FAQs

GENERAL	
When is the **baseline** day?	Calendar day on which randomisation occurs.
What is **day 1**?	The first calendar day after the randomisation (baseline) day. 00:00 – 23:59
What is the **study day** timeframe?	00:00 – 23:59
REDCap **screening number**	Site to generate their own screening numbers. Suggest using site initial and number e.g. E001, E002, E003...
Is ABC registered on the **NIHR Associate PI** scheme?	Yes. Can have multiple APIs at site as long as PI happy to support. ABC Post ICU is registered for the scheme under CPMS ID 46218
What happens if a pt is **transferred** to an acute, non study hospital?	• Cannot continue the intervention. • Continue daily data as far as possible • Complete f/u • Complete final discharge date (or other outcome) at the date pt discharged from final acute hospital.
Can we enroll pt who has already participated?	No
ELIIBILITY CRITERIA	
Inclusion: [1] Patient who received level 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support and/or **at least two organ**	All vasoactive drugs and inotropes are considered organ support for eligibility. ie the drugs in the SOFA assessment. Examples include: noradrenaline, vasopressin,

support) Which **blood pressure drugs** are considered organ support for inclusion?	iloprost, metraminol So if the pt were on oxygen and one or more vasoactive drug or inotrope then they'd have 2 organ support. **Not**: amiodarone, labetalol, GTN
Inclusion: [1] Patient who received level 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support and/or **at least two organ support**) Which **oxygen delivery** methods are considered organ support for inclusion?	All oxygen delivery methods are considered organ support. From nasal cannula to intubation and ventilation.
Inclusion: [1] Patient who received level 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support and/or at least two organ support) Would **plasma exchange** count as organ support?	No
Inclusion: [1] Patient who received level 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support and/or at least two organ support) What if the two organ support is not simultaneous? E.g. oxygen and vasoactive administered at different times.	Ask the clinician in charge whether they consider the patient has received level 3 care in terms of the clinical definitions used in the UK during their ICU stay.

Inclusion: [1] Patient who received level 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support and/or at least two organ support) For individuals **transferred/repatriated** from other ICUs where they received level 3 care (defined above) but have not received organ support in your ICU. Are they eligible?	Yes. As long as it is part of the current episode of care. E.g. repatriated from abroad or transferred following ECMO.
Inclusion: [3] Hb≤94g/L when ready for ICU discharge or during the first seven days following the decision by the treating clinician that the patient is ready for ICU discharge **Hb change.** The Hb was ≤94g/L during screening period but, before randomising, is reported as >94g/L. Are they still eligible?	No. The most recent Hb is used to confirm eligibility. (NB/ if an Hb result returns >94g/L **after** randomisation, transfuse based on this result as per protocol.)
Inclusion: [5] Patient expected to remain in study hospital until hospital discharge There's a possibility the pt might be transferred to another acute hospital. Should they be recruited?	This is down to your judgement. If you think they will stay in your acute hospital for most of their post ICU care then recruit. If you think transfer is likely to be early, then best not. The logic would be that once they transfer they are less likely to become anaemic again as less sick, so would likely stay on the different anaemia trajectory. We would encourage as much data collection as possible.

Inclusion: [13] Patient recovering from variceal bleeding due to chronic liver disease Would a patient admitted with forms of bleeding other than variceal, due to liver disease be eligible?	Yes
Exclusion: [3] Primary neurological admission Are patients who have been admitted following an **out of hospital cardiac arrests** eligible?	As long as the OOHCA has not caused neuro damage or caused the pt to have had cardiac surgery, they would be eligible.
Exclusion: [3] Primary neurological admission Does a **spinal fusion** count as a neuro admission?	No – that's orthopaedics even if operated on by neurosurgeon
Exclusion: [3] Primary neurological admission **Hepatic encephalopathy** possibly causing seizures. Where does this lie within the neuro admission?	If that caused the admission or contributed to it then it's an exclusion. If the admission was unrelated, then they can be eligible.
Exclusion: [3] Primary neurological admission Would a pt admitted with **meningoencephalitis** be excluded?	Yes
Exclusion: [5] Currently receiving or planned to receive end-of-life care' Patient receiving **palliative chemotherapy**, are they excluded?	Yes

Exclusion: [9] Patient receiving regular erthyropoietin (or any erythropoiesis stimulating agent) treatment for anaemia prior to ICU admission. Patient was taking **ferrous fumarate** prior to ICU admission, are they excluded?	Regular ferrous fumarate prior to ICU admission is not an exclusion if it is a long term therapy.
Exclusion: [11] Readmission to ICU during current hospitalisation episode and not enrolled following previous ICU admissions. Patient was transferred to another ICU for ECMO and transferred back. Are they excluded?	Patients readmitted to unit after tertiary referral such as ECMO are eligible.
If someone has received a **RBC transfusion prior** to screening and recruitment, are they eligible?	Yes
INTERVENTION	
APACHE II score - 1st 24hrs in ICU	The APACHE II score should be derived from the worst results from the **1st 24hrs in ICU**. Collect from: ENGLAND & WALES - CMP system used in most ICU. SCOTLAND - WardWatcher. Click '24 Hour Physiology', then 'Score'. Or calculate using a tool such as: https://www.mdapp.co/apache-ii-score-calculator-158/
Baseline research blood sample A transfusion has been given, do I still take the baseline research blood sample?	Yes, do take a baseline research sample even if a transfusion has been given. Ensure that is noted in the 'comments' section of the sample log

Research blood sample If baseline blood sample not collected (but consented to) should you collect 30D sample?	Yes. Ideally both but if cannot obtain one, still collect the other.
Research blood sample Are **high risk blood** samples accepted?	Yes. Ensure they are labelled appropriately with yellow high risk stickers. And note it on the log.
Questionnaires – baseline How are baseline questionnaires completed if the participant lacks capacity?	Baseline Recalled SF-36 should be deferred until the participant has regained capacity. Baseline Health Service Utilisation Questionnaire should be completed with NOK/proxy.
Transfusion not given within 48hrs	Record as a deviation. This is **not** a violation.
Hb changes before indicated transfusion given... Hb = trigger value ↓ No transfusion is given ↓ Hb retested within 48hrs of that trigger. This result is no longer a triggering value so no transfusion now required as per protocol.	This is not a deviation. Latest Hb determines the protocol. NOT a deviation if a repeat Hb is done clinically within the 48 hours before an indicated transfusion, with a result that changes the intervention as per protocol.
30D / 90D / 180D Health Care Utilisation Questionnaire – what if the participant has remained in hospital?	As per guidance on the questionnaire, then only complete Qu 1 & 2. 'If you have not left hospital since the 1 month follow up answer questions 1 and 2 only.'
A **new infection** is identified but course of abx not presecribed. Should this be recorded?	No. Only record a new infection if it **is being treated with abx**.
The participant has **deteriorated** and been **readmitted to ICU**. How do I manage the intervention?	'Pause' the ABC trial intervention. Follow the local ICU transfusion guidelines. Not necessary to withdraw the participant. Continue all data collection and safety/deviation reporting. When fit for discharge again, restart the trial intervention as per protocol.

	So basically patient is suspended while back in (or not left) ICU.
Alternative and additional RBC Treatments	Medications that **should** be recorded: Folate, ferrous sulphate, ferrous fumerate, forceval (contains B12)