BRITISH SOCIETY OF GASTROENTEROLOGY

NHS Blood and Transplant

Multi Regional Audit of Blood Component Use in Patients with Cirrhosis

BASL British Association for the Study of the Liver

NHS South Central Regional Transfusion Committee

Acknowledgements

Participating Organisations

All clinical staff who supported and participated in the audit.
Please see Appendix 1 for all staff who participated.

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Executive Summary

1. This was the first national audit of the use of blood components in patients with cirrhosis.
2. 85 organisations/hospitals provided data on 1333 consecutive cases of cirrhosis during a 4 week period starting between February – April 2013.
3. Local hospital audit support was highly variable, which had an impact on the number of completed cases submitted from some hospitals.
4. The final dataset comprised 1313 cases, with 840/1313 (64%) males, mean age 58 years.
5. The most common aetiology of cirrhosis was alcohol (70%) followed by non-alcoholic fatty liver disease (12%) and viral hepatitis (11%).
6. 964/1313 (73%) of admissions were due to decompensated cirrhosis. 275/1313 (21%) cases had a positive septic screen
7. Case fatality during follow-up was 128/1313 (10%) overall, with decompensated cirrhosis reported as the most frequent cause of death 52/128 (41%).
8. There were 35/1313 (3%) cases of reported thrombotic events of which 29/1313 (2%) were venous thromboses and 6/1313 (<1%) were arterial thromboses.
9. 391/1313 (30%) patients were transfused at least one blood component
10. For 153/391 (39%) cases the main transfusion indication was prophylaxis (not for bleeding) and for 238/391 (61%) cases the main indication was treatment of bleeding
11. For the 238 cases transfused for bleeding, gastro-intestinal bleeding was the most common cause 192/238 (81%). 150/238 (63%) received red cell transfusions alone, which were administered at variable haemoglobin concentrations. In patients with gastrointestinal bleeding who received red blood cells, the pre-transfusion threshold was greater than 80g/L prior to red cell transfusion in 54/220 (25%).
12. For the 153 cases receiving transfusions for prophylaxis, 94/153 (61%) received transfusions when no procedure was planned. The majority of these were red cell transfusions for the treatment of anaemia 85/94 (90%) but a small number received Fresh Frozen Plasma (FFP) 11/94 (12%) or platelets 5/94 (5%).
13. For the 59/153 (39%) cases receiving transfusion for prophylaxis prior to interventions, the more common procedures requiring cover by transfusion were paracentesis, surgery and central/femoral line insertion. FFP was the most common single blood component transfused in 34/59 (58%) followed by platelets 25/59 (42%).
14. 4/72 (6%) hospitals reported having guidelines for patients with liver disease.
15. In 48/185 (26%) of patients transfused with red cells for gastrointestinal bleeding, the pre-transfusion haemoglobin was greater than 80g/L.
16. In 103/185 (56%) of patients transfused with red cells for gastrointestinal bleeding, the pre-transfusion haemoglobin was greater than 70g/L.
17. In 81/101 (80%) of patients transfused with red cells prophylactically, the pre- transfusion haemoglobin was less than 80g/L.
18. In 13/16 (81%) of patients transfused with FFP prophylactically before a moderate/high-risk procedure, the pre-transfusion INR was greater than 1.5.
19. In 12/18 (67%) of patients transfused with FFP prophylactically before a low-risk procedure, the pre-transfusion INR was greater than 2.
20. In 16/25 (64%) of patients transfused with platelets prophylactically before a procedure, the pre-transfusion platelet count was less than $50x10^9$/L

Recommendations Including Research

- Every Trust / Hospital should develop guidelines for use of blood for transfusion for patients with cirrhosis, and approved by the hospital transfusion committee. Whilst these guidelines may be incorporated into general guidelines for use of blood, patients with liver disease have distinct co-morbidities and risks of fluid overload.
- In a haemorrhage setting, use of red cells when patients are not critically bleeding in shock, should be consistent with national guidelines (National Institute for Health and Care Excellence, 2012) and emerging evidence that a liberal approach to transfusion in cirrhosis and gastrointestinal bleeding may be harmful [Villanueva et al, 2013].
- In a haemorrhage setting, a more pragmatic transfusion approach for non-red cell components may be indicated, as results of coagulation testing may not be rapidly available. FFP and cryoprecipitate may need to be issued in an empirical manner initially based on the clinical severity of bleeding, but clinicians should be aware of the risk of blood components in patients with cirrhosis, including fluid overload and the concerns of precipitating thrombotic events. Vascular and portal pressures may be high in a large subset of these patients and injudicious use of blood may precipitate harm and risks of circulatory overload. This is an area of pressing need for research.
- The use of FFP for prophylaxis in non-bleeding patients needs careful scrutiny. This audit has shown that non-bleeding patients continue to receive FFP with normal or only minor derangements of the prothrombin time (PT) or INR. There is a requirement for further education about the limitations of standard coagulation tests and for quality improvement research.
- Trusts / Hospitals should encourage transfusion laboratory staff to challenge medical staff about the requesting of blood components where there is no clear clinical indication as defined by guidelines e.g. prophylaxis using FFP prior to procedures.
- Given the prevalence of in-hospital venous thromboembolism, routine chemical thromboprophylaxis must be considered in hospitalised, non-bleeding, patients.

Background

1. Why was this audit required?

The Epidemiology and Survival of Transfusion Recipients (EASTR) study showed that liver and gastrointestinal diseases are the leading indication for transfusion of blood components in the UK (Wells et al, 2009). A national fresh frozen plasma (FFP) audit in 2007 indicated that cirrhosis accounted for 19% of all FFP transfusions although this survey enrolled patients of all diagnostic groups and was unable to capture detailed information on use and reasons for transfusion in this cohort (Allard et al, 2009). A specific intention was to repeat this audit with a focus on one patient group.

Cirrhosis is a complex acquired disorder of haemostasis. Recent evidence has changed the paradigm about haemostasis in cirrhosis (Tripodi and Mannucci, 2011), in that there is not hypo-coagulability in stable cirrhosis, but a resetting of the pro- and anti-coagulation factors such that clot formation remains normal providing platelet count is $50x10^9$/l or more. Moreover as the severity of liver disease increases there is a tendency to a pro-coagulant state (Gatt et al, 2010)

Patients with cirrhosis are commonly transfused blood components for either prophylaxis or treatment of bleeding complications. Prophylactic use of blood components occurs prior to invasive procedures such as paracentesis, liver biopsy, thoracocentesis, and endoscopy. Despite British Committee for Standards in Haematology (BCSH) guidance (O'Shaughnessy et al, 2004), it is common practice to transfuse blood components to patients prophylactically on the basis of an abnormal prothrombin time (PT) or international normalised ratio (INR).

There is likely to be variation in practice with respect to products/volumes infused, laboratory triggers for transfusion and monitoring effects of transfusion.

Although the predominant haemostatic phenotype has traditionally been considered to be a bleeding diathesis, venous thrombosis is common (Amitrano et al, 2004). Therefore transfusion of plasma blood components based upon perceived coagulopathy indicated by conventional coagulation indices may not only be inappropriate, but may be harmful, by potentially increasing the risk of thrombotic complications and exacerbating already elevated portal pressures resulting in an risk of bleeding from varices. In addition, inappropriate use of blood for transfusion exposes patients to other risks related to the use of blood components e.g. transfusion associated circulatory overload (TACO) (Narick et al, 2012) or transfusion-related acute lung injury (TRALI) (Vlaar and Juffermanns, 2013).

The predominant bleeding phenotype of patients with cirrhosis relates to haemorrhage from gastro-oesophageal varices. Not only do conventional coagulation indices poorly predict the risk of developing re-bleeding, they are also poor predictors of outcomes following bleeding (Jairath et al, 2014). Other important determinants of bleeding include splanchnic pressures, presence of sepsis, renal failure and endothelial dysfunction, but there is little information on how these patient risk factors interact in large studies of practice (Tripodi and Mannucci, 2011).

This multi- regional audit was undertaken to establish current patterns of use of blood components in patients with cirrhosis, comparing practice against existing guidelines, as well as exploring clinical and laboratory indications, nature of interventions and outcomes. We also collected data on the use of dynamic testing using rotational thromboelastometry (ROTEM) or thromboelastography (TEG) methodology for patients with cirrhosis who bleed and base transfusion treatments on data obtained from these tests.

2. Description of the audit

This project was designed to collect information on patients admitted with a diagnosis of cirrhosis with respect to their use of blood components during the course of their admission. All hospitals registered with the British Society of Gastroenterology (BSG) across the United Kingdom were invited to participate.

