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Study Protocol: First nationwide comparative audit of acute lower gastrointestinal bleeding in the United Kingdom

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Declarations of interest

None declared

ABSTRACT

Introduction

Acute lower gastrointestinal bleeding (LGIB) is a common indication for emergency hospitalisation worldwide. In contrast to upper gastrointestinal bleeding, patient characteristics, modes of investigation, transfusion, treatment and outcomes are poorly described. There are few clinical guidelines to inform care pathways and the use of endoscopy, including (diagnostic and therapeutic yields), interventional radiology and surgery are poorly defined. As a result there is potential for wide variation in practice and clinical outcomes.

Methods and Analysis

The UK Lower GI Bleeding Audit is a large nationwide audit of adult patients acutely admitted with LGIB or those who develop LGIB whilst hospitalised for another reason. Consecutive, unselected presentations with LGIB will be enrolled prospectively over a two month period at the end of 2015 and detailed data will be collected on patient characteristics, comorbidities, use of anticoagulants, transfusion, timing and modalities of diagnostic and therapeutic procedures, clinical outcome, length of stay and mortality. These will be audited against pre-defined minimum standards of care for LGIB. It is anticipated that over 80% of all acute hospitals in England and some hospitals in Scotland, Wales and Northern Ireland will participate. Data will be collected on the availability and organisation of care, provision of diagnostic and therapeutic gastrointestinal endoscopy, interventional radiology, surgery and transfusion protocols.

Ethics and Dissemination

This audit will be conducted as part of the national comparative audit programme of blood transfusion through collaboration with specialists in gastroenterology, surgery and interventional radiology. Individual reports will be provided to each participant site as well as an overall report and disseminated through specialist societies. Results will also be published in peer-reviewed journals. The study has been funded by NHS Blood and Transplant and the Bowel Disease Research Federation and endorsed by the Association of Coloproctology of Great Britain and Ireland.

STRENGTHS AND LIMITATIONS

Strengths:

- This is the first nationwide audit of LGIB and is likely to be the largest prospective observational study of LGIB of its kind to date
- It will provide a novel appraisal of the standards of care of acute LGIB
- All aspects of care throughout the patient journey will be described and audited, allowing detailed evaluation of many components of care
- The cases are unselected and thus are an accurate reflection of the case mix presenting to UK hospitals
- Inclusion of hospitals based on routine admission of LGIB patients as opposed to size or location makes this audit representative of care in the UK as a whole, and therefore the results are widely applicable

Limitations:

- As the volume of data to be collected represents a large body of work, the completeness of data may not be as high as desired
- The identification of cases relies on daily case capture, sustained over two months. It is likely that some cases will be missed and this may be a particular problem for patients that are admitted at a weekend
- Although case ascertainment and data collection are prospective, this study relies on accurate record keeping in patients' notes and electronic records, which may be unreliable
- The analysis will be retrospective, with no opportunity to go back to further investigate deviations from the assumed clinical standards

INTRODUCTION

Acute lower gastrointestinal bleeding (LGIB) is defined as bleeding arising distal to the ligament of Treitz and is estimated to account for 15,000 hospital admissions each year in the UK[1]. Population-based data from Europe suggests the incidence is rising and that mortality rates may be as high as those for upper gastrointestinal bleeding (UGIB)[2]. Bleeding can arise from multiple sources such as diverticula, haemorrhoids, polyps, colorectal cancer, intestinal ischaemia, colitis and angiodysplasia[3]. Risk factors for bleeding include increasing age[3], as well as the use of anti-platelets medications, anticoagulants[2] and non-steroidal anti-inflammatory drugs (NSAIDs)[4].

The spectrum of disease leading to hospitalisation can range from trivial and self-limiting bleeding through to catastrophic, life-threatening haemorrhage requiring emergency intervention with mesenteric embolisation or surgery. There are few data on mortality but it is estimated to be between 4 and 8%[3,5].

LGIB is also a common indication for the transfusion of red blood cells (RBCs). A multicentre study from the North of England suggested that 17% of RBCs were transfused for gastrointestinal bleeding[6]. This is relevant given the recent randomised evidence that the liberal use of RBCs after UGIB may be associated with harm[7].

Unlike UGIB, there are few large studies providing detailed information on patient characteristics, transfusion and pathways of care in LGIB. The approach to diagnosis and intervention in terms of the use of endoscopy or radiology is uncertain and there is likely to be considerable variation in practice. This is reflected in the almost complete absence of

national or international guidelines for LGIB, compared to at least four high profile guidelines for UGIB[9-11].

Identifying the source of bleeding following presentation with LGIB poses a diagnostic challenge. Flexible sigmoidoscopy and colonoscopy may enable direct visualisation of the bleeding point, but this may be limited by poor bowel preparation in the acute setting. Although urgent lower GI endoscopy (within 12 hours) may be more likely to identify a source, there may be little associated beneficial impact on clinical outcome or length of stay[12,13]. Endoscopic therapy using chemical or mechanical haemostatic agents is becoming increasingly sophisticated, but it is not known whether these are routinely used for LGIB, as they are for UGIB or their effectiveness.

Increasingly a bleeding source may also be identified using computerised tomographic angiography (CTA) or mesenteric angiography (MA). If active extravasation of contrast is visualised on angiography, mesenteric embolisation offers a minimally invasive method to control haemorrhage avoiding the need for surgery. Although there is potential risk of developing associated colonic ischaemia after embolisation, the development of super-selective embolisation may to reduce this[14,15]. Whether this has resulted in a reduction in the requirement for major abdominal surgery and its associated complications is not known.

In 2015 the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in the UK conducted a national audit of all hospitalised patients with severe GI bleeding (defined as those that received ≥4 units red cells)[16]. Significant opportunities to improve care were identified and recommendations to end the traditional separation of UGIB and LGIB were made[16]. It also highlighted the need for research in LGIB and endorsed the development of risk stratification methods relevant to all GI bleeding.

Providing a comprehensive interventional radiology or endoscopic therapy service poses a significant demand on resources. Many units in the UK are still not able to provide 24/7 emergency care[17], a problem that has been exacerbated by the recent vascular configuration.

This may mean that patients are being transferred between hospitals for definitive treatment, when indicated. There are no contemporary data on the number of acute hospitals providing access to emergency interventional radiology and lower gastrointestinal endoscopy. The associated impact on patient access to these services is unknown.

Objectives

The overall objective of this nationwide audit is to characterise the clinical characteristics, management strategies and outcomes of patients with acute LGIB presenting to UK hospitals. Specific objectives include:

1. Description of the use of inpatient investigations (lower GI endoscopy, CT, interventional radiology, nuclear medicine and surgery) and their associated diagnostic yield (including factors associated with failed investigation), comparing in and out of hours availability and demand, complications and effect on length of stay, re-admissions, morbidity and mortality.
2. Evaluation of therapeutic modalities (endoscopic haemostasis, embolisation and surgery) focussing on indication, availability and therapeutic yield with regard to re-bleeding, need for further procedures and the associated impact on outcomes.
3. Quantification of blood product transfusion in comparison to established national guidelines and protocols[18,19].

4. Description of the management and current treatment strategies for patients on long-term anticoagulants who develop LGIB.
5. Identification of both institutional and patient specific risk factors for poor outcome to aid the triage of patients presenting with LGIB.

Reporting contemporaneous data on presenting characteristics, requirement of inpatient investigation and success of treatment will allow the future development of guidelines on the optimal management of LGIB with the aim of improving patient care, reducing variation in practice and ultimately improving outcomes.

METHODS AND ANALYSIS

This is a UK-wide, prospective audit of all admissions presenting with, or developing LGIB whilst an established inpatient. Hospitals will be recruited from September 2015. Case ascertainment will last for two months and all data must be submitted by the end of January 2016.

NHS Blood and Transplant has an established audit programme that regularly conducts national projects examining the use of blood products within the UK. These audits are used to examine current practice in comparison to established guidelines and have led to many successful projects across therapeutic areas. As well as comparing blood management to national protocols these audits present an opportunity to compare practice in other aspects of clinical care, such as best practice in perioperative and medicines management.

The cases

The audit will include all unselected patients that present with LGIB that results in an admission to hospital or develops whilst patients are admitted for another reason. Cases will be eligible if they fulfil the following criteria: age ≥ 16 years, history of bright or dark blood per rectum, maroon coloured stool or blood mixed in with stool, clots *per rectum* or passage of melaena without haematemesis.

Melaena without haematemesis is included so that cases of small bowel bleeding are not missed. Previous reports have shown that it can be difficult to distinguish upper from lower GI sources of bleeding[16] so to optimise the identification of LGIB the inclusion criteria are deliberately broad. This means that a small number of patients with UGIB may be captured

in the dataset, but this is reflective of the uncertainties that may exist in routine clinical care. There are two opportunities in the patient questionnaire to indicate that an UGIB case has been included; if the patient has an endoscopy that identifies the source of bleeding to be proximal to the ligament of Treitz the data collector can select that the source of LGIB was from the upper GI tract, or can indicate that there is not enough data to determine whether the case is a true case of LGIB. The data from these patients will be collected centrally and will undergo the same cleaning protocol as for LGIB patients, but will be excluded from any analysis specific to LGIB.

We aim to identify all cases of LGIB within a two-month period, starting on 1st September 2015. Every identified case or potential case must be registered for inclusion. We are aiming to identify at least 1000 cases of acute LGIB. This estimate is based upon the UK population incidence of LGIB and the benchmarked against the number of cases that were recruited in the 2007 national audit of UGIB and the use of blood[20].

Data will be collected until discharge/transfer from hospital, death or up to day 28 (whichever occurs first) Re-admission data will be collected until up to 28 days post discharge. This means that some follow-up data will continue to be collected after the ascertainment period.

Recruitment of sites

All NHS Trusts in England admitting acute surgical and medical admissions will be contacted directly and invited to participate. Letters and emails explaining the rationale and aims will be sent to the Medical Director, Chief Executive, Clinical Audit Department and the Haematologist with primary responsibility for transfusion, as well as Transfusion

Practitioners within each acute hospital. Medical Directors will be asked to give permission for their hospital to participate and to provide the contact details of their Clinical Lead for Surgery. The Clinical Lead will then be provided with information about the methodology and timeline of the audit and asked to nominate a local audit lead to co-ordinate the project. Non-responders will be sent two further reminder letters. If there is no response after three formal requests it will be assumed that the hospital will not be participating.

This study will be advertised to NHS hospitals in Scotland, Wales and Northern Ireland via their national blood services. Independent hospitals will not be invited to participate since GI bleeds are predominantly managed in the NHS. As indicated in June 2015 there were 140 eligible NHS trusts in England, and we aim to recruit 80% of these.

Data Collection

Two broad categories of data will be collected; organisational and individual patient data.

