>Control</td>
</tr>
<tr>
<td>Warrnambool</td>
<td>5</td>
<td>5</td>
<td>1.56</td>
<td>Control</td>
</tr>
<tr>
<td>Bunbury</td>
<td>30</td>
<td>28</td>
<td>8.72</td>
<td>Control</td>
</tr>
<tr>
<td><strong>Total Control</strong></td>
<td><strong>175</strong></td>
<td><strong>165</strong></td>
<td><strong>51.40</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Expected Total</strong></td>
<td><strong>300</strong></td>
<td><strong>321</strong></td>
<td><strong>100.00</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Table 4.2

*Actual Proportion of Patients Sampled from Each Participating Hospital*

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Expected</th>
<th>Actual</th>
<th>Actual proportion %</th>
<th>Randomised group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berwick</td>
<td>5</td>
<td>5</td>
<td>1.51</td>
<td>Intervention</td>
</tr>
<tr>
<td>Subiaco</td>
<td>151</td>
<td>155</td>
<td>46.84</td>
<td>Intervention</td>
</tr>
<tr>
<td><strong>Total Intervention</strong></td>
<td><strong>156</strong></td>
<td><strong>160</strong></td>
<td><strong>48.35</strong></td>
<td></td>
</tr>
<tr>
<td>Ballarat</td>
<td>47</td>
<td>49</td>
<td>14.80</td>
<td>Control</td>
</tr>
<tr>
<td>Bendigo</td>
<td>38</td>
<td>38</td>
<td>11.48</td>
<td>Control</td>
</tr>
<tr>
<td>Geelong</td>
<td>47</td>
<td>49</td>
<td>14.80</td>
<td>Control</td>
</tr>
<tr>
<td>Warrnambool</td>
<td>5</td>
<td>5</td>
<td>1.51</td>
<td>Control</td>
</tr>
<tr>
<td>Bunbury</td>
<td>28</td>
<td>30</td>
<td>9.06</td>
<td>Control</td>
</tr>
<tr>
<td><strong>Total Control</strong></td>
<td><strong>165</strong></td>
<td><strong>171</strong></td>
<td><strong>51.65</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Sampled Totals** | 321 | 331 | 100.00
Table 4.3

*Final Number of Patients Analysed*

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Recruited</th>
<th>Used</th>
<th>Used proportion %</th>
<th>Randomised group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berwick</td>
<td>5</td>
<td>5</td>
<td>1.51</td>
<td>Intervention</td>
</tr>
<tr>
<td>Subiaco</td>
<td>206</td>
<td>155</td>
<td>46.84</td>
<td>Intervention</td>
</tr>
<tr>
<td><strong>Total Intervention</strong></td>
<td><strong>211</strong></td>
<td><strong>160</strong></td>
<td><strong>48.35</strong></td>
<td></td>
</tr>
<tr>
<td>Ballarat</td>
<td>49</td>
<td>49</td>
<td>14.80</td>
<td>Control</td>
</tr>
<tr>
<td>Bendigo</td>
<td>38</td>
<td>38</td>
<td>11.48</td>
<td>Control</td>
</tr>
<tr>
<td>Geelong</td>
<td>49</td>
<td>49</td>
<td>14.80</td>
<td>Control</td>
</tr>
<tr>
<td>Warrnambool</td>
<td>5</td>
<td>5</td>
<td>1.51</td>
<td>Control</td>
</tr>
<tr>
<td>Bunbury</td>
<td>30</td>
<td>30</td>
<td>9.06</td>
<td>Control</td>
</tr>
<tr>
<td><strong>Total Control</strong></td>
<td><strong>171</strong></td>
<td><strong>171</strong></td>
<td><strong>51.65</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>382</strong></td>
<td><strong>331</strong></td>
<td><strong>100.00</strong></td>
<td></td>
</tr>
</tbody>
</table>

The numbers of major joint replacement surgery at each of the participating hospital was known to vary significantly from approximately five per month in Berwick and Warrnambool to 120 per month in Subiaco. The variation which occurred as a result of the sampling strategy was controlled for during the analysis.

All orthopaedic surgeons at the participating hospitals were contacted by letter (Appendix C) and asked to give written permission for their major joint replacement patients (total knee, total hip and total shoulder replacement) to be approached regarding recruitment into this study. Once written permission and Human Research Ethics Approval (HREC) had been obtained patients deemed eligible were approached by a registered nurse at the pre-admission clinic of each hospital. Inclusion criteria are listed below:
• aged over 18 years;
• able to read and understand English;
• admitted for elective hip, knee or shoulder replacement;
• normal bowel function prior to admission; and
• able to give written informed consent.

The following excluded the patient from recruitment into the study:

• unable to read and understand English;
• patients who were confused and disorientated;
• history of ulcerative colitis, Crohn’s disease, intestinal obstruction or perforation, toxic megacolon; or
• Pregnant or breastfeeding.

Table 4.4 details the sampling procedure used across all participating hospitals.
### Table 4.4

**Summary of Sampling Procedure**

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Dates of recruitment</th>
<th>Minimum number required</th>
<th>Actual number recruited</th>
<th>Eligible patients approached</th>
<th>Number of withdrawals</th>
<th>Reasons for withdrawal</th>
<th>Number declined</th>
<th>Reasons for declining</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subiaco</td>
<td>August 2011-March 2012</td>
<td>151</td>
<td>206</td>
<td>249</td>
<td>0</td>
<td>n/a</td>
<td>43</td>
<td>Not specified (n=39)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Worried about diabetes (n=1) Continence issues (n=1) Didn’t want any follow up (n=1) Prefer to continue current laxative regime (n=1)</td>
</tr>
<tr>
<td>Berwick</td>
<td>April 2011-June 2011</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>n/a</td>
<td>0</td>
<td>n/a</td>
</tr>
<tr>
<td>Location</td>
<td>Dates</td>
<td>47</td>
<td>49</td>
<td>58</td>
<td>0</td>
<td>n/a</td>
<td>9</td>
<td>Required post operative rehabilitation (n=9)</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>---</td>
<td>-----</td>
<td>---</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Ballarat</td>
<td>April 2011-August 2011</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bendigo</td>
<td>May 2011-June 2011</td>
<td>38</td>
<td>38</td>
<td>38</td>
<td>0</td>
<td>n/a</td>
<td>0</td>
<td>n/a</td>
</tr>
<tr>
<td>Warrnambool</td>
<td>May 2011-July 2011</td>
<td>5</td>
<td>5</td>
<td>7</td>
<td>0</td>
<td>n/a</td>
<td>2</td>
<td>Not specified (n=2)</td>
</tr>
<tr>
<td>Geelong</td>
<td>May 2011-August 2011</td>
<td>47</td>
<td>49</td>
<td>63</td>
<td>0</td>
<td>0</td>
<td>10</td>
<td>Required post operative rehabilitation (n=10)</td>
</tr>
<tr>
<td>Bunbury</td>
<td>June 2011-July 2011</td>
<td>28</td>
<td>30</td>
<td>42</td>
<td>0</td>
<td>n/a</td>
<td>12</td>
<td>Not specified (n=12)</td>
</tr>
</tbody>
</table>
Instruments and Materials

1. The Bristol Stool Chart (Appendix A) was used by patients each morning to self-assess their stool type and number and report this information to their nurse. Patients at control hospitals were then administered aperients as per their doctor or hospital’s standard protocol while patients at intervention hospitals received aperients as per the treatment protocol. The face and content validity of the protocol was previously assessed by physicians, orthopaedic surgeons, orthopaedic nursing staff, a clinical dietician and continence nurse specialist who all agreed the protocol would enable standardised recording of stool type and provided clear guidelines for aperients at intervention hospitals.

2. The Data Collection Form (Appendix D) comprised three parts. Part 1 was used by the pre-admission clinic registered nursing staff to collect pre-operative demographic data and screen for exclusion criteria which would exclude the patient from the study. In addition, patients were asked about their use of calcium channel blockers, tricyclic antidepressants and any opiate-based medication, all of which are associated with an increased risk of constipation. A baseline bowel assessment was also completed at this time and included information about baseline Bristol Stool Chart type, stool frequency per week and use of laxatives. Part 2 was completed by a registered nurse on the orthopaedic ward and included information about length of pre-operative fasting, duration of intravenous fluids and the time of commencement of solid food. Part 3 was used to record follow-up information approximately one week after discharge. The patient was contacted by telephone and asked about analgesia and laxative use post discharge and whether he/she had experienced any constipation since returning home.
3. Control Hospitals recorded Bristol Stool Chart type at 1000 hr each day and recorded this on the Control Hospital Stool Recording Chart (Appendix E);

4. Intervention Hospitals recorded Bristol Stool Chart type at 1000 hr each day and recorded this on the Intervention Hospital Stool Recording and Medication Administration Chart (Appendix F). In addition this chart provided space for nurses to sign for the administration of aperients as per the protocol.

5. The treatment protocol was based on the administration of polyethylene glycol (PEG) with electrolytes, marketed in Australia as Movicol®. Movicol® is an inert, iso-osmotic laxative that works by attracting water into the bowel via its high osmotic pressure. This water then acts as both a stool bulking and softening agent, which aids defaecation (Belsey, Geraint, & Dixon, 2010).

**Data Collection**

Prior to the study commencement each hospital nominated a study liaison nurse. This nurse assisted with data collection, acted as a liaison between each hospital and the researcher and was a resource for ward nursing staff with any questions about the study.

**Training**

A site visit to each participating hospital was undertaken by the researcher prior to the study commencement. The purpose of this visit was to provide training for the study liaison nurse, pre-admission clinic nurses and ward nursing staff and encompassed the following:

- provision of comprehensive education about the background to the study and its aims;
• detailed education regarding the process of patient recruitment i.e. how to identify potential patient participants, as well as the inclusion and exclusion criteria;
• obtaining informed consent from suitable patients; and
• processes to ensure the accurate data collection, patient privacy and the secure storage of data.

It was also necessary to provide consistent education to ward nursing staff at the intervention hospitals as these nurses were responsible for administering aperients in accordance with the protocol. Education provided to the ward nursing staff on the first pre-study site visit included background to the study, inclusion and exclusion criteria, familiarisation with the bowel protocol, contraindications to the administration of any of the medications (e.g. recent bowel surgery or an active bowel inflammatory disease) and the documentation required to be completed for the study. Due to the nature of shift work those nurses unable to attend this education session were provided with a Caregiver Information Sheet (Appendix G).

A second visit was made to several participating Victorian hospitals midway through the data collection process. Not all sites were visited as those recruiting small numbers of patients (Berwick and Warrnambool) had completed their data collection by this time. This second visit was undertaken to ensure that accurate data was being collected. This was ensured by reviewing a random selection of patient records against the Data Collection Form by two nurses independent of the data collection. The visit was also used to answer any questions which may have arisen. Frequent visits were made to St John of God Hospital Subiaco as this was the site required to recruit the largest number of patients.
Procedure

Patients were recruited to this study over a thirteen month period from May 2011 to May 2012. Recruitment commenced at Berwick, Warrnambool, Bendigo, Ballarat and Geelong in May and June 2011, at Bunbury in July 2011 and at Subiaco in August 2011. Data were collected in three phases:

1. Pre-admission Clinic

Patients were recruited at the pre-admission clinic (PAC) of each hospital after being identified as possibly suitable for inclusion from the operation list for that week. Patients were approached by a registered nurse and given a copy of the control or intervention hospital Patient Information Letter (Appendix H) as well as the opportunity to ask any questions about the study. This opportunity was also used to exclude any patient with a history of ulcerative colitis, toxic megacolon or bowel perforation, or who was pregnant or breastfeeding. The presence of a colostomy in itself was not a reason for exclusion. Those patients who agreed to participate were asked to sign the Patient Consent Form (Appendix I). Once informed, written consent was received baseline demographic data was obtained from both the patient’s hospital identification label (name, age, gender,) and direct patient questioning (type of operation being undertaken, use of tricyclics antidepressants, calcium channel blockers or opiate based medication). In addition, a baseline bowel assessment was documented (baseline BSC number, usual stool frequency per week and current use of laxatives).

2. Orthopaedic Ward

The study liaison nurse was responsible for ensuring the data of all patients recruited in the PAC was taken to the ward ready for patient admission. Once admitted to the orthopaedic ward patients recruited into the study were identified by the inclusion of a laminated Bristol Stool Chart (BSC) and
either a control or intervention hospital stool recording form in their end of
bed documentation folder. Registered or enrolled nursing staff began
recording BSC number at 1000 hrs daily from day one post operatively. This
time was chosen as during the inpatient stay frequency of observations
usually decreases as the patient moves towards discharge. However all
patients continued to have at least daily observations which were usually
recorded around 1000 hrs. At this time the patient was asked to report their
BSC number for the previous 24 hours as per the laminated BSC which was
either fixed to the wall above the patient’s toilet or kept in the end of bed
documentation folder. As the nursing staff recorded BSC type as identified
and reported by the patient using the BSC, no interpretation of stool type
was required. Nursing staff at control hospitals were asked to administer
aperients as per their hospital or ward protocol or as directed by the patient’s
doctor. Patients at intervention hospitals received bowel management as per
the protocol which was dependent on both their BSC type and post operative
day. The nurse was required to sign for the aperients that had been
administered on both the inpatient medication chart and the stool recording
chart. Patients had the option to refuse any protocol intervention and
nursing staff could also withhold the aperients if deemed necessary but
record the reason why in the administration signing box.

3. Phone Follow up After Discharge
All patients were followed up by telephone approximately one week after
discharge by the study liaison nurse at each hospital. This call was made to
record information about analgesia and laxative use since discharge, whether
the patient had suffered with constipation since discharge and had they not
returned to normal bowel function on discharge, whether they had at the
time of the follow up phone call. For those patients who had not returned to
normal bowel function at the first follow up phone call, a second phone call
was made two weeks after discharge seeking the same information. Follow up did not extend beyond this time.

**Interrater Variability**

Data were collected at three time points: pre-admission clinic; during the inpatient stay and post discharge by phone call. The use of data collection nurses at each hospital (N = 7) meant the issue of interrater variability needed to be addressed. Described as the degree to which two or more independent observers agree on what they are coding or scoring (Polit & Beck, 2012) interrater (or interobserver) variability is an important part of ensuring the rigor of any study. Traditional test-retest reliability was not used in this study due to the diverse geographical distribution of the hospitals and nurses recording patient self-reported information or transcribing data from fluid balance or observation charts. Whilst Polit and Beck (2012) believe that careful training and the use of clear categories and tools does much to ensure consistency between observers, the measurement and recording of such patient data is a core part of basic nursing practice and as such it was not felt that specialised education in the act of transcribing information was required.

As previously discussed, initial education and training was carried out at each site for ward nursing staff, the study liaison nurse and PAC nursing staff. As all ward nursing staff were unable to be present at these education sessions Caregiver Information Sheet (Appendix G) was distributed to all nursing staff working on every orthopaedic ward included in the study. This sheet detailed the background to the study and what information needed to be collected. All sheets gave information consistent with either control or intervention hospitals. The study liaison nurse at each hospital was trained by the researcher and acted as a resource to answer questions to ensure a
consistent approach to data collection. In addition the researcher was available by email and visited each hospital midway throughout the data collection phase to ensure that any questions or problems were addressed promptly and that data collection was entered correctly and consistently between sites.

Data Analysis

Analysis between control and intervention hospitals.