The BSG in conjunction with NHS Blood and Transplant (NHSBT) invited all staff on the current BSG membership lists. The project was also supported by the British Association for the Study of Liver Disease (BASL) and Regional Transfusion Committees. Interested parties registered with the BSG. They were then sent supporting documentation plus a link to an online data collection tool. The data collection tool was piloted in 3 sites prior to the main audit and modified using an iterative process. An organisational audit was also carried out to supplement the clinical information.

The audit was subject to approved governance processes for audit activity where all data is anonymised. Participants were provided with an 8 digit unique login to the data collection tool. Data collection was largely facilitated by junior medical staff attached to the local Gastroenterology and Hepatology specialities in participating organisations. The local blood transfusion communities within these organisations were also informed.

Audit Methods and Analysis

All hospitals with representation on the BSG membership list were invited to participate in the audit. In addition, Hospital Transfusion Committees (HTCs) and Regional Transfusion Committees (RTCs) were also informed and provided with updates and reminders.

Inclusion criteria for participants were a confirmed diagnosis of cirrhosis by standard criteria and admission to hospital as an inpatient during the study period. Data were collected on consecutive patients with cirrhosis admitted under the care of gastroenterologists or hepatologists over a 4 week period. The 4 week data collection

period was selected from a 3 month window (February to April 2013) in order to allow organisations to conduct the audit in accordance with local resources. Data on each participant was collected for a maximum of 4 weeks after admission or until transfer, discharge or death (whichever came first). Patients attending as outpatients, day-case endoscopy units and those outside gastroenterology/hepatology services were excluded on pragmatic grounds.

Data was entered online by junior medical staff attached to the gastroenterology or hepatology specialities in each hospital that took part in the audit. Transfusion Practitioners and Transfusion laboratory managers assisted where necessary. Data were entered online onto a bespoke designed data entry form. The form allowed up to 80 cases to be submitted and each case could be re-visited in order to update or add new information during the course of the admission. Data downloads were as comma separated files with conversion to standard Microsoft Excel spreadsheet format. After audit completion, data was examined for anomalies and out-of-range results using conditional formatting and visual examination. A clinical panel reviewed the dataset and a full audit trail of data cleaning was kept. As an audit, it was recognised that data completeness was dependent on local resources and the availability of staff and time.

The clinical form specified that the patient must have a diagnosis of cirrhosis to be included in the audit. An online Frequently Asked Questions (FAQ) facility was provided to define diagnostic criteria and explain data entry requirements. The data collection included blood component transfusion details, standard test results pre and post transfusion, renal/liver function and outcomes. Full copies of the data collection forms used for clinical and organisational data are given as appendices 2 and 3. A copy of the FAQ sheet is given as appendix 4.

There were some variations in expressed units for some parameters. For example, haemoglobin levels were sometimes reported in g/dl. These were standardised during the cleaning process. Data have been analysed principally in the context of bleeding and transfusion practice in line with haematological, biochemical and physiological markers.

Given that for some hospitals, the numbers of submitted cases was small, it was not felt appropriate to provide results for individual hospital data.

If hospitals wish to see and access their own data,
please contact Brian Hockley at brian.hockley@nhsbt.nhs.uk

3. Standards of the audit

There is a paucity of evidence available that relate directly to blood component use in patients with cirrhosis. One of the purposes of the audit is to use the information to refine these standards further as they apply to this demographic.

The following standards were developed by the project group and applied:

- Guidelines
  - All hospitals should have guidelines on transfusion for cirrhosis
- Red cells
  - Only transfuse if haemoglobin <80g/L for patients with gastrointestinal bleeding (NICE) (National Institute for Clinical Excellence, 2012)
  - Only transfuse red cells prophylactically if haemoglobin <80g/L
- Fresh frozen plasma
  - Should not be used for pre-procedure transfusion if:
    - INR ≤1.5 for high risk procedures (e.g. surgery) (Patel et al, 2013)
    - INR ≤2 for low risk procedures (e.g. paracentesis) (Patel et al, 2013)
- Platelets
  - Should not be used for pre-procedure transfusion unless platelet count <$50x10^9$/L (British Committee for Standards in Haematology, 2003)

Results

1. Demographics and Cohort Details

85 out of 110 (77%) organisations who registered to participate in the audit submitted data on a total of 1333 consecutive cases of cirrhosis. 20 cases were subsequently excluded from the dataset; in 8 cases data were entered where no diagnosis of cirrhosis was indicated, and in a further 12 cases critical information was missing or had been entered incorrectly. These data were not followed up principally because the data completers in their respective organisations were no longer available.

Participating Sites

Participating centres included 4 liver transplant units. 41% of centres had between 400 and 600 beds and 52% had over 600 beds. 7% did not indicate.

Organisational Data

72/85 (85%) hospitals returned organisational questionnaires. The questionnaires were sent to transfusion practitioners. A follow up was also sent to laboratory managers in participating hospitals in England and to consultant staff who agreed to participate in Scotland, Northern Ireland and Wales. The questionnaire asked for information regarding ranges used for haematological parameters, use of haemostatic tools to guide transfusion and bed numbers. A copy of the questionnaire is provided as appendix 2.

4/72 (6%) hospitals said they had specific transfusion guidelines for patients with cirrhosis. 18/68 (26%) said they had access to global tools of haemostasis (such as thromboelastography) and 7/72 (10%) indicated use of these tools to guide transfusion of blood components in patients with liver disease including cirrhosis.

Sample dataset

1313 cases comprised the final dataset for analysis. There were 849/1313 (65%) males and 463/1313 (35%) females with one indicating transgender (mean age 58 years, mode 55 years, range 81 years, min/max 19 -100 for both genders).

The following tables report on the ethnicity distribution, admitting specialty, primary cause of cirrhosis and primary reason for admission, for this dataset.

Table 1 – Ethnicity

Ethnicity	n (%)
White British	1178 (90)
Other White	32 (2)
Other black background	2 (<1)
White Irish	20 (1)
Pakistani	15 (1)
Indian	12 (<1)
African	11 (<1)
Other Asian	9 (<1)
Caribbean	8 (<1)
Bangladeshi	6 (<1)
Chinese	5 (<1)
White/Black Caribbean	2 (<1)
Not stated	13 (<1)
Total	**1313**

Table 2 – Admitting Speciality *

Admitting Speciality	n (%)
Gastroenterology	736/1313 (56)
Hepatology	354/1313 (27)
General Medicine	204/1313 (16)
Surgery	25/1313 (2)
Other	82/1313 (6)
Total	**1401***

* 88 patients admitted under more than one specialty

Table 3 – Primary Cause of Cirrhosis

Cirrhosis Cause	n (%)
Alcohol	921/1313 (70)
Non-alcoholic Fatty Liver Disease	162/1313 (12)
Hepatitis C	132/1313 (10)
Primary Biliary Cirrhosis	34/1313 (3)
Haemochromatosis	21/1313 (2)
Autoimmune Disease	21/1313 (2)
Primary Sclerosing Cholangitis	19/1313 (1)
Hepatitis B	16/1313 (1)
Other viral cause	2/1313 (<1)
Other *	88/1313 (7)
Total	**1416 ****

* 25 cases entered under “other” category were classified as “cryptogenic”. ** 103 patients had more than one cause for their cirrhosis

Table 4 – Primary Reason for Hospital Admission

Primary Reasons for Admission	n (%)
Decompensated cirrhosis (not otherwise specified)	326/1313 (25)
Increasing Ascites/Oedema	263/1313 (20)
Gastrointestinal Bleeding	192/1313 (15)
Encephalopathy	183/1313 (14)
Paracentesis	142/1313 (11)
Sepsis	110/1313 (8)
Surgical Procedure	50/1313 (4)
Transplant Assessment	37/1313 (3)
Endoscopy	22/1313 (2)
Fracture	13/1313 (<1)
Biopsy	9/1313 (<1)
Total	**1347 ***

* 34 patients admitted for more than one reason

Reasons given in table 4 are not mutually exclusive.

Summary Box 1

- Two-thirds of admissions were male
- The mean age was 58 years
- 90% of admissions were White British
- 83% of cases were admitted under the care of Gastroenterology/Hepatology
- Alcohol was the primary aetiology of cirrhosis in 70% of cases
- The primary reason for hospital admission was due to clinical features of decompensated cirrhosis

2. Baseline laboratory parameters

Table 5 indicates median values and inter-quartile range for standard laboratory parameters for the whole patient cohort.

