POSTVenTT (**POST** operative **Variations in** anaemia treatment**T** and **Transfusions**)

Prospective audit of anaemia after major abdominal surgery
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Project Timeline

Patients will be collected in a prospective, sequential manner for two sets of two-week periods. The follow up is at 30 days.

The Audit will commence following full approvals and set up. There will be two periods of data collection, each of two-week duration. Data will be completed, cleaned and checked with data lock on December 31\textsuperscript{st} 2021.
Introduction

Anaemia affects nearly a quarter of the world\textsuperscript{1} and is common in surgical patients with a third of patients presenting with preoperative anaemia and three quarters of patients discharged from hospital with anaemia\textsuperscript{2}. The World Health Organisation defines anaemia as an insufficient circulating red cell mass, with a haemoglobin (Hb) concentration of $< 130 \text{ g.l}^{-1}$ for men and $< 120 \text{ g.l}^{-1}$ for women\textsuperscript{1}.

Perioperative anaemia is associated with increased postoperative complications and delayed patient recovery leading to increased post-operative morbidity and mortality\textsuperscript{1-7}. Anaemia also leads to an increased use of allogeneic blood transfusions\textsuperscript{7-10}, which is an independent risk for poorer patient outcomes\textsuperscript{10-13}.

Postoperative anaemia can be due to blood loss at operation or secondary to the inflammatory process associated with surgery, which causes an increase in hepcidin production resulting in functional iron deficiency\textsuperscript{13-15} and reduced red cell production.

In recent years, there has been a significant increase in the use of intravenous iron therapy for preoperative anaemia in line with major international guidelines\textsuperscript{15}. This is common practice in Australia and New Zealand.

The POSTVenTT (POST operative Variability in anaemia treatmenT and Transfusion) audit aims to increase our understanding of variability in adherence to anaemia management guidelines and to assess the impact of anaemia management in clinical care following major abdominal surgery\textsuperscript{16}. 
## Audit Standards

Relevant audit standards Australian National Blood Authority and AAGBI guidelines

<table>
<thead>
<tr>
<th><strong>Pre-operative Standards:</strong></th>
<th></th>
</tr>
</thead>
</table>
| **1.** Preoperative anaemia should be identified and managed | Patient Blood Management Guidelines, Australian National Blood Authority 2012 Module 2 - Perioperative<sup>17</sup>  
• preoperative anaemia should be identified, evaluated and managed to minimise RBC transfusion, |

<table>
<thead>
<tr>
<th><strong>Intra-operative Standards:</strong></th>
<th></th>
</tr>
</thead>
</table>
| **1.** In major surgery tranexamic acid should be given | Patient Blood Management Guidelines, Australian National Blood Authority 2012 Module 2 - Perioperative<sup>17</sup>  
• the use of intravenous tranexamic acid is recommended |

<table>
<thead>
<tr>
<th><strong>Post-operative Standards:</strong></th>
<th></th>
</tr>
</thead>
</table>
| **1.** Restrictive blood transfusion should be standard of care | The National Blood Authority’s Patient Blood Management Guideline 2012 Module 4 – Critical Care<sup>17</sup>,  
• In critically ill patients, a restrictive transfusion strategy should be employed |
| **2.** Post-Operative Hb levels should be measured | International consensus statement on the management of postoperative anaemia after major surgical procedures  
• All patients who have undergone major surgery (defined as blood loss > 500 ml or lasting > 2 h) and who had pre-operative anaemia or moderate-to-severe blood loss during surgery must be screened for anaemia after surgery<sup>18</sup>. |
| **3.** Oral iron should not be prescribed | International consensus statement on the management of postoperative anaemia after major surgical procedures  
• In patients with postoperative anaemia, early oral iron therapy is not clinically effective; its routine use in this setting is not recommended. |

The POSTVenTT audit is designed to be complementary to ongoing quality improvement efforts in acute and elective surgical care, for example the RECON audit in 2019 and The Australian and New Zealand Emergency Laparotomy Audit – Quality Improvement (ANZELA-QI)

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**DRAFT-pending HREC review**

POSTVenTT Protocol v5.0 25<sup>th</sup> Mar 2021

Clinical Trials Network Australia (CTANZ)
Methods

1. Summary:
This is a clinical audit, which will involve mini-teams of 1 – 4 collaborators per speciality group per data collection period. These teams will collect data over two continuous 14-day periods on all consecutive patients undergoing major abdominal surgery at participating hospitals, with a follow-up of up to 30 postoperative days. A consultant will supervise all mini-teams.

