Student Audit and Research in Surgery

A multicentre assessment of NSAIDs as risk factors for post-operative adverse events

A multi-centre, medical student led audit of the effect NSAIDs have on post-operative adverse events following elective and emergency bowel resection.

Study protocol v3.7

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# Contents

## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steering Committee</td>
<td>2</td>
</tr>
<tr>
<td>Contents</td>
<td>3</td>
</tr>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Study Questions</td>
<td>6</td>
</tr>
<tr>
<td>Methods</td>
<td>7</td>
</tr>
<tr>
<td>Appendix A: Key steps for successful inclusion of your centre</td>
<td>12</td>
</tr>
<tr>
<td>Appendix B: How to register an audit</td>
<td>13</td>
</tr>
<tr>
<td>Appendix C: Letter recommending audit status for this study</td>
<td>14</td>
</tr>
<tr>
<td>Appendix D: Required data fields</td>
<td>15</td>
</tr>
<tr>
<td>Appendix E: Data definitions</td>
<td>16</td>
</tr>
<tr>
<td>Appendix F: Completed fields in the data</td>
<td>21</td>
</tr>
<tr>
<td>Appendix G: Projected timeline</td>
<td>23</td>
</tr>
<tr>
<td>Appendix H: References</td>
<td>24</td>
</tr>
</tbody>
</table>
Introduction

Scope

Non-steroidal anti-inflammatory drugs (NSAIDs) are regularly used as post-operative analgesics. NSAIDs are recommended for use by the Enhanced Recovery After Surgery Society (ERAS; http://www.erasociety.org/index.php/eras-guidelines), and are also frequently used outside of ERAS protocols as part of the World Health Organisation’s Pain Relief Ladder (http://www.who.int/cancer/palliative/painladder/en/)\(^1\),\(^2\). They are effective adjuncts for post-operative analgesia and are generally considered safe for post-operative use.

There is conflicting new evidence from recent studies, including a population level analysis published in the *British Medical Journal*\(^3\)-\(^5\), suggesting that NSAIDs may increase the rate of adverse events following gastrointestinal resection. This follows concerns about cardiovascular and gastrointestinal side-effects of NSAIDs identified in adenoma prevention trials\(^6\),\(^7\). The proposed mechanisms for adverse effects of NSAIDs include reduced collagen synthesis, down-regulation of prostaglandin expression and increased microthrombus and microembolus formation\(^8\),\(^9\).

Consequently, NSAIDs may contribute to a range of post-operative outcomes through the same mechanisms. More data regarding the effect of NSAIDs is needed to tailor their future indications; particularly as they represent an important class of analgesia in the opiate sparing, enhanced recovery era. Randomised, controlled trials to evaluate NSAIDs would not be feasible in this context as very large numbers of patients would be needed. Consequently, observational data is desirable and will help to improve the care of patients undergoing major surgery\(^10\).

This multicentre study aims to audit the safety-risk profile of post-operative NSAIDs in the post-operative period in current British practice. The risk-adjusted safety of NSAIDs will be determined. Elective and emergency laparotomy for bowel resection is a high volume and activity with a large degree of variation, representing an important area for quality improvement. This protocol outlines the structure for a medical student led, multicentre audit.

Delivery

The Multicentre Appendicectomy Study identified wide variation in practice and outcomes from appendicectomy across 95 centres\(^11\). By including 3326 patients over a two-month period in 2012, it acted as proof of principle that clinician-driven, multicentre, snapshot data collection is feasible and can lead to high quality risk-
adjusted data. The outcomes considered were relevant to modern practice, were delivered quickly and did not rely on administrative data. This study was performed through collaborative networks of trainees.

Medical students and junior doctors (FY1-CT2 grade) are frequently keen to participate in significant research and audit projects, but outside of formalised research degrees are often unable to identify mechanisms of collaboration. Due to their distribution across many hospitals and their ability to penetrate to the heart of the hospital, they represent a natural network to perform a multicentre audit of practice. The multicentre model can deliver large numbers of patients quickly, reducing the burden on the individual student or doctor during their training, whilst allowing meaningful datasets to be collected.