An independent samples t test was used to test for differences between normally distributed continuous variables. The chi-square was used to test for differences between categorical variables. Where any cells had an expected count of less than five, Fishers Exact Probability Test was used. Logistic regression was undertaken to assess the effect of age, gender, group (control or intervention), the length of pre-operative fasting, anaesthetic type, operation type and length of stay on the binary variable, normal bowel function at discharge (set at five days). Five days was chosen because it was the median length of stay for all hospitals except Berwick (median length of stay four days) and Subiaco (median length of stay seven days). Although Subiaco’s length of stay was longer than other study hospitals, senior management staff conceded their length of stay was longer than usual. Age, gender and hydration status (measured as hours of pre-operative fasting) were modelled because they were frequently reported in the literature as being relevant to the development of post operative constipation. Length of stay was also modelled as the hospital environment does not allow the patient to eat and drink as they normally would at home, neither does it provide opportunities to return to normal tasks and increase mobility or necessarily provide optimum toileting facilities (i.e. privacy). Anaesthetic type was also modelled as the difference in anaesthetic types between groups.
was significant and it was unclear whether this was a contributing factor in the development of post operative constipation.

The generalised linear model was used to assess the effect of age, gender, group (control or intervention), length of pre-operative fasting, anaesthetic type, operation type and length of stay on the continuous variable *days to normal bowel function*.

As previously discussed total shoulder replacements were excluded from both the logistic regression and linear mixed model analysis (*n* = 3) due to the small numbers and as including them caused convergence difficulties and spurious results. Convergence occurs when an extreme value occurs on the frequency distribution of either the dependent or independent variables which prevents coefficients from converging (Allison, 2008). It is more likely to occur when the sample size is small, as was the case for total shoulder replacements in this study. Biostatistical advice was that due to the very small number of these operations (*n* = 3) removing them would have no impact on the final results. Consequently the original hypothesis was amended to reflect this change in the study population.

As this was a cluster randomised trial, the generalised linear mixed model was used to test for cluster effects between control and intervention hospitals with results confirming that clustering had no effect on outcomes.

**Ethical Considerations**

Approval for the study was gained from the University of Notre Dame Australia (UNDA) Human Research Ethics Committee (HREC) on 13 December 2010 (approval number 010145F) (Appendix J) and the St John of God HREC on 9 December 2010 (approval number 449) (Appendix K).
addition the study was submitted to the Australian and New Zealand Clinical Trials Registry on 1 December 2011 with approval granted on 4 January 2012. The Universal Trial Number is U1111-1126-0176 (Appendix L) and registration number 1261200014853.

In total 206 patients were recruited from the largest intervention hospital between August 2011 and May 2012. At data entry stage it was noted that a significant amount of inpatient data was either missing or incomplete from the first 51 patients recruited at this site. A decision was made to suspend patient recruitment and further data collection at that stage as continuing was considered unethical and would significantly compromise the rigor of the intended study. A meeting with the Director of Nursing and other significant stakeholders was held and it was agreed that a currently employed orthopaedic registered nurse should be recruited to assist with ensuring complete and accurate data collection across the two orthopaedic wards. For consistency, as it was agreed to be a paid position, all Directors of Nursing (DoN) at other participating hospitals were contacted and an offer of payment was made for the hours required to collect data at their divisions. None of the DoNs requested back payment and were happy to absorb the cost of data collection within their own hospital. This measure was taken to ensure continuity and integrity of data collection and was not envisaged at the time of the original ethics proposal. Hence, a subsequent amendment detailing this requirement was forwarded in writing to both HRECs with approval from SJGH HREC received on 7 December 2011 (Appendix M) and UNDA HREC on 15 December 2011 (Appendix N).

Written, informed consent was obtained from patients prior to entry into the study. Patients who did consent for inclusion were given a copy of the Patient Information Letter (Appendix H) to keep. This sheet provided the
telephone contact details of both the principal researcher and the UNDA HREC should the patient have any questions about the study after being consented.

There were no perceived risks to patients in either control or intervention groups with the administration of aperients being a standard part of post operative bowel care. Advice from both participating control and intervention hospitals was that current post-operative orthopaedic bowel management was ad hoc with no consistent or routine approach across any of the hospitals. Consequently patients in the control group continued to receive ad hoc bowel care according to their own personal preference or the preference of their doctor or nurse. Patients in the intervention group received Movicol®️, an aperient available over-the-counter at both supermarkets and pharmacies in Australia. Multiple factors influence the scheduling of medications in Australia including potential for abuse, need for the substance, purpose of use and the inherent safety of the medication. Mediations are classified in nine Schedules according to the degree of control required over their availability with progression through the Schedules signifying increased control (Australian Government, 2008; Therapeutic Goods Administration, 2008). Movicol®️ is non-scheduled meaning that it is considered very safe (National Health and Medical Research Council, 1997). Patient confidentiality was ensured by number coding participants in the database. The database itself is password protected and accessible only by the principal researcher. All hard copy data collected as part of the study is being kept in a locked filing cabinet for five years from the date of publication as stipulated by section 2.1 of the Australian Code for the Responsible Conduct of Research (National Health and Medical Research Council, 1997).
Chapter 5 - Results

This chapter will describe the statistical techniques applied to the data for this study. The results will then be presented.

Data Analysis

The data were analysed using univariate and multivariate statistical techniques within the Statistical Package for the Social Sciences (SPSS) Version 20. Analyses were two-tailed with the significance level set at 0.05 for all tests. As recommended by Gore (1981), exact $p$ values have been quoted in tables throughout this chapter to enable the reader to interpret the closeness of the decisions.

As previously described in Chapter 4, five hospitals were designated as control sites and two hospitals were designated as intervention sites. Of the two intervention sites, one was allocated to recruit a minimum of five patients and the other allocated to recruit a minimum of 151 patients. As previously discussed in Ethical Considerations (page 91), soon after recruitment began at the second and largest intervention site, it was noted that a significant amount of critical inpatient and follow-up data (i.e. recording of Bristol Stool Chart type for each inpatient day, Movicol® administration, and recording of return to normal bowel function post discharge) was either missing or largely incomplete from the first 51 patients recruited. As discussed previously, it was felt that continuation would be unethical and would significantly compromise the rigor of the study. Hence the decision was made to suspend patient recruitment and further data collection until a strategy could be implemented to ensure more stringent data collection in accordance with the study protocol. Data from these patients was excluded from the final analysis.
In view of this unforeseen event, it was necessary to compare the cases of incomplete data with cases of complete data to demonstrate that all cases were drawn from the same population. Baseline data that was normally distributed was assessed using an independent samples t test. When the data was not normally distributed a Mann-Whitney U test was used. Categorical variables were analysed using a Chi square and where cells had less than five the Fishers Exact Test was used. Logistic regression was undertaken to assess the effect of age, gender, group (control or intervention), anaesthetic type, operation type, length of pre operative fasting and length of stay on the binary variable, *normal bowel function at discharge* (set at day five). The generalised linear model was used assess the effect of age, gender, group, length of pre-operative fasting, anaesthetic type, operation type and length of stay on the continuous variable *days to normal bowel function*.

Missing data was minimal and estimated not to exceed 1-1.5% of the total data volume.

In an attempt to improve the reporting of randomised controlled trials (RCT) a group of scientists and editors developed the CONSORT (Consolidated Standards of Reporting Trials) statement (Altman et al., 2001). The CONSORT statement consists of a checklist and a diagram which documents the flow of participants through a trial. The diagram requires the researcher to report on patient numbers for enrolment, allocation to groups, follow-up and analysis allowing the reader to easily understand patient flow through the study. Figure 5.1 shows the CONSORT diagram for this study.
Figure 5.1

CONSORT Diagram

Assessed for eligibility ($n=458$)

Excluded ($n=76$)
- Declined to participate ($n=57$)
- Ineligible as booked for rehabilitation ($n=19$)

Randomised (N=382)

Allocated to control ($n=171$)
- Received control intervention ($n=171$)
- Did not receive control intervention ($n=0$)

Allocated to intervention ($n=211$)
- Received treatment intervention ($n=211$)
- Did not receive treatment intervention ($n=0$)

Lost to follow up ($n=0$)
Discontinued intervention ($n=0$)

Analysed ($n=171$)
- Excluded from analysis ($n=0$)

Preliminary analysis ($n=211$)
- Excluded from analysis as largely incomplete ($n=51$)
- Analysed ($n=160$)
Baseline comparison of complete and incomplete cases.

Table 5.1 shows the baseline comparison of complete and incomplete cases. None of the variables showed statistically significant differences indicating there was no difference between these groups.

Table 5.1
Comparison of Baseline Variables for Incomplete and Complete Cases

<table>
<thead>
<tr>
<th>Variable</th>
<th>Incomplete cases</th>
<th>Complete cases</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n = 51$</td>
<td>$n = 331$</td>
<td></td>
</tr>
<tr>
<td>Age$^*$</td>
<td>68.18 (7.16)</td>
<td>66.29 (9.50)</td>
<td>0.175</td>
</tr>
<tr>
<td>Baseline BSC type$^*$</td>
<td>3.55 (0.67)</td>
<td>3.72 (1.01)</td>
<td>0.252</td>
</tr>
<tr>
<td>Gender$^*$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>27 (52.90)</td>
<td>154 (46.50)</td>
<td>0.393</td>
</tr>
<tr>
<td>female</td>
<td>24 (47.10)</td>
<td>177 (53.50)</td>
<td></td>
</tr>
<tr>
<td>Frequency of bowel actions per week$^*$</td>
<td>7.53 (2.62)</td>
<td>7.67 (3.25)</td>
<td>0.768</td>
</tr>
<tr>
<td>Hours of pre-operative fasting$^*$</td>
<td>11.5 (5.22)</td>
<td>10.37 (4.09)</td>
<td>0.086</td>
</tr>
<tr>
<td>Pre-operative use opioids$^*$</td>
<td>4 (7.80)</td>
<td>15 (4.50)</td>
<td>0.300</td>
</tr>
<tr>
<td>Pre-operative use calcium channel blockers$^*$</td>
<td>4 (7.80)</td>
<td>17 (5.10)</td>
<td>0.504</td>
</tr>
<tr>
<td>Pre-operative use laxatives$^*$</td>
<td>8 (16.0)</td>
<td>58 (17.00)</td>
<td>0.777</td>
</tr>
<tr>
<td>Pre-operative use tricyclic antidepressants$^*$</td>
<td>2 (3.90)</td>
<td>15 (4.50)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Note. $^* n$ (%), $^* M$ (SD)

As demonstrated in Table 5.1 there was no statistically significant difference on any measure between patients whose data was incomplete and complete.
Further analysis centres on the 331 patients in the dataset of all complete cases.

**Baseline comparison of control and intervention group variables.**

A baseline comparison of both the control and intervention groups was undertaken with the results shown in Table 5.2. Statistically significant differences were found in three variables: gender \((p = 0.004)\); length of pre-operative fasting (in hours) \((p = 0.003)\) and anaesthetic type \((p = 0.000)\). As 155 of the 160 intervention patients were from a single hospital site it is likely that both the length of pre-operative fasting and anaesthetic type reflect both hospital policy and/or procedure or doctors preferences. Regional anaesthesia was the most commonly performed anaesthetic type at control hospitals with 63.2% \((n = 108)\) of patients receiving it compared with 6.9% \((n = 11)\) at the two intervention hospitals. Similarly, general anaesthesia was most commonly performed at the two intervention hospitals with 81.2% \((n = 130)\) of patients receiving it compared with 22.2% \((n = 38)\) of patients at the five control hospitals. Similar numbers of patients received combined regional and general anaesthesia at both hospital groups: control 14.6% \((n = 25)\) versus 11.9% \((n = 19)\) at intervention hospitals.

Gender differences between hospital groups are harder to explain. Significantly higher numbers of male patients received joint replacement surgery at control hospitals (54.4% versus 38.1%) and significantly higher numbers of female patients received joint replacement surgery at intervention hospitals (61.9% versus 45.6%). No plausible explanation can be offered for these differences in gender frequency.
Table 5.2

*Baseline Comparison of Control and Intervention Group Variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>Intervention</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( n = 171 )</td>
<td>( n = 160 )</td>
<td></td>
</tr>
<tr>
<td>Age(^+)</td>
<td>65.64 (10.1)</td>
<td>66.99 (8.9)</td>
<td>0.199</td>
</tr>
<tr>
<td>Baseline BSC type(^+)</td>
<td>3.71 (0.9)</td>
<td>3.72 (1.1)</td>
<td>0.962</td>
</tr>
<tr>
<td>Gender(^*)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>93 (54.4)</td>
<td>61 (38.1)</td>
<td>0.004</td>
</tr>
<tr>
<td>female</td>
<td>78 (45.6)</td>
<td>99 (61.9)</td>
<td></td>
</tr>
<tr>
<td>Pre-operative use of opioids(^\ast)</td>
<td>10 (5.8)</td>
<td>5 (3.1)</td>
<td>0.234</td>
</tr>
<tr>
<td>Pre-operative use of calcium channel blockers(^\ast)</td>
<td>11 (6.4)</td>
<td>6 (3.8)</td>
<td>0.269</td>
</tr>
<tr>
<td>Pre-operative use of tricyclic antidepressants(^\ast)</td>
<td>9 (5.3)</td>
<td>6 (3.8)</td>
<td>0.508</td>
</tr>
<tr>
<td>Pre-operative use of laxatives(^\ast)</td>
<td>25 (14.7)</td>
<td>33 (20.9)</td>
<td>0.143</td>
</tr>
<tr>
<td>Hours of pre-operative fasting(^+)</td>
<td>10.03 (4.3)</td>
<td>8.77 (3.2)</td>
<td>0.003</td>
</tr>
<tr>
<td>Anaesthetic type(^*)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>38 (22.2)</td>
<td>130 (81.2)</td>
<td></td>
</tr>
<tr>
<td>Regional</td>
<td>108 (63.2)</td>
<td>11 (6.9)</td>
<td>0.000</td>
</tr>
<tr>
<td>Regional and GA</td>
<td>25 (14.6)</td>
<td>19 (11.9)</td>
<td></td>
</tr>
<tr>
<td>Surgery type(^\ast)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip</td>
<td>79 (46.2)</td>
<td>78 (48.8)</td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>90 (52.6)</td>
<td>81 (50.6)</td>
<td>0.836</td>
</tr>
<tr>
<td>Shoulder</td>
<td>2 (1.2)</td>
<td>1 (0.6)</td>
<td></td>
</tr>
</tbody>
</table>

*Note.* \( n(\%) \), \( \ast M(SD) \)
**Group effect for post operative variables.**

A comparison of three post-operative variables was undertaken between control and intervention hospitals: day first mobilised; length of stay (days) and days to normal bowel function. All three results were found to be highly statistically significant ($p = 0.000$) with the results comparing control and intervention groups displayed in Table 5.3.

Day first mobilised and length of stay were measured as there was some suggestion in the literature they may be possible contributors to the development of post operative constipation. Days to normal bowel function was compared as this was the main outcome variable for the study.

Whilst the day the patients were first mobilised was statistically significant ($p = 0.000$) both groups were mobilised on day one post operatively (control 1.175 days versus 1.437 days) therefore the statistical difference was not considered clinically significant.

Length of stay was also statistically significant ($p = 0.000$) with patients in the control group staying on average 4.96 days versus 7.07 days for the intervention group. Once again it is likely that this difference is due to the large number of intervention patients coming from a single hospital site ($n = 155$) and therefore a reflection of this hospital’s procedural guidelines or doctor’s inpatient preference.