Organisation data:

Organisational data will record the availability of services for the investigation and treatment of LGIB. This will be available as a paper questionnaire and an electronic survey. Outcomes include the in- and out-of-hours availability of endoscopy, interventional radiology and surgery. Data on how patients access these investigations and treatment in hospitals without onsite services will be collected. The provision of massive transfusion protocols and gastrointestinal bleeding guidelines will be established (Table 1). Each hospital will complete one copy of this questionnaire.

Individual patient data:

Patient data will include the clinical characteristics and outcomes of patients with acute LGIB. The data collection includes questions on clinical examination findings, the timing use and results of endoscopy, radiology and surgery, the prevalence of different aetiologies of

LGIB and the use, timing and volume of blood products. Outcomes will include length of stay, in-hospital morbidity and mortality, re-admission rates, re-bleeding rates and transfusion requirements. Data on anticoagulation will be collected, looking at methods of reversal used, and whether national protocols have been followed (Table 2). All data will be obtained prospectively from patient notes and electronic hospital records.

The clinical details for each patient identified will be entered into an online questionnaire, which is accessed by a site-specific, password-protected website. Entry of data from each case will take 20-40 minutes to complete depending upon its complexity. Paper versions of the questionnaire will also be posted to sites to facilitate the collection of data for those sites with limited computer access. Cases and sites will be given a unique code to enable data entry without using any patient or hospital identifiers. Each participating hospital will be given a unique login and password to ensure data integrity. No patient identifiers will be collected at any time

The website automatically downloads all data into a central database regardless of whether the site has indicated that the data are complete. This allows monitoring of the participants' progress and regular counts of the registered cases. Once the site is content that it has entered a complete dataset, a tick-box finalises the dataset. This then alerts the central team that the data entry for the case is finished, and the dataset will be checked for any missing mandatory data or nonsensical responses. Audit Leads within each hospital will be contacted to provide additional or corrected data where necessary. This will happen on a daily basis throughout and after the study period to ensure data are as complete as possible. To ensure contemporaneous data collection, whilst the study is live, the project group will also review any cases that are incomplete but inactive for more than one week and contact the hospital lead to encourage their completion.

A team consisting of an audit Lead, case identifier and several data enterers will collect the data in each NHS trust. The audit lead will ensure that cases are being identified and entered and that the data are complete and accurate. We expect that the leads will predominantly be colorectal or general surgical consultants or registrars, although they may be from any specialty. The audit lead will be responsible for co-ordinating the audit in their hospital, working with the case identifier and supporting the case enterers.

Questionnaire design

The questionnaires were piloted at ten potentially eligible sites in the UK. Each site was asked to review the questionnaires and record feasibility of data collection for each question via a standardised grading system.

Seven sites returned the organisational questionnaire pilot and all but two questions were answered as expected. The questions found to be difficult to complete asked for a recording of the availability of guidelines, which were uniformly unanswered. On review it was decided that the data collected by these questions was non-essential and time-consuming. These questions were removed from the dataset.

Six hospitals were asked to identify and complete patient-specific questionnaires on five cases of LGIB. All mandatory questions were deemed feasible and accessible. The remainder of the questions were reviewed and clarified. No questions were excluded. Wording and phrasing was amended for questions deemed ambiguous based upon the pilot exercise. Answers were reviewed to ensure data was interpretable and reproducible.

Case Identification

There are no hospital diagnostic codes specific to LGIB. Methods aimed at identifying LGIB cases by mapping to 'classification trees' using codes such as the International Classification of Disease (ICD)[21] have been shown to have varying performance[22]. A previous large prospective audit on UGIB successfully identified cases by contacting clinical teams[20]. As referral pathways may differ between hospitals, it can be difficult to create a standardised method that is reproducible nationally.

To establish a pattern of hospital admission locations for patients with acute LGIB, five hospitals (including a tertiary referral centre for interventional radiology and a small district general hospital) were asked to describe their referral pathways and pilot the process of case identification. Eleven potential departments and wards were identified as likely to accommodate patients with LGIB. Over a two week period, each hospital was instructed to contact each location multiple times to identify locations with the highest and lowest case yield. (Table 3)

Feedback on ease of case identification, time spent and suggestions for other locations were collected. Of the five hospitals, only one site was able to provide data for the complete time period, identifying 28 cases of LGIB. The low response rate of the other hospitals indicates that this kind of case ascertainment is not reproducible or reliable. A recent national audit of severe gastrointestinal haemorrhage demonstrated that unlike UGIB, which may present to a range of departments and specialities, LGIB presents to a more limited selection of locations[16], namely surgery, gastroenterology and general medicine wards. This was also demonstrated by the 28 cases identified here; all but one case was identified by daily contact with the admitting surgical team and acute medical admissions unit. To maximise

case ascertainment in this national study, Audit Leads will be asked to have daily contact with surgical admission units and the surgical on-call team, daily contact with medical admission units and on-call team and visits to the gastroenterology wards three times per week.

Data analysis

Once all datasets are indicated as finished by the local site, checked for any missing data and incorrect entries amended they will be downloaded into one unifying database. Any duplicates will be removed. Variations in spelling of drug names, abbreviations and treatments will be standardised.

Although most questions require a single fixed response, there are several with an 'other' option. Where appropriate these will be recoded as one of the other fixed responses or compiled into an appendix. The question asking for the documented cause of the bleeding is a free-text box. Where possible this will be mapped to the ICD-10: Classification of diseases of the digestive system[21]. Any responses not fitting this classification will be compiled into an appendix. Any diagnoses that pertain to UGIB will be flagged.

Data will be collected on several baseline co-morbidities, including those listed in the Deyo modification[23] of the Charlson Co-Morbidity Index[24]. The Charlson index has been used in administrative datasets but its application to clinical data is more difficult as some of the definitions are subjective. To enable its use in a clinical setting we made the following amendments on pragmatic clinical grounds; (1) mild or and moderate liver disease was stratified into non-cirrhotic and cirrhotic respectively for ease of categorisation using medical notes; (2) Congestive cardiac failure is usually classified by the New York Heart

Association criteria[25] but the criteria may not be reproducible in a review of surgical notes. This was changed to include patients on pharmacotherapy or with clinical examination findings consistent with heart failure; (3) Peptic ulcer disease was classified by the use of pharmacological acid suppression; (4) renal disease was re-classified as chronic kidney disease stage 2-3 and stage 4 to represent moderate and severe respectively[26]. A Charlson Co-morbidity index will be calculated for each case. A retrospective review of a national database showed that a Charlson index ≥ 2 was independently associated with in-hospital mortality in patients admitted with LGIB[3].

The cases identified as UGIB will then be excluded from any further analysis. Audit standards applied to the remaining LGIB cohort, but cases will be grouped, where relevant, to allow comparative analysis particularly focussing on risk factors for poor outcome. Proposed subgroups include established inpatients and *de novo* presentations, transferred and non-transferred patients and groups stratified by Charlson co-morbid status.

Calculating the hospital resources required by patients admitted with acute LGIB requires estimates of bed occupancy and frequency of inpatient and outpatient investigation and treatment. Hospital bed requirements will be described using data on length of stay, new discharge to a nursing home or rehabilitation facility and re-admission rates. The type, frequency and waiting time for investigations will be calculated and comparisons by type of investigation will be made. Length of stay for patients who undergo inpatient treatment (as well as investigation) will be calculated in comparison to those that do not. The aim is to identify investigations and treatments associated with reduced length of stay, re-bleeding rates and need for transfusion.

The draft tables for the analysis are included in Appendix 1.

Audit Standards

The development of audit standards using existing guidelines is limited by the lack of national guidance. The most relevant guidelines that include LGIB are the Scottish Intercollegiate Guidelines Network (SIGN) guidelines[9]. As there is no NICE equivalent guideline for LGIB, these have been adopted where appropriate. The NCEPOD report on GI bleeding[16] also made recommendations on LGIB, and these have also been included. Where guidelines on specific aspects of the management of LGIB do not exist, British Society of Gastroenterology and NICE guidelines on the management of UGIB[8] have been interchanged as the auditable standard, as appropriate. The British Committee for Standards in Haematology[27] and NICE guidelines on the use of red blood cells, platelets and fresh frozen plasma[28] have been used as standards for transfusion. Recommendations made by the Association of Surgeons of Great Britain and Ireland[29] and the National Emergency Laparotomy Audit[30] on peri-operative care have also been adopted where applicable. Recommendations on safe staffing have been taken from the British Society of Interventional Radiology statement[31]. In areas where no guidelines exist, expert opinion has been sought. Organisation of services and principles of patient care will be audited against an amalgamation of these standards, as detailed in Tables 1 and 2.

ETHICS AND DISSEMINATION

This audit is carried out as part of the National Comparative Audit of Blood Transfusion programme, which is supported by the National Blood Transfusion Committee in England. As this is an audit of established methods of care and it will not influence patient management whilst it is being conducted, it is not subject to ethical consideration by the NHS Research Ethics Committee[32]. As stated in the *NHS Code of Practice* (2003) patient information may be collected for clinical audit without prior patient consent. No patient identifiers are collected as part of this audit.

A steering group made up of representatives from NHS Blood and Transplant, Association of Coloproctology of Great Britain and Ireland, British Society of Interventional Radiologists and the National Comparative Audit of Blood Transfusion Programme will monitor progress of the study. Participating hospitals will have access to their own results via a site-specific report that will be submitted to the named contact in each participating hospital only. There will be no publication of the performance of individual hospitals.

We expect that the combined national results will be disseminated via two main publications; description of patient characteristics and outcomes, and evaluation of organisational services. These will be published on behalf of the UK Lower GI Bleeding Collaborative, which will be made up of the study leads and data enterers. The audit lead is responsible for the integrity of the data provided by their site. The steering group will act as guarantors of the publications.

Conclusions

Although LGIB is common there is limited evidence on clinical presentations, use of resources and management outcomes. Many smaller studies[13,14] have attempted to evaluate methods of investigation and treatment of LGIB but have been limited by numbers. This multi-national audit in the UK is sufficiently large to capture infrequent outcomes such as complications related to infrequent investigations, interventions and report on overall mortality. It will provide a comprehensive commentary of the current management strategy of LGIB in the UK and identify areas for improvement. It will also facilitate geographical comparison of care to ensure standardisation of practice and will provide the basis for a unified approach to patient care. At the time of submission of this manuscript, data entry and data cleaning is on-going and several queries are pending from sites. Once these are obtained it is anticipated that the database will be locked in April 2016, after which the data will be analysed and presented according to the analysis plan. Dissemination of the audit report is expected in May 2016.

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Authors' contributions

Miss Kathryn Oakland designed the study and wrote the manuscript. Mr Richard Guy and Prof. Neil Mortensen developed audit developed standards related to surgery and critically reviewed the manuscript. Dr Raman Uberoi developed audit standards related to radiology and critically reviewed the manuscript. Frances Seeney and Gary Collins provided statistical support and critically reviewed the manuscript. John Grant-Casey designed the audit and electronic data tool and critically reviewed the manuscript. Prof Mike Murphy developed audit standards related to transfusion and critically reviewed the manuscript. Dr Vipul Jairath designed the study, developed audit standards related to gastroenterology and endoscopy and wrote the manuscript.

