

**EVALUATION OF COMPLIANCE TO ALBUMIN USE REGULATIONS IN CLINICAL
WARDS: A FUNCTION FOR IRAQI CLINICAL PHARMACISTS IN RATIONAL USE OF
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ABSTRACT

Human albumin solution is one of the highly specialized drugs. It is available in governmental (public) hospitals from the company for drugs and medical appliances marketing (KIMADIA) in the approved 20% strength. Due to the wide variety of indications for its use as well as its high cost, it is a strain to keep it available all times in hospitals. This study was a prospective study evaluating the use of albumin in Iraqi governmental hospitals. All patients receiving albumin were documented by clinical pharmacists in the hospitals from Nov 2023 up to Feb 2025. They were 12718 patients. The categorization and analysis was according to the approved Iraqi **IV Albumin Administration Guidelines**. The results showed that 12.6% of cases were within the highly indicated category, 56.07% were likely indicated, 6.68% were for doubtful indications, and 3.19% were not indicated cases, while the others were not categorized because the indications were not clear for categorization. This study showed that the results were identical to other countries. This means that the problem is the same for using this drug.

KEYWORDS: Albumin, guidelines, clinical pharmacy.**INTRODUCTION**

Albumin is the natural protein in human plasma, which is synthesized by the liver. Physiologically it is essential in maintaining oncotic pressure – which is also called colloid-oncotic pressure (COP) – and so maintains the balance between the intracellular and extracellular spaces and so prevents fluids from leaking from blood vessels to the extravascular. It is also essential in transporting hormones, drugs, vitamins, amino acids and fatty acids as well as being an essential player in regulation of the acid-base balance.

The normal serum levels for adults range from 3.5 to 5.5 g/dL. Low levels indicate liver disease, kidney disease, or inflammation, with a high rate of mortality and may need clinical intervention and replacement, while high levels may be a sign of dehydration. The most important disadvantage of albumin is its high treatment cost although the Cochrane Injuries Group Albumin

Reviewers (led by Ian Roberts et al.) showed that albumin use could lead to a higher mortality rate in critically ill patients.^[1] These findings show that albumin's use should be only in patients where a clear benefit has been found.

The world health organization (WHO) has defined the rational use of drugs (RUD) as the marketing, distribution, prescription, and use of drugs in a society with special emphasis on their medical, economic and social consequences. Drug use evaluation (DUE) is related to the RUD at the patient level to assess the actual process of prescribing, dispensing or administering a drug (indications, dose, drug interactions, etc.).^[2] The WHO objectives of DUE include ensuring that drug therapy meets current standards of care, controlling drug cost, preventing problems related to medication, evaluating the effectiveness of drug therapy and identification of areas of practice that require further

education of practitioners.^[3] In Iraq RUD is one of the most important functions of clinical pharmacists in which drug use evaluation is the main tool for evaluating using drugs rationally, both on the patient and population levels. According to the results of the evaluation the appropriate measures are taken for the optimization and correction needed. The most important parameters concerning the work of the clinical pharmacists are the indications, dosing, duration, and monitoring.^[4] Prioritization of DUE studies depends on a variety of factors: cost, availability, indication, pharmacology, high alertness, dosing regimen, treatment duration, patient monitoring, etc^[5] to help in any changing or interventions to reach rational use of drugs.

Serum albumin is produced mainly in the liver. Its function includes regulating oncotic pressure, transporting hormones, fatty acids, and some drugs, as well as being one of the plasma buffers.^[6] Albumin is one of the high cost, high alertness drugs with often shortages, and a wide range of indications, with limited, evidence-based indications, and inappropriate use, and hence there is a need for clear guidelines for its use. Its approval for hypovolemic conditions as a plasma volume expander and maintaining cardiac output in the treatment of certain types of the shock when other non-protein colloids cannot be used, is to optimize patient outcomes while minimizing unnecessary costs evaluation of its use is an urgent need.^[7] Hypoalbuminemia, which is the most urgent indication for albumin use, could be due to a variety of conditions due to either decreased production or malnutrition: nephrotic syndrome, paracentesis, liver cirrhosis, burns, acute or chronic inflammation, organ transplantation, etc. Therefore, it needs special considerations by the clinical pharmacists during discussions with physicians for indications and dosing, during providing, educating nurses and patients, and during administration and monitoring and follow-up. Guidelines for prescribing Albumin have been found to reduce overall costs of treatment.^[8] Irrational use of Albumin has been reported to be 18-91%^[9] were 50% of adverse drug reactions (ADRs) were due to it.^[10]