The difference between groups on the variable days to normal bowel function was also highly significant ($p = 0.000$) and the main outcome measure for this study. Control patients took a mean of 10.64 days to return to normal bowel function compared to 5.06 days for patients in intervention hospitals, a result likely due to the effect of the intervention protocol.
Table 5.3

*Overall Group Effect for Post Operative Variables*

<table>
<thead>
<tr>
<th>Post operative variables</th>
<th>Control n = 171</th>
<th>Intervention n = 160</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M(SD)</td>
<td>M(SD)</td>
<td>Mdn</td>
</tr>
<tr>
<td>M(SD)</td>
<td>Mdn</td>
<td>Mdn</td>
<td></td>
</tr>
<tr>
<td>M(SD)</td>
<td>Mdn</td>
<td>Mdn</td>
<td></td>
</tr>
<tr>
<td>M(SD)</td>
<td>Mdn</td>
<td>Mdn</td>
<td></td>
</tr>
<tr>
<td>Day first mobilised</td>
<td>1.175 (0.7)</td>
<td>1.437 (0.7)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>[1.0]</td>
<td>[1.0]</td>
<td></td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>4.96 (2.1)</td>
<td>7.07 (2.0)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>[5.0]</td>
<td>[7.0]</td>
<td></td>
</tr>
<tr>
<td>Days to normal bowel function</td>
<td>10.64 (7.0)</td>
<td>5.06 (2.0)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>[9.0]</td>
<td>[5.0]</td>
<td></td>
</tr>
</tbody>
</table>

**Comparison of days to normal between groups.**

Days to normal bowel function has been tabled cumulatively in Table 5.4. Days one to three were grouped together as most post-operative patients do not experience a bowel motion prior to this time. Days four to seven were tabled individually as this is when most change occurred between control and intervention groups. As most intervention patients had returned to normal bowel function by day seven (93.9%) days 8-14 were grouped together. By day 14, 99.5% of intervention patients had returned to normal bowel function compared with only 75.2% of control patients. Those patients who had not returned to normal bowel function by day 14 were collectively grouped together as 15+ days.
Table 5.4

**Days to Normal between Control and Intervention Groups**

<table>
<thead>
<tr>
<th>Days to normal</th>
<th>Control $n = 171$</th>
<th>Control Cumulative</th>
<th>Intervention $n = 160$</th>
<th>Intervention Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n$ ($%$)</td>
<td>%</td>
<td>$n$ ($%$)</td>
<td>%</td>
</tr>
<tr>
<td>1-3 days</td>
<td>24 (13.5)</td>
<td>13.5</td>
<td>24 (15.0)</td>
<td>15.0</td>
</tr>
<tr>
<td>4 days</td>
<td>15 (8.8)</td>
<td>22.3</td>
<td>46 (28.8)</td>
<td>43.8</td>
</tr>
<tr>
<td>5 days</td>
<td>10 (5.9)</td>
<td>28.2</td>
<td>39 (24.4)</td>
<td>68.2</td>
</tr>
<tr>
<td>6 days</td>
<td>11 (6.5)</td>
<td>34.7</td>
<td>27 (16.9)</td>
<td>85.1</td>
</tr>
<tr>
<td>7 days</td>
<td>13 (7.6)</td>
<td>42.3</td>
<td>14 (8.8)</td>
<td>93.9</td>
</tr>
<tr>
<td>8-14 days</td>
<td>56 (32.9)</td>
<td>75.2</td>
<td>9 (5.6)</td>
<td>99.5</td>
</tr>
<tr>
<td>15+ days</td>
<td>42 (24.8)</td>
<td>100.0</td>
<td>1 (0.5)</td>
<td>100.0</td>
</tr>
</tbody>
</table>

**Group effect for post discharge variables.**

Table 5.5 shows the overall group effect for the following post discharge variables: analgesia use since discharge; opioid use since discharge; non-steroidal anti-inflammatory drugs (NSAID) use since discharge; paracetamol use since discharge; constipation since discharge and laxative use since discharge.

Two variables showed statistically significant differences: use of paracetamol since discharge ($p = 0.003$) and constipation since discharge ($p = 0.000$). Of those patients in the control group 91.8% reported having taken paracetamol since discharge compared with 79.4% of intervention patients.

No significant differences were found between groups on the use of opioids ($p = 0.584$) or NSAID use ($p = 0.121$) during this time.
At follow up, 57.1% of patients in the control group reported having experienced symptoms of constipation since discharge compared with only 31.2% of intervention patients.

Of note, minimal data was missing from all but one variable; analgesia since discharge.
### Table 5.5

**Overall Group Effect for Post Discharge Variables**

<table>
<thead>
<tr>
<th>Post discharge variables</th>
<th>Control $n = 171$</th>
<th>Intervention $n = 160$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n$ (%)</td>
<td>$n$ (%)</td>
<td></td>
</tr>
<tr>
<td>Analgesia since discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>170 (99.4)</td>
<td>155 (96.9)</td>
<td>0.111</td>
</tr>
<tr>
<td>No</td>
<td>1 (0.6)</td>
<td>5 (3.1)</td>
<td></td>
</tr>
<tr>
<td>Opioids since discharge*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>143 (84.1)</td>
<td>131 (81.9)</td>
<td>0.584</td>
</tr>
<tr>
<td>No</td>
<td>26 (15.6)</td>
<td>26 (16.2)</td>
<td></td>
</tr>
<tr>
<td>NSAID since discharge*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (1.2)</td>
<td>7 (4.4)</td>
<td>0.121</td>
</tr>
<tr>
<td>No</td>
<td>167 (98.2)</td>
<td>150 (93.8)</td>
<td></td>
</tr>
<tr>
<td>Paracetamol since discharge*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>156 (91.8)</td>
<td>127 (79.4)</td>
<td>0.003</td>
</tr>
<tr>
<td>No</td>
<td>13 (7.6)</td>
<td>30 (18.8)</td>
<td></td>
</tr>
<tr>
<td>Constipation since discharge*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>97 (57.1)</td>
<td>50 (31.2)</td>
<td>0.000</td>
</tr>
<tr>
<td>No</td>
<td>73 (42.9)</td>
<td>110 (68.8)</td>
<td></td>
</tr>
<tr>
<td>Laxatives since discharge*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>74 (43.8)</td>
<td>64 (40.0)</td>
<td>0.504</td>
</tr>
<tr>
<td>No</td>
<td>95 (56.2)</td>
<td>96 (60.0)</td>
<td></td>
</tr>
</tbody>
</table>

*Note.* *missing data

**Logistic regression for normal bowel function at day five.**

Table 5.6 shows the result of the logistic regression analysis. Six independent variables were modelled: age; gender; group (control or intervention); length of pre-operative fasting; anaesthetic type (general, regional, general +
regional) and length of stay on the binary variable, normal bowel function by day five. Three variables were found to be statistically significant: allocated group \( (p = 0.000) \); regional + general anaesthetic \( (p = 0.042) \) and length of stay \( (p = 0.002) \). A significant predictor of days to normal bowel function at day five (considered normal length of stay) was being in the intervention group with an odds ratio (OR) of 7.17, 95\% CI [3.38, 15.19]. This result indicated that patients in the intervention group were seven times more likely to have returned to normal bowel function by day five compared with patients recruited at control hospitals. Those patients who received a combined general plus regional anaesthesia recorded an OR 2.46, 95\% CI [1.03, 5.85] indicating they were 2.46 times more likely to have returned to normal bowel function by day five than those who received a general anaesthetic. Length of hospital stay scored an OR 0.82, 95\% CI [0.72, 0.93] meaning that for every extra day a patient stayed in hospital they were ~20\% less likely to have returned to normal bowel function by day five.
Table 5.6

Variables Associated with Days to Normal Bowel Function at Day Five

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.02</td>
<td>0.99-1.05</td>
<td>0.145</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- female</td>
<td>1.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>- male</td>
<td>1.01</td>
<td>0.60-1.71</td>
<td>0.959</td>
</tr>
<tr>
<td>Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- control</td>
<td>1.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>- intervention</td>
<td>7.17</td>
<td>3.38-15.19</td>
<td>0.000</td>
</tr>
<tr>
<td>Length of pre operative fasting</td>
<td>1.01</td>
<td>0.94-1.08</td>
<td>0.891</td>
</tr>
<tr>
<td>Anaesthetic type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- general</td>
<td>1.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>- regional</td>
<td>0.77</td>
<td>0.38-1.59</td>
<td>0.484</td>
</tr>
<tr>
<td>- general + regional</td>
<td>2.46</td>
<td>1.03-5.85</td>
<td>0.042</td>
</tr>
<tr>
<td>Type of operation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- total hip replacement</td>
<td>1.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>- total knee replacement</td>
<td>1.02</td>
<td>0.62-1.70</td>
<td>0.939</td>
</tr>
<tr>
<td>Length of stay</td>
<td>0.82</td>
<td>0.72-0.93</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Generalised linear model for days to normal bowel function.

The generalised linear model (GLM) was used to assess the impact of the independent variables of age; gender; group (control or intervention); length of pre-operative fasting; anaesthetic type; operation type and length of stay on the dependent continuous variable, days to normal bowel function. The results are summarised in Table 5.7. The GLM is a type of regression model.
which examines fixed effects on the dependent variable (Everitt & Howell, 2008).

Table 5.7 confirms four statistically significant results. The grouping category was highly significant \( (p = 0.000) \) with a \( \beta \) coefficient of -6.155 for intervention indicating that patients in intervention groups took an average of six days less than those in control groups to return to normal bowel function. Length of stay was also highly significant \( (p = 0.000) \) with a \( \beta \) coefficient of 0.430 indicating that for each extra inpatient day, it took 0.43 days longer to return to normal bowel function. A \( \beta \) coefficient of 1.24 confirmed that patients who had a total knee replacement took 1.24 days longer to return to normal bowel function than those who underwent total hip replacement \( (p = 0.027) \). When compared with those who received general anaesthesia (GA), a \( \beta \) coefficient of -2.223 indicated that patients who received combined regional and GA took around 2 days less to return to normal bowel function when compared with those who received a GA \( (p = 0.014) \).
Table 5.7

Variables Associated with Days to Normal Bowel Function

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.26</td>
<td>0.390</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- female</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>- male</td>
<td>-0.477</td>
<td>0.410</td>
</tr>
<tr>
<td>Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- control</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>- intervention</td>
<td>-6.155</td>
<td>0.000</td>
</tr>
<tr>
<td>Length of pre operative fasting</td>
<td>0.075</td>
<td>0.330</td>
</tr>
<tr>
<td>Anaesthetic type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- general</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>- regional</td>
<td>0.672</td>
<td>0.401</td>
</tr>
<tr>
<td>- general + regional</td>
<td>-2.223</td>
<td>0.014</td>
</tr>
<tr>
<td>Type of operation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- total hip replacement</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>- total knee replacement</td>
<td>1.238</td>
<td>0.027</td>
</tr>
<tr>
<td>Length of stay</td>
<td>0.430</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Note.  b = beta coefficient - differences between means control versus intervention groups

Effect of cluster randomisation technique

Since it was not possible to use a randomised controlled trial design where patients are randomised to control or intervention groups, it was necessary to control for cluster randomisation of hospitals. The generalised linear mixed model (GLMM) was used to compare data between clusters i.e. control hospitals vs intervention hospitals on the main outcome variable days to normal bowel function. The GLMM modelled both the random and
fixed effects between control hospitals (Bendigo, Ballarat, Geelong, Bunbury and Warrnambool) and intervention hospitals (Subiaco and Berwick) and despite the small number of hospitals in each cluster, no differences were found between control and intervention cluster groups.
Chapter 6 - Discussion

The following discussion will present and explore the relevance of the major findings from this study in relation to methodological, theoretical and clinical issues. This will be followed by a discussion about the strengths and limitations of the study. The final chapter will present the conclusions from this study in addition to implications and recommendations for nursing practice, education and future research.

The principal hypothesis developed and tested in this study was that patients who undergo a knee or hip replacement and are treated with the Murdoch Bowel Protocol © (the Protocol) will experience a statistically significant reduction in time taken to return to normal bowel function compared with patients who receive standard post operative bowel management. The purpose of this study was to test the effect of the Protocol on time taken to return to normal bowel function in post major joint replacement patients. The study also sought to determine whether differences in age; gender; length of pre-operative fasting, anaesthetic type or operation type influenced the time taken to return to normal bowel function post-operatively.

Total hip and total knee replacement surgeries are two of the most commonly performed elective orthopaedic procedures in Australia with over 80,000 performed in 2011 (Australian Orthopaedic Association, 2012). The number of these procedures is increasing annually having risen 7.9% from 2009 to 2010 (Australian Orthopaedic Association, 2011). Of these, over 60% were undertaken in private hospitals. It could be argued that the public hospital cohort may represent a different patient demographic but not all patients undergoing this procedure in a public hospital represent a particular socio-economic demographic or are considered ‘high risk’ due to multiple
co-morbidities which once necessitated public hospital admission. Many private hospitals house high-dependency or intensive care units enabling them to care for patients with complex medical needs. Clinical trials are often undertaken across both public and private hospitals with recruitment not differentiating between cohorts on the basis of this alone. Of interest, the Protocol has been requested for use across multiple public hospitals in both Australia and New Zealand suggesting the problems experienced at the researcher’s hospital are similar to those experienced in public hospitals.

The study originated after several clinical incidents and a clinical audit at the researcher’s hospital showed considerable room for improvement in relation to post operative bowel management in the surgical orthopaedic patient cohort. Discussions with colleagues at other hospitals both within Western Australia and interstate revealed that the problems we experienced were not unique to us and were widespread. Despite the large volume of literature acknowledging these patients were at high risk for developing severe post operative constipation due to multiple factors including the administration of opioid analgesia, no robust evidence existed about how to best manage the problem. The lack of evidence and clinical guidelines meant that patients were often treated in an ad hoc manner dependent on the experience and preference of both their nursing and medical staff. The development and testing of the Protocol was a logical step to provide the evidence needed to assist nurses to provide care for what is a basic but poorly managed aspect of clinical care. A follow-up clinical audit conducted at the researcher’s hospital one year after implementation of the Protocol revealed significantly improved results and positive responses from both medical and nursing staff and patients. This success saw multiple other hospitals, both public and private across both Australia and New Zealand request use of the Protocol, with one orthopaedic surgeon requesting its use at multiple Perth hospitals.
at which he worked. Whilst happy for the Protocol to be used it was important to emphasise that no formal evaluation of the protocol had been conducted hence the urgent need for a robust assessment of the intervention.

The theoretical framework for this study was based on the Neuman Systems Model and was considered the most appropriate framework to guide this study. Its emphasis is on the patient and his/her response to various stressors in the environment, stressors which the nurse must identify and remediate. In addition, primary, secondary and tertiary prevention strategies are key components of the framework and are particularly relevant in the context of this Protocol.

**Summary of Findings**

**Comparison of complete and incomplete cases.**

As previously discussed, soon after data collection began at the largest intervention hospital it was noted that a significant amount of critical data was missing for the first 51 patients recruited. The large amount of missing data meant these incomplete cases were not suitable for inclusion into the study and recruitment recommenced after remedial measures had been implemented. To demonstrate that all cases were drawn from the same population the 51 incomplete cases were compared with the 331 complete cases. No statistically significant differences were found in any of the baseline variables confirming no difference between these groups. Subsequent analysis was conducted on completed cases only.