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Competing interests statement

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Tables

Table 1: Audit standards and associated specific outcomes within the organisational variables

Relevant audit standard	Specific outcomes
(1) Patients with any acute GI bleed should only be admitted to hospitals with 24/7 access to on-site endoscopy, interventional radiology (on-site or covered by a formal network), on-site abdominal surgery, on-site critical care and anaesthesia[16]	Number of UK hospitals with 24/7 access to flexible sigmoidoscopy and colonoscopy Proportion of UK hospitals with no provision for out of hours endoscopic therapy for LGIB Availability of a consultant-led service and the competence of on-call endoscopists at providing therapy at lower GI endoscopy Availability of out of hours endoscopy nurses Proportion of UK hospitals with onsite IR or access via an agreed referral pathway and proportion with no arrangements in place Number of UK hospitals that admit LGIB with no in or out of hours provision for major abdominal surgery Availability of level 2 and 3 care
(2) Endoscopy lists should be organised to ensure GI bleeds are prioritised[16]	Availability of defined endoscopy slots for LGIB
(3) There should be a minimum of 6 interventional radiologists on an out of hours rota[31]	Mean number of interventional radiologists on an out of hours rota and the number of hospitals covered Mean number of trained interventional radiology nurses available out of hours
(4) Routine daily input from Medicine for the Care of Older People should be available to patients aged ≥70 admitted under surgical teams[30, 33]	Identification of the speciality teams that admit patients with LGIB Availability of specialist care for elderly patients
(5) A massive transfusion protocol should be readily available* in all hospitals[34]	Location and dissemination of guidelines on the management of major haemorrhage
(6) Local arrangements should be in place to provide compatible blood urgently for patients with major bleeding[27, 34]	Availability of on-call transfusion laboratory staff
(7) Guidelines on gastrointestinal bleeding should be readily available* in all hospitals[16, 24]	Location and dissemination of guidelines on the management of GI bleeding

*Readily available is defined as provided on the hospital intranet and displayed on the wall in admission units.

Table 2: Audit standards and specific outcomes within the patient variables

Relevant audit standard	Specific outcomes
(1) All patients with rectal bleeding should undergo digital rectal examination and proctoscopy or rigid sigmoidoscopy[16]	Frequency of digital rectal examination, proctoscopy, rigid sigmoidoscopy and their findings
(2) All patients admitted with LGIB should have a full blood count, coagulation screen and routine biochemistry (consensus opinion)	Frequency of anaemia, thrombocytopenia and deranged clotting Frequency of acute kidney injury Number of patients not tested
(3) Continue low-dose aspirin for secondary prevention of vascular events in patients with lower gastrointestinal bleeding in whom haemostasis has been achieved or are considered to have stopped bleeding spontaneously[8]	Prevalence of co-morbidities Prevalence of anti-platelet use, effect on severity of bleeding, number of patients with aspirin withheld and frequency of cardiovascular complications
(4) Stop other non-steroidal anti-inflammatory drugs (including cyclooxygenase-2 inhibitors) during the acute phase in patients presenting with lower gastrointestinal bleeding[8]	Prevalence of NSAIDS and numbers withheld
(5) Emergency anticoagulation reversal in major haemorrhage* should be with 25-50U/kg 4 factor PCC and 5mg Vitamin K IV[35] (6) Reversal for non-major bleeding should be with 1-3mg IV vitamin K[35]	Prevalence of anti-coagulants and NOACs, need for reversal agents and the impact on outcomes Methods of warfarin reversal Number of patients that trigger a massive haemorrhage alert
(7) Use restrictive red blood cell transfusion thresholds (70 g/litre and a haemoglobin concentration target of 70–90 g/litre after transfusion) for patients who need red blood cell transfusions and who do not have major haemorrhage or acute coronary syndrome[28]	Number of red cell transfusions per patient Threshold and target haemoglobin concentrations used and the frequency of inappropriate or unnecessary blood transfusions Prevalence of pharmacological haemostatic agents such as tranexamic acid
(8) Offer platelet transfusion to patients with LGIB who are actively bleeding and have a platelet count of less than 30 x 109/litre[28] (9) Do not routinely give more than a single adult dose of platelets in a	Number of platelet transfusions per patient Frequency of inappropriate or unnecessary platelet transfusions Threshold and target platelet parameters Platelet dose

transfusion[28]	
(10) In LGIB offer fresh frozen plasma to patients who have either a fibrinogen level of less than 1g/litre or a prothrombin time (international normalised ratio) or activated partial thromboplastin time greater than 1.5 times normal[8] (11) Use a dose of at least 15 ml/kg when giving FFP transfusions[28]	Number of fresh frozen plasma and cryoprecipitate transfusions per patient Threshold and target clotting parameters Frequency of inappropriate or unnecessary use of FFP and cryoprecipitate FFP dose
(12) The cause and site clinically significant lower gastrointestinal haemorrhage** should be determined following the early use (within 24 hours) of colonoscopy or flexible sigmoidoscopy or the use of computed tomography angiography or digital subtraction angiography[9]	Frequency of inpatient flexible sigmoidoscopy, colonoscopy and CTA Mean waiting time to investigation Frequency and modality of endoscopic haemostasis Number of endoscopies required to reach a diagnosis Frequency of embolization Re-bleeding rate and complications Prevalence of patients with clinically significant bleeding bleeding** who had no inpatient investigations
(13) Patients with LGIB with clinically significant bleeding** should have an OGD unless the cause has been established using another modality of investigation within 24 hours[8]	Number of patients requiring an OGD and number of cases presenting as LGIB subsequently found to have an upper GI source Mean waiting time to OGD
(14) When surgery is contemplated, a formal assessment of the risk of death and complications should be undertaken by a clinician and documented in the patient record[29, 30] (15) Localised segmental intestinal resection or subtotal colectomy is recommended for the management of colonic haemorrhage uncontrolled by other techniques[9] (16) Surgical procedures with a predicted mortality >10% should be conducted under the direct supervision of a consultant surgeon (CCT holder) and consultant	Rationale for surgery particularly if first-line treatment Use and findings of surgical risk prediction scores Type of surgery and findings Seniority of operating surgeon and anaesthetist Post-operative complications (pneumonia, peri-operative myocardial infarction, venous

anaesthetist unless the consultants are satisfied that the delegated staff have adequate competency, experience, manpower and are adequately free of competing responsibilities[29]	thromboembolism, wound complications, anastomotic leak) Post-operative intensive care requirements Re-bleeding rates
Outcomes	In-hospital morbidity (venous thromboembolism, acute coronary syndrome, stroke, pneumonia, acute kidney injury and hospital acquired infection) In-hospital mortality and cause of death 28 day re-admissions (further LGIB and other causes) Length of stay Discharge destination (own home, nursing home or rehabilitation facility)

*Major haemorrhage is defined as the loss of > 1 blood volume in 24 hours, loss of 50% of total blood volume in under 3 hours, bleeding in excess of 150ml/minute in adults *(Nice 2015),* for the purpose of this audit is defined as patients that triggered a massive haemorrhage alert or equivalent *(consensus opinion).*

**Clinically significant bleeding: SBP<100, HR >100 and the need for ≥ 1 unit red cell transfusion *(consensus opinion)*

Table 3: Pilot case identification tool

Location	Present in your hospital (Y/N)	Frequency of contact	Number of cases identified Week 1	Number of cases identified Week 2	Comment
Surgical Assessment Unit		Daily			
Endoscopy unit		Daily			
On-call Surgical Registrar		Daily			
A&E Nurse in Charge		Daily			
Medical Assessment Unit		Daily			
Blood Bank		X3 per week			
Adults Wards		X3 per week			
Emergency theatre		X2 per week			
GI Bleed Unit		Daily			
Interventional Radiology Suite		X3 per week			
Death Certificates		weekly			

Appendix: Results Tables - Principle Findings, Patient Data and Organisational Standards

Identified cases

	National Audit N (%) Cases	Your site N (%) Cases
Total		
Definite LGIB		
Cases excluded as found to be UGIB at endoscopy		
Insufficient data to decide		

Patient Demographics

	National Audit	Your Site
Mean age [SD]		
Male sex		
Charlson Co-morbidity index *0* *1* *2* *≥3*		
Presentation *De novo admission* *LGIB in an established inpatient*		
Patients transferred out *All* *For endoscopy* *For interventional radiology* *For surgical input*		
Patients with clinically significant bleeding*		
Patients with major haemorrhage**		

*Clinically significant bleeding defined as SBP<100, HR >100 and the need for ≥ 1 unit red cell transfusion. ** Major haemorrhage is defined as patients that triggered a massive haemorrhage alert or equivalent

Investigation and Treatment

	National Audit (n patients (%)	Your Site (n patients (%)
Inpatient diagnostic flexible sigmoidoscopy or colonoscopy		
Inpatient OGD		
Inpatient therapeutic flexible sigmoidoscopy or colonoscopy		
CT angiography *Total* *Extravasation of contrast*		
Mesenteric angiography		

Total *Extravasation of contrast*		
Mesenteric Embolisation		
Laparotomy for bleeding		
No inpatient treatment for LGIB		

Transfusion

	National Audit (n %)	Your Site (n %)
Total volume of red cell transfusion (n patients): *None* *1 unit* *2 unit* *3 unit* *≥4 unit transfusions* Mean (±SD) red cell transfusions per patient		
Total volume of FFP (n patients): *1 unit* *2 unit* *3 unit* *≥4 unit* Mean (± SD) FFP transfusions per patient		
Total volume of platelet transfusion (n patients) *1 unit* *2 unit* *>2 unit* Mean (±SD) number of platelet transfusions per patient		

Table: Patient Outcomes

	National Audit	Your Site
Cause of bleeding *Anorectal* *Diverticular* *Colitis* *Ischaemic* *Inflammatory Bowel Disease* *Undetermined* *Colorectal Cancer* *Angiodysplasia* *Other*		
Length of Stay (median and		

range)		
Mortality *All cause* *Due to LGIB*		
Discharge destination *Home* *New discharge to nursing home/care home*		
Re-admitted within 28 days *All re-admissions* *Further LGIB*		

Patient Data Audit Standards

Audit Standard 1: All patients with lower GI bleeding should undergo digital rectal examination (SIGN 2008)

	National Audit Patients n (%)	Your Site Patients n (%)
Did the patient have a digital rectal examination? *Yes* *No* *Unknown*		
N (%) meeting Standard		

Audit Standard 2: All patients with rectal bleeding should undergo proctoscopy or rigid sigmoidoscopy (SIGN 2008)*

	National Audit Patients n (%)	Your Site Patients n (%)
Total patients with rectal bleeding *Proctoscopy* *Rigid sigmoidoscopy*		
N (%) meeting Standard		

*Rectal bleeding is defined as bright or dark red blood per rectum or clots

Audit Standard 3: All patients admitted with LGIB should have a full blood count (FBC), coagulation screen and routine biochemistry (consensus opinion)