Albumin is supplied to governmental hospitals from the company for drugs and medical appliances marketing (KIMADIA) in the approved 20% strength. It has been noticed that there is a high usage rate which affects the availability and cost. The section of clinical pharmacy in collaboration with the department of consultant committees in the directorate of technical affairs approved the new **IV Albumin Administration Guidelines**, in different levels – highly indicated, likely indicated, doubtful indication, as well as the not indicated group as a tool for the rational use of this drug. (figure 1).

The prescribing process of albumin was also been restricted by a special form to be approved directly by two physicians.

AIM

The aim of this study was to evaluate the use of Albumin and its concordance with rational government treatment guidelines, the appropriateness of prescribing and economic repercussions form inappropriate use in different levels of Iraqi hospitals.

METHODS

A prospective study was designed to include all patients receiving albumin – in the approved dosage form (20% strength) in hospitals from different governorates in Iraq. The study continued from November 2023 up to February 2025. The indications for albumin use were documented by the clinical pharmacists in the wards and compared with the guidelines approved by the ministry of Health. Documentation was made in the excel program, and was designed to include the patient data, the physician's information, the indication, and the dose. The specialty of the ward was not mentioned as the goal of the study was to measure the compliance with guidelines for indications in general regardless of the specialty. The analysis of the data was focused on concordance of the indication with the ministerial guidelines as a percentage with different indications. Any detailed analysis was beyond the scope of this study.

The following approved guidelines were prepared by the clinical pharmacy section in the directorate of technical affairs for the indications were albumin is to be used and the approval was by the ministerial consultant committees in the same directorate.



IV Albumin Administration Guidelines

- Physicians are the responsible persons for the diagnosis of cases that will need albumin.
- Physicians should state the provisional period of treatment
- Clinical pharmacists are responsible for evaluation of all IV albumin orders, to ensure compliance with this guideline
- Orders of albumin should include the dose (according to the bottle size)
- Clinical pharmacists should follow-up with the period of treatment
- In case of indications not stated in these guidelines, more than one physician should sign the request form
- Approved dosage forms by the NCSD:
 - Human albumin 200mg/ml, low salts (130–160mmol/L Na)
 - Human albumin 200mg/ml

Indications	Recommendations
Highly Indicated	
Large Volume Paracentesis in patients with cirrhosis and refractory ascites associated with portal hypertension (>4 L removed with documented cirrhosis)	Albumin 20%; 6-8g for every liter of ascitic fluid removed
Malnutrition syndromes: (patients with diarrhea associated with enteral feeding intolerance if all the following conditions are met: <ul style="list-style-type: none"> Significant diarrhea (>2 liters per day) Serum albumin is < 2 g/dl) 	
Ascites not responsive to diuretics, (if serum albumin <3 g/dL)	
Burns: (not in the resuscitation phase in the first 24 hours after burn injuries), according to the body surface area (BSA)	
Hyperbilirubinemia of the newborns	
Plasma exchange (with isotonic solutions)	
Severe hypoalbuminaemia with low plasma volume and generalized oedema where salt and water restriction with plasma volume expansion are required	
Likely Indicated	
Plasmapheresis	Based on plasma volume and serum fibrinogen level)
For diagnosis of Suspected HRS	Albumin: 1g/kg/day for 2 days (max 100g/ day)
Hepatorenal Syndrome (HRS), confirmed Defined as: <ol style="list-style-type: none"> Serum creatinine >1.5 mg/dL in the presence of cirrhosis Absence of shock, ongoing bacterial infection, and/or current treatment with nephrotoxic drugs Absence of sustained improvement in renal function after discontinuation of diuretics and a trial of albumin 1 g/kg Absence of proteinuria (<500 mg/day) or hematuria (<50 red cells per high-power field) Absence of ultrasonographic evidence of obstructive uropathy or parenchymal renal disease 	<ul style="list-style-type: none"> Albumin: 25-50g/day for a total of 72 hrs (starting 1-2 days after initial diagnostic trial of albumin, if applicable), and consult nephrology and hepatology to determine whether to continue Should be used in addition to octreotide