**Baseline comparison of variables.**

A comparison of baseline variables was undertaken between the control \((n = 171)\) and intervention \((n = 160)\) groups. Statistically significant results were found in three variables; hours of pre-operative fasting; type of
anaesthetic and gender. As 155 of the 160 intervention patients were recruited from a single hospital site it is likely that both the length of pre-operative fasting and anaesthetic type reflect hospital policy and/or procedure or doctors’ preferences. As discussed in the literature review, the evidence surrounding the importance of adequate hydration remains conflicted yet despite this it remains a mainstay of constipation prophylaxis and treatment. For this reason it was analysed in this study. Pre-operative fasting times were found to differ markedly across all participating hospitals with a medians ranging from four to 15 hours with the mean fasting time for control hospitals 10.03 hours (SD 4.3) vs a mean fasting time of 8.77 hours (SD 3.2) for intervention hospitals. As patients generally only commence intravenous fluids on induction of anaesthesia these rates were considered particularly high. The Australian and New Zealand College of Anaesthetists fasting guidelines recommend that healthy adults having an elective procedure take limited solid food up to six hours prior to anaesthesia and clear fluids totalling not more than 200 mls per hour up to two hours prior to anaesthesia (Australian and New Zealand College of Anaesthetists, n.d.). The effect of hydration on the main outcome measure was analysed using the generalised linear model and is reported later in this chapter.

Regional anaesthesia is the most commonly performed anaesthetic type at control hospitals with general anaesthesia most commonly performed at intervention hospitals. Similar numbers of patients received combined regional and general anaesthesia at both hospital groups. Gender differences between hospital groups are harder to explain. Significantly higher numbers of male patients were operated on at control hospitals and significantly higher numbers of female patients were operated on at intervention hospitals. No plausible explanation can be offered for these differences in gender frequency.
**Effect of possible confounding post-operative variables.**

A comparison of two possible confounding post-operative variables was undertaken; post-operative day first mobilised and length of inpatient stay. Days to normal bowel function was the main outcome measure for this study and was also analysed here. All three results were found to be highly statistically significant between control and intervention groups. Whilst post-operative day to first mobilisation was found to be statistically significant between groups it was not considered clinically significant as the median day to first mobilisation was day one for both hospital groups. The length of stay was also found to be highly statistically different between groups with control patients staying on average 4.96 days (median five days) compared with intervention patients who stayed an average of 7.07 days (median seven days). Several factors may account for this including doctor preference or hospital policy and procedural differences. It is possible that a shorter length of stay may have contributed to less pain and self-management education of patients leading to higher analgesia use post discharge. This outcome however was not measured. As 155 of 160 intervention patients were recruited from a single hospital, these site specific differences could have a significant impact on the intervention group outcomes. Of note, anecdotal reports confirm that none of the patients at intervention hospitals required prolonged length of stay for the management of post operative constipation. Days to normal bowel function was the main outcome measure for this study. The differences between groups was highly statistically significant with the control group reporting a longer time to normal bowel function compared with the intervention group \((p = 0.000)\).

**A comparison of days to normal between groups.**

Days to normal bowel function was tabled cumulatively across groups to compare differences. Days one to three were grouped together as most post-
operative patients do not experience a bowel motion prior to this time. Days four to seven were tabled individually as this is when most change occurred between control and intervention groups. As most intervention patients had returned to normal bowel function by day seven (93.9%) days 8-14 were grouped together. By day 14, 99.5% of intervention patients had returned to normal bowel function compared with only 75.2% of control patients. Those patients who had not returned to normal bowel function by day 14 were collectively grouped together as 15+ days. Of note, the comparative results showed that by day five (median length of stay for the control hospitals) only 28.2% of control patients had returned to normal bowel function vs 68.2% in the intervention group, with this figure increasing to 42.3% in the control group and 93.9% in the intervention group by day seven. As post-operative joint replacement management follows a very similar care path it is highly likely that these significant differences are due to the intervention protocol.

Post discharge comparison of variables.

Analysis of multiple post discharge variables was undertaken between groups. The use and type of analgesia taken as well as laxative use were analysed as was the incidence of constipation post discharge. The vast majority of patients from both groups continued to take analgesia after discharge with opiates taken by 84% of those in the control group and 82% of those in the intervention group. Paracetamol was also commonly used with 91.8% of control patients and 79.4% of intervention patients reporting having taken it since discharge. The use of non-steroidal anti-inflammatory drugs (NSAID) was minimal and likely due to the suggestion they may inhibit bone healing.

Laxative use was compared across groups with 44% of those in control groups taking laxatives after discharge compared with 40% in the
intervention group. It is important to note that the Protocol did not continue after discharge although some patients did confirm they continued using Movicol® after discharge. This is particularly relevant when considering the majority of patients were discharged on opioid analgesia.

When telephoned approximately one week after discharge patients were asked if they had experienced constipation since leaving hospital. In the control group 57% of patients and 31% of intervention patients reported constipation after discharge which was a highly statistically significant result. Whilst this measure was subjective and self-reported by patients (not using the Bristol Stool Chart) the difference is so significant it likely reflects the effect of the intervention protocol administered whilst an inpatient. Despite this positive result for the intervention group, 31% represents a high proportion of patients experiencing constipation post discharge. This outcome supports the introduction of targeted information for patients and their carers about the ongoing risk of constipation associated with opioid usage after discharge.

**Variables associated with normal bowel function by day five.**

Logistic regression was used to model six independent variables: age; gender; group (control or intervention); length of pre-operative fasting; anaesthetic type (general, regional and general + regional) and length of stay on the dependent binary variable, normal bowel function by day five. Overall three variables were found to be statistically significant: allocated group (control or intervention); regional + general anaesthetic and length of stay. A significant predictor of days to normal bowel function at discharge was being in the intervention group. Results indicated that patients in the intervention group were *seven times more likely* to have returned to normal bowel function by day five compared with patients recruited to the control
groups. Those patients who received combined general plus regional anaesthesia were almost two and a half times more likely to have returned to normal bowel function at day five than those who received a general anaesthetic. It is possible the combined anaesthetic resulted in a reduced dosage of anaesthetic agents and/or a reduced need for post operative analgesia. These variables may have contributed to a faster return to normal bowel function however their inclusion was beyond the scope of this study and should be evaluated in future research. Length of hospital stay was also significant finding; for every extra day a patient stayed in hospital they were ~20% less likely to have returned to normal bowel function by day five.

**Variables affecting days to normal bowel function.**
The generalised linear model (GLM) was used to assess the impact of the independent variables age; gender; group (control or intervention); length of pre-operative fasting; anaesthetic type; operation type and length of stay on the dependent continuous variable, days to normal bowel function. Of note, gender, age, and length of pre-operative fasting were not found to influence days to normal bowel function. Four statistically significant results were found. Of note, those in the intervention group took an average of *six days less* than those in the control groups to return to normal bowel function; each extra inpatient day meant an extra half a day to return to normal bowel function; and those who had a TKR took 1.24 days longer to return to normal bowel function than those who underwent THR. When compared with general anaesthesia (GA) patients who underwent combined regional and GA took on average *two days less* to return to normal bowel function.

**Summary of Study Findings**
Data were collected over three time periods: at pre-admission; during hospitalisation and at telephone follow-up approximately one week after
discharge. Those patients who had not returned to normal bowel function at the time of the first post-discharge telephone call were telephoned again approximately one week later. Multiple variables were evaluated to assess their relationship to the dependent variable, time taken to return to normal bowel function. Incomplete \((n = 51)\) and complete \((n = 331)\) cases were initially compared with none of the variables showing any differences hence all further analysis was conducted on complete cases only.

The recruitment of 155 of the 160 intervention cases from a single hospital resulted in statistically significant differences across some outcome measures which were most likely a result of hospital specific policies, procedural guidelines or clinician preferences. These were length of stay, anaesthetic type and day first mobilised although the latter was not considered clinically significant.

Of those intervention patients treated with the Protocol 68.2% had returned to normal bowel function by day five compared with 28.2% of those in the control group. By day seven these figures had increased to 93.4% compared with 42.3% respectively. Whilst there was no significant difference in the proportion of patients who took opioid analgesia post discharge there was a highly statistically significant difference in the numbers of patients who reported constipation during follow-up phone calls with 57.1% reporting this in the control group vs 31.2% in the intervention group. When all relevant variables were taken into account the allocation of patients from hospitals randomised into either control or intervention clusters was the most significant predictor of days to normal bowel function. Patients allocated to intervention hospitals were seven times more likely to have returned to normal bowel function by day five and took six days less to return to normal bowel function compared to those from control hospitals (mean 5.06 days in
intervention versus mean 10.64 days in control). Age, gender and length of pre-operative fasting were not found to be significant contributors to the outcome variable.

These results confirm the administration of opioids was the main contributing factor to the development of constipation in the post-operative orthopaedic patient cohort. They also demonstrate that administration of the Murdoch Bowel Protocol resulted in a statistically significant reduction in time taken to return to normal bowel function in post operative major joint replacement patients and support the research hypothesis.

Comparing the Conceptual Framework with the Empirical Evidence

In this study the post operative major joint replacement patient was at the heart of the Neuman Systems Model. The flexible line of defence works to buffer intra, inter and extra personal stressors invading the patient’s normal line of defence (or usual wellness state). These stressors include the administration of an anaesthetic agent as well as opioid analgesia; an alteration to usual diet and fluid intake; a decrease in usual levels of mobility and the possibility of a lack of private bathroom facilities. As the normal line of defence is penetrated by the stressors listed above, a variance from usual wellness occurs and the flexible lines of resistance are activated. The flexible lines of resistance seek to stabilise the patient and return them equilibrium and good health with interventions best initiated either before or after these lines are penetrated.

Examples of primary prevention strategies which reduce or eliminate the identified risks include ensuring private toileting facilities, monitoring bowel habits to identify early signs of constipation, increasing dietary fibre and fluid intake and encouraging early mobilisation. Secondary prevention
strategies which can be implemented after the flexible lines of resistance have been penetrated include early identification of constipation and implementing the Murdoch Bowel Protocol©. Tertiary prevention strategies which aim to assist with reconstitution (the return of system stability following treatment for stressor reaction) include ensuring adequate discharge education about risk factors, early signs and management strategies for constipation for the patient and their carer (if applicable) and a recommendation that Movicol® be continued at home should symptoms of constipation reoccur. As most patients will continue taking opioid analgesia after discharge these strategies are particularly important.

Whilst the aim of management is a return to the patient’s normal state of wellness, reconstitution depends on the patient’s reaction which in itself is influenced by individual variables including time exposed to the stressors discussed above. As major joint replacement surgery aims to improve quality of live it is likely that with the nurses’ assistance, the patient will return to a higher level of wellness.

The empirical evidence gathered as a result of this study confirms the Murdoch Bowel Protocol© acts to expand the flexible line of defence providing greater protection to the patient and strengthening their normal line of defence. Should the normal line of defence be penetrated the Protocol strengthens the lines of resistance and helps return the patient to a state of equilibrium and good health.

Data Collection Issues
The collection of data at all participating hospitals was completed by registered and enrolled nursing staff. The primary nursing contact at each hospital was trained by the researcher although the Bristol Stool Chart was
completed at 1000 hrs daily by each patient’s attending nurse and based on a self-reported stool type by each patient. As previously discussed, during the data input stage it was noted that a significant amount of critical inpatient and follow-up data (i.e. recording of Bristol Stool Chart type for each inpatient day, Movicol® administration, and recording of return to normal bowel function post discharge) was either missing or incomplete from the first 51 patients recruited from the largest intervention hospital. It was felt that continuation would be unethical and would significantly compromise the rigor of the study. Hence the decision was made to suspend patient recruitment and further data collection until a strategy could be implemented to ensure more stringent data collection in accordance with the study protocol. Discussions with key stakeholders from that hospital confirmed that a registered nurse already employed on the orthopaedic ward of that hospital could be recruited to oversee complete and accurate data collection of all 155 recruited patients. The need for this was not envisaged prior to commencement of the study.

**Interrater Variability**

As previously discussed in the Methods chapter as patients were recruited across seven hospitals the issue of interrater variability needed to be addressed. Data were collected at three time points: pre-admission clinic; during the inpatient stay and post discharge by phone call. Initial training was carried out at each site but as all nursing staff were unable to be present at these education sessions a ‘Frequently Asked Questions’ sheet was distributed to all nursing staff working on every orthopaedic ward included in the study. This sheet detailed the background to the study, what information needed to be collected and how to record it. All sheets gave consistent information for either control or intervention hospitals.
One main contact and liaison nurse at each hospital was trained by the researcher and acted as a resource to answer questions to ensure a consistent approach to data collection. In addition the researcher was available by email and visited each hospital midway throughout the data collection phase to ensure that any questions or problems were addressed promptly and that data was entered correctly and consistently between sites. Traditional test-retest reliability was not used in this study due to the diverse geographical distribution of the hospitals and nurses recording patient self-reported information or transcribing data from fluid balance or observation charts. The measurement and recording of such data is a core component of basic nursing practice and as such it was not considered necessary to provide education in the act of transcribing information.

Limitations and Strengths

Limitations. Limitations to this study were identified and are discussed below. This study was conducted in private hospitals across two Australian states. It could be argued the patient population differs between public and private hospitals, however that argument is not considered valid. Private hospitals regularly operate on patients with complex medical and surgical problems and with multiple co-morbidities. Many private hospitals have high-dependency or intensive care units and some have emergency departments. In addition, a lack of health insurance does not in itself reflect a patient’s demographic status and large clinical trials are routinely conducted across both public and private hospitals. Further, many hospitals both public and private have requested use of the Protocol confirming that post operative orthopaedic constipation is a problem experienced across all hospital sectors.
A further limitation is the recruitment of 155 of 160 intervention patients from a single hospital. Sample numbers were based on the proportion of major joint replacements conducted at each hospital each month. Hospitals which participated in this study ranged from a 70 bed regional hospital undertaking approximately five major joint replacements per month to a 548 bed metropolitan hospital undertaking approximately 120 major joint replacements per month. This wide variation in the number of operations performed accounted for the difference in patient recruitment numbers across the seven hospitals.

A potential limitation already discussed relates to the unusable data from the largest intervention hospital. This limitation was overcome by suspending the study and improving data collection strategies resulting in complete data for all complete cases. As described earlier, analysis between complete and incomplete cases revealed no differences confirming the non-inclusion of this data resulted in no bias.

**Strengths.**

The limitations of this study were balanced by considerable strengths. A well-controlled cluster randomised trial was used. This legitimate form of randomised controlled trial (RCT) methodology was chosen to avoid confusion for nursing staff should both control and intervention patients be recruited from a single hospital. In addition it was likely that contamination could occur due to patients wishing to be enrolled in the intervention arm of the study due to prior experience with post-operative constipation or the development of constipation whilst an inpatient. These important constraints were avoided by randomising hospitals as ‘clusters’ rather than randomising the patients within them. The use of clusters hospitals meant there was no risk of contamination.
A further strength was that the researcher was blind to data collection. This lack of personal involvement eliminated bias and preserved the integrity of the recorded data.

Anecdotal feedback was received from multiple patients at the intervention hospitals, all of which were positive. Comments included "love Movicol thank you"; "thought the protocol was fabulous"; "this is a great study, say thanks to the researcher for me"; "very happy with this new regime"; "Movicol was fantastic, better than last knee surgery" and "was type 1 after previous hip surgery, now type 4".

