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Human Albumin Solution Guideline for Practice
Version 5

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Central Index Number:	C0659

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Considerations for all documents		**Y/N**	**Action**	
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[1] As defined in section 7.3 of the Trust-wide Document Control Policy

VERSION CONTROL SUMMARY

Version:	Page/Section of Document:	Description of change: (List all amendments made to the document. "Review" or "Update" is not sufficient information.)	Date Exec Director/Chair of DLB approval for RDRO:	Date approved:	Date published:
V1-2010		New document	N/A	Sept 2010	Sept 2010
V2-2014		New format for guidelines applied	N/A	11/12/2013	Jan 2014
V3-2014		Information on recent studies included. Properties of 4.5% and 20% further defined. Indications for use clarified.	N/A	11/12/2013	Jan 2014
V4-2020		Review – no major changes	N/A	11/08/2020	14/08/2020
V4.1-2023		Review – Minor change – 5% concentration no longer manufactured. Reformatted.	28/06/2023	NA	18/07/2023
V5-2026		Review. Added references list. Added information on requesting and collection of HAS.	N/A	10/06/2026	11/06/2026

If a document is being updated in line with actions following a serious incident, patient safety incident or Never Event, please state this in the 'Description of change' column.

DOCUMENT CONTRIBUTORS

Please list the details of all who contributed to the development of this document.

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1. INTRODUCTION

1.1 Human Albumin Solution is widely used in clinical practice; however, there are no formal guidelines governing its use in the United Kingdom. In many clinical settings, the supporting evidence base is limited, and several alternative therapies are available.

1.2 Human albumin accounts quantitatively for more than half of the total protein in the plasma and represents about 10% of the protein synthesis activity of liver.

1.3 The most important physiological function of albumin lies within its contribution to oncotic pressure of blood and transport function (hormones, enzymes, medicinal products and toxins).

1.4 Under normal circumstances, the average half-life of albumin is about 19 days. In critically ill patients, albumin can leak out of the vascular space in substantial amounts at an unpredictable rate.

1.5 The benefits of Human Albumin Solution are controversial; proponents argue that in addition to maintaining plasma oncotic pressure that Human Albumin Solution has a number of secondary functions which might be beneficial. These secondary functions include an antioxidant potential, endothelial stabilisation, an anti-inflammatory effect and the binding and transport of numerous plasma constituents and drugs. However, two Cochrane reviews published in 1998 and updated in 2011 concluded that there was no evidence that Human Albumin Solution reduces mortality when compared to cheaper alternatives such as saline (Roberts *et al.,* 2011).

1.6 The largest study evaluating the clinical use of Human Albumin Solution was the Saline versus Albumin Fluid Evaluation (SAFE) study (2004). The overall conclusion of this study was that in patients in intensive care, use of either 4% albumin solution or normal saline for fluid resuscitation resulted in similar outcomes at 28 days. However various subgroup analysis did reveal interesting results: there was a trend towards decreased mortality in septic shock patients treated with albumin (relative risk of death, 0.87; 95%CI, 0.74-1.02). Increased mortality in trauma patients (relative risk, 1.36; 95% CI, 0.99-1.86), especially those with traumatic injury (relative risk, 1.62; 95% CI, 1.12-2.34). was observed in the albumin treatment group.

1.7 The ALBIOS trial (Caironi *et al*. 2014) specifically examined the use of Human Albumin Solution in patients with severe sepsis. The trial showed that the use of 20% Human Albumin in the first 7 days of an ITU admission was associated with a higher mean arterial pressure (P=0.03) and a lower net fluid balance (P=<0.001) but there was no significant difference in overall survival.

2. PURPOSE

2.1 To provide guidance to clinicians when making the decision to prescribe and administer Human Albumin Solution.

2.2 To ensure that Human Albumin Solution is prescribed only when clinically indicated and alternatives have been explored and rejected as inappropriate or ineffective.

2.3 To provide a benchmark for clinical audit.

3. CONSENT

3.1 Appropriate consent from the patient must be obtained before administration of Human Albumin Solution. As it is a blood product prepared from human plasma, it is important to remember that patients who refuse blood products (for example Jehovah's Witnesses) may have objections to its use.

4. RISKS

4.1 Blood products are inherently very safe in the UK, however, specific risks associated with the use of Human Albumin Solution include circulatory overload, infusion/allergic reactions and a theoretical risk of transmission of vCJD.

5. REQUESTING HUMAN ALBUMIN SOLUTION

5.1 Human Albumin Solution is supplied by the transfusion laboratory and is requested via ICE. It will be issued into a blood fridge and must be collected by a staff member with BloodTrack access (see Blood Transfusion Policy C0160).

It contains no clotting factors or blood group antibodies and crossmatching is not required.