	National Audit Patients n (%)	Your Site Patients n (%)
Laboratory test *Full blood count* *Coagulation Screen* *Biochemistry*		
All 3 completed		

Any 2 completed ≤ 1 completed		
N (%) meeting Standard		

Audit Standard 4: Continue low-dose aspirin for secondary prevention of vascular events in patients with lower gastrointestinal bleeding in whom haemostasis has been achieved or are considered to have stopped bleeding spontaneously (developed from Nice 2012)

	National Audit Patients n (%)		Your Site Patients n (%)	
	All	Aspirin stopped	All	Aspirin stopped
Patients on aspirin: *Bleeding stopped spontaneously* *- LGIB not requiring intervention or transfusion* *- LGIB requiring only transfusion* *Haemostasis achieved* *- LGIB requiring endoscopic therapy* *- LGIB requiring interventional radiological treatment* *All*				
N (%) meeting Standard				

Audit Standard 5: Stop other non-steroidal anti-inflammatory drugs (including cyclooxygenase-2 [COX-2] inhibitors) during the acute phase in patients presenting with lower gastrointestinal bleeding (developed from Nice 2012)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients on NSAID NSAID stopped		
N (%) meeting Standard		

Audit Standard 6: Emergency anticoagulation reversal in major haemorrhage should be with 25-50U/kg 4 factor PCC and 5mg Vitamin K IV (BSCH 2013)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that triggered a MHP* and were on warfarin: *All* *Received appropriate PCC*** *Received appropriate Vitamin K*		
N (%) meeting Standard		

For the purpose of this audit, major haemorrhage is defined as patients who triggered a Major Haemorrhage Protocol. *Major Haemorrhage Protocol

** Prothrombin Complex Concentrate

Audit Standard 7: Reversal for non-major bleeding should be with 1-3mg IV vitamin K (BCSH 2013)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that were on Warfarin: *All* *Meet criteria for non-major bleeding** *Received appropriate Vitamin K*		
N (%) meeting Standard		

***** For the purpose of this audit, non-major bleeding is defined as bleeding that does not meet the criteria for clinically significant bleeding (defined as SBP<100, HR≥100 and the need for ≥ 1 unit red cell transfusion).

Audit Standard 8: Use restrictive red blood cell transfusion thresholds (70 g/litre and a haemoglobin concentration target of 70–90 g/litre after transfusion) for patients who need red blood cell transfusions and who do not have major haemorrhage or acute coronary syndrome (Nice 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that received a red cell transfusion: *All* *Number that met criteria for restrictive transfusion threshold* *Number transfused at ≤ 70g/l* *Number transfused at >70g/l*		
N (%) meeting Standard		
Patients that received a red cell transfusion: *Median number of units within an episode [IQR]* *Number with a post-transfusion Hb <70g/l* *Number with a post-transfusion Hb 70-90g/l* *Number with a post-transfusion Hb >90 g/l*		
N (%) meeting Standard		

Audit Standard 9: Offer platelet transfusion to patients with LGIB who are actively bleeding and have a platelet count of less than 30 x 109/litre (developed from Nice 2015)

For the purpose of this audit, actively bleeding is defined as those with a HR≥100, SBP <100 and needing ≥ 1 unit blood.

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that received a platelet transfusion: *Number with a platelet count ≥ 30* *Number with a platelet count < 30 without clinically significant bleeding*		

Number with a platelet count < 30 with clinically significant bleeding		
N (%) meeting Standard		

Audit Standard 10: Do not routinely give more than a single adult dose of platelets in a transfusion (Nice 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Median number of platelet doses transfused per transfusion episode [IQR] Number that received >1 adult dose		
N (%) meeting Standard		

Audit Standard 11: *In LGIB offer fresh frozen plasma (FFP) to patients who have a prothrombin time (international normalised ratio) or activated partial thromboplastin time greater than 1.5 times normal (developed from Nice 2012)*

	National Audit Patients n (%)	Your Site Patients n (%)
Number of patients that received FFP *INR or APTT > 1.5 times normal and received FFP*		
N (%) meeting Standard		

Audit Standard 12: Use a dose of at least 15 ml/kg when giving fresh frozen plasma transfusions (Nice 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Number of patients that received FFP *Mean dose (range) ml/kg* *Number patients who received ≥ 15mg/kg*		
N (%) meeting Standard		

Audit Standard 13: The cause and site clinically significant lower gastrointestinal haemorrhage should be determined following the early use (within 24 hours) of colonoscopy or flexible sigmoidoscopy or the use of computed tomography angiography or digital subtraction angiography (developed from SIGN 2008)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients with clinically significant bleeding Patients with clinically significant bleeding that did		

not undergo any inpatient endoscopy or radiology Patients with clinically significant bleeding who underwent: *Colonoscopy or flexible sigmoidoscopy:* *-All* *-Within 24 hours* *CTA* *-All* *-Within 24 hours* *MA* *-All* *-Within 24 hours*		
N (%) meeting Standard (total undergoing endoscopy, CTA or MA within 24 hours)		

Audit Standard 14: Patients with LGIB with clinically significant bleeding should have an OGD unless the cause has been established using another modality of investigation within 24 hours (developed from Nice 2012)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients with clinically significant bleeding *Source of bleeding identified at Colonoscopy, sigmoidoscopy or proctoscopy* *Source of bleeding identified at CT* *Remaining patients that underwent OGD* *- All* *- Within 24 hours*		
N (%) meeting Standard		

Audit Standard 15: When surgery is contemplated, a formal assessment of the risk of death and complications should be undertaken by a clinician and documented in the patient record (adapted from ASGBI 2012 and NELA 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients who underwent surgery Number that had a surgical risk score used		
N (%) meeting Standard		

Audit Standard 16: Localised segmental intestinal resection or subtotal colectomy is recommended for the management of colonic haemorrhage uncontrolled by other techniques (SIGN 2008)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients who underwent surgery *Right hemicolectomy* *Extended right hemicolectomy* *Sigmoid colectomy* *Anterior resection* *Subtotal colectomy* *Panproctocolectomy* *Other*		
N (%) meeting Standard		

Audit Standard 17: Surgical procedures with a predicted mortality >10% should be conducted under the direct supervision of a consultant surgeon (CCT holder) and consultant anaesthetist unless the consultants are satisfied that the delegated staff have adequate competency, experience, manpower and are adequately free of competing responsibilities (ASGBI 2012)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients who underwent surgery with predicted mortality > 10% *Performed by:* *Consultant* *Associate specialist/staff grade* *SpR/StR/research fellow/clinical fellow-supervised* *SpR/StR/research fellow/clinical fellow-unsupervised* *Unknown*		
N (%) meeting Standard		

Organisational Audit Standards

Standard 1: Patients with any acute GI bleed should only be admitted to hospitals with 24/7 access to on-site endoscopy, interventional radiology (on-site or covered by a formal network), on-site abdominal surgery, on-site critical care and anaesthesia (NCEPOD 2015)

Endoscopy

	National Audit n (%)
Does your hospital provide in-hours colonoscopy or flexible sigmoidoscopy for lower GI bleeding? *Yes* *No* *Unknown*	

Does your hospital provide out-of-hours colonoscopy or flexible sigmoidoscopy for lower GI bleeding? *Yes* *No* *Unknown*	
N (%) meeting Standard	

Interventional Radiology

	National Audit
What are the arrangements for in-hours* interventional radiology for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place* *Other*	
N (%) meeting Standard	
What are the arrangements for out-of-hours** IR for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place* *Other*	
N (%) meeting Standard	

The provision of IR is divided into *in hours (9am-5pm Monday to Friday) and **out of hours (5.01pm-8.59am Monday to Friday and throughout the weekend).

Abdominal Surgery

	National Audit
What are the arrangements for in-hours emergency abdominal surgery for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place*	
N (%) meeting Standard	
What are the arrangements for out-of-hours emergency abdominal surgery for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place*	
N (%) meeting Standard	

Critical Care

	National Audit
Does your hospital have any Critical Care on-site? *Yes* *No*	
N (%) meeting Standard	

Summary of All Modalities

	National Audit n (%)
N hospitals meeting all standards for: 4 modalities 3 modalities 2 modalities ≤ 1 modality	

Audit Standard 2: Endoscopy lists should be organised to ensure that GI bleeds are prioritised (NCEPOD 2015)

	National Audit
Are there Monday-Friday defined emergency endoscopy slots that can be used for flexible sigmoidoscopy or colonoscopy for lower GI bleeding? Yes No Unknown	
N (%) meeting Standard	

Audit Standard 3: There should be a minimum of 6 interventional radiologists on the rota (BSIR provision statement)

	National Audit
How many interventional radiologists are on the rota that can provide embolisation for lower GI bleeding? *Hospitals with < 6* *Hospitals with ≥ 6* *No data*	
N (%) meeting Standard	

Audit standard 4: Routine daily input from Medicine for the Care of Older People should be available to patients aged ≥ 70 admitted under surgical teams (adapted from NCEPOD 2012 and NELA 2015)

	National Audit
Are elderly patients admitted under the care of	

surgical teams routinely reviewed by a Care of the Elderly doctor (or equivalent)? *Yes* *No* *Unknown*	
N (%) meeting Standard	

Audit standard 5: A massive transfusion protocol should be readily available in all hospitals (developed from Department of Health guidance)

	National Audit
Does your hospital have separate written guidelines for blood transfusion in patients with major haemorrhage? *Yes* *No* *Unknown*	
N (%) meeting Standard	
How are these guidelines made available? *Provided on hospital intranet* *Displayed on wall in admissions units* *Both* *Other*	
N (%) meeting Standard	

Audit standard 6: Local arrangements should be in place to provide compatible blood urgently for patients with major bleeding (BCSH 2015 and DoH guidance 2010)

	National Audit
Are on-call transfusion laboratory staff on site at all times*? *Yes* *No* *Unknown*	
N (%) meeting Standard	

*24 hours/day, seven days/week

Audit standard 7: Guidelines on gastrointestinal bleeding should be readily available in all hospitals (developed from DoH guidance and NCEPOD 2015 recommendations)

	National Audit
Does your hospital have written guidelines for the management of GI bleeding? *Yes* *No* *Unknown*	
N (%) meeting Standard	

How are these guidelines made available? *Provided on hospital intranet* *Displayed on wall in admissions units* *Both* *Other* *Unknown*	
N (%) meeting Standard	

BMJ Open

Study Protocol: First nationwide comparative audit of acute lower gastrointestinal bleeding in the United Kingdom

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Title: Study Protocol: First nationwide comparative audit of acute lower gastrointestinal bleeding in the United Kingdom

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Declarations of interest

None declared

ABSTRACT

Introduction

Acute lower gastrointestinal bleeding (LGIB) is a common indication for emergency hospitalisation worldwide. In contrast to upper gastrointestinal bleeding, patient characteristics, modes of investigation, transfusion, treatment and outcomes are poorly described. There are few clinical guidelines to inform care pathways and the use of endoscopy, including (diagnostic and therapeutic yields), interventional radiology and surgery are poorly defined. As a result there is potential for wide variation in practice and clinical outcomes.