Integration with registrar networks

A secondary aim of this project is to develop a network of junior trainees with an audit and research interest. It is intended that these individuals will feed directly into established regional trainee collaboratives, strengthening their numbers for future projects. We envisage this happening both during this project, as the collaboratives engage students, and after its completion, once the students graduate. This will help nurture a future generation of research-active surgeons. A regularly updated list of the regional collaborative contacts can be found at http://www.asit.org/resources/collaboratives.

Contacts

Please contact us using any means within this protocol. Also, please register yourself for updates at http://goo.gl/bJ6iri if you’re a student, or http://goo.gl/B8n7Kf if you are a doctor.
Study Questions

01 Audit Standard

Post-operative NSAIDs administration is recommended by the Enhanced Recovery After Surgery Society (http://www.erassociety.org/index.php/eras-guidelines). NSAIDS are also frequently prescribed outside of ERAS protocols as part of the World Health Organisation’s Pain Relief Ladder (http://www.who.int/cancer/palliative/painladder/en/). They are considered to be safe post-operative analgesics, with no increase in the rate of post-operative complications. The gold standard for this audit is that 15% of patients will experience an adverse event within 30 days post-operatively11,12, which will be equivalent in those taking and not taking NSAIDs, following risk adjustment.

02 Audit aim

The objective of this multicentre study is to audit the safety profile of post-operative NSAIDs in current British surgical practice.

03 Primary audit questions

1. Are post-operative NSAIDs, when stratified for timing of administration and confounding variables, associated with an increase in the rate of post-operative adverse events?

2. What are the other risk factors for poor outcome following elective and emergency surgery involving bowel resection?
Methods

01 Summary
Prospective inclusion of consecutive patients undergoing bowel resection over a 14-day period at your local hospital.

02 Primary Objective
The primary objective is to assess whether NSAIDs increase the risk of post-operative adverse events. Other data collected will provide accurate risk adjustment.

03 Inclusion Criteria
- Consecutive patients undergoing upper or lower gastrointestinal bowel resection (other than appendicectomy). Bowel resection is defined as complete transection and removal of a segment of rectum, colon, small bowel, stomach or oesophagus. A list of procedures is provided in the Required Data Fields section.
- Consecutive means that all patients operated on in the hospital undergoing a bowel resection should be included.
- Elective or emergency timing
- Open (midline or non-midline), laparoscopic or laparoscopically-assisted procedures
- 18 years of age or above

Methods to identify consecutive patients include:
1. Daily review of elective theatre lists
2. Daily review of team handover sheets/ emergency admission lists/ ward lists (both elective and emergency)
3. Daily review of theatre logbooks (both elective and emergency)

04 Exclusion Criteria
- Appendicectomy for acute appendicitis. Patients who undergo incidental appendicectomy as part of another procedure (e.g. right hemicolecetomy) may be included.
- Any procedure with bowel repair, but without resection (e.g., perforated ulcer, peritoneal washout, closure of stoma).
- Wedge resection without complete bowel transection (e.g. wedge resection of Meckel’s Diverticulum).
- Trauma indication (e.g. road traffic accident)
- Gynaecological primary indication (e.g. Hartmann’s during surgery for ovarian cancer)
- Urological primary indication (e.g. ileal conduit)
05
Timeline
1. The study will run over a 14-day, consecutive time period to best suit your availability:
   a. Period 1: 0800 Tuesday 24th September to 0759 Monday 7th October.
   b. Period 2: 0800 Tuesday 1st October to 0759 Monday 14th October.
   c. Period 3: 0800 Tuesday 8th October to 0759 Monday 21st October.

Where possible (with enough students and support), two teams of students can cover periods 1 and 3 consecutively, working together to deliver 30-day follow-up. This will boost patient inclusion and is encouraged if feasible.

06
Centres
- Any UK hospital that performs gastrointestinal surgery is eligible.
- All participating centres will be required to register their details with the Steering Committee and complete a pilot audit prior to the audit commencing.
- Centres must ensure that they can include consecutive patients and provide >95% data completeness.

07
Local approval
All data collected will measure current practice. No changes to normal patient treatment will be made. Therefore, this study should be registered as an audit of current practice at each participating centre. It is the responsibility of the local team at each site to ensure appropriate local audit approval (or equivalent) is completed for their centre. Participating centres will be asked to confirm that they have gained formal audit approval at their site.

