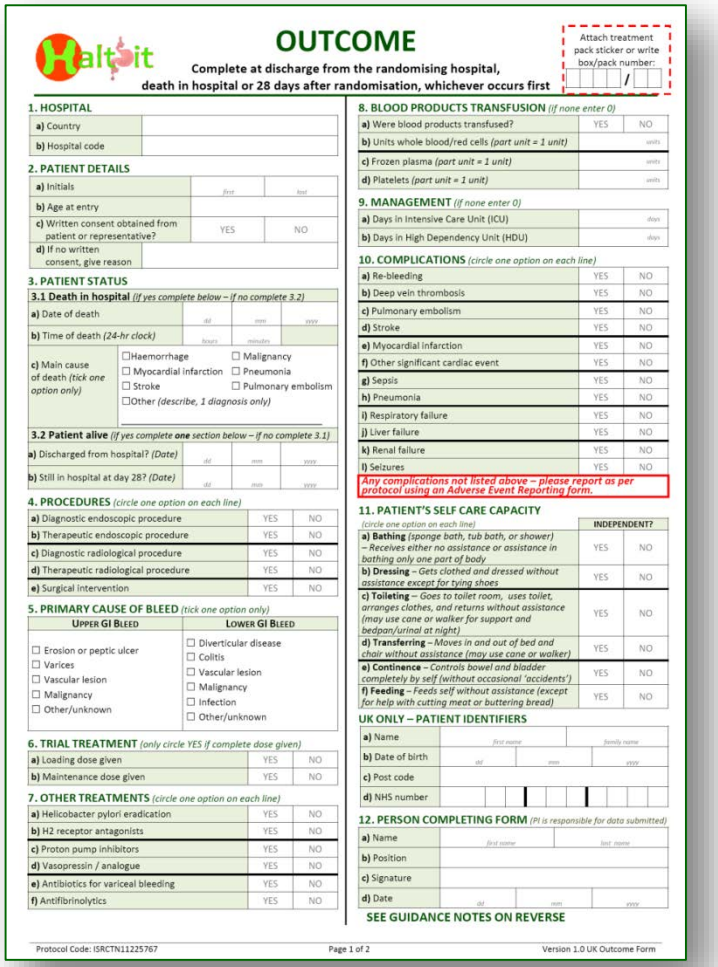
Haemorrhage alleviation with tranexamic acid - Intestinal system

HOW TO COMPLETE THE OUTCOME FORM

Completing the outcome form

- The Outcome Form should be completed at:
  - 28 days from randomisation OR
  - at prior death or discharge
- Days are counted from the date of randomisation (28 days = exactly 4 weeks) e.g. a patient randomised on 1 May: outcome due 29 May
- Use a paper form to collect outcome data directly from the patient's medical records
- Use permanent ink when completing form



OUTCOME

Complete at discharge from the randomising hospital, death in hospital or 28 days after randomisation, whichever occurs first

Attach treatment pack sticker or write box/pack number:

1. HOSPITAL

a) Country	
b) Hospital code	

2. PATIENT DETAILS

a) Initials	first	last
b) Age at entry		
c) Written consent obtained from patient or representative?	YES	NO
d) If no written consent, give reason		

3. PATIENT STATUS

3.1 Death in hospital *(if yes complete below – if no complete 3.2)*

a) Date of death	dd	mm	yyyy
b) Time of death *(24-hr clock)*	hours	minutes	

c) Main cause of death *(tick one option only)*

☐ Haemorrhage ☐ Malignancy
☐ Myocardial infarction ☐ Pneumonia
☐ Stroke ☐ Pulmonary embolism
☐ Other *(describe, 1 diagnosis only)*

3.2 Patient alive *(if yes complete **one** section below – if no complete 3.1)*

a) Discharged from hospital? *(Date)*	dd	mm	yyyy
b) Still in hospital at day 28? *(Date)*	dd	mm	yyyy

4. PROCEDURES *(circle one option on each line)*

a) Diagnostic endoscopic procedure	YES	NO
b) Therapeutic endoscopic procedure	YES	NO
c) Diagnostic radiological procedure	YES	NO
d) Therapeutic radiological procedure	YES	NO
e) Surgical intervention	YES	NO

5. PRIMARY CAUSE OF BLEED *(tick one option only)*

Upper GI Bleed	Lower GI Bleed
☐ Erosion or peptic ulcer	☐ Diverticular disease
☐ Varices	☐ Colitis
☐ Vascular lesion	☐ Vascular lesion
☐ Malignancy	☐ Malignancy
☐ Other/unknown	☐ Infection
	☐ Other/unknown

6. TRIAL TREATMENT *(only circle YES if complete dose given)*

a) Loading dose given	YES	NO
b) Maintenance dose given	YES	NO

7. OTHER TREATMENTS *(circle one option on each line)*

a) Helicobacter pylori eradication	YES	NO
b) H2 receptor antagonists	YES	NO
c) Proton pump inhibitors	YES	NO
d) Vasopressin / analogue	YES	NO
e) Antibiotics for variceal bleeding	YES	NO
f) Antifibrinolytics	YES	NO