Methods and Analysis

The UK Lower GI Bleeding Audit is a large nationwide audit of adult patients acutely admitted with LGIB or those who develop LGIB whilst hospitalised for another reason. Consecutive, unselected presentations with LGIB will be enrolled prospectively over a two month period at the end of 2015 and detailed data will be collected on patient characteristics, comorbidities, use of anticoagulants, transfusion, timing and modalities of diagnostic and therapeutic procedures, clinical outcome, length of stay and mortality. These will be audited against pre-defined minimum standards of care for LGIB. It is anticipated that over 80% of all acute hospitals in England and some hospitals in Scotland, Wales and Northern Ireland will participate. Data will be collected on the availability and organisation of care, provision of diagnostic and therapeutic gastrointestinal endoscopy, interventional radiology, surgery and transfusion protocols.

Ethics and Dissemination

This audit will be conducted as part of the national comparative audit programme of blood transfusion through collaboration with specialists in gastroenterology, surgery and interventional radiology. Individual reports will be provided to each participant site as well as an overall report and disseminated through specialist societies. Results will also be published in peer-reviewed journals. The study has been funded by NHS Blood and Transplant and the Bowel Disease Research Federation and endorsed by the Association of Coloproctology of Great Britain and Ireland.

STRENGTHS AND LIMITATIONS

Strengths:

- This is the first nationwide audit of LGIB and is likely to be the largest prospective observational study of LGIB of its kind to date
- It will provide a novel appraisal of the standards of care of acute LGIB
- All aspects of care throughout the patient journey will be described and audited, allowing detailed evaluation of many components of care
- The cases are unselected and thus are an accurate reflection of the case mix presenting to UK hospitals
- Inclusion of hospitals based on routine admission of LGIB patients as opposed to size or location makes this audit representative of care in the UK as a whole, and therefore the results are widely applicable

Limitations:

- As the volume of data to be collected represents a large body of work, the completeness of data may not be as high as desired
- The identification of cases relies on daily case capture, sustained over two months. It is likely that some cases will be missed and this may be a particular problem for patients that are admitted at a weekend
- Although case ascertainment and data collection are prospective, this study relies on accurate record keeping in patients' notes and electronic records, which may be unreliable
- The analysis will be retrospective, with no opportunity to go back to further investigate deviations from the assumed clinical standards

INTRODUCTION

Acute lower gastrointestinal bleeding (LGIB) is traditionally defined as bleeding arising distal to the ligament of Treitz, accounts for 20% of all hospitalisations for gastrointestinal haemorrhage in the UK[1] and has a crude incidence of 87/100,000[2]. Whilst the source of bleeding is not always apparent after presentation, it can further be considered to arise from either the mid gastrointestinal tract (between the Treitz angle and the ileocaecal valve) or from the colon (between the ileocaecal valve and the rectum). Population-based data from Europe suggests the incidence is rising and that mortality rates may be as high as those for upper gastrointestinal bleeding (UGIB)[3]. Bleeding can arise from multiple sources such as diverticula, haemorrhoids, polyps, colorectal cancer, intestinal ischaemia, colitis and angiodysplasia[4]. Risk factors for bleeding include increasing age[4], as well as the use of anti-platelets medications, anticoagulants[3] and non-steroidal anti-inflammatory drugs (NSAIDs)[5].

The spectrum of disease leading to hospitalisation can range from trivial and self-limiting bleeding through to catastrophic, life-threatening haemorrhage requiring emergency intervention with mesenteric embolisation or surgery. There are few studies reporting mortality. In a population based study, the mortality was found to be 1.2%[2]. A sample of an American national hospitalisation database estimated in-hospital mortality at 3.9%[4], whereas a sample of Spanish hospitals estimated mortality from any lower GI event to be 8.8% [6].

LGIB is also a common indication for the transfusion of red blood cells (RBCs). A multicentre study from the North of England suggested that 17% of RBCs were transfused for gastrointestinal bleeding[7]. This is relevant given the recent randomised evidence that the liberal use of RBCs after UGIB may be associated with harm[8].

Unlike UGIB, there are few large studies providing detailed information on patient characteristics, transfusion and pathways of care in LGIB. The approach to diagnosis and intervention in terms of the use of endoscopy or radiology is uncertain and there is likely to be considerable variation in practice. This is reflected in the almost complete absence of national or international guidelines for LGIB, compared to at least four high profile guidelines for UGIB[10-12].

Identifying the source of bleeding following presentation with LGIB poses a diagnostic challenge. Flexible sigmoidoscopy and colonoscopy may enable direct visualisation of the bleeding point, but this may be limited by poor bowel preparation in the acute setting. Although urgent lower GI endoscopy (within 12 hours) may be more likely to identify a source, there may be little associated beneficial impact on clinical outcome or length of stay[13, 14]. Endoscopic therapy using chemical or mechanical haemostatic agents is becoming increasingly sophisticated, but it is not known whether these are routinely used for LGIB, as they are for UGIB or their effectiveness.

Increasingly a bleeding source may also be identified using computerised tomographic angiography (CTA) or mesenteric angiography (MA). If active extravasation of contrast is visualised on angiography, mesenteric embolisation offers a minimally invasive method to control haemorrhage avoiding the need for surgery. Although there is potential risk of developing associated colonic ischaemia after embolisation, the development of super-selective embolisation may to reduce this[15, 16]. Whether this has resulted in a reduction in the requirement for major abdominal surgery and its associated complications is not known.

In 2015 the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in the UK conducted a national audit of all hospitalised patients with severe GI bleeding (defined as those that received ≥4 units red cells)[17]. Significant opportunities to improve care were identified and recommendations to end the traditional separation of UGIB and LGIB were made[17]. It also highlighted the need for research in LGIB and endorsed the development of risk stratification methods relevant to all GI bleeding.

Providing a comprehensive interventional radiology or endoscopic therapy service poses a significant demand on resources. Many units in the UK are still not able to provide 24/7 emergency care[18], a problem that has been exacerbated by the recent vascular configuration.

This may mean that patients are being transferred between hospitals for definitive treatment, when indicated. There are no contemporary data on the number of acute hospitals providing access to emergency interventional radiology and lower gastrointestinal endoscopy. The associated impact on patient access to these services is unknown.

Objectives

The overall objective of this nationwide audit is to characterise the clinical characteristics, management strategies and outcomes of patients with acute LGIB presenting to UK hospitals. Specific objectives include:

1. Description of the use of inpatient investigations (lower GI endoscopy, CT, interventional radiology, nuclear medicine and surgery) and their associated diagnostic yield (including factors associated with failed investigation), comparing in

and out of hours availability and demand, complications and effect on length of stay, re-admissions, morbidity and mortality.

2. Evaluation of therapeutic modalities (endoscopic haemostasis, embolisation and surgery) focussing on indication, availability and therapeutic yield with regard to re-bleeding, need for further procedures and the associated impact on outcomes.
3. Quantification of blood product transfusion in comparison to established national guidelines and protocols[19, 20].
4. Description of the management and current treatment strategies for patients on long-term anticoagulants who develop LGIB.
5. Identification of both institutional and patient specific risk factors for poor outcome to aid the triage of patients presenting with LGIB.

Reporting contemporaneous data on presenting characteristics, requirement of inpatient investigation and success of treatment will allow the future development of guidelines on the optimal management of LGIB with the aim of improving patient care, reducing variation in practice and ultimately improving outcomes.

METHODS AND ANALYSIS

This is a UK-wide, prospective audit of all admissions presenting with, or developing LGIB whilst an established inpatient. Hospitals will be recruited from September 2015. Case ascertainment will last for two months and all data must be submitted by the end of January 2016.

NHS Blood and Transplant has an established audit programme that regularly conducts national projects examining the use of blood products within the UK. These audits are used to examine current practice in comparison to established guidelines and have led to many successful projects across therapeutic areas. As well as comparing blood management to national protocols these audits present an opportunity to compare practice in other aspects of clinical care, such as best practice in perioperative and medicines management.

The cases

The audit will include all unselected patients that present with LGIB that results in an admission to hospital or develops whilst patients are admitted for another reason. Cases will be identified using presenting symptoms as opposed to examination findings or discharge diagnoses, and thus will include mid-gastrointestinal bleeding as well as bleeding distal to this, since presenting signs and symptoms will be similar. Cases will be eligible if they fulfil the following criteria: age ≥ 16 years, history of bright or dark blood per rectum, maroon coloured stool or blood mixed in with stool, clots *per rectum* or passage of melaena without haematemesis.

Melaena without haematemesis is included so that cases of small bowel bleeding are unlikely to be missed. Previous reports have shown that it can be difficult to distinguish upper from lower GI sources of bleeding[16] so to optimise the identification of LGIB the inclusion criteria are deliberately broad. This means that a small number of patients with UGIB may be captured in the dataset, but this is reflective of the uncertainties that may exist in routine clinical care. There are two opportunities in the patient questionnaire to indicate that an UGIB case has been included; if the patient has an endoscopy that identifies the source of bleeding to be proximal to the ligament of Treitz the data collector can select that the source of LGIB was from the upper GI tract, or can indicate that there is not enough data to determine whether the case is a true case of LGIB. The data from these patients will be collected centrally and will undergo the same cleaning protocol as for LGIB patients, but will be excluded from any analysis specific to LGIB.

We aim to identify all cases of LGIB within a two-month period, starting on 1st September 2015. Every identified case or potential case must be registered for inclusion. We are aiming to identify at least 1000 cases of acute LGIB. This estimate is based upon the UK population incidence of LGIB and the benchmarked against the number of cases that were recruited in the 2007 national audit of UGIB and the use of blood[21].

Data will be collected until discharge/transfer from hospital, death or up to day 28 (whichever occurs first) Re-admission data will be collected until up to 28 days post discharge. This means that some follow-up data will continue to be collected after the ascertainment period.

Recruitment of sites

All NHS Trusts in England admitting acute surgical and medical admissions will be contacted directly and invited to participate. Letters and emails explaining the rationale and aims will be sent to the Medical Director, Chief Executive, Clinical Audit Department and the Haematologist with primary responsibility for transfusion, as well as Transfusion Practitioners within each acute hospital. Medical Directors will be asked to give permission for their hospital to participate and to provide the contact details of their Clinical Lead for Surgery. The Clinical Lead will then be provided with information about the methodology and timeline of the audit and asked to nominate a local audit lead to co-ordinate the project. Non-responders will be sent two further reminder letters. If there is no response after three formal requests it will be assumed that the hospital will not be participating.

This study will be advertised to NHS hospitals in Scotland, Wales and Northern Ireland via their national blood services. Independent hospitals will not be invited to participate since GI bleeds are predominantly managed in the NHS. As indicated in June 2015 there were 140 eligible NHS trusts in England, and we aim to recruit 80% of these.