Table 5 – Key Laboratory Parameters (n =1313)

Investigation	Median (IQR)
Albumin (g/L)	30 (25-34)
Alanine Transaminase (iu/L)	33 (22-52)
Bilirubin (µmol/L)	39 (20-84)
Alkaline Phosphatase (iu/L)	154 (110-383)
Sodium (mmol/L)	135 (130-139)
Creatinine (µmol/L)	75 (56-110)
Urea (mmol/L)	6 (4-10)
White Cell Count ($x10^9$/L)	9 (6-13)
C reactive protein (mg/L)	28 (8-65)

Table 6 – Cultures

	Blood n (%)	Urine n (%)	Ascitic Culture n (%)	Stool n (%)
Culture sent	448/1313 (34)	430/1313 (33)	496/1313 (38)	184/1313 (14)
Positive	82/448 (18)	106/430 (25)	68/496 (14)	19/184 (10)

A total of 1558 cultures were sent from 1313 patients, of which 275/1558 (18%) were positive. 650 (50%) patients were prescribed antibiotics during the study period and 84 (6%) patients were prescribed antifungals.

Table 7 – Cultures in patients with decompensated cirrhosis

This lists those cultures which were sent in patients presenting with decompensated cirrhosis. This included patients with one or more of the following - encephalopathy, increasing ascites and gastrointestinal bleeding (n = 708/1313 (54%) as 256 patients were admitted with more than one feature of decompensated cirrhosis).

	Blood n (%)	Urine n (%)	Ascitic Culture n (%)	Stool n (%)
Culture sent	283/708 (40)	269/708 (38)	341/708 (48)	119/708 (17)
Positive	48/283 (17)	56/269 (21)	46/341 (13)	12/119 (10)

In patients with decompensated cirrhosis, a total of 1012 cultures were sent from 708 patients, of which 162/1012 (16%) were positive.

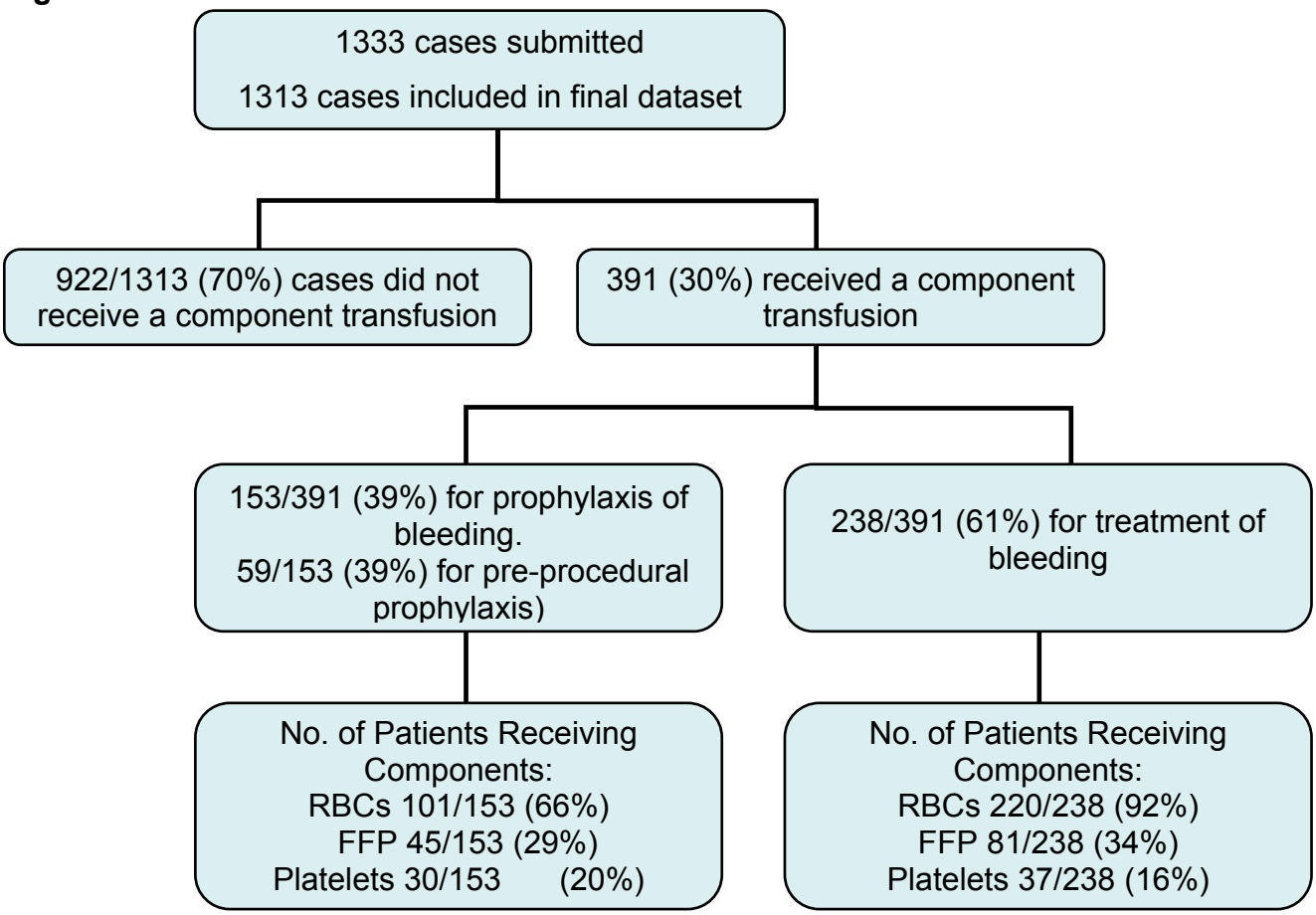
Summary Box 2

- 283/208 (40%) of patients admitted with features of decompensated cirrhosis had blood cultures sent. Of these 17% (48/283) were positive
- 149/192 (78%) of patients with gastrointestinal bleeding were prescribed antibiotics

3. Use of Blood Components

Figure 1 illustrates the number of patients receiving transfusion of any blood component during the study period and the main indication for transfusion. In total 391 (30%) of all patients were transfused a blood component during the study period; 922 (70%) did not receive a blood component.

Figure 1



In total 391 (39%) cases were transfused. Of these, 238 (61%) patients received a transfusion for the treatment of bleeding and 153 (39%) patients received a transfusion for prophylaxis. In the prophylaxis group, 94 (61%) were transfused in the absence of any planned or undertaken procedure.

Table 8 reports the median (IQR and Range) number of units of blood components transfused in all transfusion episodes (bleeding and for prophylaxis)

Table 8 – Component Use (median, IQR and range)

	Red Blood Cells	Platelets	Fresh Frozen Plasma	Cryoprecipitate
Median (IQR) Range	2 1 1-28	1 1 1-5	4 2 1-22	2 8 1-15

Table 9 – Procoagulant Drug Use

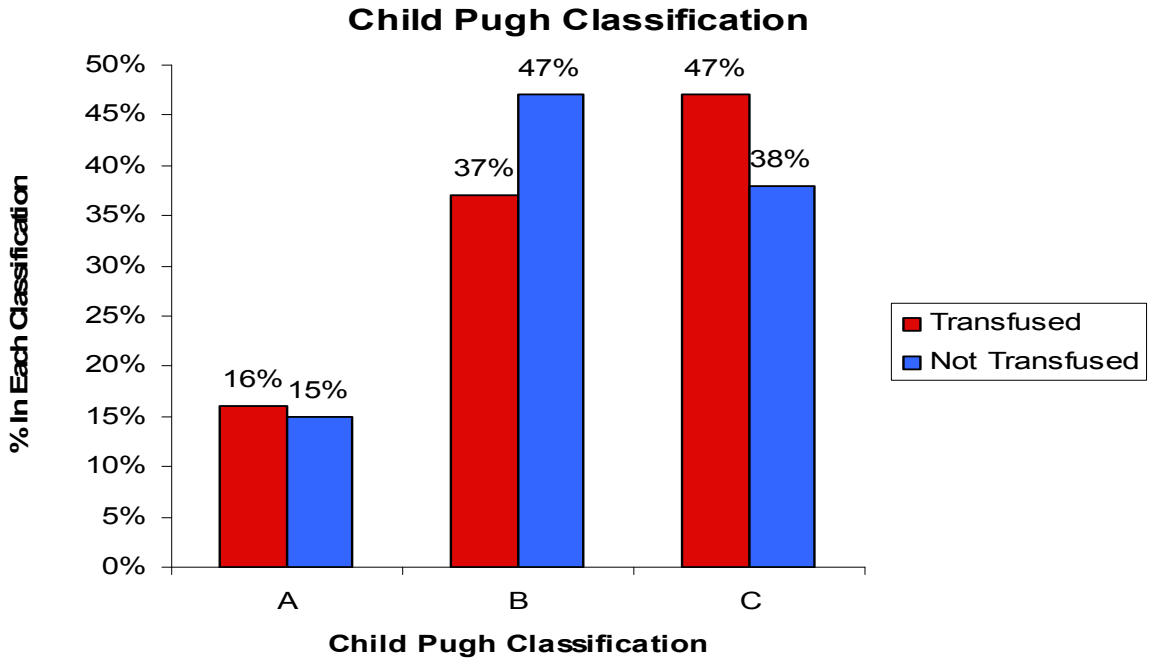
Drug Administered *	Treatment of Bleeding n = 238	Prophylaxis n = 153
Tranexamic Acid	11	1
Prothrombin Complex	4	0
Factor VIIa	0	0

