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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

Gail Ross-Adjie
University of Notre Dame Australia

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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 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?
No further follow up

Intervention hospitals
Aperients as per intervention protocol

Not yet returned to normal bowel function?
Final follow up phone call one week later
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>
<tr>
<td><strong>Sampled Totals</strong></td>
<td><strong>321</strong></td>
<td><strong>331</strong></td>
<td><strong>100.00</strong></td>
<td></td>
</tr>
</tbody>
</table>
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-May 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)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Continence issues (n=1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Didn’t want any follow up (n=1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>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>Clinic</td>
<td>ICU</td>
<td>Total</td>
<td>Inpatient</td>
<td>Rehab</td>
<td>Outpatient</td>
<td>Required post operative rehabilitation</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>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>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 12612000014853.

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. Medications 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).