8. BLOOD PRODUCTS TRANSFUSION *(if none enter 0)*

a) Were blood products transfused?	YES	NO
b) Units whole blood/red cells *(part unit = 1 unit)*	units	
c) Frozen plasma *(part unit = 1 unit)*	units	
d) Platelets *(part unit = 1 unit)*	units	

9. MANAGEMENT *(if none enter 0)*

a) Days in Intensive Care Unit (ICU)	days
b) Days in High Dependency Unit (HDU)	days

10. COMPLICATIONS *(circle one option on each line)*

a) Re-bleeding	YES	NO
b) Deep vein thrombosis	YES	NO
c) Pulmonary embolism	YES	NO
d) Stroke	YES	NO
e) Myocardial infarction	YES	NO
f) Other significant cardiac event	YES	NO
g) Sepsis	YES	NO
h) Pneumonia	YES	NO
i) Respiratory failure	YES	NO
j) Liver failure	YES	NO
k) Renal failure	YES	NO
l) Seizures	YES	NO

Any complications not listed above – please report as per protocol using an Adverse Event Reporting form.

11. PATIENT'S SELF CARE CAPACITY

(circle one option on each line)

	Independent?	
a) **Bathing** *(sponge bath, tub bath, or shower) – Receives either no assistance or assistance in bathing only one part of body*	YES	NO
b) **Dressing** *– Gets clothed and dressed without assistance except for tying shoes*	YES	NO
c) **Toileting** *– Goes to toilet room, uses toilet, arranges clothes, and returns without assistance (may use cane or walker for support and bedpan/urinal at night)*	YES	NO
d) **Transferring** *– Moves in and out of bed and chair without assistance (may use cane or walker)*	YES	NO
e) **Continence** *– Controls bowel and bladder completely by self (without occasional 'accidents')*	YES	NO
f) **Feeding** *– Feeds self without assistance (except for help with cutting meat or buttering bread)*	YES	NO

UK ONLY – PATIENT IDENTIFIERS

a) Name	first name		family name
b) Date of birth	dd	mm	yyyy
c) Post code			
d) NHS number			

12. PERSON COMPLETING FORM *(PI is responsible for data submitted)*

a) Name	first name	last name
b) Position		
c) Signature		
d) Date	dd	mm yyyy

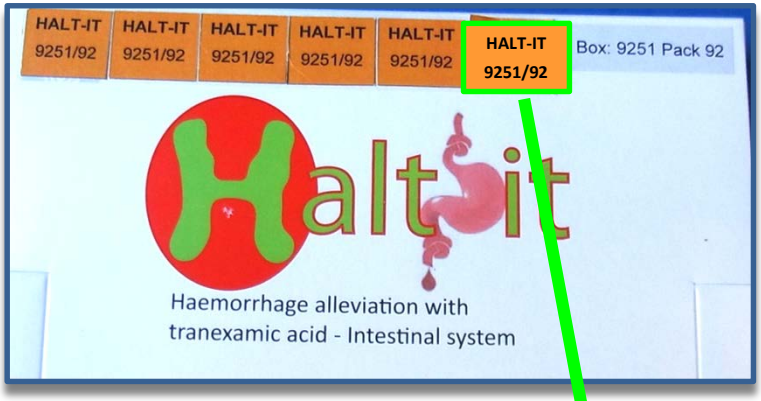
SEE GUIDANCE NOTES ON REVERSE

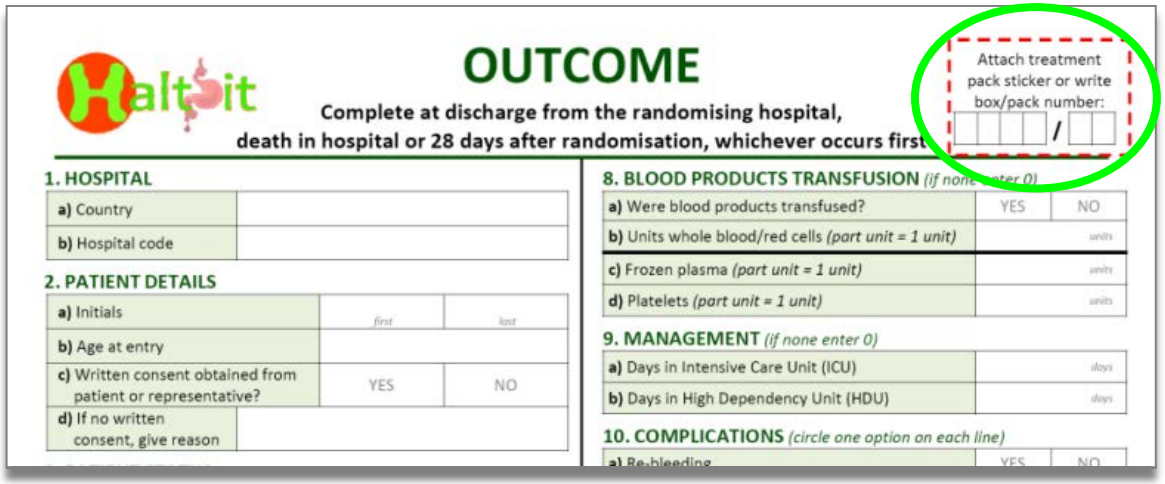
Protocol Code: ISRCTN11225767 Page 1 of 2 Version 1.0 UK Outcome Form