08
Data Collation and Governance
Data will be collected in a Microsoft Excel spreadsheet, due to its relatively greater availability compared to other methods. With Excel, local investigators shall be able to hold their data securely on local hospital computers, before transmitting anonymous data securely.

Data should be collected and held on local hospital computers with patient identifiers to facilitate follow-up. Data will then be submitted centrally with all patient identifiers removed (including removal of patient ID). The data should be sent from a secure NHS email address (e.g., hospital email) to a secure nhs.net email address. Files will be encrypted and cleaned to ensure anonymity, being held centrally on password protected NHS computer systems.

09
Pilot
In order to overcome a learning curve in identifying patients and relevant data, all participating centres will be asked to complete patient identification and the initial stages of the data collection form for one day in the week leading up to the main
starting date. This will also familiarise local teams with hospital pathways and data systems.

Any problems encountered will be addressed through email (STARSurgUK@gmail.com) with the steering committee and teleconferencing where appropriate. Along with a minimum required data completeness (95%), this will also act as a surrogate for quality assurance.

10 Dataset
Data domains that relate to the patient, surgeon, operation, hospital, operative method and postoperative period will be collected. A complete list of data fields and corresponding definitions is provided below. In order to maximise completion of data, the minimum required dataset has been designed to be brief and to test only those factors that are likely to be relevant.

The data collection Excel spreadsheet should be password protected and held securely. An example of completed fields for the form is shown in the appendix.

11 Outcome Measures
Primary outcome measure
The primary outcome measure is the 30-day adverse event rate. These will be measured using the internationally standardised and validated Clavien-Dindo classification (see data definitions). Complications will be analysed both overall, and stratified for severity. Additional specific questions will be asked about anastomotic leak, wound infection and intra-abdominal/pelvic abscess. The Centre for Disease Control definition of wound infection will be used (definitions for surgical-site infection, SSI)\(^{13}\).

Secondary outcome measures
The secondary outcome measure will be the 30-day mortality rate.

Analysis of all outcome measures will be performed confidentially for both the patient and the surgeon; details on the operating surgeon are not being collected other than their grade.

12 Missing Data
In order to maximise data completion and to emphasise its importance to collaborators, contributing centres with >5% missing data (i.e., less than 95% completeness) will be excluded from the study. Regular reminders will be sent to participating centres. An additional regression model using a multiple imputation dataset will be tested.

13 Follow-up
The primary and secondary outcome measures will be recorded if they occurred at any point from the post-operative Day 1 to postoperative Day 30. Because this is an audit of current practice, no changes to normal follow-up should be made. However,
centres should be proactive in identifying post-operative events (or an absence of them), within the limits of normal follow-up. Local follow-up arrangements may include:

- Review the patient, or patient notes, during admission and before discharge to identify in-hospital complications.
- Review the patient in outpatient clinic or via telephone at 30 days.
- Check hospital records (electronic or paper) or handover lists for re-attendances or re-admissions.
- Check for A&E re-attendances.
- Review imaging reports to check for unplanned imaging events; these may have occurred without re-admission to hospital but represent a problem.

14 Statistical analysis
At an average rate of 20 bowel resection in a 14-day period from 45 centres, this study should include a minimum of 900 patients. This will provide 80% power to detect a meaningful increase in the adverse event rate seen with NSAIDs, from 15% to 20% (\( \alpha =0.05 \), matched 1:1, power = 0.8).

Differences between demographic groups will be tested with the \( \chi^2 \) test. Multivariable binary logistic regression will be used to test the influence of variables on the outcome measures. Variables entered into these models will be those that were clinically plausible and that occurred before the outcome event. They will be pre-defined, and used to adjust the main explanatory variables irrespective of statistical outcome. To confirm the validity of models, taking into account the random variation of different hospitals and the potential for missing data, the following models will be created:

- A multilevel model, including the hospital as a random effect at the second level. Variables included in the fixed part of the model will be those judged to be clinically relevant, and will include country and HDI level.
- A single level, fixed effect regression model using complete case analysis.
- To test for the impact of missing data, model 2 will be repeated with multiple imputation.

Model fit and calibration will be tested. Data will be analysed using SPSS version 19.0 and the R Foundation Statistical Programme 3.0.0. One of the authors experienced in this type of statistics will perform this analysis (AB).