* refers to number of patients who received the drug

Child-Pugh scores were derived to classify the severity of cirrhosis based on bilirubin, albumin, prothrombin time, severity of ascites and hepatic encephalopathy. 379 (29%) did not have sufficient information documented in the clinical records to derive the score. The Child-Pugh score is a prognostic index for chronic liver disease. Two year survival for Child Pugh A is 85%, Child Pugh B is 57% and Child Pugh C is 35%)

Figure 2 indicates the proportions in Child Pugh classifications A, B and C for both the transfused and non-transfused groups

Figure 2



Class A score = 5-6 Class B score = 7-9 Class C score = 10 -15

Summary Box 3

- 391/1313 (30%) of patients were transfused at least one blood component during their admission
- The main reason for transfusion was for treatment of bleeding 238/391 (61%).
- In the prophylactic group, most patients received transfusion in the absence of a planned procedure
- For the 238 cases receiving blood components for bleeding, 220/238 (92%) of patients received red cells, 81/238 (34%) received FFP, 37/238 (16%) received platelets and 13/238 (5%) cryoprecipitate
- For the 153 cases receiving blood components as prophylaxis, 101/153 (66%) of patients received red cells, 45/153 (29%) FFP, 30/153 (20%) platelets and 3/153 (2%) cryoprecipitate
- No patients with bleeding were administered Factor VIIa
- 11/238 (5%) of patients transfused for bleeding were administered tranexamic acid

Use of blood

The audit was focussed around a 24 hour period and collected information about all blood components transfused during this time. The “transfusion episode” started with the administration of any component. Participants were asked to differentiate between bleeding as the result of the presenting condition or bleeding considered related to a procedure. In some cases there was more than one cause of bleeding.

Blood tests taken on first presentation to hospital were recorded. Blood test results were also requested for the point closest to the transfusion episode.

For haemoglobin, prothrombin time, international normalised ratio (INR) and activated partial thromboplastin time (APTT), all of these parameters were completed in 83% of all cases on admission where transfusion for bleeding was indicated. For those transfused for the prophylaxis of bleeding, 79% of cases had all of these indices recorded on admission. Results from the point closest to the transfusion episode were used where these existed. These data are presented in the next sections (tables 10 – 24) for patients transfused for bleeding or for prophylaxis.

4. Transfusion for Bleeding

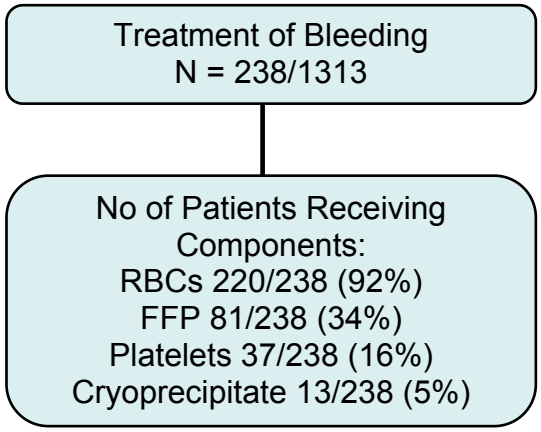


Table 10 – Transfused for Bleeding

Site of Bleed	n (%)
Gastrointestinal Bleeding	192/238 (81)
Bleeding following a Procedure	16/238 (7)
Trauma	7/238 (3)
Epistaxis	7/238 (3)
Subdural Haemorrhage	2/238 (<1)
Haemoptysis	1/238 (<1)
Retroperitoneal Haemorrhage	1/238 <1)
Other *	12/238 (5)
Total	238

* Received component for treatment of bleeding but not clear reason located by data submitters

In 16 cases it was indicated that there was bleeding following a procedure. The procedures are listed below.

Table 11 – Bleeds and Procedures

Procedure	Number of Bleeds n (%)
Gastroscopy	8/16 (50)
Surgery	3/16 (19)
Paracentesis	2/16 (13)
Central Line	1/16 (6)
Chest Drain	1/16 (6)
Colonoscopy	1/16 (6)

Haemoglobin Concentrations and Use of Red Cells

220/238 (92%) received a red blood cell transfusion and of these 236/238 (99%) had a pre-transfusion haemoglobin taken. Table 12 reports haemoglobin thresholds prior to receipt of red cells in all patients transfused for bleeding. Data are also presented on whether or not patients had haemodynamic compromise. This was defined as either a heart rate of >100 beats per minute and/or a systolic blood pressure of <100mmHg. Table 13 presents the same information for patients who presented with gastrointestinal bleeding.

Table 12 – Haemoglobin thresholds prior to red cell transfusion in patients with bleeding

Haemoglobin prior to red cell transfusion g/L	Overall n (%)	Haemodynamic compromise n (%)
≤ 70	97/220 (44)	56/97 (58)
71 - 80	69/220 (32)	36/69 (52)
81 - 90	28/220 (14)	18/28 (64)
91- 100	12/220 (6)	11/12 (92)
> 100	14/220 (11)	11/14 (79)

Table 13 – Haemoglobin thresholds prior to red cell transfusion in patients with gastrointestinal bleeding

Haemoglobin prior to red cell transfusion g/L	Overall n (%)	Haemodynamic compromise n (%)
≤ 70	82/185 (44)	53/82 (63)
71 – 80	55/185 (30)	31/55 (56)
81 – 90	23/185 (12)	15/23 (65)
91- 100	11/185 (6)	10/11 (91)
> 100	14/185 (8)	8/14 (57)

Use of platelets, FFP and cryoprecipitate in patients with bleeding

A total of 57 adult therapeutic units of platelets were transfused to 37/238 (16%) patients treated for bleeding. 9/37 (24%) were double doses; 2/37 (5%) patients received 3 units of platelets, 1/37 (3%) patients received 4 units and 1/37 (3%) received 5 units of platelets in one transfusion episode. 285 units of FFP were used in 81/238 (34%) patients treated for bleeding. Results on platelet counts, INR and fibrinogen concentrations prior to transfusions are shown in the next three tables.

Table 14 – Platelets

Platelet count (x10^9/L) prior to platelet transfusion	Overall n (%)	Haemodynamic compromise n (%)
≤ 20	6/37 (16)	1/6 (17)
21-50	14/37 (38)	6/14 (43)
51-100	10/37 (27)	6/10 (60)
> 100	4/37 (11)	2/4 (50)
Not checked	3/37 (8)	1/3 (33)

Table 15 – Fresh Frozen Plasma

INR prior to FFP transfusion	Overall n (%)	Haemodynamic compromise n (%)
≤ 1.5	11/81 (14)	8/11 (73)
1.6-2.0	31/81 (38)	20/31 (65)
2.1-2.5	7/81 (9)	3/7 (43)
> 2.5	11/81 (14)	7/11 (64)
Not checked	21/81 (26)	13/21 (62)

Table 16 – Fibrinogen Levels

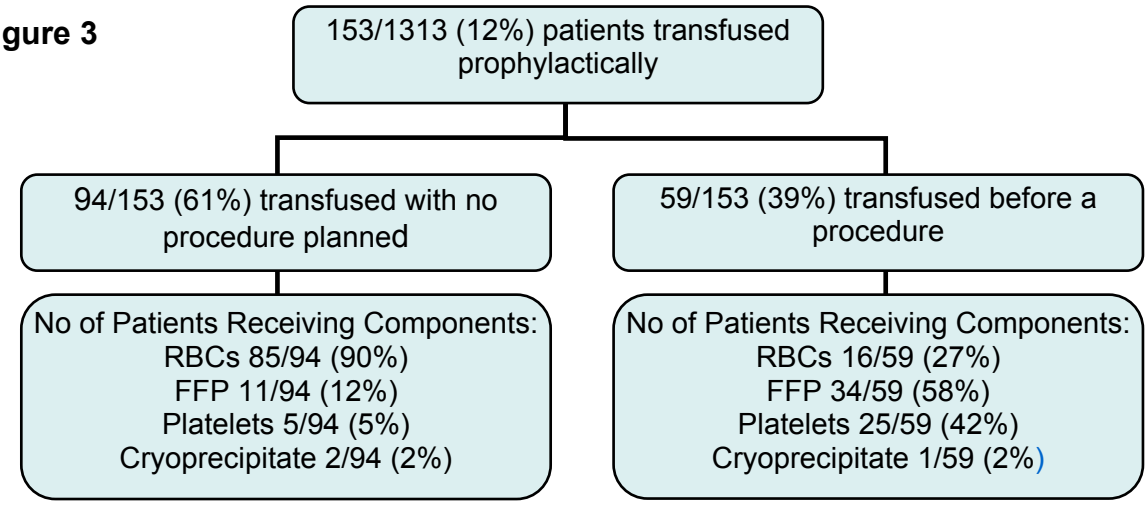
Fibrinogen (g/L) prior to cryoprecipitate transfusion	Overall n (%)	Haemodynamic compromise n (%)
≤ 1	3/10 (30)	1/3 (33)
1.1-2.0	6/10 (60)	3/6 (50)
2.1-2.5	1/10 (10)	1/1 (100)