Data Collection

Two broad categories of data will be collected; organisational and individual patient data.

Organisation data:

Organisational data will record the availability of services for the investigation and treatment of LGIB. This will be available as a paper questionnaire and an electronic survey. Outcomes include the in- and out-of-hours availability of endoscopy, interventional radiology and surgery. Data on how patients access these investigations and treatment in hospitals without onsite services will be collected. The provision of massive transfusion

protocols and gastrointestinal bleeding guidelines will be established (Table 1). Each hospital will complete one copy of this questionnaire.

Individual patient data:

Patient data will include the clinical characteristics and outcomes of patients with acute LGIB. The data collection includes questions on clinical examination findings, the timing use and results of endoscopy, radiology and surgery, the prevalence of different aetiologies of LGIB and the use, timing and volume of blood products. Outcomes will include length of stay, in-hospital morbidity and mortality, re-admission rates, re-bleeding rates and transfusion requirements. Data on anticoagulation will be collected, looking at methods of reversal used, and whether national protocols have been followed (Table 2). All data will be obtained prospectively from patient notes and electronic hospital records.

The clinical details for each patient identified will be entered into an online questionnaire, which is accessed by a site-specific, password-protected website. Entry of data from each case will take 20-40 minutes to complete depending upon its complexity. Paper versions of the questionnaire will also be posted to sites to facilitate the collection of data for those sites with limited computer access. Cases and sites will be given a unique code to enable data entry without using any patient or hospital identifiers. Each participating hospital will be given a unique login and password to ensure data integrity. No patient identifiers will be collected at any time

The website automatically downloads all data into a central database regardless of whether the site has indicated that the data are complete. This allows monitoring of the participants' progress and regular counts of the registered cases. Once the site is content that it has entered a complete dataset, a tick-box finalises the dataset. This then alerts the central team that the data entry for the case is finished, and the dataset will be checked for any

missing mandatory data or nonsensical responses. Audit Leads within each hospital will be contacted to provide additional or corrected data where necessary. This will happen on a daily basis throughout and after the study period to ensure data are as complete as possible. To ensure contemporaneous data collection, whilst the study is live, the project group will also review any cases that are incomplete but inactive for more than one week and contact the hospital lead to encourage their completion.

A team consisting of an audit Lead, case identifier and several data enterers will collect the data in each NHS trust. The audit lead will ensure that cases are being identified and entered and that the data are complete and accurate. We expect that the leads will predominantly be colorectal or general surgical consultants or registrars, although they may be from any specialty. The audit lead will be responsible for co-ordinating the audit in their hospital, working with the case identifier and supporting the case enterers.

Questionnaire design

The questionnaires were piloted at ten potentially eligible sites in the UK. Each site was asked to review the questionnaires and record feasibility of data collection for each question via a standardised grading system.

Seven sites returned the organisational questionnaire pilot and all but two questions were answered as expected. The questions found to be difficult to complete asked for a recording of the availability of guidelines, which were uniformly unanswered. On review it was decided that the data collected by these questions was non-essential and time-consuming. These questions were removed from the dataset.

Six hospitals were asked to identify and complete patient-specific questionnaires on five cases of LGIB. All mandatory questions were deemed feasible and accessible. The remainder of the questions were reviewed and clarified. No questions were excluded. Wording and phrasing was amended for questions deemed ambiguous based upon the pilot exercise. Answers were reviewed to ensure data was interpretable and reproducible.

Case Identification

There are no hospital diagnostic codes specific to LGIB. Methods aimed at identifying LGIB cases by mapping to 'classification trees' using codes such as the International Classification of Disease (ICD)[22] have been shown to have varying performance[23]. A previous large prospective audit on UGIB successfully identified cases by contacting clinical teams[21]. As referral pathways may differ between hospitals, it can be difficult to create a standardised method that is reproducible nationally.

To establish a pattern of hospital admission locations for patients with acute LGIB, five hospitals (including a tertiary referral centre for interventional radiology and a small district general hospital) were asked to describe their referral pathways and pilot the process of case identification. Eleven potential departments and wards were identified as likely to accommodate patients with LGIB. Over a two week period, each hospital was instructed to contact each location multiple times to identify locations with the highest and lowest case yield. (Table 3)

Feedback on ease of case identification, time spent and suggestions for other locations were collected. Of the five hospitals, only one site was able to provide data for the complete time period, identifying 28 cases of LGIB. The low response rate of the other hospitals indicates

that this kind of case ascertainment is not reproducible or reliable. A recent national audit of severe gastrointestinal haemorrhage demonstrated that unlike UGIB, which may present to a range of departments and specialities, LGIB presents to a more limited selection of locations[17], namely surgery, gastroenterology and general medicine wards. This was also demonstrated by the 28 cases identified here; all but one case was identified by daily contact with the admitting surgical team and acute medical admissions unit. To maximise case ascertainment in this national study, Audit Leads will be asked to have daily contact with surgical admission units and the surgical on-call team, daily contact with medical admission units and on-call team and visits to the gastroenterology wards three times per week.

Data analysis

Once all datasets are indicated as finished by the local site, checked for any missing data and incorrect entries amended they will be downloaded into one unifying database. Any duplicates will be removed. Variations in spelling of drug names, abbreviations and treatments will be standardised.

Although most questions require a single fixed response, there are several with an 'other' option. Where appropriate these will be recoded as one of the other fixed responses or compiled into an appendix. The question asking for the documented cause of the bleeding is a free-text box. Where possible this will be mapped to the ICD-10: Classification of diseases of the digestive system[22]. Any responses not fitting this classification will be compiled into an appendix. Any diagnoses that pertain to UGIB will be flagged.

Data will be collected on several baseline co-morbidities, including those listed in the Deyo modification[23] of the Charlson Co-Morbidity Index[25]. The Charlson index has been used in administrative datasets but its application to clinical data is more difficult as some of the definitions are subjective. To enable its use in a clinical setting we made the following amendments on pragmatic clinical grounds; (1) mild or and moderate liver disease was stratified into non-cirrhotic and cirrhotic respectively for ease of categorisation using medical notes; (2) Congestive cardiac failure is usually classified by the New York Heart Association criteria[26] but the criteria may not be reproducible in a review of surgical notes. This was changed to include patients on pharmacotherapy or with clinical examination findings consistent with heart failure; (3) Peptic ulcer disease was classified by the use of pharmacological acid suppression; (4) renal disease was re-classified as chronic kidney disease stage 2-3 and stage 4 to represent moderate and severe respectively[27]. A Charlson Co-morbidity index will be calculated for each case. A retrospective review of a national database showed that a Charlson index ≥ 2 was independently associated with in-hospital mortality in patients admitted with LGIB[4].

The cases identified as UGIB will then be excluded from any further analysis. Audit standards applied to the remaining LGIB cohort, but cases will be grouped, where relevant, to allow comparative analysis particularly focussing on risk factors for poor outcome. Proposed subgroups include established inpatients and *de novo* presentations, transferred and non-transferred patients and groups stratified by Charlson co-morbid status.

Calculating the hospital resources required by patients admitted with acute LGIB requires estimates of bed occupancy and frequency of inpatient and outpatient investigation and treatment. Hospital bed requirements will be described using data on length of stay, new discharge to a nursing home or rehabilitation facility and re-admission rates. The type,

frequency and waiting time for investigations will be calculated and comparisons by type of investigation will be made. Length of stay for patients who undergo inpatient treatment (as well as investigation) will be calculated in comparison to those that do not. The aim is to identify investigations and treatments associated with reduced length of stay, re-bleeding rates and need for transfusion.

The draft tables for the analysis are included in Appendix 1.

Audit Standards

The development of audit standards using existing guidelines is limited by the lack of national guidance. The most relevant guidelines that include LGIB are the Scottish Intercollegiate Guidelines Network (SIGN) guidelines[10]. As there is no NICE equivalent guideline for LGIB, these have been adopted where appropriate. The NCEPOD report on GI bleeding[17] also made recommendations on LGIB, and these have also been included. Where guidelines on specific aspects of the management of LGIB do not exist, British Society of Gastroenterology and NICE guidelines on the management of UGIB[9] have been interchanged as the auditable standard, as appropriate. The British Committee for Standards in Haematology[28] and NICE guidelines on the use of red blood cells, platelets and fresh frozen plasma[29] have been used as standards for transfusion. Recommendations made by the Association of Surgeons of Great Britain and Ireland[30] and the National Emergency Laparotomy Audit[31] on peri-operative care have also been adopted where applicable. Recommendations on safe staffing have been taken from the British Society of Interventional Radiology statement[32]. In areas where no guidelines exist, expert opinion has been sought. Organisation of services and principles of patient care will be audited against an amalgamation of these standards, as detailed in Tables 1 and 2.

ETHICS AND DISSEMINATION

This audit is carried out as part of the National Comparative Audit of Blood Transfusion programme, which is supported by the National Blood Transfusion Committee in England. As this is an audit of established methods of care and it will not influence patient management whilst it is being conducted, it is not subject to ethical consideration by the NHS Research Ethics Committee[32]. As stated in the *NHS Code of Practice* (2003) patient information may be collected for clinical audit without prior patient consent. No patient identifiers are collected as part of this audit.

A steering group made up of representatives from NHS Blood and Transplant, Association of Coloproctology of Great Britain and Ireland, British Society of Interventional Radiologists and the National Comparative Audit of Blood Transfusion Programme will monitor progress of the study. Participating hospitals will have access to their own results via a site-specific report that will be submitted to the named contact in each participating hospital only. There will be no publication of the performance of individual hospitals.

We expect that the combined national results will be disseminated via two main publications; description of patient characteristics and outcomes, and evaluation of organisational services. These will be published on behalf of the UK Lower GI Bleeding Collaborative, which will be made up of the study leads and data enterers. The audit lead is responsible for the integrity of the data provided by their site. The steering group will act as guarantors of the publications.

Conclusions

Although LGIB is common there is limited evidence on clinical presentations, use of resources and management outcomes. Many smaller studies[14,15] have attempted to evaluate methods of investigation and treatment of LGIB but have been limited by numbers. This multi-national audit in the UK is sufficiently large to capture infrequent outcomes such as complications related to infrequent investigations, interventions and report on overall mortality. It will provide a comprehensive commentary of the current management strategy of LGIB in the UK and identify areas for improvement. It will also facilitate geographical comparison of care to ensure standardisation of practice and will provide the basis for a unified approach to patient care. At the time of submission of this manuscript, data entry and data cleaning is on-going and several queries are pending from sites. Once these are obtained it is anticipated that the database will be locked in April 2016, after which the data will be analysed and presented according to the analysis plan. Dissemination of the audit report is expected in May 2016.