Completing the outcome form

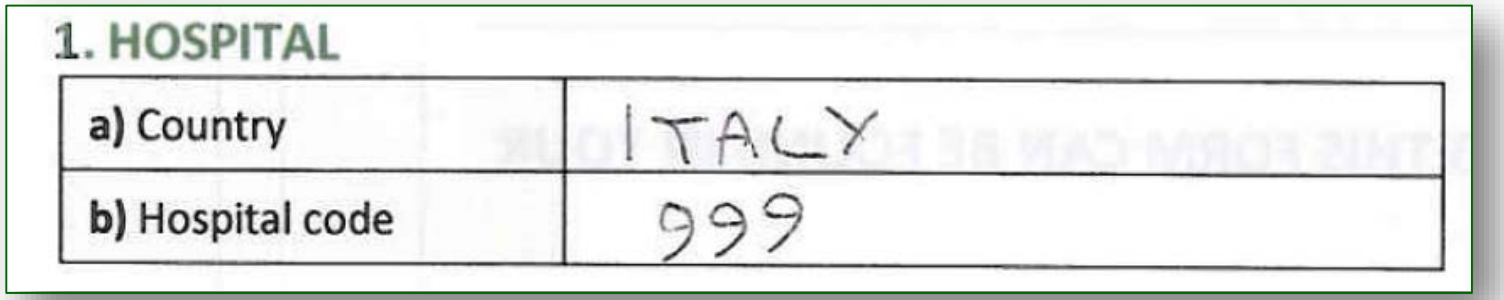
IMPORTANT

There is space at the top of the form for the orange sticker from the drug pack. If you no longer have the sticker, please write the **box/pack number** clearly in the space provided.





Section 1 – About your hospital



1. HOSPITAL

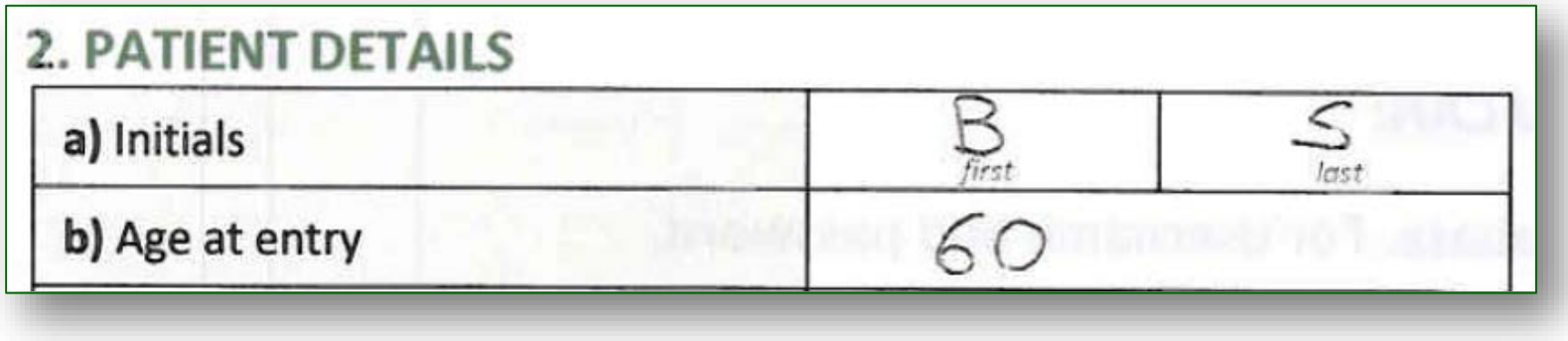
a) Country	ITALY
b) Hospital code	999

1. HOSPITAL

(a) Country: Write the name of your country in full

(b) Hospital code: Enter the ID code for your site – the 3-digit number on the contact page of your Study File