15 Organisation
- A core Steering Committee will be responsible for protocol design, data handling, analysis and drafting of the paper.
- The Steering Committee will be responsible for use of data.
- In each centre, a medical student will need to form a mini-team with an FY1-consultant grade doctor. An additional student or doctor will make this team up to three people per centre. Please see Appendix A for how to achieve this.
Together, these mini-teams should gain audit approval with support from a local consultant, put in place means of identifying all eligible patients and all the required data, and plan to ensure data completeness.

Each mini-team is responsible for audit registration, accuracy of data, anonymising data, completeness of collaborator/centre name.

Students can form mini-teams by either approaching doctors in their local hospital, or by approaching a member of an existing registrar led research collaborative (http://www.asit.org/resources/collaboratives).

16 Delivery

Medical students will disseminate and deliver this study. Existing networks, social media and medical school Surgical Societies will be used to recruit centres. The protocol will be available by email and an instructional YouTube video. Participants are encouraged to share the protocol with interested colleagues.

At each medical school, a local lead should take responsibility for dissemination of the protocol and audit tools. Many medical students will not know how to set up and deliver an audit. To help them, we have included a list of key steps. This is also available online as a short instructional YouTube video. Finally, this advice has been placed in a PowerPoint presentation, which local leads can give at group meetings.

In order to finalise this and provide the opportunity for feedback, delegates from each medical school will be invited to a meeting at the Royal College of Surgeons, where the protocol will be discussed openly and interactively. The opportunity to discuss tips and tricks will be available.

17 Audit Registration

Local min-teams should use the guides within this protocol to register this study as an audit at their centre. We have sought advice from the Hillingdon Hospital Research and Development Department who approved this study as an audit. This confirms our opinion that you do not to contact your own R&D department, but you still need to register with your audit department. You may use the letter in Appendix C to support your application, although it carries no authority within your trust.

18 Authorship

A maximum of three collaborators per mini-team for each two week data collection/ follow-up period at each centre will be listed as ‘Pubmed’ citable authors.

Submitting centres with >5% missing data will result in exclusion of that centre from analysis; this includes authorship. Approval to participate from a consultant/senior does not alone constitute authorship; each collaborator should participate in creating the local system, registering the audit, identifying patients, collecting data, and completing follow-up.
Appendix A: Key steps for successful inclusion of your centre

1. Form a **mini-team**. A **medical student** should be leading the team and driving this forward. You should be aiming to work with at least one motivated junior doctor. You should identify someone suitable: someone you know working there (e.g. an FY1), a junior doctors you don’t know but who works on the team, the consultant who will be supervising you, the consultant in charge of audit. You can also walk onto the ward, speak to an FY1 and ask them who the best FY1/2 is to help you run this; this approach often succeeds. If you struggle, please contact us and we will try and find someone. Your local registrar collaboratives are also likely to have someone working in that hospital ([http://www.asit.org/resources/collaboratives](http://www.asit.org/resources/collaboratives)).

2. Choose your **14 day consecutive period** to best suit your availability:
   a. Period 1: 0800 Tuesday 24th September to 0759 Monday 7th October.
   b. Period 2: 0800 Tuesday 1st October to 0759 Monday 14th October.
   c. Period 3: 0800 Tuesday 8th October to 0759 Monday 21st October.

   Where possible (with enough students and support), two teams of students can cover periods 1 and 3 consecutively, working together to deliver 30-day follow-up.

3. Ensure that you gain **formal audit approval** from your hospital’s clinical audit department. You will need a consultant surgeon to support you and sign the hospital’s audit form. You should use this protocol to complete and support your audit proposal. **It is essential that you begin this process immediately**; approval can take up to a month in some instances. **You may have to go to the hospital before your placement formally starts to ensure you’ll be ready.** See below: ‘How to register your audit’.

4. Complete a **practice** audit day: Complete 1 day of audit in your hospital of choice in the week prior to the main start day, and record the relevant information on the designated data collection form. This will allow you to become familiar with the best way to identify patients, and data collection methodology. Contact us with any queries from the day. This will allow the steering committee to iron-out any unidentified problems.