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Authors' contributions

Miss Kathryn Oakland designed the study and wrote the manuscript. Mr Richard Guy and Prof. Neil Mortensen developed audit developed standards related to surgery and critically reviewed the manuscript. Dr Raman Uberoi developed audit standards related to radiology and critically reviewed the manuscript. Frances Seeney and Gary Collins provided statistical support and critically reviewed the manuscript. John Grant-Casey designed the audit and electronic data tool and critically reviewed the manuscript. Prof Mike Murphy developed audit standards related to transfusion and critically reviewed the manuscript. Dr Vipul Jairath designed the study, developed audit standards related to gastroenterology and endoscopy and wrote the manuscript.

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Competing interests statement

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Tables

Table 1: Audit standards and associated specific outcomes within the organisational variables

Relevant audit standard	Specific outcomes
(1) Patients with any acute GI bleed should only be admitted to hospitals with 24/7 access to on-site endoscopy, interventional radiology (on-site or covered by a formal network), on-site abdominal surgery, on-site critical care and anaesthesia[16]	Number of UK hospitals with 24/7 access to flexible sigmoidoscopy and colonoscopy Proportion of UK hospitals with no provision for out of hours endoscopic therapy for LGIB Availability of a consultant-led service and the competence of on-call endoscopists at providing therapy at lower GI endoscopy Availability of out of hours endoscopy nurses Proportion of UK hospitals with onsite IR or access via an agreed referral pathway and proportion with no arrangements in place Number of UK hospitals that admit LGIB with no in or out of hours provision for major abdominal surgery Availability of level 2 and 3 care
(2) Endoscopy lists should be organised to ensure GI bleeds are prioritised[16]	Availability of defined endoscopy slots for LGIB
(3) There should be a minimum of 6 interventional radiologists on an out of hours rota[31]	Mean number of interventional radiologists on an out of hours rota and the number of hospitals covered Mean number of trained interventional radiology nurses available out of hours
(4) Routine daily input from Medicine for the Care of Older People should be available to patients aged ≥70 admitted under surgical teams[30, 33]	Identification of the speciality teams that admit patients with LGIB Availability of specialist care for elderly patients
(5) A massive transfusion protocol should be readily available* in all hospitals[34]	Location and dissemination of guidelines on the management of major haemorrhage
(6) Local arrangements should be in place to provide compatible blood urgently for patients with major bleeding[27, 34]	Availability of on-call transfusion laboratory staff
(7) Guidelines on gastrointestinal	Location and dissemination of guidelines on

bleeding should be readily available* in all hospitals[16, 24]	the management of GI bleeding

*Readily available is defined as provided on the hospital intranet and displayed on the wall in admission units.

Table 2: Audit standards and specific outcomes within the patient variables

Relevant audit standard	Specific outcomes
(1) All patients with rectal bleeding should undergo digital rectal examination and proctoscopy or rigid sigmoidoscopy[16]	Frequency of digital rectal examination, proctoscopy, rigid sigmoidoscopy and their findings
(2) All patients admitted with LGIB should have a full blood count, coagulation screen and routine biochemistry (consensus opinion)	Frequency of anaemia, thrombocytopenia and deranged clotting Frequency of acute kidney injury Number of patients not tested
(3) Continue low-dose aspirin for secondary prevention of vascular events in patients with lower gastrointestinal bleeding in whom haemostasis has been achieved or are considered to have stopped bleeding spontaneously[8]	Prevalence of co-morbidities Prevalence of anti-platelet use, effect on severity of bleeding, number of patients with aspirin withheld and frequency of cardiovascular complications
(4) Stop other non-steroidal anti-inflammatory drugs (including cyclooxygenase-2 inhibitors) during the acute phase in patients presenting with lower gastrointestinal bleeding[8]	Prevalence of NSAIDS and numbers withheld
(5) Emergency anticoagulation reversal in major haemorrhage* should be with 25-50U/kg 4 factor PCC and 5mg Vitamin K IV[35] (6) Reversal for non-major bleeding should be with 1-3mg IV vitamin K[35]	Prevalence of anti-coagulants and NOACs, need for reversal agents and the impact on outcomes Methods of warfarin reversal Number of patients that trigger a massive haemorrhage alert
(7) Use restrictive red blood cell transfusion thresholds (70 g/litre and a haemoglobin concentration target of 70–90 g/litre after transfusion) for patients who need red blood cell transfusions and who do not have major haemorrhage or acute coronary syndrome[28]	Number of red cell transfusions per patient Threshold and target haemoglobin concentrations used and the frequency of inappropriate or unnecessary blood transfusions Prevalence of pharmacological haemostatic agents such as tranexamic acid
(8) Offer platelet transfusion to patients	Number of platelet transfusions per patient

with LGIB who are actively bleeding and have a platelet count of less than 30 x 109/litre[28] (9) Do not routinely give more than a single adult dose of platelets in a transfusion[28]	Frequency of inappropriate or unnecessary platelet transfusions Threshold and target platelet parameters Platelet dose
(10) In LGIB offer fresh frozen plasma to patients who have either a fibrinogen level of less than 1g/litre or a prothrombin time (international normalised ratio) or activated partial thromboplastin time greater than 1.5 times normal[8] (11) Use a dose of at least 15 ml/kg when giving FFP transfusions[28]	Number of fresh frozen plasma and cryoprecipitate transfusions per patient Threshold and target clotting parameters Frequency of inappropriate or unnecessary use of FFP and cryoprecipitate FFP dose
(12) The cause and site clinically significant lower gastrointestinal haemorrhage** should be determined following the early use (within 24 hours) of colonoscopy or flexible sigmoidoscopy or the use of computed tomography angiography or digital subtraction angiography[9]	Frequency of inpatient flexible sigmoidoscopy, colonoscopy and CTA Mean waiting time to investigation Frequency and modality of endoscopic haemostasis Number of endoscopies required to reach a diagnosis Frequency of embolization Re-bleeding rate and complications Prevalence of patients with clinically significant bleeding bleeding** who had no inpatient investigations
(13) Patients with LGIB with clinically significant bleeding** should have an OGD unless the cause has been established using another modality of investigation within 24 hours[8]	Number of patients requiring an OGD and number of cases presenting as LGIB subsequently found to have an upper GI source Mean waiting time to OGD
(14) When surgery is contemplated, a formal assessment of the risk of death and complications should be undertaken by a clinician and documented in the patient record[29, 30] (15) Localised segmental intestinal resection or subtotal colectomy is recommended for the management of colonic haemorrhage uncontrolled by other techniques[9]	Rationale for surgery particularly if first-line treatment Use and findings of surgical risk prediction scores Type of surgery and findings

(16) Surgical procedures with a predicted mortality >10% should be conducted under the direct supervision of a consultant surgeon (CCT holder) and consultant anaesthetist unless the consultants are satisfied that the delegated staff have adequate competency, experience, manpower and are adequately free of competing responsibilities[29]	Seniority of operating surgeon and anaesthetist Post-operative complications (pneumonia, peri-operative myocardial infarction, venous thromboembolism, wound complications, anastomotic leak) Post-operative intensive care requirements Re-bleeding rates
Outcomes	In-hospital morbidity (venous thromboembolism, acute coronary syndrome, stroke, pneumonia, acute kidney injury and hospital acquired infection) In-hospital mortality and cause of death 28 day re-admissions (further LGIB and other causes) Length of stay Discharge destination (own home, nursing home or rehabilitation facility)

*Major haemorrhage is defined as the loss of > 1 blood volume in 24 hours, loss of 50% of total blood volume in under 3 hours, bleeding in excess of 150ml/minute in adults *(Nice 2015),* for the purpose of this audit is defined as patients that triggered a massive haemorrhage alert or equivalent *(consensus opinion).*

**Clinically significant bleeding: SBP<100, HR >100 and the need for ≥ 1 unit red cell transfusion *(consensus opinion)*

Table 3: Pilot case identification tool

Location	Present in your hospital (Y/N)	Frequency of contact	Number of cases identified Week 1	Number of cases identified Week 2	Comment
Surgical Assessment Unit		Daily			
Endoscopy unit		Daily			
On-call Surgical Registrar		Daily			
A&E Nurse in Charge		Daily			
Medical Assessment Unit		Daily			
Blood Bank		X3 per week			
Adults Wards		X3 per week			
Emergency theatre		X2 per week			
GI Bleed Unit		Daily			
Interventional Radiology Suite		X3 per week			
Death Certificates		weekly			

Appendix: Results Tables - Principle Findings, Patient Data and Organisational Standards

Identified cases

	National Audit N (%) Cases	Your site N (%) Cases
Total		
Definite LGIB		
Cases excluded as found to be UGIB at endoscopy		
Insufficient data to decide		

Patient Demographics

	National Audit	Your Site
Mean age [SD]		
Male sex		
Charlson Co-morbidity index *0* *1* *2* *≥3*		
Presentation *De novo admission* *LGIB in an established inpatient*		
Patients transferred out *All* *For endoscopy* *For interventional radiology* *For surgical input*		
Patients with clinically significant bleeding*		
Patients with major haemorrhage**		

*Clinically significant bleeding defined as SBP<100, HR >100 and the need for ≥ 1 unit red cell transfusion. ** Major haemorrhage is defined as patients that triggered a massive haemorrhage alert or equivalent

Investigation and Treatment

	National Audit (n patients (%)	Your Site (n patients (%)
Inpatient diagnostic flexible sigmoidoscopy or colonoscopy		
Inpatient OGD		
Inpatient therapeutic flexible sigmoidoscopy or colonoscopy		
CT angiography *Total* *Extravasation of contrast*		
Mesenteric angiography		

Total *Extravasation of contrast*		
Mesenteric Embolisation		
Laparotomy for bleeding		
No inpatient treatment for LGIB		

Transfusion

	National Audit (n %)	Your Site (n %)
Total volume of red cell transfusion (n patients): *None* *1 unit* *2 unit* *3 unit* *≥4 unit transfusions* Mean (±SD) red cell transfusions per patient		
Total volume of FFP (n patients): *1 unit* *2 unit* *3 unit* *≥4 unit* Mean (± SD) FFP transfusions per patient		
Total volume of platelet transfusion (n patients) *1 unit* *2 unit* *>2 unit* Mean (±SD) number of platelet transfusions per patient		

Table: Patient Outcomes

	National Audit	Your Site
Cause of bleeding *Anorectal* *Diverticular* *Colitis* *Ischaemic* *Inflammatory Bowel Disease* *Undetermined* *Colorectal Cancer* *Angiodysplasia* *Other*		
Length of Stay (median and		

range)		
Mortality *All cause* *Due to LGIB*		
Discharge destination *Home* *New discharge to nursing home/care home*		
Re-admitted within 28 days *All re-admissions* *Further LGIB*		

Patient Data Audit Standards

Audit Standard 1: All patients with lower GI bleeding should undergo digital rectal examination (SIGN 2008)

	National Audit Patients n (%)	Your Site Patients n (%)
Did the patient have a digital rectal examination? *Yes* *No* *Unknown*		
N (%) meeting Standard		

Audit Standard 2: All patients with rectal bleeding should undergo proctoscopy or rigid sigmoidoscopy (SIGN 2008)*