Section 2 – About the patient



2. PATIENT DETAILS

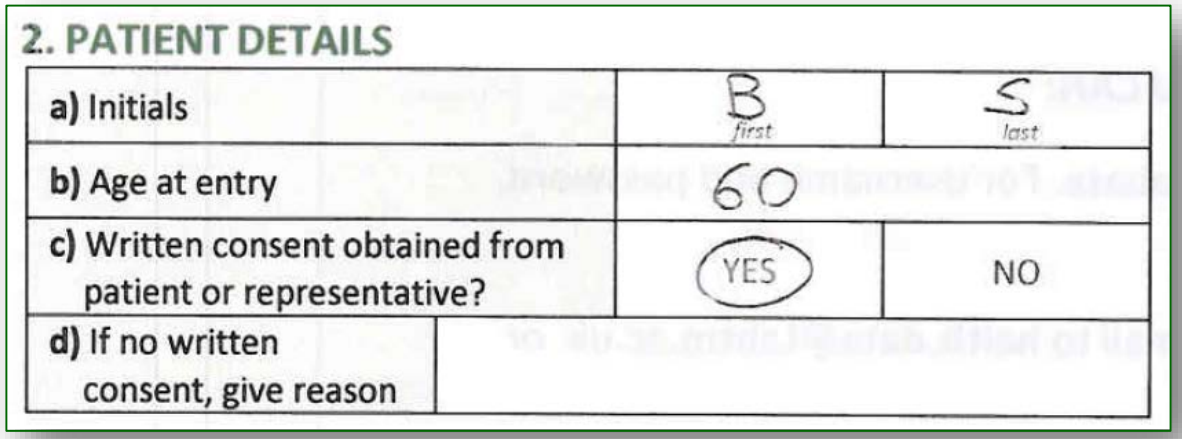
a) Initials	B (first)	S (last)
b) Age at entry	60	

2. PATIENT DETAILS

a) Initials: from the FIRST name and LAST name, e.g. Bilbo Frodo Samwell = BS. If only one name is known enter that single initial.

b) Age at entry: Enter age in years at the time of randomisation.
If unknown, please enter *approximate* age in years

Section 2c and 2d – Written consent



2. PATIENT DETAILS

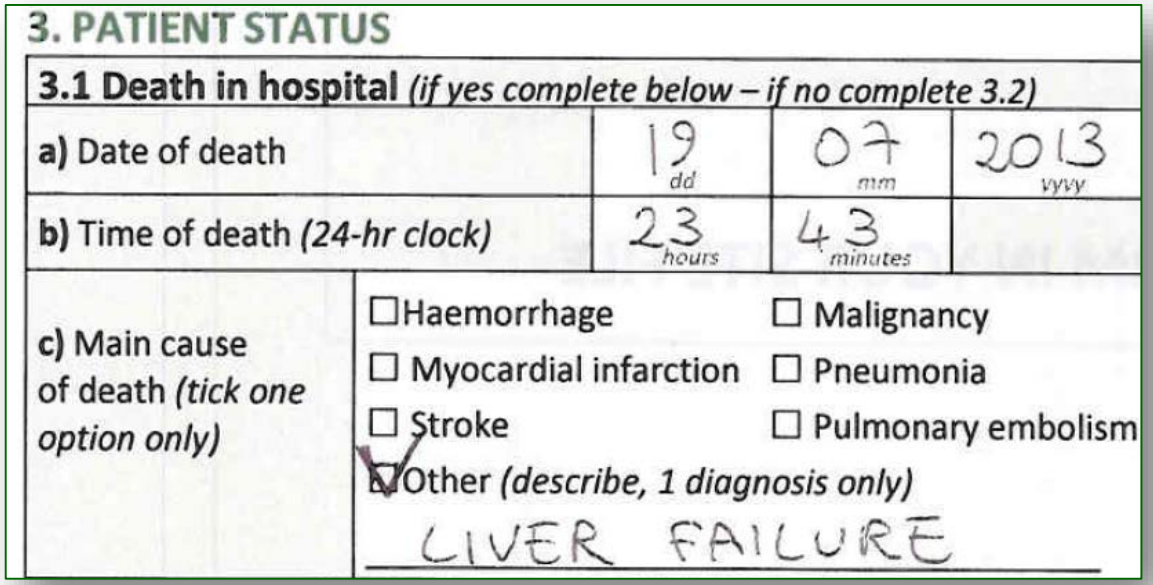
a) Initials	B (first)	S (last)
b) Age at entry	60	
c) Written consent obtained from patient or representative?	(YES)	NO
d) If no written consent, give reason		

2. PATIENT DETAILS

c) Written consent obtained from Patient or Representative? Answer YES if written consent has been obtained before or after randomisation from either patient or personal/professional representative.

d) If no written consent, give reason. If you answer NO to the above question, provide reason why written consent has not been obtained.