2. Study Aims:
   • **Primary Aim**: To audit compliance with pre-, intra-, and postoperative guidelines for management of anaemia in patients undergoing major abdominal surgery.
   • **Secondary Aims**
     - To characterise incidence of anaemia following major abdominal surgery.
     - To identify risk factors associated with postoperative anaemia.
     - To explore associations between postoperative anaemia and rate of postoperative complications.
     - To explore association of postoperative anaemia with short-term outcomes (length of stay, readmission to Hospital).
     - To audit the use or iron therapy or blood transfusion.

3. Project Timeline:
   • The suggested overall data collection period will be four months. There will be two periods of data collection. In each period, each mini-team will collect data over a 2-week, consecutive period with subsequent 30-day follow-up.
   • Patients should be included if they were operated on during the data collection periods as specified above.
   • The 30-day follow-up is defined as 30-days from the day of discharge from hospital for the patient’s index operation.
   • Additional data collection periods may be added later in the study, to give flexibility to include further centres in Australia or New Zealand with logistical difficulties in study start up.
4. Patient Eligibility:

Summary: The study population will include consecutive adult patients undergoing major emergency or elective abdominal surgery.

Inclusion criteria:

- **Age**: Adult, 18 years or above.
- **Procedure**: A major abdominal surgery is defined as an operation with an incision into the abdominal cavity and anticipated duration of more than one hour. Procedures performed using any surgical approach, including open, laparoscopic, and robotic surgery are included.
- **Urgency**: Patients undergoing planned (elective or expedited) or unplanned (emergency) surgery.

Exclusion criteria:

- **Procedures**: Abdominal surgery classified as minor operations such as; laparoscopic appendicectomy (emergency or elective), endoscopy procedures, transanal or transurethral procedures.
- **Indication**: Palliative procedures as determined pre-operatively and explicitly stated in the medical record or consent form.
- **Extent of surgery**: Operations that are either
  - staged with a planned return for reoperation (such as but not exclusively, damage control laparotomy or burns surgery).
  - Change in operative plan such that during the first procedure it is determined that a re-operation is necessary, even if the patient was enrolled pre-operatively
- **Return to theatre**: Each patient should only be included in the study once. Patients returning to theatre due to complications following earlier surgery can be included, as long as their index procedure has not already been included in the POSTVenTT study.

5. Covariates:

Data will be collected on adherence to anaemia management guidelines, and confounding factors for risk of anaemia to permit accurate risk adjustment of outcomes, particularly the use of intravenous iron and also blood transfusion. Without appropriately adjusting for risk factors, it is likely that any findings would be biased and unable to be appropriately analysed. A full list of required data fields is available in the appendix, and on the REDCap database.
6. Outcome Measures, Follow Up, and Data Collection:

Primary outcome measure: Adherence to selected National Blood Authority and International consensus statement guidelines for anaemia management (percentage, %).

Anaemia is defined as Haemoglobin < 120g/L in women and <130g/L in men.

Secondary outcome measures:

- Post-Operative anaemia following discharge from Post anaesthetic recovery area/HDU/ICU and day 3, 7 (or weekly thereafter).
- Post-Operative Blood transfusion.
- Haemoglobin level at discharge from hospital.
- 30-day postoperative complication rate (defined according to the Clavien-Dindo classification: see appendix).
- Critical care bed days up to 30 days postoperatively.
- Length of in-patient stay up to 30 days postoperatively.
- Trigger for MET call.
- Re-admission to ICU or HDU.
- Patient frailty.
- Reoperations.
- Readmission to hospital within 30 days and 90 days following discharge after index operation.

Methods of data collection:

This project will involve the formation of mini-teams of 1 – 4 collaborators. These teams will prospectively collect data over a continuous 14-day period on all eligible patients undergoing abdominal surgery at participating hospitals, with a 30-day postoperative follow up for each patient. To ensure data is collected on all consecutive eligible patients these teams will review elective theatre lists, handover sheets/emergency admission and ward lists, and theatre logbooks (both elective and emergency) on a daily basis. Mini-teams should be supervised by up to two consultants (one surgeon, one anaesthetist) at each site.