	National Audit Patients n (%)	Your Site Patients n (%)
Total patients with rectal bleeding *Proctoscopy* *Rigid sigmoidoscopy*		
N (%) meeting Standard		

*Rectal bleeding is defined as bright or dark red blood per rectum or clots

Audit Standard 3: All patients admitted with LGIB should have a full blood count (FBC), coagulation screen and routine biochemistry (consensus opinion)

	National Audit Patients n (%)	Your Site Patients n (%)
Laboratory test *Full blood count* *Coagulation Screen* *Biochemistry*		
All 3 completed		

Any 2 completed ≤ 1 completed		
N (%) meeting Standard		

Audit Standard 4: Continue low-dose aspirin for secondary prevention of vascular events in patients with lower gastrointestinal bleeding in whom haemostasis has been achieved or are considered to have stopped bleeding spontaneously (developed from Nice 2012)

	National Audit Patients n (%)		Your Site Patients n (%)	
	All	Aspirin stopped	All	Aspirin stopped
Patients on aspirin: *Bleeding stopped spontaneously* *- LGIB not requiring intervention or transfusion* *- LGIB requiring only transfusion* *Haemostasis achieved* *- LGIB requiring endoscopic therapy* *- LGIB requiring interventional radiological treatment* *All*				
N (%) meeting Standard				

Audit Standard 5: Stop other non-steroidal anti-inflammatory drugs (including cyclooxygenase-2 [COX-2] inhibitors) during the acute phase in patients presenting with lower gastrointestinal bleeding (developed from Nice 2012)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients on NSAID NSAID stopped		
N (%) meeting Standard		

Audit Standard 6: Emergency anticoagulation reversal in major haemorrhage should be with 25-50U/kg 4 factor PCC and 5mg Vitamin K IV (BSCH 2013)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that triggered a MHP* and were on warfarin: *All* *Received appropriate PCC*** *Received appropriate Vitamin K*		
N (%) meeting Standard		

For the purpose of this audit, major haemorrhage is defined as patients who triggered a Major Haemorrhage Protocol. *Major Haemorrhage Protocol
** Prothrombin Complex Concentrate

Audit Standard 7: Reversal for non-major bleeding should be with 1-3mg IV vitamin K (BCSH 2013)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that were on Warfarin: *All* *Meet criteria for non-major bleeding** *Received appropriate Vitamin K*		
N (%) meeting Standard		

***** For the purpose of this audit, non-major bleeding is defined as bleeding that does not meet the criteria for clinically significant bleeding (defined as SBP<100, HR≥100 and the need for ≥ 1 unit red cell transfusion).

Audit Standard 8: Use restrictive red blood cell transfusion thresholds (70 g/litre and a haemoglobin concentration target of 70–90 g/litre after transfusion) for patients who need red blood cell transfusions and who do not have major haemorrhage or acute coronary syndrome (Nice 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that received a red cell transfusion: *All* *Number that met criteria for restrictive transfusion threshold* *Number transfused at ≤ 70g/l* *Number transfused at >70g/l*		
N (%) meeting Standard		
Patients that received a red cell transfusion: *Median number of units within an episode [IQR]* *Number with a post-transfusion Hb <70g/l* *Number with a post-transfusion Hb 70-90g/l* *Number with a post-transfusion Hb >90 g/l*		
N (%) meeting Standard		

Audit Standard 9: Offer platelet transfusion to patients with LGIB who are actively bleeding and have a platelet count of less than 30 x 109/litre (developed from Nice 2015)

For the purpose of this audit, actively bleeding is defined as those with a HR≥100, SBP <100 and needing ≥ 1 unit blood.

	National Audit Patients n (%)	Your Site Patients n (%)
Patients that received a platelet transfusion: *Number with a platelet count ≥ 30* *Number with a platelet count < 30 without clinically significant bleeding*		

Number with a platelet count < 30 with clinically significant bleeding		
N (%) meeting Standard		

Audit Standard 10: Do not routinely give more than a single adult dose of platelets in a transfusion (Nice 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Median number of platelet doses transfused per transfusion episode [IQR] Number that received >1 adult dose		
N (%) meeting Standard		

Audit Standard 11: *In LGIB offer fresh frozen plasma (FFP) to patients who have a prothrombin time (international normalised ratio) or activated partial thromboplastin time greater than 1.5 times normal (developed from Nice 2012)*

	National Audit Patients n (%)	Your Site Patients n (%)
Number of patients that received FFP *INR or APTT > 1.5 times normal and received FFP*		
N (%) meeting Standard		

Audit Standard 12: Use a dose of at least 15 ml/kg when giving fresh frozen plasma transfusions (Nice 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Number of patients that received FFP *Mean dose (range) ml/kg* *Number patients who received ≥ 15mg/kg*		
N (%) meeting Standard		

Audit Standard 13: The cause and site clinically significant lower gastrointestinal haemorrhage should be determined following the early use (within 24 hours) of colonoscopy or flexible sigmoidoscopy or the use of computed tomography angiography or digital subtraction angiography (developed from SIGN 2008)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients with clinically significant bleeding Patients with clinically significant bleeding that did		

not undergo any inpatient endoscopy or radiology Patients with clinically significant bleeding who underwent: *Colonoscopy or flexible sigmoidoscopy:* *-All* *-Within 24 hours* *CTA* *-All* *-Within 24 hours* *MA* *-All* *-Within 24 hours*		
N (%) meeting Standard (total undergoing endoscopy, CTA or MA within 24 hours)		

Audit Standard 14: Patients with LGIB with clinically significant bleeding should have an OGD unless the cause has been established using another modality of investigation within 24 hours (developed from Nice 2012)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients with clinically significant bleeding *Source of bleeding identified at Colonoscopy, sigmoidoscopy or proctoscopy* *Source of bleeding identified at CT* *Remaining patients that underwent OGD* *- All* *- Within 24 hours*		
N (%) meeting Standard		

Audit Standard 15: When surgery is contemplated, a formal assessment of the risk of death and complications should be undertaken by a clinician and documented in the patient record (adapted from ASGBI 2012 and NELA 2015)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients who underwent surgery Number that had a surgical risk score used		
N (%) meeting Standard		

Audit Standard 16: Localised segmental intestinal resection or subtotal colectomy is recommended for the management of colonic haemorrhage uncontrolled by other techniques (SIGN 2008)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients who underwent surgery *Right hemicolectomy* *Extended right hemicolectomy* *Sigmoid colectomy* *Anterior resection* *Subtotal colectomy* *Panproctocolectomy* *Other*		
N (%) meeting Standard		

Audit Standard 17: Surgical procedures with a predicted mortality >10% should be conducted under the direct supervision of a consultant surgeon (CCT holder) and consultant anaesthetist unless the consultants are satisfied that the delegated staff have adequate competency, experience, manpower and are adequately free of competing responsibilities (ASGBI 2012)

	National Audit Patients n (%)	Your Site Patients n (%)
Total number of patients who underwent surgery with predicted mortality > 10% *Performed by:* *Consultant* *Associate specialist/staff grade* *SpR/StR/research fellow/clinical fellow-supervised* *SpR/StR/research fellow/clinical fellow-unsupervised* *Unknown*		
N (%) meeting Standard		

Organisational Audit Standards

Standard 1: Patients with any acute GI bleed should only be admitted to hospitals with 24/7 access to on-site endoscopy, interventional radiology (on-site or covered by a formal network), on-site abdominal surgery, on-site critical care and anaesthesia (NCEPOD 2015)

Endoscopy

	National Audit n (%)
Does your hospital provide in-hours colonoscopy or flexible sigmoidoscopy for lower GI bleeding? *Yes* *No* *Unknown*	

Does your hospital provide out-of-hours colonoscopy or flexible sigmoidoscopy for lower GI bleeding? *Yes* *No* *Unknown*	
N (%) meeting Standard	

Interventional Radiology

	National Audit
What are the arrangements for in-hours* interventional radiology for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place* *Other*	
N (%) meeting Standard	
What are the arrangements for out-of-hours** IR for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place* *Other*	
N (%) meeting Standard	

The provision of IR is divided into *in hours (9am-5pm Monday to Friday) and **out of hours (5.01pm-8.59am Monday to Friday and throughout the weekend).

Abdominal Surgery

	National Audit
What are the arrangements for in-hours emergency abdominal surgery for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place*	
N (%) meeting Standard	
What are the arrangements for out-of-hours emergency abdominal surgery for lower GI bleeding? *On-site service* *Agreed referral protocol to another hospital* *Ad hoc arrangements* *No arrangements in place*	
N (%) meeting Standard	

Critical Care

	National Audit
Does your hospital have any Critical Care on-site? *Yes* *No*	
N (%) meeting Standard	

Summary of All Modalities

	National Audit n (%)
N hospitals meeting all standards for: 4 modalities 3 modalities 2 modalities ≤ 1 modality	

Audit Standard 2: Endoscopy lists should be organised to ensure that GI bleeds are prioritised (NCEPOD 2015)

	National Audit
Are there Monday-Friday defined emergency endoscopy slots that can be used for flexible sigmoidoscopy or colonoscopy for lower GI bleeding? Yes No Unknown	
N (%) meeting Standard	

Audit Standard 3: There should be a minimum of 6 interventional radiologists on the rota (BSIR provision statement)

	National Audit
How many interventional radiologists are on the rota that can provide embolisation for lower GI bleeding? *Hospitals with < 6* *Hospitals with ≥ 6* *No data*	
N (%) meeting Standard	

Audit standard 4: Routine daily input from Medicine for the Care of Older People should be available to patients aged ≥ 70 admitted under surgical teams (adapted from NCEPOD 2012 and NELA 2015)

	National Audit

Are elderly patients admitted under the care of surgical teams routinely reviewed by a Care of the Elderly doctor (or equivalent)? *Yes* *No* *Unknown*	
N (%) meeting Standard	

Audit standard 5: A massive transfusion protocol should be readily available in all hospitals (developed from Department of Health guidance)

	National Audit
Does your hospital have separate written guidelines for blood transfusion in patients with major haemorrhage? *Yes* *No* *Unknown*	
N (%) meeting Standard	
How are these guidelines made available? *Provided on hospital intranet* *Displayed on wall in admissions units* *Both* *Other*	
N (%) meeting Standard	

Audit standard 6: Local arrangements should be in place to provide compatible blood urgently for patients with major bleeding (BCSH 2015 and DoH guidance 2010)

	National Audit
Are on-call transfusion laboratory staff on site at all times*? *Yes* *No* *Unknown*	
N (%) meeting Standard	

*24 hours/day, seven days/week

Audit standard 7: Guidelines on gastrointestinal bleeding should be readily available in all hospitals (developed from DoH guidance and NCEPOD 2015 recommendations)

	National Audit
Does your hospital have written guidelines for the management of GI bleeding? *Yes* *No* *Unknown*	

N (%) meeting Standard	
How are these guidelines made available? *Provided on hospital intranet* *Displayed on wall in admissions units* *Both* *Other* *Unknown*	
N (%) meeting Standard	