Section 3.1 – Death in hospital



3. PATIENT STATUS

3.1 Death in hospital *(if yes complete below – if no complete 3.2)*

a) Date of death	19 *dd*	07 *mm*	2013 *yyyy*
b) Time of death *(24-hr clock)*	23 *hours*	43 *minutes*	

c) Main cause of death *(tick one option only)*

- ☐ Haemorrhage
- ☐ Malignancy
- ☐ Myocardial infarction
- ☐ Pneumonia
- ☐ Stroke
- ☐ Pulmonary embolism
- ☑ Other *(describe, 1 diagnosis only)*: LIVER FAILURE

Only complete if the patient dies

a) Enter date of death in the format DD/MM/YYYY e.g. 19/07/2013

b) Enter the time of death in the format hh/mm e.g. 23/43

c) Indicate (with a tick ✓) the primary cause of death – if more than one cause, please enter **ONLY the main cause**

Section 3.2 – Patient alive

Only complete if the patient is alive

3.2 Patient alive *(if yes complete **one** section below – if no complete 3.1)*			
a) Discharged from hospital? *(Date)*	28 *dd*	11 *mm*	2013 *yyyy*
b) Still in hospital at day 28? *(Date)*	*dd*	*mm*	*yyyy*

- Enter the date of discharge or 'still in hospital at 28 days' in the format DD/MM/YYYY e.g. 28/11/2013

- **Only one line to be completed**

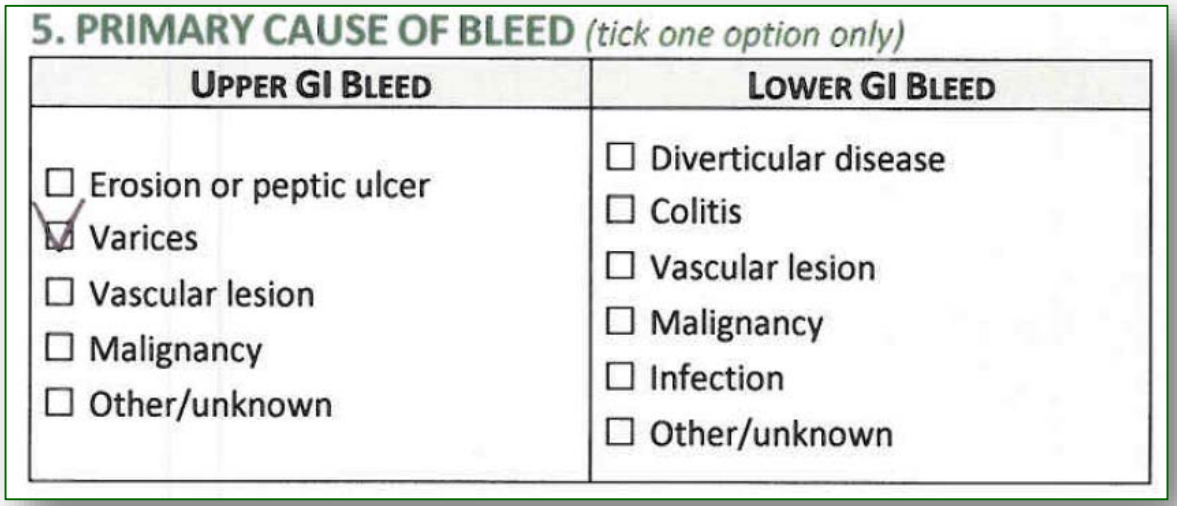
Section 4 – Procedures

4. PROCEDURES *(circle one option on each line)*

a) Diagnostic endoscopic procedure	YES	NO
b) Therapeutic endoscopic procedure	YES	NO
c) Diagnostic radiological procedure	YES	NO
d) Therapeutic radiological procedure	YES	NO
e) Surgical intervention	YES	NO

- Complete questions **a–e** according to the procedures the patient received AFTER RANDOMISATION
- Circle one option on each line – do not leave blank

Section 5 – Primary cause of bleed



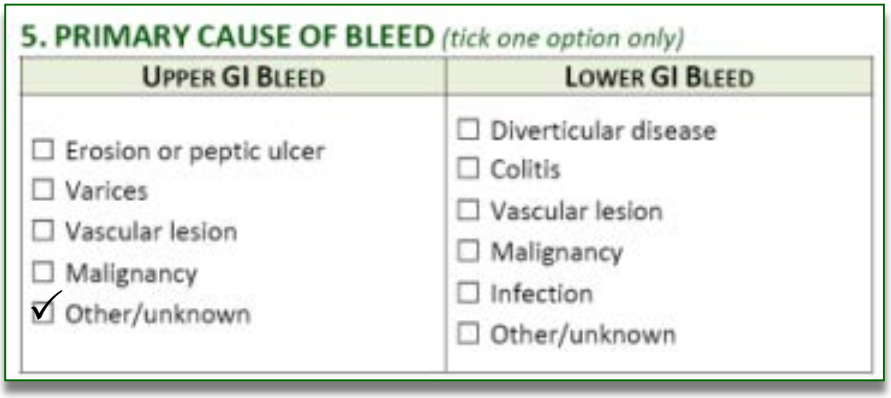
5. PRIMARY CAUSE OF BLEED *(tick one option only)*