Information will be collected through patient information systems, including accessing:

- Patient charts (written and electronic)
  - Medication charts
  - Discharge summaries

DRAFT-pending HREC review
POSTVenTT Protocol v5.0 25th Mar 2021
Clinical Trials Network Australia (CTANZ)
- Relevant letters from outpatient clinics and surgeons’ rooms

**REDCap database:**

All relevant data will be inputted into a Case Report Form (Appendix) and subsequently transferred into the REDCap database. All Case Report Forms will be stored securely with the Investigator Site File (ISF) for the time period required by institutional protocol and/or local governance approvals, and subsequently destroyed.

The REDCap application and data repository will be held in The University of Western Australia (UWA) data centre and governed by UWA information technology and security processes. This includes appropriate best practices such as network firewalls, system and security monitoring and two factor authentication.

REDCap access privileges will be managed and maintained by the UWA Clinical Trials Unit (CTU) to ensure that users can only access data relevant to their site. That is, each site user will only have access to their site’s data. REDCap also implements authentication to validate the identity of users that log in to the system.

REDCap maintains an audit trail that logs user activity, including contextual information (e.g. the project or record being edited). Whether the activity be entering data, exporting data, modifying a field, running a report, or add/modifying a user, among a plethora of other activities, REDCap logs actions. The logging record can be viewed by users who have appropriate privileges.

Sites only hold the identifiable data (an identifiable master list of patients for this project will be kept at each site) and the de-identified data will be entered into the UWA REDCap. The master list will be retained on a password protected computer and have restricted access to only staff directly involved with the project as determined by data access groups at each site. The master list will be managed and retained on a password protected computer and destroyed once the project is closed (or when approvals have expired). No identifiable information from the master list will leave each site unless otherwise specified in an agreement or approved protocol. Data will be stored for at least five years after the completion of research activity.

All sites will flag and screen patients as per institutional protocol and will be required to keep a log of patient details in their ISF. Data capture can be on paper CRF and held locally or de-identified data can be entered directly to the UWA REDCap database. No identifiable data will be transferred to the REDCap database from any site. Patients will be only re-identifiable by their Redcap ID via the patient log at the site.

### 7. Quality assurance:

**Design:** This protocol was written with guidance from an expert cross-speciality advisory group and reviewed by the project expert advisory group, Professor Toby Richards (UWA, Australia), Dr Peter Pockney (University of Newcastle, Australia), Dr Deborah Wright (University of Otago, New Zealand) and inputs from the trainees involved in the core management of the project.
Data completeness: Following data collection, only data sets with >95% data completeness will be accepted for pooled national analysis. To emphasise the importance of data completeness to collaborators, data collection periods with >5% missing data points will be excluded from the study and collaborators from those periods withdrawn from the published list of citable collaborators.

Validation: This methodology for snapshot audit has been widely validated across multiple datasets internationally demonstrating high levels of case ascertainment (typically 90 to 95%) and data accuracy (96 to 98%) \(^{19-23}\). A process of data validation by independent assessors will be performed on a sample of participating centres in each country.

Patient and service user involvement: The James Lind Alliance (JLA) is an international non-profit initiative established in 2004 \(^{24}\). It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritise unanswered questions or evidence uncertainties that they agree are the most important. POSTVenTT will collect data to address the following JLA priority areas in Perioperative Care:
- How can patient care around the time of emergency surgery be improved?
- What outcomes should we use to measure the 'success' of anaesthesia and perioperative care?
- How can we improve recovery from surgery for elderly patients?

8. Authorship:
In accordance with Research Collaborative authorship guidelines \(^{25}\), all research outputs from POSTVenTT will be listed under a single corporate authorship (POSTVenTT Collaborative). All collaborators will be listed as PubMed-citable collaborators within the POSTVenTT Collaborative in accordance with the roles defined below (so long as the minimum requirements for authorship are met).

- **Writing Group**: A group of medical students, junior doctors and external advisory board members responsible for the overall scientific content, data analysis, and preparation of research manuscripts.
- **Steering Committee**: A core group of medical students and junior doctors who have overall responsibility for protocol design, project co-ordination, and data handling.
- **Statistical Analysis**: A small team of dedicated statisticians who take overall responsibility for the statistical analysis plan and quality assurance of data analysis.
- **External Advisory Group**: A panel of cross-disciplinary field experts who are able to ensure contextual and scientific relevance of the protocol design, data fields and data interpretation.
- **Regional Leads**: A network of trainees and students across all ANZ training networks. They will be
responsible for co-ordinating mini-teams at local hospitals, and act as a link between mini-teams / hospital leads, and the steering committee. Requirements for authorship on POSTVenTT outputs include:

- Effective and responsive communication with the POSTVenTT steering committee, and with local collaborators throughout their time as Regional Leads.
- Recruitment of at least two mini-teams in at least one centre in their area, with a minimum of one centre meeting the criteria for inclusion within the POSTVenTT dataset.