**Application of the Murdoch Bowel Protocol© to Clinical Practice**

This study has confirmed the Murdoch Bowel Protocol© is a simple, reliable and easy to use tool requiring no modifications to its current format. As such it can be considered the gold standard for the treatment of opioid induced constipation. Whilst the Protocol does suggest patient review by a dietician or continence nurse specialist if required, it is acknowledged that these resources may not be available at all hospitals. In these circumstances the patient should be reviewed by a more senior nurse with knowledge of bowel assessment and management.

The Protocol has been used at the researcher’s hospital since May 2010 and during this time clinical audit has been undertaken annually and confirms improvements across all outcome measures. Anecdotally patients have also reported increased satisfaction with bowel management. Further, there have been no episodes of increased lengths of stay for management of constipation and emergency department management of faecal impaction in this group has decreased significantly at the hospital. Given this hospital performs a large proportion of the total hip and knee replacement operations
undertaken in Western Australia, this is clinically significant result as it reflects the likely outcome of the whole cohort of major joint replacement patients. This study has shown highly statistically significant results for the main outcome measure demonstrating that management using the Murdoch Bowel Protocol© results in a significant reduction in time taken to return to normal bowel function in the post-operative major joint replacement cohort. Whilst the issue of opioid induced constipation is a significant concern for post operative orthopaedic patients, the safety and efficacy of the protocol means that its use can be extended to other patient groups also suffering from opioid induced constipation including paediatric populations. Despite its ability to cause severe constipation, opioid analgesia remains a mainstay for the management of moderate to severe pain both for inpatients and outpatients meaning that many patients suffer from unnecessary pain and discomfort. As an inert iso-osmotic laxative, non-scheduled, freely available over-the-counter and suitable for both adults and children, Movicol® has been proven to be a safe, efficacious and well-tolerated agent for the management of opioid induced constipation.

The use of Microlax® enemas was not examined in this study. Whilst intervention hospital Microlax® usage could be assessed, the ad hoc bowel management approach in control hospitals could not, meaning a comparison of usage was not possible.

Summary of Chapter
Despite the limitations of this study, the considerable strengths justify the valuable contribution of the Murdoch Bowel Protocol© to clinical practice in a basic but poorly managed aspect of patient care. This robust quantitative RCT with highly statistically significant results for the main outcome measure has provided the empirical evidence to support use of the Murdoch
Bowel Protocol© in all patients taking opioid analgesia, notwithstanding the need for replication of the study in other discreet populations e.g. paediatrics, oncology and maternity.
This study produced findings of theoretical and clinical significance. The multi-site study was comprehensive and rigorous and supported the hypothesis for the study: that patients who undergo a knee or hip replacement and receive the study protocol will experience a statistically significant reduction in time taken to return to normal bowel function compared with patients who receive standard bowel management. As discussed previously in the Statement of Purpose (page 5) shoulder replacements were not included in the study hypothesis, as their small numbers ($n = 3$) prevented convergence of coefficients and caused spurious results.

A total of 331 patients were recruited across seven hospitals in two Australian states in this cluster randomised trial. Two hospitals were randomised as intervention hospitals, five hospitals were randomised as controls. Patients at intervention hospitals who received the Murdoch Bowel Protocol® were seven times more likely to have returned to normal bowel function by day five compared with patients recruited at control hospitals. Age, gender and length of pre-operative fasting were not found to be significantly associated with days to normal bowel function at discharge (day five). Length of stay was significant with each extra inpatient day resulting in an extra 0.43 days to return to normal bowel function. Patients who received combined regional and general anaesthesia took approximately two days less to return to normal bowel function when compared with patients who received general anaesthesia while total knee replacement patients took approximately one day longer to return to normal bowel function compared with those who underwent total hip replacement. The study also confirmed that post-operative constipation in this patient cohort is opioid induced.
Future Research Directions

The robust empirical evidence provided by this nursing study is unique in the area of opioid-related post-operative constipation in the orthopaedic population. It has confirmed that despite the scope of the problem nurses have managed this important clinical problem according to tradition and habit and without the benefit of an evidence based protocol. This has often resulted in lengthy discomfort for patients with the risk of significant complications which have at times necessitated increased lengths of stay or readmission to hospital for treatment of faecal impaction.

This study explored and tested the effect of the Murdoch Bowel Protocol® on post operative constipation in patients who underwent major joint replacement surgery. It would be prudent to replicate this study on general orthopaedic patients (including spinal surgery patients), other post surgical patient groups, oncology patients who experience similar complications related to the administration of opioid analgesia and paediatric populations. Movicol® is contraindicated in those with serious underlying gastrointestinal disorders (Crohn’s disease, ulcerative colitis, intestinal obstruction or perforation, toxic megacolon). For this reason it would be prudent to exclude patients who have undergone general abdominal surgery from patient recruitment unless prior approval is received from their medical practitioner. Movicol® is being increasingly prescribed for pregnant and breastfeeding women due to its efficacy and inert composition. Whilst the product information no longer lists pregnancy and breastfeeding as contraindications for use, it does recommend use in this patient group only on medical advice. Replicating this research would further test the reliability and sensitivity of measures used in this study.
Summary of Recommendations

**Clinical nursing.**

1. If not already in place, Movicol® and Microlax® enemas should be placed on nurse-initiated medication lists to enable widespread use of the Murdoch Bowel Protocol® in the adult orthopaedic setting.

**Future research.**

1. This study should be replicated in other patient groups who are administered opioid analgesia: general orthopaedic patients (including those undergoing spinal surgery); general surgical patients (e.g. urology and gynaecology), oncology, maternity and paediatric populations.

2. Future randomised controlled trials should measure analgesia usage and include a cost-benefit analysis of the Murdoch Bowel Protocol® on length of stay.

**Education.**

1. Findings from this study should be incorporated into orthopaedic and general nursing education programs.

2. Nursing education should be undertaken in relation to:
   a. undertaking baseline bowel assessments;
   b. the importance of clean and private bathroom facilities where possible; and
   c. the importance of discharge education about ongoing bowel management when discharged on opioid analgesia.
## Bristol Stool Chart

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Separate hard lumps, like nuts (hard to pass)</td>
</tr>
<tr>
<td>Type 2</td>
<td>Sausage-shaped but lumpy</td>
</tr>
<tr>
<td>Type 3</td>
<td>Like a sausage but with cracks on its surface</td>
</tr>
<tr>
<td>Type 4</td>
<td>Like a sausage or snake, smooth and soft</td>
</tr>
<tr>
<td>Type 5</td>
<td>Soft blobs with clear-cut edges (passed easily)</td>
</tr>
<tr>
<td>Type 6</td>
<td>Fluffy pieces with ragged edges, a mushy stool</td>
</tr>
<tr>
<td>Type 7</td>
<td>Watery, no solid pieces. <strong>Entirely Liquid</strong></td>
</tr>
</tbody>
</table>
### Studies related to Incidence of Constipation

<table>
<thead>
<tr>
<th>Authors (Year)</th>
<th>Design</th>
<th>Sample (N)</th>
<th>Measures</th>
<th>Findings</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Hayes and Gibler (1995) | Case study | Death from constipation | • 60% incidence of constipation in patients taking clozapine | • Clozapine only  
• Not generalisable |
| Nazarko (1996)   | Discussion paper | Incidence, causes and management | • 38% incidence for older adults at home  
• 59% in nursing homes  
• 79% of inpatients  
• Incidence higher in women  
• Suggests diet and fluid modifications and gentle exercise | • UK only  
• Poorly referenced |
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Incidence and characteristics</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norton (1996)</td>
<td>Discussion paper</td>
<td>Incidence, causes and management</td>
<td>• &lt;70 years of age not associated with BO frequency</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Increased incidence in women</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• ~10% incidence in general population</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• No evaluation of aperients</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• 26.6% in 45-50 yrs</td>
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<td>• 27% in 70-75 yrs</td>
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<td></td>
<td></td>
<td></td>
<td>• Women &gt; men</td>
</tr>
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<td></td>
<td></td>
<td>• Haemorrhoids and gynaecological surgery increase incidence</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Parity increases incidence in younger cohort</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Australian females only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Didn’t include all known associated factors</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Relied on self reporting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Low response rate in the older group</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Type</td>
<td>Study Focus</td>
<td>Findings</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hinrichs &amp; Huscobee</td>
<td>Discussion paper</td>
<td>Incidence, effect of fluids, fibre and exercise and toileting regime</td>
<td>- ~10 incidence in the general USA population</td>
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<tr>
<td></td>
<td></td>
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<td>- 25% incidence in ‘older’ adults</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>- Highest incidence in African-Americans, age &gt;60, women, lower socioeconomic status and decreased physical activity</td>
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<tr>
<td>Pappagallo (2001)</td>
<td>Survey of opiate users (76)</td>
<td>Incidence, bowel habits and treatment options</td>
<td>USA survey sample vs study sample:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- 40% incidence of constipation in opioid users</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- 55% taking aperients vs 80%</td>
</tr>
<tr>
<td>Levin, Barrett &amp;</td>
<td>Case report and literature</td>
<td>Case report</td>
<td>- 14% incidence of constipation in patients taking clozapine</td>
</tr>
<tr>
<td>Mendelowitz (2002)</td>
<td>review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authors</td>
<td>Year</td>
<td>Methodology</td>
<td>Main Findings</td>
</tr>
<tr>
<td>-------------------------</td>
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<td>-------------------------------------------------------------------------------</td>
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<tr>
<td>Annells &amp; Koch (2003)</td>
<td></td>
<td>Survey design (90), qualitative methodology</td>
<td>Effect of diet, fluid and exercise as preventative strategies • 80% of UK community nurses focus on constipation treatment</td>
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<tr>
<td>Boshard, Dreher, Schnegg &amp; Búla (2004)</td>
<td></td>
<td>Discussion paper</td>
<td>Incidence and discussion of general measures and laxative classes • 15-20% incidence in general community • Up to 50% in nursing home patients</td>
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<tr>
<td>Lacy &amp; Cole (2004)</td>
<td></td>
<td>Discussion paper</td>
<td>Incidence and Treatment options • 50% laxative use in the elderly • No evidence that extra fibre or increased fluids helps • PEG effective in the ambulatory population</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Type</td>
<td>Incidence and Pathophysiology</td>
<td>Findings</td>
</tr>
<tr>
<td>----------------------------------------------</td>
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<td>-----------------------------------------------------------------------------------------------</td>
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</table>
| Ramkumar & Rao (2005)                        | Systematic review    | Incidence, efficacy and safety of traditional medical therapies                               | • 2-20% incidence  
• More common in women, elderly, lower socio-economic classes and nonwhite population                      | Systematic review   |
| Panchal, Müller-Schwefe & Wurzelmann (2007)  | Discussion paper     | Incidence and pathophysiology                                                               | • 15-90% incidence in patients taking opiates                                                                      | Discussion paper    |
| Davies, Green, Mottram & Pirmohamed (2008)   | Pilot study (46)     | Incidence and impact of nutritional status                                                    | • 71.7% incidence  
• High incidence in older age group ($p < 0.05$) and those with poor nutritional status ($p < 0.05$)    | Only fractured neck of femur  
• Single site
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Paper Type</th>
<th>Study Details</th>
<th>Key Findings</th>
</tr>
</thead>
</table>
| Ho, Kuhn & Smith (2008) | Discussion paper | Update on treatment options | - 2-28% incidence in general US population  
- Requires approx 2.5 million physicians visits annually  
- In 2004 >$800 million on laxatives  
- One of the most common gastro symptoms in orthopaedic patients in recovery stage |
| Nikoletti, Young, Levitt, King, Chidlow & Hollingsworth (2008) | Retrospective, descriptive study | Assess bowel problems and impact, self care practices and info needs post surgery | - Altered bowel habits in 71.3% of post surgery patients  
<p>| | | | - Patients 6-24 months after colorectal surgery for cancer only |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Key Findings</th>
</tr>
</thead>
</table>
| Peppas, Alexious, Mourtzoukou & Falagas (2008) | Systematic review  | - 17.1% incidence in Europe  
- 15.3% incidence in Oceania  
- Female, increased age, lower socioeconomic status and educational class additional risk factors  
- Different definitions and diagnostic criteria in some countries  
- Some constipation self reported  
- Only articles in English and French |
| Healey (2009)                | Literature review  | - >95% of patients taking opioids report constipation  
- USA only  
- Only naloxone and methylnaltrexone |
| Lin, Fu, Dunning, Zhang, Ho, Duke & Lo (2009) | Systematic review  | - 2-28% incidence with average around 15%  
- One in three constipated US adults will seek medical attention  
- US spend $6.9 billion on medical treatment for constipation annually  
- $1 billion on laxatives annually  
- Many poor quality studies included |
<table>
<thead>
<tr>
<th>Reference</th>
<th>Article Type</th>
<th>Summary</th>
<th>Cited:</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miakowski (2009)</td>
<td>Discussion paper</td>
<td>Incidence, causes and management</td>
<td>Hydration status, Duration of immobility, Age, Length of pre operative fasting, Previous opiate use as factors contributing to post operative constipation</td>
<td>Main management options for paralytic ileus only</td>
</tr>
<tr>
<td>McCrea, Miakowski, Stotts, Macera and Varma (2009)</td>
<td>Literature review</td>
<td>Effect of age and gender on incidence of constipation</td>
<td>Higher incidence in women, Prevalence increases with age, Lack of research on the topic given the magnitude of the problem</td>
<td>North America only</td>
</tr>
<tr>
<td>Spinzi, Amato, Imperiali, Lenoci, Mandelli, Paggi, Radaelli, Terreni &amp; Terruzzi (2009)</td>
<td>Discussion paper</td>
<td>Incidence and management strategies for constipation</td>
<td>Incidence approx 5% in Germany, 18% in US, More common in women and lower socio-economic classes</td>
<td>Discussion paper</td>
</tr>
<tr>
<td>Reference</td>
<td>Type of Study</td>
<td>Topic</td>
<td>Key Points</td>
<td>Notes</td>
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</table>
| Selby & Corte (2010) | Electronic article | Incidence and treatment options | - 6-30% incidence in Australian population  
- Increased incidence in females, older age groups, lower socio-economic groups, history of depression and sexual abuse | Australian statistics only |
| Belsey, Geraint & Dixon (2010) | Systematic review | Efficacy of PEG over placebo or other laxatives | - North American incidence 12-19%  
- Women twice as likely as men to be affected | Sponsored by Norgine, manufacturers of Movicol® (PEG) |
| Camilleri (2011) | Discussion paper | Review of new opioid antagonists | - ~40% of non-cancer patients taking opioids experience opiate induced constipation | Discussion article |
| Mugie, Benninga & Di Lorenzo | Systematic review | Epidemiology of constipation in the general and paediatric population | - 16% median incidence worldwide  
- Females, increased age & lower socioeconomic status associated with increased incidence | Systematic review |
| Ishihara et al. (2012) | Multisite retrospective study (619) | Evaluate effect of prophylactic laxatives | - Up to 64% incidence of constipation in patients taking opioids | Oncology patients only |
## Studies related to the Causes and Contributing Factors for Constipation