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Postoperative volume resuscitation after Cardiac Surgery, or major surgery in the liver or bowel (as a post-operative volume expander, as a last choice of treatment after crystalloids or non-protein colloids)	Albumin 5% used if ≥3L crystalloid has been given within a 24-hr period without adequate hemodynamic response: • includes crystalloids given as a bolus • excludes maintenance fluids and fluids given intraoperatively
Spontaneous Bacterial Peritonitis (SBP) and cirrhosis Defined as patients with ascitic fluid, PMN counts ≥250 cells/mm ³ plus at least one of the following: 1- Serum creatinine >1 mg/dL 2- Blood urea nitrogen >30 mg/dL 3- Total bilirubin >4 mg/dL	Albumin: 1.5 g/kg within 6-hrs of detection (day 1), and 1g/kg on day 3
Major hepatic Resection (>40% resected), (In patients with serum albumin <2.5g/dL if crystalloids alone fail to achieve adequate intravascular volume)	Albumin, 25 gm/day until albumin is ≥2.5 gm/dL. • If serum albumin remains <2.5, may continue albumin dosing up to 4 days.
Postoperative Liver Transplant May be useful for the control of ascites and peripheral edema if serum albumin is <2.5 gm/dL	Albumin, 25 gm/day until albumin is ≥2.5 gm/dL. If serum albumin remains <2.5, may continue albumin dosing up to 4 days; consult liver surgeons thereafter for consideration of continued use.
Doubtful benefit (approved by nephrologist)	
Severe (acute) Nephrotic Syndrome Albumin may be considered in cases with: • severe refractory edema with anasarca or pulmonary edema, with the following criteria: – >3 g/day of urinary protein excretion + hypercholesterolemia + hypoalbuminemia – loop diuretic resistance (insufficient response to IV bolus dose of ≥160 mg furosemide followed by ≥8hr infusion of ≥20mg/hr furosemide) • symptoms and signs of sub-acute intravascular volume depletion, including: – oliguria, – poor peripheral perfusion, – abdominal pain, raised creatinine and haematocrit; – always under supervision of consultant paediatric nephrologist	Albumin, 25 gm in combination with diuretics to affect adequate diuresis. Additional dosing must be approved by nephrologist.
Acute nephrosis /chronic glomerulonephritis and subsequent hypoalbuminemia	Short-term albumin use, in conjunction with diuretic therapy, is appropriate for patients with: acute, severe peripheral or pulmonary edema who have failed diuretic therapy, serum albumin < 2 g/dL, with marked hypovolemia and/or acute pulmonary oedema and/or acute kidney injury

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Not indicated (NOT approved)	
1- Albuminaemia > 2.5 g/dL (with the exception of the particular cases listed above) 2- Acute Respiratory Distress Syndrome 3- Septic Shock 4- Hypovolemic, bleeding and hemorrhagic shock (Albumin is used as a second choice when solutions of crystalloids or non-protein colloids (first choice treatment) have already been used at maximum doses without having produced a clinically adequate response and cases which non-protein colloids are contraindicated) 5- Non haemorrhagic shock 6- Traumatic Brain Injury 7- Cerebral Ischaemia 8- Major Trauma 9- Wound healing 10- Hypoalbuminemia in the absence of oedema and acute hypotension 11- Ascites responsive to diuretics 12- Kidney Transplant 13- Abdominal Compartment Syndrome 14- Burns; in the first 24 hours after burn injuries 15- The use of albumin in the immediate post-operative period is never advised for any other type of operation, other than the aforementioned 16- Acute normovolaemic haemodilution in surgery 17- Malnutrition 18- Protein-losing enteropathies and malabsorption 19- Acute or chronic pancreatitis 20- Haemodialysis with no evidence of malnutrition 21- Ovarian hyperstimulation syndrome	