**Local (Hospital) Leads**: A single lead point of contact for data collection at each site who has overall responsibility for site governance registration and coordinating handover between local collaborator teams. Local Leads should be prospectively identified by Regional Leads (although remain an optional role), and these are recommended to be the junior doctor or a senior medical student within the mini-team, and only one person can fulfil this role. Minimum requirements for authorship on POSTVenTT outputs include:

- Primary person responsible in obtaining local approvals for conduct of the POSTVenTT audit.
- Active involvement in a mini-team during a data collection period at the centre, which meets the criteria for inclusion within the POSTVenTT dataset.
- Co-ordination of handover between all local collaborator teams at the centre, and involvement in local dissemination of POSTVenTT results.
- Presentation of local results at their centre from the POSTVenTT audit (or otherwise arranges another collaborator to present on their behalf).

**Local collaborators (data collectors)**: A team of up to 4 people responsible for data collection per specialty group over a specific 2-week period at a particular centre. Reflecting the cross-specialty nature of the POSTVenTT study, up to one mini-team (4 members) will be permitted per specialty group (if these surgeries are conducted by separate specialty teams at the centre), defined as:

1. Colorectal surgery
2. Upper GI surgery/ Hepatobiliary surgery
3. Vascular surgery
4. Urology
5. Gynaecological surgery

This gives a maximum of 20 collaborators per data period per hospital. Please note that, mini-team size and the total number of collaborators required at each site will be at the discretion of the regional lead according to the specialty organisation and caseload of each hospital. Minimum requirements for authorship on POSTVenTT outputs include:
o Compliance with local audit approval processes and data governance policies.

o Active involvement in data collection over at least one data collection period at a centre, which meets the criteria for inclusion within the POSTVenTT dataset.

o Collaboration with the regional / local lead to ensure that the audit results are reported back to the audit office / clinical teams.

- **Supervising Consultant:** up to two consultants, one in a surgical specialty, and one in anaesthesia or critical care must supervise data collection in each hospital. Minimum requirements for authorship on POSTVenTT outputs include:

  o Sponsorship of local audit registration, and responsible to ensure local collaborators act in accordance with local governance guidelines.

  o Inclusion of at least one data collection period at their centre, which meets the criteria for inclusion within the POSTVenTT dataset.

  o Facilitation of local audit results presentation and support of appropriate post-audit interventions.

  o Completion of workplace-based assessments for students or trainees (e.g. RACS), if requested.

Criteria for centre inclusion within POSTVenTT:

- Obtain of all appropriate local approvals for conduct of the POSTVenTT audit.

- Successful completion of at least one data collection period at the centre (with a minimum of one eligible patient per period included). Individual data collection periods will only be included when:

  i. >95% data completeness has been achieved.

  ii. All data for the period has been uploaded within the specified deadlines.

Please note if these criteria are not met, then the contributing mini-team and/or the centre may be removed from the dataset and authorship list (please get in contact as soon as potential issues arise so we can support as many centres to be included as possible).
## Appendix: Data Dictionary