<table>
<thead>
<tr>
<th>Authors (Year)</th>
<th>Design Sample (N)</th>
<th>Measures</th>
<th>Findings</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ogilvy &amp; Smith (1995)</td>
<td>Discussion paper</td>
<td>Effect of anaesthesia on the gastrointestinal tract</td>
<td>• Gastrointestinal motility may be markedly reduced by anaesthetic agents and types although different agents produce varying effects</td>
<td>• Discussion paper</td>
</tr>
<tr>
<td>De Luca &amp; Coupar (1996)</td>
<td>Discussion paper</td>
<td>Comparison of opioid action in the gut between humans and other species</td>
<td>• Confirms constipating effect of opiates</td>
<td>• Discussion paper</td>
</tr>
<tr>
<td>Harari, Gurwitz, Avorn, Bohn &amp; Minaker (1996)</td>
<td>Survey findings (42,375)</td>
<td>Investigate relationship between age and bowel habits</td>
<td>• Decline in bowel movement frequency not an inevitable consequence of ageing</td>
<td>• Survey findings in USA only</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Type</td>
<td>Summary</td>
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<tr>
<td>Norton (1996)</td>
<td>Discussion paper</td>
<td>Causes of constipation nursing management - Multiple causes of constipation, Lists multiple types of aperient, Discussion of aperient types but no evaluation of their effectiveness</td>
<td></td>
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</tr>
<tr>
<td>Lindeman, Romero, Liang, Baumgartner, Koehler &amp; Garry (2000)</td>
<td>Cross sectional (883)</td>
<td>Review effect of increasing fluid intake - No association between increased fluid intake and constipation ( p = 0.496 ), Compared 6-8 glasses of water per day not &gt;8 as recommended, Association not cause and effect, Self-reported so possibly inaccurate, Definition of constipation not supplied so probable classification error</td>
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<tr>
<td>Bytzer, Howell, Leemon, Young, Jones &amp; Talley (2001)</td>
<td>Postal questionnaire (8555)</td>
<td>Examine association between social class and gastrointestinal symptoms - Incidence of upper and lower gastrointestinal symptoms increased with declining social class, Australia only, Self-reported, Lowest response rate in lowest social class</td>
<td></td>
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</tr>
<tr>
<td>Study</td>
<td>Methodology</td>
<td>Title</td>
<td>Findings</td>
<td>Notes</td>
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</table>
| Annells & Koch (2003)               | Survey design (90) Qualitative methodology | Effect of diet, fluid intake and exercise as preventative strategies | - Patients report little improvement by increasing intake of fibre and fluid and exercise levels  
- No evidence to support the effect of increased exercise on chronic constipation    | Convenience sample |
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Type</th>
<th>Title</th>
<th>Findings</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Bradley, Kennedy, Turcea, Rao & Nygaard (2007) | Prospective study (103) | Prevalence and risk factors for constipation in pregnancy | - 1<sup>st</sup> trimester 24%  
- 2<sup>nd</sup> trimester 26%  
- 3<sup>rd</sup> trimester 16%  
- 3/12 postpartum 24% | - Small study size  
- Single centre study with a homogenous population  
- Non random sampling  
- No control group |
| Cullen & O'Donoghue (2007) | Discussion article | Causes of constipation in pregnancy         | - Up to 40% incidence throughout pregnancy  
- Those with no prior history may develop constipation during pregnancy  
- Preexisting constipation may be worsened  
- Discusses physiological reasons for constipation | - Discussion article |
<table>
<thead>
<tr>
<th>Authors</th>
<th>Design</th>
<th>Measures</th>
<th>Findings</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayes &amp; Gibler (1995)</td>
<td>Case study</td>
<td>Death from constipation</td>
<td>• Death from aspiration secondary to bowel obstruction</td>
<td>• Clozapine related case study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Development of a clozapine constipation protocol</td>
<td></td>
</tr>
<tr>
<td>Glia &amp; Lindberg (1997)</td>
<td>Self administered</td>
<td>Quality of life index</td>
<td>• General well being of patients with chronic constipation lower than those of general population p= &lt;0.001</td>
<td>• Chronic constipation sufferers only</td>
</tr>
<tr>
<td></td>
<td>questionnaires (102)</td>
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<td></td>
<td>• Small sample size</td>
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<td>• Tool used not specifically developed to measure the impact of constipation</td>
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<tr>
<td>Levin, Barrett &amp; Mendelowitz (2002)</td>
<td>Case report</td>
<td>Death from constipation</td>
<td>• Multiple deaths related to complications of clozapine induced constipation</td>
<td>• Clozapine related</td>
</tr>
<tr>
<td>Researcher(s)</td>
<td>Study Type</td>
<td>Findings</td>
<td>Limitations</td>
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<tr>
<td>Dennison, Prasad, Lloyd, Bhattacharyya, Dhawan &amp; Coyne (2005)</td>
<td>Systematic review</td>
<td>Quality of life and economic impact of constipation</td>
<td>Lack of recent data on economic impact</td>
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<td></td>
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<td></td>
<td>Most studies look at effect on older adults</td>
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<tr>
<td>Norwood, Lykostratis, Garcea &amp; Berry (2005)</td>
<td>Retrospective audit (35)</td>
<td>Incidence of acute colonic pseudo-obstruction post orthopaedic surgery</td>
<td>Not proven to be caused by orthopaedic surgery</td>
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<tr>
<td>Martin, Barghout &amp; Cerulli (2006)</td>
<td>Discussion paper</td>
<td>Estimated cost of care of patients with constipation in US</td>
<td>United States of America only</td>
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<tr>
<td></td>
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<td></td>
<td>Based on 2001 survey results</td>
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<tr>
<td>Source</td>
<td>Type</td>
<td>Description</td>
<td>Management</td>
<td>Notes</td>
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</table>
| Swegle & Logemann (2006)                    | Discussion article | Management of opioid induced adverse effects                              | • Stool softeners usually ineffective  
• Paucity of studies evaluating laxatives  
• Need to use non drug treatments to minimize risk | Discussion article                      |
<p>| Chute, Cox, Archer, Bready &amp; Reiber (2008)  | Case report        | Complication of constipation                                               | • Bladder rupture and death secondary to faecal impaction                            | Not generalisable                         |
| Office of Safety and Quality In Healthcare WA (2009) | Case report        | Complication of constipation                                               | • Aspiration from bowel obstruction due to constipation                              | Related to psychotropic medications       |
| Hibbard, Propst, Frank &amp; Wyse (2009)        | Literature review and case reports | Fatal complications of clozapine related constipation and bowel obstruction | • Seven reports of death from bowel obstruction causing feculent vomiting or bowel necrosis | Clozapine related deaths only            |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Article Type</th>
<th>Description</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hjalte, Berggren, Bergendahl &amp; Hjortsberg (2010)</td>
<td>Review article</td>
<td>Estimate direct and indirect costs of opioid induced bowel dysfunction</td>
<td>- Significantly higher costs for inpatients with constipation</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Assumption that constipation was opioid induced</td>
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<tr>
<td></td>
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<td></td>
<td>- Study did not control for pain so costs may have been underestimated</td>
</tr>
<tr>
<td>Annemans (2011)</td>
<td>Review article</td>
<td>Socioeconomic impact of opioid use for cancer and non-cancer patients</td>
<td>- Constipation most commonly reported side-effect of opioid use</td>
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<td></td>
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<td></td>
<td>- QoL decreases with chronic constipation</td>
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<td>Hard to quantify but significant financial burden</td>
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<td>- Paucity of studies looking at economic burden</td>
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<td>- Different definitions makes it hard to compare studies</td>
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<tr>
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<td>- Difficult to assess indirect costs as may be hidden by direct cost estimates</td>
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<td>- Benefit of analgesia not considered when assessing cost</td>
</tr>
</tbody>
</table>
| Sun, DiBonaventura, Purayidathil, Wagner, Dabbous & Mody (2011) | Survey analysis | Effect of chronic constipation on health outcomes and health resource use | - Decreased quality of life $p = <0.01$
- Higher level of work absenteeism $p = <0.01$
- Higher number of presentations for medical care $p = <0.01$

| - Chronic constipation only
| - USA only |
### Studies Related to Treatment of Constipation

<table>
<thead>
<tr>
<th>Authors</th>
<th>Design Sample (n)</th>
<th>Measures</th>
<th>Findings</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Groth (1988)  | Convenience sample of 22 matched pairs (44) | Does bran increase spontaneous bowel movements  
Does bran decrease need for other laxatives | ● Cites significant results between groups but difficult to interpret | ● Poorly designed  
● Single site study  
● Small sample with no sample size calculation  
● Grouped according to personal preference  
● Difficult to interpret results |
| Schmelzer (1990) | Comparative study (16) | Does bran increase bowel movements and decrease other laxative use | ● No difference between groups  
$p = 0.09$ and  
$p = 0.072$ | ● Very small sample with no sample size calculation  
● Single site study  
● Not all ate the recommended intake of bran  
● Relied on self reporting of bowel type |
<table>
<thead>
<tr>
<th>Reference</th>
<th>Type</th>
<th>Description</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hall, Raken, Karstens, Swanson &amp; Davidson (1995)</td>
<td>Quality initiative</td>
<td>Develop and evaluate a constipation protocol (bran, 1500 ml fluid, privacy, upright positioning, abdominal strengthening)</td>
<td>- Reduction in constipation incidence from 59% to 9% and laxative and enema use from 59% to 8% over three years</td>
<td>Self reported, No statistical analysis</td>
</tr>
<tr>
<td>Nazarko (1996)</td>
<td>Discussion article</td>
<td>Discusses non laxative options</td>
<td>- Recommends baseline and ongoing assessment, fibre rich diet, increased mobility, adequate fluid intake and review of constipating causing medications</td>
<td>Discussion article</td>
</tr>
<tr>
<td>Bandolier (1997)</td>
<td>Systematic review</td>
<td>Review abdominal massage for constipation</td>
<td>- No evidence to support abdominal massage for constipation</td>
<td>Old paper</td>
</tr>
<tr>
<td>Source</td>
<td>Type</td>
<td>Title</td>
<td>Findings</td>
<td>Comments</td>
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</tr>
<tr>
<td>Hinrichs &amp; Huseboe (2001)</td>
<td>Discussion article</td>
<td>Use of fluids, fibre, exercise and toileting regime</td>
<td>• Recommends use of high fibre ‘power pudding’</td>
<td>• No details of intervention • No results of intervention</td>
</tr>
<tr>
<td>Stumm, Thomas, Coombes, Greenhill &amp; Hay</td>
<td>Comparative study</td>
<td>Compare pear juice and bran on bowel function and laxative requirements in orthopaedic patients</td>
<td>• Says no difference in time taken to first bowel motion between groups • Pear juice increased rate of bowel opening after seven days $p = 0.045$</td>
<td>• Single site study • Self volunteers • Results for first outcome not reported with $p$ • No sample size calculation • Non adherence to the study protocol • Inaccurate data recording • Ad hoc use of laxatives • Poor compliance with bran supplement</td>
</tr>
<tr>
<td>Kurz &amp; Sessler (2003)</td>
<td>Discussion article</td>
<td>Role of new opioid antagonists</td>
<td>• Advocates increasing fibre and fluid intake and increased exercise although admits probably not useful for OIC • Recommends opioid antagonists methylnaltrexone</td>
<td>• No evidence to support increased fibre and fluid recommendations • No evidence cited for opioid antagonists</td>
</tr>
<tr>
<td>Reference</td>
<td>Study Type</td>
<td>Description</td>
<td>Key Findings</td>
<td>Notes</td>
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<tr>
<td>Bosshard, Dreher, Schnegg and Bula (2004)</td>
<td>Discussion article</td>
<td>Discusses general measures and evaluates all laxative classes</td>
<td>• Cites little evidence to guide management</td>
<td>• Treatment algorithm for chronic constipation only</td>
</tr>
<tr>
<td>Neri, Blasi, Castro, Grandinetti, Ricchi &amp; Facchinetti (2004)</td>
<td>Pilot study (40)</td>
<td>Evaluate PEG in pregnant women</td>
<td>• PEG increased number of bowel actions ( p &lt; 0.01 ) • Constipation resolved in 73% of women</td>
<td>• Used PEG 4000</td>
</tr>
<tr>
<td>Ramkumar &amp; Rao (2005)</td>
<td>Systematic review 1966-2003</td>
<td>Efficacy and safety of traditional medical treatments for constipation</td>
<td>• Grade A evidence to support PEG and tegaserod (opioid antagonist) • Grade B for psyllium • Grade C for bran, Docusate, Bixacodyl and Senna</td>
<td>• Paucity of evidence for commonly used laxatives</td>
</tr>
<tr>
<td>Study</td>
<td>Title</td>
<td>Design</td>
<td>Purpose</td>
<td>Findings</td>
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<tr>
<td>Kaçmaz &amp; Kaşıkçı (2007)</td>
<td>Quasi-experimental design (60)</td>
<td>Evaluate effect of bran supplementation on orthopaedic patients</td>
<td>• Increased size of stool at day five $p = 0.016$</td>
<td>• Volunteer patients • Non random group assignment • No sample size calculation • Single site study • No stool to standardize stool recording</td>
</tr>
<tr>
<td>Holzer (2008)</td>
<td>Discussion paper</td>
<td>Discusses role of new opioid receptor antagonists</td>
<td>• Phase I and II studies confirm therapeutic and safety profile of methyl-naltrexone and alvimopan</td>
<td>• Discussion paper</td>
</tr>
<tr>
<td>Ho, Kuhn and Smith (2008)</td>
<td>Discussion paper</td>
<td>Update on treatment options</td>
<td>• Report good preliminary results from methyl-naltrexone and alvimopan</td>
<td>• Discussion paper</td>
</tr>
<tr>
<td>Koch, Melenhorst, van Gemert &amp; Baeten (2008)</td>
<td>Prospective study (39)</td>
<td>Investigate effectiveness of colonic irrigation</td>
<td>• Highly significant results across multiple outcome measures</td>
<td>• Small sample size • Select patient group with intractable defaecation disorders • Unable to generalise</td>
</tr>
<tr>
<td>Name (Year)</td>
<td>Type</td>
<td>Summary</td>
<td>Findings</td>
<td>Sample</td>
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</tbody>
</table>
| Nikoletti, Young, Levitt, King, Chidlow & Hollingsworth (2008) | Retrospective descriptive study (101) | Assess bowel problems and impact, self care practices and information needs post colorectal surgery | - Various self-care practices suitable for different patients eg. diet, medication  
- More education needed for patients | Colorectal cancer patients |
| Healey (2009) | Literature review (19 articles) | Reports on effectiveness of opioid antagonists | - Methyl-naltrexone more effective in reducing opioid induced constipation | Only reviewed naloxone and methylnaltrexone |
| Kyle (2009) | Discussion paper | Discusses a constipation risk assessment tool | - Once risk assessed guidelines suggests preventative strategies | Norgine sponsored tool  
- Absence of other risk tools to compare it with |
<p>| Kyle (2009) | Discussion paper | Discusses treatment options and complementary therapies | - Cites minimal evidence to support some common treatment | Discussion article |</p>
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Type</th>
<th>Summary</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>Lin, Fu, Dunning, Zhang, Ho, Duke and Lo (2009)</td>
<td>Systematic review</td>
<td>Evaluate effect of traditional Chinese medicine on constipation</td>
<td>- Suggests traditional Chinese medicine more effective than Chinese medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Unable to evaluate acupuncture due to poor study designs</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>- Many poor quality studies included</td>
</tr>
<tr>
<td>Spinzi, Amato, Imperiali, Lenoci, Mandelli, Paggi, Radaelli, Terreni &amp;</td>
<td>Discussion paper</td>
<td>Identify evidence based interventions for prevention and management of constipation</td>
<td>- Conflicting evidence about bran, fluid intake and exercise</td>
</tr>
<tr>
<td>Terruzzi (2009)</td>
<td></td>
<td></td>
<td>- Weak evidence for stimulant laxatives</td>
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<td></td>
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<td>- Grade A evidence for PEG</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Early support for methylnaltrexone</td>
</tr>
<tr>
<td>Belsey, Geraint &amp; Dixon (2010)</td>
<td>Systematic review</td>
<td>Efficacy of PEG over placebo or other laxatives</td>
<td>- PEG more effective in all studies ( p = 0.003 )</td>
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<td></td>
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<td></td>
<td>- Sponsored by Norgine, manufacturers of Movicol (PEG)</td>
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<tr>
<td>Reference</td>
<td>Type of Study</td>
<td>Description</td>
<td>Findings</td>
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<tr>
<td>Faaborg, Christensen, Buntzen, Laurberg &amp; Krogh (2010)</td>
<td>Pilot study (12)</td>
<td>Effect of colonic irrigation on anorectal function</td>
<td>Rectal compliance unaltered; Evaluate long term use only; Small sample size</td>
</tr>
<tr>
<td>Madsen, Magor &amp; Parker (2010)</td>
<td>Pilot study (28)</td>
<td>Compare PEG with Coloxyl with Senna® in post operative orthopaedic patients</td>
<td>Days to bowel movement earlier with PEG $p = 0.001$; More reported nausea with PEG although not significant $p = 0.14$; PEG more cost effective; Protocol not closely followed</td>
</tr>
<tr>
<td>Camilleri (2011)</td>
<td>Discussion article</td>
<td>Review of new opiate antagonists</td>
<td>Large high quality trials necessary on new generation drugs; Discussion article</td>
</tr>
<tr>
<td>Hawley, Barwick &amp; Kirk (2011)</td>
<td>Pre-post multisite audit (180)</td>
<td>Evaluate the Victoria Bowel Performance Scale (audit tool)</td>
<td>Improved bowel documentation $p = &lt;0.001$; Inter rater variability; Oncology patients</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Type</td>
<td>Intervention/Comparison</td>
<td>Findings</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lee-Robichaud, Thomas, Morgan &amp; Nelson (2011)</td>
<td>Intervention review</td>
<td>PEG vs lactulose for chronic constipation</td>
<td>All studies showed higher stool frequency per week, relief of abdominal pain and less need for other laxatives with PEG</td>
</tr>
<tr>
<td>Linari, Schofield &amp; Horrom (2011)</td>
<td>Retrospective study</td>
<td>Evaluate effectiveness of Bisacodyl suppositories prn vs on day one in THR and TKR</td>
<td>THR constipation decrease $p = 0.001$</td>
</tr>
<tr>
<td></td>
<td>(847)</td>
<td></td>
<td>No reduction for TKR $p = 0.24$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McNicol, Boyce, Schumann &amp; Carr (2011)</td>
<td>Intervention review</td>
<td>Compare efficacy and safety of opioid antagonists for opiate induced bowel dysfunction (OBD)</td>
<td>Alvimopan and methylnaltrexate promising</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Insufficient evidence to support naloxone for OBD</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Study Design</td>
<td>Investigate Prescribing Trends for Laxatives in the UK</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>-------------------------------</td>
<td>----------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| Shafe, Lee, Dalrymple & Whorwell (2011)           | Cohort study (over 3,000,000 records) | • Lactulose and senna prescribing decreasing  
• PEG prescribing increasing  
• PEG replacing lactulose for pregnant women |
| Ishihara, Ikesue, Matsunaga, Suemaru, Kitaichi et al (2012) | Multisite retrospective study (619) | • Less constipation in patients treated with prophylactic laxatives  
\( p = <0.001 \) |