UPPER GI BLEED	LOWER GI BLEED
☐ Erosion or peptic ulcer ☑ Varices ☐ Vascular lesion ☐ Malignancy ☐ Other/unknown	☐ Diverticular disease ☐ Colitis ☐ Vascular lesion ☐ Malignancy ☐ Infection ☐ Other/unknown

- Indicate (with a tick ✓) the primary cause of GI bleeding – if more than one cause, please enter **ONLY the main cause**
- If the main cause is unknown but Upper GI bleeding is suspected tick "other/unknown" under Upper GI Bleed.
- Alternatively, if Lower GI bleeding is suspected tick "other/unknown" under Lower GI Bleed

Section 5 – Primary cause of bleed

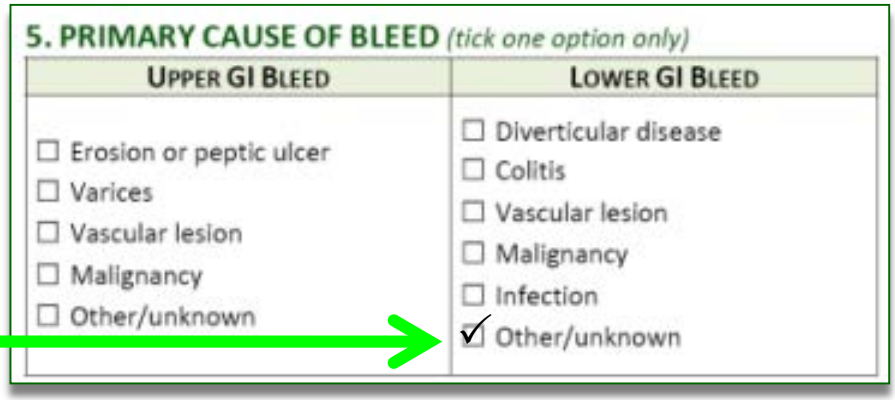
If the main cause is unknown but Upper GI bleeding is suspected tick "other/unknown" under Upper GI Bleed.



5. PRIMARY CAUSE OF BLEED *(tick one option only)*

UPPER GI BLEED	LOWER GI BLEED
☐ Erosion or peptic ulcer	☐ Diverticular disease
☐ Varices	☐ Colitis
☐ Vascular lesion	☐ Vascular lesion
☐ Malignancy	☐ Malignancy
☑ Other/unknown	☐ Infection
	☐ Other/unknown

Alternatively, if Lower GI bleeding is suspected tick "other/unknown" under Lower GI Bleed



5. PRIMARY CAUSE OF BLEED *(tick one option only)*

UPPER GI BLEED	LOWER GI BLEED
☐ Erosion or peptic ulcer	☐ Diverticular disease
☐ Varices	☐ Colitis
☐ Vascular lesion	☐ Vascular lesion
☐ Malignancy	☐ Malignancy
☐ Other/unknown	☐ Infection
	☑ Other/unknown

Section 6 – Trial treatment

Please ensure you circle one choice on EACH LINE

6. TRIAL TREATMENT *(only circle YES if complete dose given)*

a) Loading dose given	(YES)	NO
b) Maintenance dose given	(YES)	NO

- You must circle one choice for EACH dose – do not leave blank
- If either dose is **only partially given** it must be entered here as **NO**
- Only a fully administered dose will be **YES**

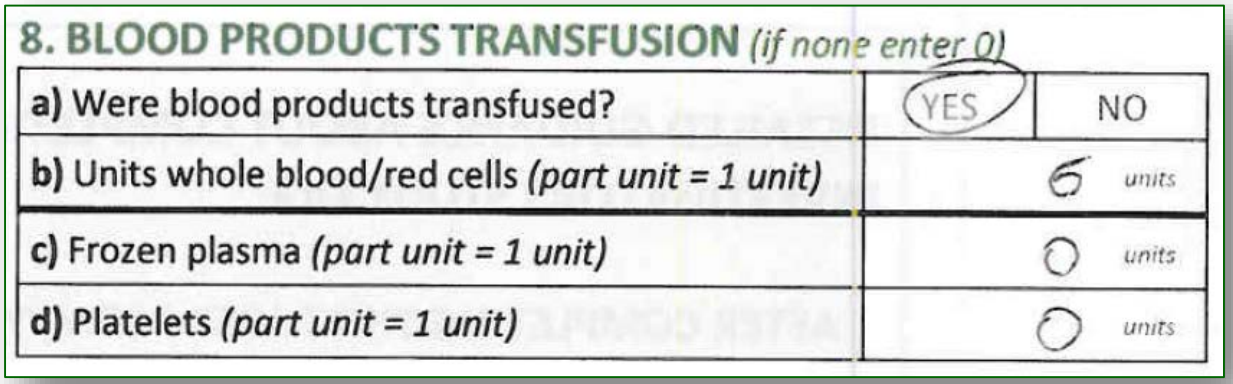
Section 7 – Other treatments

7. OTHER TREATMENTS *(circle one option on each line)*

a) Helicobacter pylori eradication	YES	NO
b) H2 receptor antagonists	YES	NO
c) Proton pump inhibitors	YES	NO
d) Vasopressin / analogue	YES	NO
e) Antibiotics for variceal bleeding	YES	NO
f) Antifibrinolytics	YES	NO