<table>
<thead>
<tr>
<th>Pre-operative Data Fields</th>
<th>Required data (definition / comment)</th>
<th>Suggested source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient age</td>
<td>Years (whole years at the time of operation)</td>
<td>Clinical notes</td>
</tr>
<tr>
<td>2. Patient gender</td>
<td>Male / Female</td>
<td></td>
</tr>
<tr>
<td>3. Cultural identity</td>
<td>European/Aboriginal/Torres Straights Islander/Maori/Pacific Peoples/Asian/Middle Eastern/Latin American/African/Other</td>
<td>Clinical notes</td>
</tr>
<tr>
<td>4. Patient height</td>
<td>Meters (record to two decimal places)</td>
<td>Drug charts</td>
</tr>
<tr>
<td>5. Patient weight</td>
<td>Kilograms (record to one decimal places)</td>
<td>Clinical notes</td>
</tr>
<tr>
<td>6. Patient ASA grade</td>
<td>Grade I-V (Full ASA classification available at: <a href="https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system">https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system</a>)</td>
<td>Anaesthetic notes</td>
</tr>
<tr>
<td>7. History of cardiac disease</td>
<td>Yes (myocardial infarction, angina, congestive cardiac failure within 30d prior to surgery, hypertension on Rx) / No</td>
<td>Admission clerking</td>
</tr>
<tr>
<td>8. Clinical Frailty Score</td>
<td>1 – 9</td>
<td>Anaesthetic notes</td>
</tr>
<tr>
<td>9. History of chronic respiratory disease</td>
<td>Yes (asthma, chronic obstructive pulmonary disease or pneumonia, bronchiectasis, pulmonary fibrosis, lung cancer, obstructive sleep apnoea, other) / No</td>
<td>Outpatient letters</td>
</tr>
<tr>
<td>10. History of Diabetes</td>
<td>Diabetes (diet controlled, tablet controlled, insulin controlled)</td>
<td></td>
</tr>
<tr>
<td>11. History of neurological disease / stroke</td>
<td>Yes / No</td>
<td></td>
</tr>
<tr>
<td>12. History of liver disease</td>
<td>Yes / No</td>
<td></td>
</tr>
<tr>
<td>13. Smoking status</td>
<td>Current (includes those who stopped smoking within 6 weeks), Ex-smoker, Never.</td>
<td></td>
</tr>
<tr>
<td>14. Anticoagulant/Antiplatelet</td>
<td>Yes / No</td>
<td></td>
</tr>
<tr>
<td>15. Pre-operative blood test values</td>
<td>Haemoglobin (grams / litre) / Creatinine / estimated Glomerular Filtration Rate (ml / min) / Ferritin (if done)</td>
<td>Pathology systems</td>
</tr>
<tr>
<td>16. Pre-operative anaemia management</td>
<td>Oral or intravenous iron clinic Yes / No</td>
<td></td>
</tr>
</tbody>
</table>

Number of days prior to operation patient received treatment

**Abbreviations:** ASA = American Society of Anaesthesiologists; Hb = Haemoglobin; PACS = Picture Archiving and Communication.
<table>
<thead>
<tr>
<th>Intra-operative Data Fields</th>
<th>Required data (definition / comment)</th>
<th>Suggested source(s)</th>
</tr>
</thead>
</table>
| 1. Operative urgency (NCEPOD Classification of Intervention) | **Immediate** (Immediate life, limb or organ-saving intervention – resuscitation simultaneous with intervention. Normally within minutes of decision to operate). **Urgent** (Intervention for acute onset or clinical deterioration of potentially life-threatening conditions, for those conditions that may threaten the survival of limb or organ, for fixation of many fractures and for relief of pain or other distressing symptoms. Normally within hours of decision to operate) **Expedited** (requiring early treatment where the condition is not an immediate threat to life, limb or organ survival. Normally within days of decision to operate). **Elective** (Intervention planned in advance of routine admission to hospital). | - Operative note  
- Admissions clerking  
- Clinical notes |
| 2. Operative procedure | **Select main procedure** (closest option from the drop-down list or enter as free text by selecting “other”).  
(1) Upper gastrointestinal tract surgery  
(2) Colorectal surgery  
(3) Hepato-pancreato-biliary (HPB) surgery  
(4) Vascular surgery  
(5) Urology  
(6) Gynaecology | - Operative note  
- Clinical notes  
- Theatre records |
| 3. Operative contamination | **Clean** (Gastrointestinal (GI) and genitourinary (GU) tract not entered). **Clean-Contaminated** (GI or GU tracts entered but no gross contamination). **Contaminated** (GI or GU tracts entered with gross spillage or major break in sterile technique). **Dirty** (There is already contamination prior to operation, e.g. faeces or bile). | - Operative note  
- Clinical notes  
- Theatre records |
| 4. Tranexamic acid use | Yes / No | - Operative note  
- Clinical notes  
- Theatre records |
| 5. Intraoperative blood transfusion | 0 / 1 / 2 / 3 / 4 / >4 | - Operative note  
- Clinical notes  
- Theatre records |
| 6. Hb at transfusion | Yes / No | - Operative note  
- Clinical notes  
- Theatre records |
| 7. Duration of procedure | Minutes  
- Total duration including anaesthetic time  
- Duration from skin incision to completion of skin closure | - Operative note  
- Clinical notes  
- Theatre records |