Summary Box 4

- 18% (238/1313) of in-patients with cirrhosis were transfused blood components for the treatment of bleeding. Of these 81% (192/238) were transfused for gastrointestinal bleeding.
- 75% (166/220) of all patients who were transfused with red cells for bleeding had a pre-transfusion haemoglobin threshold of <80 g/L
- 74% (137/185) of those patients with gastrointestinal bleeding who were transfused with RBCs had a pre-transfusion Hb threshold of < 80 g/L. 44% (82/185) of those with gastrointestinal bleeding who were transfused with RBCs had a pre-transfusion Hb threshold of < 70g/L.
- 54% (20/37) of patients with bleeding who were transfused platelets had a pre-transfusion platelet count of <50 x 10^9/L.
- 60% (49/81) of patients who were bleeding and transfused FFP had a pre-transfusion INR of >1.5.
- Cryoprecipitate was only used in a total of 4% (10/238) patients with bleeding.

5. Transfusion for Prophylaxis

Figure 3



Component Use and Procedures in Prophylactically Transfused Patients

153 patients received blood components where the indication was for prophylaxis and not for treatment of bleeding. Of these patients, 94/153 (61%) received blood components for prophylaxis where no procedures were planned or undertaken. 74/94 (79%) of this group of patients were transfused red blood cells where the primary stated reason was for correction of anaemia. 20/94 (21%) patients transfused prophylactically were indicated in the data submissions as having no clear reason to explain the transfusion

The Tables below summarise findings for overall component use in the patients receiving blood components for prophylactic indications.

Table 17 – Prophylaxis and No Procedure Planned

	Red Blood Cells	Platelets	Fresh Frozen Plasma
Median (IQR) Range	2 0 1-5	1 1 1-2	4 1.5 2-10

* 1 patient received 2 pools and 1 patient received 4 pools of Cryoprecipitate

Table 18 – Prophylaxis with Procedures

	Red Blood Cells	Platelets	Fresh Frozen Plasma
Median (IQR) Range	2 1 1-18	2 1 1-3	4 2 1-22

* 2 pools of cryoprecipitate were used for 1 patient

* 43 units of Fresh Frozen Plasma were given to 11/94 (11%) of patients. The Table below summarises information on use of red cells transfusions and haemoglobin concentrations for the whole prophylactic cohort

Table 19 – Haemoglobin concentrations and use of red cells

Haemoglobin (g/L) prior to red cell transfusion	Numbers of cases n (%)
≤ 70	43/101 (44)
71 - 80	38/101 (41)
81 – 90	13/101 (16)
91- 100	3/101 (8)
> 100	4/101 (42)

In total 59 patients received any blood components in the context of prophylaxis for procedures. These procedures, defined by low, moderate and high risk (Patel et al, 2013) were:

Table 20 – Procedures

Procedure	Number of cases n (%)
Low risk	
Paracentesis	18/59 (31)
Central line	6/59 (10)
Thoracocentesis	4/59 (7)
Moderate risk	
Surgery	15/59 (25)
Endoscopy	10/59 (17)
Liver biopsy	5/59 (8)
High risk	
Neurosurgery	1/59 (2)

Tables 21 & 22 show the results for platelet counts and INR values for those who underwent a specific procedure and received platelets or FFP respectively. Please note, a smaller subset received FFP and/or platelets but where no procedure was undertaken and this is shown as a footnote in the table.

Tables 21 – Platelet counts in prophylaxis patients prior to a procedure.

Platelet Count (x10^9/L) prior to procedures where platelets transfused	Number of Cases n (%)
≤20	3/25 (12)
21-50	13/25 (52)
51-100	8/25 (32)
>100	1/25 (4) *

* Single case of prophylaxis prior to neurosurgery

** 5 cases where no procedure planned also received platelets

Table 22 – Use of FFP in prophylaxis patients prior to a procedure.

INR prior to procedures where FFP transfused	Mod/high Risk Procedures n (%)	Low risk procedures n (%)
≤1.5	3 (19)	1 (6)
1.6-2.0	7 (44)	5 (28)
2.1 or more	6 (37)	12 (67)
Total	16	18

* 11 patients received FFP with no procedure planned

Summary Box 5

- 153/1313 (12%) of patients with cirrhosis were transfused blood components for prophylaxis. Of these only 39% (59/153) were transfused before an invasive procedure.
- 81/101 (81%) received red cells at a haemoglobin <80g/L for prophylaxis
- 34/45 (76%) patients who received FFP for prophylaxis received it prior to a procedure. For those who underwent higher risk procedures 13/16
- (81%) had a pre-transfusion INR >1.5. For lower risk procedures 12/18 (67%) had an INR >2.
- 25/30 (83%) patients who were transfused with platelets received them prior to a procedure and 16/25 (64%) had a pre-procedure platelet count of <50x10^9/L.
- Cryoprecipitate was rarely transfused for prophylaxis

6. Patient Outcomes – mortality and thrombotic events

Table 23 describes the main outcomes of patients enrolled into the study, including mortality at end of study (Day 28) or at discharge (or death if earlier)

Table 23 – Outcomes

Outcome	All Cohort n (%)	Not Transfused n (%)	Transfused for Bleeding n (%)	Transfused Prophylactically n (%)
Still in Hospital	131/1313 (10)	72/922 (8)	37/238 (16)	22/153 (14)
Discharged	1012/1313 (77)	766/922 (83)	147/238 (62)	99/153 (65)
Transferred	31/1313 (2)	16/922 (2)	10/238 (4)	5/153(3)
Died	128/1313 (10)	59/922 (6)	42/238 (18)	27/153 (18)
Missing data	11/1313 <1)	9/922 (<1)	2/238 (<1)	0

Case fatality was 128/1313 (10%) at Day 28. Causes of death are reported in Table 24. In 52 patients the cause of death was indicated as decompensated cirrhosis; in 33 cases the primary indication was sepsis; 16 from carcinoma and 11 from haemorrhage.

Table 24 – Principle Reasons for Death

Other Reasons for Death	Frequency n (%)
Decompensated cirrhosis	52 (41)
Sepsis	33 (26)
Carcinoma	16 (13)
Haemorrhage	11 (9)
Cardiac disease	8 (6)
Multi-organ failure	4 (3)
Ischaemic liver injury	2 (2)
Stroke	2 (2)
Total	128

Thrombotic events

There were 35 (3%) cases of arterial (<1%) or venous thrombotic/thromboembolic events (2%) in hospital or up to day 28. These patients had the event confirmed during their hospital stay but it is not possible to determine if they occurred in hospital or were present beforehand. This compares to a rate of symptomatic venous thromboembolism of approximately 1% (Leizoroviz et al, 2004) and asymptomatic venous thromboembolism of 13% in general medical in-patients who do not receive thromboprophylaxis (National Institute for Health and Care Excellence, 2010).

Table 25 –Thrombotic Events

Event	n (%)
Portal vein thrombosis	18/35 (51)
Deep vein thrombosis	8/35(23)
Pulmonary embolus	3/35 (9)
Stroke	2/35 (6)
Myocardial infarction	2/35 (6)
Aortic thrombus	1/35 (3)
Graft thrombosis (femoro-popliteal)	1/35 (3)

There was 1 reported incident of a transfusion reaction.
This was described as Transfusion Related Lung Injury (TRALI).

Summary Box 6

- Case fatality was 10%.
- The major cause or reported death was decompensated liver disease 52/128 (41%)
- Haemorrhage was reported as the cause of death in 11/128 (9%) cases
- Thrombosis/thromboembolic disease was reported in 3% cases; 29/1313 (2%) patients had an in-hospital venous thromboembolic event and 5/1313 (<1%) patients had an in-hospital arterial thromboembolic event.