- UK only
- Does not include over the counter laxative purchases

- Oncology patients
Appendix C
Letter to Orthopaedic Surgeons

Dear Doctor

Re: Study to evaluate the effectiveness of a bowel intervention protocol for analgesia related post-operative constipation

Unfortunately, 2009 saw several adverse incidents relating to orthopaedic bowel management at St John of God Hospital Murdoch. A clinical audit was undertaken which identified multiple areas for improvement. As a consequence of this an evidence-based, graduated approach to bowel management was developed by a multi-disciplinary group (Continence Specialist Nurse, Orthopaedic Learning & Development Facilitator, Coordinator Nursing Policy & Research and Clinical Dietician). The Murdoch Bowel Management Protocol (attached) was tabled at both the Murdoch Physicians Craft Group and Orthopaedic Craft Group in late 2009 and ratified without changes. It was also ratified without changes by the Murdoch Drugs, Therapeutics and Blood Transfusion Committee at their March 2010 meeting.

The Protocol involves multiple approaches to constipation prevention and management: diet, fluid intake, physical activity (as able), ceasing constipation causing medication (if possible) and the administration of several unscheduled bowel medications if required: Movicol and possibly a Microlax enema.

The protocol was introduced to the orthopaedic wards at St John of God Murdoch in May 2010 and feedback from nursing staff has been very positive. Consequently a cluster randomised trial is proposed across seven St John of God Hospitals in Victoria and Western Australia to evaluate the intervention. The study is being undertaken by Gail Ross-Adjie, a St John of God Murdoch employee and PhD nursing student at the University of Notre Dame Fremantle. I write to seek your support and would like your permission to approach your post-operative orthopaedic patients to invite them to participate. This study has received human research ethics approval from both the University of Notre Dame and the St John of God Ethics Committee.

Patient demographic and medical details would be collected from both groups. The control group will receive current bowel management and the intervention group will receive bowel management according to the Protocol. If you consent to your patient’s being recruited into this study and if necessary receiving medications as per the attached Protocol, please sign below and return to:

Gail Ross-Adjie
Coordinator Nursing Clinical Practice, Policy & Research
St John of God Hospital Murdoch
PhD candidate
University of Notre Dame Fremantle.
gross-adjie@student.nd.edu.au

I ________________ consent for my post-operative patients to be invited to participate in the analgesia related constipation study and receive bowel management according to the attached Bowel Management Protocol if randomised to the intervention group. I understand that this may involve the administration of Movicol and possibly a Microlax enema if required. Nurses will administer these medications and sign for them on the front of the medication chart.

Signed: ____________________________

160
### Appendix D
Data Collection Tool

**Bowel Intervention Study**

<table>
<thead>
<tr>
<th>Hospital ___________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone number for follow-up phone call ___________________________</td>
</tr>
<tr>
<td>Date of operation (dd/mm/yyyy) ___________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender (circle one):</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operation this admission:</th>
<th>THR</th>
<th>TKR</th>
<th>TSR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Does the patient have a history of ulcerative colitis, Crohn’s disease, toxic megacolon, bowel perforation or are they pregnant or breastfeeding? If ‘yes’ to any of the above this patient is NOT suitable for recruitment into the study.

Does the patient usually take any of the following medication groups?
- Opiate based medications (eg. Oxycontin, Fentanyl patches, MS Contin) 1
- Tricyclic antidepressants (eg. Amitriptyline, Doxepin, Imipramine, Doxepin) 2
- Calcium channel blockers (eg. Diltiazem, Amlodipine, Verapamil, Nifedipine) 3

**Baseline bowel assessment**

<table>
<thead>
<tr>
<th>Bristol stool chart number (type 1-7)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Usual stool frequency per week</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Do you usually use laxatives?</th>
<th>Yes</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If ‘yes’ type of laxative and frequency of use</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Length of pre-operative oral fasting – IN HOURS from commencement of pre-operative fasting until the commencement of oral fluids</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What DATE and TIME did fasting commence?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What DATE and TIME did surgery commence?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Duration of intravenous fluids - IN HOURS (usually commenced on OT and continued until taking adequate oral volumes of fluid)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What DATE and TIME did the patient commence solid food?</th>
</tr>
</thead>
</table>
FOLLOW-UP PHONE INFORMATION

Patients to be telephoned one week after discharge then two weeks after discharge if they have still not returned to normal bowel habit after one week.

Date of 1st follow-up phone call ________________________
Date of 2nd follow-up phone call ________________________

1. When did you return to your ‘normal’ bowel function?
   - Before I left hospital [ ]
   - Best estimate of the date that you returned to normal bowel function ________________________
   - Still not returned to normal bowel function [ ]
   - If still not returned to normal bowel function, what does your stool look like now? (record Bristol Stool type, you may need to prompt patients e.g. type 1 hard pebbles – type 7 completely liquid stool) __________________________________

   If the patient has not returned to a normal bowel habit please inform them they will receive a follow-up phone call in one week’s time.

2. Have you taken laxatives since discharge from hospital?
   - Yes 1
   - No 2
   - If ‘yes’ state the type of laxative and frequency of use ________________________
   - ________________________________________________________________

3. If the patient has taken laxatives since discharge have they taken more or less than you did before you went into hospital?
   - More 1
   - Less 2

   Please use this section if a second follow-up phone call required.

   Best estimate of the date that you returned to normal bowel function ________________________
   - Still not returned to normal bowel function [ ]
   - If still not returned to normal bowel function, what does your stool look like now? (record Bristol Stool type, you may need to prompt patients e.g. type 1 hard pebbles – type 7 completely liquid stool) ________________________

   Please thank the patient for their participation in the study!

Checklist for data collection nurses

Have you:
- [ ] Completed this form entirely?
- [ ] Attached a photocopy of the patient’s medication chart/s?
- [ ] Attached a photocopy of the patient’s epidural chart? N/A
- [ ] Attached a copy of the patient’s PCA chart? N/A
- [ ] Attached the stool chart completed by ward nursing staff?

Thank you!
**Appendix E**

Control Hospital Stool Recording Chart

**Bristol Stool Chart**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Separate hard lumps, like nuts (hard to pass)</td>
</tr>
<tr>
<td>2</td>
<td>Sausage-shaped but lumpy</td>
</tr>
<tr>
<td>3</td>
<td>Like a sausage but with cracks on the surface</td>
</tr>
<tr>
<td>4</td>
<td>Like a sausage or snake, smooth and soft</td>
</tr>
<tr>
<td>5</td>
<td>Soft blobs with clear-cut edges</td>
</tr>
<tr>
<td>6</td>
<td>Fluffy pieces with ragged edges, a mushy stool</td>
</tr>
<tr>
<td>7</td>
<td>Watery, no solid pieces. Entirely Liquid</td>
</tr>
</tbody>
</table>

Attach Patient ID label here

<table>
<thead>
<tr>
<th>Post-op Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bristol Stool Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix F

Intervention Hospital Stool Recording and Medication Administration Chart

Please sign for medication administered in the appropriate box. Ensure medications are also documented on Medication Chart HR 810.

This chart does not replace Medication Chart HR 810.

<table>
<thead>
<tr>
<th>Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bristol Stool Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Movicol AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microlax Enema AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Movicol PM (if required)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

R - Refused
W – Withheld (state why)
Appendix G
Caregiver Information Sheet

Analgesia Related Constipation Study for Total Hip and Total Knee Replacement Patients

Dear Colleague

As you would be aware, analgesia related constipation is a major problem in orthopaedic patients, particularly those undertaking major joint replacement. In response to this St John of God Hospital Murdoch introduced an evidence based bowel protocol in May 2010. This protocol (printed on the back of this sheet) uses the Bristol Stool Chart as a standardised measure of stool type with Movicol® then administered according to the degree of constipation recorded. The success of this protocol at Murdoch has now seen it being evaluated across seven St John of God hospitals in Victoria and Western Australia including this one.

What do you need to do?
The protocol is very easy to use. Only patient’s whose orthopaedic surgeon has consented for them to be involved, will be invited to join the study. A data collection nurse at your hospital will invite eligible patients to take part and ensure that informed consent is gained. The patient will be asked to record their stool type using the Bristol Stool Chart type 1-7 whenever they use their bowels. They are asked to record their stool type, date and time during their hospital admission on a chart located in their bathroom. If they have difficulty they will ask for your help.

For patients in ‘control’ hospitals you will not be required to do anything else as patient’s bowels will be managed using the usual post-operative bowel management regime at your hospital. For patients in ‘intervention’ hospitals we ask that you record the patient’s stool at 1000 on the Bowel and Medication Recording Chart but then manage the patient’s bowels using the bowel protocol.

Frequently asked questions

- What is the patient wants to continue to take their own laxatives?
  - The protocol will be explained to the patient by the data collection nurse. If they wish to continue to take their own bowel management regime they will not be eligible to take part in the study.

- What if the patient refuses to take the Movicol or a Microlax enema on a particular day?
  - The patient has every right to refuse to take these but this should be recorded as an ‘R’ (for refused) on the Medication Administration chart.

- What is the doctor charts post operative laxatives for the patient?
  - If a patient is recruited into the study their surgeon has given permission for them to receive bowel management as per the protocol and this should be administered.

- How many patients need to be recruited?
  - 320 patients will be recruited into this study (160 into each group). We anticipate that data collection will be completed by June 2011

- What if I have any questions about the study?
  - Most questions should be able to be answered by the data collection nurse at your hospital. If not call Gail Ross-Adjie, principal researcher on 041 709 4257

Thank you for your support in relation to this study.
INFORMATION SHEET

Appendix H
Patient Information Letter – Control Hospital

Analgesia related constipation study in post operative joint replacement patients

Dear patient
This letter has been prepared to provide you with the information you require to decide whether or not you would be prepared to assist in our research study.

Background to the Study:
The painkillers given after total hip and total knee replacement surgery are a common cause of post-operative constipation. This constipation can result in pain and discomfort and may even require staying in hospital for a longer period of time to manage it or returning to hospital for management of constipation.

What is the aim of the study?
The aim of the study is to determine whether using a more specific bowel care protocol whilst in hospital results in lower rates of constipation and a faster return to normal bowel patterns in post-operative total hip and total knee replacement patients.

Who is doing the study?
The principal researcher for this study is Gail Ross-Adjie a PhD student from the School of Nursing, University of Notre Dame Fremantle and an employee of St John of God Hospital Murdoch. Gail will be supervised by Professor Leanne Monterosso and Professor Max Bulsara Chair of Biostatistics, both from the University of Notre Dame Fremantle, Western Australia. This study is also being funded by St John of God Health Care

What will be expected of you if you agree to participate in this study?
Seven St John of God hospitals across Victoria and Western Australia are participating in this study with each hospital chosen to be either a control hospital (will continue with their current bowel management program) or an intervention hospital (will give consenting patients the study bowel protocol). This hospital has been chosen to be a control hospital meaning that your post operative bowel management will be the same as is usually given in this hospital.

If you agree to participate some information about your past medical and surgical history will be obtained by a data collection nurse as well as some details about your operation and the medications you are taking while in hospital. In your bathroom you will find a coloured chart, the Bristol Stool Chart which shows a stool picture against a number from type 1 – type 7. We ask you to fill in the chart every time you use your bowels including the bowel type, day and time. If you have any difficulty filling in this chart, please ask your nurse for assistance. While in hospital, your bowel management will be the usual for this hospital.