**Abbreviations:** NCEPOD: National Confidential Enquiry into Patient Outcome and Death. WHO = World Health Organisation
<table>
<thead>
<tr>
<th>Post-operative Data Fields</th>
<th>Required data (definition / comment)</th>
<th>Suggested sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Critical care admission</td>
<td>Date of admission</td>
<td></td>
</tr>
<tr>
<td>2. Critical care bed days (if yes)</td>
<td>Date of discharge</td>
<td></td>
</tr>
<tr>
<td>3. Highest inpatient complications</td>
<td>None / Clavien-Dindo Grade I-V (see appendix for the Clavien-Dindo scale).</td>
<td>– Clinical notes</td>
</tr>
<tr>
<td>4. Reoperation</td>
<td>Yes/No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>List operation performed &amp; date</td>
<td></td>
</tr>
<tr>
<td>5. Post-operative length of stay (hospital)</td>
<td>Date of Discharge</td>
<td></td>
</tr>
<tr>
<td>7. Blood Transfusion in post-operative period</td>
<td>None/Units 1/2/3/4/&gt;4</td>
<td>– Pathology systems</td>
</tr>
<tr>
<td></td>
<td>Hb immediately prior to transfusion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subsequent transfusions in remainder of post op period Y/N</td>
<td></td>
</tr>
<tr>
<td>8. Discharge Destination</td>
<td>Home / rehabilitation / nursing or supported care</td>
<td>– Discharge letter</td>
</tr>
<tr>
<td>9. Haemoglobin level</td>
<td>Admission to HDU / ICU / extended recovery</td>
<td>– Pathology systems</td>
</tr>
<tr>
<td></td>
<td>Discharge from HDU / ICU / extended recovery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lowest Hb in first 3 days postoperatively</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Last recorded before discharge from hospital</td>
<td></td>
</tr>
<tr>
<td>30-day Data Fields</td>
<td>Required data (definition / comment)</td>
<td>Suggested sources</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>----------------------------</td>
</tr>
</tbody>
</table>
| 1. RE – admission                   | Yes / No  
If yes complete readmission form                                                                 |                            |
| 2. Hb level                         | 4-6 weeks                                                                                             | Telephone follow-up        |
| 3. Location                         | Home/rehabilitation/nursing or supported care                                                         | Follow up clinic           |
| 4. 30-day Infection                | Was there post-operative infection Yes/ No  
Respiratory / urinary / wound / other                                                                  | Clinical notes             |
<p>| 5. Highest 30-day complication grade| None / Clavien-Dindo Grade I-V (see appendix for the Clavien-Dindo scale).                            |                            |
| 6. Clinical Frailty score           | 1-9                                                                                                   | Clinical Notes             |</p>
<table>
<thead>
<tr>
<th>Readmission Data Fields</th>
<th>Required data (definition / comment)</th>
<th>Suggested sources</th>
</tr>
</thead>
</table>
| 1. Reason for Readmission | Planned Y reason free text
Unplanned Y see appendix
Scored as per CD scale | – Clinical notes |
| 2. Haemoglobin level | On admission
Lowest Hb day 1-3
Last recorded before discharge from hospital | – Pathology systems |
| 3. Blood transfusion | 0 / 1 / 2 / 3 / 4 | – |
| 4. Readmission to HDU / ICU | Date of admission | – |
| 5. Discharge from HDU / ICU (if yes) | Date of discharge | – |
| 6. Reoperation | Yes / No date
List operation performed & date
repeat intraoperative and post-operative data | – Discharge letter
– Clinical notes |
| 7. Length of stay (hospital) | Number (days from the first re-admission day to day of discharge. If the patient has not been discharged prior to the end of 30-day re-admission, enter '31'). | – |
| 8. Discharge Destination | Home / rehabilitation / nursing or supported care | – |
Appendix: Clavien-Dindo Classification System:

Adverse post-operative events may be classified in different ways:

- **Failure of treatment** – This occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.

- **Sequelea**: The recognised consequences of a given procedure; for example, gut malabsorption following an extensive small bowel resection or immune deficiency following splenectomy.