5.2 Human Albumin Solution is available in two forms:

Isotonic solutions (4.5% in volumes of 250 to 500 mL): Often used to replace subacute plasma volume loss caused by burns, pancreatitis or trauma, and as a replacement fluid in plasma exchange.

Concentrated solutions (20% in volumes of 100 mL): Indications may include initiating diuresis in hypoalbuminaemic patients with liver cirrhosis or nephrotic syndrome, removal of large volumes of ascites in patients with portal hypertension and to assist the reduction of high bilirubin levels by exchange transfusion in the newborn (unconjugated bilirubin binds to albumin)

The isotonic and 20% preparations are very different in their scope and should not be used interchangeably. The 4.5% solution has the same oncotic pressure as plasma and its uses are quite different from the hyperoncotic 20% solution.

6. INDICATIONS FOR USE

6.1 **Therapeutic indications**

The aim of treatment is to restore and maintain circulatory blood volume where volume deficiency has been demonstrated, and use of colloid is appropriate. Albumin has a bigger effect on the intravascular volume and stays longer in the circulation, and in some patients may be beneficial.

6.2 **Appropriate Specific indication**

- Nephrotic Syndrome – in combination with diuretics
- During drainage of ascitic fluid to prevent renal dysfunction due to increased renin activity and hyponatraemia (thereby preventing post-paracentesis circulatory dysfunction). The dose is as per the ascitic fluid drainage protocol – 100 ml of 20% Human Albumin Solution for every 3 litres of ascites drained.
- Severe burns after the first 24 hours (usage before this time has been demonstrated to cause paradoxical pulmonary oedema).
- Acute Respiratory Distress Syndrome where use of diuretics has caused fall in effective plasma volume.
- Acute liver injury to support plasma oncotic pressure and bind excessive bilirubin, activated plasmin, toxins etc.
- Renal dialysis if the patient becomes hypotensive.

Hepatorenal Syndrome (HRS) along with Glypresin (a vasopressin analogue). The dose is as per HRS guideline – 1g/kg (Max 100g /day) per day for two or more days until improvement in renal function. Either 4.5% or 20% concentrations may be used depending on the fluid status of the patient.

6.3 **Inappropriate indications**

- Intravascular volume expansion after trauma or major surgery.
- As part of total parenteral nutrition.
- In long term supplementation of albumin in nephrotic syndrome.

7. PRESCRIPTION AND ADMINISTRATION

7.1 Human Albumin Solution must be prescribed and documented on the Trust's dedicated blood components prescription chart. The traceability tag must be completed and returned to the laboratory, and the product marked as Transfused on BloodTrack.

7.2 Human Albumin Solution is administered by the intravenous route. The infusion rate should be adjusted according to individual circumstances and indications.

7.3 The exact dose and strength of the Human Albumin Solution depends on the size of the patient, severity of illness and on continuing fluid/protein loss. Measures of adequacy of circulatory volume and not plasma albumin level should be used to determine the dose required.

7.4 Administer via a standard intravenous (IV) giving set. It does not require a transfusion filter. Albumin is packed in a glass bottle and must be vented during use.

7.5 Human Albumin Solution must not be diluted with water as this may cause haemolysis in recipients.

7.6 If large volumes are administered, the product should be warmed to room temperature or body temperature before use.

7.7 Do not use cloudy solutions or if they have deposits.

7.8 Once the container Human Albumin Solution (HAS) has been pierced, the contents should be used immediately. Any remains of the product must be discarded.

If the unit of HAS is not used within 30 mins of removal from temperature controlled storage clinician must be notified and decision made whether it can still be used.

Each unused unit of HAS must be returned back to Blood Bank as soon as possible and scanned back into the fridge via the red kiosk. Lab staff must also be notified of this.

Please note: when collecting multiple bottles of HAS from Blood Bank each bottle must be scanned out separately on the red kiosk scanner. Failure to do so will result in further alerts and errors on the BloodTrack system and these must be acted upon.

7.9 To maintain pharmaceutical product quality, HAS is stored at controlled temperature between +2℃and +25℃

Therefore each unused unit of HAS must be returned back to Blood Bank as soon as possible and scanned back into the fridge. Lab staff must also be notified of this as they will review the product upon returning.

Please note: when collecting multiple bottles of HAS from Blood Bank each bottle must be scanned out separately on the red kiosk scanner. Failure to do so will result in further alerts and errors on the BloodTrack system and these must be acted upon. Each alert will be investigated.

8. MONITORING

8.1 The haemodynamic performance should be monitored regularly during the administration of Human Albumin Solution. This may include:

- Blood pressure and heart rate.
- Central venous pressure or pulmonary artery wedge pressure.

- Urine output.
- Electrolytes, haemoglobin or haematocrit.

9. CONTRADICTIONS, SPECIAL WARNINGS AND PRECAUTIONS

9.1 Human Albumin Solution is contraindicated if the patient has hypersensitivity to albumin preparations or to any of their excipients.