- Complete questions **a–f** according to the procedures the patient received AFTER RANDOMISATION
- Circle one option on each line – do not leave blank

Section 8 – Blood product transfusion



8. BLOOD PRODUCTS TRANSFUSION *(if none enter 0)*		
a) Were blood products transfused?	YES	NO
b) Units whole blood/red cells *(part unit = 1 unit)*	6 units	
c) Frozen plasma *(part unit = 1 unit)*	0 units	
d) Platelets *(part unit = 1 unit)*	0 units	

- Complete questions **a–d** according to transfusion received AFTER RANDOMISATION
- If none please enter 0
- Circle one option on each line – do not leave blank

Section 9 – Management

9. MANAGEMENT *(if none enter 0)*	
a) Days in Intensive Care Unit (ICU)	2 days
b) Days in High Dependency Unit (HDU)	0 days

- If there is no ICU or HDU department or if the patient was not admitted to ICU or HDU, please write 0
- Part day counts as 1
- Please ensure you answer each line – do not leave blank

Section 10 – Complications

- All complications listed must be a confirmed diagnosis
- You must circle either YES or NO for ALL complications
- Any complication not listed here but fulfils the Adverse Event criteria (see Protocol page 11) should be reported using the **'Adverse Event Reporting Form'**

10. COMPLICATIONS *(circle one option on each line)*

a) Re-bleeding	YES	(NO)
b) Deep vein thrombosis	YES	(NO)
c) Pulmonary embolism	YES	(NO)
d) Stroke	YES	(NO)
e) Myocardial infarction	YES	(NO)
f) Other significant cardiac event	YES	(NO)
g) Sepsis	YES	(NO)
h) Pneumonia	YES	(NO)
i) Respiratory failure	YES	(NO)
j) Liver failure	(YES)	NO
k) Renal failure	YES	(NO)
l) Seizures	YES	(NO)

Any complications not listed above – please report as per protocol using an Adverse Event Reporting form.

IT IS ESSENTIAL THAT ALL QUESTIONS ARE ANSWERED

Section 11 – Self care capacity

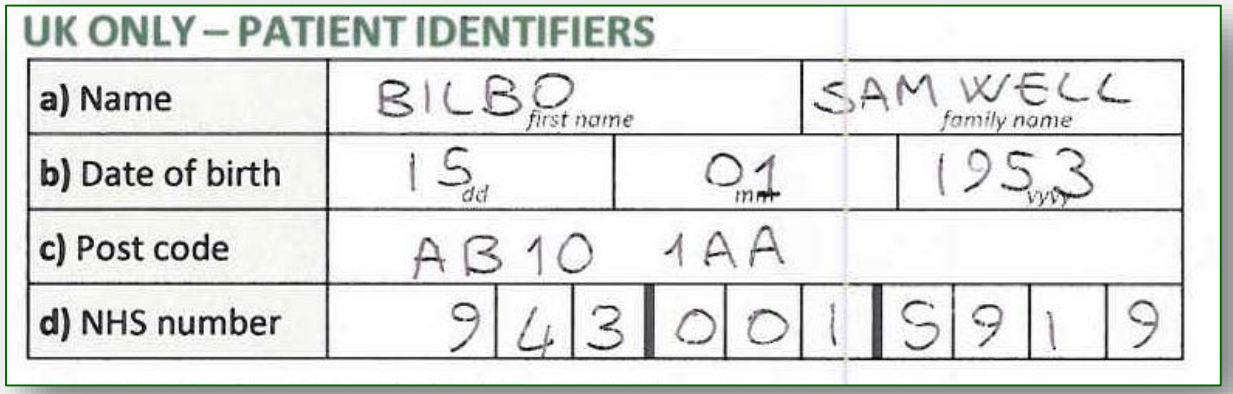
11. PATIENT'S SELF CARE CAPACITY *(circle one option on each line)*	INDEPENDENT?	
a) Bathing *(sponge bath, tub bath, or shower) – Receives either no assistance or assistance in bathing only one part of body*	YES	NO
b) Dressing – *Gets clothed and dressed without assistance except for tying shoes*	YES	NO
c) Toileting – *Goes to toilet room, uses toilet, arranges clothes, and returns without assistance (may use cane or walker for support and bedpan/urinal at night)*	YES	NO
d) Transferring – *Moves in and out of bed and chair without assistance (may use cane or walker)*	YES	NO
e) Continence – *Controls bowel and bladder completely by self (without occasional 'accidents')*	YES	NO
f) Feeding – *Feeds self without assistance (except for help with cutting meat or buttering bread)*	YES	NO

Read the description of each question **a–f**

For guidance on this section, see the presentation **"Guidance to complete the Katz Index of Independence in Activities of Daily Living"** or Section 17.1 of the MOP.