5. Check regularly for **follow-up** information for your patient cohort for a **30-day period**. Identify patients and enter ongoing data; this study is **prospective**. **Do not wait until the end of the audit period**; that is retrospective. Talk to your chosen consultant about the best way to do this, which will vary from centre to centre, and may include:
   - Review the patient, or patient notes, during admission and before discharge to identify in-hospital complications.
   - Review the patient in outpatient clinic or via telephone at 30 days
   - Check hospital records (electronic or paper) or handover lists for re-attendances or re-admissions; check for A&E re-attendances.
   - Review imaging reports to check for **unplanned** imaging events; these may have occurred without re-admission to hospital but represent a problem.

   **Be proactive in identifying post-operative adverse events** (e.g. visit patients on the ward, discuss with medical team, daily checking of hospital notes etc.). This will prevent under-estimating true rates.

6. Avoid **missing data**: complete all fields. If more than 5% of patients at your centre are missing data, your centre and name cannot be included. Don’t add or remove any columns from the spreadsheet.

7. **Anonymise** your dataset: Data protection is essential. **Please delete column A** (the first column, patient ID number) before emailing your dataset back to us.
Appendix B: How to register an audit

This may seem daunting but is in fact quite straightforward. Every hospital has an audit department and it is a simple case of approaching them with the information we have prepared.

1. There is a lot to do in order to create a team, register and approve the audit, and identify ways to collect data. **The best way is to start at least a month before the study opening date.** If your placement does formally begin by then, you should go to the hospital or make contact before then. Registering the audit, and receiving approval back, can take a month (although is often quicker).

2. Create a mini-team for your audit. Approach someone you know (e.g. an FY1-2), the consultant who will be supervising you, someone working in the surgical team (who you may not know), or contact us and we will try and find someone suitable for you.

3. Contact your hospital’s **Clinical Audit Department**

   Preferably by phone in the first instance and then by email. They will provide you with a standard audit form to complete, via email or from the intranet. You can **copy and paste** from this protocol. We have provided a sample letter from the Research and Development Department of a participating centre, who agree that this is an audit. This can be used to support your application (although it carries no specific permission for your hospital). Ensure that the audit department know that this is part of a larger project and that you will send anonymised data for central collation via secure nhs.net email addresses. The junior doctor on your team can help you with this.

4. Consultant signature

   Once the form is completed, you may need to ask your supervising consultant to sign it. The junior doctor on your team can help you with this.

5. Form submission

   Submit the form and protocol to the Audit Department as soon as possible. Keep the written approval somewhere safe (this may be an email), as you will be asked to confirm that formal approval was granted.
Appendix C: Letter recommending audit status for this study

This letter can be used to support your audit application, as it gives one R&D department’s confirmation that this is an audit. However, it carries no specific permission for your hospital, and you still need to seek approval from your hospital’s own audit department.

The Hillingdon Hospitals NHS Foundation Trust

Research and Development Office
Education Centre
Hillingdon Hospital
Piedl Health Road
Uxbridge
Middlesex
6th August 2013

Chetan Khatri,
Medical Student
Hillingdon Hospital

Dear Chetan,

Re Audit Project. A multi-centre, medical student led, snapshot audit of the effect NSAIDs have on post-operative adverse events following elective and emergency bowel resection.

Thank you for your emails with details of the above project you are requesting to carry out at the Hillingdon Hospital NHS Trust. I have reviewed the protocol and you have given me the following assurance regarding the data protection issues, which were my only concerns.

You have agreed:-

- In the spreadsheet where data is inputted to highlight the importance of removing patient ID field before submission
- In instructions to potential centres highlight the importance again
- Accept data only by nhs net emails, both sent from and to.

I confirm that, in my opinion, this study is not research and probably fall under the Audit / service evaluation category.

Before you start your project you will need to get the approval of the consultants whose patients’ data you are reviewing and it will to be logged with Anita Maudley in the Clinical Audit Department at the Trust (extension 3787).

Please do not hesitate to contact me if I can be of further assistance.