9.2 Human Albumin Solution must be used with caution in conditions where hypervolaemia and its consequences or haemodilution could represent a special risk to the patient.

Examples of such conditions are:

- Decompensated cardiac failure
- Hypertension
- Oesophageal varices
- Pulmonary oedema
- Haemorrhagic diathesis
- Severe anaemia
- Renal and post renal anuria

9.3 No specific interaction of Human Albumin Solution with other medicinal products is known.

9.4 The safety of Human Albumin Solution in pregnancy has not been established in controlled clinical trials. However clinical experience suggests no harmful effects are to be expected on the course of the pregnancy, the foetus or neonate.

10. COMPLICATIONS

10.1 Allergic reaction/anaphylactic shock – the infusion should be stopped immediately and appropriate therapy implemented.

10.2 Circulatory overload and hyper-hydration – the colloid osmotic pressure of 20% Human Albumin Solution is 4 times that of blood plasma hence care has to be taken to ensure adequate hydration of the patient to prevent increased intracranial pressure especially in patients with acute liver failure.

10.3 Electrolyte imbalance – 20% Human Albumin Solution is relatively low in electrolytes compared to 4.5% Human Albumin Solution and is thus better suited for patients with renal impairment in conditions such as Hepatorenal failure/Renal dialysis/Nephrotic syndrome etc).

10.4 Haemostasis – if a large volume of Human Albumin Solution have been used, it is advisable to request measurement of the patient's coagulation parameters and haematocrit in case they need correction.

10.5 Hypervolaemia/Overdosing – adequate care and monitoring needs to be undertaken. The infusion should be stopped at the first signs or symptoms of cardiovascular overload (raised Jugular Venous Pressure (JVP), pulmonary oedema, hypertension, raised venous pressure, headache and dyspnoea).

10.6 Mild reactions such as flush, urticaria, fever and nausea are rare and usually resolve on slowing the rate of infusion or stopping it completely.

11. REFERENCES

Caironi, P., Tognoni, G., Masson, S., Fumagalli, R., Pesenti, A., Romero, M., Fanizza, C., Caspani, L., Faenza, S., Grasselli, G., Iapichino, G., Antonelli, M., Parrini, V., Fiore, G., Latini, R. and Gattinoni, L. (2014). Albumin Replacement in Patients with Severe Sepsis or Septic Shock. *New England Journal of Medicine*, 370(15), pp.1412–1421. doi: https://doi.org/10.1056/nejmoa1305727

Roberts I, Blackhall K, Alderson P, Bunn F, Schierhout G. Human albumin solution for resuscitation and volume expansion in critically ill patients. Cochrane Database Syst Rev. 2011 Nov 9;2011(11):CD001208.

The SAFE Study Investigators (2004). A Comparison of Albumin and Saline for Fluid Resuscitation in the Intensive Care Unit. *New England Journal of Medicine*, 350(22), pp.2247–2256. doi: https://doi.org/10.1056/nejmoa040232

APPENDIX A: QUALITY ASSURANCE CHECKLIST

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		Y/N/ n/a	COMMENTS (to author for amendments)
1	**Title of document**		
	Is the title clear and unambiguous	Y	
2	**Type of document (e.g. procedure, guidance)**		
	Is it clear whether the document is a procedure, guideline, SOP?	Y	
3	**Introduction**		
	Are reasons for the development of the document clearly stated?	Y	
4	**Content**		
	Are all sections of the front cover completed correctly?	Y	
	Is the document in the correct Trust approved format?	Y	
	• Paragraphs numbered consecutively	Y	
	• Headers: only on front page to contain logo	Y	
	• Footers: on every page except front page	Y	
	Has the Author's Checklist (pg. 2) been fully updated?	Y	
	Are the Version numbers correct in the title, summary and the footers?	Y	
	Has the Version Control Summary (pg. 3) been fully updated with changes?	Y	
	Has the Document Contributors section (pg. 3) been completed?	Y	
	Are the objectives/aims clearly stated?	Y	
	Does this document concern the handling, moving or storage of personal identifiable or commercially sensitive information? If yes, has a Summary Privacy Impact Assessment been completed?	N/A	
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	Is the type of evidence to support the document explicitly identified?	Y	
	Are associated documents referenced?	Y	
6	**Approval Route**		
	Has email approval been received for change of review date only?	N/A	
	Does the document identify which committee/group will approve it?	Y	
	Does the document meet the criteria for Second Level approval or Information Only?	Y	Info only

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CORPORATE GOVERNANCE COMPLIANCE TEAM:		
1.	Date comments returned to author by Compliance Lead:	
2.	Date of Corporate Governance Compliance Team approval:	22 April 2026
3.	Name of Compliance Lead:	Carly Goddard 

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Chair's Name	Dr Lynda Menadue	**Date**	21/05/2026
Signature			

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