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

1. HOSPITAL
   a) Country
   b) Hospital code

2. PATIENT DETAILS
   a) Initials
   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
   - Erosion or peptic ulcer
   - Varices
   - Vascular lesion
   - Malignancy
   - Other/unknown
   Lower GI Bleed
   - Diverticular disease
   - Colitis
   - Vascular lesion
   - Malignancy
   - 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)
   c) Frozen plasma (part unit = 1 unit)
   d) Platelets (part unit = 1 unit)

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)
    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 (P1 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
DETAILED GUIDANCE ABOUT COMPLETING THIS FORM CAN BE FOUND IN YOUR INVESTIGATORS STUDY FILE

AFTER COMPLETING THIS PAPER FORM, YOU CAN:

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