Comparisons of Results to Standards

- **Guidelines**
  - All hospitals should have guidelines on transfusion for cirrhosis
    - 4/72 (6%) hospitals had transfusion guidelines for patients with cirrhosis
- **Red cells**
  - Transfuse if haemoglobin <80g/L for patients with gastrointestinal bleeding (NICE) (National Institute for Clinical Excellence, 2012)
    - In 137/185 (74%) of patients transfused with red cells for gastrointestinal bleeding, the pre-transfusion haemoglobin was less than 80g/L
  - Only transfuse red cells prophylactically if haemoglobin <80g/L
    - In 81/101 (80%) of patients transfused with red cells prophylactically, the pre-transfusion haemoglobin was less than 80g/L
- **Fresh frozen plasma**
  - Should not be used for pre-procedure transfusion if:
    - INR <1.5 for high risk procedures (e.g. surgery) (Patel et al, 2013)
      - In 13/16 (81%) of patients transfused with FFP prophylactically before a moderate/high-risk procedure, the pre-transfusion INR was greater than 1.5
    - INR <2 for low risk procedures (e.g. paracentesis) (Patel et al, 2013)
      - In 12/18 (67%) of patients transfused with FFP prophylactically before a low-risk procedure, the pre-transfusion INR was greater than 2
- **Platelets**
  - Should not be used for pre-procedure transfusion unless platelet count <$50x10^9$/L (British Committee for Standards in Haematology, 2003)
    - In 16/25 (64%) of patients transfused with platelets prophylactically before a procedure, the pre-transfusion platelet count was less than $50x10^9$/L

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Appendix 1 – Participants (registering clinician in bold)

Consultant Staff	Name of Organisation *	Cases Submitted
Dr Rebecca Jones Dr Phaedra Tachtatzis Dr Lynsey Corless Dr Marina Karakantza	St James's Hospital Leeds	63
Dr Martin James Ms Kayley Anderson Dr Roma Patel Dr Alice O' Brien	Nottingham Queens Medical Centre	55
Dr Debbie Shawcross Dr Alek Mijovik Dr Suman Verna Mr Edward Tranah Mr Dominic Aldridge	Kings College Hospital	51
Dr Stewart McPherson Dr Ali Anwar	Newcastle Teaching Hospitals NHSFT	45
Dr Andrew Austin Dr Nivedita Ghosh	Royal Derby Hospital	39
Dr Aileen Smith	Derriford Hospital, Plymouth Hospitals NHSFT	35
Dr Adrian Stanley Dr Mohammed Mustafa	Glasgow Royal Infirmary	35
Dr Alison Brind	North Staffs University Hospital	32
Dr Salil Singh Dr Sophie Benoliel	Royal Bolton Hospital	32
Dr Shishir Shetty Dr New Ni Than	Queen Elizabeth Birmingham	31
Dr John Wong Dr R Sringeri Dr A McCulloch Dr Courtenay Evans	Coventry University Hospital	26
Dr Douglass Thornburn Dr Gautam Mehta Dr Endip Dhesi	Royal Free London	26
Dr Nick Stern Dr Margaret Corrigan	Aintree University Hospital	24
Dr Jane Collier Dr Chris Burton	John Radcliffe Hospital	24
Dr Sushma Saksena **Ms Janet Ryan** **Ms Gill McAnaney**	County Durham/Darlington NHSFT	23
Dr Andrew Fowell Dr Rory Peters Dr James Neil	Queen Alexander Hospital, Portsmouth	23
Dr Safa Al Shamma Dr Tom Hollingsworth Dr Ron Basuroy	Royal Bournemouth and Christchurch	23
Dr Martin Phillips	Norfolk and Norwich University Hospital	22
Dr Kara Wye Ms Mandy Walters	Shrewsbury and Telford NHSFT	22
Dr Darren Craig Dr Rohit Sinha	South Tees NHS Trust	22
Dr Sam Thompson Dr Claire Kelly	Western Sussex Hospitals Worthing	22
Dr Yiannis Kallis Dr Rebecca Preedy Dr Siddarth Kotta	Royal London (Inc Barts)	21
Dr Ulrich Thalheimer Dr Emma Wesley Dr Briony Conduit	Royal Devon and Exeter	20
Dr Julie Dobson Dr Suzanne Griffiths	St Helens and Knowsley NHS FT	20
Dr Alexandra Daley Dr Nidhi Sagar Dr Kerry Cumiskey Dr Chris Dobson Dr Mark Andrew	Heart of England NHS Trust	19

Dr Neill McDougall Dr Phill Hall Dr Conor Braniff	Royal Victoria Hospital Belfast	19
Dr Stirling Pugh **Dr Iftikhar Ahmed**	Taunton and Somerset NHSFT	19
Dr Marie McMahon Dr Raf Al-Hameed	Trafford/Central Manchester NHSFT	19
Dr John Dillon Dr MH Miller Dr JCM Patterson	Ninewells Hospital Dundee	18
Dr Acuth Shenoy Dr Ian Gooding Dr Bhavin Bakrania Dr Nazmin Begum Ms Susan Trower	Colchester General Hospital	14
Dr Grant Caddy	Ulster Hospital Dundonald	14
Dr Jayaprakash Anthoor Dr John Ciaputa Dr Vladimir Gusev Dr Pitsien Lang Ping Nam	Wansbeck Hospital	14
Dr Magda Smith Dr Preya Patel	Barking Havering and Redbridge Hospitals	13
Dr Emily Johns Dr G Webb Dr Al Hasani	Buckinghamshire NHS Trust	13
Dr Abdul Wahab	Dumfries and Galloway Royal Infirmary	13
Dr Anthony Norman Dr Pradeep Sanghi	Lincoln County Hospital	13
Dr Alistair McNair	Queen Elizabeth Woolwich	13
Dr George Sabala	Calderdale and Huddersfield NHS Trust	12
Dr Lorna Panter	Darlington Memorial Hospital	12
Dr Nicholas Taylor Dr Peter Eddowes Dr Ruth Willott	Kings Mill Hospital Sutton-in-Ashfield	12
Dr Kathryn Nash Dr Teresa Hydes Dr Daniel Neville Dr Alasdair Warwick	Southampton General Hospital	12
Consultant Staff	**Name of Organisation***	**Cases Submitted**
Dr Richard Johnston Dr Maria Saunders	Torbay Hospital	12
Dr Richard Crofton Dr Marc Cram Dr Heather Lafferty Dr Pradeep Pardeshi	Wishaw General Hospital	12
Dr T Mathialahan	Wrexham Maelor Hospital	12
Dr Ali Taha	Crosshouse Hospital Kilmarnock	11
Dr Sanjay Gupta	Croydon University Hospital	11
Dr Harriet Gordon Dr Markus Gwiggner Dr Nikki Taylor	Hampshire Hospitals NHSFT	11
Dr Gavin Wright	Basildon University Hospital	10
Dr M Karmo Ms Sarah Dale	Countess of Chester NHS Trust	10
Dr Athar Saeed Dr Lucy Walker	Queen Elizabeth Gateshead	10
Dr Iain Murray	Royal Cornwall Hospital	10
Dr Gary Bray Dr Neil Halliday Ms Natasha Hughes	Southend University Hospital	10
Dr Harriet Mitcheson Dr Ahmed Holeihel Dr Sibby Punnoose	Sunderland Royal Hospital	10
Dr Sharan Shetty	Dudley Group of Hospitals	9
Ms Ellen Strakosch Dr Sen Sambit Dr Tessa Cacciottolo	Luton and Dunstable University Hospital	9