Albumin dose calculation: (to obtain a serum albumin 2.5 g/dL):

Dose (g) = [desired albumin conc (2.5 g/dL) - actual albumin conc (g/dL)] x plasma volume (0.8 x body weight in kg)

MONITORING

- Dose should be assessed daily according to the patient's condition at all times (fluid and electrolyte therapy should be adjusted)
- Adjust dose and rate of infusion to avoid fluid overload
- Correct dehydration when administering concentrated solution, is essential if:
 - a- history of cardiovascular disease
 - b- increased capillary permeability
 - c- risk of haemodilution (e.g. severe anaemia or hemorrhagic disorders)
 - d- risk of hypervolaemia (e.g. oesophageal varices or pulmonary oedema)
 - e- vaccination against hepatitis A and hepatitis B
- Albumin should be discontinued as soon as therapy is no longer required according to monitored parameters.
 - a- Albumin therapy may not be necessary in patients with plasma albumin ≥ 2.5 g/dL
 - b- Blood pressure: SBP > 100 mmHg or MAP > 60 mmHg
 - c- Urine output: > 0.5 ml/kg/hr
 - d- Improvement in condition(s) for which albumin was initiated
 - e- Oedema improvement
 - f- Other measures of fluid responsiveness

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RESULTS

The data collected were for 12718 patients receiving albumin. The indications were categorized according to the (IV Albumin Administration Guidelines) mentioned above into highly, likely, doubtful, and not indicated.

The mean hospitalization period for patients was 11.13 days (109 – 1) and the mean days of albumin administration was 4.86 days.

The highly indicated cases were 1611 corresponding to (12.67%) of the studied population. The highest indications were liver cirrhosis with paracentesis of large volume >4liters if s.cr>=1.10, burns with sepsis, >40% resection of the liver with serum albumin <2 g/dL, hyperbilirubinemia, and kidney transplantation serum albumin <2.5g/dL. These corresponded to 12.33% of the whole cases.

The likely indicated cases were 8051 corresponding to 63.3% of the whole cases. The highest of these indications were hypoalbuminemia, septicemia, liver cirrhosis with ascites, hypoalbuminemia with sepsis, and hepatorenal syndrome, which corresponded to 57.78% of the whole cases.

The doubtful indicated cases were 814 corresponding to 6.4% of the cases in the study. Acute nephrotic syndrome and acute severe peripheral or pulmonary edema showed the highest amongst them in a 6.22% of the whole cases.

Malnutrition syndrome, hypovolemic bleeding and ARDS were the highest (3.27%) within the cases not

indicated for albumin according to the guidelines. The cases in the not indicated group were 1088 cases corresponding to (8.55%) of the whole cases. Others include 80 different indications none of them is within the previous three groups.

As clinical pharmacists depend on the clinical picture and the final diagnosis given by the physician, therefore there was a group that could not be categorized because they don't have a clear description to be entered in the categorized data. These were 1154 cases which represented 9.08% of the whole cases.

DISCUSSION

In this present study, we have evaluated the administration of albumin according to the approved guidelines in Iraq. These guidelines were based on the different rational use protocols that depend on evidence-based assessment of the prescription by the physicians in the hospitals. Other studies have shown results for evaluating the entire problem. In both cases it is obvious that the rational use of this drug is a big challenge.

In our study the highly indicated cases were distinguished from the likely indicated which was not done in other studies.