Please be assured that if you refuse to participate in this study your care in hospital will not affected in any adverse way.
How will your privacy be protected?
All data collection for this study will be undertaken by nurses employed by St John of God Health Care. The information will be stored in a locked filing cabinet in the ward Nurse Manager’s office. On completion of the data collection the principal researcher Gail Ross-Adjie will collect all completed data forms to ensure that patient confidentiality is maintained. All data will be de-identified meaning that your name will not appear on any computer record associated with this study. The study information will be entered onto a password protected computer file and will only be available to the research team. Signed consent forms and data collection forms will be stored in a locked filing cabinet at the School of Nursing at the University of Notre Dame Fremantle. The results will be published in a professional journal with no identifiable information.

Voluntary participation and your right to refuse.
Your participation is entirely voluntary and if you do agree to participate you are free to withdraw from the study at any time without penalty. If you do choose to withdraw from the study you have the right to withdraw any unprocessed data previously supplied up to that point. If you agree to participate in the study you will need to sign the attached consent form which once signed will be retained by the principal researcher Gail Ross-Adjie.

Are there any risks involved in this study?
As this is a control hospital there is no risk to you as you will be managed using the usual bowel protocol for this hospital.

Who can you contact if you have any questions about the study?
Any questions about this study can be directed to the principal researcher Gail Ross-Adjie Ph: 08 9333 9751

Who can you contact if you have any concerns about the study?
If you have any concerns about the conduct of this research project you may contact the Executive Officer, Human Research Ethics, The University of Notre Dame Australia Ph: 08 9443 0870

Who has given permission for this study to proceed?
This study has been approved by the St John of God Healthcare Human Research Ethics Committee and the Human Research Ethics Committee at the University of Notre Dame Fremantle.

Thank you for your assistance with this study.

Gail Ross-Adjie
Appendix H
Patient Information Letter – Intervention Hospital

Analgesia related constipation study in post operative joint replacement patients

Dear patient
This letter has been prepared to provide you with the information you require to decide whether or not you would be prepared to assist in our research study.

Background to the Study:
The painkillers given after total hip and total knee replacement surgery are a common cause of post-operative constipation. This constipation can result in pain and discomfort and may even require staying in hospital for a longer period of time to manage it or returning to hospital for management of constipation.

What is the aim of the study?
The aim of the study is to determine whether using a more specific bowel care protocol whilst in hospital results in lower rates of constipation and a faster return to normal bowel patterns in post-operative total hip and total knee replacement patients. This protocol has been successfully used at St John of God Hospital Murdoch with very good results for our patients. The aim of this study is to evaluate the use of the protocol in a larger group of patients.

Who is doing the study?
The principal researcher for this study is Gail Ross-Adjie a PhD student from the School of Nursing, University of Notre Dame Fremantle and an employee of St John of God Hospital Murdoch. Gail will be supervised by Professor Leanne Monterosso, School of Nursing and Professor Max Bulsara Chair of Biostatistics, both from the University of Notre Dame Fremantle, Western Australia. This study is also being funded by St John of God Healthcare.

What will be expected of you if you agree to participate in this study?
Seven St John of God hospitals across Victoria and Western Australia are participating in this study with each hospital chosen to be either a control hospital (will continue with their current bowel management program) or as an intervention hospital (will give consenting patients the study bowel protocol). This hospital has been randomised as an intervention hospital meaning that your post operative bowel management will be the study bowel protocol.

If you agree to participate some information about your past medical and surgical history will be obtained by a data collection nurse as well as some details about your operation and the medications you are taking while in hospital. In your bathroom you will find a coloured chart, the Bristol Stool Chart which shows a stool picture against a number from type 1 – type 7. Every time you use your bowels you are asked to fill in the chart with your stool type, day and time of bowel movement and bowel management will be given according to the bowel protocol. If you have any difficulty completing this chart, please ask your nurse for help. The protocol is based on Movicol™ a powdered laxative which is added to water and drunk. Movicol™ is a commonly used over-the-counter laxative although any patient who has a known allergy to Movicol™ (polyethylene glycol) should not participate in this study.
Please be assured that if you refuse to participate in this study your care in hospital will not affected in any adverse way.

**How will your privacy be protected?**
All data collection for this study will be undertaken by nurses employed by St John of God Healthcare. The information will be stored in a locked filing cabinet in the ward Nurse Manager’s office. On completion of the data collection the principal researcher Gail Ross-Adjie will personally collect all completed data forms to ensure that patient confidentiality is maintained. All data will be entered onto a password protected computer file and will only be available to the research team. Signed consent forms and data collection forms will be stored in a locked filing cabinet at the School of Nursing at the University of Notre Dame Fremantle. The results will be published in a professional journal with no identifiable information.

**Voluntary participation and your right to refuse.**
Your participation is entirely voluntary and if you do agree to participate you are free to withdraw from the study at any time without penalty. If you do choose to withdraw from the study you have the right to withdraw any unprocessed data previously supplied up to that point. If you agree to participate in the study you will need to sign the attached consent form which once signed will be retained by the principal researcher Gail Ross-Adjie

**Are there any risks involved in this study?**
The Bowel Care Protocol is based on the current best evidence in relation to the management of constipation. The protocol has been discussed and accepted for use by your orthopaedic surgeon. The medications administered in this study are considered very safe over-the-counter laxatives and are commonly used. The main difference in this study is that they are administered in a more ordered way. Patients with a known allergy to Movicol™ or with a history of blockage of the bowel, hole in the bowel, inflammation of the bowel and back passage (ulcerative colitis), Crohn’s disease or toxic megacolon should not participate in the study. Patients who are pregnant or breastfeeding are also excluded from this study. The most common side effects reported with the use of Movicol™ are abdominal discomfort and possibly abdominal bloating. These symptoms are usually mild and resolve on their own. These symptoms are typical of most laxatives and usually don’t stop a patient from taking this medicine.

**Who can you contact if you have any questions about the study?**
Any questions about this study can be directed to the principal researcher Gail Ross-Adjie Ph: 08 9333 9751

**Who can you contact if you have any concerns about the study?**
If you have any concerns about the conduct of this research project you may contact the Executive Officer, Human Research Ethics, The University of Notre Dame Australia Ph: 08 9443 0870

**Who has given permission for this study to proceed?**
This study has been approved by the St John of God Healthcare Human Research Ethics Committee and the Human Research Ethics Committee at the University of Notre Dame Fremantle, Western Australia.

Thank you for your assistance with this study.

Gail Ross-Adjie
Appendix I
Patient Consent Form

The effect of an evidence based bowel protocol on time taken to return to normal bowel function in post operative major joint replacement patients
Principal Researcher: Gail Ross-Adjie
Research Supervisors: Professor Leanne Monterosso, Professor Max Bulsara

INFORMED CONSENT FORM

I, (participant's name) _______________________________ hereby agree to being a participant in the above research project.

- I have read and understood the Information Sheet about this project and any questions have been answered to my satisfaction.
- I understand that I may withdraw from participating in the project at any time without prejudice.
- I understand that all information gathered by the researcher will be treated as strictly confidential.
- I agree that any research data gathered for the study may be published provided my name or other identifying information is not disclosed.

<table>
<thead>
<tr>
<th>PARTICIPANT’S SIGNATURE:</th>
<th>DATE:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>RESEARCHER’S FULL NAME:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>RESEARCHER’S SIGNATURE:</th>
<th>DATE:</th>
</tr>
</thead>
</table>

If participants have any complaint regarding the manner in which a research project is conducted, it should be directed to the Executive Officer of the Human Research Ethics Committee, Research Office, The University of Notre Dame Australia, PO Box 1225 Fremantle WA 6959, phone (08) 9433 0943.
Appendix J

HREC approval: The University of Notre Dame Australia

12 January 2011

Ref. #: 010145F

Gail Ross Adjie
2 Lambeth Street
Mount Claremont WA 6010

Dear Gail,

I am writing to you in regards to your Full Risk Application for Ethics Clearance for your proposed research project, to be undertaken for the research component of your course at The University of Notre Dame Australia.

The title of the project is: “The effect of an evidence-based bowel protocol on time taken to return to normal bowel function in post-operative major joint replacement patients”

Your proposal has been reviewed by the University’s Human Research Ethics Committee, and based on the information provided has been assessed as meeting all the requirements as mentioned in the National Statement on Ethical Conduct in Human Research (2007). I am therefore pleased to advice that ethical clearance has been granted for this proposed study.

Please note the following conditions of approval which apply to your research project:

• Ethics approval for this project is valid for 3 years. Under the National Statement you are required to report on the project’s progress on an annual basis and the first annual report is therefore due in January 2012. Once your project is completed you are required to complete the Annual Report as a Final Report on your project. You are also required to notify the HREC Executive Officer in writing if this project is abandoned. The Annual Report form can be found at: http://www.nd.edu.au/research/hrec/apply.shtml.

• As a researcher you are required to immediately report to the HREC Executive Officer anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability and any complaints made by participants regarding the conduct of the project.

• If the design of the study, the choice of instrument, or its manner of administration is altered in any significant way as the study progresses, you are required to submit an amendment in regards to the changes for ethical consideration to the HREC. The Amendment Form can be found at: http://www.nd.edu.au/research/hrec/apply.shtml.

On behalf of the Human Research Ethics Committee, I wish you well with what promises to be a most interesting and valuable study.

Yours sincerely,

Nicolette van Dijk
Executive Officer, Human Research Ethics Committee
Research Office

cc Professor Selma Allies, Dean, School of Nursing
Mila Bultsara, Supervisor
Appendix K
HREC approval: St John of God Health Care

9 December 2010

Ms Gail Ross-Adjie
2 Lambeth Mews
MT CLAREMONT WA 6010

Dear Ms Ross-Adjie

Re: The effect of an evidence-based bowel protocol on time taken to normal bowel function in post-operative major joint replacement patients (Our ref No: 449)

Thank you for your reply of 9 December 2010, attaching the amended Information Sheet to Doctors. This has been circulated out of session to the St John of God Health Care Ethics Committee ("the Committee"), and a final minor amendment has since been forwarded to you by email.

Further to my letter of 2 December 2010, I now confirm final approval for your study to be conducted at St John of God Hospitals in Subiaco, Bunbury, Berwick, Geelong, Bendigo, Ballarat and Warmambool ("the participating sites").

As per the Committee's ethical approval granted for the study on 2 December 2010, please find attached a signed and dated Committee membership list.

The Committee is a Human Research Ethics Committee (HREC) that is constituted and operates in accordance with the National Statement. In line with the National Statement requirements, researchers need to keep the Committee and the participating sites promptly and regularly informed on the progress of their approved research including:
1. any serious, and suspected, unexpected serious adverse events, any unforeseen events, any significant protocol deviations or violations, any withholding or withdrawal of study approval by another HREC/institution, and any allegation or suspicion of research misconduct, that may affect continued ethical approval of the study.
2. any proposed changes to the research/research documentation as previously approved by the Committee, including any proposed study extensions.
3. when the study is completed, abandoned, terminated, suspended or withdrawn.

The Committee would also appreciate receiving at a minimum an annual study progress report as well as a final report on the study results and/or any subsequent publications.

I wish you well with your study.

Yours sincerely,

[Signature]

Professor Con Michael
(as a delegate of St John of God Health Care)

Enc.

cc. A/Prof. Kate Birrell, Group Director of Nursing

St John of God Health Care Inc. ARBN 011 960 911. ABN 21 930 207 958 [Limited Liability] Incorporated in Western Australia
Appendix L
Australian and New Zealand Clinical Trials Registration Number

Gail Ross-Adjie - Your ACTRN (registration number): ACTRN12612000014853

From:   <info@actr.org.au>
To:     <Gail.Ross-Adjie@sjog.org.au>
Date:   4/01/2012 12:13 PM
Subject: Your ACTRN (registration number): ACTRN12612000014853

Dear Gail,

Re: The effect of an evidence based bowel protocol on time taken to return to normal bowel function in post operative major joint replacement patients

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12612000014853

Date submitted: 1/12/2011 4:21:16 PM
Date registered: 4/01/2012 3:05:56 PM
Registered by: Gail Ross-Adjie

**Please note that as your trial was registered after the first participant was enrolled, it does not fulfil the criteria for prospective registration and will therefore be marked as being Retrospectively Registered on our website.**

If you have already obtained Ethics approval for your trial, could you please send the ANZCTR a copy of at least one Ethics Committee approval letter? A copy of the letter can be sent to info@actr.org.au (by email) OR (61 2) 9565 1863, attention to ANZCTR (by fax).

Please be reminded that the quality and accuracy of the trial information submitted for registration is the responsibility of the trial’s Primary Sponsor or their representative (the Registrant). The ANZCTR allows you to update trial data, but please note that the original data lodged at the time of trial registration and the tracked history of any changes made will remain publicly available.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333
F: +61 2 95 65 1863
E: info@actr.org.au
W: www.ANZCTR.org.au

file://C:\Documents and Settings\MUGMR\Local Settings\Temp\XPgrpwise\4\04427... 18/01/2012

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Appendix L
Universal Trial Number

Gail Ross-Adjie - UTN application 23 November 2011 - Step 2

From: <utnmarg@who.int>
To: <Gail.Ross-Adjie@sjog.org.au>
Date: 23/11/2011 1:04 PM
Subject: UTN application 23 November 2011 - Step 2

The Universal Trial Number (UTN) is U1111-1126-0176

This UTN should be recorded in the trial protocol and used in all correspondence relating to this trial.

The UTN is not a registration number. To register your trial you will need to submit the UTN, along with the WHO 20 item data set, to any of the WHO Primary Registries. Please make sure that you provide the UTN when you submit your trial for registration.

This is an automated email. Please do not reply to this message.
Appendix M
HREC approval for study amendment:
St John of God Health Care

7 December 2011

Ms Gail Ross-Adjie
Coordinator Nursing Clinical Practice, Policy & Research
St John of God Hospital Murdoch
100 Murdoch Drive
MURDOCH WA 6150

Dear Ms Ross-Adjie

Re: The effect of an evidence-based bowel protocol on time taken to normal bowel function in post-operative major joint replacement patients (Our ref. No. 449)

Thank you for keeping the St John of God Health Care Ethics Committee (“the Committee”) updated on the progress of the above study.

I advise that the Committee at its meeting on 7 December 2011, approved the following amendment to the Protocol:

1. the employment of a data collection nurse to ensure complete and accurate data collection, and
2. an increase in the recruitment numbers for the intervention arm to compensate for the incomplete datasets; and
3. noted the study has been registered with the ANZ Clinical Trials Registry, as per your letter of 6 November 2011.

Please find attached signed and dated Committee membership list.

Yours sincerely

[Signature]

Professor Con Michael
Chairman
St John of God Health Care Ethics Committee

Enc.
Appendix N
HREC approval for study amendment:
The University of Notre Dame Australia

15 December 2011

Mrs Gail Ross Adjie
2 Lambeth Mews
Mt Claremont WA 6010

Reference Number: 010145F

Dear Gail,

I am writing to you in regards to the amendment to your approved research project. The title of the project is: "The effect of an evidence-based bowel protocol on time taken to return to normal bowel function in post-operative major joint replacement patients."

I am pleased to advise that your proposed amendment has been reviewed by the university’s Human Research Ethics Committee, and has been assessed as having met all the requirements as stated in the National Statement on Ethical Conduct in Human Research (2007). Ethical clearance has therefore been endorsed for this amendment to your study.

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with what promises to be a most interesting and valuable study.

Yours sincerely,

Dr Natalie Giles
Executive Officer, Human Research Ethics Committee
Research Office

cc: Prof Selina Alves, Dean, School of Nursing
    A/Prof Adrian Morgan, SRC Chair, School of Nursing
References