Dr Christopher Meaden Dr Katherine White Dr Michael Roberts	Morecambe Bay University Hospitals	9
Dr Howard Klass	North Manchester General Hospital	9
Dr Shareef Tholoor Dr Tapas Das Dr Balraj Appadu	Peterborough and Stamford NHSFT	9
Dr Julia Maltby Dr Benjamin Arnold Dr Joanna Lee	Royal United Hospital Bath	9
Dr Clement Kiire Dr Pauline Skipworth	Southport and Ormskirk Hospitals NHS Trust	9
Dr Coral Holywood Dr David Tate Dr Khalid Zachariah	Gloucestershire Hospitals FT	8
Dr Bob Grover Dr Wiqar Gondal Dr Richard Appleby	Hillingdon Hospital	8
Dr Cheryl Hassell Dr Thomas Chapman Dr Lennard Lee	Milton Keynes Hospital	8
Dr Jane Metcalf Dr David Mitchell	North Tees University Hospital NHSFT	8
Dr Roger McCorry	Preston, Lancashire Teaching Hospitals	8
Dr Jeremy Sherman Dr Adrian Gelsthorpe	South Warwickshire NHSFT	8
Dr S Bharathi	Warrington Hospital	8
Ms Tracy Hitchin Dr Anupa Kumar	Ipswich Hospital	7
Dr Leonie Grellier	St Mary's Hospital Isle of White	7
Dr Neill McDougall Dr Rynan Scott	Belfast City Hospital	6
Dr Konrad Koss	East Cheshire NHS Trust	6
Dr Levi Sasson Ms Christine Ellis Dr Angharad Pryce	Heatherwood Wexham Park	6
Dr John Dillon	Perth Royal Infirmary	6
Ms Tanya Hawkins Dr Sonali Patel Dr Kim On	Royal Berkshire Hospital	6
Dr Simon Whalley	West Suffolk Hospital	5
Dr Mathew Foxton	Chelsea and Westminster NHSFT	4
Dr Kashif Sheikh	James Paget University Hospital	4
Dr Debasish Das	Kettering General Hospital	4
Dr Neill McDougall Dr Emma Toner	Mater Inforium Hospital Belfast	4
Dr Sulleman Moreea	Bradford Teaching Hospitals	3
Dr Denis Burke Dr Edmund Derbyshire	Cumberland Infirmary, Carlisle	3
Dr George Abouda Dr Shairoz Samji	Hull and East Yorkshire NHS Trust	3
Dr T Mathialahan	Ysbyty Gwynedd	3
Dr Charles Milson Dr Prashant Kant	York Hospitals	2
Dr Brian McKaig Dr Chirag Kothari	Royal Wolverhampton NHS Trust	1
	Total	1313

Participants names and organisations are as submitted to the audit group at registration and to confirm acknowledgement of participation

We have attempted to obtain the names who all those who contributed to this audit. This was not always possible to provide. All contributions are gratefully appreciated. A letter of participation will be provided on request by emailing: brian.hockley@nhsbt.nhs.uk

Appendix 2 – Clinical Data Collection Form (paper)

BRITISH SOCIETY OF GASTROENTEROLOGY

South Central Regional Transfusion Committee

Audit of Blood Component use in patients with Liver Cirrhosis

Data Collection Tool – Paper Version.

Please use this if you prefer to complete cases in this way and enter data to the online system later.

If you are unable to enter this data online, please return this completed form to: Brian Hockley, Sheffield Blood Centre, Longley Lane, Sheffield, S5 7JN.

DO NOT ENTER ANY PATIENT IDENTIFIABLE INFORMATION ON THIS FORM

Please aim to review patient case notes within ~48 hours after admission and look at transfusion records for this patient. We would suggest trying to review patient case notes at least weekly, until the end of audit. Data collection will require collaboration between the local transfusion service (transfusion practitioners) and local gastroenterology / hepatology service (doctors/gastroenterology specialist nurses).

Audited Patient Number: ..... (*01,02* etc.)

This should correspond to the audited patient number on the online system

Organisation submitting form: .....

.....

A. Patient Characteristics

1. Does this patient have Liver Cirrhosis?

Yes ☐ No ☐ If No, this patient is not eligible for this audit

4. Date and time of hospital admission: ..... / ..... / ..... (*DD / MM / YYYY*)

5. Time of hospital admission: ..... : ..... am / pm

3a. Patient's year of birth: ..... (*YYYY*)

3b. What is the patient's gender? Male: ☐ Female: ☐

3c. Under which speciality was this patient being treated?

Gastroenterology ☐ General medicine ☐

Hepatology ..... ☐ Surgery ..... ☐

Other: .....

.....

3e. Ethnicity:

White British ☐ White Irish ☐ Any other white background ☐

Mixed

White and Black Caribbean ..... ☐ White and Black African ..... ☐

White and Asian ..... ☐ Any other mixed background ☐

Asian or Asian British

Indian ..... ☐ Pakistani ..... ☐

Bangladeshi ..... ☐ Any other Asian background ☐

Black or Black British

Caribbean ☐ African ☐ Any other Black background ☐

Chinese or other ethnic group

Chinese ..... ☐

Any other ethnic group not included above ☐

a. Primary Aetiology of Liver Cirrhosis

Alcohol ☐ Viral ☐ Hepatitis C virus ☐ Hepatitis B virus ☐

Non-alcoholic fatty liver disease ☐ Autoimmune ☐ Primary biliary cirrhosis ☐

Primary sclerosing cholangitis ☐ Haemochromatosis ☐

Other: .....

b. Primary reason for hospital admission *Please tick ✓ all that apply*

Decompensated liver cirrhosis ☐ Variceal haemorrhage ☐

Oesophageal varices ☐ Gastric varices ☐ Encephalopathy ☐

Increase ascites / oedema ☐ Sepsis ☐

For a procedure ☐

Paracentesis ☐ Biopsy ☐ Surgery ☐ Endoscopy ☐

Transplant assessment ☐ Fracture ☐

Other: .....

6. Clinical Examination

Presence of ascites

Not documented ☐ None ☐ Mild ☐ Moderate ☐ Severe ☐

6a. *Hepatic encephalopathy*

Not documented ☐ None ☐

Grade 1 ..... ☐ (sleep disturbance/impaired concentration/depression/anxiety/irritability)

Grade 2 ..... ☐ (drowsiness/disorientation/poor short-term memory/disinhibited behaviour)

Grade 3 ..... ☐ (confusion, amnesia, anger or other bizarre behaviour)

Grade 4 ..... ☐ (coma)

B. Baseline Laboratory Tests

If you are unable to locate result write Don't Know.
If you are sure the test was not done write Not Done

What was the first recorded FBC on admission to hospital?

7. Haemoglobin (g/dl) .....
8. Platelets ($x10^9$/ l) .....
9. White cell count ($x10^9$/ l) .....

What was the first recorded coagulation screen on admission to hospital?

10. Prothrombin time (PT) (secs) .....
11. International normalised ratio (INR) .....
12. Activated partial thromboplastin time (APTT) (secs) .....

    12a. Activated partial thromboplastin time ratio .....

13. Fibrinogen (g / l) .....

What was the first recorded LFT an admission to hospital?

14. Albumin ((g / l) .....
15. Alanine transaminase (ALT) (iu / l) .....
16. Bilirubin (µmol / l) .....
17. Alkaline Phosphatase (iu / l) .....

What was the first recorded biochemistry on admission to hospital?

18. Sodium (mmol / l) .....
19. Creatinine (µmol / l) .....
20. Urea (mmol / l) .....

Transfusion requirements and reasons for transfusion.

We are interested in the total transfusion requirements for 24 hours after the first transfusion of any blood component. The 24 hour period therefore represents the transfusion episode.

6. Has the patient been transfused with any blood products?

   Yes ☐ if yes, proceed to question 22 No ☐ if no, proceed to question 34

7. Did the patient receive any of the following blood component(s) in the 24 hours?

   Please tick all that apply

   Cryoprecipitate Yes ☐ No ☐

   Fresh frozen plasma Yes ☐ No ☐

   Platelets Yes ☐ No ☐

   Prothrombin complex concentrates (e.g. octaplex/beriplex) Yes ☐ No ☐

   Red Blood Cells Yes ☐ No ☐

8. What was the MAIN indication for THIS transfusion?

Treatment of bleeding ☐

Prophylaxis of Bleeding ☐ (please go to question 27)

Unclear ..... ☐

9. If the patient received a blood component for the treatment of bleeding what was the site of bleeding?

Varcieal haemorrhage ..... ☐

- Oesophageal ..... ☐
- Gastric ..... ☐
- Both ..... ☐
- Other (e.g. rectal varices) ☐
- Non-variceal haemorrhage ..... ☐

Lower gastrointestinal haemorrhage ☐

Epistaxis ..... ☐ Intracranial haemorrhage ..... ☐

Subdural haemorrhage ..... ☐ Retroperitoneal haemorrhage ☐

Other : .....

Other : (non variceal) .....

25) Did the patient have a procedure?

Yes ☐ No ☐

25a) If Yes, please indicate which procedure(s) resulted in the patient bleeding

Central line ☐ Chest drain ☐ Colonoscopy ☐

Endoscopic retrograde cholangiopancreatography (ERCP) ☐

Gastroscopy ☐ Liver biopsy ☐ Paracentesis ☐

Surgery ..... ☐ Other .....

25c) Did the patient have evidence of haemodynamic compromise due to bleeding in the 4 hours prior to admission?
(defined as Systolic BP <100mm Hg and/or heart rate > 100bpm)

Yes ☐ No ☐

26) If the patient received a blood component for the prophylaxis of bleeding what was the indication for the transfusion?