- **Complication**: Any deviation from the normal post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification, the factor determining the severity of a complication is the treatment required. Consequently, a given complication may be graded differently depending on how it has been managed. For example, an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade IIIb).

Some other considerations:

- Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The only exception to this is intra-operative death; this is classified as grade V.

- All post-operative adverse events are included, even when there is no direct relationship to the surgery.

- All adverse events within the follow-up period (30 days) are included, even after following discharge.

- Diagnostic procedures are not included. For example, a diagnostic oesophagoduodenoscopy (OGD) to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic OGD with clipping of a bleeding vessel would be considered a grade IIIa complication. Since negative exploratory laparotomies are considered to be diagnostic procedures, they should not be recorded as complications.
<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition (examples listed in italics)</th>
</tr>
</thead>
</table>
| I     | Any deviation from the normal postoperative course without the need for pharmacological (other than “allowed therapeutic regimens”), surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics.  
**Examples:** ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids. |
| II    | Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.  
**Examples:** Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia. |
| IIIa  | Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA).  
**Examples:** Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures. |
| IIIb  | Requiring surgical, endoscopic or radiological intervention, under GA.  
**Examples:** Return to theatre for any reason. |
| IVa   | Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA).  
**Examples:** Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke |
| IVb   | Life-threatening complications requiring critical care management with multi-organ dysfunction. |
| V     | Death of a patient |
## Appendix: Infection

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abdominal collections</strong></td>
<td>Postoperative collection altering the normal postoperative course management and requiring antibiotics or radiological/endoscopic/surgical intervention</td>
</tr>
<tr>
<td><strong>Respiratory infections</strong></td>
<td>Pneumonia defined by the US Centers for Disease Control criteria as</td>
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<td></td>
<td>- CXR evidence of</td>
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<td></td>
<td>- New or progressive and persistent infiltrates</td>
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<td></td>
<td>- Consolidation</td>
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<td></td>
<td>- Cavitation</td>
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<tr>
<td></td>
<td>AND one of</td>
</tr>
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<td></td>
<td>- Fever (&gt;38°C) with no other recognised cause</td>
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<td></td>
<td>- Leucopenia (WCC &lt;4 × 10^9 /L) or Leucocytosis (WCC &gt;12 × 10^9 /L)</td>
</tr>
<tr>
<td></td>
<td>- Age &gt;70 years AND altered mental status (no other recognised cause)</td>
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<tr>
<td></td>
<td>OR two of</td>
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<tr>
<td></td>
<td>- New onset purulent sputum or change in character of sputum</td>
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<tr>
<td></td>
<td>- Increased respiratory secretions</td>
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<tr>
<td></td>
<td>- Bronchial breath sounds. New onset cough, dyspnoea or tachypnoea. Worsening gas exchange (hypoxaemia, increased oxygen demand.</td>
</tr>
<tr>
<td><strong>Urinary infections</strong></td>
<td>A positive culture on urine sample</td>
</tr>
<tr>
<td><strong>Wound infections</strong></td>
<td>An infection that occurs after surgery in the part of the body where the surgery took place requiring either medical, radiological, endoscopic or surgical intervention (defined by Centers for Disease Control and Prevention)</td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
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</tbody>
</table>
Appendix: Clinical Frailty Score

Clinical Frailty Scale*

1. Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2. Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.

3. Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.

4. Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slow” or tired during the day.

5. Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6. Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (e.g., standby) with dressing.

7. Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8. Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. Terminally Ill – Approaching the end of life. This category applies to people with a life expectancy <6 months who are not otherwise evidently frail.

Scoring frailty in people with dementia:
The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In severe dementia, they cannot do personal care without help.
Appendix: Reason for Re-admission to Hospital

List admitting diagnosis and group to: -

INFECTION – GENERAL
   Such as; chest, urinary etc

INFECTION – WOUND
   Wound related complications including abscess

POST OPERATIVE COMPLICATION – GENERAL
   Such as; ileus, urinary retention, blocked drain, ‘off legs’.

POST OPERATIVE COMPLICATION – PAIN
   Where the main complication is ‘in pain’

TRANSFUSION – BLOOD or IRON
Appendix: List of Investigators

Professor Toby Richards
Dr Peter Pockney
Professor David Watson
Sophie Wallace
Dr Deborah Wright
References


DRAFT-pending HREC review
POSTVennTT Protocol v5.0 25th Mar 2021
Clinical Trials Network Australia (CTANZ)