Patient identifiers

This section is only for Sites in ENGLAND and WALES



UK ONLY – PATIENT IDENTIFIERS		
a) Name	BILBO (first name)	SAM WELL (family name)
b) Date of birth	15 (dd) / 01 (mm) / 1953 (yyyy)	
c) Post code	AB10 1AA	
d) NHS number	943 001 5919	

PATIENT IDENTIFIERS

a) **Name:** provide FIRST name and LAST name, e.g. Bilbo Frodo Samwell = Bilbo Samwell. If only one name is known enter that single name.

b) **Date of birth:** Enter date of birth in the format DD/MM/YYYY e.g. 15/01/1953

c) **Post code:** Enter UK post code e.g. AB10 1AA

d) **NHS number:** Enter NHS number from clinical records

Section 12 – Person completing the form

This section must be completed in full – it is a declaration that the data is valid

12. PERSON COMPLETING FORM *(PI is responsible for data submitted)*

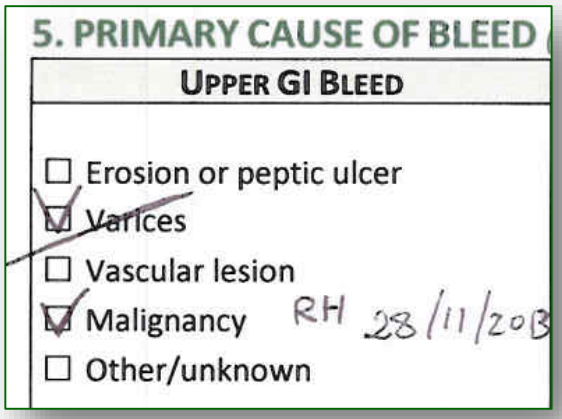
a) Name	ROBIN *first name*	HOOD *last name*	
b) Position	RESEARCH NURSE		
c) Signature	Robin Hood		
d) Date	28 *dd*	11 *mm*	2013 *yyyy*

Corrections

If you enter an incorrect value on the form:

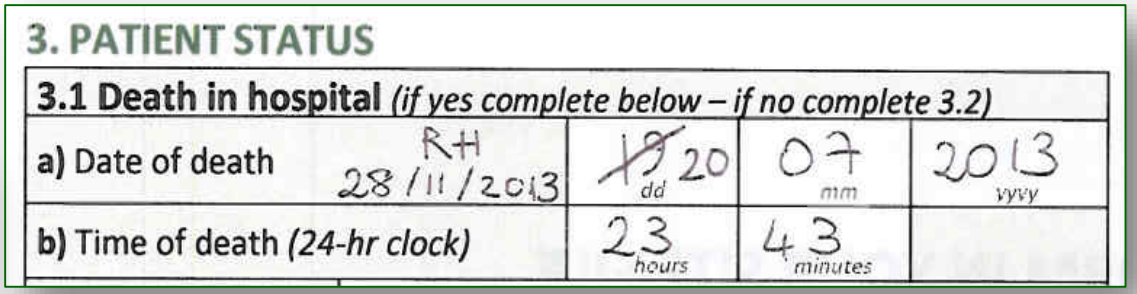
- cross out the incorrect value so it is still visible
- enter the correct value alongside
- enter the date and your initials next to each change

EXAMPLES


5. PRIMARY CAUSE OF BLEED

UPPER GI BLEED

- ☐ Erosion or peptic ulcer
- ☑ Varices
- ☐ Vascular lesion
- ☑ Malignancy RH 28/11/2013
- ☐ Other/unknown


3. PATIENT STATUS

3.1 Death in hospital *(if yes complete below – if no complete 3.2)*			
a) Date of death RH 28/11/2013	~~19~~ 20 dd	07 mm	2013 yyyy
b) Time of death *(24-hr clock)*	23 hours	43 minutes	

Please store original forms in
Section 16 of your Study File

SEE SEPARATE GUIDANCE ABOUT HOW TO SEND THE DATA FORMS TO THE TCC

JOIN THE GLOBAL COLLABORATION

haltit.Lshtm.ac.uk

Trial Coordinating Centre
London School of Hygiene & Tropical Medicine
Room 180, Keppel Street, London WC1E 7HT

Tel +44(0)20 7299 4684
Fax +44(0)20 7299 4663
Email: haltit@Lshtm.ac.uk

UKCRC Registered Clinical Trials Units

Haltit
Haemorrhage alleviation with tranexamic acid - Intestinal system