However comparing our results with other studies show comparable results:

Our study showed that liver cirrhosis with paracentesis of large volume >4 liters if $s.cr \geq 1.10$ corresponded to 9.1% of the cases while in two Spanish hospitals where paracentesis in cirrhotic patients showed 25.9%. Our study distinguished between the highly indicated case of hypoalbuminemia + edema and abdominal ascites (0.075%) and the likely indicated case of hypoalbuminemia with sepsis (36.5%), while in a study in two Spanish hospitals the cumulative cases of hypoalbuminemia where (24.9%), and in a private hospital in Bangkok it was (48%). On the other hand, liver cirrhosis, in our study corresponding to (9.86%) of the cases was less than that in the two Spanish hospitals study which showed an (18.6%) result and just equal (9%) to the private hospital in Bangkok. In total the not-indicated group in our study (8.55%) was much less than the Bangkok study (35.6%).^[11,12]

It has been shown that large volume drainage of ascites ($>4L$) may lead to hemodynamic instability and severe hypotension; and this is why it is considered to be in the highly indicated group. Similarly acute kidney impairment is considered in this group because the unstable hemodynamics affects their functions.

It has also been shown that hypoalbuminemia (< 30 g/L) which is common in critically ill patients is associated with high morbidity and mortality rates. Sepsis with hypoalbuminemia and the hepatorenal syndrome have been placed in the likely indicated group for this reason.

Hypoalbuminemia, with and without sepsis, showed a result of (36.4%) in our study, while it was (25.3%) in the Wellstar North Fulton Hospital study. These results are comparable if we consider that they are in the likely indicated group. However, the highly indicated and likely indicated groups collectively in our study make a result of (76%), which is a bit higher than the Wellstar North Fulton Hospital study which was (67.7%). This gives a conclusion that administration of albumin for an appropriate indication was comparable in both studies. Acute nephrotic syndrome and hydronephrosis on the other hand are both in the doubtful indicated group, which collectively correspond to 4.8% of the cases. The Wellstar North Fulton Hospital study showed a 10.8% of the cases in this same group.^[13]

Albumin was used in not indicated cases in (8.55%) of the cases, the highest which were malnutrition syndrome, hypovolemia, pancreatitis, severe gastroenteritis. In these cases it is supposed that adequate calories by oral, enteral, or amino acid administration should be adequate. The cause of the hypoalbuminemia should be corrected before starting colloid or albumin in an attempt for treatment since albumin is not always available as well as its expensiveness.^[14,15,16] The same has been seen in the study done by Vermeulen LC et al, who found that the percentage was (36.2%), and the study done by Tarin Remohi MJ et al in an Iranian hospital who found that the percentage was about 30-50%, and the study carried out by Talasaz AH et al who showed an improper use of about (35%) as well as in Thailand which showed (35.6%) inappropriate use, with hypoalbuminemia, nephrotic syndrome, and nutritional supplementation being the highest inappropriate indication.^[17,18,19]

From the clinical point of view of course there could be justification for any indication that albumin has been used. For example in acute nephrotic syndrome, which is considered within the doubtful group, proteinuria is the main cause of edema and hypovolemia, and finally venous thromboembolism. Albumin is used in this case to restore euvoemia.^[20,21] It is essential to put in mind that whatever the clinical justification is, guidelines put into consideration the availability, cost and adverse events of albumin, and hence any deviation from them leads to wasting resources for patients and community.

The lower percentages in our study (8.55%) could be due to the higher compliance with ministerial guidelines and the effectiveness of the clinical pharmacists who take an important role in rationalizing the use of Albumin. Similar results have been seen in the study carried out in Tehran in which there was a 79.3% reduction in the inappropriate prescription of albumin which showed the essential role of clinical pharmacists in hospital settings.^[22]

CONCLUSION

- The high rate of irrational use of Albumin highlights the need for monitoring its use

- The higher the cases in the highly indicated group is, the higher compliance is with ministerial regulations
- On the contrary of other countries, in Iraq there are detailed guidelines for the use of albumin in different indications, which make it useful to take this in consideration when comparing our results with other settings and countries.
- This study was the first conducted to evaluate the compliance with the ministerial guidelines for albumin use in public hospitals and the role of clinical pharmacists in optimizing its use. It is needed to carry out educational campaigns to increase awareness for following ministerial guidelines of this drug and provide physicians with information to change their practice in dealing with such a high-cost and critical medication.
- The higher the compliance with guidelines, the lower would be the wastage of this drug, and the more indicated cases would get access to it.
- Crystalloids should stay the first line in resuscitation, due to availability and cost. Colloids should be saved for unresponsive cases

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