Yours faithfully,

Gay Bineham
R&D Manager

Switchboard: 01895 238282  Main Fax: 01895 814867  Minicom (Test Phone): 01895 279379
The Hillingdon Hospital with Mount Vernon

@STARSurgUK; STARSurgUK@gmail.com

14
## Appendix D: Required data fields

<table>
<thead>
<tr>
<th>#</th>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient ID</td>
<td>Local hospital field; delete before transmission</td>
</tr>
<tr>
<td>2</td>
<td>Patient age (whole years)</td>
<td>Years</td>
</tr>
<tr>
<td>3</td>
<td>Patient gender</td>
<td>Male, Female</td>
</tr>
<tr>
<td>4</td>
<td>ASA score</td>
<td>I, II, III, IV, V</td>
</tr>
<tr>
<td>5</td>
<td>History of ischaemic heart disease</td>
<td>Yes/no</td>
</tr>
<tr>
<td>6</td>
<td>History of congestive heart failure</td>
<td>Yes/no</td>
</tr>
<tr>
<td>7</td>
<td>History of cerebrovascular disease (stroke or transient ischemic attack)</td>
<td>Yes/no</td>
</tr>
<tr>
<td>8</td>
<td>History of diabetes</td>
<td>No, diet, controlled, tablet controlled, insulin controlled</td>
</tr>
<tr>
<td>9</td>
<td>Chronic kidney disease (creatinine &gt; 177 umol/L)</td>
<td>Yes/no</td>
</tr>
<tr>
<td>10</td>
<td>Was the patient taking a peri-operative statin? (see definitions)</td>
<td>Yes high dose (40mg +OD simvastatin or equivalent), Yes low dose (5-20mg OD simvastatin or equivalent), No</td>
</tr>
<tr>
<td>11</td>
<td>Date of operation</td>
<td>DD/MM/YY</td>
</tr>
<tr>
<td>12</td>
<td>Time of operation</td>
<td>24 hour clock</td>
</tr>
<tr>
<td>13</td>
<td>Primary operation performed</td>
<td>Hartmanns, left hemicolectomy, right hemicolectomy, subtotal colectomy, panproctocolectomy, anterior resection, abdominoperineal resection, small bowel resection, complete gastrectomy, partial gastrectomy, oesophagectomy, Whipples, other (free text)</td>
</tr>
<tr>
<td>14</td>
<td>Elective or Emergency</td>
<td>Elective/ Emergency</td>
</tr>
<tr>
<td>15</td>
<td>Anastomosis performed</td>
<td>Handsewn, stapled, stoma</td>
</tr>
<tr>
<td>16</td>
<td>Stoma formation</td>
<td>Planned temporary, permanent, none</td>
</tr>
<tr>
<td>17</td>
<td>Underlying pathology/ indication</td>
<td>Diverticular disease, hernia, malignancy, polyp, ischaemic bowel, adhesional obstruction, faecal perforation, ulcerative colitis, Crohn’s disease, other</td>
</tr>
<tr>
<td>18</td>
<td>Highest post-operative glycaemic reading within 24 hours of surgery</td>
<td>Value (mmol/L)</td>
</tr>
<tr>
<td>19</td>
<td>Post-operative critical care admission</td>
<td>Planned, unplanned, none</td>
</tr>
<tr>
<td>20</td>
<td>Post-operative ERAS pathway used?</td>
<td>Yes, no</td>
</tr>
<tr>
<td>21</td>
<td>Was an NSAID used post-operatively?</td>
<td>Yes - Ibuprofen, Yes -diclofenac, Yes - naproxen, Yes - celecoxib, Yes - rofecoxib, Yes - other, No</td>
</tr>
<tr>
<td>22</td>
<td>What day was the first dose of NSAID given?</td>
<td>Day 1-7 (day 1 is day of surgery), none given</td>
</tr>
<tr>
<td>23</td>
<td>What dose of NSAID was given? (see definition)</td>
<td>Low, high</td>
</tr>
<tr>
<td>24</td>
<td>Total length of stay (days)</td>
<td>Days</td>
</tr>
<tr>
<td>25</td>
<td>30-day re-admission?</td>
<td>Yes, no</td>
</tr>
<tr>
<td>26</td>
<td>Surgical Complication Grade (Clavien-Dindo Classification, list most severe Grade I-IV)</td>
<td>I-IV</td>
</tr>
<tr>
<td>27</td>
<td>Anastomotic leak</td>
<td>Yes/no</td>
</tr>
<tr>
<td>28</td>
<td>Wound infection</td>
<td>Yes/no</td>
</tr>
<tr>
<td>29</td>
<td>Intra-abdominal/pelvic abscess</td>
<td>Yes/no</td>
</tr>
<tr>
<td>30</td>
<td>Cardiovascular event</td>
<td>Yes/no</td>
</tr>
</tbody>
</table>
Appendix E: Data definitions

This section provides a data dictionary for key terms above, where not self-explanatory. It also provides information on where will be best to find this data, shown in italics. Much of this data you can collect yourself once you know how and have access. Some of it, you may need help from one of the junior doctors in your mini-team.