Pre- or peri-procedural

Central/femoral line ☐ Chest drain ☐ Colonoscopy ☐

Endoscopic retrograde pancreatography ☐ Gastroscopy ☐

Liver biopsy ... ☐ Percutaneous ☐ Transjugular ☐

Paracentesis ☐ Surgery ..... ☐ N/A ..... ☐

Other : .....

What were the total amounts of blood components transfused in the 24hr episode (write Don't know if unable to locate or tell if the investigations other than baseline, have been carried out. If you are sure investigations were not done, write "Not done".

Red blood cells (RBC)

27) Total number of RBC units transfused : .....

27a) What was the haemoglobin level closest to and up to 24 hours prior to Transfusion : .....

Fresh frozen plasma (FFP)

28) Total number of units transfused : .....

28a) What was the PT closest to and up to 24 hours prior to transfusion? .....

28b) What was the INR closest to and up to 24 hours prior to the transfusion? .....

28c) What was the APTT closest to and up to 24 hours prior to transfusion? .....

28d) What was the APTT Ratio closest to and up to 24 hours prior to transfusion? .....

Platelets

28) Total number of adult doses transfused .....

29a) What was the platelet count closest to and up to 24 hours prior to transfusion .....

Cryoprecipitate or Cryosupernatant

30) Total no of units of cryoprecipitate transfused (5 units = 1 pool) .....

30a) Was a fibrinogen level checked prior to replacement .....

30b) If checked what was the fibrinogen level closest to and up to 24 hours prior to transfusion .....

31) Were the following agents administered in the 24 hour period?

Please tick ✓ all that apply

Antifibrinolytic ..... Yes ☐ No ☐ Aprotinin ..... Yes ☐ No ☐

Factor VIIa ..... Yes ☐ No ☐ Tranexamic Acid Yes ☐ No ☐

None on these given Yes ☐ No ☐

32) Please complete the following table for results after the 24 hour period. This 24 hour period commences after transfusion of the first component – use worst results if more than one test undertaken. If you are unable to tell or cannot locate, write Don't know. If you are sure the investigation has not been carried out write "Not done".

	24 hour period
Haemoglobin (g/dl)	
Platelets ($x10^9$/l)	
PT (secs)	
INR (ratio)	
APTT (secs)	
APTTR (ratio)	
Fibrinogen (g/l)	

D. Renal Impairment and Infection

34) What was the maximum value of creatinine (µmol/l) during the study period? .....

34a) What was the lowest recorded creatinine (µmol/l) in the patient's medical records in the 28 days before admission? .....

Markers/Surrogate markers of infection

35) Was the patient prescribed antibiotics at any point during the study period?

Yes ☐ No ☐

36) Was the patient prescribed antifungals for a suspected fungal infection at any point during the study period?

Yes ☐ No ☐

37) What was the maximum WCC ($x10^9$/l) recorded in the study period? .....

37a) What was the maximum C reactive protein (CRP) (mg/l) recorded in the study period? .....

38) Did the patient have any of the following during the study period?

Blood culture Yes ☐ No ☐

38a) If yes was it positive? Yes ☐ No ☐

39) Urine culture Yes ☐ No ☐

39a) If yes was it positive? Yes ☐ No ☐

40) Stool culture Yes ☐ No ☐

40a) If yes was it positive? Yes ☐ No ☐

41) Ascitic culture Yes ☐ No ☐

41a) If yes was it positive? Yes ☐ No ☐

42) Ascitic fluid cell count Yes ☐ No ☐

42a) If yes what was the polymorph count (cells/µl)? .....

E. Outcomes

43) How many transfusion episodes did the patient have during the study period?

None ☐ One ☐ Two or more ☐

44) Did the patient have any transfusion reactions during the study period?

Yes ☐ (proceed to question 44a) No ☐ (proceed to question 44c)

44a) What was the nature of the transfusion reaction?

Please tick ✓ all that apply

Suspected transfusion-related acute lung injury (TRALI) ..... ☐

Suspected transfusion-associated circulatory overload (TACO) ☐

Allergic reaction reported to SHOT ..... ☐

44b) Any other transfusion reaction? (please state which)

.....

44c) Has the patient had a confirmed thrombosis during the study period?

Yes ☐ (proceed to question 46d) No ☐ (proceed to question 47)

44d) What type of thrombosis did the patient have?

Please tick ✓ all that apply

Pulmonary embolism ☐ Deep vein thrombosis ☐

Budd-Chiari syndrome ☐ Portal vein thrombosis ☐

Other .....

45) What was the outcome for this patient?

Discharged from hospital ..... ☐ (audit is now complete)

Still in hospital 28 days after admission ..... ☐ (audit is now complete)

Transferred to another unit ..... ☐ (audit is now complete)

Death in hospital within 28 days of admission ☐ (please go to question 47a)

45a) If the patient died what was the perceived/likely main cause of death?

Decompensated liver cirrhosis ☐

Haemorrhage ..... ☐

Sepsis ..... ☐

Other (please state) .....

(the audit is now complete)

Please transfer these data to the online system and keep this paper record locally in a safe place. Make sure the audited patient number written on this form corresponds to the audited patient number used for the online submission if you enter this data online.

If you are unable to submit data online, please send this form to:

Brian Hockley
Data Analyst and Audit Manager
Sheffield Blood Centre
Longley Lane
Sheffield, S5 7JN

Brian.Hockley@nhsbt.nhs.uk
Tel : 01143584836
Mob : 07764280404

or Log on using by selecting your trust and entering your password at:

https://nhsbtaudits.co.uk/

Appendix 3 – Organisational Audit Tool

BRITISH SOCIETY OF GASTROENTEROLOGY

South Central Regional Transfusion Committee

Multi Regional Audit of the use of Blood Components in Patients with Liver Cirrhosis – Organisational Audit Tool

Organisational questions

1. Does your hospital have transfusion guidelines specifically for patients with liver disease or cirrhosis?

   Yes ☐ No ☐

   2a) Does your hospital use global tools of haemostasis to guide transfusion of blood components?

   Yes ☐ No ☐ Don't know ☐

   If yes, answer questions 2b and 2c

   2b) If yes which? Rotational thromboelastometry (ROTEM) ☐

   Thromboelastography (TEG) ..... ☐

   Multiplate ..... ☐

   Other .....

   2c) Does your hospital use global tools of haemostasis used to guide transfusion of blood components in patients with liver disease or cirrhosis?

   Yes ☐ No ☐

3) What is your laboratory's normal range for prothrombin time?

.....

4) What is your laboratory's normal range for activated partial thromboplastin time?

.....

5) What is your laboratory's current mean normal prothrombin time (MNPT) and international sensitivity index (ISI)?

.....

6a) Which thromboplastin do you use for PT? .....

6b) Which thromboplastin do you use for APTT? .....

7) How many beds are there in your hospital?

200 or less ☐ 201-400 ☐ 401-600 ☐ 601 or more ☐

Please return this completed form to:

Brian Hockley
Data Analyst and Audit Manager
Sheffield Blood Centre
Longley Lane
Sheffield, S5 7JN

Brian.Hockley@nhsbt.nhs.uk
Tel : 01143584836
Mob : 07764280404

Appendix 4 – Frequently Asked Questions

Q. What do I do about patients already on the wards?

A. Only include new admissions during your selected 4 week period

Q. What happens if a patient is admitted twice in this 4 week period

A. Only count the first admission

Q. When can I recruit patients?

A. You can recruit new admissions right up to the 4th of April if you wish, but bear in mind this will mean you may be collecting data until early May.

Q. When do I collect data?

A. You need to collect data on each patient over 4 consecutive weeks or until discharge, move to another hospital or death.

Q. What if they have not had any transfusions?

A. You should include all cirrhotics regardless of whether they have been transfused or not. We are interested in all patients with cirrhosis, as denominator data and to tell us about those patients for comparison who don't receive transfusions.

Q. What about day cases?

A. Cirrhotic patients attending for routine outpatient endoscopy or outpatient appointments do not need to be included. We would however, like to include patients attending for ascitic drainage when possible.

Who to include:

“Cirrhosis can be confirmed by liver biopsy or suspected on the basis of clinical symptoms, laboratory tests and ultrasound findings. For example, a patient with alcohol withdrawal alone would not be included. A patient with deranged LFTs and suggestion of cirrhosis on an abdominal ultrasound could be included (even if they hadn't had a biopsy). It's a clinical judgement. We are interested in all patients with cirrhosis, as denominator data and to tell us about those patients for comparison who don't receive transfusions".

If you require further information on documentation relating to this audit, please contact: brian.hockley@nhsbt.nhs.uk