- **Patient ID (notes)** – this is the local patient identifier, to be used to track patients.
  
  This column must be deleted prior to transmission of the final dataset.

- **Patient age (notes)** – in whole years

- **American Society of Anaesthesiologists score** *(take from anaesthetic chart, filed in notes)*

  I – a normal healthy patient
  II – a patient with mild systemic disease
  III – a patient with severe systemic disease
  IV – a patient with severe systemic disease that is a constant threat to life
  V – a moribund patient not expected to survive without the operation

- **Peri-operative statin use** *(current drug chart; admission clerking document, electronic prescribing; old drug chart filed in notes)* – peri-operative statin use is defined as once daily pre-operative use of any duration AND administration in at least one of the first 7 post-operative days. Simvastatin ≥40mg and above is taken as being high dose. Other statin cut-offs for high doses are:

  a. Atorvastatin (Lipitor) ≥20mg
  b. Rosuvastatin (Crestor) ≥5mg
  c. Lovastatin ≥80mg
  d. Pravastatin ≥80mg
  e. Ezetimibe/Simvastatin (Vytorin) ≥10/10

- **Primary operation performed** *(operation note, filed in notes or on computer)* – this should record the main procedure performed.
- **Elective or Emergency** *(operation note, clinical notes)* – Elective surgery is defined as any planned admission for surgery including expedited surgery; Emergency surgery is that performed on the same admission as diagnosis.

- **Anastomosis performed** *(operation note, filed in notes or on computer)* – any joining of two completely disjointed ends of bowel. A stapled anastomosis which is reinforced with handsewn sutures should be recorded as stapled.

- **Underlying pathology/indication** *(clinical notes, or operation note, filed in notes or on computer)* – this should record the main cause leading to surgery.

- **Highest post-operative glycaemic reading within 24 hours of surgery** *(anaesthetic/recovery chart filed in notes; ITU charts, nursing notes at the end of the bed)* – this optional field can be completed if a reading was made as part of normal care. The highest value in the first 24 hours should be recorded, and may either be by finger-prick method, by serum analysis (either blood gas analysis or laboratory). The value should be given in either mg/dl or mmol/l, depending on local reporting standards. This should be indicated in the email when returning data.

- **Post-operative critical care admission** *(notes)* – A planned admission is when the decision is made pre-operatively for a planned post-operative admission to critical care. An unplanned admission occurs when the patient returned to the ward after theatre and was subsequently transferred to critical care, or due to intra-operative incident mandating critical care. If no critical care admission was made, this should be entered as “none.” For this study, critical care refers to level 2 (HDU) or 3 (ITU) care, including intensive/critical care (1:1 nursing ratio) or high dependency care (1:2 nursing ratio).
- **Post-operative ERAS (Enhanced Recovery After Surgery) programme**
  (*nursing notes at end of the bed*) – mark as yes if the patient was part of the hospital’s ERAS programme.

- **Post-operative NSAID administration** (*current drug chart; old drug chart filed in notes*) – If multiple NSAIDs were used, only one should be recorded in this preference: diclofenac, ibuprofen, other NSAID.

- **NSAID dose** (*current drug chart; old drug chart filed in notes*) –

<table>
<thead>
<tr>
<th>NSAID type</th>
<th>Low dose</th>
<th>High dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>&lt; 100mg daily</td>
<td>≥ 100mg daily</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>&lt; 1200mg daily</td>
<td>≥ 1200mg daily</td>
</tr>
<tr>
<td>Naproxen</td>
<td>&lt; 750mg daily</td>
<td>≥ 750mg daily</td>
</tr>
<tr>
<td>Celecoxib</td>
<td>&lt; 200mg daily</td>
<td>≥ 400mg daily</td>
</tr>
<tr>
<td>Rofecoxib</td>
<td>&lt; 12.5mg daily</td>
<td>≥ 25mg daily</td>
</tr>
<tr>
<td>Others: see</td>
<td>See low dose section</td>
<td>See medium and high dose section</td>
</tr>
<tr>
<td><a href="http://www.ncbi.nlm.nih.gov/books/NBK42997/">link</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Length of stay** (*computers/ notes*) – calculated from the day of admission to the day of discharge. The day of admission counts as day 1, and the day of discharge as a whole day. Thus staying from Monday to Friday counts as a 5-day length of stay (“5” should be entered).

- **30-day mortality** (*computer, notes*) – related to all-cause mortality that occurs up to and including the post-operative Day 30.

- **30-day readmission** (*computer, notes*) – related to re-admission to the same or any other hospital following discharge, by Day 30.
- **Clavien-Dindo Classification of Surgical Complications**\(^2\) (*computer, notes, outpatients*)– the highest grade should be recorded. A complication may, for different patients, be entered at different grades depending on the severity for that patient. Examples are listed in *italics*.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. <em>Example: Surgical site infection treated with wound opening and without antibiotics, ileus, thrombophlebitis, confusion, delirium</em></td>
</tr>
<tr>
<td>II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. <em>Example: Surgical site infection treated with antibiotics, myocardial infarction treated medically, deep venous thrombosis treated with clexane, anastomotic leak, pneumonia treated with antibiotics, urinary tract infection, C difficile diarrhoea, cardiac complication not requiring invasive/ITU intervention</em></td>
</tr>
<tr>
<td>III</td>
<td>Requiring surgical, endoscopic or radiological intervention <em>Example: Return to theatre for any reason, endoscopic therapy, interventional radiology, anastomotic leak</em></td>
</tr>
<tr>
<td>IV</td>
<td>Life-threatening complication (including CNS complications)‡ requiring critical care management <em>Example: single or multiorgan dysfunction requiring critical care management, sepsis, pneumonia with ventilator support, renal failure with filtration, cardiac event with inotropes</em></td>
</tr>
<tr>
<td>V</td>
<td>Death of a patient</td>
</tr>
</tbody>
</table>

- **Anastomotic leak** (*computer, notes, radiology systems, outpatients*)– defined as an anastomotic leak detected clinically/symptomatically, radiologically, and/or intra-operatively.

- **Pelvic abscess** (*computer, notes, radiology systems, outpatients*) – detected clinically/ symptomatically, radiologically, or intra-operatively.
- **Wound infection** (*computer, notes, outpatients*)– We advise adherence to the Centre for Disease Control’s definition of surgical site infection, which is any one of:

  1. Purulent drainage from the incision
  2. At least two of: pain or tenderness; localised swelling; redness; heat; fever;
     AND The incision is opened deliberately to manage infection or the clinician diagnoses a surgical site infection
  3. Wound organisms AND pus cells from aspirate/ swab

- **Cardiovascular event** (*computer, notes, outpatients*)– include myocardial infarction, unstable angina, sudden death from cardiac causes, ischaemic and haemorrhagic stroke, transient ischaemic attack, peripheral arterial thrombosis, peripheral venous thrombosis and pulmonary embolus⁷.
Appendix F: Completed fields in the data
Appendix G: Projected timeline

1. August 2013 – develop networks, advertising and student registration (via web survey)
2. Tuesday, 10 September – meeting for delegates at Royal College of Surgeons
3. Consecutive 14-day period for patient inclusion is either (choose ONE which is better for your timetable):
   a. Period 1: 0800 Tuesday 24th September to 0759 Monday 7th October.
   b. Period 2: 0800 Tuesday 1st October to 0759 Monday 14th October.
   c. Period 3: 0800 Tuesday 8th October to 0759 Monday 21st October.
   Where possible (with enough students and support), two teams of students can cover periods 1 and 3 consecutively, working together to deliver 30-day follow-up.
4. Taking the day of surgery as Day 1, 30 day follow-up is completed for the last patient on either
   a. Period 1: Monday 4th November
   b. Period 2: Monday 11th November
   c. Period 3: Monday 18th November
5. Return of data by 1st December
6. March 2014 – presentation at the Association of Surgeons in Training (ASiT) Conference medical student parallel session
Appendix H: References


